Health Literacy
in the Context of Migration

Analysis of Determinants and Intervention Effectiveness to Improve Health Literacy in Migrants

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For my mother!

“We’ve had a lot of trouble with Western mental health workers…They would do this bizarre thing. They didn’t take people out in the sunshine, where you begin to feel better…They didn’t involve the whole community…Instead what they did was they took people one at a time into dingy little rooms and had them talk for an hour about bad things that happened to them.”

Rwandan man (Solomon, 2010)

CONTENTS

ABSTRACT

Background: Health literacy (HL), understood as the “knowledge, motivation, and competences to access, understand, appraise, and apply health information” (Sørensen et al., 2012, p. 3), is widely considered to be a crucial factor for effective disease management and autonomous health-related decision-making. It is a multidimensional construct compounded by societal and environmental factors, situational conditions, and personal determinants. International studies found that migrants are more likely to face difficulties in processing health information than persons without migration experience. These difficulties can have various reasons, for example, language (barriers) or a lack of familiarity with a new country's health system. Gender has been associated with HL, but quantifiable effects are often small and ambiguous. In the context of migration, it is still unclear how personal factors such as gender, situational or systemic conditions affect HL in the healthcare domain and how HL can be improved by tailored interventions.

Aims: Drawing on the integrated model of HL (Sørensen et al., 2012), this PhD project aimed to investigate 1) which factors influence HL in transcultural healthcare interactions, 2) whether interventions to improve HL in migrants are effective, and 3) whether female or male migrants benefit differently from these interventions.

Methods: Three studies contributed to this dissertation. Studies I and II consisted of two different qualitative content analyses (Kuckartz, 2019) based on five focus group discussions with 31 healthcare professionals (HCP) in Germany. Both aimed at exploring the determinants of HL in transcultural healthcare interactions from the perspective of HCPs. Study I examined how societal and environmental factors as well as situational and personal determinants influence HL in these settings. Study II focused on gender as a personal factor of HL, examining its influence on healthcare interactions between HCPs and persons with a migrant background. In study III, a Cochrane effectiveness review of intervention studies to improve HL in migrants was conducted, following the Cochrane recommended methodology and PRISMA guidelines (Higgins et al., 2023). Results were summarised in meta-analyses, whenever possible, or synthesised narratively. Main findings of studies I-III are discussed and contextualised against the results of a Cochrane Qualitative Evidence Synthesis (QES; Aldin et al., in press) linked to study III. The QES included qualitative studies with participants of the interventions in the effectiveness review.

Results: In Study I, challenges such as a systemic lack of time and economic pressure were cited as key barriers to an effective and satisfactory flow of information between HCP and their migrant patients. The need for additional time and resources, including funding for professional interpreters and cultural mediators was emphasised. A shared migrant background of HCPs and their patients positively influenced informational exchange and building of trustful relationships. Some HCPs, however, perceived this personal factor as stressful, particularly when interpreting for others. In Study II, gender-related aspects, such as considerable language barriers among Turkish migrant women in comparison to Turkish men, were identified as barriers to accessing, understanding, and appraising health information in healthcare interactions. Study III included 28 RCTs and six cluster-RCTs (8,249 participants in total) that addressed HL either as a concept or its components. The review showed that certain intervention types such as self-management programmes, HL skills building courses, or audio/-visual education without personal feedback, can improve HL among migrants (e.g. functional HL skills or disease-specific knowledge), particularly in the short-term. A considerable research gap was discovered regarding gender; it remains unclear whether migrant women or men benefit differently from HL interventions.

Discussion: In transcultural healthcare interactions, the relationality and context-sensitivity of HL is particularly evident, indicating that well-known issues in the German health system exacerbate in the context of migration. System-related factors such as a lack of time and economic pressure or personal determinants such as gender and a shared migrant background were found to play a vital role for a successful flow of health information. These factors interact and reinforce each other and are closely interwoven with accessing, understanding, and appraising as well as applying health information. The findings of this dissertation highlight that HCPs are crucial in facilitating the individual HL of their patients. However, they can only act under the given systemic conditions, which currently impede their ability to respond adequately to the diverse HL needs of all of their patients. At the level of individual HL promotion, study III found that some types of HL interventions have the potential to mitigate certain HL-specific challenges such as understanding health information. However, despite a rigorous grouping procedure, there was considerable heterogeneity between studies, making it inappropriate to draw general conclusions.

Conclusion: Shifting the focus of HL research and practice to health systems and governments and their responsibility to create the right conditions for HL, rather than on individuals, HCPs and organisations (inter-)acting within the system, seems necessary in order to develop and implement sustainable interventions to strengthen HL. There is a need for well-designed intervention studies that 1) explicitly aim at improving HL, 2) are target group-specific and gender-sensitive, 3) are collaborative in design, and 4) measure HL over time (> 6 months after the intervention) with validated measurement tools.

ZUSAMMENFASSUNG

Hintergrund: Gesundheitskompetenz (GK), verstanden als Wissen, Motivation und Fähigkeiten, Gesundheitsinformationen (GI) zu finden, zu verstehen, zu beurteilen und anzuwenden (Sørensen et al., 2012), wird als wichtiger Faktor für gelingendes Krankheitsmanagement und autonome gesundheitsbezogene Entscheidungsfindung angesehen. Als multidimensionales Konstrukt wird GK durch gesellschaftliche und umweltbedingte Faktoren, situative und persönliche Determinanten beeinflusst. Internationale Studien haben festgestellt, dass Migrant*innen eher Schwierigkeiten bei der Verarbeitung von GI haben als Menschen ohne Migrationserfahrung (z. B. durch Sprachbarrieren oder weil sie das Gesundheitssystem des Aufnahmelandes nicht gut kennen). Gender wurde mit GK assoziiert, aber die quantifizierbaren Unterschiede sind oft gering und nicht immer eindeutig. Im Kontext von Migration ist unklar, wie sich persönliche Faktoren wie Gender, situative oder systemische Bedingungen im Anwendungsbereich der Gesundheitsversorgung auswirken und wie GK durch Interventionen verbessert werden kann.

Ziele: Unter Anwendung des integrierten Modells der GK (Sørensen et al., 2012) zielte dieses PhD-Projekt darauf ab, 1) zu untersuchen, welche Faktoren GK in transkulturellen Interaktionen im Gesundheitswesen beeinflussen, 2) ob Interventionen zur Verbesserung der GK von Migrant*innen wirksam sind und 3) ob Frauen oder Männer mit Migrationserfahrung unterschiedlich von diesen Interventionen profitieren.

Methodik: Drei Studien trugen zu dieser Dissertation bei. Die Studien I und II bestehen aus zwei qualitativen Inhaltsanalysen (Kuckartz, 2019), die auf fünf Fokusgruppendiskussionen mit 31 Gesundheitsprofessionellen (GP) in Deutschland basieren. Beide zielten darauf ab, die Determinanten von GK in transkulturellen Interaktionen im Gesundheitswesen aus der Perspektive der GP zu untersuchen. Während Studie I untersuchte wie gesellschaftliche und umweltbedingte Faktoren sowie situative und persönliche Determinanten, die GK in diesen Settings beeinflussen, legte Studie II den Fokus auf Gender als persönliche Determinante von GK. In Studie III wurde ein Cochrane-Review von Interventionsstudien zur GK-Förderung bei Migrant*innen durchgeführt, dessen Ergebnisse, wenn möglich, in Meta-Analysen oder narrativer Synthese zusammengefasst wurden. Die Haupterkenntnisse aller Studien werden gemeinsam mit den Ergebnissen einer Cochrane Qualitativen Evidenzsynthese (QES; Aldin et al., im Druck) diskutiert, die mit Studie III verlinkt ist. Die QES umfasste qualitative Studien mit Teilnehmenden der jeweiligen Interventionen.

Ergebnisse: In Studie I wurden systematischer Zeitmangel und ökonomischer Druck als zentrale Hindernisse für effektiven und zufriedenstellenden Informationsfluss in transkulturellen Interaktionen angeführt. Der Bedarf an zusätzlicher Zeit und Ressourcen sowie der

Finanzierung professioneller Dolmetscher*innen und Kulturmittler*innen, wurde betont. GP mit eigenem Migrationshintergrund beschrieben diesen persönlichen Faktor als überwiegend positiv für Informationsaustausch und Aufbau vertrauensvoller Beziehungen. Einige empfanden es jedoch als belastend, z.B. wenn sie häufig für Kolleg*innen dolmetschten. In Studie II wurden genderspezifische Faktoren wie z. B. ausgeprägte Sprachbarrieren bei türkischen Frauen im Vergleich zu türkischen Männern als Hemmnisse für Zugang, Verständnis und Beurteilung von GI beschrieben. Studie III schloss 28 RCTs und sechs Cluster-RCTs (8249 Teilnehmende) ein, die GK entweder als Konzept oder ihre Komponenten adressierten. Bestimmte Interventionstypen wie Selbstmanagementprogramme, Kurse zur Förderung von GK oder audiovisuelle Edukation ohne persönliches Feedback können die GK von Migrant*innen verbessern (z. B. funktionale GK oder Wissen). Eine erhebliche Forschungslücke wurde in Bezug auf Gender festgestellt. So bleibt unklar, ob Frauen oder Männer mit Migrationserfahrung unterschiedlich von GK-Interventionen profitieren.

Diskussion: In transkulturellen Interaktionen im Gesundheitswesen wird die Relationalität und Kontextsensitivität von GK besonders deutlich. Bekannte Probleme des deutschen Gesundheitssystems scheinen sich im Migrationskontext zu verschärfen. Systemische Faktoren wie Zeitmangel und ökonomischer Druck oder persönliche Determinanten wie Geschlecht und ein geteilter Migrationshintergrund zwischen GP und Patient*in spielen eine zentrale Rolle für den erfolgreichen Informationsfluss in diesem Setting. Diese Faktoren interagieren und verstärken sich gegenseitig und sind eng mit Zugang, Verständnis und Bewertung von GI verknüpft. Die Ergebnisse dieser Dissertation machen deutlich, dass GP bei der Förderung individueller GK eine entscheidende Rolle spielen. Diese können jedoch nur unter den gegebenen systemischen Bedingungen handeln, die ihnen erschweren, angemessen auf die unterschiedlichen Bedürfnisse all ihrer Patient*innen einzugehen. Auf der Ebene der individuellen GK-Förderung zeigten die Ergebnisse, dass einige Interventionstypen das Potenzial haben, bestimmte GK-spezifische Herausforderungen zu mildern. Trotz eines rigorosen Gruppierungsprozesses bestand jedoch erhebliche Heterogenität zwischen den Studien, die es uns erschwerte, eindeutige Schlussfolgerungen zu ziehen.

Schlussfolgerung: Eine Verlagerung des Fokus von GK-Forschung und -Praxis auf Gesundheitssysteme und Regierungen und deren Verantwortung, geeignete Rahmenbedingungen für GK zu schaffen, anstatt auf Individuen, GP und Organisationen, die innerhalb des Systems (inter-)agieren, erscheint notwendig, um nachhaltig wirkende Interventionen zur Stärkung von GK zu entwickeln und umzusetzen. Es besteht Bedarf an gut konzipierten Interventionsstudien, die 1) explizit auf GK-Förderung abzielen, 2) zielgruppen- und genderspezifisch sind, 3) kollaborativ angelegt sind und 4) GK im Zeitverlauf (> 6 Monate nach der Intervention) mit validierten Messinstrumenten messen.

STUDIES CONTRIBUTING TO THIS CUMULATIVE DISSERTATION

Study I

Baumeister, A., Chakraverty, D., Aldin, A., Seven, Ü. S., Skoetz, N., Kalbe, E., & Woopen, C. (2021). "The system has to be health literate, too" - Perspectives among healthcare professionals in transcultural treatment settings. *BMC Health Services Research*, *21*(1), 716. https://doi.org/10.1186/s12913-021-06614-x

Study II

Chakraverty, D., **Baumeister, A**., Aldin, A., Jakob, T., Seven, Ü. S., Woopen, C., Skoetz, N., & Kalbe, E. (2020). Gender-specific aspects of health literacy: perceptions of interactions with migrants among healthcare providers in Germany. *International Journal of Environmental Research and Public Health*, *17*(7). https://doi.org/10.3390/ijerph17072189

Study III

Baumeister, A., Aldin, A., Chakraverty, D., Monsef, I., Jakob, T., Seven, Ü. S., Kalbe, E., Skoetz, N., & Woopen, C. (2019). Interventions for improving health literacy in migrants [protocol]. *Cochrane Database of Systematic Reviews,* (4). CD013303. https://doi.org/10.1002/14651858. CD013303

Baumeister, A., Aldin, A., Chakraverty, D., Huebner, C., Adams, A., Monsef, I., Skoetz, N., Kalbe, E., & Woopen, C. (2023). Interventions for improving health literacy in migrants. *Cochrane Database of Systematic Reviews,* *11*(11):CD013303. https://doi.org/10.1002/14651858.CD013303

Related publications

Aldin, A., **Baumeister, A.**, Chakraverty, D., C., Monsef, I., Noyes, J., Woopen, C., Kalbe, E., & Skoetz, N. (in press). Gender differences in the context of interventions for improving health literacy in migrants: a synthesis of qualitative evidence. *Cochrane Database of Systematic Reviews.*

Chakraverty, D., **Baumeister, A.**, Aldin, A., Seven, Ü. S., Monsef, I., Skoetz, N., Woopen, C., & Kalbe, E. (2021). Gender differences of health literacy in persons with a migration background: a systematic review and meta-analysis. *BMJ Open*, *12*(7), e056090. https://doi.org/10.1136/bmjopen-2021-056090

Aldin, A., Chakraverty, D., **Baumeister, A.**, Monsef, I., Noyes, J., Jakob, T., Woopen, C., Kalbe, E., & Skoetz, N. (2019). Gender differences in health literacy of migrants: a synthesis of qualitative evidence [protocol]. *Cochrane Database of Systematic Reviews*, (4). CD013302. https://doi.org/10.1002/14651858.CD013302

LIST OF ABBREVIATIONS

AAHLS	All Aspects of Health Literacy Scale
AHRQ	Agency of Healthcare Research and Quality
AMA	American Medical Association
AVE	Culturally and Literacy Adapted Audio-/visual Education
BHLS	Brief Health Literacy Screen
BMBF	Bundesministerium für Bildung und Forschung
CBPR	Community Based Participatory Research
CHW	Community Health Workers
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COVID-19	Coronavirus Disease 2019
EBM	Evidence Based Medicine
FGD	Focus Group Discussion
GCM	Global Compact for Safe, Orderly and Regular Migration
GLIM	Gender-specific Aspects of Health Literacy in Individuals with Migration background
HCP	Healthcare Professional
HL	Health Literacy
HLQ	Health Literacy Questionnaire
HLS-EU	Health Literacy Survey Europe
HLS-EU-Q	European Health Literacy Survey Questionnaire
HLSBC	Culturally and Literacy Adapted Health Literacy Skills Building Course
IOM	International Organization for Migration
LHE	Lay Health Educators
MEDLINE	Medical Literature Analysis and Retrieval System Online
MD	Mean Difference
M-POHL	Action Network on Measuring Population and Organizational Health Literacy
ORG-HLR	Organisational Health Literacy Responsiveness
NVS	Newest Vital Sign
PsycInfo	Psychological Information Database

RCT	Randomized Controlled Trial
REALM	Rapid Estimate of Adult Literacy in Medicine
REALM-SF	Rapid Estimate of Adult Literacy in Medicine – Short Form
RevMan	Review Manager
RoB	Risk of Bias
RQ	Research Question
SMP	Culturally and Literacy Adapted Self-Management Programme
SILS	Single Item Literacy Screener
SMD	Standardized Mean Difference
S-TOFHLA	Short Test of Functional Health Literacy in Adults
TE	Culturally and Literacy Adapted Telephone Education
TOFHLA	Test of Functional Health Literacy in Adults
WHO	World Health Organization

LIST OF TABLES AND FIGURES

1 INTRODUCTION

As the year 2024 begins, the world is facing tremendous pressing issues, many of which began even before the idea of this dissertation arouse. Some of these, such as the war in Ukraine, the escalated conflict in the Middle East, and other crises, claim new victims every day and further fuel the already rising international migration flows (International Center for Migration Policy Development, 2023; International Organization for Migration, 2024). Others, such as the COVID-19 pandemic, began and ended during the time of writing but nevertheless caused yet unforeseeable long-term consequences for the world's health systems, revealing their understaffing and inadequate preparation for health crises of this magnitude as well as their suffering from underinvestment (OECD, 2023a).

The years of the pandemic have left traces: rarely has it been more evident that the continuous provision of easily accessible, evidence-based health information is essential to enable citizens to make self-determined, informed health decisions. Rarely has it been more apparent how controversial personal health decisions can get when they potentially affect the well-being of others. And rarely has it been more visible how difficult it is for individuals and society to filter the *good* from the flood of complex, sometimes contradictory information, and to adopt appropriate health behaviours (e.g. keeping a distance, reducing contacts) despite the knowledge of potential harm to one's own health and that of others. Thus, the “greatest health crisis in a century“ (OECD, 2023a, p. 3) seriously impacted the scientific and public view on the importance of health literacy (HL) and HL interventions at individual and organisational levels.

In particular, but not exclusively, the societal and economic consequences of en- or even pandemics, national and international conflicts over power, territory, religion, and resources, and the consequences of an ongoing climate change pose major threats to people all over the world, forcing many of them to flee their usual places of residence, often under devastating circumstances, seeking refuge in new places they must henceforth, for a time or even forever, call *home*.

Certainly, migration is a complex phenomenon and cannot be broken down to people’s escape from humanitarian or natural crises. People migrate for various reasons: some flee from political or religious persecution, some are seeking relatively better living conditions or job opportunities, and others simply want to learn about other cultures and broaden their horizons by studying or working abroad (Castelli, 2018; International Center for Migration Policy Development, 2023; International Organization for Migration, 2019a; Moore & Shellman, 2004). Besides these manifold external factors, the motives for and the consequences of migration are shaped by several socio-demographic characteristics such as ethnicity or 'race'[1], age, or gender. Of these, gender may have the greatest impact on the experiences individuals make pre-, peri-, and post-migration (Migration Data Portal, 2023a). A migrant's gender[2] may affect which health information is sought and accessed, how it is understood and evaluated, and how it is translated into health decisions (Aldin et al., 2019).

Processing health information can be challenging for everyone (HLS19 Consortium, 2021; Jordan & Hoebel, 2015; Pelikan et al., 2013; Schaeffer et al., 2021; Sørensen et al., 2015) but may be particularly defiant when one is entering a new health system with little or no knowledge of, for example, the cultural practices, communicative norms (including the language) or commonly accepted gender rules. However, sufficient processing of health information necessitates not only comprehensive skills and resources on the individuals' site, but also appropriate social and political conditions as well as the provision of easy-to-access, trustworthy, and evidence-based health information (Baumeister et al., 2023).

HL, understood as the "knowledge, motivation and competences to access, understand, appraise, and apply health information" (Sørensen et al., 2012), is widely regarded as crucial factor to effective disease management and improved health outcomes (Baumeister et al., 2019). Furthermore, HL is critical for self-determined (Woopen, 2015) and informed decision-making and related to individual and community empowerment[3] (World Health Organization, 2021). Evidence suggests that subjective HL, i.e. self-perceived difficulties to deal with health information and to navigate the health system (Schaeffer et al., 2016), is associated with one's general subjective health status and health-related quality of life

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[1] Albeit a scientifically unjustifiable (Williams, 1997), (scientific-)racism reinforcing (Dordunoo et al., 2022) and, moreover, also inconsistently used concept (Kaplan & Bennet, 2003), the term 'race' is still included in research designs as a variable to examine health outcomes (Dordunoo et al., 2022). I explicitly distance myself from its application in both research and everyday life contexts. Due to the still frequent use of 'race' or ethnicity, also to describe migrant groups such as so-called Hispanix/Latinx (López et al., 2010), it appears in this dissertation, although unintentionally.

[2] For a conceptual placement of the relational concept *gender* in contrast to the biological concept *sex* and an explanation why the term gender is used in this dissertation, see chapter 1.3 Gender as determinant of migrants' health literacy.

[3] Empowerment, broadly understood as a process or mechanism that leads people, organisations and societies gaining control over their affairs (Rappaport, 1987), is often mentioned in relation to HL; some researchers view HL as important to empowerment processes (e.g. Abel, 2007; Nutbeam, 1998; American Medical Association, 1999; Kickbusch et al., 2005; Sørensen et al., 2012; Abel & Sommerhalder, 2015). Central to these empowerment processes is the belief of individuals or groups that they have the competencies to make self-determined decisions about their lives. As individual HL, in the broader sense, can also be understood as a decision-making competence, it can be argued that HL is important for empowerment. Others, such as P. J. Schulz and Nakamoto (2013), however, warn against equating the concepts and argue in favour of a strict empirical and conceptual separation as a high level of HL would not necessarily lead to higher empowerment and vice versa. They argue that a high level of HL without simultaneous high level of empowerment could force patients to become dependent on health care providers. On the other hand, a high level of empowerment without a high level of HL may lead to dangerous health decisions due to overestimation of one's own abilities (P.J. Schulz & Nakamoto, 2013).

(HLS19 Consortium, 2021). In contrast, ‘low’ levels of HL have been associated with higher rates of chronic diseases, more frequent hospitalisations and emergency treatments, higher healthcare expenditures, the reduced use of preventive measures, lower treatment adherence, and an increased risk of morbidity and mortality (Berkman et al., 2011; Eichler et al., 2009; HLS19 Consortium, 2021; Rasu et al., 2015; Sørensen et al., 2015). Internationally, HL is discussed as one of the key determinants of health (Nutbeam & Lloyd, 2021; Paasche-Orlow et al., 2005; Pelikan et al., 2018; Schaeffer et al., 2018).

Many migrants[4] are facing barriers in accessing health information and -services, in understanding and evaluating the latter, and in deriving self-determined, informed health decisions. All of these are aspects are often associated with so-called ‘HL limitations’ (Berens, Klinger, Mensing, et al., 2022; Christy et al., 2017; Mantwill & Schulz, 2017; Morris et al., 2022; Poza-Méndez et al., 2023; Quenzel & Schaeffer, 2016; Wangdahl et al., 2014). As with migration experiences, gender could have a significant impact on the HL-related resources and needs of migrants; a personal factor of HL yet under-researched, especially in the context of migration (Chakraverty et al., 2022).

This cumulative dissertation is concerned with three phenomena, each of which is complex and independently regarded as a determinant of health: *HL*, *migration,* and *gender*.

Due to its necessary narrowness, it is not possible to do equal justice to all three constructs. For this reason, the focus is on HL, its facets and determinants with particular reference to the context of migration. However, I understand HL as a situational, multidimensional, and dynamic process (Sørensen et al., 2012) which is co-created in social relations (Samerski, 2019; Papen, 2009). Thus, HL is a relational construct determined by individual resources, including different forms of (health) knowledge and personal characteristics, as well as external factors such as one’s current situation, the political context and the health system one is expected to navigate (Dodson et al., 2015; HLS19 Consortium, 2021; Nutbeam, 2023; Sørensen et al., 2012). Furthermore, migration is an inherently gendered phenomenon as gender-specific role expectations and power dynamics play a central role in all cultures around the world shaping the entire migration process (International Organization for Migration, 2015). For this reason, I take an explicit look at gender-specific aspects of HL in the context of migration and explore whether migrant women or men benefit differently from HL interventions.

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[4] Being aware of the heterogeneity of people categorised as migrants, in this dissertation, the term migrant is used as an umbrella term for people who move away from their usual place of residence either temporarily or permanent, referring to refugees, asylum seekers, economic migrants, immigrants and other people who migrated themselves (International Organization for Migration, 2018). A detailed description of the migration terms used is found in the section 1.2.1 Relevance and key terms.

1.1 Health Literacy

Today, HL is a worldwide noticed concept in the field of public health research. A search for the term in the scientific database PubMed in January 2024 returned a total of 29,789 results along with a large list of suggestions for refining the search. For example, in terms of disease-specific concepts such as mental HL or HL in distinct groups (e.g. migrants) to HL measurement or HL interventions.

More than twenty years ago, there were researchers calling HL "old wine in new bottles" (Tones, 2002), thereby questioning the necessity “for extending the original formulation of health literacy and incorporating in it re-packaged new versions of existing theoretical formulations” (Tones, 2002, p. 289) such as *empowerment*, *critical environmental education*, and *health education,* or *health-related decision-making* (Tones, 2002).

Nowadays, HL is all the more a highly regarded concept in public health and health services research, thus also receiving increasing attention from health policy makers around the world with various (inter-)national initiatives and action plans aiming to raise global awareness for the need to promote HL at individual, population and organisational levels (Trezona et al., 2017; Weishaar et al., 2019).[5]

This attention gained for the topic of HL was particularly induced by the alarming results of several population studies conducted in the early 2000s, for example, in Northern America (Kutner et al., 2006), Australia (Adams et al., 2009), Canada (T. S. Murray et al., 2008) and later also in Europe (Sørensen et al., 2015), indicating a strong association between HL and health status or -behaviour and revealing a considerably unequal distribution of HL levels between population groups (i.e. the ‘social gradient’ of HL).

However, despite the current broad consensus on the relevance of HL for disease management, disease prevention, and health promotion, there is no common understanding of which individual skills and abilities constitute HL, how strongly and in what way they are influenced by external factors such as the health system, or how they should be measured (Baumeister et al., 2023; Mackert et al., 2015; Sørensen, 2019). This is not surprising as the realm of HL integrates both research and practical applications derived from various disciplines and domains such as education or health psychology, health services research, and social sciences (Abel & Sommerhalder, 2015; Nielsen-Bohlman et al., 2004). Still, new specifications of definitions describing HL for different contexts or populations are being developed (Sørensen, 2019). Thus, HL continues to be constantly evolving.

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[5] For example, the German National Action Plan on Health Literacy (2018) has identified the promotion of HL among people with a migration background as one of its priority action goals (Schaeffer et al. 2018).

But let's start at the beginning.

1.1.1 The two paradigms in health literacy research – now and then

In general, in HL research, two paradigms can be distinguished. Both are operating largely separately from each other (Pleasant & Kuruvilla, 2008)[6], although there have been noticeable convergences in recent years: on the one hand, the clinical approach, which was commonly referred to in the early years of HL research in North America (up to and around the millennium). On the other hand, the public health approach, firstly described by the World Health Organization in 1998 (WHO) (Nutbeam, 1998), which is now widely applied in Europe, Asia, and Australia.

In the following, I will briefly describe some selected definitions, models, and frameworks that are widely cited and have been, or still are, commonly used to describe, measure, or improve HL in different contexts.[7]

The clinical approach – health literacy as risk factor

The clinical approach refers to an individual's poor literacy skills regarding health as a potential *risk factor* that needs to be addressed in the provision of clinical care (Nutbeam, 2008). From this perspective, HL is primarily of interest to those individuals who are at risk for developing a disease or those who are already suffering from physical or mental health problems (Pleasant & Kuruvilla, 2008).

First coined by Scott Simonds (1974) in the school context, HL was initially limited to describing the individual techniques and skills needed to read and understand medical instructions or health-related documents (Tones, 2002). However, the concept did not receive increased attention until around the turn of the millennium, after several studies consistently suggested that there was a relationship between the ability to read and understand medical information and one's health outcomes, hospitalisation rates, or use of preventive measures (Adams et al., 2009; Baker et al., 1998; Dewalt et al., 2004; Kutner et al., 2006). In accordance to that, the Ad Hoc Committee on Health for the Council of Scientific Affairs of the American Medical Association (AMA) defined HL in 1999 as "the constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the

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[6] As two of the firsts, Peasant and Kuruvilla (2008) described the development of the two distinctive approaches on how to research and measure HL, proposing a more comprehensive view on the construct by taking into account clinical as well as public health approaches.

[7] Due to the necessary narrow focus of this dissertation, some meaningful definitions and conceptual models are not presented in this section, particularly in the area of (public) HL. For example, Soellner et al. (2009), Freedman et al. (2009), or Kickbusch et al. (2005) should be mentioned in this regard. However, these were also considered in the conceptualisation of the integrated model of HL by Sørensen et al. (2012), which was applied in this dissertation and developed based on a systematic review and analysis of HL definitions and models.

healthcare environment” (American Medical Association, 1999, p. 553). Today, these basal cognitive skills are subsumed under the term *functional HL* (Nutbeam, 2000).

This focus on the individual's relationship with the health system and health professions was slightly refined by Ratzan and Parker (2000), whose HL definition was later taken up again by the Institute of Medicine (US) Committee on Health Literacy of the Department of Health and Human Services (2004) and received world-wide attention in the past 20 years. In their landmark publication *Health Literacy: A Prescription to End Confusion* the researchers around Lynn Nielsen-Bohlman described HL as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (Ratzan & Parker, 2000 cited by Nielsen-Bohlman et al., p. 4)

As in the AMA's definition, individual factors such as the communication skills of the individual and his or her knowledge of the links between lifestyle, health, and causes of disease are highlighted. On the other hand, systemic and environmental factors such as the cultural context and the health system are considered as determinants of HL (Nielsen-Bohlman et al., 2004). Thus, HL is here described as a context-specific construct that can be influenced by social interactions and (health) system conditions such as the way in which health information is delivered (Nutbeam, 2008).

Most of the disease-specific HL concepts can be assigned to the clinical approach, as the goals are improved management of one's own illness, effective and satisfactory interaction with HCPs, and successful navigation of the health system.

The public health approach – health literacy as an asset

Around the millennium, the concept of HL was detached from the medical context and further developed from a health promotion perspective. The public health approach considers HL as an asset and outcome to health education and communication (Brooks et al., 2017). Effective HL promotion may, in turn, lead to empowered health decision-making and greater control over one’s health (Nutbeam, 2008) and the health of others.

In 1998, the renowned public health researcher Don Nutbeam developed a definition of HL for the *Health Promotion Glossary* of the WHO that emphasises the interrelation between personal and social skills (e.g. reading and writing abilities) on the one hand and the responsibility and motivation of individuals to competently handle health information on the other hand. According to this definition, “health literacy represents the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand

and use information in ways which promote and maintain good health" (Nutbeam, 1998, p. 357).

Improving access to health information and promoting skills for efficiently using it is seen as one key prerequisite for the promotion of HL. However, HL education is, as one element of HL promotion, also described as a societal task emphasising its role for empowerment: "Health literacy means more than being able to read pamphlets and successfully make appointments. By improving people's access to health information and their capacity to use it effectively, health literacy is critical to empowerment" (Nutbeam, 1998, p. 357).

In 2000, Nutbeam went even further: he essentially shaped our modern understanding of individual HL by embedding the construct into a pyramidal system representing the outcomes of health education and health promotion measures. According to his three-step model, HL is represented at three functional levels that can be promoted either separately or together with targeted measures.

Starting with the first, most basal level, *functional HL* was explained to be enhanced by enabling the individual to understand health information by improving literacy and numeracy skills in the medical context or providing literacy adapted easy-to-access health information. The second level, *communicative/interactive HL*, describes more advanced cognitive, social, and motivational skills that enable the individual to act independently on the basis of knowledge and to actively engage with the health system. Interventions may include, for instance, support services and self-management programmes within which the individual should learn to act independently, self-motivated, and self-confident to maintain or improve one's own health. The third level of *critical HL* enables the individual to critically appraise and analyse health-related information, to make informed choices and to interact with the general environment in a reflective, attentive manner (Nutbeam, 2000, pp. 263–265).

In the last two decades, the distinction between *functional, interactive,* and *critical HL proposed* by Don Nutbeam in 2000, has been widely accepted, with further refinement by other authors (Chinn, 2011; Ishikawa et al., 2008; Johnson et al., 2019; Sykes & Wills, 2018; Sykes et al., 2013). Particularly, the concept of *critical HL* (Nutbeam, 2000) has become more popular in recent years. Through its explicit focus on the critical appraisal of health information on the one hand, social interactions, and engagement in social action on the other hand, it is regarded as a crucial resource to improve individual and community empowerment and to explain and reduce health-related inequalities (Abel & Benkert, 2022; Sykes & Wills, 2018).

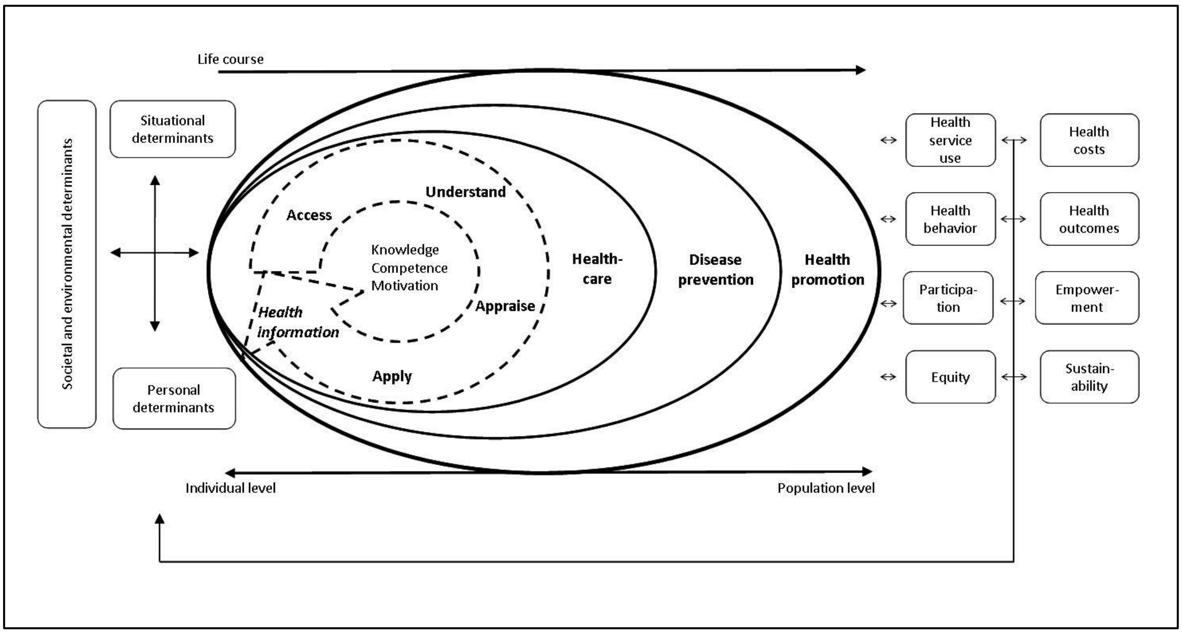
In 2012, research on HL also gained popularity among researchers and health policy-makers in the European region, when the *European HL Consortium* for the first time provided population-based data on citizens' HL in eight European countries (Sørensen et al., 2015). During the *European Health Literacy Survey* (HLS-EU) project (2009-2011), Sørensen et al. (2012) summarised 17 definitions and twelve concepts of HL in the English-language literature from 1998 to 2009 and subjected their components to a systematic analysis. The following integrated definition was derived from the results of the analysis:

> Health literacy is linked to literacy and encompasses people's knowledge, motivation and competences to access, understand, appraise, and apply health information to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course (Sørensen et al., 2012, p. 3).

Based on this definition, Kristine Sørensen and colleagues developed an integrated model of HL considering individual, social, and systemic influencing factors and determinants that can affect individual HL, as well as the three health domains (disease management, disease prevention, and health promotion) in which HL unfolds its impact. This model aimed at integrating the different dimensions of HL, being empirically verifiable and considering the consecutive steps of processing health information (access, understand, appraise, and apply). Here, HL is understood as a relational, dynamic, and multidimensional concept that is context- and situation-specific (Sørensen et al., 2012). Figure 1 shows the integrated model developed by the researchers of the HLS-EU.

Figure 1

Integrated model of health literacy



Note. From “Health literacy and public health: A systematic review and integration of definitions and models” by Kristin Sørensen et al., 2012, *BMC Public Health, 12*:80, p. 9. CC BY 2.0

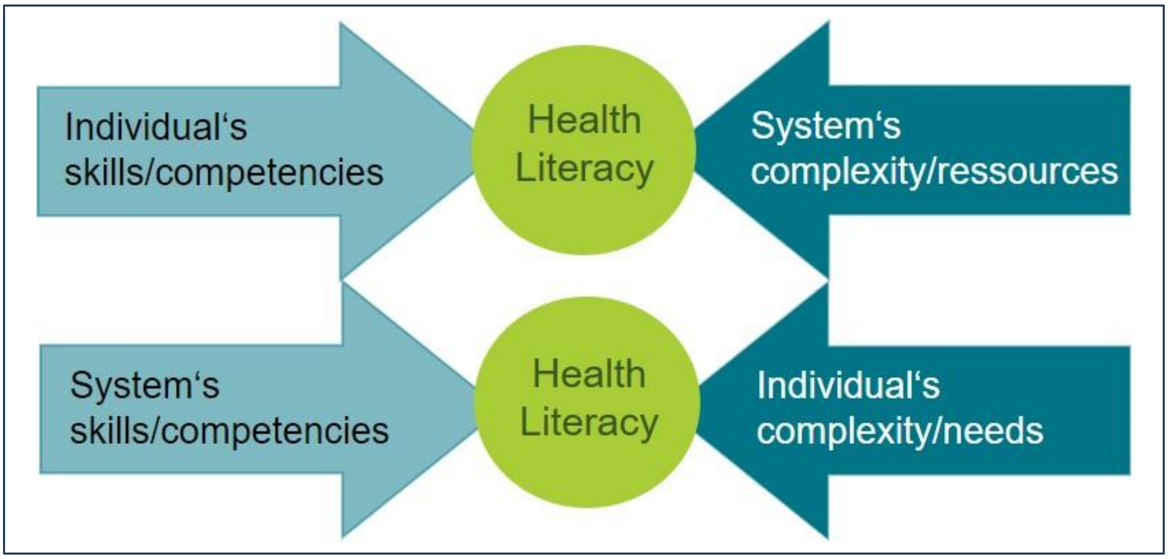
According to this model, HL is influenced by personal factors (e.g. gender), situational factors (e.g. social support, current physical environment) as well as social and environmental factors (culture, language, political system). Accordingly, migration can be understood either as a *personal* factor of HL because a person possesses a migrant background or as a *situational* factor as the migrant background influences the present circumstances and experiences made by an individual (Baumeister et al., 2021; Chakraverty et al., 2020). These aspects, in turn, interact with environmental and societal conditions, such as the receiving country’s health system-related HL responsiveness (e.g. Trezona et al., 2017; see 1.1.2 Organisational health literacy). All these factors can have an impact on how individuals may access, understand, evaluate, or use information, and in turn shape interactions within health systems (Baumeister et al., 2021).

As Ruth Parker already noted back in 2009, the degree to which people have the capacity to access and process health information depends to a large extent on the complexity of the available information and the requirements within the (health) system, since HL is determined by individual abilities and resources on the one hand and structural, situational, and political conditions on the other hand (Parker, 2009).[8] It is the interplay of these external and internal factors that may enable individuals to derive decisions (Sørensen et al., 2012) or take actions (Nutbeam & Lloyd, 2021) from the information obtained that will – at best – have a positive impact on their health and quality of life.

Figure 2 shows this dynamic interplay between individual and system factors influencing HL, highlighting how individual's skills, competencies and needs intersect with system's complexity, resources and competencies.

Figure 2

Health literacy as a relational construct



Note. Own presentation, adapted from "Measuring health literacy: What? So what? Now what?" by Parker, R., 2009, in L. M. Hernandez (Ed.), *Measures of Health Literacy: Workshop Summary* (pp. 91–98). National Academies Press (https://www.ncbi.nlm.nih.gov/books/NBK45386/) and from *Health literacy champion tips: Making the match by* Sørensen, K., 2023 *(*https://www.kristinesorensen.net/_files/ugd/76600e_67c05f31b584431fb61b79b112d131f6.pdf)

Responding to the ongoing debate of advancing the HL concept and emphasising the relational and dynamic character of HL, new modified definitions were recently developed. For example, in 2021 the WHO replaced their longstanding definition of HL used in their *Health Promotion Glossary of Terms* and explicitly emphasised the important role of organisational structures as well as the availability of resources that enable HL in the first place:

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[8] This view on HL as a (social-)relational construct has been adopted and refined by other researchers, such as Dodson et al., 2015; HLS19 Consortium, 2021; World Health Organization, 2021, Bröder et al., 2017, and is now commonplace in HL research.

> Health literacy represents the personal knowledge and competencies that accumulate through daily activities, social interactions and across generations. Personal knowledge and competencies are mediated by the organizational structures and availability of resources that enable people to access, understand, appraise and use information and services in ways that promote and maintain good health and well-being for themselves and those around them (World Health Organization, 2021, p. 6).

With this definition, the WHO highlights the *social aspect* of HL, which was particularly evident during the COVID-19 pandemic, when the need for social responsibility and solidarity was stressed regarding individual, collective, and political health decisions (Paakkari & Okan, 2020).

1.1.2 Organisational health literacy

In line with the understanding of HL as a *relational* concept, the ability of healthcare organisations to respond to individual resources and needs regarding health information processing has been increasingly focused on in recent years. The concepts of *organisational HL* (Farmanova et al., 2018) and *HL responsiveness* (Trezona et al., 2017) refer to all organisational or system-related efforts, respectively, that support people to navigate the health system, to understand health information and services, and to use them in a way that is conducive to health (Brach et al., 2012). Cindy Brach and her colleagues at the Institute of Medicine's *Roundtable on Health Literacy* were the first to describe the *ten attributes of a health literate healthcare organisation* in their 2012 discussion paper (Brach et al., 2012). These were defined, among others, to adequately meet the needs of populations with a range of HL abilities, to avoid stigma, to provide easy access to health information and services, to ensure successful communication between health care providers and patients through the use of HL strategies (e.g. assure comprehension at all points of contact), and to use a participative approach in designing, implementing and evaluating health information and services (Brach et al., 2012).

Since then, various international efforts have been made to specify the requirements for health literate healthcare organisations and to develop new assessment tools for the measurement of organisational HL. Building on the ‘ten attributes’ formulated by Brach et al. (2012), the first European research projects, such as in Germany (Ackermann Rau et al., 2014; Kowalski et al., 2015), Austria (Dietscher et al., 2015), or France (Henrard et al., 2019), have taken up the organisational HL concept, developed it further and evaluated the first European self-assessment tools for healthcare institutions on their way to becoming health literate healthcare organisations (Ackermann Rau et al., 2014; Brega et al., 2019; Dietscher et al., 2015). Meanwhile, efforts to measure and promote organisational HL exist for quite different healthcare organisations (e.g. in facilities for people with disabilities (Rathmann et al., 2020) and areas of application (e.g. breast cancer patients in inpatient treatment, Ernstmann et al., 2017).

In the context of migration, there are related concepts such as *inter- or cultural competence* (inter alia Leung et al., 2014; Napier et al., 2014), *intercultural opening of the health system* (e.g. Falge & Zimmermann, 2014; Schröer, 2007) or *cultural and linguistic competency* (Office of Minority Health, 2023) pursuing similar goals with regard to persons with migration experience (Baumeister et al., 2023).These approaches include *inter alia* to improve cultural appropriateness of health information, awareness of cultural factors in personal interactions and services, and to ensure high-quality and efficient health care for all patients regardless of their cultural background or any other personal characteristics. A thorough implementation of such concepts can serve as a fruitful starting point towards addressing the HL-related needs of diverse populations as they consider several components relevant for improving information transfer and -processing in the health context. Thus, addressing the cultural competence and HL of both health systems and HCPs can enhance patient satisfaction and health outcomes, and mitigate health disparities (McCann et al., 2013).

Trezona et al. (2017) developed the *Organisational Health Literacy Responsiveness (ORG-HLR)* framework, which outlines organisational HL as a *system-based* proactive capacity to address the diverse needs of persons living in a society. The researchers explicitly refer to the supportive role of healthcare institutions and their professions in decision-making based on personal preferences (as opposed to emphasising the individual capacities to make good health decisions). At the same time, they stress the responsibility of policy-makers to create the necessary conditions, including the provision of financial resources, so that healthcare organisations are capable to adequately respond to individual HL needs (Trezona et al., 2017). The initiators of the German National Action Plan on HL also took up these demands in their official report published in 2018. The researchers explicitly emphasised that the German health system must be designed to be ‘user-friendly’ and ‘health literate’ and that the promotion of HL should be anchored structurally and programmatically in the health system *and* its organisations (Schaeffer et al., 2018).

HCPs can be viewed as “smallest executive unit of healthcare organizations” (Baumeister et al., 2021, p. 2). They act as central contact points and informational sources regarding health-related problems (Schaeffer et al., 2021) and can therefore contribute to applying the attributes of health literate healthcare organisations in treatment settings.

This is where the concept of *professional HL* sets in: in general, HCPs are facing new challenges due to the exponential increase of new global knowledge and, simultaneously, the ever-fast obsolescence of existing knowledge (Schaeffer et al., 2023). More than ever, they must be able to keep up to date with new (medical) knowledge and in doing so, to process substantial amounts of information, critically appraise it and distil the knowledge that is relevant to their respective professional practice (Schaeffer et al., 2023). A key element in applying this new, current and best available knowledge to patients is "good communication and listening skills" (Kickbusch et al., 2005, p. 16).

In 2023, Schaeffer and colleagues developed a definition of professional HL based on the integrated HL definition as proposed by Sørensen et al. (2012).

> Professional health literacy includes the motivation, knowledge and skills, to find, understand and use professionally relevant knowledge and information in different forms, and use them in order to act professionally in accordance with the "state of the art" and to and to prepare, convey and communicate knowledge and information relevant to health and illness in a way that it can be understood, (critically) assessed and used by patients to make decisions about health issues (Schaeffer et al., 2023, p. 13).[9]

This definition places emphasis on the significant role of HCPs in maintaining and improving HL in health encounters. Particularly in the context of healthcare interactions, the role of the HCP's professional HL is crucial for an effective and satisfactory flow of information (Baumeister et al., 2021), and thus, the maintenance and improvement of a patient's individual HL.

1.1.3 Context- and disease-specific approaches to health literacy

Drawing on the work of the HLS-EU Consortium 2012, in the year 2019 the WHO-Europe initiated the *Action Network on Measuring Population and Organizational Health Literacy (M-POHL)* involving 28 countries in the European region that committed to measure HL regularly in order to review changes regarding populational HL and to initiate necessary steps for its promotion (HLS19 Consortium, 2021). In the HLS-2019, however, not only generic, but also context-specific HLs such as *navigational HL*, *communicative HL with physicians*, *digital HL*, and *vaccination HL* were measured. Focussing on the various aspects of

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[9] Own translation. Due to the currency of this definition, it has not been included in the constituent considerations of this PhD project. Both, the results of the related empirical survey on professional HL in Germany, Austria, and Switzerland (Schaeffer et al., 2023), as well as the methodological and practical implications that this concept entails in the context of migration are reflected in the discussion section (see 4 Discussion).

HL that evolve in different contexts, the initiators of M-POHL concluded that there is no ‘one fits it all’ solution for researching and practising HL. Thus, it would be more appropriate to look closely in which areas of life particular HL-related challenges are present and should be addressed (HLS19 Consortium, 2021).

Besides such context-specific HLs that are subject to the specific fields of application but do not focus on a certain health topic, a variety of disease-specific definitions and models have emerged in the last years. Disease-specific HLs have been developed for various medical disciplines such as psychiatry (*mental HL*), oncology (*cancer HL*), immunology (e.g. *HIV HL*) or dentistry (*dental HL*) (Mackert et al., 2015). These approaches define HL about the specific requirements of a particular disease for an individual, like understanding or following a therapeutic regimen. They typically focus on the acquisition of knowledge about the respective illness, suggesting a causal relationship between knowledge and the corresponding health behaviours (Baumeister et al., 2023). What all these disease-specific approaches have in common is that dealing successfully with one's own disease, navigating the health system, and interacting with HCPs are essential concerns. Differences can be seen in the focus on individual components of HL and, consequently, in the possible insights gained from research (Baumeister et al., 2022).

The concept of mental HL, for example, has been developed detached and independently from the generic concept of HL (Baumeister et al., 2022).[10] Anthony F. Jorm, widely viewed as the most important pioneer in the field of mental HL, defined it as „knowledge and beliefs about mental disorders which aid their recognition, management or prevention“ (Jorm et al., 1997, p. 184). He later extended the definition by mental disorder-related knowledge that is necessary to benefit one’s own and others’ mental health (Jorm, 2000). He refers to the ability to recognise mental disorders and having the knowledge about their risk factors and causes, but also to know about effective self-help strategies and when to seek professional help or the help of others (Jorm, 2000). Since its first mention, several mental disorder-specific sub-concepts have emerged (e.g. *depression literacy* (Griffiths et al., 2004), *suicide literacy* (Batterham et al., 2013) or *schizophrenia literacy* (Furnham & Blythe, 2012); new mental disorder-specific assessment tools are continuously evolving (Baumeister et al., 2022).

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[10] See Baumeister et al. (2022) for a deeper elaboration of the conceptual differentiation between mental HL and generic HL, an overview of the current state of research, and approaches to interventions in this context.

1.1.4 Operationalisation of (individual) health literacy

In line with the development of the HL concept, the scope of application and investigation grew accordingly. Thus, in the almost thirty years of extensive research on HL, a variety of different measurement instruments were developed and tested in different populations. Since the construct is so incomparably defined, the existing measurement instruments conclusively refer to the respective underlying definition or conception of HL (Abel & Sommerhalder, 2015). In March 2024, the publicly available data base *Health Literacy Tool Shed*, listed 280 different assessment tools measuring HL in and across populations (U.S. Department of Health and Human Services, 2024).

In the following, I will provide a brief overview of the measurement tools that have been commonly used in the past two decades and thus have shaped our current understanding of the HL determinants and associated health outcomes; explicitly without claiming completeness. For a deeper insight in existing measurement tools to assess individual HL, its strengths and weaknesses, it shall be referred to the variety of systematic reviews conducted in the field of HL. An overview for the measurement of HL in adults can be found, for example, in Altin et al. (2014), Guzys et al. (2015), and Nguyen et al. (2017); for children and adolescents in Okan et al. (2018); for disease-specific tools in Wei et al. (2015), Wei et al. (2016) or (E.-H. Lee et al., 2017).[11]

Generic health literacy measurement tools

In the empirical literature, the research on HL has long focused on the prevalence of impaired health-related literacy or numeracy skills (i.e. *functional HL* (Nutbeam, 2000)). Most studies – particularly those conducted in the US – used unidimensional assessment instruments. These tools assess, for example, the ability to recognize words (general medical terms), reading comprehension, or the ability to perform minor arithmetic operations in a medical context (Baumeister et al., 2022).

The first widely used test to measure functional HL was the *Rapid Estimate Assessment of Adult Literacy in Medicine (REALM)*. The three-to-five-minute test targets word recognition and reading skills and includes 66 words related to health and medicine that become progressively more difficult (Davis et al., 1991). The 22-minute *Test of Functional Health Literacy (TOFHLA)* goes one step further than the REALM by asking comprehension questions

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[11] Since the concept of organisational HL has gained increasing importance in recent years, new measurement tools for assessing this facet of HL have also been steadily developed and implemented. However, the contributions of this dissertation are not concerned with the measurement of organisational HL, following that a detailed description of the related measurement tools is not intended. For a deeper insight into the assessment of organisational HL, see Schougaard et al. (2020), or Bremer et al. (2021).

in a medical context and numerical skills (for example, simple arithmetic operations) in addition to reading skills. To date, the TOFHLA is validated in many languages, *inter alia,* in English (Parker et al., 1995) and Spanish (TOFHLA-S) and in its condensed version (S-TOFHLA), respectively (Baker et al., 1999). Using the TOFHLA as a reference standard, the *Newest Vital Sign Test (NVS)* was developed, also capturing the functional level of HL. It queries the understanding of health information, such as the nutritional information of an ice cream package or an educational sheet for a coronary angiography (Weiss et al., 2005).

One of the most popular subjective screening instruments for self-rated functional HL is the *Brief Health Literacy Screen (BHLS)* developed by Chew et al. (2004). The three-item screener (full version)[12] was initially developed to quickly identify patients with low literacy skills and correspondingly their advanced demands on health professionals' communication skills. It asks about one's perceived ability to understand and read health information and whether one needs help with written medical information. The BHLS is validated and used in various languages such as English and Spanish (Sarkar et al., 2011), or French (Chouinard et al., 2022).

The *All Aspects of Health Literacy Scale (AAHLS)* (Chinn & McCarthy, 2013) and the *Functional Communicative and Critical Health Literacy Scale (FCCHL)* (Ishikawa et al., 2008) ask for self-assessed skills in the areas of functional, interactive, and critical HL with 14 items each. Both are following Nutbeam's pyramidal HL model.

The 47-item *Health Literacy Survey-Europe Questionnaire (HLS-EU-Q)* is based on the definition presented by Sørensen et al. (2012) and was developed specifically for the HLS-EU (Sørensen et al., 2013). Since its development, the HLS-EU-Q has been used in various population studies within Europe (Pelikan et al., 2013; Schaeffer et al., 2016). Most recently, it has been extensively revised and refined for the HLS 2019-2021, resulting in the new HLS_{19} Q47 which has been applied across 17 European countries (HLS19 Consortium, 2021).

Like the HLS-EU-Q, the *Health Literacy Questionnaire (HLQ)* was developed to measure HL in populations. It comprises 44 questions that encompass nine conceptually separate domains of HL (e.g. 'feeling understood and supported by healthcare providers' (domain 1) or 'social support for health' (domain 4)) allowing for the calculation of a differentiated HL profile. The aim of the HLQ is to identify subgroups that have special needs in certain dimensions so that targeted interventions can be derived to promote the areas identified as

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[12] The single item literacy screener is a widely used version of the BHLS.

problematic (Osborne et al., 2013). It is validated in many languages, inter alia in English (Osborne et al., 2013), German (Nolte et al., 2017) and Danish (Maindal et al., 2016).

Disease-specific measurement tools

Vignettes (Jorm et al., 1997) are among the most frequently applied measurement instruments of disease-specific HL and are mainly used in the field of mental HL (Wei et al., 2015). In the case of its application in mental HL research, such a vignette typically describes, pictorially or in writing, a person suffering from a specific disease such as depression. They are designed to meet the diagnostic criteria of international classification systems such as the DSM-V (American Psychiatric Association, 2013) or ICD-11 (World Health Organization, 2022a). Respondents are specifically asked whether the person described on the vignette might be suffering from a disorder and, if so, which disorder, how the person might best be helped, and the potential benefits of different intervention approaches. The interventions mentioned include presenting to the general practitioner, specialist, or hospital, joining a support group, taking medication, or initially talking to family members or friends in confidence (Chamberlain et al., 2012; Goldney et al., 2002; Jorm et al., 2000; Reavley et al., 2014). Other disease-specific assessment tools are based on already established tests such as the TOFHLA (Gazmararian et al., 2000) or REALM (van Servellen et al., 2003), or use questionnaires that ask about disease-specific knowledge for example with regard to diabetes (Yeh et al., 2018) or HIV (van Servellen et al., 2003). These tools are either used alone or in combination, to assess different components of HL in the respective disease-specific context.

1.2 Migration

1.2.1 Relevance and key terms

Current global estimates indicate that in the year 2020 approximately 3.6% of the world's population, or 281 million people, were international migrants (i.e. they were born abroad and/or held a foreign citizenship) (International Organization for Migration, 2021). In 2022, 145 million people lived in OECD countries outside their place of birth representing a 10.6% share foreign-born of the total OECD population (OECD 2023b). Due to the climate change and an increasing instability of the world's ecosystem, researchers expect these numbers to even rise in the future (International Center for Migration Policy Development, 2023; Kaczan & Orgill-Meyer, 2020).

According to the International Organization for Migration (IOM), *migration* is defined as

> the movement of a person or a group of persons, either across an international border, or within a state. It is a population movement, encompassing any kind of movement of people, whatever its length, composition and causes; it includes migration of refugees, displaced persons, economic migrants, and persons moving for other purposes, including family reunification (International Organization for Migration, 2018).

Similarly to the conceptualisation of HL, there are no uniformly applied definitions of the terms *migration* or *migrant* at the international level, but there are several core aspects that are widely accepted (International Organization for Migration, 2021). The IOM, for example, proposes to use the term *migrant* as an umbrella term reflecting the "common lay understanding of a person who moves away from his or her place of usual residence, whether within a country or across an international border, temporarily or permanently, and for a variety of reasons" (International Organization for Migration, 2019b).

In Europe, the concept of *migratory background* (synonym: *migrant background* or *migration background*) is also common, referring to people of whom "at least one of their parents previously entered their present country of residence as a migrant" (European Commission, 2019). Thus, it also includes second-generation migrants.

The German category *person with migration background* goes even further: it is related to the citizenship rather than one's direct or indirect migration experience.[13] According to the

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[13] Germany belongs to the most popular immigration countries in the world (International Organization of Migration, 2021). In 2023, 29.7% of the people living in Germany had a migration background. Thereof, 19.1% had a direct migration experience (Statistisches Bundesamt, 2024b).

micro census of the Federal Statistical Office, a person has a migration background if he or she, or at least one parent, was not born with German citizenship (Bundesamt für Migration und Flüchtlinge, 2018).[14] It is based on the assumption that people with a migration experience continue to be shaped by the culture in their country of origin long after the migration process and long after calling that former country *home* and that they may pass on this cultural imprint from generation to generation (Spallek & Razum, 2016).

There are no clear definitions of when people cease to have a so-called 'migration background' or are considered to be German (Spallek & Razum, 2016). However, there are proposals to adapt the terminology: the German Federal Statistical Office has recently introduced the additional category of *immigrants and their descendants* – synonymous with *people with a history of immigration* (Statistisches Bundesamt, 2024a). In this category, people with a one-sided migrant background (e.g. on the father's side) are no longer regarded as people with a migration background. In addition, the third generation (i.e. migrants' grandchildren) is explicitly excluded by this definition. Thus, this category is closer to the European Commission's *persons with a migrant background*, which focuses on the migration experience rather than nationality.

Persons with a migration background (or synonym, those with a migrant background) are diverse in terms of their (family) reasons for and experiences during migration, their socio-economic status and health behaviour (Razum et al., 2008), but also regarding their world views, their cultural imprint and -identity. Thus, all these terms, be it *person with a migration background* or *immigrants and their descendants* (as defined within Germany), or *person with a migrant background* (as defined within the European Commission), and even the term *migrant*, describe extremely heterogeneous groups of people whose need for differentiation goes far beyond ethnic, religious, and socio-economic attribution patterns; this should be taken into account in all debates on migration (and health) and is always implicit in the considerations of this dissertation.

For reasons of thematic limitation, this dissertation is primarily concerned with the context of *international migration* and persons with a direct migration experience (i.e. first-generation migrants) and their children (i.e. second-generation migrants). In line with the definition proposed by the European Commission described above, the term *person with a migrant background* is therefore used as a generic term for *both* first- and second-generation migrants, irrespective of the reasons for migration.

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[14] Although having a direct or indirect migration experience, the displaced persons of the Second World War and their descendants are *by definition* not counted as part of the population with a migration background because they themselves and their parents were born with German citizenship.

The term *migrant* is used to denote *first-generation* migrants only, thereby referring to refugees, asylum seekers, displaced people, economic migrants, immigrants, wandering people, and other individuals who have migrated themselves (International Organization for Migration, 2018). Whenever applicable, distinctions will be made between international migrants who crossed international borders and internal migrants, who did not.

To avoid conceptual fraying, the term *person with a migration background* will only be used with explicit reference to the German definition (e.g. when the term is used in studies conducted in Germany), as this denotation is accordingly often used by German scholars. The new category of *immigrants and their descendants* is not used as empirical data is scarce due to its currency.

1.2.2 Migration and health (inequality)

Despite major international efforts in the field of public health and growing technical and medical progress, health inequalities are still strongly associated with ethnicity, socio-economic status, and education (Lampert et al., 2018; Whitehead & Dahlgren, 2021)

International studies on the health of first-generation migrants[15] consistently indicate that – *on average* – these are exposed to greater health risks, have poorer health status, and are more likely to engage in risky health behaviours in comparison to the majority population (Razum, 2008; United Nations, 2017; World Health Organization, 2018). However, linking health and migration remains complex, not least due to internationally divergent definitions of the term *migrant* (World Health Organization, 2018) and a lack of comparable data (sets) in this context (Dyck et al., 2019; Rechel et al., 2013). For example, German national statistics are based on distinctive definitions regarding the migration background and record various migration-related data (e.g. number of migrants, age, origin, educational situation), which sometimes differ greatly from one another. In addition, these statistics contain numerous definitional variations as well as discrepancies in the statistical recording of relevant migration characteristics (e.g. Microcensus versus Central Register of Foreigners).

Nevertheless, migration is, at least due to its close interconnectedness with other socio-demographic factors such as the socio-economic status, physical conditions, age, or sex, widely acknowledged as a social determinant of health (Castañeda et al., 2015; Davies et al., 2009).

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[15] Referring to both international and internal migrants.

The healthy migrant effect

The *healthy migrant effect* postulates the paradox that international migrants are often healthier (Malmusi et al., 2010) and have lower mortality rates (Swerdlow, 1991) than persons of the majority population with a similar social status. It assumes that most people migrating are young and active (selection effect) and that migrants are therefore in above-average health at the time of arrival in the destination country (Razum & Rohrmann, 2002). For example, a meta-analysis published in 2018 (Aldridge et al., 2018) found lower mortality rates in migrants in comparison to the majority population. However, the authors raised concerns about the generalizability of this finding as the available data of high quality primarily stemmed from studies conducted in high-income countries. In addition, research suggests that the reported 'advantage' of lower mortality rates among immigrants diminishes over time (Abraído-Lanza et al., 2005; Fuller-Thomson et al., 2011).

Consequently, the reliability of the conclusion that there really is a *healthy migrant effect* is limited to those who migrated to high-income countries and its applicability may not extend to certain disadvantaged migrant groups such as undocumented migrants. Moreover, it does not fully account for the intricate and multifaceted nature of the migratory process (Galatolo et al., 2022) as European statistics suggest that international migrants have an increased risk for a range of non-communicable (e.g. diabetes) and communicable diseases (e.g. HIV, hepatis b or c), conditions related to women's and children's health (e.g. increased death birth rates or higher rates of cervical cancer) or mental disorders[16] (Rechel, 2011; Rechel et al., 2013; World Health Organization, 2018).

The reasons for these findings are at least as diverse as are the people assigned to the category *person with a migrant background*. For example, migrants often – but not always – have a lower socio-economic status, poorer education, and are more often in precarious working conditions than the majority population (International Organization for Migration, 2009; Lokhande, 2016; Loschert et al., 2023). A low socio-economic status and low formal educational attainment are widely considered key determinants of health inequalities – also among non-migrants (Lampert & Kroll, 2014; Statistisches Bundesamt, 2011). In addition, there are many studies revealing migrants' multiple barriers to healthcare services, particularly with regard to undocumented migrants, asylum seekers, or refugees (e.g. Graetz et

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[16] Of course, these examples do not apply equally to all migrants. There are sometimes great differences in terms of regions of origin, ethnic groups or migrant status, and as most of the listed diseases are caused multifactorial, people's social status, education, and pre-, peri- and post-migration experiences need to be taken into account, too. However, this, although admittedly necessary differentiation, is beyond the scope of this PhD thesis.

al., 2017; Lebano et al., 2020; Winters et al., 2018)[17] and experiences of structural discrimination in the receiving country (Burgess et al., 2008; Geldermann et al., 2023; Immordino et al., 2022; Lebano et al., 2020). Besides issues of perceived or experienced discrimination, there are several other reasons such as communication difficulties (inclusively but not limited to language barriers) and cultural differences leading to dissatisfaction with HCPs and services and issues to access healthcare without a permanent resident status (Hiam et al., 2019).

COVID-19 health disparities in migrant groups

A particularly recent example is the COVID-19 pandemic, which caused an exceptionally high number of fatal victims in migrants and ethnic minority groups. For example, in the United States (Centers for Disease Control and Prevention, 2020; Tai et al., 2021), more (severe) cases were reported among migrants from Hispanic origin, African Americans and other ethnic minorities. The same is true for migrants and ethnic minorities in the European Union: of 65 studies included in a meta-analysis by Mazzalai et al. (2023), 45 reported more severe outcomes and higher mortality rates related to COVID-19 in these groups compared with the majority population.

Reasons for these findings are manifold: many migrants, and refugees in particular, were living in overcrowded housing situations sharing a small flat (or a small room) with others, partly not even family members and they disproportionately often worked in sectors or positions that placed them at risk of COVID-19 (Greenaway et al., 2020; Lupieri, 2021). In addition, vaccination rates were disproportionately low among these groups (Immordino et al., 2022). Thus, the pandemic has – once more and in all clarity – brought to surface the prevalent health disparities between migrants and ethnic minorities and majority populations, thereby accentuating the complex interrelation between “socioeconomic health determinants and long-standing structural inequalities” (Greenaway et al., 2020, p. 1) in many parts of the world.

However, it is notable that the pandemic posed major threats not only to the physical but also to the mental health of people around the world. These included, for example, isolation and loneliness due to contact restrictions, increased economic stress, or the exacerbation of existing mental health problems such as anxiety and depression.

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[17] Klein and Knesebeck (2018) systematically reviewed 63 articles on healthcare access of migrants and non-migrants in Germany. They found considerably lower healthcare usages in first-generation migrants (not further specified), people with a two-sided migrant background, children and adolescents as well as migrant women compared to the majority population. The utilisation rates varied in terms of healthcare sectors.

Based on an extensive systematic analysis of existing systematic reviews and meta-analyses, in March 2022, the WHO published a report indicating a global rise in the prevalence of anxiety and depression of 25 % (World Health Organization, 2022b). However, what COVID-19 did to the mental health of refugees and other migrants remains only to be assumed; none of the eligible systematic reviews or meta-analyses examined the impact of COVID-19 on the mental health of migrants, respectively.

1.2.3 Migration and mental health (literacy)

The distribution of mental disorders is quite diverse among people with a migration background living in Germany, especially among refugees and asylum-seekers (Schouler-Ocak, 2015). However, international studies indicate that some mental disorders such as depression and/or anxiety (Lindert et al., 2009) are more prevalent in first-generation migrants (i.e. labour migrants and refugees) than in the general population. Moreover, the results from European studies suggest that some groups of migrants (e.g. from the Caribbean and Africa) with specific life-world-related factors or exposures to certain environmental factors (e.g. social disadvantages and exclusion or discrimination) are at greater risk for psychotic disorders (Heinz et al., 2013; Veling et al., 2014). Furthermore, migrant women in Europe are more likely to commit suicide (Heredia et al., 2013; Razum & Zeeb, 2004) than non-immigrant women.

However, despite an equal or even greater need, migrants tend to underutilise mental health services with a particular large gap in health service provision for refugees and asylum-seekers, and among immigrant men (Derr, 2016; Kirmayer et al., 2007; C. J. L. Murray et al., 2012). In addition, many of them seek professional help for mental health problems only in case of high suffering (Magaard et al., 2017).

The reasons for the observed access barriers are manifold and of course they have similarities to those for physical illnesses. However, when it comes to mental health, other HL-related aspects that are important to accessing, understanding, appraising, and applying health information. Especially, the attitudes and beliefs about certain mental illnesses, stigmatisation tendencies, and the knowledge of when to seek professional help, how to find it, and ultimately the ability to make use of it – in short mental HL – becomes an essential asset. For example, the term ‘depression’ encompasses varying meanings across cultures and in numerous languages so that there may not be precise equivalents to describe this condition, leading to potential distortions in cross-cultural comparisons (Bhugra et al., 2021). In some countries, common mental health conditions such as depression are not even considered illnesses, but rather a “natural mood swing” (Bhugra et al., 2014) that cannot be ameliorated by formal health care. Instead, it is anticipated that these conditions will recover through social and emotional support from family members or through religious, conventional, alternative, and complementary healing approaches (Ventevogel et al., 2013). In addition, there is a prevalence of intense stigma surrounding mental health issues in many immigrant communities which hinders access to and utilisation of mental health services (Kohrt & Mendenhall, 2015). Thus, interventions for improving mental HL and reducing mental health stigma among certain immigrant communities seems to be even more important in times of ever-present and multiple crises that may threaten the mental and physical health of people around the world.

1.2.4 The life course approach to migrants' health

People categorised as migrants or persons with a migrant/migration background themselves are not inherently vulnerable for (mental) health issues, but their health and well-being are significantly influenced by the conditions they encounter during the various stages of migration (Agbata et al., 2019).

To better understand migrants' particular health situations, Spallek et al. (2011) therefore advocate for looking at their entire course of life. The so-called *life course approach* divides the life course of migrants into three phases in which health-related exposures have a direct or indirect impact on their health: before, during and after migration (Spallek et al., 2011).

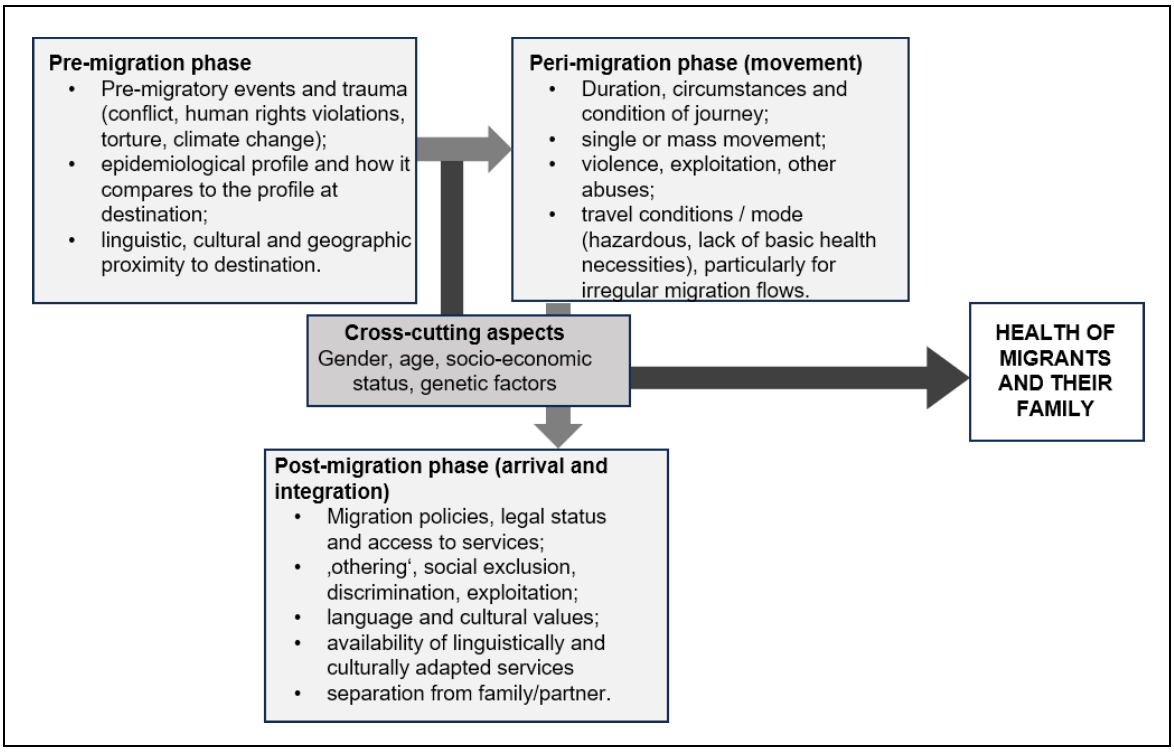
The pre-migration phase involves the decision-making process and the preparations before moving. During the migration phase, the actual physical movement of individuals from one location to another takes place. Lastly, the post-migration phase pertains to the integration of the immigrant into "the social and cultural framework of the new society" (Bhugra et al., 2011, p. 2). For example, and among other factors, living standards and distributive justice in the country of origin (Waxenegger et al., 2019), but also pre-migratory events and traumas such as conflicts, human rights violation, and persecution (Carlsson & Sonne, 2018), or nature catastrophes (International Organization for Migration, 2015) influence migratory flows and also shape peri- and post-migration experiences and, in turn, migrants' (mental) health. Thus, the interactions between migration processes including the risks and exposures experienced in the countries of origin as described above, but also the transit situation (involving different methods such as traveling by plane, walking across deserts, or hiding in overcrowded trucks), and destination (including safe shelters, refugee camps, or living underground due to illegal status), have a profound impact on the health of migrants and their descendants (World Health Organization, 2018).

A systematic review on the *healthy immigrant effect* in Canada found that there is a variation of immigrants' health across the life-course, within each stage, and by different health outcomes. The authors conclude that policies related to migrants' health must be targeted to the specific life-course stages, within each age group, and to those health outcomes for which migrants are particularly disadvantaged (Vang et al., 2015).

The following graphic, adapted from the Migration Data Portal (2023b), shows the multifaceted factors that influence the health of migrants and their families along the phases of migration.

Figure 3

Factors influencing the health of migrants and their families



Note. Own presentation, adapted from *Migration and Health* by Migration Data Portal, 2023b (https://www.migrationdataportal.org/themes/migration-and-health)

To sum up, Spallek and Razum (2016) constitute that a migrant background functions as a kind of surrogate for a multitude of underlying mechanisms and processes. Migration influences health and health influences who migrates (p. 163).

1.3 Gender as determinant of migrants’ health literacy

The influence of sex and gender on health has been increasingly documented in the last twenty years (Oertelt-Prigione, 2023). It has been shown to influence the emergence, development, diagnosis, and treatment of diseases (Oertelt-Prigione & Regitz-Zagrosek, 2012). Today, sex and gender are considered core determinants of health (Krieger, 2003).

1.3.1 Gender versus sex – a brief conceptual placement

The term *sex* typically refers to biological and physiological processes (Sandford, 1999), whereas the term *gender* is widely used to describe roles, behaviours, identities, and relations (Hammarström & Annandale, 2012). In other words, sex refers to the invariant, biological differences of being female or male, like the anatomy of a body, whereas gender refers to the “cultural meaning and form that that body acquires, the variable modes of that body’s acculturation” (Butler, 1986, p. 35).

To date, gender and queer theory has advanced well beyond the traditional binary man-woman dichotomy (Chakraverty et al., 2020; Marinucci et al., 2022), acknowledging the dynamic and intersectionality of gender (-identity) with other social categories such as ‘race’, ‘class’, or ‘sexuality’ (Harris & Bartlow, 2015; Shields, 2008). Nevertheless, most humans undergo a developmental process leading to the establishment of one of the two primary biological sexes (Loof, 2018).

Although some researchers argue that the strict separation between sex and gender may be more of a theoretical discussion, as in our daily life biology and behaviour do constantly overlap and interact (Fausto-Sterling, 2005; Regitz-Zagrosek, 2012), it seems to be more appropriate to talk about gender when it comes to relational processes and personal experiences rather than biological determinants describing personal features and genetic expressions.

The IOM provides a definition of gender that is applicable to the dynamic context of migration, emphasising the need to understand and address gender roles and -identity as well as relationships in a comprehensive and culturally sensitive manner:

> Gender refers to the socially constructed roles and relationships, personality traits, attitudes, behaviors, values, relative power and influence that society ascribes to people based on their assigned sex. Gender is relational and refers not simply to women, men or other gender groups, but to the relationship between them. Although notions of gender are deeply rooted in every culture, they are also changeable over time and have wide

> variations both within and between cultures (International Organization for Migration, 2015, p. 12).

Since HL is a (social-)relational concept which is dynamic and determined by personal, situational, social, and environmental factors (Sørensen et al., 2012), the term gender is used when denoting particularities of HL in female and male persons with a migrant background.

1.3.2 Migration as inherently gendered phenomenon

A person's gender may influence both the reasons to migrate and the health outcomes experienced before, during, and after migration. Thus, the process of migration is inherently gendered, indicating the intersectionality between gender and migration to have synergistic effects on female and male migrants' health (Douki et al., 2007; Malmusi et al., 2010; Wandschneider et al., 2020).

The body of literature demonstrating that women who migrate encounter distinct health hazards compared to their male counterparts before, during, and after the migration process, is quite dense (e.g. Douki et al., 2007; Malmusi et al., 2010; Schouler-Ocak & Kurmeyer, 2017). Some specific health risks are disproportionately prevalent among women, such as instances of sexual violence, abuse, human trafficking, and risks related to pregnancy (Douki et al., 2007; OECD, 2023b; Schouler-Ocak & Kurmeyer, 2017). Other issues relate to specific integration challenges migrant women may face. The *International Migration Outlook 2023* recently published by the OECD (2023b) describes the "double disadvantage" migrant women face when migrating to OECD countries due to their status both as migrants *and* as women: male immigrants commonly enter through labour market or humanitarian avenues, while women tend to arrive through family migration channels. This dynamic, so the report, has significant implications, as family migrants often fall into "a blind spot in migration and integration policies" (p. 4) with limited access to structured integration programmes or job offers compared to humanitarian- or labour migrants, respectively (OECD, 2023b).

In contrast, migrant men are more prone to experiencing accidents, physical exertion, and occupational hazards because of migration (Malmusi et al., 2010). Furthermore, a comprehensive analysis of social epidemiological literature revealed that increased adherence to traditional gender norms, elevated levels of gender inequality, instances of gender-based discrimination, and gender-based violence were linked to adverse health outcomes among migrant populations (Wandschneider et al., 2020). These gender-specific circumstances and experiences can influence why people need health information and affect how it is accessed, processed, and translated into health decisions (Aldin et al., 2019).

However, researchers claim a considerable lack of gender aggregated data in international migration research (Bircan & Yilmaz, 2023; Nawyn, 2010). For this reason, the *Global Compact for Safe, Orderly and Regular Migration (GCM)*[18], amongst others (e.g. United Nations, 2016a, 2016b), strongly calls for the improvement of data on migration and, in particular, the disaggregation by sex in order to reveal gender-related gaps and inequalities through the identification and analysis of specific vulnerabilities and capacities of female and male migrants (Migration Data Portal, 2023a; United Nations, 2019).

1.3.3 Gender-specific aspects of health literacy in the context of migration

There is a growing body of empirical research investigating the determinants of individual HL in different contexts. In recent years, both gender and migration have received increasing attention in this regard (Svensson et al., 2017). While the evidence base for an association between migration and HL seems to be quite consistent, this is not the case for gender. Although there are several studies suggesting a relationship between gender and HL, the effect sizes and the direction of effects are ambiguous (Berkman et al., 2011; H. Y. Lee et al., 2015; Pelikan et al., 2013; Quartuccio et al., 2018).

In the context of migration, the available data is also not fully conclusive. In a representative U.S. study, for example, it was discovered that factors such as being male, having lower educational achievements, belonging to a ‘racial’ or ‘ethnic minority’, advanced age, experiencing reduced income, and having immigrated to the USA more recently were linked to diminished levels of estimated functional HL (Kutner et al., 2006). A German population study found that migrants with low language proficiency and older people with a migration background living in Germany were considerably more likely to perceive subjective HL limitations than the majority population. They reported problems in accessing health information, its processing, and translation into health decisions (Quenzel & Schaeffer, 2016; Schaeffer et al., 2016); gender was no variable of significance (Schaeffer et al., 2016). A number of international studies from Australia, Canada, the United states, and other European countries, also found associations between an ethnic minority status, limited language proficiency, or a direct migration experience and observable or self-reported difficulties in dealing with health information (Beauchamp et al., 2015; Christy et al., 2017; Mantwill &

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[18] The GCM is an inter-governmentally negotiated agreement, i.e. a non-binding compact between UN-Member states that encompasses 23 objectives for the management of international migration and its dimensions. It has been adopted by the General Assembly on 19 December 2018 with the majority of the Heads of UN member states approving (United Nations, 2019).

Schulz, 2017; Ng & Omariba, 2014; Wångdahl et al., 2014). A potential association with the participants' gender was not reported in these studies.

A systematic review and meta-analysis published in 2022 (Chakraverty et al., 2022)[19] found a small but significant difference between the HL scores of female and male migrants' HL scores, with women scoring higher than men. However, there was substantial heterogeneity between studies and the difference vanished when excluding studies with a high risk of bias. One other interesting finding was that an additional 27 studies focusing on the HL of exclusively female migrants were identified. However, these could not be incorporated into the analysis due to the absence of eligible studies concerning male migrants. This clearly indicates a significant research gap pertaining to HL among male migrants (Chakraverty et al., 2022).

Three recently published studies which have not been included in the systematic review of Chakraverty et al. (2022) reported gendered results for HL in migrants. One study that used a performance-based assessment tool for assessing HL in African immigrants living in the USA reported that gender was not a variable of statistical significance (Morris et al., 2022). Berens, Klinger, Mensing, et al. (2022) compared HL levels among migrants and their descendants living in Germany with the use of the HLS_{19} Q47 and found higher scores for subjectively assessed general HL, disease prevention literacy and health promotion literacy among women. Poza-Méndez et al. (2023) applied a short form of the self-assessment tool HLS-EU-Q (with 16 items) in persons who migrated to Spain primarily from Arabic and African countries. They also found that women reported slightly less difficulties in HL-related tasks ($p = 0.054$).

Overall, it can be concluded that quantitative studies *alone* do not provide satisfactory results regarding the nature and extent of gender-specific factors and differences in HL among persons with a migrant background.

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[19] The systematic review has been conducted as part of the GLIM-project, which is closely related to this PhD thesis (see 2 The PhD Project).

1.4 Interventions for improving health literacy

> Given the power of health literacy to help individuals help themselves to be better able to find, understand, evaluate, communicate, and use information to make informed decisions and lead healthier lifestyles, it is worth examining what strategies might be helpful to further advance health literacy (Pleasant et al., 2015, p. 1177).

With the first population-based studies that found HL limitations to a considerable amount in American (Kutner et al., 2006), Australian (Adams et al., 2009), and European populations (Pelikan et al., 2013; Schaeffer et al., 2017; Sørensen et al., 2015; van der Heide et al., 2013), voices calling for the development of targeted HL promotion strategies grew louder. Consequently, various countries such as the USA, China, Australia, and several European nations, governments, and national agencies have devised comprehensive strategies and action plans to enhance HL among their populations (Australian Commission on Safety and Quality in Health Care, 2014; European Commission, 2023; Schaeffer et al., 2018; U.S. Department of Health and Human Services, 2010; Weishaar et al., 2019).

As early as 1998, the WHO described the promotion of HL as critical to empowerment, active and informed decision-making in health, and as key to reduce health inequalities (Nutbeam, 1998). Since then, several interventions for improving HL or mitigating the effects of low (health-related) literacy have been developed, implemented, and evaluated. Up until now, however, the vast majority of evaluated interventions have taken place within clinical settings, primarily concentrating on task-oriented (e.g. maintaining medication adherence) and functional aspects of HL (e.g. improving information comprehension) (Nutbeam et al., 2018). Less studies have been conducted in the health promotion and prevention setting aiming at improving more advanced skills such as critically evaluating (offline or online) health information and acting on it in a self-determined and active manner (Nutbeam et al., 2018).

Interventions that aim to mitigate the effects of low literacy are usually targeted to populations with either low reading and writing abilities, people with language barriers, or both. These studies often use simplified written material, pictograms, or audiovisual formats such as videos to transfer health information. One landmark publication stemmed from Berkman et al. (2004), who conducted one of the first systematic reviews on HL and HL interventions in this field. In 2011, the original review has been updated and now belongs to the most highly cited papers in HL research (Berkman et al., 2011; Sheridan et al., 2011). The authors found that specific design features of interventions that are targeted to “low”-HL-populations (e.g. presenting essential information first, presenting information in simple language or formats, or substantiated by video or illustrated narratives) are effective in terms of improving the comprehension of health information. Furthermore, they found that interventions with multiple components such as intensive self- and disease-management or adherence programs can mitigate the effects of “limited” HL regarding reduced emergency department visits and hospitalisations and reduced disease prevalence (Berkman et al., 2011). Other systematic reviews were largely consistent to Berkman et al. (2011) with a vast majority also indicating that enhancing the understanding of health information and guidance among individuals scoring low on HL measures can be achieved by adjusting communication methods and implementing interventions that combine various strategies of knowledge transfer. These improvements correlated with better health outcomes, including changes in chronic disease risks. Additionally, for individuals already affected by a certain condition, they were linked to diminished reported disease severity, decreased unplanned emergency department visits, and fewer hospitalisations (Manafo & Wong, 2012; Taggart et al., 2012).

A more recent systematic review by Walters et al. (2020) included 22 studies that applied a pre/post measure for HL in adult populations. The review found that fifteen of these studies demonstrated significant improvements in HL. In addition, seven out of eight studies that also focused on health behaviour found a significant effect on this outcome. The authors constitute that the most commonly used intervention format was small group education, followed by text and social media messages, one to one education, and other audio-visual formats such as multi-media learning or apps. According to the authors, all formats showed promise to be effective in improving HL.

To date, many more literature reviews on HL interventions in different settings targeting various populations were published. These included either interventions for people with certain chronic conditions such as mental health problems (Xia et al., 2011; Z. Xu et al., 2018), diabetes (Ran et al., 2022) or HIV (Perazzo et al., 2017), community populations in general (Nutbeam et al., 2018), or young people (Marinucci et al., 2022). Others focused on disadvantaged populations such as people with low socioeconomic status (Stormacq et al., 2020). Some systematic reviews specifically focussed on certain intervention formats such as e-HL interventions (Jacobs et al., 2016). Again others, assessed the effects of HL interventions carried out in certain regions of the world such as Europe (Visscher et al., 2018) or in low-and middle-income countries (Meherali et al., 2020).

However, in the context of migration, many of these reviews do not apply a HL framework for analysis purposes or they do not use meta-analysis for synthesising the results (or, if not possible, follow reporting guidelines for narrative synthesis (Campbell et al., 2020)), or they do not use rigorous methods for assessing the certainty in the body of evidence as typically done in Cochrane reviews (Schünemann et al., 2022).[20]

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[20] See 2.2.2 Systematic reviews – climbing the ‘evidence pyramid for details regarding the methods used in the effectiveness review (Baumeister et al., 2023) contributing to this PhD thesis.

2 THE PHD PROJECT

The contributions to this cumulative dissertation were built upon research undertaken as part of the project *Gender-specific health literacy in individuals with a migration background: Systematic review including a meta-analysis of individual participant data (GLIM)*, which was funded by the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung (BMBF); Grant No. 01GL1723).

2.1 Research Questions

Drawing on the integrated model introduced by Sørensen et al. (2012), this PhD project aimed (1) to examine how personal, situational, and societal and environmental determinants influence HL in transcultural[21] treatment settings, (2) to assess the effectiveness of interventions for improving HL in migrants, and (3) to assess whether migrant women or men benefit differently from these interventions.

The qualitative studies I+II (Baumeister et al., 2021; Chakraverty et al., 2020) were guided by the following research questions:

1) How do personal, situational, and societal and environmental factors influence HL in transcultural treatment settings from the perspective of HCPs in Germany?
2) What role does gender as a personal factor of HL play in the way HCPs in Germany perceive HL-related challenges, needs and applied solutions in their interactions with persons with a migrant background?

The research questions addressed by study III, the Cochrane effectiveness review (Baumeister et al., 2019; Baumeister et al., 2023), are as follows:

1) How effective are interventions for improving HL in migrants?
2) Do migrant women or men benefit differently from these interventions?

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[21] Against the background of a constructivist understanding of culture, the concept of *transculturality*, as described by Welsch (1995, 1997), is based on the assumption that cultures are not to be understood as homogeneous entities or clearly disjunct units but – as a result of globalisation – that they are increasingly interlinked and intermingled. In this regard culture is not regarded as something that divides but something that connects. From this perspective, the interaction of two cultures is always characterised by various points of contact that can lead to a blurring of cultural boundaries, and possibly even to their complete abolition.

2.2 Methods

This cumulative dissertation pursued a mixed-methods approach including (1) primary research from two independent qualitative content analyses (Kuckartz, 2019) of five FGDs with HCPs in Germany (study I+II) and (2) secondary research from a Cochrane effectiveness review evaluating interventions for improving HL in migrants (study III).

In this chapter, I briefly describe the methods applied in a general manner, referring to the current gold standards of the respective approach. In the discussion section, the challenges discovered in the research process and the solutions applied are discussed to reflect on the methods used, referring to general limitations and strengths (see 4 Discussion).

As a preliminary remark, it is to be emphasised that neither qualitative nor quantitative methods are to be viewed superior to the other. Both have advantages and disadvantages (Al-Busaidi, 2008). Therefore, there is a growing number of researchers calling for overcoming the quantitative-qualitative debate and its related methodological distinction; mixed-methods designs are gaining popularity (Kelle, 2022; Schreier & Odağ, 2020). Depending on the research question, it can be highly fruitful to use the variety of quantitative and qualitative research methods available in a complementary way to achieve an in-depth understanding of complex phenomena (Al-Busaidi, 2008; Pope et al., 2002).

2.2.1 Qualitative Research – examining the details, in-depth

Sound research begins with a rational foundation, typically rooted in a theoretical concept or a perspective (Sullivan & Sargeant, 2011). Qualitative research methods may be used to “explore, describe, or generate theory, especially for uncertain and ‘immature’ concepts; sensitive and socially dependent concepts (Roche 1991); and complex human intentions and motivations (Harris 2003)” (Maudsley, 2011, e95).

But what do we mean by the term *qualitative research*?

According to Flick (2002), qualitative research is used as an umbrella term for several hermeneutic, reconstructive, and interpretative approaches used in social sciences. Thus, qualitative research comes in a multitude of shades with different facets reflecting either the research question, the phenomenological context, or both. A comprehensive and universally applied definition has not yet been established (Aspers & Corte, 2019).

Against the background of a systematic literature analysis of existing definitions and assumptions made regarding qualitative research, Aspers & Corte (2019) identified four notions they consider central to qualitative work:

Distinctions: Qualitative research contributes significantly to scholarly knowledge by generating new distinctions, setting it apart from quantitative analysis, which typically deals with variables' that are taken for granted.[22] The significance of these distinctions is assessed in the context of the research community's existing knowledge to facilitate this evaluation in a rational discussion (pp. 150-151).

Process: Creating new knowledge through qualitative research requires and iterative process. The key idea is that the researcher's initially assumed categories often undergo qualitative transformations based on the discoveries made during the research (pp. 151-152).

Closeness: Qualitative researchers establish direct, "close" contact with the subjects under investigation and/or the materials they are analysing primarily due to their research methods. Qualitative researchers, through the often long and close engagement with their data (e.g. images, text, or human interactions), continually evaluate their intuitions, assumptions, and hypotheses as their research unfolds. They test these ideas against a dynamic reality, which can either affirm or challenge them, and frequently guides the research into new directions (pp. 152-153).

Improved understanding: Improved understanding is referred to as the result of a research process, after incorporating all the other elements. In qualitative research, understanding holds a distinct position as it encompasses both the knowledge conditions and the final outcome of the process. Understanding necessitates meaning, and this meaning is drawn primarily from the context, particularly the data being examined (pp. 153-154).

The elaboration on these four essential notions in qualitative research results in the following definition:

Qualitative research is

> an iterative process in which improved understanding to the scientific community is achieved by making new significant distinctions resulting from getting closer to the phenomenon studied. Qualitative research, as defined here, is consequently a combination of two criteria: (i) how to do things–namely, generating and analyzing empirical material,

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[22] Quantitative analyses do not work exclusively with pre-defined variables. For example, meta-analyses can also produce new ones (Aspers & Corte 2019), especially if qualitative approaches are also used to identify similarities and differences between the primary research investigated as in the two systematic reviews (Baumeister et al. 2023; Aldin et al. 2024) presented in this cumulative dissertation.

> in an iterative process in which one gets closer by making distinctions, and (ii) the outcome–improved understanding novel to the scholarly community (p. 155).

Focus group discussions

FGDs are commonly used in health research and education, mainly when it is important to investigate a research question in a way that is target group-oriented, practical and resource-saving (M. Schulz et al., 2012, p. 7). In a moderated discussion, small groups of participants are stimulated to discuss a given topic based on an initial information input (the stimulus) (Chakraverty et al., 2020). Thus, FGDs facilitate data collection via group interaction that is centred on the respective topic chosen by the researcher(s) (here, broadly speaking: HL as understood by Sørensen et al. (2012) in the context of migration). The researcher's focus drives the process, with the data originating from the group interaction itself (Morgan, 1996). It is important, however, that the objective of data collection is not to reach a consensus among the individuals involved in the conversation, but rather to explore as many diverse aspects of a subject as feasible (Littig & Wallace, 1997). In this regard, participants are encouraged to talk with each other[23]; the discussion is intended to be interactive (Krueger & Casey, 2014).

FGDs are loosely structured by an interview guide that serves as orientation for the moderator and contains questions reflecting the research subject as well as additional in-depth questions (so-called *probing questions*).[24] Herewith, comparability between multiple FGDs shall be improved as it helps the moderator to ensure that the a priori determined relevant themes are captured in each discussion; at best without dominating it. Thus, the interview guide is used flexibly and kept thematically comprehensive. During the research process, it can be adapted to ensure a well-founded answer to the questions set (Zwick & Schröter, 2012).

Concerning the recommended number of participants in each FGD, no clear guidelines are available (usually six to twelve participants are recommended). A recent literature review found reported numbers ranging from three to 21 participants; the median was ten (Nyumba et al., 2018). As the objective of qualitative research is not to reach comprehensive generalisability or even representativeness (Al-Busaidi, 2008), typically a purposive sampling is

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[23] That approach implies an attentive but professionally reserved moderator who does not see himself as a discussion leader but rather as a *stimulus-provider*. The moderator also ensures that the good rules of communication are followed (see also Baumeister et al., 2021; Chakraverty et al., 2020, for a detailed description of methods applied regarding the moderation of FGDs in our studies).

[24] Probing questions are used to deepening topics mentioned by the participants or to steer the conversation to aspects not yet mentioned in the respective discussion (Peterson & Baron, 2007).

applied based on factors such as gender or occupation (as in study I+II, included in this dissertation) (Al-Busaidi, 2008). Participants are usually invited as individuals who are asked to talk about a specific topic in their role, e.g. as consumers, affected persons, or members of a professional group such as HCPs (Dürrenberger & Behringer, 1999)

So far, there is also no general guideline for the number of FGDs in a research project. As a rule of thumb, Morgan (1996) proposed that per project three to five FGDs should be conducted. As another guideline, the level of theoretical saturation is mentioned in the literature. Theoretical saturation is reached when no new insights are gained by conducting further discussion rounds (Guest et al., 2016). Conducting two to three focus group discussions typically covers a minimum of 80% of the research topic under investigation (Guest et al., 2016).

2.2.2 Systematic reviews – climbing the ‘evidence pyramid’

One aim of this PhD project was to evaluate whether interventions for improving HL in migrants are effective. Establishing claims about the effectiveness of health-related interventions can be carried out best by the “conscientious, explicit, and judicious use of current best evidence.” (Sackett et al., 1996, p. 71) – in short, with evidence-based medicine (EBM). In its original sense, EBM involves combining personal clinical expertise with the current best available, i.e., the currently most reliable, external clinical evidence obtained through systematic research (Sackett et al., 1996), in order to derive treatment decisions that work best for individual patients while minimising the risk of adverse events or at least maximising their predictability.

In the realm of EBM, high emphasis is put on quantitative research. Particularly, randomised controlled trials (RCT) are valued in this approach due to their ascribed ability “to examine cause-effect relationships between an intervention and an outcome” (Hariton & Locascio, 2018, p. 1716). The randomisation procedure is seen as key to reduce biases from primary studies, which becomes evident in the concept of a *research evidence hierarchy*. It presupposes that certain research designs such as RCTs are inherently superior to others (e.g. observational studies) in terms of validity (e.g. Murad et al., 2016) and that, in general, evidence syntheses are higher valued than single studies. Thus, systematic reviews and meta-analyses are widely regarded as top of the pyramid (Hoffman et al., 2013). This is not surprising, as decision makers in public health practice and policy depend on reliable, pertinent, and systematically synthesised evidence to make sound decisions (Cumpston et al., 2022).

A systematic review “attempts to identify, appraise and synthesize all the empirical evidence that meets pre-specified eligibility criteria to answer a specific research question.”

(Cochrane, n.d.). Systematic reviews follow a structured, clear, and replicable procedure to identify, assess critically, and synthesise all relevant empirical evidence that meets the pre-determined eligibility criteria (Bouck et al., 2022; Lasserson et al., 2023). They are considered a valuable tool not only for summarising the effectiveness of treatments or health services, but also for shedding light on the gaps and limitations in current research (Eden, 2008). Thus, systematic reviews play a crucial role in advancing scientific knowledge, informing research priorities, and aiding decision-making in healthcare and other fields.

Not all systematic reviews synthesise evidence from RCTs only. There is a wide range of systematic review types that capture a range of purposes. For example, systematic reviews of cross-sectional studies do not aim to assess the effectiveness of health interventions but rather to provide an overview of the current evidence on a particular topic (e.g. our systematic review on gender-differences in the HL of persons with a migration background (Chakraverty et al., 2022)). Other types may be systematic reviews of diagnostic test accuracy or prognosis studies, systematic reviews of methodology, or overviews of reviews, i.e. meta-reviews (Cumpston et al., 2023). The latter four are published in the renowned Cochrane Library.

A special type of a systematic review is the *Qualitative Evidence Synthesis (QES)*, which summarises the evidence of qualitative studies and, if necessary, re-analyses them based on the published (or unpublished) primary data according to the respective research question of the review (e.g. Aldin et al., in press). QES that are conducted alongside an effectiveness review of intervention studies can enhance decision-makers' knowledge by offering supplementary evidence to increase the comprehension of the interventions' complexity, contextual differences, implementation issues, and the stakeholders' (e.g. participants of the intervention studies) preferences or experiences (Noyes et al., 2023).

Systematic reviews can use different methods to synthesise the results of primary studies: (1) meta-analysis (including, for example, meta-analysis of studies, network meta-analysis, or meta-analysis of individual participant data), (2) narrative synthesis (including narrative synthesis of qualitative or quantitative data), or (3) a combination of both (as conducted in study III, presented in this PhD thesis). A meta-analysis involves statistically summarising the available evidence from at least two or more different trials. It offers potential benefits such as enhanced precision of effect estimates or the chance to resolve uncertainties arising from conflicting individual study results (Deeks et al., 2023).

However, sometimes it is not feasible or appropriate to pool results. Particularly, when a review is concerned with “complex” (intervention) studies which is often the case in public health reviews (Cumpston et al., 2022). A prevalent challenge in these public health reviews that frequently encompass a wide range of study designs, outcomes, contexts, populations, and interventions, is often a large heterogeneity, encompassing both statistical and methodological variations (Petticrew et al., 2013). Other synthesis methods become necessary, also, when data is incompletely reported in primary studies and a meta-analysis is not possible. Alternative synthesis methods offer a narrower scope of information for healthcare decision-making compared to meta-analysis. However, when they are conducted with the use of rigorous pre-defined methods that are transparently reported using established reporting standards such as the *Synthesis Without Meta-analysis (SWiM)* guideline (Campbell et al., 2020)[25], they are more preferable to a purely narrative description where certain results are given priority over others without proper justification (McKenzie & Brennan, 2023).

Cochrane Reviews

Cochrane is an international network and a not-for-profit organisation with a clear mission: being an "independent, diverse, global organization that collaborates to produce trusted synthesized evidence, make it accessible to all, and advocate for its use." Cochrane, 2024, Our mission). Cochrane reviews are internationally acknowledged as the gold standard for high-quality information about the effectiveness of healthcare interventions (Cochrane, 2024). Both protocols and reviews are published in the *Cochrane database of Systematic Reviews*, the most important journal for systematic reviews in health and social care representing one of the core elements of the Cochrane library (Cumpston et al., 2023).

What sets Cochrane apart from other journals publishing systematic reviews are its rigorous methods. Since its foundation in 1973, Cochrane played a special role in fostering the methodology of systematic reviews. The regularly updated Cochrane handbook (Higgins et al., 2023) is the key reference work for review authors and contains answers to the most important questions concerning the specific methodological requirements and quality standards of Cochrane Reviews. In addition to the application of the Cochrane Risk of Bias (RoB) tools (e.g. among others, RoB I (Higgins et al., 2011), as applied in our review), Cochrane Reviews specify the creation of *Summary of Findings* tables. These contain all results of a review as well as the essential information of relative and absolute effects of the information reviewed, the amount of available evidence, and the certainty (or quality) of the available evidence (Schünemann et al., 2022).

To assess the certainty of evidence, Cochrane adopted the GRADE approach developed by *The Grading of Recommendations Assessment, Development and Evaluation (GRADE)*

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[25] The SWiM guideline was developed to provide guidance on transparent reporting in reviews of interventions where alternative synthesis methods are employed (Campbell et al., 2020). It is to be seen as a supplement to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA; http://www.prisma-statement.org).

working group. The approach offers a “common, sensible and transparent approach to grading quality (or certainty) of evidence and strength of recommendations” (GRADE working group, 2024, The GRADE working group). Applying the GRADE approach implies that the certainty in the body of evidence found in a systematic review or a health technology assessment is evaluated through the consideration of the following five domains*: risk of bias, inconsistency, indirectness, imprecision,* and *publication bias* resulting in four levels of certainty for a body of evidence related to a given outcome.[26] These are reflected in *high, moderate, low,* and *very low certainty* (Schünemann et al., 2022). The four levels of certainty are then transformed to statements which can be used by review authors to communicate the review’s results to users (e.g. in the *Summary of Findings Tables,* the results section or in the discussion). Figure 4 provides a simplified overview of the wording template to formulate statements in systematic reviews and other decision tools in accordance with the GRADE working group (Santesso et al., 2020).

Figure 4

GRADE wording matrix of review results

	Important benefit or harm	**Less important benefit or harm**	**No important benefit or harm**
High certainty	Increases/ decreases	Increases/ decreases slightly	Little to no difference
Moderate certainty	Probably increases/ decreases	Probably increases/ decreases slightly	Probably little to no difference
Low certainty	May increase/ decrease	May increase/ decrease slightly	May make little to no difference
Very low certainty	We are uncertain whether intervention increases/decreases outcome		

Note. Adapted from GRADE guidelines 26: informative statements to communicate the findings of systematic reviews of interventions by Santesso et al., 2020, *Journal of Clinical Epidemiology*, *119*, p. 129. CC BY-NC-ND

For example, a systematic review found an important short-term effect of intervention A compared to intervention B on an outcome X, i.e. intervention A was found to be superior to intervention B. However, the certainty in the evidence was rated as being low because of risk of bias concerns in five out of ten studies reporting the respective outcome or because of imprecise effect estimates. Following, the GRADE-approach, the corresponding

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[26] A detailed overview on how to apply the GRADE approach, and to interpret and communicate the results of systematic reviews is provided, for example, in Schünemann et al. (2022) and Santesso et al. (2020).

statement to communicate this result could be as follows: intervention A *may increase* [outcome X] in the short-term, when compared to intervention B.

Besides the many Cochrane Methods Groups (e.g. the *GRADEing Methods Group*) which focus on specific methods and review types pertinent to Cochrane Reviews, there are several thematic *Cochrane Review Groups* that are dedicated to helping authors in producing high-quality reviews for their particular research topic.

In this dissertation, two Cochrane Reviews have been directly or indirectly included. Firstly, the effectiveness review (here referred to as study III) that aimed to assess the effectiveness of interventions for improving HL in migrants (Baumeister et al., 2023) and secondly, the linked QES that aimed to explore gender-specific aspects of HL in migrants and to explain potential gender differences found in the effectiveness review (Aldin et al., in press). The results of this cumulative dissertation are discussed in light of the results of the QES as it is to be seen as an integral part of the whole PhD project.

3 SYNOPSIS OF STUDY RESULTS

3.1 Study I+II: Health literacy in transcultural treatment settings

This chapter builds on the following two publications representing two independent analyses based on the same data collected in five focus group discussions with 31 HCPs conducted in Cologne, Germany between 2018 and 2019.

Study I

Baumeister, A., Chakraverty, D., Aldin, A., Seven, Ü. S., Skoetz, N., Kalbe, E., & Woopen, C. (2021). "The system has to be health literate, too" - perspectives among healthcare professionals on health literacy in transcultural treatment settings. B*MC Health Services Research*, *21*(1), 716. https://doi.org/10.1186/s12913-021-06614-x

Study II

Chakraverty, D., **Baumeister, A.**, Aldin, A., Jakob, T., Seven, Ü. S., Woopen, C., Skoetz, N., & Kalbe, E. (2020). Gender-specific aspects of health literacy: Perceptions of interactions with migrants among healthcare providers in Germany. *International Journal of Environmental Research and Public Health*, *17*(7). https://doi.org/10.3390/ijerph17072189

Background

In recent years, *organisational HL* has increasingly gained the attention of researchers and policy makers fostering various discussions on the responsibility of healthcare organisations to provide evidence-based, high-quality information that is easy accessible and understood, and to enable people to evaluate and act on the information by making self-determined, preference-based decisions regarding one's heath and the health of others (Schaefer et al., 2019; see also 1.1.2 Organisational health literacy).

One central aspect of organisational HL is effective communication. HCPs are working on one of the key leverage points for HL, as they are expected to assure an effective and satisfactory flow of information on the basis of the currently best available evidence. They must find, understand, and evaluate the information, and communicate it in a way that their patients and clients are enabled to make a fully-informed, self-determined decision that is conducive to their health. Many of them regularly interact with persons who have a direct or indirect migration experience. As the social-relational processes of HL culminate in the treatment situation, considering their views can be profound to gain a deeper understanding of the factors that influence how persons with a migrant background access, understand, appraise, use, and communicate health information in the healthcare setting. The two studies reported here aimed to examine the perceived HL-related challenges and needs, as well as the applied solutions of HCPs in Germany when engaging with persons with a migrant background in their everyday professional life. Drawing on the integrated model of HL (Sørensen et al., 2012), a particular focus was set on personal factors such as gender, situational conditions, and societal and environmental factors such as system-related conditions that may affect the flow of information in transcultural treatment settings.

The study has been approved by the local Ethics Committee of the Medical Faculty of the University of Cologne.

Methods

We applied a qualitative research design by conducting FGDs (see 2.2 Methods) with HCPs in Germany. Applying a purposive and snowball sampling method, we recruited participants from diverse resources (e.g. the *Cologne Health Guide*[27] or through online searches) representing various healthcare professions (e.g. physicians, nurses, physiotherapists) with direct contact to migrants and/or their descendants. Inclusion criteria were a degree or certificate in a health-related profession and regular professional contact to persons with a migrant background for at least two years.

The FGDs were moderated by three researchers (AA, AB, and DC)[28] taking turns as leading moderators of the respective discussion. Following the introduction of moderators, participants were presented with the concept of HL (Sørensen et al., 2012) and the definition of a migrant background that we used in the project (see 1.2 Migration). The moderator encouraged the participants to openly share their experiences, whether aligning with those of others or not. We used a pretested interview guide which was developed for the purpose of the studies (study I and study II) including a starting question and several probing questions related to the topic of HL in transcultural treatment settings.[29]

Every FGD was transcribed verbatim and analysed using qualitative content analysis according to Kuckartz (2019). We applied a deductive-inductive categorisation procedure, meaning that we followed predefined deductive categories which were derived from the

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[27] The *Health Guide* is out of service. The version applied can be found at: https://www.wiku-koeln.de/fileadmin/user_upload/201405_gww_14_online-1.pdf

[28] Angela Aldin, Annika Baumeister, Digo Chakraverty.

[29] For pretesting, we held two FGDs with ten researchers from the Cologne Center for Ethics, Rights, Economics, and Social Sciences of Health (CERES) at the University of Cologne and the Department of Medical Psychology, experienced in qualitative research methods. Six had practical experience in the health system and six had a migrant background. The initial pretest addressed methodological and ethical concerns in facilitating FGDs, the second pretest aimed to pilot and improve the interview guide, which has been published with study I (Baumeister et al., 2021).

research questions and the integrated model of HL by Sørensen et al. (2012), but explicitly allowed for new inductive themes and categories to emerge from the collected data. AB and DC deductively developed a basic set of main categories reflecting

1. HCPs perceived *challenges, needs,* and *applied solutions* in their professional contact to persons with a migrant background, and
2. the components of HL including the *knowledge*, *motivation,* and *competencies* to *access, understand, appraise*, and *apply* health information (Sørensen et al., 2012).

Inductive categories derived from the data were subordinated or were used as new main- or subcategories. A first category system was independently developed by AB and DC and coded alongside the transcript of the first FGD. On the basis of the merged and converted category system, each transcript was independently coded by the two researchers and refined through discussion as needed. A third researcher (AA) was involved, when the category system needed further clarification or discrepancies in the coding process emerged. This category system served as basis for two independent analyses.

Study I aimed to investigate how personal, situational, and societal and environmental factors influence HL in transcultural treatment settings from the perspective of HCPs in Germany.

Study II aimed to examine the role of gender as a personal factor in HL and how it affects HCPs' perceived HL-related challenges, needs, and applied solutions in interactions with individuals with a migrant background.

Results

Between January 2018 and May 2019, we conducted five FGDs with 31 HCPs. Almost half of the participants were physicians and/or psychologists, others had a degree in nursing or another therapeutic or counselling profession (e.g. ergo-, speech therapist, or trauma counsellor). In total, 16 participants (51.6%) had a migrant background (i.e., they either had a direct migration experience or at least one of their parents did).[30]

In the following, condensed versions of both analyses that were conducted alongside the basic category system are presented. The results of each analysis are published separately in detail (Baumeister et al., 2021; Chakraverty et al., 2020). A merged overview of the category systems used in both studies is shown in table 1.

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[30] In detail, the characteristics of the participants are described in the original publications attached to this cumulative dissertation; see Appendix 2. Original Publications.

Table 1

Merged overview of the category systems used in Study I and II

Factors that influence HL[2]	**Challenges**[1]	**Applied solutions**[2]
	Subcategory[3]	Subcategory[3]
Societal and environmental factors • System-related factors	• Systemic lack of time and economic pressure	• Investment of additional, unpaid time • Falling back on stereotypes and prejudices to save time
Situational factors • Psychosocial/psychiatric vs. medical (physical) care • Inpatient vs. outpatient care	• Planning and controlling the current workload in outpatient care	
Personal factors (PF) (1) (shared) migrant background (2) Gender	• *PF (1)* ▪ Ad hoc interpreting outside one's own treatment situation	• *PF (1)* ▪ Refusal of interpreting for others or providing treatment in native language ▪ List of staff who speak foreign languages
Processing steps[3]	**Challenges**[1]	**Applied solutions**[2]
	Subcategory[3]	Subcategory[3]
Access	• *PF (1)* ▪ Mismatch between provision and actual use of health services • *PF(2)* ▪ Husbands as gatekeepers ▪ Gender of HCP as factor ▪ Shame in healthcare situation	• Easily accessible services and outreach counselling • *PF (2)* ▪ Covering part of the body to mitigate shame
Understand	• Uncertainty about the causes of unsuccessful communication • *PF (2)* ▪ Gender-specific aspects of language barriers	• Recourse to professional interpreters and cultural mediators • Recourse to lay interpreters (medical staff, relatives)
Appraise	• Insecurity in dealing with patients' needs and expectations • Patients' distrust in HCPs and the German health system	• Initiating unnecessary examinations to regain patients' trust • *PF (2)* ▪ Women as pioneers for the acceptance of psychotherapy
Apply	• Patients' non-compliance with medical appointments	• Patience in communicating health information to patients

Note. [1]Categories *deductively* derived from the objective of the study; [2]Categories *deductively* derived from the guiding model (Sørensen et al., 2012); [3]Subcategories *inductively* derived from the statements of the HCPs (Baumeister et al., 2021; Chakraverty et al., 2020).

Specific findings from study I: personal, situational, and societal and environmental factors of HL in transcultural treatment settings

Steps of health information processing

Challenges reported in relation to *accessing* healthcare and -information included a 'mismatch between provision and actual use of health services'. Helpful solutions were 'easily accessible services and outreach counselling' as mentioned by some participants. *Understanding* each other and being understood was also regarded as challenging as the participants perceived 'uncertainty about the causes of unsuccessful communication'; they found it not always clearly distinguishable whether communication problems came from language barriers (understanding what was *said*) or due to literacy problems (understanding what was *meant*), or both. Recurring to professional interpreters and cultural mediators was unanimously seen as best solution to this problem (e.g. via video conference). While seeking assistance from family members or medical personnel to act as lay interpreters was seen as beneficial in specific circumstances. It was, however, perceived as insufficient when serving as a substitute for trained professional interpreters. The importance of funding for interpreting services was strongly stressed. Challenges regarding the *appraisal* of health information were the migrant 'patients' distrust in HCPs and the German health system' on the one hand and the HCPs' 'insecurity in dealing with patients' expectations and needs' on the other hand. A reported solution to this was the 'initiation of unnecessary examinations to regain patients' trust' which was perceived as neither adequate nor cost-efficient by the participants. Challenges in *applying* health information were particularly reported with regard to patients' non-compliance with appointments. In this case, HCPs found that 'patience in communicating health information to patients' was key to help them understanding how things are going in the German health system.

Factors that influence health literacy in transcultural treatment settings

In all treatment settings, *societal and environmental factors* were reported to constrain the flow of information*,* including a 'systemic lack of time and economic pressure' (with remuneration based on lump sums in the German health system perceived as main reason by some participants. The HCPs referred to a number of solutions already in use, but these all were considered to be rather unsatisfactory. One of the most prominent and at the same time devalued solution was 'falling back on stereotypes and prejudices to save time'. This included, for example, using the stereotypical label 'morbus mediterraneus', which categorises individuals from Southern European countries as overly expressive and plaintive, leading to doubts about the genuine pain intensity complained by these patients. Some HCPs reported that they caught themselves falling back on these patterns but that they also observed it with other HCPs. Other solutions included ‘investing additional, unpaid time’ or taking the time from other patients less in need.

Situational factors such as ‘planning and controlling the current workload’ were reported to differ tremendously between treatment settings. These challenges were described to be particularly exacerbated in migration contexts as many migrants (with a profound language barrier) needed more time than others. Differences emerged between psychiatric and medical outpatient care, especially in Germany where making appointments is standard, yet acute cases are promptly treated in medical care. In contrast, psychiatric care was reported to often lack the same flexibility.

Besides gender as one of the *personal factors* influencing HL in transcultural treatment situations (see Particular results of study II), the inductive coding of the data revealed that a personal migrant background of HCPs had a particular influence on the perceived satisfaction with, and the efficiency of the information flow in these settings. The majority of participants with a migrant background saw this *personal factor* as an asset to increase patients’ trust in them with a particular impact on how shared information was evaluated and applied by their migrant patients. However, some of these HCPs, particularly nurses, also reported challenges such as the high level of responsibility they felt when interpreting ad hoc for colleagues, sometimes to the point of outright refusal to interpret outside their own care situation. This was also supported by some physicians reporting that they experience these uncomfortable feelings towards the use of the native language in treatment situations or even total denial by some of their colleagues, too. Other, more satisfactory, solutions reported included, for example, the provision of a 'list of staff who speak foreign languages' in order to have medical staff with the appropriate language skills readily available – provided that these lists are drawn up on a voluntary basis.

Specific findings from study II: Gender as influencing factor of health literacy in transcultural treatment settings

Steps of health information processing

HCPs reported gender-related challenges in *accessing* health information and -services including husbands acting as gatekeepers to migrant women's healthcare access. This was often due to a preference for female HCPs. Gender also influenced female HCPs’ credibility in some cases. The HCPs stated that shame sometimes hindered examinations, leading to time-consuming strategies like covering the body. Regarding the processing step of *understanding,* language barriers were reported to compound gender-related issues, especially for less-educated, German-speaking first-generation Turkish migrant women. The systemic lack of time mentioned above (study I) was reported to exacerbate these gender-specific challenges. In this regard, again, health insurance-funded cultural and language mediators/interpreters were emphasised as a highly sought-after solution. Regarding *appraising* health information, the participants reported that scepticism towards psychotherapy was more common among male migrants. Some second-generation females encouraged their mothers to accept psychotherapy, normalising it among the community, including men, which was regarded as a positive development and strong attitude of these women. No gender-specific results were found for *applying* health information.

Factors that influence HL in transcultural treatment settings

As both studies' analyses rely on the same FGDs, the greatest challenges regarding the factors influencing HL in transcultural treatment settings (see Particular results of study I) remain similar. However, putting these in context to the research question of how the personal factor *gender* influences HL in transcultural treatment settings, the data revealed that overcoming gender-specific barriers such as 'shame in treatment situations' or a 'husband as gatekeeper' in addition to language barriers and problems of understanding each other and being understood may all the more exacerbate reported issues such as the 'systemic lack of time and economic pressure'.

Discussion

We aimed to explore how HCPs perceive HL-related challenges, needs, and solutions in transcultural interactions. Specifically, we examined personal factors, particularly gender, as well as situational, and systemic conditions shaping HL in these settings from the perspective of HCPs, more than half of whom had a migrant background themselves.

Most experiences were related to first-generation migrants with a focus on interactions with migrants primarily immigrated from Turkey and Arab countries, especially when gender-specific aspects of HL were discussed. The study found that successful transcultural interactions aren't solely determined by individual knowledge and skills of HCPs or patients, but rather result from a complex interplay of internal and external factors that affect information delivery and processing. These factors include societal, environmental, situational, and personal ones that intertwine and influence each other.

HCPs reported solutions such as covering parts of the body to reduce shame, using cultural and language mediators/interpreters, and women acting as pioneers in accepting psychotherapy, especially among migrant men.

A systemic lack of time and economic pressure were reported to pose significant challenges, especially for HCPs in physical care settings. Migrant patients' distrust regarding the German health system and its representatives, coupled with HCP’s feelings of uncertainty or even tendencies to stereotype migrants, served as additional challenges to the effective and satisfactory flow of health information. Sharing the personal factor of having a migrant background was perceived to positively influence relationships by increasing trust, but it was reported to also introduce challenges to HCPs related to interpreting outside one's own treatment situation. Trust emerged as a key factor, impacting both access to health information and its appraisal. HCPs expressed the need for more time and cultural/language interpreters to enhance mutual understanding as understanding each other was considered as key element of HL in the context of transcultural treatment settings.

These studies have their limitations, such as potential generalisations about diverse migrant groups, possible reproduction of stereotypes by the HCPs included in our FGDs, and, although generalising to populations is not inherently intended by qualitative research, a lack of representativeness. Further research involving migrant perspectives is recommended to gain a more comprehensive understanding of (gender-related) HL particularities in migrants and their direct descendants. Despite the emphasis on HL as a social-relational construct and the interdisciplinary approach of the research team, selection bias may have influenced the participant pool. While the study reached saturation in categorised responses, the dynamic nature of qualitative research means new categories might emerge under different circumstances.

Conclusion

Known problems in the provision of health care for the majority population (i.e., systemic lack of time, economic pressure) appear to be exacerbated in the context of migration. The expanding diversity among patients highlights the growing need for healthcare organizations that are culturally sensitive and health-literate with a diverse workforce. HCPs who act as interpreters should be given sufficient time. However, lay interpreting should not be misunderstood as an adequate substitute for lack of access to professional interpreters and cultural mediators.

3.2 Study III: Interventions for improving health literacy in migrants

This chapter builds on the following two publications including a systematic review published in the Cochrane Database of Systematic Reviews and the respective Cochrane protocol.[31]

Baumeister A, Aldin A, Chakraverty D, Monsef I, Jakob T, Seven ÜS, Anapa G, Kalbe E, Skoetz N & Woopen C. (2019). Interventions for improving health literacy in migrants [protocol]. *Cochrane Database of Systematic Reviews*, (4): CD013303. https://doi.org/10.1002/14651858.CD013303

Baumeister A, Aldin A, Chakraverty D, Hübner C, Adams A, Monsef I, Skoetz N, Kalbe E & Woopen C. Interventions for improving health literacy in migrants. *Cochrane Database of Systematic Reviews*, *11*(11): CD013303. https://doi.org/10.1002/14651858. CD013303

Background

HL is widely recognised as a social determinant of health (Nutbeam & Lloyd, 2021). It is important for autonomous decision-making as well as a successful navigation in the health system (HLS19 Consortium, 2021; Woopen, 2015).

Many international studies found a correlation between a direct migration experience and challenges in accessing, understanding, appraising, or applying health information (Beauchamp et al., 2015; Berens, Klinger, Mensing, et al., 2022; Christy et al., 2017; Quenzel & Schaeffer, 2016; Tsoh et al., 2016). Nonetheless, HL research suggests that having a migrant background is not the sole factor at play (Berens, Klinger, Carol et al., 2022; Ganahl et al., 2016; HLS19 Consortium, 2021); instead, it appears to magnify health inequalities. Thus, improving HL on the individual, societal, and organisational level is important for an equitable promotion of migrants' health.

This systematic review aimed to assess the effectiveness of interventions to improve HL in migrants and to find out whether female or male migrants benefit differently from these interventions.

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[31] Differences between protocol and review are not presented in this synopsis but rather elaborated on in the general discussion section. In this regard, they are placed in the context of the general challenges we encountered in conducting research on HL in the context of migration (see 4 Discussion).

Methods

We ran electronic searches until the 2nd of February 2022 in the following databases: CENTRALs, MEDLINE, EMBASE, PsychInfo, and CINAHL. In addition, we searched trial registries (e.g. clinicaltrials.gov) for finished and ongoing studies. We used the ‘RCT classifier’, a study filter for RCTs to increase the probability of retrieving relevant search results.

We included RCTs and cluster-RCTs that addressed HL either as a comprehensive concept or, at least, one of its components (e.g. knowledge, motivation, competencies, access, understand, appraise, or apply health information). Our objective was not to equate general HL interventions, which encompass various activities addressing all four steps of health information processing, with interventions that specifically target just one step (e.g. applying). Instead, our goal was to provide a comprehensive understanding of the impact of HL interventions by using the integrated HL model (Sørensen et al., 2012) as an overarching framework for our deductive analysis of the four steps of health information processing. Furthermore, we did not limit our scope to particular settings or diseases as we intended to present a broad overview of interventions designed to improve HL in migrant populations.

We used the methodological procedures recommended by Cochrane (Higgins et al., 2022) including a rigorous application of Cochrane’s Risk of Bias Tool (Higgins et al., 2011), if necessary, the re-calculation of missing or potentially biased data (e.g. concerning unit of analysis issues in cluster-RCTs), and the rating of certainty of the evidence according to the GRADE approach (Schünemann et al., 2022). As this is an equity-focussed, theory-driven review, we also followed the PRISMA-Equity statement (Welch et al., 2012; 2015) and extended the data extraction form with 1) recommended characteristics to capture equity-relevant data such as reflected in the PROGRESS-Plus concept (Place of residence, Race/ethnicity/culture, Occupation, Sex, Religion, Education, Socioeconomic status, Social capital, age, disability and sexual orientation), and 2) other characteristics we considered relevant regarding health equity and HL in the context of migration (e.g. certain intervention features such as cultural or linguistic adaption)[32].

Outcome categories were: a. HL, b. quality of life (QoL), c. knowledge, d. health outcomes, e. health behaviour, f. self-efficacy, g. health service use, and h. adverse events.

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[32] For more details on how equity was addressed in this review and a detailed list of extracted data, see Baumeister et al. (2023), specifically the sections 'Considering equity in health literacy' (p. 43) and 'Data extraction and management' (pp. 50-51).

We applied a three-step approach to group the included studies and to examine possibilities for meta-analysis.[33] Firstly, studies were grouped in terms of their main components with regard to content-related and methodological features (i.e. intense or simple health education, self-monitoring, role modelling, motivational counselling, or redesign of written medical instructions). Secondly, the identified main components were set in relation to specific design features considered relevant for the intervention effect (e.g. provider interactions, number and frequency of sessions, intensity and total duration of the intervention programme). The process resulted in the following study groups:

- culturally and literacy adapted self-management programme;
- culturally adapted HL skills building course;
- culturally and literacy adapted telephone education;
- culturally and literacy adapted audio-/visual education without personal feedback; and
- culturally and literacy adapted medical instruction (Baumeister et al., p.53).

In a third step, these groups were again ordered according to the comparator, including

- no HL intervention (i.e. attention placebo, wait-list control or usual care/no intervention);
- unrelated HL intervention (i.e. same method or mode of delivery, but information on a *different* health topic);
- written information on the *same* health topic (i.e. written pamphlet/brochure, written pictogram); and
- another HL intervention (i.e. information on the *same* health topic in a different format)[34] (Baumeister et al., 2023, p. 54)

We conducted meta-analyses when studies were judged similar enough in terms of setting, intervention, comparison, and outcome measures to ensure meaningful conclusion from statistically pooled results. We reported the remaining results in a narrative synthesis following the SWiM guideline (Campbell et al., 2020).

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[33] The grouping procedure was developed and conducted by the first author (AB) and independently reviewed by a second author (AA or DC). The final assessment was made by at least two authors with discrepancies resolved by involving a third author.

[34] As HL involves the processing of health information in various contexts, we labelled comparator interventions delivering information on a *different* health topic than the intervention as 'unrelated HL interventions.' The category 'no HL intervention,' encompassed all comparators that didn't meet the predefined criteria for HL interventions.

Results

The search yielded 17,233 results. In total, we included 28 RCTs and six cluster-RCTs with 8,249 participants, reported in 94 references. All trials were conducted in high-income countries including migrants with a variety of health conditions. All interventions were adapted to the participant’s culture, language, and literacy skills. In the following, the grouped interventions are briefly described in descending order regarding the complexity level:

Culturally and literacy adapted self-management programmes targeted individuals with either chronic diseases or certain disease risks and low literacy or language proficiency. These interventions typically involved intensive health education, a self-monitoring maintenance phase, and monthly motivational counselling for up to twelve months.

Culturally adapted HL skills building courses involved intensive group-based health education focused on enhancing HL skills in disease prevention settings. These included diverse strategies such as risk communication, interactive role-plays for practising communication with HCPs, culture-sensitive narratives through multimedia, and various activities to improve reading, writing, and numeracy skills related to health.

Culturally and literacy adapted telephone education included a tailored telephone education (lasting about 20 minutes) related to shared-decision making and additional mailed health brochures.

Culturally and literacy adapted audio-/visual education without personal feedback used simple health education delivered through various audio-/visual formats (e.g. video, interactive touchscreen computer, or text messages). Aims were improving knowledge, understanding, and attitudes related to a specific disease or preventive service (e.g. screening, vaccines) with the ultimate goal to encourage specific health behaviours. Educational messages were typically embedded in culture-sensitive narratives including role modelling approaches.

Culturally and literacy adapted medical instructions were single strategy interventions that included the presentation of written medical information using, for example easy-to-understand, culturally adapted terminology, or pictograms supported by verbal or video instructions (e.g. in medication plans). Improved understanding and use of prescribed medications were the primary objectives of these studies.

Compared with no or unrelated HL intervention[35]

Short-term effects (<six weeks post-intervention)

When compared with no HL intervention, *culturally and literacy adapted self-management programmes* probably improve self-efficacy slightly (SMD 0.28, 95% CI 0.06 to 0.50; two studies; *N* = 333); moderate certainty. They may also improve HIV-related HL assessed as understanding (MD 4.25, 95% CI 1.32 to 7.18) and recognising HIV terms (MD 3.32, 95% CI 1.28 to 5.36); one study; *N* = 69). *Culturally and literacy adapted self-management programmes* may slightly improve health behaviours such as blood glucose monitoring or medication adherence (three studies; *N* = 514; narrative synthesis), but they may have little or no effect on health-related knowledge (two studies; *N* = 321; narrative synthesis) or subjective health status (MD 0.38, 95% CI -0.13 to 0.89; one study; *N* = 69); low certainty. Due to a lack of evidence, we are uncertain whether there are short-term effects on quality of life, health service use, or adverse events, when compared with no HL intervention.

Low certainty evidence indicated that *culturally adapted HL skills building courses* compared with an unrelated HL intervention may improve health-related knowledge (MD 10.87, 95% CI 5.69 to 16.06; two studies; *N* = 111) and any generic HL, when assessed with performance-based measurement tools (SMD 0.48, 95% CI 0.20 to 0.75; two studies; *N* = 229) but they may have little or no effect on depression literacy (MD 0.17, 95% CI -1.28 to 1.62; one study; *N* = 37) or any health behaviour such as fat-related dietary habits (two studies; *N* = 229, narrative synthesis). We do not know if *culturally adapted health literacy skills building courses* improve quality of life, health outcomes, health service use, self-efficacy, or adverse events compared with an unrelated HL intervention, because our certainty in the evidence was either very low or we did not find any short-term evidence for these outcomes.

Moderate certainty evidence indicated that *culturally and literacy adapted audio-/visual education without personal feedback* compared with no HL intervention probably improves depression literacy (MD 8.62, 95% CI 7.51 to 9.73; one study; *N* = 202) and health service use (MD -0.59, 95% CI -1.11 to -0.07; one study; *N* = 157), with probably little or no effect on health behaviour assessed as child's up-to-date immunisation (RR 1.07, 95% CI 0.91 to 1.25; one study; *N* = 135). Low certainty evidence also indicated that it may improve self-efficacy (MD 3.51, 95% CI 2.52 to 4.50; one study; *N* = 133) and may slightly improve

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[35] The following section contains mainly paraphrases, but also short direct quotations from the abstract published in Baumeister et al. (2023). This is because of the specific wording recommended in the Cochrane Handbook for communicating the results of Cochrane reviews (Higgins et al., 2022; Schünemann et al., 2022).

health-related knowledge (MD 8.44, 95% CI -2.56 to 19.44; two studies; *N* = 293) and applying of health information assessed as intention to seek depression treatment (MD 1.8, 95% CI 0.43 to 3.17; one study; *N* = 120). We also found low certainty evidence indicating that c*ulturally and literacy adapted audio-/visual education without personal feedback* may have little or no effect on depression (SMD -0.15, 95% CI -0.40 to 0.10; two studies; *N* = 337), when compared with no HL intervention. We are uncertain whether it has an effect on quality of live or adverse events as we did not find any short-term evidence for these outcomes in this comparison.

Culturally and literacy adapted medical instructions compared with no HL intervention may improve understanding of health information (three studies; N = 478), but it may have little or no effect on medication adherence (MD 0.5, 95% CI -0.1 to 1.1; one study; *N* = 200); low certainty. We are uncertain whether they have a short-term effect on quality of life, health outcomes, knowledge, health service use, self-efficacy, or adverse events as no evidence was found for these outcomes.

Medium-term effects (up to and including six months post-intervention)

Culturally adapted HL skills building courses may slightly improve health-related knowledge six months post-intervention (three studies; *N* = 788; narrative synthesis); low certainty. Low certainty evidence also indicated that they may improve or reduce screening adherence (RR 2.68, 95% CI 0.33 to 21.83; two studies; *N* = 440) six months post-intervention, when compared to an unrelated HL intervention. However, the effect sizes appear to vary considerably. We are uncertain whether *culturally adapted HL skills building courses* have an effect on the application of health information (i.e. the intention to change nutritional habits, self-efficacy, health service use, or adverse events at six months post-intervention, when compared to no or unrelated HL intervention.

We are uncertain whether there are medium-term effects of other HL interventions, when compared with no or unrelated HL intervention, as no direct evidence was identified.

Long-term effects (> six months post-intervention)

Moderate certainty evidence from one study that *culturally and literacy adapted telephone education* with an unrelated HL intervention indicated that it probably improves appraising health information by reducing decisional conflict (MD – 5.70, 95% CI -10.24 to -1.16, N = 431), when assessed seven months post-intervention. *Culturally and literacy adapted telephone education* probably has little or no long-term effect on applying health information assessed as prostate cancer screening intention (RR 1.00, 95% CI 0.92 to 1.10, N = 431), health behaviour (Prostate cancer Antigen (PSA) testing) (RR 0.93, 95% CI 0.82 to 1.07, N = 490), or anxiety (MD -0.14, 95% CI -0.55 to 0.27, N = 431). However, it probably improves knowledge (MD 6.9, 95% CI 6.88 to 6.92), N = 431) in the long-term, when compared to unrelated HL intervention. We did not find evidence for quality of life, self-efficacy, or health service use in this comparison, and we are uncertain whether there are long-term effects of other HL interventions because no direct evidence was identified.

Compared with written information on the same topic

Short-term effects (<six weeks post-intervention)

When compared with written information on the same topic, moderate certainty evidence indicated that *culturally and literacy adapted self-management programmes* probably improves print literacy (MD 9, 95% CI 2.9 to 15.1) and health numeracy slightly (MD 0.7, 95% CI 0.15 to 1.25); one study; *N* = 209. Furthermore, they probably improve self-efficacy (SMD 0.47, 95% CI 0.3 to 0.64; four studies; *N* = 552). *Culturally and literacy adapted self-management programmes* may improve any disease-specific HL (SMD 0.67, 95% CI 0.27 to 1.07; four studies; *N* = 955), knowledge (MD 11.45, 95% CI 4.75 to 18.15; six studies; *N* = 1,101) and some health behaviours such as diabetes self-care abilities or medication adherence (four studies; *N* = 797). However, they may have little or no effect on health information appraisal (MD 1.15, 95% CI -0.23 to 2.53; one study; *N* =329); low certainty. We do not know whether *culturally and literacy adapted self-management programmes* improve QoL, health outcomes, health service use or adverse events at the short-term, as there was either a lack evidence or our certainty in the evidence was low/very low.

When compared with written information on the same topic, moderate certainty evidence indicated that *culturally and literacy adapted audio-/visual education without personal feedback* probably has little or no effect on diabetes HL (MD 2, 95% CI -0.15 to 4.15; one study; *N* = 240) but probably improves the appraisal (MD -9.88, 95%CI -12.87 to -6.8) and application of health information (RR 1.51, 95%CI 1.29 to 1.77); one study; *N*=608. We found low certainty evidence indicating that it may slightly improve health-related knowledge (MD 8.35, 95% CI -0.32 to 17.02; three studies; *N* = 987). We are uncertain whether c*ulturally and literacy adapted audio-/visual education without personal feedback* has a short-term effect on QoL, depression, health behaviour, self-efficacy, health service use, or adverse events as no evidence was found for these outcomes.

Medium-term effects (up to and including six months post-intervention)

Culturally and literacy adapted self-management programmes may slightly improve high blood pressure HL six months after the programme was completed (MD 4.10, 95% CI 0.97 to 7.23, one study, *N* = 242); low certainty. Low certainty evidence indicated that they may have little or no effect on knowledge (MD 3.87, 95% CI -0.46 to 8.19, two studies, *N* = 298), depression (MD -0.32, 95% CI -0.90 to 0.27, two studies, *N* = 267), and self-efficacy (MD - 0.20, 95% CI -11.16 to 0.76; one study; *N* = 242) up to six months post-intervention. *Culturally and literacy adapted self-management programmes* may, however, slightly improve health behaviour (two studies, *N* =265, narrative synthesis); low certainty, but the outcome measures and size of effects appear to be variable. We are uncertain whether there is a medium-term effect on quality of life, health service use, or adverse events as there was no direct evidence identified.

Low certainty evidence indicated that c*ulturally and literacy adapted audio-/visual education without personal feedback* may slightly improve competencies (inhaler use technique) (MD 0.98, 95% CI 0.26 to 1.70, two studies, *N* = 176), but it may have little or no medium-term effect on understanding of health information (two studies, *N* = 128, narrative synthesis) or health behaviour (any cancer screening uptake) (RR 1.07, 95% CI 0.95 to 1.20, two studies, *N* = 803), when compared with written information on the same topic. We are uncertain whether c*ulturally and literacy adapted audio-/visual education without personal feedback* have a medium-term effect on quality of life, knowledge, self-efficacy, health service use, or adverse events due to very low certainty or because of no evidence found.

Long-term effects (> six months post-intervention)

Moderate certainty evidence from one study with *N* = 445 participants indicated that c*ulturally and literacy adapted audio-/visual education without personal feedback* probably improves documentation of advance care planning (RR 1.49, 95% CI 1.13 to 1.97) twelve months post-intervention with probably little or no long-term effect on anxiety (MD -0.70, 95% CI – 1.40 to 0.00). We are uncertain whether there are any long-term effects on HL, quality of life, knowledge, self-efficacy or health service use, when HL interventions are compared with written information on the same topic as there was no direct evidence identified.

AVE compared with another AVE

We do not know if *narrative videos* are superior to *factual knowledge videos* because the short-term evidence is of very low certainty and no evidence was found for medium- or long-term effects.

Gender differences

Only three studies delivered gender-separate data related to the intervention's effectiveness. We found low certainty evidence of one study indicating that the diabetes HL may improve slightly more in female than in male migrants at the long-term, when they received c*ulturally and literacy adapted audio-/visual education without personal feedback* (MD 5.00, 95% CI 0.62 to 9.38; one study, *N* = 118). However, we are uncertain whether female or male migrants benefit differently from other interventions as either the evidence is of very low certainty or we did not find evidence for short-, medium, or long-term differences between the genders.

Discussion

The aim of this review was to assess the effectiveness of HL interventions for migrants and to evaluate whether female or male migrants benefit from these interventions in different ways. We found that some culturally and literacy adapted types of HL interventions such as self-management programmes, HL skills building courses, audio-/visual education without personal feedback, or telephone education have small to moderate positive effects on HL, for example, by improving understanding of medical terminology, health-related knowledge, or application of health information.

However, there are some points that need to be discussed. The heterogeneity among the included studies made it impractical and inappropriate to combine all individual study results and conduct comprehensive meta-analyses. Although we were able to pool at least some of the results and perform meta-analyses for studies that were similar enough to be grouped together, there was substantial statistical heterogeneity in some of the analyses, even with strict grouping. This limited our ability to draw solid conclusions from this review. We conducted p*ost hoc* subgroup analyses based on design features like programme duration and sensitivity analysis that excluded studies with a high risk of bias were conducted to address this heterogeneity.

Most studies in this review had short- or medium-term durations, with only a few assessments conducted beyond six months post-intervention. This limited our understanding of the long-term effects of HL interventions. Furthermore, only two studies reported unintended consequences or adverse events, indicating a gap in our knowledge regarding the potential drawbacks of these interventions.

While we used the integrated model of HL (Sørensen et al., 2012) as a framework for our analysis, it was not applied in any of the included studies, which limited our ability to evaluate the interventions using all its components. Most of the studies were conducted in the USA, which could explain the low adoption of the integrated model of HL as it is more common in Europe (e.g. Sørensen et al., 2015; HLS-EU19 Consortium, 2021) and Asia (e.g. Duong et al., 2017; Duong et al., 2019). Additionally, many of the studies focused on functional HL and understanding of health information, with a less comprehensive approach that considers the procedural aspects of health information processing. Nonetheless, all studies implicitly or explicitly addressed some aspects of HL in their design or evaluation of interventions.

In terms of gender, the lack of gender-segregated scores and the predominance of studies focusing on women made it difficult to draw conclusions about gender differences in the effectiveness of interventions.

Conclusion

There is a need for more rigorous research, including well-powered RCTs explicitly designed to promote HL among migrants. Specifically, there is a need for more robust, long-term studies that comprehensively assess HL with validated assessment tools. Most of the studies have been conducted in the USA and other high-income countries, emphasising the necessity for studies representing the diversity of health systems around the world. There is a lack of studies investigating potential gender-related differences in response to HL interventions among migrants.

4 DISCUSSION

This PhD project applied a mixed-methods approach referring to findings from FGDs with HCPs in Germany (studies I+II) and a Cochrane effectiveness review (study III). All studies were linked through the applied analysis framework, the integrated model of HL (Sørensen et al., 2012). The findings obtained from studies I+II provided an in-depth view on the perceived HL-related challenges, needs, and applied solutions of HCPs when interacting with persons with a migrant background. Study I more broadly aimed to examine how personal determinants, situational, and systemic factors shape HL in transcultural treatment settings. Study II took a closer look at gender as a personal factor of HL in the context of migration and examined its influence in transcultural healthcare interactions.

Stud III pursued the aims to (1) assess the effectiveness of interventions for improving HL in first-generation migrants and (2) to assess whether female or male migrants benefit differently from these interventions. This effectiveness review is linked to a QES (Aldin et al., 2019; 2024) conducted in parallel. The QES synthesised the evidence of qualitative studies in which the participants of the intervention studies came to word and shared their lived experiences with HL interventions and their perspectives on distinct aspects of HL. The main goal of the QES was to investigate the potential presence and significance of gender differences in the HL of migrants. In this regard, it aimed to uncover the factors that might contribute to gender differences in the four steps of health information processing – namely, access, understand, appraise, and apply. Moreover, it examined any potential gender differences in the effectiveness of HL interventions as assessed in the linked effectiveness review. The QES included 27 trial-sibling studies[36] that were related to 24 interventions included in the linked review (Aldin et al., in press).

In order to contextualise the main findings of this cumulative dissertation and to discuss these in light of the lived experiences of those concerned, I will frequently refer to the QES (Aldin et al., 2019, Aldin et al., in press) in this discussion.

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[36] A trial-sibling study is a qualitative study that is directly associated with a quantitative intervention study included in an effectiveness review. It may include participants who were involved in the development and design, the delivery/implementation, and/or the evaluation of the respective intervention (Aldin et al., in press).

4.1 Main Findings

Finding 1. *Known issues in health systems around the world (e.g. a systemic lack of time or economic pressure) are impeding HL in transcultural treatment settings at several levels. In the context of migration, these deficiencies become particularly evident.*

A systemic lack of time and economic pressure were named as two of the most prominent factors shaping the flow of health information in transcultural treatment settings. Although a familiar problem in many health systems around the world (Birkhäuer et al., 2017), these conditions were perceived as highly stressful by the HCPs who participated in the FGDs. Especially in the context of migration, where the overarching challenges that come along with time restrictions and economic pressure were seen as particularly aggravating. The participants noted that adequately counselling and treating patients with limited language proficiency, a lack of health system knowledge, or low literacy skills requires additional time and effort, often reported to lead to the investment of extra, unpaid time on the side of the HCPs. While this approach was not always successful and not satisfactory, it was considered the most effective way to address these issues.

Interestingly, time pressure was reported mainly by HCPs in medical (physical) care, while psychiatric professions seemed to be less affected in this respect. This distinction underscores the importance of recognising the unique challenges specific to different treatment settings when examining transcultural interactions. However, differences in perceived barriers to adequately promote HL due to a lack of time also seem to exist in relation to the different health professions, as a recent survey on *professional HL*[37] of HCPs in Germany and Austria found. In this study nurses felt more burdened through systemic conditions than physicians. Notably, nurses less frequently reported having the opportunity for uninterrupted discussions (reported as rarely/never by 37.2 %) compared to physicians (8.1%). Likewise, having adequate time for their patients was reported as rarely/never by 34.1% of the nurses and 10.9% physicians. Finding suitable spaces for patient interactions was also less prevalent among nurses (reported as rarely/never by 34.4%) compared to physicians (4.3%) (Schaeffer et al., 2023). The authors conclude that the overall working conditions for

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[37] The concept of *professional HL* is quite new and therefore could not be considered in the design of this PhD project. However, studies I+II explicitly examined aspects of the concept in line with the understanding of HL as a co-produced good (Baumeister et al., 2021; Chakraverty et al., 2020) and (situated) social practice (see also Papen, 2009; Samerski, 2019).

nurses are notably more challenging. However, they also constate that all HCPs would benefit from better working conditions as these were associated with easier task realization in general (Schaeffer et al., 2023).

Effective communication between patients and HCPs relies on the communication skills of both the patient including his/her language proficiency and the communication skills of the HCPs, which involve, for instance, using plain language and dedicating sufficient time for explanations (D’Agostino et al., 2017; Kerr et al., 2020; Oliveira et al., 2015). HCPs’ communication skills can significantly impact patients’ ability to communicate health issues, self-efficacy, medication adherence, and health outcomes (Tavakoly Sany et al., 2020). However, studies have demonstrated that when individuals are required to process intricate information under time pressure, they tend to rely on heuristic shortcuts such as stereotypes (Chaiken & Ledgerwood, 2012; Dijker & Koomen, 1996); an approach that was also prominently discussed by the participants of the FGDs. For instance, certain HCPs reported the present use of stereotypical terms such as ‘morbus meditarreneus’ in healthcare practice to characterise the assumed excessive pain expression among individuals from Southern European countries. These stereotypes may contribute to the perpetuation of subtle racism against individuals with a migrant background, a problem that stubbornly persists within health systems (Hamed et al., 2020; Stepanikova, 2012) and that has recently become particularly pronounced during the COVID-19 Pandemic (Devakumar et al., 2020).

In the effectiveness review (study III), a lack of time or economic pressure was not directly addressed. In the linked QES (Aldin et al., in press), however, we found that the migrant participants included in the intervention studies felt that many HCPs act under time pressure. These expressed concerns regarding the limited time available during their doctor's appointments to discuss their health issues and adequately explain disease symptoms and potential treatments. At the same time, the QES found that many migrants referred to HCPs as a significant primary source of health information typically consulting them to inform their health-related decisions, seek therapeutic advice, or obtain general guidance when uncertain about their well-being (Aldin et al., in press). Therefore, it seems all the more important to take a deeper look at the specific systemic conditions that challenge HCPs in their everyday practice and hinder them from enabling their patients to make self-determined and informed (i.e. health literate) health decisions based on the best available evidence.

Finding 2. *A shared migrant background of HCPs and their patients plays a crucial role for a satisfactory and effective flow of health information in transcultural healthcare encounters.*

Central results of the FGDs presented in the studies I+II were that having a migrant background as an HCP significantly impacts how health information is accessed, understood, appraised, and applied by their migrant patients. Sharing a migrant background (not necessarily in the sense of a common country of origin) was perceived as highly advantageous with regard to building trustful relationships and reducing existing distrust in HCPs. In this regard, trust emerged as crucial for a reciprocally satisfactory exchange of information. It seems to especially impact accessing health information and services as well as evaluating them. This finding is in line with those of the QES indicating that feelings of trust (or a lack of trust) significantly impact the appraisal of health information in migrants (Aldin et al., in press). Explanations are not only to be found in a shared language or the experience of migration. Although the issue of language barriers – a well-known factor impeding health communication and hindering access to health information and services (Rasi, 2020; Suphanchaimat et al., 2015) – were frequently reported in our FGDs and by the migrants included in the studies of the QES, our findings also highlighted that mutual understanding depends on more than just the mere exchange of factual information. Expressing personal health concerns can prove challenging, even for those who are literate in their native language. Language barriers and cultural disparities in comprehending illness or articulating pain may pose additional difficulties for individuals from diverse migrant backgrounds. Consequently, this may result in misunderstandings and false assumptions about the person's HL (Baumeister et al., 2021).

In line with this, Schaeffer et al. (2023) found that a considerable number of physicians (39.7%) and nurses (30.8%) perceived it as rather/very difficult to assess the extent to which cultural differences make the understanding of exchanged information more difficult (Schaeffer et al., 2023). In addition, these results were backed from studies included in the QES as some migrants were concerned about the ‘health systems' lack for cultural competency and sensitivity’ emphasising the role of a good doctor-patient relationship to influence migrants’ appraisal of health information (Aldin et al., in press). A shared migrant background may help overcoming language barriers as well as cultural particularities such as differences in health and risk perceptions.

However, not all participants of our FGDs perceived a shared migrant background as unreservedly positive. Some reported more ambivalent feelings about using the shared language and culture. On the one hand, they found enriching situations in which they actively chose to translate for German colleagues or to provide language-concordant treatment. On the other hand, this positive experience contrasted with situations where they felt obligated to interpret for others or were "caught off guard" by sudden requests (Baumeister et al., 2021, p. 10). In addition, interpreting was at times perceived stressful given the already high workload in healthcare settings, and some felt the high responsibility of lay interpreting as burdensome. Implementing a voluntary-based list of staff who speak foreign languages was a strategy rated as rather useful, in contrast to refusing interpreting for others in general. Nevertheless, the call for an improved funding of professional interpreters and cultural mediators, for example in the form of easy-accessible video interpreters, was unanimously the most appreciated and consistently demanded solution.

Schaeffer et al. (2023) also found that access to interpreting and translation services is only possible to a limited extent for HCPs in Germany: 68.9 % of physicians reported they can only use them sometimes or rarely, 39 % rarely or never. The situation was described to be even worse for nurses: 75% reported only having access to interpreting services sometimes or rarely, 50.3 % even rarely or never. The nationwide, at best state-subsidised, provision of video or telephone remote interpreting services could be a feasible, time saving, thus cost-effective way to overcome language barriers or potentially harmful outcomes due to informal interpreting of low quality and to improve patient-provider satisfaction (Fiedler et al., 2022; Ji et al., 2021). However, a recent feasibility trial in Germany indicates that doctors in primary care settings lack awareness of the potential adverse effects of informal interpreting and the advantages of professional interpreting. The authors propose to consider interpreting as an essential part of medical care, thus including it on the list of medical services covered by health insurance (Fiedler et al., 2022).

It can be expected that AI-based solutions to overcome language barriers will play an increasingly important role in the future. For example, *Google Translate* (https://translate.google.com/) is already widely used by HCPs when no interpreter (lay or professional) is available at short notice, including our FGD participants. The development of *secure*[38] AI-

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[38] In terms of ensuring data protection, e.g. regarding sensitive personal data as well as the quality of the translated dialogue content, e.g. regarding the overall translation performance and the assurance of cultural sensitivity.

based solutions for the healthcare sector would be desirable, especially in view of the lack of time, personal, and financial resources in all areas of healthcare.

Finding 3. *Gender is an important, but significantly understudied, factor that influences HL in the context of migration and should be taken into account in the development, implementation, and evaluation of HL intervention for migrants.*

The findings from study II revealed that gender either directly or indirectly influences HL in the context of migration. It is important to note, however, that the participants mentioned gender-issues particularly for migrants from Turkey, followed by nations from the Arab regions. Patients with an assigned Islamic faith were also commonly cited. There was little mention of gender-specific aspects in interactions with people from other religious or regional backgrounds. One reason for this finding may lie in the fact that many of the HCPs themselves had an Arab or Turkish migrant background and therefore frequently interacted with people from these regions (Chakraverty et al., 2020).

The gender-specific findings found in the QES stemmed from studies including female migrants from either Korea (K. Kim et al., 2017), Afghanistan (Shirazi et al., 2013; Shirazi et al., 2015), or Latin America (Baezconde-Garbanati et al., 2013). However, all these studies included women only, although one study reported to have implemented health education (regarding breast cancer screening) for the women’s husbands, too (Shirazi et al. 2013; Shirazi et al., 2015). Details were, however, not reported.

Although we contacted the authors of every study included in the effectiveness review (study III), we obtained gendered scores related to the intervention effects of only three studies (Calderón et al., 2014; Soto Mas et al., 2018; Sudore et al., 2018). In line with the results from our previously published systematic review on gender differences in the HL of migrants (Chakraverty et al., 2022), we found a pronounced disproportionate share of studies including either only or at least predominantly women, revealing a considerable lack of studies concerned with (improving) the HL of migrant men. We found low-certainty evidence from one study suggesting that female migrants may derive greater benefits from audio-/visual education without personal feedback regarding diabetes-specific HL (Calderón et al., 2014). Another study evaluating a similar intervention type, found little or no difference in health behaviour between female and male migrants receiving audio-visual education at twelve months post-intervention (Sudore et al., 2018). For our other predefined outcome categories, either no evidence assessing gender differences was identified or our certainty in the evidence was very low. Thus, we cannot definitively tell whether female or male migrants experience different benefits from the identified interventions.

However, the fact that we were unable to derive meaningful gender-specific results from the quantitative intervention studies does not allow the conclusion that in the context of migration, HL is not influenced by gender-specific aspects and that these should not be taken into account in the development, implementation, and evaluation of HL interventions: in the FGDs, gender was reported to indirectly influence HL through exaggerating existing issues in health systems such as a systemic lack of time that were reported to interact with language barriers and gender-specific issues that were perceived as even more time consuming. Gender was also reported to directly affect health information processing particularly with regard to accessing, understanding, and appraising health information.

Regarding accessing health information, the participants of the FGDs reported, for example, that husbands, here foremost referring to those of women with an Arab and Turkish migrant background, sometimes act as ‘gatekeepers’ when it comes to treatment situations with male doctors including the attempt to control the situation (e.g. by being present) or even refusing treatment if only male doctors are available. This is in line with the findings of the QES (Aldin et al., in press) indicating that Afghan migrant women perceive their husbands as gatekeepers as these were reported to be regarded as decision-makers in the family who are strongly involved in the health choices of their wives. Taken together, the results of both studies (study II and the QES) one may suggest that the personal perceptions of Afghan women reported in the QES could also apply to (some) women from Turkey or other Arab cultural backgrounds as indicated in study II.

In the FGDs, we further found that the gender of the HCP was an important factor related to accessing health information and services, which was primarily reported with regard to migrants’ preferred access to HCPs from the same sex and shame in healthcare situations involving nudity such as in physical examinations or washing situations in case of care need (related foremost to female migrants assumed to be of Islamic faith). Female HCPs also felt their expertise questioned because of their gender by some male migrants (here reported with regard to migrants from Russia). These findings are also supported by the results of the QES indicating that Korean and Afghan women preferred access to female doctors.

Regarding understanding of health information, the perceptions of the HCPs (study II) that women with a Turkish/Arabic migration background often have greater language barriers than their husbands and that these language barriers cannot always be clearly distinguished from literacy barriers (study I) were also supported by the findings of the QES. It found that Afghan women's limited English proficiency and low literacy skills, in terms of unfamiliarity with the foreign language, but also general problems in reading and writing, to be barriers to understanding health information and communicating personal health issues with HCPs. However, these findings stem from only one, albeit large qualitative study with Afghan women, thus speaking for, if at all, Afghan women only (Aldin et al., in press).

Regarding appraising and applying health information our FGDs indicated that motherhood, which was assumed to be of higher value than for women of German origin, may be an important factor influencing the appraisal of health information. In line with this, the QES found that 'women's role in the community' was perceived as a barrier for maintaining their own health and making it a priority.

Finding 4. *Certain culturally and literacy adapted HL intervention types such as self-management programmes, health literacy skills building courses or audio-/visual education without personal feedback show promise in improving (components of) HL. However, there is a notable gap in understanding long-term effects, adverse events, and potential gender differences in the benefit of these interventions.*

Study III explored HL interventions for migrants, drawing from 28 randomised controlled trials (RCTs) and six cluster-RCTs involving 8,249 participants with a wide range of conditions.

All of the included studies evaluated interventions were culturally and literacy adapted: they were delivered in the participants' native (preferred) language and used a variety of culture-sensitive formats to ensure information comprehension. Almost all interventions with a direct provider contact (e.g. face-to-face or telephone) were delivered by people of the respective community (e.g. ley health educators or community health workers).

Although already anticipated at protocol stage (Baumeister et al., 2019), one major finding on the methodological level was the considerable heterogeneity regarding interventions, participants, and comparisons we encountered.[39] Therefore, the studies were categorised into nine main comparisons with eight of these reflecting variations in intervention components, complexity, and comparators. The ninth comparison related to gender-specific results on the effectiveness of interventions. These have been discussed in accordance with Finding 3.

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[39] The issue of heterogeneity is discussed in detail in section 4.3.1 Producing Cochrane reviews on health literacy, migration, and gender.

The first and second comparisons focused on culturally and literacy adapted self-management programmes either compared with no HL intervention (*comparison 1*) or written information on the same topic (*comparison 2*). Results of comparison 1 suggested probably important short-term effects of self-management programmes on disease-specific HIV-HL (low certainty evidence), alongside moderate-certainty evidence of slight improvements in self-efficacy immediately post-intervention. The findings of comparison 2 indicated probable slight improvements in health numeracy and an important effect on generic print literacy in the short term (moderate certainty evidence). Additionally, improvements were found for health-related knowledge (low certainty evidence) and self-efficacy (moderate certainty evidence). There is only one other Cochrane review assessing the effectiveness of self-management programmes in people with osteoarthritis indicating that in comparison to usual care, these programmes may slightly improve self-management skills, pain, individual function, and osteoarthritis symptoms (Kroon et al., 2014). However, apart from self-efficacy, the outcomes of interest differed from those of the effectiveness review (study III) contributing to this dissertation. In addition, HL was not the focus of this review and migrants were not the population of interest. No systematic review was found on self-management programmes designed for migrants.[40]

Comparison 3 assessed culturally and literacy adapted HL skills building courses versus no or unrelated HL interventions. Low certainty evidence indicated important short-term improvements in generic functional HL and health-related knowledge with knowledge being slightly improved also at medium-term (low certainty evidence). Three out of seven studies in this category used the setting of second language courses to incorporate HL skills building curricula. The other four studies used very similar components such as group-based education and different methods of knowledge transfer (e.g. practicing medical terminology, role plays, or using illustrated narratives), although outside the specific language school-based setting. There is one other systematic review that assessed the effectiveness of HL skills building curricula incorporated in second language courses (X. Chen et al., 2015). It included all three studies assessed in the presented Cochrane effectiveness review, too. X. Chen et al. (2015) concluded that these curricula are effective in improving (functional) HL and knowledge. Thus, the review’s results do not differ considerably from ours. However, we described the findings with more uncertainty, which may be due to the fact that X. Chen et al. (2015) did not conduct a systematic risk of bias assessment and more than half of the

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[40] To the best of my knowledge, the systematic grouping procedure developed to facilitate the summary and evaluation of individual study results in study III was the first to be used in a systematic review of HL interventions in migrants, although efforts to group individual studies at a broader level have been made by other review authors in the HL field before (e.g. Sheridan et al., 2011). For this reason, not all comparisons could be found in other systematic reviews to discuss the results.

studies were evaluated using other than randomised controlled designs (Baumeister et al., 2023).

Comparison 4 evaluated culturally and literacy adapted telephone education compared with an unrelated HL intervention (i.e. telephone education about a different health topic). Moderate certainty evidence from a large, high-quality study suggested probably important long-term effects on the appraisal of health information by reducing decisional conflict regarding the use of prostate cancer screening measures. Long-term effects were also found on health-related knowledge, although less important.

Further comparisons explored interventions such as culturally and literacy adapted audio-/visual education without personal feedback compared with no HL intervention (*comparison 5*), written information (*comparison 6*), or another audio-/visual education without personal feedback (*comparison 7*), revealing mixed findings on HL improvements. For example, when compared with no HL intervention, these audio-/visual interventions may have a less important short-term effect on diabetes HL or *applying* health information, i.e. the intention to seek treatment for depression, but important effects were found on self-efficacy (low certainty evidence). Compared either with no HL intervention or written information, they may also have a less important short-term effect on any health-related knowledge. At medium-term, important effect on health service use, i.e. (child's) emergency room visits were found.[41]

In *comparison 8,* culturally adapted medical instruction was compared with no HL intervention indicating that these rather simple interventions may improve medication understanding. This finding is consistent with the results of other systematic reviews evaluating HL interventions in various populations, which suggest that simple language and visual aids such as pictograms are useful in improving comprehension of written information (Sheridan et al., 2011).

Comparison of intervention effects (study III) with the participants' views in the QES

Out of the 34 studies included in study III, the effectiveness review, 29 studies used qualitative methods involving persons of the 'target population' to either inform the development of the intervention or to evaluate its feasibility and/or effectiveness. In total, 27 studies were included in the linked QES.[42] Thus, the huge majority of studies involved *consumers* (i.e.

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[41] Due to the high heterogeneity of the included studies described above, the findings regarding the effectiveness of certain HL-intervention types are rather fragmented. A full overview is provided in section 3.2 Study III: Interventions for improving health literacy in migrants, as well as in the published review (Baumeister et al., 2023).

[42] We contacted all authors of studies with missing information regarding potential (un-)published qualitative data. Details on the process of identifying and including studies for the linked QES and the measures used to ensure participation of consumers are described in Aldin et al. (2024).

migrants or people of the respective community) at some point of the intervention's development, its implementation, or evaluation phase.[43]

The linked QES (Aldin et al., in press) explored the intervention effects from the participants' point of view and found that some of the perceived effects were attributable to the components of HL (e.g. knowledge or the steps of health information processing), but the participants reported no intervention effects that could be directly related to the appraisal of health information. In addition, we were not able to obtain qualitative evidence for the participants' perceived intervention effects for all four HL intervention types as identified in the effectiveness review (see 3.2 3.2 Study III: Interventions for improving health literacy in migrants). They were found primarily for intervention types categorised as audio-/visual education without personal feedback followed by only one study evaluating a HL skills building course. Furthermore, we were unable to explain any of the gender-specific findings in the effectiveness review in terms of female versus male migrants benefiting from these interventions with those in the QES, although it is to be noted that the very few gender-specific findings for audio/visual training without personal feedback were small, ambiguous and of low certainty.

However, some results can be compared and shed light on the perceived effectiveness of the interventions from the participants' perspective: the QES found that the participants perceived their disease-specific knowledge improved, which in turn was reported to positively influence their ability to access health information. Specifically, participants reported enhanced knowledge about the root causes, symptoms, and potential treatment options for a particular condition, such as depression (Aldin et al., in press). Notably, individuals of Latinx origin who read a printed photonovel telling the story of a depressed Latina were most likely to make this observation. The intervention was categorised as audio-/visual education without personal feedback. The effectiveness review also identified low certainty evidence suggesting that there may be important effects of this intervention type on health-related knowledge, compared with either no HL intervention or written information on the same health topic. Knowledge was primarily assessed as disease-specific knowledge across the intervention studies (Baumeister et al., 2023). Concerning disease-specific HL, however, the effectiveness review's findings were less unanimous. Moderate evidence from one study suggested that audio-/visual education without personal feedback probably improves depression literacy (assessed as depression knowledge) compared to no HL intervention.

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[43] The following section is based in part on the discussion section of the unpublished QES "Integration of intervention effects as perceived by the participants" (Aldin et al., in press). It was adapted and expanded for the purpose of this thesis.

Yet, this effect was not as pronounced in diabetes literacy, with one study providing moderate certainty evidence showing little to no effect, when compared with information conveyed in written form. Diabetes HL, in this context, encompassed knowledge and beliefs about diabetes (Baumeister et al., 2023).

Participants who were included in the QES perceived their ability to navigate the health system navigation improved when exposed to audio-/visual education without personal feedback. This perception arose from their acquired knowledge in the intervention on the navigation of the health system in the host country. The primary source of this insight was an intervention focused on child health, where parents of Latinx origin watched a brief video on how to navigate a new health system and seek health services needed. In addition, they received interactive text messages over a ten-month period (Aldin et al., in press). However, this finding should be viewed with caution as it is based on a single, albeit quite large, qualitative study (*N* = 79) and more of these evaluations are needed to derive meaningful statements on whether audio-/visual education can improve health system navigation from the perspective of migrants. The corresponding RCT, which assessed health service use (child's emergency room visits) and health behaviour (child's up-to-date immunisation) up to three months post-intervention, indicated that this intervention type probably leads to a reduction in emergency room visits. However, there was probably little or no effect on the child's up-to-date immunisation status (Baumeister et a., 2023).

Regarding understanding health information, the QES found one study evaluating a HL skills building course. The participants reported that they perceived to have increased knowledge and understanding about cardiovascular health after participating in the intervention. The study also addressed functional HL (reading and numeracy skills) and English skills including several methods of knowledge transfer in order to practice HL skills according to a newly developed HL curriculum incorporated in a conventional ‘English as second language’ course. FoFeresr example, participants reported learning how to read and understand nutrition labels relevant to their cardiovascular health. Participants felt the course improved their ability to understand the information provided by each of the food labels studied and to recognise its impact on their health. In addition, the participants learned reading, understanding, and filling in certain health forms (Aldin et al., in press). In the effectiveness review, a pooled analysis of two studies in the same intervention category indicated that HL skills building courses may have an important effect on any generic HL when assessed as functional HL with a performance-based measurement tool (e.g. TOFHLA (Parker et al., 1995)) (Baumeister et al., 2023).

In terms of applying health information, the QES found that audio-/visual education without personal feedback increased the participant’s personal confidence in talking about their own feelings and symptoms of depression (Aldin et al., in press). In the effectiveness review, we found moderate to low certainty evidence that some interventions improved self-efficacy, which is closely linked to one's behaviour (intent), and in turn, to health-related decision-making.[44] The effectiveness review also found a small effect of audio-/visual education without personal feedback on the participants' intention to seek help for depression (low certainty evidence) (Baumeister et al., 2023). This is in line with the QES' findings indicating that the intervention helped the participants to understand the 'importance of asking for help' as they acknowledged the significance of discussing their emotions with family and friends and recognised that seeking professional assistance in the event of (mental) health issues is appropriate (Aldin et al., in press).

Overall, it is to postulate that we were not able to explain most of the findings of the effectiveness review – particularly the very few gender-related ones – although we found 27 trial-sibling studies related to 24 interventions. Potential reasons are as follows:

1) none of the studies included in either of the both reviews aimed at investigating gender differences; and

2) most of the trial sibling studies included in the QES used formative evaluation (i.e. studies conducted to inform the development and design of an intervention to tailor it to the needs of the population of interest and the context (Gittelsohn et al., 2006)). Although this 'consumer' involvement is highly desirable as it indicates that in the context of migration, many researchers seek out to actively involve those concerned in the research process, it led to the fact that these study participants were typically not asked to report on the perceived intervention effects. The other nine studies were process evaluations (i.e. studies that are conducted to assess and explain intervention outcomes from the perspective of the participants (K. F. Cheng & Metcalfe, 2018; Gittelsohn et al., 2006)). While process evaluations are typically conducted during or after a trial, in the QES all identified evaluations took place after the intervention has been administered (Aldin et al., in press). Nevertheless, only five studies reported on the participants' perceived intervention effects, limiting the body of evidence to be discussed in this cumulative dissertation to a considerable amount.

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[44] According to Bandura (1997) self-efficacy is understood as the "beliefs in one's capabilities to organize and execute the courses of action required to produce given attainments" (p. 3).

4.2 Conceptual Implications

4.2.1 Health literacy and the integrated model

HL is a multidimensional concept which is inconsistently defined and measured (Mackert et al., 2015; Sørensen, 2019). To establish a common understanding of what constitutes HL and how it could best be measured and promoted, it is necessary to examine existing concepts and models regarding their applicability, to reflect on them critically and, if necessary, to develop them further.

A lack of a clear theoretical foundation and/or a common theme connecting the various conceptualisations and applications of HL have long been discussed (Abel & Sommerhalder, 2015; Pithara, 2019; Sørensen et al., 2012; Sykes et al., 2013). In 2019, Pleasant et al. constated that even some of the widely used measurement tools such as the TOFHLA (Parker et al., 1995) or the REALM (Murphy et al., 1993) lack a sound definition of HL (Pleasant et al., 2019). This is not surprising as the concept is rooted in education and literacy research (see 1.1.1 The two paradigms in health literacy research – now and then) and was mostly developed from practical applications (Abel & Sommerhalder, 2015). The attempt to ground the concept in theory came later and was thus shaped by the respective research discipline or application area resulting in various definitions and conceptual models applied today (Abel & Sommerhalder, 2015).

The scientific discourse regarding the conceptualisation of HL revolves around the pros and cons of focusing on *one* general HL concept in contrast to *several* disease- or context-specific HL concepts (Baumeister et al., 2022). For instance, Mackert et al. (2015) advocate for the benefits of one comprehensive concept of general HL, applicable across various health domains. However, disease-specific approaches such as the concept of mental HL, as introduced by Jorm et al. (1997), and further developed by, for example, Kutcher et al. (2015) or Bjørnsen et al. (2017), indicate that the rather narrow focus on one application field can yield practical and clinically relevant empirical results in the respective disease-specific context (Baumeister et al., 2022).

This fragmented HL landscape was also reflected in the heterogeneity of HL interventions included in the Cochrane effectiveness review (study III). Hardly any study used an established HL model to guide the development, implementation, and evaluation of the intervention; none referred to the integrated model of HL. Only one study used a HL theory as the basis for developing a HL focused self-management programme for Koreans with diabetes type 2 (M. T. Kim et al., 2020); and this was developed specifically for the purpose of the study. Instead, in total 19 theories of health promotion and health behaviour change or other learning theories were used and set into relation to HL promotion (for more details, see Baumeister et al., 2023, table 15). Among others, studies most often referred to Bandura's social-cognitive theory (Bandura, 1977b, 2002) and theory of self-efficacy (Bandura, 1977a, 1997), the health belief model and its variations (e.g. Champion & Skinner, 2008; Janz & Becker, 1984), the theory of reasoned action/planned behaviour (Ajzen, 1991, 2011; Fishbein & Ajzen, 1975), or adult learning theories (Knowles, 1984). The diversity of theories and models used in HL interventions for migrants indicates that, just as there is no universally accepted theory of HL in general, the same is true for its promotion (Mantwill et al., 2015; Nutbeam & Lloyd, 2021).

The researchers involved in the first HLS-EU (2009-2011) aimed to do justice to the conceptual diversity in HL research and thus developed the currently most comprehensive integrated conceptual model of HL (Sørensen et al., 2012). Today, it is well established in Europe and experiences a high level of acceptance and use in other parts of the world such as Asia (e.g. Duong et al., 2017; Duong et al., 2019).

Although it starts from the individual, tends to neglect some important other facets of the concept such as critical HL (Nutbeam, 2000) or organisational HL (e.g. Brach et al. 2012), and remains mainly descriptive in nature, the integrated model provides useful points of orientation for exploring the connection between HL and the broader field of health equity, because of its comprehensive focus, its operability (e.g. Sørensen et al, 2015; HLS19 Consortium, 2021), and its explicit openness to context-, situation- and disease-specific aspects of HL that unfold their impact in the different health domains (disease management, disease prevention and health promotion). Thus, it may serve as a fruitful starting point for the application of a generic HL model in different contexts. Disease-, and context-specific concretisations on the basis of one comprehensive model or theory (for example, but not exclusively, the integrated model) could also facilitate the comparability of research results in this field (Baumeister et al., 2022). Furthermore, it could help to better determine which HL components are to be improved by certain HL intervention types and thus, to develop more efficient and targeted interventions to promote HL in different contexts. In Europe, the WHO Action Network M-Pohl is already working to achieve this, for example through the European population surveys HLS_{19} (HLS19 Consortium, 2021) and HLS_{24} (M-POHL, 2023).

The strict application of the integrated model in this cumulative dissertation brought several advantages: it enabled us to generate a profound understanding of what constitutes HL in the context of migration (in the realm of healthcare encounters) and to identify useful approaches for the development of future HL interventions for migrants. However, we also encountered notable challenges, especially related to data analysis and -synthesis: studies I+II showed, for example, that in the context of transcultural healthcare interactions, the four steps of health information processing – access, understand, appraise, and apply – were neither disjunctive nor strictly sequential (Baumeister et al., 2021) making it difficult to develop a robust category system based on established methods of qualitative content analysis (Kuckartz, 2019). Instead, the results suggest that these interact with and mutually reinforce each other, influenced to a considerable extent by individual, situational, societal, and environmental factors (Baumeister et al., 2021).

One might argue that it is not necessary to strictly separate the HL components from each other as it is an explicitly dynamic, context-specific, and multifaceted construct that does not intend to follow a given chain of action. The steps of accessing and applying health information, for example, are rather action-based, whereas the steps of understanding and appraising reflect rather cognitive-volitional aspects of health-related decision-making. This is why a *one-sided* illumination on HL with a focus only on facilitating a desired health behaviour or achieving a better state of health falls short. The findings presented in this dissertation showed that particularly the appraisal of health information but also the access and use of health services and information are strongly dependent on individual value concepts, cultural norms, religious and spiritual beliefs regarding health and illness, and (dis-)trust in health institutions or HCPs. Thus, ‘good’ HL cannot be derived exclusively from improved understanding of relevant (disease-specific) knowledge.

Study III indicated that categorising HL intervention studies based on carefully developed grouping criteria (e.g. intervention components, comparisons, or HL-related outcomes according to an underlying HL model (e.g. Sørensen et al., 2012)) may assist decision-makers, future reviewers, and other researchers in deriving meaningful insights from HL interventions. However, this review revealed that, at least thus far, the application of the integrated model of HL and the consideration of its components as a framework for evaluating the effectiveness of HL interventions, has been limited (Baumeister et al., 2023). This finding can be explained with the following observations: firstly, the interventions identified were mainly conducted in Northern America, with no studies originating in Europe, where the integrated model of HL is well-established. Additionally, the broader approach of addressing not only functional HL or numeracy but also incorporating *procedural* aspects of health information processing is a rather recent development (see 1.1 Health Literacy). The majority of studies focused on literacy aspects, aiming to enhance comprehension or model health behaviour by addressing the impacts of low literacy and limited language proficiency in specific health settings (Baumeister et al., 2023). However, despite only some studies using the term *health literacy*, all studies implicitly or explicitly addressed certain components of HL in their interventions, thus delivering information about what aspects of individual HL – against the background of the applied model – are to be improved.

The key question arising from the discussion around the conceptualisation of *individual* HL is, whether it is understood as a purely *action-relevant concept* aiming at a 'desired' health behaviour to achieve a 'better' state of health (e.g. American Medical Association, 1999; Nielsen-Bohlman et al., 2004) or whether the focus is rather on maintaining and improving the individual's quality of life by making self-determined, fully informed health decisions (Sørensen et al., 2012) or, as the WHO (2021) stresses, on using information or services "in ways that promote and maintain good health and well-being for themselves *and* [emphasis added] those around them." (p. 6).[45] The latter implies that, in principle, a personal decision against a certain medical intervention (e.g. cancer treatment), although it would most likely contribute to one's health, at least in the long run, can also be health literate – as long as the decision was made against the background of the best currently available information, corresponds to one's own value system and is conducive to one's quality of life.

Of course, it is not quite that simple: according to current understandings of HL (e.g. Bitzer & Sørensen, 2018; Paakkari & Okan, 2020; World Health Organization, 2021), it is explicitly a *relational concept* (or a *social practice* as Samerski (2019) postulates), i.e. the potential effects of *one's* health decisions on *others* (e.g. smoking in the public) must inevitably be considered in individual decisions; a facet of the construct that Chakraverty (2023) is calling *social HL.* Thus, understanding HL as a *social-relational concept* that is acquired, negotiated, and applied through engagement with others, implies that considering the influence of social interactions becomes essential when assessing individual HL and developing HL interventions (see also Harsch, 2022; Papen, 2009; Samerski, 2019, for differentiated perspectives on HL as a *social practice*).

Nevertheless, as HL is multidimensional, it is *also* an action-related concept intricately linked to health behaviour – at least indirectly through the emphasis on sound health decisions. Therefore, other concepts established in health psychology could be approached to help explaining variations in individual HL levels. For example, the Health Action Process Approach (HAPA) model (Schwarzer, 2016). Very simply put, the HAPA model focuses on motivational components (e.g. goal setting) and volitional components (e.g. planning an action) prior to an action fulfilled. In the motivational phase, individuals form intentions based on risk perception and outcome expectancies, and in the volitional phase they engage in action planning and coping planning to transition from intention to actual behaviour.

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[45] The concept *quality of life* comes from sociology and social policy. It refers to the individual evaluative judgement of major aspects, or the entirety, of a life or a society. The concept of *well-being* is rooted in psychology and is also an 'abstraction', applied to describe the quality of one of the various valued aspects of (an individual's) life, of some set of it, or the life as a whole (Gasper, 2007; 2010). Well-being is more often used to refer to 'actual experiences', whereas quality of life is more often used to refer to context or environments; the range of meanings of both concepts overlap, though (Gasper, 2010).

Until a goal is set, a person is a *non-intender* (Lippke & Renneberg, 2006). The process of goal setting is influenced by the perceived personal risks (e.g. risk for a heart attack), the expected results of an action, and the expectations of self-efficacy. Self-efficacy is important for goal setting on the one hand and actual planning of a behaviour on the other. The *non-intender* has become an *intender* and the motivational phase ends (Lippke & Renneberg, 2006). The following process from intention to action is influenced by environmental barriers and resources such as social support; both the action and the intention must be "shielded" from distractors (Lippke & Renneberg, 2006; Schwarzer, 2016). Furthermore, the expectation of self-efficacy plays a key role in this model; according to the theory, it helps to persevere, to shield against distractors and to use personal and social resources in such a way that the behaviour can be carried out in a targeted manner (Lippke & Renneberg, 2006). Thus, the HAPA model acknowledges the dynamic interaction between individual factors, personal and social resources as well as the environment and their joint influence on health decisions (i.e. behaviour intent) and behaviour (Lippke & Renneberg, 2006; Schwarzer, 2016).[46]

If behaviour is an outcome of HL, i.e. HL is upstream of behaviour, the question arises as to when *exactly* these motivational and volitional aspects of health behaviour come into play and *how* they are intertwined with the components of HL as proposed in the integrated model (Sørensen et al., 2012). According to the model, motivation is on an equal footing with competencies (e.g. reading and writing abilities) but also knowledge (see Figure 1. Integrated model of health literacy). However, how these three "prerequisites and tools" (Baumeister et al., 2019) of health information processing interact with each other and thus, influence health information seeking and finding, understanding, appraising, and applying remains unspecified.

In recent years, several studies have demonstrated associations between HL and health behaviours (e.g. Berkman et al., 2011; HLS19 Consortium, 2021; Husson et al., 2015; Lim et al., 2021; McAnally & Hagger, 2023). In addition, relations between 'inadequate' HL and health outcomes have shown to be mediated by health behaviour (Mayberry et al., 2018),

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[46] Another example of an established theory that is often approached in intervention studies on HL is Bandura's *social cognitive theory* (Bandura, 1977b, 2002). It aims at explaining human behaviour through a dynamic and reciprocal three-way model. This model posits that individual behaviour is a result of personal factors (e.g. preferences, personality) and environmental influences (e.g. social norms) that are in constant interaction with each other (Bandura, 1977b; Bandura, 2002). It emphasises the importance of observational learning, imitation and modelling in the development of human behaviour. In this theory, self-efficacy plays a crucial role in shaping cognition, motivation and behaviour (See also Bandura's theory of self-efficacy, which posits that an individual's expectations of self-efficacy determine the initiation of a behaviour, the effort expended, and the duration of the behaviour in the face of barriers and aversive experiences (Bandura, 1977a).

i.e. poor health outcomes of persons with ‘inadequate’ HL may be partially attributed to low levels of health behaviour participation (McAnally & Hagger, 2023).

However, which factors influence the decision to search for information on a particular health topic in the first place and, ultimately, to select a respective information source has hardly been investigated to date. The need for more research in this regard became clear, at least in the years of the COVID-19 pandemic when mis- or disinformation, the so-called *infodemic,* was up to mischief (J. W. Cheng & Nishikawa, 2022). Overall, motivational aspects of information seeking and processing have yet been understudied in HL research, although there are increasing efforts to better understand the relationship between (subjective) HL and social-cognitive constructs such as self-efficacy.

Self-efficacy was considered an (independent) predictor of subjective HL in the general population (Berens et al., 2021) and in migrants (Berens, Klinger, Carol, et al., 2022). The strong association between HL and self-efficacy has also been shown in other studies, primarily conducted in disease-specific contexts such as diabetes management (Inoue et al., 2013; E.-H. Lee et al., 2016; Y.-J. Lee et al., 2016; Osborn et al., 2010; X. Y. Xu et al., 2018) or in school-aged children (Fretian et al., 2020). In addition, Sheeran et al. (2016), who reviewed 204 experimental studies, found that interventions inducing changes to attitudes, norms, and self-efficacy all led to medium effects on health behaviour intent and small effects to health behaviour. Y.-J. Lee et al. (2016) examined links between self-efficacy, selfcare activities, and quality of life in people with diabetes type 2. They found that HL had a direct impact on self-efficacy and selfcare activities but also indirectly impacted selfcare activities through self-efficacy. In addition, research found pathways from HL to knowledge (A. M. Chen et al., 2020; McAnally & Hagger, 2023; Osborn et al., 2011) and from knowledge to self-efficacy (McAnally & Hagger, 2023; Osborn et al., 2011). McAnally & Hagger (2023) conducted a multilevel-meta-analysis of 203 studies with $N = 210{,}622$ participants and also found self-efficacy to partially mediate the direct effect from HL to health behaviour.

Taken together, there is a reasonable theoretical, but also empirically indicated, assumption that social cognitive variables such as self-efficacy may play a significant role in the mechanism linking individual HL to health behaviour and that it should be taken into account and explicitly targeted in the development of future HL interventions aiming at improving individual HL.

The studies contributing to this dissertation showed that (dis-)trust in the health system and HCPs may be key a factor that affects how persons with a migrant background seek information, evaluate and translate it into health decisions (Baumeister et al., 2021; Baumeister et al., 2023; Aldin et al., in press), indicating that there is a need for further research that examines the potential associations of feelings of (dis-)trust with HL in the context of migration.

Nevertheless, it is to constitute that in the migration context, complex interactions between pre-, peri-, and post-migration experiences, personal characteristics (e.g. gender), and general environmental factors such as political and health system conditions of the receiving country also come into play. With regard to gender, particularly, intersectionality concerns play a role as gender roles and power relations have shown to affect HL in several ways (Aldin et al., in press; Chakraverty et al., 2020; Chakraverty, 2022). Thus, a profound theoretical reflection – by this, I certainly mean going into more depth than this dissertation is able to – is essential to better understand the role of HL in the broader realm of health equity and to enable, if that is the conclusion, a theoretically sound, culture-sensitive conceptual refinement of the concept.

4.2.2 Migrant's 'vulnerability' regarding health literacy

In the past years, quantitative measures to assess HL in different disease-specific contexts and health settings flooded scientific databases (U.S. Department of Health and Human Services, 2024) (see 1.1.4 Operationalisation of (individual) health literacy) reflecting an ever-growing body of evidence to measure HL within and across various populations. These large-scale population studies (e.g. Kutner et al., 2006; Sørensen et al., 2015; HLS19 Consortium, 2021) have significantly contributed to raise awareness for the unequal distribution of individual HL, which is, as these studies showed, closely linked to health and social inequalities (Baumeister et al., 2023; Bittlingmayer et al., 2020).[47]

Against the background of the well documented correlations of 'low' HL (in the sense of quantitative object considerations) with various adverse health outcomes (e.g. Berkman et al., 2011; see also 1 Introduction), the growing awareness for (group-specific) differences in HL, certainly is to be viewed positive. Not least, it has fostered great scientific and also political attention leading to the initiation of national action plans and HL initiatives around the world (e.g. Schaeffer et al., 2018; Weishaar et al., 2019; see 1.1 Health Literacy).

Nevertheless, there are tendencies in HL research towards a view that is primarily 'deficit-oriented' – and this should be reflected critically. In the current practice, people are categorised along a single linear dimension of competence which can be seen as problematic

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[47] The social gradient of HL refers to older and (chronically) ill individuals, people with low social status, financial deprivation, or low educational attainment, and a direct migration experience (i.e. migrants) (e.g. Sørensen et al., 2015; HLS19 Consortium, 2021; Schaeffer et al., 2016; Schaeffer et al., 2021).

(Bittlingmayer et al., 2020, p. 123), because – as Bittlingmayer et al. (2020) argue – it inadequately considers the diverse perspectives and processes of meaning-making within actual social groups (p. 128) related to health. Additionally, it struggles to adequately address the multifaceted nature of inequality structures and processes (Bittlingmayer et al., 2020) as prevalent within and across societies around the world. Harsch (2022) postulates further that current HL debates often concentrate on the individual's characteristics and competencies associated with 'poor' HL, thereby neglecting to consider the factors and situations that contribute to this 'vulnerability'[48] regarding HL.

Thus, "relating vulnerability to a set of personal or situational characteristics [i.e. HL] may run the risk of ignoring the social, institutional, legal, and economic conditions that create inequality (…) and thus also vulnerability in itself" (Gilodi et al., 2022, Structural Vulnerability).

However, HL is relational, context- and situation-specific and thus*, multidimensional* (Dodson et al., 2015; Parker, 2009; Sørensen et al., 2012). Accordingly, 'adequate' or 'inadequate' HL must be seen as *multifactorial*. Neglecting the relevance of external factors, such as the social environment and the health system one is expected to navigate, can contribute to portraying 'inadequate' HL as a given characteristic of migrants (or other groups of people with 'inadequate' HL) and thus misleadingly overemphasise personal determinants over the situational, societal, and environmental factors such as the health system's HL responsiveness (Trezona et al., 2017) influencing an individual's HL.

Although this process is likely to be unconscious and non-intended to be harmful (or even exclusive to migrants), similar aspects are discussed in the political discourse around *ableism.* The term circumscribes a perspective that sets certain cognitive and physical abilities as the norm and thereby influences the evaluation and social positioning of all people living in a society (Köbsell, 2016). Similar to other 'isms', the focus is on meeting or failing to meet these socially constructed normality requirements (Köbsell, 2016, p. 3).[49]

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[48] In healthcare, vulnerability is commonly used but inconsistently defined (Clark & Preto, 2018). A quite recent definition of Boldt (2019) describes it as "a state of physical, emotional and cognitive stability that is in danger of being disturbed and destroyed due to being susceptible to destabilizing influences." (Boldt, 2019, p. 2). In HL research, the term vulnerability is foremost used to describe people with certain shared characteristics that score lower than average on a quantitative assessment tool to measure HL (e.g. Paasche-Orlow, 2005; Quenzel & Schaeffer, 2016; Sørensen et al., 2015).

[49] For example, in the current discussion around HL, having 'adequate HL' seems to be constructed as normality requirement for all people. In contrast, having 'low' HL represents the failure to meet this norm. However, recent population studies from Germany, found that more than half of the general population, i.e. 58.8%, have 'low' HL (Schaeffer et al., 2021). These results are consistent with many other studies around the world (e.g. Sørensen et al., 2015; HLS19 Consortium, 2021; Kutcher et al., 2006; Berkmann et al., 2011; Paasche-Orlow et al., 2005), indicating that having 'adequate HL' isn't the 'norm' at all.

In the case of HL, assessment categories such as 'low', 'sufficient', and 'excellent' force normative attribution patterns that divide people into ‘health literate’ and ‘illiterate’, ‘competent’ and ‘incompetent’.[50] Creating such categorisations, particularly in the research context, should not be rejected per se, as they help to identify people who need special support in accessing and processing health information but it should at least be critically reflected regarding the consequences that this rather deficit-oriented view on HL – a still primarily cognitivist concept – may have for those labelled as ‘vulnerable’ or being ‘at risk’ for so-called *HL limitations.*

On the other hand, ignoring detected HL deficits, would suggest a misconceived notion of solidarity with weaker and underprivileged individuals and groups (Bittlingmayer et al, 2020, p. 128) as deficits that manifest themselves, for example, in the spectrum of individual or family resources for action – along income, educational resources, literacy and health skills – should be made clearly visible to enable decision makers to respond adequately (Bittlingmayer et al., 2020).

However, it should be kept in mind that, when it comes to research on sensitive, potentially stereotype-reproducing topics (such as HL, gender and migration), the way in which these phenomena are talked about is very powerful. Especially, when the focus is on *socially marginalised* or *minority groups*, who already experience disadvantages and are at risk of being stereotyped or even discriminated because of personal characteristics such as religious beliefs, region of origin, gender, or others (Matheson et al., 2019).

Our understanding of vulnerability influences how we oversee and categorise individuals, rationalise government involvement in citizens' lives, distribution of resources in society, and how social responsibilities are defined (Brown, 2011). Thus, it is important to reflect the potential influence that classifying people along certain HL levels may have on the social positioning of those who are categorised as ‘limited health literate’ and thus labelled as ‘vulnerable’ in this regard. Under certain circumstances, such categorisation can even foster stigmatisation and exclusion (Brown, 2011; Gilodi et al., 2022) of people with certain personal characteristics or combinations of characteristics (e.g. a migrant woman of Islamic faith with low language proficiency). Thus, it may even increase the feeling of otherness among people with different cultural, religious, or philosophical beliefs than those anchored in our Western worldview, instead of reducing it as intended – particularly, when external circumstances making people vulnerable to ‘low’ HL (as attested in large quantitative surveys) are not adequately communicated and consequently addressed, as argued above.

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[50] The German translation of HL (‘Gesundheitskompetenz’, i.e., ‘health competence’) approaches the concept of *competence*. The term suggests, at least semantically, that HL is a matter of personal competence.

This PhD project's aims were also based on the assumption that migration is a *risk factor* for problems related to health information seeking and accessing, its understanding and appraisal, and ultimately its application – in the receiving country. This was, and still is, reasonable given the many studies indicating an association between lower HL scores and migration (see 1 Introduction). However, from recent population studies on subjective HL conducted in 15 European countries, we know that it is far from true for *all* migrants, or their descendants. In these studies persons with a migrant background did not perceive that they have more difficulties in health information processing than the respective majority populations (Berens, Klinger, Mensing, et al., 2022; HLS19 Consortium, 2021). Again, this highlights that 'low' HL is multifactorial and that having a migrant background is unlikely to be the sole reason for HL differences between these groups and the majority population.

To sum up, more research is necessary to understand the mechanisms linking HL to the broader realm of health inequalities combining the results of qualitative *and* quantitative studies that adopt a consequent *resource-oriented approach* to HL (Bittlingmayer et al., 2020) *without* neglecting the fact that migrants and people falling into other deprived socio-demographic categories (e.g. socio-economically disadvantaged people) tend to score lower in quantitative HL surveys (e.g. Berkman et al, 2011) and that they tend to report more difficulties in health information processing than the majority population (e.g. Sørensen et al., 2015). This might also help to improve the effectiveness of future HL interventions for migrants (see 4.4.2 Implications for).

4.3 Methodological Implications

4.3.1 Producing Cochrane reviews on health literacy, migration, and gender

In this dissertation, two Cochrane reviews were either directly (study III) or indirectly (QES, Aldin et al., in press) included. Along with the principles of EBM (Sackett et al., 1996), Cochrane has traditionally focused on systematic reviews of RCTs. However, in the past years the scope has been expanded to incorporate various kinds of evidence rather than insisting on RCTs only. Today, study designs other than classic RCTs and its variants (Higgins et al., 2023) such as non-randomised studies are also permitted in Cochrane reviews (e.g. when insufficient RCTs are available) (Reeves et al., 2023). The move toward including non-RCTs and implementing ‘less formal’ methods such as rapid reviews is in line with the evolving understanding of EBM and the desire to provide evidence-based information more rapidly and flexible, but less formal and rigid to decision-makers, particularly in fast changing environments (e.g. at times of the COVID-19 pandemic) (Greenhalgh et al., 2022; Pfaff & Schmitt, 2021, 2023). The movement of EBM+ explicitly encourages the consideration of various study designs such as pragmatic trials or observational studies in order to better understand how interventions might work in real-world scenarios and particularly in situations where RCTs are either impractical or unethical; i.e. “where rapid decision-making is needed to save lives and protect health” (Greenhalgh et al., 2022, p. 253).[51] Pfaff and Schmidt (2023) prognose the ‘classic’ EBM approach to move more and more from formalised to less formalised describing the evolving paradigm shift as “‘the organic turn’ in evidence-based medicine” (Pfaff & Schmitt, 2021, 2023).

With these considerations in mind, it could be argued that in cases where interventions are complex, multifaceted, or involve dynamic interactions such as in HL interventions for migrants, relying solely on (variants of) RCTs may neither capture the full spectrum of effects nor counteract potential implementation issues (e.g. recruitment of so-called ‘hard-to-reach’ groups). As there is currently a very limited number of RCTs aimed directly at improving HL in migrants, this approach could increase the chances of finding intervention studies based on proper HL theories and models, and thus improve theory building in HL research. In addition, it may help to improve the meaningfulness of review results (in this specific research context) for decision-makers and may foster the deeper examination of HL intervention components working in the context of migration.

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[51] Cochrane, for example, produced a range of rapid reviews and living systematic reviews related to COVID-19 in order to keep evidence bases up-to-date and provide evidence rapidly to decision-makers around the world (e.g. Ceravolo et al., 2020; Boutron et al., 2020; https://covid-nma.com/).

However, including other study designs than (variants of) RCTs would further increase the huge heterogeneity of studies in this field as described in the following sections. Thus, if also non-randomised studies are planned to be included in future reviews on HL interventions for migrants, it would become all the more important to keep the focus more narrowly to the concept of HL and the settings in which it unfolds its impact to adequately account for the heterogeneity present in this research field.

In the following, I elaborate on the challenges we encountered in the process of producing Cochrane reviews on the phenomena of interest, thereby reflecting on the methodological implications for future reviews.

Managing heterogeneity

Due to the historical development of the initially narrowly defined concept of HL, interventions to promote HL are correspondingly manifold. In order to filter out those interventions relevant to us, we systematically subordinated all potentially eligible studies to the umbrella framework of HL (Sørensen et al., 2012). Because of HL's proximity to other social-cognitive constructs (e.g. shared decision-making[52]), its empirical correlation with health behaviours (e.g. Berkman et al. 2011; Sørensen et al., 2015; HLS-19 Consortium, 2021), and thus, the frequent application of theories and models aiming to explain health behaviour that inform the intervention development, makes these interventions not always clearly distinguishable from other programmes focusing primarily on modelling behaviour change.

(1) Screening and selecting studies

During the screening process we were confronted with a huge number of heterogenous studies leading to the decision that the terms *health literacy* or *literacy* had to be explicitly referenced at full-text stage to prevent conceptual fraying. Consequently, studies considered for inclusion needed to be specifically designed to improve HL or to address the effects of lower literacy in the realm of health. The intention to consider at least literacy-related aspects had to be evident. In doing so, we accepted that we were excluding potentially relevant studies that evaluated interventions very similar to those actually included but failed to explicitly report that they considered (health) literacy aspects or aimed to improve HL (for details, see Baumeister et al. 2023; section 'Discussion').

For the preparation of future reviews on HL in the context of migration, it seems advisable to go even further and keep a narrow focus on HL as a concept including only studies that

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[52] Shared decision-making describes a process in which patients come to a decision about diagnostic measures, treatment strategies, or other medical (support) services together with the HCP on the basis of evidence-based information and under consideration of their personal situation, preferences, and attitudes (Elwyn et al., 2010).

explicitly aim to improve HL, apply a HL theory, or model to develop the intervention and measure it at least baseline and/or as an outcome. In this regard, it could help to also include other study designs such as non-randomised trials as argued previously and to consequently manage the heterogeneity with more sophisticated methods such as a rigorous study-grouping-approach:

(2) Three-step grouping approach

To manage the huge heterogeneity of the studies we developed a three-step approach to group the studies according to 1) the main intervention components, 2) the intervention complexity, and the 3) comparators (see Study III: Interventions for improving health literacy in migrants; section 'Methods'). This approach enabled us to conduct meta-analyses for at least some outcomes and to report others in a narrative synthesis. To further enhance the understanding of this review's results, all findings reported in text and tables were presented along the grouped categories resulting in nine comparison groups.[53] However, the approach is limited in so far as the judgements regarding the similarity of interventions and comparators depended on our subjective interpretation of what HL constitutes and to what extent certain intervention features such as group education or audio-/visual formats affect the results of the predefined outcome categories. In addition, it depended on the details of information reported in the trial, which was often considerably poor (Baumeister et al., 2023).

Nevertheless, future reviews concerned with such 'complex' interventions may benefit from this review's applied three-step-approach to identify studies similar enough to be synthesised either in a meta-analysis or in a narrative synthesis. We developed clear grouping criteria based on the studies identified and the groups remained stable after our update search in February 2022, indicating that this method is reliable, replicable and may be applied to other review types, too.

(3) The variety of outcomes, outcome measures and assessment time points

One other challenge that impeded statistical pooling of results concerned the variety of outcomes and outcome measures as well as the various time points at which these outcomes were assessed. HL is context- and situation-specific. It is expressed in many different ways and the majority of quantitative measurement tools that are currently in use won't be able to depict the construct with all its facets. In other words, assessing the individual HL of

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[53] Interventions and comparators were divided in eight comparison groups. Female and male migrants' benefit of any HL intervention was presented as the ninth comparison group in order to present these findings related to the review's second research question separately from the other findings.

migrants comprehensively or the HL improvements made through an intervention, respectively, needs an equally comprehensive approach (e.g. the combination of performance and self-assessment tools).

We anticipated this variety and pre-defined overarching outcome *categories* instead of single outcome measures at protocol stage: 1) HL (including knowledge, motivation, competences, and access, understand, appraise, and apply health information), 2) quality of life, 3) health outcomes, 4) health behaviour, 5) health service use; 6) individual skills, and 7) adverse events. In addition, we pre-defined categories reflecting different assessment time points in short-term, medium-term, and long-term based on the recommendations of the Cochrane Handbook (Higgins et al., 2023). In contrast to the protocol, the outcome category 'individual skills' was later renamed to 'self-efficacy' as we identified various outcome measures reflecting different forms of self-efficacy (e.g. self-efficacy to manage one's disease (again assessed with multiple measures) or self-efficacy to identify a disease, etc.). In addition, self-efficacy has been associated with HL in various studies (e.g. Berens et al., 2021; Chen et al., 2020; E.-H. Lee et al., 2016; Xu et al., 2018). Thus, the decision improved clarity in reporting the review's results.

For future reviews, it seems advisable to pre-assess, if possible, at least some intervention studies that may fulfil the inclusion criteria to be as clearly as possible about the outcomes, or in the case of very complex reviews such as the one presented in this dissertation, the outcome categories one is expecting to be confronted with. This presupposes that reviewers are already very familiar with the HL concept and can transfer the findings to the specific research question. In addition, other reviews in the broader field of research (e.g. on HL in persons with chronic diseases) could be consulted in advance or a pilot search could be carried out (if sufficient studies are expected to be identified).

Some of the authors of the effectiveness review contributing to this dissertation, including the first author, already had relevant experience with the HL concept prior to conducting the review. For this reason, we were able to anticipate the large number of outcomes and accordingly worked with predefined outcome categories.

(4) Pooling results in meta-analyses

We pooled results whenever we judged studies similar enough to be synthesised together (i.e. when at least two studies in a comparison measured the same outcome in a comparable way). Nevertheless, despite strict grouping and careful post hoc subgroup analyses (e.g. by specific design features such as length of the programme) as well as sensitivity analyses excluding studies at high risk of bias, statistical heterogeneity remained high, sometimes considerably limiting the extent to which firm conclusions could be drawn. The reasons for this finding are discussed in detail in the published review, but to name the most important ones: 1) the analyses often contained studies with small sample sizes. Sometimes only two studies with less or slightly over 100 participants contributed to one analysis, 2) many of the studies were poorly reported leading to the calculation of missing values which, in turn, reduced comparability of standard deviations, and 3) in the absence of standardised measures for HL and HL-related outcomes, we did not restrict the analysis to validated assessment tools. Thus, the applied outcome measures differed tremendously. The latter resulted in either the post hoc standardisation of measurement tools or the calculation of standardised mean differences (SMD) to enable pooling. For example, disease-specific knowledge measures referred to the respective context applied but also differed in the scales used. Thus, we standardised them on a scale ranging from zero to 100. In addition, rules of thumb were used to calculate SMDs (Higgins et al., 2023) which was, however, not possible for all outcome measures. For example, when they were used by one study only or when we were not able to obtain a 'minimally important difference' for the respective measure. In these cases, the judgement of whether the effect was important or not remained subjective, limiting the interpretation of results and leading to downgrading our certainty in the evidence.

Grouping the studies and pooling their results was the most challenging part of the review. Therefore, I decided later in the process to consult an experienced statistician to seek advice for and discuss the most challenging analyses as well as to reassure that the calculations done were correct.

As a concluding remark, it is not better to say than with the words of Deeks et al. (2023): "**Do not start here!**" (Deeks et al., 2023, para 1). Synthesising evidence from heterogenous studies that use a variety of outcome measures is challenging, whether the syntheses is narrative only, a meta-analysis, or both. Thus, it seems indispensable to properly prepare the data one is confronted with as the results of meta-analyses can be highly misleading when review authors do not pay suitable attention to the steps necessary before synthesising the results (Deeks et al., 2023). The strict grouping procedure developed for and applied in the effectiveness review was key to master the amount of different data.

Linking an effectiveness review to a QES

When we started preparing the protocols to both the effectiveness review (Baumeister et al., 2019) and the QES (Aldin et al., 2019), we were among the firsts to conduct two linked Cochrane reviews in parallel. QES are still quite new to Cochrane and standardised methods to conduct this kind of reviews were missing, although there were some QES published in the Cochrane library to rely on.[54]

The challenges we encountered in the process of conducting the QES are out of the scope of this dissertation. However, as the QES is linked to the effectiveness review, it is worth to shortly elaborate on the circumstances leading to the methodological differences between the protocol and the final review. At the time of the effectiveness review's publication, the QES was not fully completed. Therefore, the integration of both reviews' findings will be published in the QES only. In addition, the planned logic model of how HL interventions might work was not developed since the results of both reviews were of too much uncertainty and heterogeneity as that we could have derived a valid model from it. In addition, only one study included in the effectiveness review applied a HL promotion theory.

Future authors of HL intervention reviews would be well advised to consult the relevant Cochrane group at an early stage, in order to benefit from those who have experience of this type of complex review and who can help the authors to find solutions that they may not have come up with themselves, or only with great difficulty and delay.

Managing the gender data gap

Missing data was also a major challenge in both the effectiveness review and the linked QES – primarily, but not exclusively, with regard to gender. Therefore, we contacted (at least) the first author of every study with missing data. All authors were contacted at least twice with mediocre success. In total, authors of three studies provided additional gender-segregated data. Although we already anticipated that we would find only a few, if any, studies publishing gender-separate effect measures, the yield was still disappointing. However, as the findings from our FGDs as well as those of the QES suggest the "Absence of Evidence [in the effectiveness review] is not Evidence of Absence" (Carl Sagan, cited by Feres & Feres, 2023, 1); in *some* migrant communities, there seem to be long established gender roles, intra-societal and intra-familial power relations that do affect how health information in host countries is accessed, understood, appraised, and applied, indicating that these factors should be taken into account when developing, implementing, and evaluating

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[54] In 2023, the first version of the Cochrane-Campbell Handbook for Qualitative Evidence Synthesis has been published online (https://training.cochrane.org/cochrane-campbell-handbook-qualitative-evidence-synthesis). The first printed edition will be published in 2024 via Wiley.

future HL interventions. Unfortunately, we were not able to investigate the role of gender in detail (particularly in relation to different migrant groups). Instead, we highlighted some specifics that may concern migrants, especially those from Arab cultures. Future research could build on these findings to thoroughly explore gender-specific aspects of HL in the context of migration, including different stakeholders reflecting various migrant communities, for example with the use of qualitative methods.[55]

In terms of quantitative research, it would be helpful to encourage researchers to publish gender-separate scores of intervention effects – may they be of statistical significance or not. The third systematic review conducted by the GLIM team, for example, revealed that a proper meta-analysis can well produce results that provide indications of gender-aspects in relation to HL on which future research can build on (Chakraverty et al., 2022). However, this requires as much gender-segregated data from as many studies as possible. Referencing to Caroline Criado-Perez' (2020) book *Invisible Women*, which is concerned with the consequences of the *gender data gap*, Chakraverty (2022) argues in his doctoral thesis that applying the gender lens to existing data when re-analysing these may often reveal "serious disadvantages for women" (p. 52). Thus, it is of major importance to improve data provision and establish a culture of open science improving the exchange of knowledge and data as proposed, for example, in the Horizon Europe Programme 2024[56]. Chakraverty (2022) also proposes to publish research data in publicly available repositories, which would be helpful to improve data availability for future review authors.

4.3.2 Researching health literacy in persons with a migrant background

In the FGDs, we distanced from the German category 'person with a migration background' as it entails German citizens whose ancestors immigrated up to three generations ago with a focus on inherited citizenship and ancestry rather than the migration experience (Will, 2019). Instead, we used the definition of the European Commission defining persons with a migrant background as either first- or second-generation migrants (European Commission, 2019). The results of the FGDs, however, showed that it is necessary for future research on HL in female and male migrants to also differentiate between first-, and second-generation migrants as the HCPs repeatedly emphasised that they do not see major differences regarding HL in persons whose parents or even grandparents migrated decades ago.

Furthermore, it is important to stress again the huge heterogeneity of migrant populations (see 1.2 Migration). It may be viewed as a limitation that our research was concerned with

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[55] We would have included all genders in both reviews but did not find any study addressing gender beyond the man-woman dichotomy.

[56] https://www.horizont-europa.de/de/Open-Science-und-Open-Data-1767.html

migrants and persons with a migrant background in general rather than focussing on certain migrant groups. However, we assumed that HL-related challenges are caused, in particular, by migration-specific factors associated with a migration experience (e.g. language barriers, navigation of an unfamiliar health care system and, depending on the country of origin, major cultural differences regarding health beliefs and communication of health issues) which is still reasonable, as our findings showed. Nevertheless, it can be argued that we would have received more specific results when we would have focused on certain migrant groups. Future research in this context should pre-assess whether it is more appropriate to focus on specific migrant groups, e.g. a region of origin, shared language, or religion, and thus to take a closer look at different socio-demographic factors associated with HL or to apply a broader approach and focus on the migration experience in general. At the end, this is always *also* a matter of financial and human resources.

The advantage of focusing on the context of migration in general enabled us to provide a broader picture of how personal, situational, and systemic factors influence accessing, understanding, appraising, and applying of health information in transcultural healthcare interactions. In addition, we were able to identify types of HL interventions that may work for migrants in general (but which are culturally and linguistically adapted to the particular community). Accordingly, the two Cochrane reviews, together with the results of the FGDs, provide a solid basis for future research that may look in more detail at the aspects of HL that are relevant to specific migrant groups in specific life situations

4.4 Implications for Practice

The implications for practice arising from the results of this cumulative dissertation are manifold and raise questions that may not be resolved in the short-term. In contrast to the other sections on the implications of this dissertation, I will briefly discuss the main implications for clinical practice based on the key findings in relation to the FGDs (studies I+II) and the Cochrane reviews (study III and QES).

4.4.1 Implications for healthcare

Although a problem well known, the systemic lack of time and economic pressure emerged as a pervasive issue in transcultural healthcare settings, particularly affecting HCPs who are working in physical care. The findings presented in this dissertation underscore the urgency and brevity of patient interactions, with HCPs facing additional stress when dealing with individuals with limited language proficiency, health system knowledge, or low literacy skills. The German remuneration system based on lump-sum-fees was cited as one reason for the economic pressure, suggesting that it is time to develop and evaluate new, innovative remuneration models for the clinical practice. Furthermore, the distinction in the perceived impact of time pressure between medical and psychiatric professions, but also between nurses and physicians, emphasises the necessity of tailoring *system-based* interventions to specific treatment settings.

The demonstrated impact of time pressure on both the provision and processing of health information in transcultural treatment settings also highlights the need for HCPs to be aware of potential heuristic shortcuts and stereotypes that may be used in stressful situations and inadvertently perpetuate subtle racism. This finding calls for training and awareness programmes to promote culturally competent and sensitive healthcare practices.

A shared migrant background showed to be conducive in building trustful relationships. However, the findings of the FGDs also acknowledge the complexity of this dynamic, with a shared language sometimes presenting further challenges and stress for HCPs. The findings stressed a particular need for improved access to professional interpreters and cultural mediators, e.g. by video or telephone remote interpreting services. Implemented on a nationwide scale, these measures could present a viable, cost-, and time-efficient solution for overcoming language *and* cultural barriers and mitigate the risks associated with informal interpreting of poor quality (Fiedler et al., 2022; Ji et al., 2021). Although major issues of the German health system won’t be resolved by this means, it might help to improve communication between HCPs and migrant patients, relieving lay interpreters from the responsibility to interpret correctly and help international migrants to navigate Germany’s complex health system.

To sum up, the findings of this cumulative dissertation indicate that HCPs play a significant role in achieving the goals of ‘good’ organisational HL, which, like individual HL, is significantly influenced by how system-related challenges are shaped and how organisations are capable to meet them. Thus, it seems crucial to place more emphasis on establishing *health literate systems* as these “can act as catalyst for health literacy as an asset and critical source of empowerment” (Sørensen et al., 2021, p. i16). In this regard, it is inevitable to shift the focus of HL research and practice to political decision-makers and their responsibilities to create appropriate conditions for healthcare organisations and HCPs to be equipped and able to respond adequately to the diverse needs of *all* people interacting within the system, namely individuals from the general population, HCPs, and healthcare organisations themselves.

4.4.2 Implications for health literacy interventions for migrants

The Cochrane effectiveness review offered insights into the impact of HL interventions for migrants. Nevertheless, it is to expect that more intervention studies are to be published in the future as the body of evidence regarding HL is continuously rising with many studies still ongoing (see Baumeister et al., 2023; section ‘Included studies’).

The implications following the effectiveness review are rather unspecific due to the heterogeneity of studies encountered. In general, it indicates that interventions should be situated in context, culturally tailored and adapted to literacy skills and language proficiency. In addition, it has been shown that several intervention types such as self-management programmes, HL skill building courses, audio-/visual education or telephone education show promise in improving HL and -related outcomes.

We did not include studies solely addressing the HL environment (e.g. HL tool kits for health systems (e.g. Dodson et al., 2015) or healthcare organisations (e.g. Lloyd et al., 2019). We would, however, have included studies that measure the effect of such interventions in migrants’ ability to access, understand, appraise, or apply health information. Unfortunately, we did not find any study directly targeted to the HL environment indicating that there is a considerable lack of research in this regard and, in turn, plenty of unexplored potential to improve HL in the context of migration.

There are several ways to either directly or indirectly address these system-related barriers in future HL interventions. Directly, for instance, through cultural competency training for

HCPs or the implementation and evaluation of either face-to-face or technology-based interpreting services such as video-interpreters, and indirectly through practicing of administrative tasks in health systems (e.g. completing forms, scheduling appointments, providing guidance on insurance policies) or improvement of health-related language skills by incorporating HL-related elements in established language courses.

Migrants who are more proficient in their native language may better comprehend health-related information when it is presented in their mother tongue (Baumeister et al., 2023). Thus, designing HL interventions in a migrant's native language can more effectively capture the nuances of their culture, beliefs, and health practices, transferring these into the cultural context of the receiving country. Adapting HL interventions culturally and linguistically may be particularly crucial for the successful implementation of HL interventions tailored for migrants. It may enhance the overall intervention experience, improve learning outcomes, and provide more accurate assessments of participants' HL levels (Baumeister et al., 2023). All interventions included in the effectiveness review were adapted to the participants language and literacy skills, and almost all were delivered by lay health educators or community health workers, some of whom were also involved in designing and evaluating the intervention. The advantages of designing interventions concordant to the participants' literacy level using, for example, simple language, pictograms, or illustrations as a substitute to written information, are apparent and have been shown to be effective in various populations apart from migrants (Sheridan et al., 2011).

In contrast, a significant contributor to research inefficiency is the lack of alignment between the goals of researchers and the needs of “end-users” (Ioannidis, 2016; Slattery et al., 2020). Collaborative research designs (understood as an umbrella term for participatory research methods such as community-based participatory research (CBPR), action research, patient/consumer involvement, stakeholder/patient engagement, or others) (Slattery et al., 2020) aim to counteract this misalignment by involving the research's end-user to varying degrees in the research process; from beginning to end, in several stages of the process, or for the matter of (formative) evaluation. In a rapid review of existing systematic reviews on research co-designs in health, Slattery et al. (2020) define the *study planning phase* as crucial because decisions made in this phase will influence all following research processes. Accordingly, the first stage of developing a HL intervention for female and/or male migrants is particularly susceptible to either pave the way for actual participation and thus the greatest possible benefit of the intervention for those concerned, or, in contrast, to early errors that can later have a negative impact on the overall effectiveness, clinical relevance, and potential benefit for them. Thus, proper involvement of both female and male members of the respective community or other relevant stakeholders (if it is a gender-specific context, e.g. cervical cancer, possibly only female migrants or persons with a uterus, respectively) is crucial. At this stage, they should be involved on par with the researchers in defining the research question and the outcomes of interest, in planning the intervention components, the delivery mode, and methods, including considerations of who should deliver the intervention and collect participant data.

Several ways of involving women and men with a migrant background in the research process might be fruitful. Figure 5 shows an overview of the most important aspects derived from the studies contributing to this dissertation, including the QES.[57]

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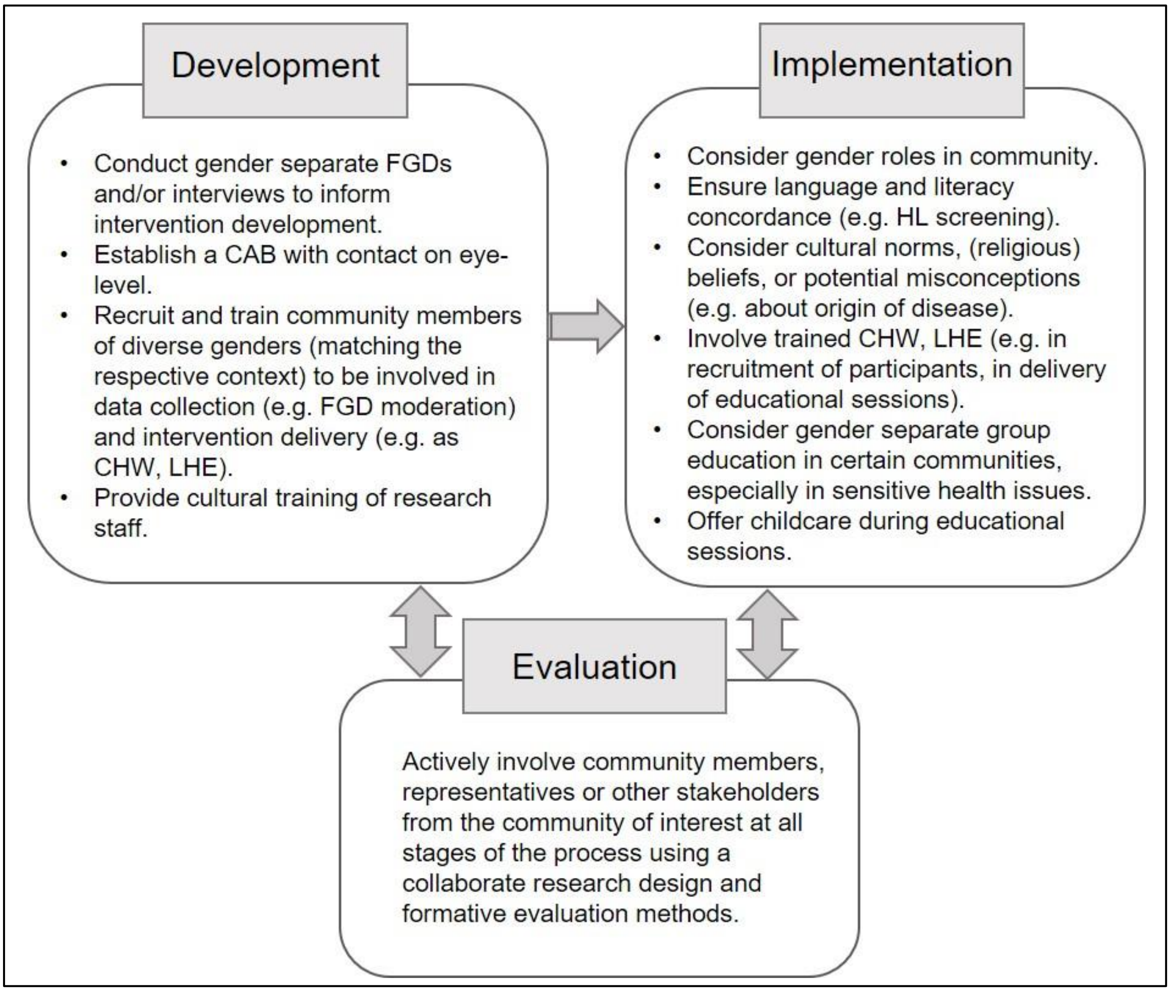
[57] Some of these aspects are also discussed in the QES (Aldin et al., in press). These are referenced throughout the text, if applicable.

Figure 5

Implications for gender-sensitive HL interventions in migrants



- Conduct gender separate FGDs and/or interviews to inform intervention development.
- Establish a CAB with contact on eye-level.
- Recruit and train community members of diverse genders (matching the respective context) to be involved in data collection (e.g. FGD moderation) and intervention delivery (e.g. as CHW, LHE).
- Provide cultural training of research staff.

- Consider gender roles in community.
- Ensure language and literacy concordance (e.g. HL screening).
- Consider cultural norms, (religious) beliefs, or potential misconceptions (e.g. about origin of disease).
- Involve trained CHW, LHE (e.g. in recruitment of participants, in delivery of educational sessions).
- Consider gender separate group education in certain communities, especially in sensitive health issues.
- Offer childcare during educational sessions.

Actively involve community members, representatives or other stakeholders from the community of interest at all stages of the process using a collaborate research design and formative evaluation methods.

Note. CAB: Community Advisory Board; CHW: Community Health Worker; LHE: Ley Health Worker.

(1) *Conducting gender-separate FGDs or interviews to inform the intervention development* (Aldin et al., in press). Questions may include inter alia: What do people concerned (i.e. end-users; Slattery et al., 2020) think they need with regard to HL interventions? Which outcome would they wish to achieve (on an individual level but also on a system-level)? What do they think how the intervention could best be designed and implemented? Are there gender-related particularities that they, as representatives of a certain community, think should be taken into account?

Although associated with the investment of substantial time, financial, and human resources, which are likely to be underestimated in new research partnerships (Newman et al., 2011), (2) *establishing a community advisory board (CAB)* is a common strategy to actively engage community members in research processes (Yuan et al., 2020). CABs often are an integral part of CBPR-projects as they are considered a useful tool in implementing collaborative research in underserved populations (Yuan et al., 2020.). Ideally, CABs should include different stakeholders representing the respective community (Israel et al., 1994). This could encompass, but is not limited to, individuals directly concerned, their representatives, and HCPs to guide and inform the development, evaluation, and implementation of HL interventions (Aldin et al., in press). They may provide advice on how to adapt the intervention to the stakeholders' needs and to ensure that the interests of female and male migrants are considered. Emphasis should be placed on establishing *mutually* satisfactory and beneficial partnerships between researchers and communities (Newman et al., 2011) to improve CABs' effectiveness (e.g. Israel et al., 1998; Quinn, 2004) and avoid frustration on both sides.

Establishing a community advisory board may substitute other even more engaging measures, such as (3) *targeted recruitment and training of community members with diverse genders* (according to the respective context as described above (1)) to encourage them in taking an active part in planning the study design, in participant recruitment and data collection, intervention delivery, interpretation/contextualisation and dissemination of results.

In order to pursue the aim of research co-design on eye-level, (4*) cultural training of the research staff* (Aldin et al., in press) should be an integral part of intervention development and evaluation. Culturally sensitive research staff may better be able to communicate with relevant stakeholders, tailor the intervention to the lived experiences of those who are supposed to benefit from the respective intervention (e.g. regarding relevant religious or spiritual practices, or cultural norms including gender roles), and to understand and avoid potential pitfalls in the research process.

Gender roles are powerful and persist in several communities all over the world. The studies contributing to this cumulative dissertation (including the QES; Aldin et al., in press) showed that gender roles also affect how health information and services are accessed and processed. They have shown to influence mutual understanding in transcultural treatment situations, particularly regarding how shared information is understood and appraised (Chakraverty et al., 2020; Aldin et al., in press). The QES further found that gender roles influence how and to whom health issues are communicated and that, in some communities, women tended to prioritise their families' well-being over their own as a result of patriarchal family structures and tied roles to men and women in the community. Thus, it seems essential to consider potential gender roles and other cultural norms and religious or spiritual health-related beliefs in the respective community of interest in future intervention development and evaluation. In a practical way, this could mean that (5) *consideration should* *be given on delivering the intervention in gender-separate groups, when cultural particularities necessitate this.* When women are targeted, it may be useful to offer childcare during intervention sessions and to determine beforehand, e.g. with the help of the CAB members, when and where the intervention should ideally take place in order to affect the women's everyday lives as little as possible.[58]

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[58] One lighthouse project should be mentioned at this point: the collaborative community research project on culture- and diversity-sensitive online health information conducted by Geldermann et al. (2023). The project consequently applied a collaborative research design involving members of the community from the first to the last phase of the project as equal partners who, after training, acted as interviewers and thus data collectors resulting in the production of culture- and diversity-sensitive educational videos on various health topics reflecting the real living reality of the community.

4.5 General Limitations and Strengths

This cumulative dissertation has its limitations, some of which are closely related to the challenges we encountered in the research process described in detail above. However, it also has considerable strengths; I will take a stand on the key issues below. Further strengths and limitations were published in the respective contributions (Baumeister et al., 2019; Baumeister et al., 2021; Baumeister et al., 2023; Chakraverty et al., 2020) and were briefly summarised in 3 Synopsis of Study Results. These will not be taken up again here to avoid repetition. The section is divided into two parts: (1) general reflexivity of this project's aims and the results' novelty, and (2) general methodological limitations and strengths of the cumulative dissertation.

General reflexivity of this project's aims, methods, results, and novelty of findings

It was more than half a decade ago when I started planning this cumulative dissertation and the overarching GLIM-project was approved by the German Federal Ministry of Health and Education. Starting point of GLIM were the results of large international population studies (e.g. Schaeffer et al., 2016; Sørensen et al., 2015) that consistently attested persons with a migrant background to have 'lower' levels of HL than the majority population, i.e., they have been – and still are – commonly described as being vulnerable to low HL (e.g. Poza-Méndez et al., 2022; Quenzel & Schaeffer, 2016; Ruedin et al., 2022). As migration is an inherently gendered phenomenon (see 1.3 Gender as determinant of migrants' health literacy), it was reasonable to assume that HL, especially in the context of migration, has gender-specific aspects that need to be investigated more in-depth (i.e. with the use of qualitative methods). Thus, we decided to use a mixed-methods approach conducting 1) primary qualitative research on the HL of women and men with a migrant background living in Germany and 2) secondary research in form of three systematic reviews that synthesised either quantitative HL studies with the use of established statistical (Cochrane) methods (e.g. Higgins et al., 2023) or qualitative studies using Cochrane's recommended methods for QES (Noyes et al., 2023).

To the best of my knowledge, there is only one systematic review on HL in disadvantaged populations (including also but not exclusively migrants) that used sophisticated methods such as meta-analysis or GRADE (Stormacq et al., 2020). However, only three of the 34 studies included in the effectiveness review have been included in the review contributing to this dissertation, too. Furthermore, we linked the effectiveness review to a QES, which is also expected to be published in the Cochrane library (Aldin et al., in press). In addition, the reviews have been linked through the common framework for analysis: the integrated model of HL (Sørensen et al., 2012).

Applying the currently most comprehensive conceptual HL model (Sørensen et al., 2012) promised a fruitful basis to explore HL in women and men with a migrant background and to analyse the effectiveness of interventions for improving HL in migrants regarding each component of (individual) HL as understood by Sørensen et al. (2012). A particular strength of this dissertation is that, to my knowledge, our studies have been the first that explicitly examined HL applying the integrated model of HL (Sørensen et al., 2012) as the common underlying analysis framework and investigated the single components as well as the role of personal, situational, environmental, and societal determinants on HL in the context of transcultural healthcare encounters and HL interventions designed for migrants; therein lies the novelty.

It is to admit that this cumulative dissertation could not address the three highly complex phenomena *HL, migration*, and *gender* with the necessary depth. As a result, some topics remained on the surface, literature could only be touched upon and theoretical reflections remained, to some extent, limited to current knowledge. However, many of the findings presented in this cumulative dissertation are new (e.g. the role of gender-specific aspects influencing HL in transcultural healthcare encounters, the identification of HL intervention types that show promise to improve HL in migrants, or the identification of research gaps in this context). These findings are important to improve the understanding of HL in migrants and persons with a migrant background, and to guide future HL interventions in this realm.

Other findings are well known (e.g. the systemic lack of time and economic pressure in the German health system or migration-specific communication barriers). Nevertheless, although known for decades, there has been no significant improvement in dealing with these challenges so far (Chakraverty et al., 2020). Thus, these issues need to be further investigated in order to develop effective solutions and thus, achieve a sustainable and equitable improvement in healthcare for people with a migrant background living in Germany.

General methodological limitations and strengths of the cumulative dissertation

Primary research with(out) primary key informants

Originally, funding was applied for one systematic review and two expert workshops with HCPs and stakeholders representing the migrant community (e.g. representatives of migrant self-help initiatives). In consultation with the funder, we decided to widen the research question and to conduct FGDs as a commonly used and appropriate mean to study potential interrelations of the phenomena of interest in a timely and practical manner (M. Schulz et al., 2012). In addition, we planned to conduct further gender-separate FGDs including female and male migrants from diverse cultural and linguistic backgrounds. However, this was not possible as additional funding has not been approved and we lacked financial and human resources[59] (Baumeister et al., 2023).

The fact that we could not interview migrants in their role as health consumers and examining their very own view on HL in healthcare encounters can be viewed as one of the main limitations of this dissertation. Even though more than 50 percent of the included HCPs had a migrant background themselves and their personal involvement was reflected in many statements, we were still only able to gain a limited impression of how HL is negotiated from the perspective of migrants and what role gender plays in their view for the successful "flow of information" (Baumeister et al., 2021) in healthcare settings.

However, the QES (Aldin et al., in press) particularly included studies examining the views and perspectives of female and male migrants who took part in interventions assessed in the effectiveness review. As many of these, yet unpublished, results underline the findings of our FGDs from the perspective of first-generation migrants, the limitation mentioned above seems less restrictive. In addition, healthcare encounters aren't a single-sided illumination, they rather are reciprocal and rely on the exchange of information, most of which is very sensitive. Thus, from a methodological point of view, taking into account the HCP's perspective was necessary and valuable.

To sum up, the choice of methods to answer the prior determined research questions is justifiable and the particular combination of these can be viewed as a strength of this cumulative dissertation: it generated new knowledge that may be used to further investigate HL in different contexts.

Applying a gender lens to health literacy without studying all genders

Another limitation of this dissertation arises from the fact that we were not able to go beyond binary gender comparisons in any of the studies contributing to this dissertation. Two reasons led to the focus on women and men:

(1) Due to the persistent gender data gap in health research (e.g. Day et al., 2020; Sebo et al., 2020), we assumed that there would be few studies providing disaggregated data for individuals who self-identify as women or men – and even less, if any, study that would have reported on gender differences beyond the man-woman dichotomy.

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[59] In order to thoroughly analyse HL from the perspective of people from different cultural and linguistic backgrounds, the FGD would have had to be conducted in the respective national language, which was not feasible with the resources at hand.

The results of the two systematic reviews (study III and QES)[60] proved us right as all of the included studies, if they dealt with gender in any way, examined gender roles of women and men.

(2) In the FGDs, we did not stimulate the discussion to be gender inclusive because we wanted to give the participants the possibility to develop the discussion as freely as possible along the given stimulus on HL, applied to healthcare interactions between HCPs and persons with a migrant background (M. Schulz et al., 2012). Some gender-specific aspects of HL were mentioned by the HCPs, all referred to women or men. In addition, other than cis-gender, heterosexual relationships were not mentioned by any of the participants. We also did not steer the discussion in this direction, though.

As a conclusive remark, the gender-specific aspects reported in study II and the QES as well as the very few gender differences found in study III are limited to women and men with a migrant background, who are presumably cis-gender and heterosexual.

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[60] This was also true for the third systematic review conducted a spart of the GLIM project (Chakraverty et al., 2022).

5 CONCLUSION

In conclusion, the research presented in this dissertation shed light on critical challenges within transcultural healthcare settings, emphasising the impact of systemic factors such as an omnipresent lack of time and economic pressure. These challenges, though recognised globally, become particularly exacerbated in the context of migration. The stress induced by these overarching issues was consistently reported by almost all HCPs who took part in our studies. Many of them reported to find themselves investing additional, unpaid time to adequately counsel patients facing language barriers, low health system knowledge, and/or limited literacy skills.

Effective communication is one of the key factors in addressing the challenges. It relies on both the HCP's and the patients' individual HL, on trust and trustfulness and on mutual understanding in the semantic, as well as cultural sense. However, systemic barriers, such as time constraints may lead to heuristic shortcuts, for example, the use of stereotypes by HCPs, which affect both patient's *and* HCP's satisfaction with transcultural healthcare interactions. The research presented in this cumulative dissertation emphasises the need for a more nuanced understanding of how personal, situational, and environmental factors influence the flow of health information in healthcare settings, but also in other health domains such as disease prevention or health promotion. A shared migrant background between HCPs and patients, for example, seems advantageous for building and maintaining trustful relationships but may also entail challenges for HCPs including perceived stress and high responsibility with regard to interpreting for others and providing treatment in the patient's native language.

Gender was found to indirectly influence HL in healthcare interactions by systemic issues and language barriers connected to gender-specific HL aspects. In addition, husbands in Turkish or Arab communities may sometimes act as gatekeepers, influencing women's access to health care, particularly in treatment situations with male doctors. Gender preferences in accessing HCPs of the same sex and concerns about nudity-related care situations contribute to further challenges. Improving funding of and access to professional interpreting services and cultural mediators seems crucial for overcoming these language and cultural barriers.

The findings of this dissertation highlighted that HCPs as “smallest executive unit of healthcare organisations” (Baumeister et al., 2021) are crucial in facilitating ‘good’ organizational HL and, in turn, the individual HL of their patients. However, healthcare organisations and HCPs can only act under the given systemic conditions and with the financial and human resources at hand. The existing deficits and challenges in this regard have been shown to significantly limit their ability to respond to the diverse HL-related needs of all of their patients. Establishing a health-literate health system (Sørensen et al., 2021) and recognising HL "as a system's performance indicator" (p. i20) necessitates shifting the focus of HL research and practice from individuals, healthcare providers, and organisations within the system to health systems and governments. This is essential for developing and implementing sustainable interventions to strengthen HL and to systematically and programmatically embed HL policies and strategies.

On the level of individual HL promotion, the effectiveness review found that some HL intervention types such as self-management programmes, HL skills building courses, or audio-/visual education without personal feedback show promise in improving HL (e.g. disease-specific knowledge or functional HL) and HL-related outcomes such as self-efficacy and some health behaviours. A considerable lack of research was found for gender, especially studies concerning migrant men are missing. Effects on potential adverse events or quality of life are also under-researched in this context. In addition, we found only limited results for long-term effects of HL interventions in migrants.

The integration of findings of the FGDs, the effectiveness review, and the QES provided a deeper look into the HL of persons with a migrant background. It also highlighted the challenges in integrating quantitative intervention effects with the participant's perspectives due to a lack of evaluation studies including migrants' view not only to develop and adapt but also to evaluate HL interventions. Despite the difficulties in obtaining qualitative evidence for all intervention types and gender-specific effects, the integration of both reviews may enrich the understanding of the complex landscape of HL interventions.

The Cochrane reviews underscored the multifaceted nature of HL interventions for migrants, highlighting the need to conduct more high-quality interventions that aim at improving HL in the context of migration, representing a diversity of health systems and migrant populations. Together, the reviews also emphasised the importance of including migrants' perspectives to improve the efficiency of HL interventions on the one hand and, most importantly, to tailor these to the very own needs as perceived by those concerned. Against the background of navigating the diverse terrain of migrant health, this comprehensive approach becomes pivotal for developing tailored interventions that align with the lived experiences of migrant women and men, ultimately fostering equitable healthcare, which is responsive to the manifold facets of individual HL needsH

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APPENDICES

Appendix 1: Scientific Contributions

Scientific contribution to study I (1st author): Annika Baumeister contributed as follows: Conceptualization of the study; recruitment of participants; implementation and moderation of the focus group discussions, data analysis with MaxQDA, interpretation and writing of the results; writing of the publication and coordination of the entire project. In addition, Ms. Baumeister presented the results of the project at international and national congresses in the form of lectures and posters. The co-authors of this publication provided particular support in the form of methodological expertise. Digo Chakraverty provided particular support in the implementation and data analysis.

Scientific contribution to study III (1st author): Annika Baumeister contributed as follows: Development, writing and publication of the protocol for the review (see further publications on the topic); screening of the results of the systematic literature search; study selection; development of a data extraction form; data extraction; quality assessment of the studies (risk of bias); statistical and narrative synthesis of the results; interpretation of the results; assessment of the confidence in the evidence (GRADE); interpretation and writing of the results; writing of the publication and coordination of the entire project. In addition, Ms. Baumeister presented the results of the project at international and national congresses in the form of lectures and posters. The co-authors of this publication provided support, in particular with methodological or clinical expertise.

A detailed description of the contributions to all studies included in this dissertation are presented in table 2.

Table 2.

Overview of the scientific contributions

	Study I	**Study II**	**Study III (Systematic Review)**	**Study III (Protocol)**
Study design	**Baumeister, A**.* Chakraverty, D.* Aldin, A.	Chakraverty, D.* **Baumeister, A.*** Aldin, A.	**Baumeister, A.** Aldin, A. Chakraverty, D.	**Baumeister, A.** Aldin, A. Chakraverty, D.
Data collection	**Baumeister, A.*** Chakraverty, D.* Aldin, A.	**Baumeister, A.*,** Chakraverty, D.* Aldin, A.	**Baumeister, A.** Aldin, A. Huebner, C. Chakraverty, D.	-
Data analysis	**Baumeister, A.** Chakraverty, D. Aldin, A.	Chakraverty, D. **Baumeister, A.** Aldin, A.,	**Baumeister, A.** Aldin, A Adams, A. Chakraverty, D.	-
Risk of Bias	-	-	**Baumeister, A.** Aldin, A.	-
Data Interpretation	**Baumeister, A.** Chakraverty, D. Aldin, A.	Chakraverty, D. **Baumeister, A.** Aldin, A.	**Baumeister, A.** Aldin, A. Chakraverty, D.	-
GRADE Assessment	-	-	**Baumeister, A.** Aldin, A.	-
Manuscript	**Baumeister, A.**	Chakraverty, D.	**Baumeister, A.**	**Baumeister, A.**
Manuscript revision	**Baumeister, A.** Chakraverty, D. Aldin, A. Seven, Ü. S. Skoetz, N. Kalbe, E. Woopen, C.	Chakraverty D. **Baumeister, A.** Aldin, A. Seven, Ü. Skoetz, N., Kalbe, E., Woopen, C.	**Baumeister, A.** Aldin, A. Chakraverty, D. Huebner, C. Adams, A. Monsef, I. Skoetz, N. Kalbe, E. Woopen, C.	**Baumeister, A.** Aldin, A. Chakraverty, D. Monsef, I. Jakob, T. Seven, Ü. S. Anapa, G. Kalbe, E. Skoetz, N. Woopen, C.

Note. More detailed information on the contributions can be found in the contributor statements of the respective studies. *These authors equally contributed to the corresponding part

Appendix 2: Original Publications

Appendix i: Study I (Focus group discussions)

Baumeister, A., Chakraverty, D., Aldin, A., Seven, Ü. S., Skoetz, N., Kalbe, E., & Woopen, C. (2021). "The system has to be health literate, too" - perspectives among healthcare professionals on health literacy in transcultural treatment settings. B*MC Health Services research*, *21*(1), 716. https://doi.org/10.1186/s12913-021-06614-x

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RESEARCH ARTICLE **Open Access**

"The system has to be health literate, too" - perspectives among healthcare professionals on health literacy in transcultural treatment settings

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Abstract

Background: Effective communication is a central aspect of organizational health literacy. Healthcare professionals are expected to ensure an effective and satisfactory flow of information and to support their patients in accessing, understanding, appraising, and applying health information. This qualitative study aimed to examine the health literacy-related challenges, needs, and applied solutions of healthcare professionals when engaging with persons with a migrant background. Based on the integrated model of health literacy (Sørensen et al., BMC Public Health 12:80, 2012), we focused on environmental, personal, and situational factors that shape health literacy in transcultural treatment settings.

Methods: We conducted five focus group discussions with healthcare professionals ($N = 31$) who are in regular contact with persons with a migrant background. Discussions were transcribed verbatim and analyzed using qualitative content analysis by applying a deductive–inductive categorization procedure. Deductive categories were derived from the integrated model of health literacy.

Results: Challenges included a mismatch in the provision and use of health services. Participants regarded easily accessible services and outreach counselling as helpful solutions. Further challenges were the migrant patients' distrust in healthcare professionals and the German healthcare system, the participants' uncertainty in dealing with patients' expectations and needs, and the patients' non-compliance with appointments. Environmental factors included systemic lack of time and economic pressure. Both were reported as impeding the flow of information in all treatment settings. Participants with a migrant background themselves ($n = 16$) regarded this personal factor as an opportunity that increased patients' trust in them. They also reported challenges such as high levels of responsibility felt when ad hoc interpreting for colleagues.

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Conclusions: Known issues observed in the delivery of healthcare for the majority population (i.e., systemic lack of time, economic pressure) appear to be intensified in the context of migration. An increasingly diverse patient clientele indicates a growing need for culture-sensitive, health-literate healthcare organizations. A corresponding diversity of the health workforce is desirable and should be strengthened by national finance and educational programs. Healthcare professionals who interpret for colleagues should be given the necessary time. Further studies are needed to develop appropriate interventions for improving health literacy at individual and organizational levels. Funding for interpreting services should be expanded.

Keywords: Organizational health literacy, Migration, Health communication, Ethnic concordance, Qualitative research

Background

In recent years, the steady increase in international migration has resulted in new discussions regarding the challenges and responsibilities for European host countries. These include, but are not limited to, ethical debates on humane and equitable living conditions, human rights and equal opportunities for newly arrived immigrants. It has also raised particular issues for health systems in responding fast to the growing healthcare needs of diverse immigrant populations.

Over the last two decades, the concept of health literacy has increasingly become the focus of health research and policy, including the development of various international initiatives and national action plans to improve health literacy at the individual and population levels [1]. Initially, health literacy was defined as a rather narrow, educational concept that linked literacy and numeracy skills to the abilities required to understand and use health-related information in the medical setting [2]. Over time, this gradually evolved into a multidimensional construct referring to a broadly defined set of individual (cognitive, motivational, and social) resources, skills, and abilities, which are closely interrelated with situational factors and environmental conditions, such as the requirements of the health system [3, 4]. According to the European Health Literacy Consortium *"Health literacy is linked to literacy and entails people's knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course."* [3] (p. 3). Based on this definition, the researchers derived the integrated model of health literacy, which emphasizes the social-relational character of health literacy by including the personal, societal, environmental, and situational factors that influence an individual's health literacy over the life course. Figure 1 presents a simplified version of the integrated model of health literacy.

Migration can thereby be understood as either a personal determinant of health literacy, i.e., having a migrant background or a situational factor, i.e., experiences of migration and being confronted with an unknown health system. Both are interrelated with societal, i.e., cultural and environmental aspects such as the health literacy responsiveness of the receiving country's health system. All these factors may influence how individuals acess information and how transcultural interactions in health systems are shaped.

European population studies on health literacy indicate that persons with a migrant background, i.e., those who either migrated themselves to another country or whose parents did so, have comparatively more difficulties in accessing, understanding and using health information than the general population [5–7]. In Germany, this was true for 71% of people with a migrant background, compared to 52.8% of the majority non-migrant population [8]. These studies align with other empirical findings, indicating that migrants and people from ethnic minorities are at high risk of low health literacy [9–12] as well as social and health-related inequalities [13–15].

Recent approaches in health literacy research and policy have been characterized by the development of more system-oriented strategies that particularly focus on the responsibility of health systems and healthcare organizations to develop, maintain and promote individual and population health literacy [16]. The promotion of organizational health literacy includes, in particular, the establishment of health-literate healthcare organizations. These should, among other factors, adequately respond to the individual needs of diverse populations with varying health literacy skills, avoid the stigmatization of such populations, promote successful interpersonal communication and ensure equitable access to reliable health information [17, 18].

Healthcare professionals represent the smallest executive unit of healthcare organizations. Many interact with persons with a migrant background on a regular basis. They work on the "focal point of health literacy" [19] (p. 3) as they are expected to ensure an effective and satisfactory flow of information and to support their migrant patients in finding, understanding, appraising, and applying the information exchanged. Thus, effective oral and written communication between healthcare professionals and healthcare consumers is one of the central aspects

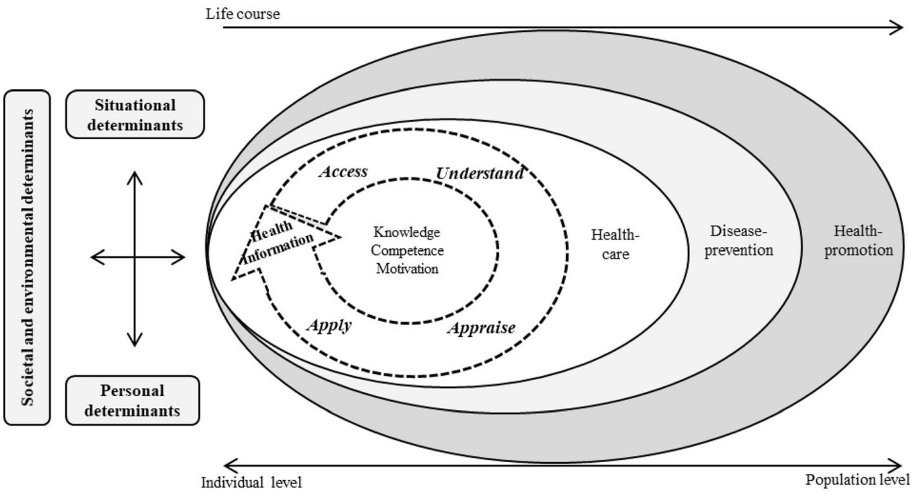

Fig. 1 Simplified version of the integrated model of health literacy. Adapted from the Sorensen et al. (2012) [3].

of organizational health literacy [20]. Both patients' health literacy limitations [21, 22] and limited language proficiency [20, 23] are common barriers to patient–provider communication. Some studies have explored the perceptions and views of migrants towards healthcare services including, for instance, satisfaction with healthcare professionals or the barriers and facilitators to healthcare services [24–26], and some have explored migrants' views on healthcare services in relation to health literacy [27]. However, there remains little evidence on the health literacy-related challenges, needs, and applied solutions in delivering healthcare for people from diverse cultural and linguistic backgrounds from the perspectives of healthcare professionals.

Aim

This qualitative study aimed to examine the health literacy-related challenges, needs, and applied solutions of healthcare professionals when engaging with their patients with a migrant background. Based on the integrated model of health literacy as our guiding analytic framework (see Fig. 1) [3], we examined the societal and environmental determinants, situational conditions, and personal factors, which may influence health literacy (i.e., access, understand, appraise, and apply health information) in transcultural treatment settings from the perspective of healthcare professionals in Germany.

Methods

The present study is part of an overarching project of Gender-specific Health Literacy in Individuals with a Migration background (GLIM), including systematic reviews [28–30] and a further qualitative analysis on gender-specific aspects of health literacy, published previously [19].

Study design

We conducted five focus group discussions with healthcare professionals ($N = 31$) between January 2018 and March 2019 in Cologne, Germany. Focus group discussions are moderated discussions in which small groups of participants are stimulated to discuss about a given topic by means of a targeted information input [31].

Participants and recruitment

Inclusion criteria were a degree in a health-related profession, at least 2 years of work experience in a clinical role (e.g., as a nurse or physician) or in health-related counselling, regular contact with persons with a migrant background, and sufficient German language skills to participate in a discussion held in German. We applied purposive and snowball sampling to recruit healthcare professionals in the area of Cologne, a metropolitan city in West Germany, through a variety of different channels. We used a local guide for migrants that contains a list of registered physicians, therapists, clinics, counselling services, and pharmacies with diverse language competencies and clustered potential participants according to their profession and language proficiency. In addition, we placed local announcements in hospitals and distributed them by the nursing directorates, screened online search engines, and activated researchers' professional contacts. Participants were invited via e-mail or by post.

In total, we invited 183 healthcare professionals to participate. In addition, we asked the executive staff of 38 institutions (e.g., ambulant nursing services, hospitals and joint practices) to share the information with their medical staff. Healthcare professionals who signaled a general interest in participating in one of the focus group discussions received further information about the study. To avoid uneasiness, we did not allow participants who shared a hierarchical work relation to participate in the same focus group discussions.

Study setting and data collection

For the purpose of pretesting, we conducted two focus group discussions with $N = 10$ researchers from the department of Medical Psychology and the Cologne Center for Ethics, Rights, Economics, and Social Sciences of Health (CERES) at the University of Cologne. All had extensive experience in qualitative research methods. Six had additional practical experiences in the health system (e.g., nurse, psychologist), and six had a migrant background. The first pretest focused on methodological and ethical issues with regard to facilitating the focus group discussions (e.g., how to avoid the use of discriminatory language or how to stimulate the discussion without too much interference from the researchers). This further served to develop the semi-structured interview guide from an initial set of questions. The aim of the second pretest was to pilot and refine the interview guide, which we provide as Additional File 1. It was continuously evaluated and adapted in the course of the research process [31].

We conducted the focus group discussions at CERES. Prior to each focus group discussion, all participants received written participant information that included a brief description of the project and its aim, the conduct of the focus group discussion, and information on data security. In addition, the participants filled out a sociodemographic questionnaire including items on age, gender, migrant background, place of residence, and occupation. Three researchers (AB, DC, AA) moderated the focus group discussions; only one took on the role of the leading moderator to structure the discussion and give the participants a clear point of orientation. After the moderators were introduced, the integrated model of health literacy [3] and the definition of a migrant background were presented to the participants to provide them with an understanding of the project's theoretical background. The moderator appealed to the participants to treat everything said during the discussion as confidential and encouraged them to elaborate on their own experiences, whether they were in line with those of the other participants or not. The audio recording began after the participants gave their informed consent (written and oral). The moderator initiated the discussions by encouraging the participants to take 3 min time to think about a concrete situation in their everyday work life that was particularly challenging with regard to health literacy and interaction with people with a migrant background. Probing questions included, for example: *"How did you deal with these challenges?", "What would you have needed to meet this challenge?"* or *"What do you think your patient/client would have wished for in this situation?".* All sessions lasted 120 min and ended with a reflection and a feedback round, on which basis the interview guide was evaluated and adapted. The participants received reimbursement of 25 €.

Each audio recording was transcribed verbatim in German language—the reported results in this article were translated in English using back-translation technique [32]. All cited quotes are provided in both German and English as Additional File 2. A research assistant, present in the background, wrote the minutes, and the researchers took additional field notes to document important thoughts that arose during the discussions. We report the results of this study according to the consolidated criteria for reporting qualitative studies (COREQ) [33].

Analysis

We conducted a theory-guided qualitative content analysis according to Kuckartz (2019) [34]. The framework that guided our analysis was the integrated model of health literacy (see Fig. 1) [3]. We used a deductive–inductive categorization procedure for the analysis. This so-called abductive approach can be used to examine the implications of the applied analytical framework against the collected data and to discover meaningful patterns in, and gain a complete understanding of, the findings [35].

AB and DC deductively developed a set of categories that reflected the research question of healthcare professionals' perceived challenges, needs, and applied solutions in communicating and interacting with their migrant patients as well as the categories drawn from the underlying framework of health literacy [36], such as the four steps of health information processing: access, understand, appraise, and apply health information. Inductive categories were derived from the data. They were subordinated to the deductive main categories or served as new main- or sub-categories, if new themes arose in the data analysis process or the data indicated the need for further distinction. AB and DC independently developed a category system alongside the transcript of the first focus group discussion. The two independent category systems were then approved, merged and converted into a common category system. On the basis of this category system, AB and DC independently coded each transcript and subsequently compared and discussed the codings. Potential discrepancies were resolved by involvement of the third author (AA). Throughout the analysis process, the category system was discussed with the author team and adapted if necessary.

We performed the coding and categorization using the MAXQDA 18.2.3 software [36], beginning with the analysis of the main categories and subsequently searching for interrelations between main- and sub-categories alongside the consented category system [37].

Results

Thirty-six healthcare professionals expressed their interest. Three healthcare professionals did not show up and another two expressed interest but were un-able to participate at the agreed appointments. Five focus group discussions of between four to nine participants were conducted. In total, 31 healthcare professionals participated in one of the focus group discussions. One person attended upon the recommendation of a previous participant. We recruited participants until saturation was reached with regard to the categorized responses [38]. Table 1 provides an overview of the participants' characteristics.

The healthcare professionals did not perceive major differences between the descendants of immigrants and the German majority with regard to their health literacy. Therefore, the following results mainly reflect the participants' views on interactions with first generation migrants with a low German language proficiency.

Four steps of health information processing (access, understand, appraise, and apply)

We describe the results alongside the integrated model of health literacy [3], starting with the four steps of health information processing (access, understand, appraise, apply) followed by the factors that influence the entire flow of information in transcultural treatment settings (societal and environmental factors, situational factors, and personal factors). Thereby, we focus on the perceived challenges reported by the healthcare professionals on the one hand, and the already applied solutions that they perceived as effective for addressing these challenges, on the other hand. We do not report the perceived needs for addressing these challenges separately, as they were often stated implicitly in relation to the challenges and applied solutions. The deductive categories *challenges* and *applied solutions* with regard to *accessing, understanding, appraising,* and *applying* health information and the respective inductive subcategories are shown in Table 2.

Table 1 Characteristics of focus group participants

Characteristics of focus group participants (*N* = 31)

Factor	n
Sex	
Male	15
Female	16
Age (years)	
age range	28–71
25–34	5
35–44	11
45–54	8
55+	7
Migrant background	
Yes	16
No	15
Region[a]	
Europe	5
Turkey	6
Other (Arabian region, Africa, Asia)	5
Occupation	
Physicians/Psychologists	15
Nursing	7
Other healthcare professionals[b]	9
Setting	
Outpatient/counseling	7
Outpatient/therapeutic	18
Inpatient	6
Specialty[c]	
Psychosocial/psychiatric care	13
Medical (physical) care	22
Client base	
Adults	26
Family	5

[a] Region of origin in participants with a migrant background
[b] including e.g., ergo therapist, physio therapist, trauma counsellor or speech therapist
[c] Multiple answers were possible

Challenges and applied solutions related to accessing health information and services

Challenge: Mismatch between provision and actual use of health services Some healthcare professionals described a mismatch between the provision and the actual use of health services and difficulties in reaching persons with a migrant background for certain measures and healthcare services. They assumed this was due to reasons including distrust in healthcare professionals and the German health system (see also challenges related to the appraisal of health information), a lack of (system-)knowledge, and a lack of involving people with a migrant background in the development of health information and the delivery of health services. One participant emphasized the latter by indicating that *"many in the* [African] *community* [are] *actually very active and* [do] *a lot of educational work (…) and I believe the* [their] *work is seen far too little."* [HCP 12, other, outpatient, without migrant background].

Thus, many health services, even when linguistically adapted, did not meet the needs of migrants. Another

Table 2 Categories related to the four steps of health information processing

Category[a]	Processing step[b]	Subcategory[c]
Challenges	Access	• Mismatch between provision and actual use of health services
	Understand	• Uncertainty about the causes of unsuccessful communication
	Appraise	• Insecurity in dealing with patients' needs and expectations • Patients' distrust in healthcare professionals and the German health system
	Apply	• Patients' non-compliance with medical appointments
Applied Solutions	Access	• Easily accessible services and outreach counselling
	Understand	• Recourse to professional interpreters and cultural mediators • Recourse to lay interpreters (medical staff, relatives)
	Appraise	• Initiating unnecessary examinations to regain patients' trust
	Apply	• Patience in communicating health information to patients

[a]Categories *deductively* derived from the objective of the study
[b]Subategories *deductively* derived from the guiding model (Sorensen et al) [3]
[c]Subcategories *inductively* derived from the statements of the healthcare professionals

participant described a counselling service for pregnant mothers and those who have recently given birth in refugee homes. However, the refugee women did not use this service. The midwives asked one of the women who was close to giving birth: "*'why don't you come* [use the service]?' *And then she said, 'I gave birth to my other four children at home with my neighbor in the kitchen, I'm glad that I'm here, that my children can play outside and I know they'll all come back in because no bombs are falling' and she didn't know that there's a maternity passport, that there are preventive examinations, that they are free of charge, the check-ups"* [HCP 6, doctor, outpatient, without migrant background].

Applied solution: Easily accessible services and outreach counselling It was stressed several times that easily accessible services were perceived as helpful for reaching people with limited language skills and low (system-)knowledge for certain health services. In particular, outreach counselling, i.e., direct personal or telephone contact with persons in need of help, was rated as effective, whereas the mere provision of written information in the form of flyers or brochures was rated less useful. One participant reported that *"they* [members of the African community] *say 'we don't need all these flyers, we need a direct contact in order to dismantle these hurdles'"* [HCP 12, other, outpatient, without migrant background].

Another participant emphasized *"that this is an important point, because people* [with a migrant background] *don't come to the counselling centers like that. So, outreach work, I think, is really a key."* [HCP 2, nurse, outpatient, with migrant background].

Challenges and applied solutions related to understanding health information

Challenge: Uncertainty about the causes of unsuccessful communication Many healthcare professionals stated that it was sometimes difficult to distinguish between difficulties in understanding health information due to low literacy skills or due to considerable language barriers on the part of the patients—sometimes, it was assumed to be a combination of both. This would lead to challenges in conveying information in a targeted manner and was considered to be equally stressful for both sender and receiver.

> *"And if there is a language barrier in addition* (...) *then it is almost impossible to even judge it. Someone is silent and you assume that it's because of the language, but maybe it has a completely different cause and you just don't realize it because you can't grasp it"* [HCP 23, nurse, inpatient, with migrant background]

Applied solution: Recourse to professional interpreters and cultural mediators Nearly all healthcare professionals emphasized a need for the sufficient funding of professional interpreters or cultural mediators who do not only speak the same language as the patient but also share the same cultural norms, values or religion. Participants with access to professional interpreters from diverse cultural and linguistic backgrounds repeatedly emphasized the positive impact both on the well-being of their patients as well as on the healthcare professionals' own workload.

> *"Thank God we have the possibility to call an interpreter in our clinic and I attach great importance to the fact that the one who comes from Iran, that he gets an Iranian interpreter and not one from Afghanistan, who speaks the same language, but they do not have the same cultural background."* [HCP 26, nurse, inpatient, w mb]

Particular emphasis was placed on the ease of use and accessibility of so-called *"video interpreters"* who offer interpreting services via video conference, provided that the costs are covered. Participants who have already had the possibility to use video interpreters in an outpatient consulting setting rated them as a helpful, quickly available, and correspondingly time-saving method to overcome language barriers as physical contact is eliminated and interpreters for various languages are made quickly available via video conference.

> *"Yeah, but it works. Well, we often accompany families who don't understand anything in the clinic and where the cleaning lady or whoever tried to* [help] *or the older son or the younger daughter and we take the interpreter, the video interpreter now very often with us to the clinic* (…) *And we experience this as very, very helpful."* [HCP 6, doctor, outpatient, without migrant background]

Applied solution: Recourse to relatives or medical staff as lay interpreters Participants indicated on several occasions that the recourse to relatives as lay interpreters could be helpful in some situations, but could not compensate for the use of professional interpreters. Some doctors reported that they instructed their native-speaking medical staff to interpret during the treatment situation. However, some stressed that this measure could not be considered equally effective and satisfactory for all treatment situations, especially when shameful topics were discussed and the limits of confidentiality stretched. One physician summarized the problem as follows:

> *"For a while, I had a female doctor's assistant who was also Turkish-speaking. It doesn't help either, because she would say: 'No, I don't want to translate anything about this topic* [erectile problems]'. *There you are left alone"* [HCP 17, doctor, outpatient, without migrant background]

Challenges and applied solutions related to the appraisal of health information

Challenge: Insecurity in dealing with patients' needs and expectations Many healthcare professionals reported a general uncertainty in responding to the needs of migrants with low language proficiency. Thus, appraising the statements of their patients regarding their needs and expectations appeared challenging. They stressed that a mutual understanding was closely related to knowledge of cultural habits, expressions of pain and dealing with issues of shame. One healthcare professional explained that he received intercultural training but wished he had been taught more about how to sufficiently respond to his African patients' needs: "*they communicate in English or French and that works linguistically quite well, but this is the group where I often realize that you don't really know how they tick"* [HCP 11, doctor, outpatient, with migrant background].

This statement was strongly supported by the other participants.

> *"Of course, I feel the same way, although I have the impression, especially with African or Asian patients, that I don't understand their facial expressions.* (...) *what do they mean? Yes, it's often something completely different from what I understand"* [HCP 14, doctor, outpatient, without migrant background].

Challenge: Patients' distrust in healthcare professionals and the German health system Almost all participants reported a pronounced distrust in German institutions and healthcare professionals on the part of many persons with a migrant background, which led to a negative appraisal of the information provided by the healthcare professionals. Some participants supposed that a relationship between language barriers, experiences of discrimination, but also a lack of (system-) knowledge were reasons for an increased distrust in healthcare professionals and the German health system. One participant assumed that the present differences between health systems—even within the European Union—contributed considerably to this feeling.

> "[In Romania], *people generally have a broad-spectrum antibiotic at home* [because these are freely available there] (...) *and then of course they come, people come here into this system and then we say: No, we don't do that, we don't give antibiotics just because you have a sore throat.* (...) *Of course, this creates a relationship of mistrust and insecurity towards our system, towards the doctors"* [HCP 25, doctor, inpatient, with migrant background]

In this regard, many participants perceived that their migrant patients often suspected they were being discriminated by German healthcare professionals.

> *"Sometimes* (...) *the accusation of racism comes up, that others would certainly be treated better in the situation and would get a different* [better] *treatment."* [HCP 24, psychologist, with migrant background]

However, this was not reported by healthcare professionals who themselves had a migrant background. These participants assumed that the health information they delivered to their migrant patients was appraised as more trustworthy than the information delivered by their German colleagues. For example, a Turkish doctor reported that he was often confronted with culture-specific ideas regarding the end of life in the intensive care unit. When it came to communicating treatment decisions not in line with the culture-specific perceptions, philosophical, or religious beliefs of the relatives of his Turkish patients, he felt he was in a more favourable position than his German colleagues:

> *"Many* [people with a migrant background] *feel that they are, yes, being treated badly or that they have disadvantages due to their migrant background, that they are patronized* (...). *I am not confronted with that. They take it from me that they say, okay, you are a doctor, a Turkish doctor and you give everything and when I then say, 'it's good now, he won't make it, your father'. Then, they believe me more than if a German colleague would say that now."* [HCP 30, doctor, inpatient, with migrant background]

Applied solution: Initiating unnecessary examinations to regain patients' trust Some healthcare professionals reported that they sometimes found themselves initiating unnecessary examinations to pacify conflicting situations and thereby regain trust when they felt that they were accused of disadvantaging their migrant patients over those of the German majority population. This strategy was rated as unsatisfactory, inefficient, and costly.

> *"I think that probably happens quite often every day that an examination is ordered in order to, let's say, pacify the situation. Starting maybe with an ECG* [electrocardiogram] *and up to bigger things* [more expensive examinations] *and so* [you can imagine] *what that also means for the* [health] *system"* [HCP 23, nurse, inpatient, with migrant background]

Challenges and applied solutions related to applying health information

Challenge: Patients' non-compliance with medical appointments A central challenge in the outpatient care of patients with a migrant background, especially those who have recently immigrated or who grew up in countries with very different health systems, was the non-arrangement of or non-compliance with appointments: "*Somehow, making appointments doesn't work."* [HCP 17, doctor, outpatient, without migrant background]. One possible reason provided by the healthcare professionals was the patients' lack of knowledge of the German health system.

Applied solutions: Patience in communicating health information to patients Some healthcare professionals emphasized the importance of communication and of establishing the reasons for the patients' non-adherence. A lack of knowledge about the health system in recently migrated persons could be met with patience and friendliness. Other immigrants, however, who have been living in Germany for many years were expected by the healthcare professionals to know the system better. These patients should be treated "*friendly but firmly,"* as one doctor of Arab descent stated. Overall, this challenge does not yet seem to have been solved satisfactorily by most of the participants.

> "[I]*t's very difficult to teach them that it's not possible* [to treat them] *without an appointment and that they have to get an appointment and sometimes we discuss for so long* (...) *But that was in the beginning* [when patients have just immigrated], *I have to say, in the meantime it's getting much better that they have understood that. I explain it calmly and I think they learn over time."* [HCP 13, doctor, outpatient, with migrant background]

Factors influencing the entire flow of information in transcultural treatment settings

The participants reported that certain societal and environmental, situational, and personal factors influenced the entire flow of information (i.e., health literacy) between healthcare professionals and their migrant patients. Therefore, these could not be assigned to one of the four steps of health information processing. Table 3 shows the deductive categories *challenges* and *applied solutions* with regard to the *societal and environmental factors, the situational factors and the personal* factors that influence health literacy in transcultural treatment settings and the respective inductive subcategories.

Challenges and applied solutions related to societal and environmental factors

Challenge: Systemic lack of time and economic pressure The participants reported that, in the context of migration, known issues related to the delivery of healthcare for the majority population appear to be intensified. Above all, system-related factors such as a systemic lack of time and economic pressure were mentioned as aggravating the effective flow of information between healthcare professionals and the patients who required special attention in treatment settings. The participants emphasized an omnipresent lack of time as being present in both the outpatient and the inpatient sectors.

> *"And in the entire health system, I believe that what I have learned in the last 30 years, nothing or*

Table 3 Categories related to the factors that shape health literacy in transcultural treatment settings

Category[a]	Factors that influence health literacy	Subcategory[d]
Challenges	Societal and Environmental Factors[b] • System-related factors[c]	• Systemic lack of time and economic pressure
	Situational Factors[b] • Psychosocial/psychiatric vs. medical (physical) care[c] • Inpatient vs. outpatient care[c]	• Planning and controlling the current workload in outpatient care
	Personal Factor[b] • (Shared) migrant background[c]	• Ad hoc interpreting outside one's own treatment situation
Applied solutions	Societal and Environmental Factor[b] • System-related factors[c]	• Investment of additional, unpaid time • Falling back on stereotypes and prejudices to save time
	Personal Factor[b] • (Shared) migrant background[c]	• Refusal of interpreting for others or providing treatment in native language • List of staff who speak foreign languages

[a] Categories *deductively* derived from the research question
[b] Categories *deductively* derived from the guiding model [3]
[c] Categories *inductively* derived from the statements of the healthcare professionals
[d] Subcategories *inductively* derived from the statements of the healthcare professionals

> *everything works so badly because we have too little time."* [HCP 9, other, outpatient, without migrant background]

Some participants explicitly named the German accounting system, which is based on lump-sum fees in the outpatient sector and Diagnosis-Related Groups (DRGs) in the inpatient sector, as reason for high economic pressure. The accounting system was regarded as particularly disadvantageous for healthcare professionals who dealt with many migrant patients who required special attention and time (e.g., due to language barriers).

> *"I think that a very big problem is that there are lump-sum fees* [in the German health system]. *There is indeed the depressed woman who comes* [who] *is of German origin and* (...) [on the other hand] *a person with a migrant background who does not understand the language* (...) *you have to invest more time. Maybe you have to invest more money, and in the end, you don't get paid for it."* [HCP 27, nurse, inpatient, with migrant background]

Applied solution: Investment of additional, unpaid time The most frequently applied solution to tackle the problem of time pressure was the investment of extra time beyond systemic guidelines. For example, some participants reported that they would often invest time beyond their actual capacities to meet the needs of patients with a migrant background, but this was at the expense of their personal free time.

> *"And then I also take a lot of time and often it's the underlying conditions* [of the health system] *that make it difficult, so mostly it's personal free time that I take"* [HCP 14, doctor, outpatient, without migrant background]

Another outpatient doctor reported that he often invests additional time for his patients who require more support, but reduces treatment time for others whenever possible.

> *"That's the way it is in a general practice, you have to take time away from one to have time with the other. But if you then have someone with a migrant background, where you notice that it doesn't work linguistically, then* [more time is needed, but] *I can't kick them out. They haven't done anything [wrong]."* [HCP 19, doctor, outpatient, without migrant background]

Applied solution: Falling back on stereotypes and prejudices to save time Some of the participants reported that they caught themselves and their colleagues falling back on stereotypes and prejudices to avoid insecurity and to save time when work was particularly hectic. For example, some health care professionals described the so-called "morbus mediterraneus", a stereotype that labelled people from Southern European countries as being particularly plaintive persons who expressed physical pain intensely. Therefore, the patients' pain intensity would have been doubted by some healthcare professionals. The participants reported that some healthcare professionals tended to resort to this cognitive short-cut to save time. These stereotypical ascriptions would, in the worst case, lead to poor health care for people with a southern European migrant background because their symptoms were not taken seriously.

> *"Well, I have now clearly noticed in our everyday life that due to this time pressure, due to this stress and the fact that we get our patients through quite quickly, we often resort to prejudices and stereotypes and then one simply says: 'Okay, yes, Mediterranean patient, just morbus mediterraneus, let's just do analgesia and send them back home.'"* [HCP 25, doctor, inpatient, with migrant background]

Challenge related to situational factors

Planning and controlling the current workload in outpatient care Situational factors such as the treatment setting (inpatient versus outpatient care) were reported to generally influence the flow of information in transcultural encounters. Some challenges, however, were reported to be aggravated in the context of migration. For example, planning and controlling the current workload in the outpatient care (see also challenge 'Patients' non-compliance with medical appointments') was stated as a problem. In this regard, the most significant differences were perceived between psychiatric and medical (physical) outpatient care. In Germany, for both the outpatient, psychiatric and the medical (physical) care, patients have to make appointments, but people with acute health problems will still be treated. This is everyday practice in medical (physical) care, but less so in psychiatric care. A physician reported on his young migrant patient who presented to the practice without an appointment for his non-acute problem. Like many other healthcare professionals working in the outpatient setting, he referred to the lack of time to discuss such problems in detail:

> *"But you shouldn't forget that a doctor's practice also means an average of five minutes of medicine. So now I can't sit down with a young man who presents this problem* [erectile dysfunction], *and say, now I take half an hour of time and listen exactly where the problem is. Then the waiting room would overflow."* [HCP 17, doctor, outpatient, without migrant background]

Another participant concurred with this: *"So, yes, so I thought, there is certainly a difference. I have a purely appointment-based practice, an order-based practice as a psychotherapist, and so I don't have the problem that patients just come along, yes. That happens to me much less."* [HCP 16, psychologist, with migrant background].

Challenges and applied solutions related to the personal factor '(shared) migrant background'

More than half of the participants were first- or second-generation migrants themselves. The majority of these healthcare professionals had roots in Turkey (see Table 1). Participants who had a personal migrant background perceived that the delivery of healthcare for migrant patients was full of opportunities with regard to reducing distrust against healthcare professionals (see challenges related to the appraisal of health information). However, they also reported challenges, particularly with regard to using their language competencies in everyday work.

Challenge: Ad hoc interpreting outside one's own treatment situation Participants reported mixed feelings about using the shared language and culture. On the one hand, they described situations in which they actively decided to translate for German colleagues or to provide language-concordant treatment. Such situations were perceived as enriching. On the other hand, this was not the case when they were obliged to interpret for others or were *"caught off guard"* by requests at short notice. Interpreting was sometimes perceived as *"stressful"* due to the high workload across all healthcare settings. Some reported that they perceived the *"high responsibility"* associated with lay interpreting as a burden.

> *"I mean, I come from a region where people don't speak pure Turkish. That's quite a slang (…). At some point I didn't want to do that anymore and I found it rather burdening and things often happened between door and hinge, and I didn't want to be held responsible for it."* [HCP 28, nurse, inpatient, with migrant background]

Applied solution: Refusal of interpreting for others or providing treatment in native language Strategies to escape interpretation included the denial of ad hoc interpreting in certain situations or even the denial of interpreting in general. One participant reported that he sometimes even covered his name to hide his migrant background or that he pretended he couldn't speak Turkish. Another participant agreed: *"I have many Turkish colleagues who handle this similarly and don't speak Turkish at all and say, okay, you* [the patient] *are in a German hospital, then you have to sort it out in German somehow"* [HCP 30, doctor, inpatient, with migrant background].

Applied solution: List of staff who speak foreign languages Several participants reported that their organizations had lists of staff who speak certain languages to enable other healthcare professionals to quickly reach out for them in ad-hoc situations. This was perceived as well received, as these lists were developed on a voluntary basis. However, the quality of interpreting was described as being person-dependent.

> *"We have, for example, a list of foreign languages spoken by the staff that was known in the clinic. Basically, every nation was represented (…) Yes, the quality was always very different, depending on who* [of the staff] *actually came to translate."* [HCP 27, nurse, inpatient, with migrant background]

Discussion

The aim of this study was to investigate how healthcare professionals perceive the health literacy-related challenges, needs, and applied solutions in transcultural interactions. We explored the societal and environmental, situational, and personal factors that potentially shape health literacy (i.e., access, understand, appraise, and apply health information) in transcultural treatment settings from the perspective of those providing treatment.

We asked the participants for concrete situations that they found challenging in their interactions with persons with a migrant background. In this regard, we referred to them as either first- or second-generation migrants. Interestingly, the participants related almost all statements to first-generation migrants and repeatedly emphasized that second-generation migrants who had grown up in Germany and were highly acculturated (e.g. in terms of language and social membership) had health literacy-related needs similar to those of the German majority population. In line with this, other studies have also indicated that having a migrant background does not, per se, imply a lower level of health literacy—at least among young people when compared to their peers without a migrant background [39–41]. It might, rather, function as a multiplier in reproducing health-related inequalities [29], as health literacy has a social gradient [5], and differences in health literacy levels can also be explained by an average lower level of education or lower social status rather than by the migrant background itself [42].

Many statements were related to people who migrated from very different health systems to Germany, often referred to as first-generation migrants of Turkish or Arab descent. This may be because some participants themselves had a Turkish ($n = 6$) or an Arab migrant background ($n = 3$), thereby attracting more patients of the same origin. Another possible reason is that Turks and Arabs belong to the largest immigrant groups in Germany [43] and are, therefore, very present in the healthcare sector.

The results of this study indicate that a successful interaction in transcultural treatment situations is not exclusively a question of the individual knowledge, motivation, skills, and abilities of the healthcare professionals and their patients. Rather, health literacy in transcultural treatment settings appears to be an interplay of several external and internal factors that influence information delivery on the one hand and information processing on the other. This finding is in line with other qualitative studies that emphasize the social-relational character of health literacy, discussing it as social practice [44] and communicative action [45]. For the purpose of this study, the integrated model of health literacy [3] provided helpful guidance. However, in the context of transcultural treatment settings, we found the four steps of health information processing—access, understand, appraise and apply—to be neither distinctive nor consecutive. Instead, our results suggest that they are interactive, thereby reinforcing each other, and are influenced (to varying degrees) by individual, situational, societal and environmental factors. In addition, we found the personal, situational, and environmental factors that influence health literacy to be strongly interrelated. They had an impact on the kind and expression of challenges perceived, but also on the choice of and satisfaction with the applied solutions, which, in turn, influence the development of current and future patient-provider relationships. Therefore, not all inductive subcategories were subordinated to one of the a priori set distinct deductive categories. In addition, we did not report perceived needs separately, as they were often implicitly stated in relation to a challenge or an applied solution. For example, the participants reported a need for professional (culture-concordant) interpreters. Likewise, those who already had access to professional interpreters reported this as a helpful solution. Thus, the reported results reflect those categories that inductively emerged from the data and that most closely matched the respective deductive main category. Figure 2 shows the pathways and interrelations of the deductive **(bold)** and inductive categories related to the four steps of health information processing described in the results.

One of the major challenges related to accessing health information and health services was a mismatch between the provision and actual use of health services. Some of these services, even when linguistically adapted, do not seem to meet the needs of persons with a migrant background. Accordingly, the involvement of migrants (i.e., people concerned) in the development and implementation of such services, their easy accessibility, and outreach counselling were rated as helpful solutions to this challenge. The European study RESTORE, for instance, found positive effects on knowledge, skills, and clinical routines when they involved migrants along with other stakeholders in the implementation of guidelines and training initiatives on cross-cultural communication [46].

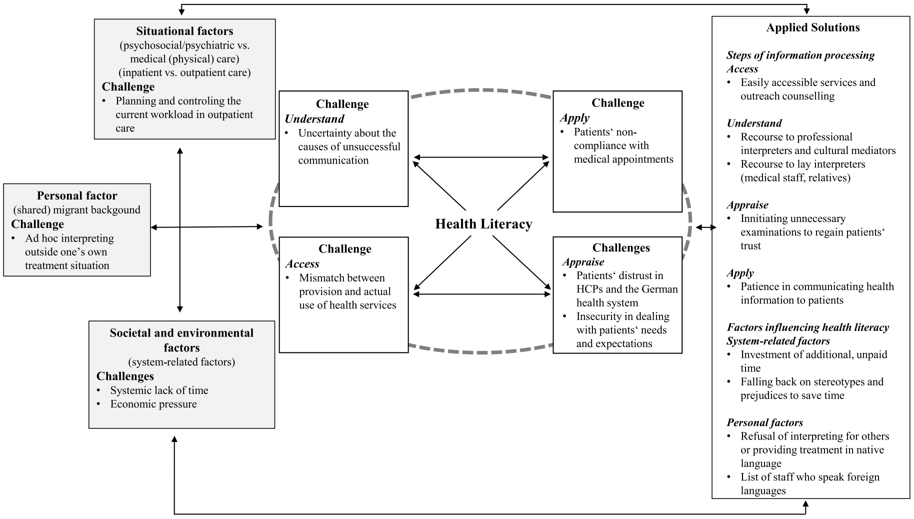

Fig. 2 Pathways of deductive main categories **(bold)** and exemplary inductive subcategories of health literacy-related challenges and applied solutions in the transcultural treatment settings. HCPs: healthcare professionals

Our results indicate that in transcultural treatment settings, the respective parties' understanding of each other depends on system-related factors such as time and the accessibility and funding of professional interpreters. Some participants reported that it was sometimes difficult to distinguish language-related problems in understanding health information from literacy-related difficulties in understanding medical information in general. Communicating personal health issues can be highly challenging, even when people are literate in their native language. Language barriers and culture-specific differences in the understanding of illness or the expression of pain can be additionally challenging for persons from diverse migrant backgrounds. This can, in turn, lead to misunderstandings and false conclusions being made about the person's health literacy. Thus, the participants regarded the funding of cultural mediators or professional interpreters with at least some professional medical knowledge (e.g., culture concordant video interpreters) as significant for overcoming the major language-related challenges in the provision of care. This finding is supported by other studies that include the perspectives of either health professions [47] or migrant patients [48]. For instance, one study conducted in Switzerland found that two thirds of the participating physicians who face language barriers have never had access to a professional interpreter, even though 87.8% would appreciate their presence in clinical practice [49]. However, our findings indicate that the mere provision of translated information material and interpreters, though indispensable, cannot solve the deeper challenges present in the provision of healthcare for people of diverse migrant backgrounds. Unless health literacy, cultural particularities and language barriers are not addressed simultaneously [50], the mutual satisfactory flow of information remains a fervent wish rather than clinical reality in transcultural treatment situations.

A key component for a mutually satisfying flow of information was trust. Our findings reveal that this factor is influential, particularly with regard to accessing health information and services as well as appraising the health information exchanged (see Fig. 2). This finding is supported by other studies which indicate that distrust in health services is one of the major barriers to healthcare access [24], whereas patients' trust in healthcare professionals can promote a willingness to seek advice, the acceptance of medical recommendations, improved treatment adherence and satisfaction, and subjective health outcomes [51]. Using heuristic shortcuts (e.g., stereotypes) when people have to process complex information under time pressure, is a well-known psychological phenomenon [52]. For example, some healthcare professionals described the stereotypical ascription "morbus meditarreneus" as being used to label the allegedly exaggerated expression of pain by persons from Southern European countries. Such stereotypes may serve the maintenance of subtle racism against people with a migrant background, which is still present in health systems [53, 54]. Furthermore, it can lead to even more distrust on the part of the patients [53] and, in the worst case, to poor medical decisions that disadvantage minority patients [54]. This is because trust is the result of people's lived experiences, and it shapes how future experiences are perceived. It can be described as a *"forward-looking evaluation of an ongoing relationship"* [55] (p. 617). Thus, trust is determined to a considerable extent by the experiences and expectations of both the healthcare professionals and their patients. Both parties' efforts to create trustful relationships may, therefore, improve the flow of information. This could be supported by (1) the implementation of culture-sensitive measures such as sufficient funding of cultural mediators and professional interpreters, (2) the integration of intercultural learning contents into the educational curricula for medical professions, and (3) the involvement of people with a migrant background in the implementation and development of health information and services.

Time and resource constraints are well known issues in many health systems worldwide [51]. Accordingly, of all the factors that influence health literacy in transcultural treatment settings, the healthcare professionals perceived system-related factors, such as the systemic lack of time and economic pressure as impeding the flow of information in transcultural treatment settings the most. The participants perceived these conditions as highly stressful. In the context of migration, however, these known issues of the German health system were perceived as particularly aggravating. The healthcare professionals reported that they required extra time and effort to treat patients with low language proficiency due to language barriers, a lack of (system-)knowledge, or low literacy skills on the patients' side. The most frequently mentioned strategy to manage these challenges included the investment of additional, unpaid time. This strategy was not always successful but it was seen as the most effective method for solving these issues. The issue of time pressure was reported mainly by participants working in the medical (physical) care, whereas the psychiatric professions seem to be less affected in this regard. This result reflects the importance of considering the particularities of different treatment settings when pinpointing specific challenges in transcultural interactions.

More than half of the healthcare professionals had a migrant background themselves. These healthcare professionals found that this personal factor positively influenced the establishment of trustful relationships and the acceptance of treatment recommendation. In line with this, a recent study from Germany found that a shared migrant background improved trust in the physician, reduced reactance-related outcomes, and improved prevention-related knowledge transfer in patients with a Turkish migrant background, especially in those with low health literacy [56]. However, challenges were also reported. In particular, the controversial discussion regarding interpreting outside one's own treatment situation revealed that it should not be assumed that a healthcare professional with certain language skills is willing to or feels secure to use these skills in a professional context. Some healthcare professionals who reported frequent ad hoc interpreting outside their own treatment situation referred to two particular issues: firstly, an additional increased workload during the time of interpreting, and secondly, a fear of not translating properly in the short time available. The reported concerns of one nurse that he may be translating incorrectly because his own language skills may not be sufficient to translate complex medical issues *"between door and hinge"* [HCP 26, nurse, inpatient, with migrant background] is in line with empirical evidence indicating that nurses untrained in interpreting frequently make mistakes when translating for other healthcare professionals. This may have considerable negative clinical implications for the patients affected [57]. In particular, ad hoc interpreting may result in incorrect medical interpretation [58]. Therefore, the overriding majority of professional associations of interpreters, training institutions, and scientists demand professional interpreting in healthcare and advise against non-professional solutions [59].

Strengths and limitations

To the best of our knowledge, this was the first study that aimed to investigate the health literacy-related challenges, needs, and applied solutions from the perspective of healthcare professionals and systematically analyze the personal, situational, and environmental factors that shape health literacy in transcultural treatment settings by applying an established health literacy framework [3].

Further strengths of this study are that the research was conducted by an interdisciplinary and multicultural research team. This meant the research team involved an advantageous combination of different genders, expertise, views, backgrounds and focal points. Reflexivity was something we considered throughout the entire research process, beginning with the conceptualization of the focus group discussions up to the final data analysis and derivation of implications. In our research team, we repeatedly discussed our understanding of health literacy as a social-relational construct, our conception of migration, and the potential influence of our attitudes and preconceptions on the dynamic of the focus group discussions, the results, and the data analysis. For example, despite the emphasis that all opinions were welcome, an egalitarian attitude may have induced rather cautious statements to avoid prejudices and stereotypes.

One limitation of this study is that a selection bias might have occurred, as many participants were highly interested in the issue. On the other hand, some focus groups also included the researcher's distant professional contacts. This may have contributed to a balance in the sample as they may have participated because of the researchers' personal approach rather than their intrinsic interest in the topic. In addition, here was a slight surplus of participants working in the outpatient setting and not all focus group discussions were balanced with regard to the participants' gender and migrant background. However, the individual focus group discussions were rather homogenous in terms of the participants' occupation (e.g., doctors or nurses), their status and outpatient or inpatient contact with persons with a migrant background. In addition, it can be assumed that all have worked in the inpatient sector at some point, either during and after their vocational or specialist training, respectively. Thus, the reported experiences were fed to some extent from both areas. Finally, although saturation was reached with regard to categorized responses, due to the nature of qualitative research, new categories might have emerged had the participants been interviewed at another time [60].

Conclusion

Health literacy in transcultural treatment settings is an interplay of environmental (i.e., system-related), situational and personal factors. Known issues observed in the delivery of healthcare for the majority population (i.e., systemic lack of time and economic pressure) appear to be intensified in the context of migration. These factors impede the flow of information in all treatment settings to various degrees. An increasingly diverse patient clientele indicates the growing need for culture-sensitive, health-literate healthcare organizations. A corresponding diversity in the health workforce in terms of culture, language, and gender is therefore highly desirable and should be strengthened by national finance and educational programs. Ad hoc solutions, such as recourse to healthcare professionals with a migrant background as lay interpreters, should not become the means of choice for compensating for deficits in the funding of professional interpreters. Interpreting for colleagues should be treated as an additional part of these healthcare professionals' work and not as an additional requirement during their leisure time. Healthcare professionals who interpret for colleagues should have the choice to do so voluntarily and should be provided with the necessary time for it. Further studies in different countries with diverse health and health insurance systems are needed in order to develop and implement appropriate interventions for improving health literacy at the individual and organizational levels. These studies should involve both healthcare professionals and people with a migrant background to ensure equitable healthcare that meets the needs of all persons being involved in the treatment situation. We call upon political decision-makers to further expand the funds for interpreting services and enable such services to be used at the lowest possible threshold, for example via video conference.

Abbreviation

HCPs: Healthcare professionals

Supplementary Information

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Additional file 1.

Additional file 2.

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Authors' contributions

AB wrote the manuscript. AB, DC and AA were responsible for the conceptualization of the study and the data collection. AB and DC were responsible for the data management and the data analysis, assisted by AA. CW, EK, NC and ÜSS applied funding. DC, AA, ÜSS, NS, EK, and CW proofread and commented on the draft. All authors read and approved the final manuscript.

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Availability of data and materials

Due to the qualitative nature of the project, the dataset is not publicly available. Personal narratives could be more readily associated with individual respondents. Data may be available on reasonable request. Contact person is Annika Baumeister: annika.baumeister@uk-koeln.de

Declarations

Ethics approval and consent to participate

The project received ethical approval through the Institutional Review Board of the Medical Faculty of the University of Cologne, Germany (n° 17–406). All participants were fully informed about the study and provided written and oral consent to participate.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no conflict of interest.

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Publisher's Note

Appendix ii: Study II (Focus group discussions)

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Gender-Specific Aspects of Health Literacy: Perceptions of Interactions with Migrants among Health Care Providers in Germany

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Abstract: Health literacy can be described as a complex process shaped by individual resources and preferences and by the nature and quality of health-related information people encounter. The main objective of this study was to explore the views of health care professionals on how gender as a personal determinant of health literacy affected their interactions with migrant patients. The interrelated challenges, needs and applied solutions were analyzed from a health literacy perspective. Five focus group discussions with health care professionals working with migrants ($n = 31$) were conducted in Cologne, Germany, audio recorded, transcribed and analyzed by qualitative content analysis. Gender-specific aspects, such as the gender of health care providers as a factor, were portrayed above all in relation to patients from Turkey and Arab countries regarding access to and understanding of health-related information. These statements exclusively represent the possibly biased or assumptions-based perspectives of health care professionals on their migrant patients and were made against the background of a systemic lack of time and the challenge of overcoming language barriers. Especially in this context, reducing time pressure and improving communication in the treatment setting may be to the benefit of all actors within healthcare.

Keywords: gender; migration; health literacy; qualitative content analysis; health care professionals

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1. Introduction

Health care can broadly be defined as the entirety of measures and activities promoting the health of human beings on a community or individual level [1]. The opportunities for achieving optimal health vary between different groups of people, with structural and social determinants influencing access to health care services and interactions between patients and health care providers. In order to gain a deeper understanding of these interactions it is important to look at factors shaping health opportunities.

The terms sex and gender originally used to be synonyms, both applied to indicate whether a person was male or female [2]. After Simone de Beauvoir's seminal work The Second Sex in

1949 [3] the debate about the social constructiveness of being a man or woman led to the term gender now widely used for gender role. In contrast, the word sex usually serves for the biological distinction between male and female persons [4]. As of today, gender and queer theory has evolved far beyond the man-woman dichotomy [5,6]. Still, it is important to look at differences between men and women as the social and societal roles associated with these genders are important factors regarding individual health. For example, men and women partly suffer from different diseases and deal with them in different ways, which demands gender-sensitive diagnostic and therapeutic techniques [7,8]. This is even more so because gender also influences the way patients are diagnosed and treated by medical personnel [9]. Gender roles, gendered power relations, religious and cultural understandings of sexuality, and gender-specific access to educational resources can vary between the world's regions [10–12]. As the number of transnational migrants has risen to an estimated 258 million in 2017 [13], a growing number of persons with different understandings of gender encounter each other within the health care systems of the host countries.

In the recent history of Germany there have been several phases of intensive immigration, the most recent one concerning refugees mainly from Syria and Iraq in 2015 [14]. In the 1950s, massive numbers of workers from Italy, Greece and above all Turkey were recruited to work in the factories of the up-and-coming German industry [15]. Although it was planned that these workers would return to their home countries, many of them decided to stay in Germany with their families. As a statistical category, the term "persons with a migrant background" has subsequently become established as a term for people who themselves or at least one of their parents were born without German nationality. This accounts for around 25% of the German population [16].

From a gender perspective, the interaction between migrants and the representatives of health care systems (e.g., health care providers) can be a challenging task for both sides. The gender of patients and physicians has been shown to influence doctor-patient interaction [17–19], and cross-cultural interactions have been described as demanding by patients and health care professionals (HCPs) [20]. The exchange of health-related information is a central aspect of the treatment situation [21]. In this regard, the ability to handle health-related information is an important factor—an ability neatly tied to the concept of health literacy.

Health literacy, a term first coined in the 1970s [22], has since been defined in numerous ways [23]. In 2012, Sørensen et al., proposed an integrated conceptual model of health literacy, reconciling 17 definitions and 12 models of health literacy [24]. Drawing on this integrated model, health literacy is defined as "the knowledge, motivation and competencies of accessing, understanding, appraising and applying health-related information within the healthcare, disease prevention and health promotion setting, respectively" [24]. Importantly, the model describes health literacy as a social-relational concept with societal, environmental, situational and personal determinants influencing a person's health literacy. Gender can be understood (and is described by Sørensen et al.,) as a personal determinant for health literacy [24] with numerous societal, environmental and situational connotations that go far beyond biological sex differences. Migration can also be integrated into the model in several ways: Having a migrant background as a personal determinant, the migration process as a situational factor, both also connecting to societal and environmental aspects that may differ between host countries.

In a recent representative study conducted in Germany, 54% of the German population indicated to have limited health literacy while with a migrant background it was 71% of persons. This is in line with international studies comparing migrant's health literacy with that of the general population [25]. Considering overall health literacy, correlations have been found between health literacy scores and gender [26–30]. However, the strength and the direction of the effects found in these studies are highly inconsistent and do not allow for a derivation of conclusive statements. It is still unclear how and in which direction gender aspects affect health literacy, especially in persons from culturally diverse backgrounds.

Within the health care systems, encounters of persons with a migrant background and HCPs typically take place in a treatment setting, with an HCP representing and acting on behalf of the health care systems of the receiving countries. HCPs work at the focal point of health literacy, where health information is obtained, understood, appraised and applied. Many of them interact with men and women of numerous different origins. The exploration of experiences from their everyday work has the potential to help in gaining a more profound understanding of how gender may affect health literacy in cross-cultural encounters in health care. There is a growing body of research on health literacy in the context of migration [31], and gender aspects in providing health care for migrants are slowly receiving attention [32]. However, relating the influence of gender-specific aspects of interactions between HCPs and migrants to the concrete steps of processing health information is a new approach which might help to comprehend the role of gender in this context.

It is important to note that this study cannot provide "objective" data on migrants and their health literacy. It can only offer the HCPs' subjective perspective on the health literacy of migrants derived from their interactions with them in the treatment setting.

This research is part of a an overarching project regarding Gender-Specific Health Literacy in Individuals with Migrant background (GLIM) which consists of systematic reviews [33–35] and a further qualitative analysis concerning organizational health literacy which is not within the scope of this study. The main objective of this study was to explore the views of health care professionals on how gender as a personal determinant of health literacy may affect their interactions with migrant patients. The interrelated challenges, needs, and applied solutions were analyzed from a health literacy perspective.

2. Materials and Methods

2.1. Focus Group Discussions (FGD)—Method and Ethical Clearance

For explorational research questions, the choice of qualitative methods is recommended [36]. An FGD is a qualitative method frequently used in health research and education as "a research technique that collects data through group interaction on a topic determined by the researcher" [37]. FGD can be used to obtain sufficient information within a short time to determine the participants' perspectives on a topic [38]. It is a moderated discussion procedure in which small groups are stimulated to discuss a given topic by means of an information input. Current studies show that with the implementation of two to three FGDs, usually at least 80% of the topics to be explored can be covered [39]. In this study, five FGD had to be conducted until saturation was reached with regard to the categorized responses. The study was approved by the Ethics Committee of the Medical Faculty of the University of Cologne (n 17-406).

2.2. Guideline Development

A guideline for the FGD was developed including the starting question and a set of probing questions for deepening topics or steering the conversation to aspects not yet mentioned in the respective discussion [40]. For the purpose of pretesting, two FGD were conducted with researchers from the department of Medical Psychology and CERES (Cologne Center for Ethics, Rights, Economics, and Social Sciences of Health) of the University of Cologne. In these FGD, the guideline was tested for consistency and structure. After the pretests, the format including the guideline, moderation and setting (guideline, length of discussion, seating order) were discussed with the participating researchers.

2.3. Participant Recruitment

Participants were recruited via purposive and snowball sampling. At first, practices and institutions listed in the Health Guide for Migrants [41], provided by the city of Cologne, were contacted via email and telephone. The guide is an electronic document which includes a list of health care institutions (hospitals, pharmacies) and practices (medical doctors, physiotherapists, midwives etc.,) which offer multilingual services. Further participants were recruited through online search, professional contacts of the researchers, and by putting a call for participation on the intranet message boards of hospitals in Cologne and the surrounding area. We included participants with a degree or certificate in a health-related profession who had been working with patients with a migrant background on a regular basis for at least two years. HCPs signaling general interest in taking part in one of the FGD received further information about the study as well as a written consent form including a data protection agreement. The material was sent to those willing to participate by e-mail or in written form. To avoid uneasiness, participants sharing a hierarchical work relation or working in the same department did not take part in the same FGD. Additional participants were recruited until saturation was reached [42].

2.4. Implementation of the FGD

At the beginning of every FGD, the participants received information material for the study and a socio-demographic questionnaire containing questions about their gender, migrant background and occupation. They were given sufficient time to read the material before signing the informed consent. Three researchers were present throughout the discussions with one being the moderator while the other two researchers posed additional probing questions in case they felt the need to dive deeper into a topic. A research assistant wrote a protocol in order to simplify the assignment of statements to the participants when transcribing the audio recordings. Two audio recording devices were used to avoid data loss.

The researchers introduced themselves and shortly explained the study purposes. The stimulus was set by introducing the concept of health literacy verbally and visually (in a poster format), the project-specific definition of a migrant background and gender as a personal determinant of health literacy. Following this, conversation recommendations were announced by the moderator including the request not to interrupt other participants and to treat everything said in the FGD as confidential. The participants were encouraged to elaborate on their own experiences, may whether they were in line with those of the other participants or not. The audio recordings were started before the participants introduced themselves, shortly describing the context in which they usually interacted with persons with a migrant background on a professional basis. After the introductions, the moderator invited the participants to share their experiences as follows: *"Well, you all work in a health care context with women and men who have a migrant background. Please take three minutes time to remember concrete situations from your day-to-day work, for example a treatment situation with the persons themselves or with their relatives, that was very typical or maybe even special and which you still have vivid memories of - regardless of whether it was solved satisfactorily. You are also welcome to take notes on this."* After three minutes, the discussion was opened by the moderator. Probing questions were set to examine the needs and applied solutions that arose from the situations described (e.g., *"How satisfied were you with the outcome of the situation?"* or *"What did you miss in this situation and what would you have needed to meet the challenge?"*). If situations were described that only affected one gender, the HCPs were asked to talk about similar situations with other genders involved (*"Does anyone else in this group have experiences regarding this kind of situation when treating male/female patients?"*). If gender-specific aspects were not mentioned during the discussions, additional probing questions were posed to gently encourage the participants to consider potentially relevant gender aspects (e.g., *"What role did your own gender play in this situation*?").

Every FGD reached the maximum of 120 min. At the end of each FGD, participants were asked for their opinion regarding the discussion, its format and what they felt needed improving. They were offered to receive information about the results. Participants received a reimbursement of 25 €.

2.5. Data Analysis

The audio records were transcribed verbatim. A qualitative data analysis software MAXQDA [43] was used to analyze the transcripts in the German language. Quotes displayed throughout this manuscript were translated and back-translated by a researcher fluent in English.

Following the recommendations for qualitative content analysis according to Kuckartz [44], a combination of deductive application of categories and inductive development of categories was performed by the involvement of two researchers (D.C. and A.B.). First, three main categories were deductively derived from the research question including perceived Challenges, Needs and Applied Solutions related to the treatment and care of people with a migrant background. In a second step, according to the guiding framework [24], additional deductive categories were applied including the four steps of health information processing Access, Understand, Appraise and Apply health information and subordinated to each of the three main categories to ensure that all inductively evolving subcategories related to health literacy could be identified. Inductive subcategories that were considered to be directly or indirectly related to Gender as a personal determinant of health literacy were exclusively derived from the data. Other inductive subcategories that arose from the text were subordinated to the three main categories Challenges, Needs, and Applied Solutions whenever possible without a considerable loss of information.

2.6. Reliability and Validity

Two researchers (D.C. and A.B.) independently coded the first FGD transcript, each researcher building inductive categories and subcategories of the deductive categories. In a second step, the two category systems were integrated into one. The two coding researchers then independently coded each of the remaining four FGD transcripts based on the preliminary category system, again reconciling and reflecting on the deductively and inductively derived main- and subcategories after a phase of independent coding. All potential discrepancies were resolved by consulting the mediating researcher (A.A.), who was highly involved in the whole research process. This research followed The Consolidated Criteria for Reporting Qualitative Studies [45].

3. Results

Between January 2018 and May 2019 we conducted five FGD with $n = 31$ participants at CERES. An overview of the characteristics of the participants is presented in Table 1.

Table 1. Main characteristics of the health care professionals (HCPs) participating in the focus group discussions (FGD) ($n = 31$).

Gender		Men	Women
Age (years)	25–34	1	4
	35–44	4	7
	45–55	5	3
	≥55	5	2
Migrant background	migrant background [1]	8	8
	no migrant background	7	8
Occupation	physicians	8	5
	psychologists	1	1
	midwife/pediatric nursing	0	2
	nursing care	3	2
	Other HCP	3	6
Total		15	16

Note. [1] Regions of origin of HCPs with a migrant background were Turkey ($n = 6$), Arab region ($n = 3$), Central Europe ($n = 2$), South Europe ($n = 2$), Eastern Europe ($n = 1$), Asia ($n = 1$), Sub Saharan Africa ($n = 1$).

The classification of the statements in this scheme shows which processing steps of health literacy were primarily influenced by gender. This could occur in two ways: (a) as a direct influence, described by gender subcategories or (b) as an indirect influence, which is represented by general subcategories. An overview of the most important categories is shown in Table 2.

Table 2. Main categories.

Main Categories [1]	**Processing Steps** [2]	**Gender Subcategories** [3]	**General Subcategories** [3]
Challenges	Access	Husbands as gatekeepers The gender of HCP as a factor Shame in the health care situation	
	Understand	Gender-specific aspects of language barriers	Language barriers Systemic lack of time
	Appraise	Skepticism towards psychotherapy The importance of motherhood	
Needs	Understand		Cultural and language mediation/interpretation Need for more time
Applied Solutions	Access	Covering parts of the body to mitigate shame	
	Understand		Cultural and language mediators/interpreters
	Appraise	Women as pioneers for the acceptance of psychotherapy	

Note. [1] Categories deductively derived from the objective of the study. [2] Subcategories deductively derived from the guiding model (Sorensen et al., 2012). [3] Subcategories inductively generated from the statements of the HCP.

3.1. Narrative Elements Used by the HCP

3.1.1. Specific Situations, Generalizations and Possible Biases

The statements of the HCP often related to specific situations that were meant to act as examples for challenges, needs and applied solutions when interacting with migrants. This must be seen with the caveat that the selection and description of these situations may give a biased picture of the interaction with migrants, as stereotypes about migrants are very common in the general population, including HCPs [46]. When a phenomenon was perceived to occur frequently, the HCP talked about it in a more general way. Generalizations, especially about minority groups, are particularly prone to be stereotypical. As stereotypes can be internalized by members of the stereotyped group as well [47], this reservation accounts for the statements of all HCPs including those who themselves were first or second generation migrants. Therefore, the statements should be regarded as subjective and selective narratives.

3.1.2. Migrant Generations and Countries of Origin

While the research question was set out to explore the experiences of HCPs in the interaction with both first- and second-generation migrants, the HCPs reported almost exclusively on their experiences with first-generation migrants. Apart from very few exceptions, the second-generation migrants were not mentioned as patients, but rather in the treatment situation where they supported their parents during the visits to and the interaction with the HCPs. Hence, gender aspects in the interaction with second-generation were also rarely addressed or mentioned. Therefore, the term *migrants* is used in the following section of this paper to address first-generation persons with a migrant background. The HCPs did not always specify the countries of origin of their patients. The countries that were mentioned most often were, first and foremost, Turkey, followed by countries from the Arab regions. Patients' affiliations with the Islamic faith were also frequently mentioned. Only very few statements concerned gender aspects in the interaction with people from other religious or regional backgrounds.

3.2. Challenges

Most statements addressed challenges. Within this main category, gendered issues affecting access to the treatment or care situation were most prominent, followed by more general challenges regarding the understanding of health-related information. No statements related primarily to the influence of gender on the processing step of applying health information.

3.2.1. Gender-Specific Challenges Regarding Access to the Treatment Setting

Husbands as Gatekeepers

Some HCPs reported situations in which their interaction with migrant women was controlled or even prohibited by the women's husbands. In some of these cases these observations were made regarding migrants from Turkey or the Arab region, but often the origin of the persons involved was not specified. While the husband's motivation to control access to his wife was not always clear to the HCP, in part of the cases his aim was to ensure his wife would not be treated by a male HCP (see the category the gender of HCP as a factor). In some situations, the husband's intervention lead to the termination of the treatment.

> *The husband was not physically present, but then he practically forbade me to talk to the wife, because he must know everything. So, confidentiality does not occur in their thinking. So that the midwife discusses something confidentially with the woman, he as the father of the child, he must know everything, so, no. That was not possible at all. Moderator: How did you solve the situation in the end? HCP: I was not allowed to come any more. He prohibited it.*
>
> – Midwife/Pediatric nurse (female, 45–54 years)

The Gender of HCP as a Factor

The gender of HCP was mentioned as a factor limiting interactions with migrant patients, mainly due to the patient's need for an HCP of the same sex. While the HCPs reported gender concordance in the treatment setting to be important for both migrant men and women, they elaborated on it mostly with regard to women, who were seen as reluctant to be treated or cared for by male HCP. This was mostly related to persons of Arab or Turkish origin. Female HCPs reported that their expertise as an HCP was in some cases questioned by male migrants, especially from Russia, who favored male HCPs. In several descriptions, the gender of HCPs also influenced the role of migrant women's husbands as gatekeepers who sometimes blocked contact of male HCP with their wives. In those cases, the gender constellation male HCPs–female patient–male husband led to complications regarding access to health care.

> *And she definitely needed help, so she wouldn't have come to the bathroom on her own, she wouldn't have come to the toilet and so that dragged on for days until you were allowed to do more than just catlick and there really was the husband who was always in the room and always intervened somehow when a male nurse or doctor was there. So that was already difficult.*
>
> – Nurse (female, 25–34)

Shame in the Health Care Situation

From the perspective of HCPs, shame of nudity was seen as a barrier for examination. This was not specified for migrants from certain regions or migration generations but for women the HCP assumed to be of Islamic faith, who were described as reluctant to undress. This regarded mainly two sorts of situations: Examination and washing of patients. Shame mainly harmed the access component of health literacy because it hindered examination, thus preventing the HCP from providing qualified health-related information for the patient. In addition, it was described as affecting understanding, for example if a low level of a person's language proficiency made it more difficult for her to understand the HCP and to explain herself to the HCP. Dealing with these situations was considered time-consuming.

> *So there are cultural things, [for example] undressing of strict, older Muslim ladies, you can forget it. Also, one must honestly say, temporarily, in the beginning I did it, but it costs half an hour of persuasion and then they stopped after the first layer. So, unfortunately that's how it is, so I have to deal with it.*
>
> – Physician (female, ≥ 55 years)

3.2.2. Gender-Specific Challenges Regarding the Understanding of Health Information

Gender-Specific Aspects of Language Barriers

Many statements dealt with how the HCP perceived migrant women's roles within the family. Especially for women of Turkish or Arab origin, aspects of these roles were often perceived as a limiting factor for the women's ability to access and, more than anything, understand health information. Most of these statements regarded first-generation migrant women of Turkish origin who migrated to Germany in the 1960s and 1970s. They were mentioned as suffering from loneliness after a long time of raising children and doing housework, sometimes showing a fatalistic or indifferent attitude to their own health. The HCP talked about the situation of these women less by describing case histories than in a general way and also related to their own emotional processes of frustration or empathy. Level of education and German proficiency within this group of female migrants was perceived as low, partly due to the fact that they originated from rural areas with little educational infrastructure. While their male counterparts were also affected by this, they were described as being more in contact with persons of the German majority population due to their working experiences, which enabled them to acquire a certain level of language proficiency.

> *So these Turkish women in particular, now, 50, 60 years old, children brought up, hardly any knowledge of German actually, also relationships lived, but basically also a lot of oppression so and now alone actually [. . .].*
>
> – Physician (male, 35–44 years)

3.2.3. General Challenges Regarding the Processing Step of Understanding Health Information

Language Barriers

While there was a gender aspect regarding language barriers in the case of the elderly Turkish women, HCP described language barriers to generally impede the exploration of medical problems of migrant patients regardless of their religion and region of origin, also hindering the transfer of important information to them. This fact was seen as detrimental for a proper treatment.

> *This considerable language barrier makes it of course difficult then to do the anamnesis and properly inform the patients legally, to carry out an intervention at all if it is not an acute emergency, and then of course the proper treatment is delayed.*
>
> – Physician (female, 25–34 years)

Systemic Lack of Time

HCP described a systemic lack of time due to factors as lump-sum fees, personnel shortages or the undersupply of areas with low socio-economic status as a major general problem, hindering them from taking the individual's needs into account. This was described as especially problematic in the treatment of migrants regardless of their respective origin or religion. Time pressure interacted with language barriers. For example, the amount of information transmitted within a given time frame could be smaller when language barriers slowed down communication. The HCP stated understanding the patient's exact needs and overcoming gender-specific barriers as time-consuming and hardly feasible under the given circumstances. A physician described his way of treating young migrant men who suffered from sexual potency problems. He reported prescribing drug therapy in such cases although he did not consider it the optimal treatment. Finding out about the cause of the problem would take more time than the HCP said he was able to spend:

> *With young men it is rarely an organic problem, it is more of a psychological problem. But you shouldn't forget that a doctor's office also means an average of five minutes of medicine. So now I can't*

> *sit down with a young man who presents this problem and say, now I take half an hour for him and listen to exactly where the problem is. Then the waiting room would overflow.*
>
> – Physician (male, ≥55 years)

3.2.4. Gender-Specific Challenges Regarding the Appraisal of Health Information

Skepticism towards Psychotherapy

In general, HCP reported skepticism towards psychological issues and psychotherapy as common among migrants and often mentioned, especially regarding persons of Turkish or Arab descent. On the one hand, these patients were described as favoring somatic explanations to health problems that were or could be of a psychological nature. On the other hand, some HCPs also mentioned the importance of spiritual support. Skepticism towards psychological issues was seen as more prevalent in male than in female migrants and sometimes attributed to a traditional approach to masculinity obliging men to be physically and mentally strong and healthy breadwinners.

> *I often hear that from patients, the Turks, who come to us to visit the psychiatrist, that is the very last alternative, if nothing at all works anymore. Those who try everything else, go to the imam; they don't believe in psychiatric diseases.*
>
> – Nurse (female, 35–44 years)

The Importance of Motherhood

The HCP observed that motherhood was a topic of major importance for migrant women of Turkish and Arab origin, more so than for women of the majority of the population. This was mainly connected to the appraisal of health information because information related to motherhood and pregnancy was considered much more relevant and valued more highly by migrant women than by women of German origin. The HCP also mentioned the necessity to gain a thorough understanding of the meaning of motherhood for migrant women in order to address the needs connected to its high priority. One physician also related this to the problem of systemic lack of time which kept her from learning more about this issue:

> *For example, we are dealing with women who have pain during sexual intercourse, and a Turkish woman who has pain during sexual intercourse or an Arab woman who has the expectation to become pregnant immediately after marriage, otherwise something is wrong, is something completely different than with a woman who perhaps has a vaginal infection. So I wish for that, but it belongs to the many things that I would like to learn, [but] for which I also probably don't have enough time.*
>
> – Physician (female, 45–54 years)

3.3. Needs

The HCPs reported their needs for solving gender-related issues within the health care setting almost exclusively on a general level addressing the understanding of health information. These needs were not limited to interactions with migrants of specific regions of origin or religions.

3.3.1. General Needs Regarding the Processing Step of Understanding Health Information

Cultural and Language Mediation/Interpretation

The need for interpretation services was stated repeatedly by the HCPs, although some expressed reservations concerning the greater need for time that could be caused by the interpretation process. Sometimes the participants combined this with the wish for those services to be covered by statutory health insurance. In several statements, the HCP wished for interpreters to act as cultural mediators as well. It was also stated that interpreters should have at least a basic level of medical knowledge.

> *Language is totally important, and I have just thought about it, we are always at the point to demand that there should be language mediators in this area [...] Actually, it would be right for the health insurance companies. The health insurance funds would reduce health costs if, I believe, they were to finance language mediators so that doctors could use them locally, etc.*
>
> – Other HCP (female, 35–44 years)

Need for More Time

While systemic lack of time was stated as a general challenge, the need for more time when dealing with persons with a migrant background played an important role as well. Time was said to be needed for overcoming language barriers but also for building a trusting relationship between HCP and patient. In this regard, the patient's appraisal of health information as coming from a trusted source was also connected to the need for more time.

> *That, I think, is also such a general topic, time, so that is something I perceive quite fundamentally, [. . .] I really need much more time to explain things [. . .].*
>
> – Other HCP (female, 35–44 years)

3.4. Solutions

The applied solutions described were related to general issues concerning the interaction with migrants as well as to challenges that had a gender-specific aspect to them. Similar to the challenges stated by the HCP, the statements related to the processing steps access, understand and appraise.

3.4.1. General Solutions Regarding the Processing Step of Understanding Health Information

Cultural and Language Mediators/Interpreters

Many HCP who had already worked with interpreters described this as helpful for the mutual understanding of HCPs and patients. On the other hand, some HCPs found the presence of a third person to complicate the relationship with the patient and slow down communication. All in all, interpreters were regarded as helpful for improving communication regardless of the genders of HCPs and patients, with no differences being stated for migrants of certain origins or religions. In one case regarding a refugee woman, consulting a remote video interpretation service helped to solve a misunderstanding concerning gender roles. Here, the husband's role as a gatekeeper preventing his wife from leaving the house had merely been assumed by the HCP.

> *We currently have a mentally ill pregnant woman, and we thought all the time, she is not allowed to go out and she is so mentally impaired that she does not go out alone, but then* [it occurred] *in a conversation that she does not know it from home, that they live in such a group of houses, inside is a yard, where the women meet, where the women move, but outside this yard, they don't go anywhere and so she can't find her doctor and doesn't come to any psychologist and we had thought the whole time, the man doesn't want that and then we had a video interpreter with us and then it came out that the man is actually completely open and just his wife isn't used to going any ways alone.*
>
> – Physician (female, ≥55 years)

3.4.2. Gender-Specific Solutions Regarding Access to Health Information

Covering Parts of the Body to Mitigate Shame

In some cases, HCPs reported that Muslim women covered parts of their bodies during examination or care, sometimes using blankets provided by the HCP for this purpose, sometimes wearing full-body suits when they were washed. Those solutions were found to be feasible, despite being cumbersome and time-consuming workarounds.

> *I notice for example that Germans sometimes [...] they come in and take off everything from bottom to top, [...] really naked. The Syrian or Iraqi or Muslim woman usually doesn't do that. [...] So first she is ashamed and when I say, for example, on the chair, I will examine the breast now, then she says "No, first I dress from below", so that she has a feeling, half of it is already covered and then she undresses the upper body.*
>
> – Physician (female, ≥55 years)

3.4.3. Gender-Specific Solutions Regarding the Appraisal of Health Information

Women as Pioneers for the Acceptance of Psychotherapy

Although the HCP found men of Turkish or Arab descent to be particularly skeptical about psychotherapy, some reported to observe a paradigm shift in that regard, with men belonging to this group slowly developing acceptance for this kind of treatment. Within this process of reappraisal, women were sometimes described to act as pioneers.

> *The first ones with a migrant background were Turkish women brought by their daughters. [. . .] And that's really a development, until it came gradually that oriental men also came with the feeling that they had a psychological problem and you had to talk about it.*
>
> – Physician (female, ≥ 55 years)

4. Discussion

This qualitative study explored the perceptions of health care professionals of gender aspects of their interactions with migrants mainly from Turkey and Arab countries. The interrelated challenges, needs and applied solutions were analyzed from a health literacy perspective. By relating the statements of HCP to the processing steps of health literacy, gender-specific challenges could be identified primarily regarding the access to health care and the appraisal of health-related information. Described needs and applied solutions mainly concerned mutual understanding between HCP and migrants.

Most of the statements concerned challenges the HCP experienced when dealing with persons with a migrant background. Three main gender-specific challenges related to the access to health information emerged from these statements: Husbands as gatekeepers regulating access of their wives to health care, the gender of HCP as a factor that could keep migrant women from receiving treatment or care from male HCPs, and shame in the health care situation hindering proper examination especially of Muslim women. The HCP rarely tried to provide explanations for such situations. Even though such situations seemed to occur mainly in the interaction with patients who were identified as Muslims by the HCP, they did not speculate on the exact role of religion in these cases. This may illustrate a lack of knowledge about Islam on part of some HCPs, but it was also the case for HCPs of Arab or Turkish origin who were more familiar with this religion than their colleagues. From the HCPs' statements, it seemed that religion was usually not addressed directly in the treatment situation. Thus, many relevant aspects remained unclear, such as whether the patient was indeed a Muslim, what Islamic subgroup he or she belonged to or how important religion was to the patient. With gender equity being comparably low in most predominantly Islamic countries [48], relating gender aspects in the interaction with migrants to their religion may be tempting but probably a premature conclusion. For example, regulating the gender relations is not exclusive to Islam but can be found in many religions including Christianity, usually putting men in the more powerful position [49]. In a highly secular country as Germany, some observations of gender aspects might be misunderstood as specific to persons of Islamic faith while they may rather be connected to religiosity in general. The understanding of health as an individual matter, as it prevails in Germany, is not shared in many countries, especially not in Islamic regions, where the health of a person is often perceived as a family affair [50]. Thus, Muslim husbands may feel responsible for the health of their wives in a more pronounced way than non-Muslims [51]. Also, mistrust in authorities was sometimes mentioned by the HCP regarding migrants from countries with authoritarian political systems. This might also play a role in the protective behavior observed in some migrant husbands. There is some evidence for the importance of gender concordance with the HCP for women of Islamic faith in general [52] and for Turkish women in Germany [53] as well as for a restraint in Muslim women concerning nudity [54,55]. Again, the HCPs did not elaborate on how religion might influence the women's perceived preferences. These categories describe that cultural differences in the personal determinant of gender were observed to primarily influence access to health care and health-related information. They also show that gender may be a personal determinant, but its impact on health literacy within the health care situation depends on the genders of all persons involved and on their respective interpretations and expectations regarding gender roles. These findings underline the social and relational character of health literacy.

The general subcategory Systemic lack of time describes a phenomenon well known in health care [56,57]. On average, primary care consultations in Germany last only 7.6 min; in a current systematic review, this was found to be one of the shortest durations among Western industrial nations [58]. Systemic lack of time can be interpreted as an omnipresent stressor concerning all actors within health care, with particular effect on the interactions with migrant patients. Research in social psychology has shown that people resort to stereotypes under time pressure [59]; this might have influenced the HCPs' perceptions and descriptions of the interactions with migrant patients as well. With systemic lack of time as a backdrop, the second general challenges subcategory regarding the understanding of health-related information directly relates to a migration-specific issue: Language barriers. If communication was impaired due to language barriers, examinations and treatments were perceived to be compromised. This is in line with research demonstrating language barriers to be a serious disadvantage for migrants trying to obtain health care [60–63]. Time pressure seems to have an even stronger impact when it comes to dealing with patients who need more time due to the necessity of overcoming language barriers. This impact is further reinforced by gender-specific aspects of language barriers. The comparably low level of German proficiency within the group of elderly Turkish women has already been documented by researchers in Germany [64]. Additionally, the HCPs reported a high prevalence of depressive symptoms combined with a rather dismissive attitude towards psychotherapy within this group. This corresponds to current research which identified first generation migrant women from Turkey as especially vulnerable for depressive disorders [65] and skepticism towards psychotherapy to be more common in first- and second-generation migrants from Turkey than in the general population [66]. This connects to further gender-specific challenges which could be identified regarding the processing step of appraising health information. Although skepticism towards psychotherapy is generally known to be more common in men than in women [67,68], the HCPs mentioned it especially regarding men from Turkey and Arabia. Some saw a part of these men to favor a more traditional interpretation of masculinity, which has been found to be common for example in Turkey [69], and which is connected to a tendency to reject psychotherapy [70]. On the other hand, the availability of insurance-covered psychotherapy is special to Germany [71] and not common in Turkey [72]; unfamiliarity with the method may contribute to the skepticism against it. The importance of motherhood the HCPs observed in migrant women was regarded as a minor challenge, illustrating how persons from different cultures may evaluate the same piece of health information differently based on the relevance it has to their lives. In Germany, voluntary childlessness is much more common than in other countries [73], so that the significance of motherhood for migrant women could be an indication of the special situation in Germany rather than a particular feature of migrant women.

Gender aspects seem to act as a reinforcing factor for the general time problem within health care in Germany. In the case of migrants, overcoming language barriers takes time. If these barriers are higher, for example due to gender-specific reasons as in the case of the elderly Turkish women, communication takes even more time. In case it is necessary for these patients to undress in the health care setting, shame may additionally slow down the process. If the HCP is a male person, shame may play an even more important role and can stall the process even further. These phenomena were mostly seen in specific subpopulations, and we may not be able to understand them without considering cultural and religious aspects that should be analyzed in further research.

The HCP did not report on the needs for specifically solving gender-specific challenges. Instead, they almost unanimously addressed the needs for more time and for cultural and language mediators/interpreters. This suggests that the HCP see the processing step of understanding health-related information as the key health literacy element in the context of migration. Importantly, in most cases understanding was described as a mutual process—understanding the patient as well as making oneself understood by the patient. Meeting the need for more time may be to the benefit of migrant patients and to that of the whole population; doctors giving more time to the individuals instead of doing "five minutes of medicine", as one physician put it in an FGD, would serve the HCP as well as the patients [74,75]. The shortage of HCPs in Germany is a widely discussed situation [76,77] which still does not seem to improve substantially [78]. Our research is in line with these observations. In the context of ongoing migration, the effects of this problem are particularly evident.

The HCPs also reported on applied solutions to solve the challenges they had elaborated on. Regarding *access* to health care, the gender-specific solution of covering parts of the body to mitigate shame of Muslim women was seen as a feasible, albeit cumbersome solution. As a general solution for addressing the processing step of understanding, some had already worked with cultural and language mediators/ interpreters, most of them reporting positive results, which is in line with studies focusing on the effectiveness of interpreter services [79–81]. Although being a general solution, this could also help with gender-specific aspects of language barriers. Regarding the processing step of appraisal, the gender-specific solution women as pioneers for the acceptance of psychotherapy seems especially remarkable in several ways, as it is (a) a solution coming from the migrants themselves and (b) an example for the (self-) empowerment of women being advantageous to men as well.

The three concepts gender, migrant background and health literacy can be understood very differently [82–84]. Within the FGD, participants addressed gender using the man-woman dichotomy with a strong emphasis on gender roles. The usage of the term migrant background was slightly different from the definition introduced by the moderators, because the participants usually referred to first generation migrants (as opposed to first- and second-generation migrants). In some respects it can be justified to examine the diversity of migrants in Germany as a group instead of focusing on certain subgroups. This is the case when it comes to phenomena associated with transnational migration in general, such as the need to find orientation in an unfamiliar health care system or to communicate in a new language. Looking at migrants in general can also reveal aspects that are special to the host countries instead of ascribing differences between migrants and non-migrants to culture, religion or other attributes of a certain migrant group. In contrast, the term migrant background, which is very common in German administration and research, covers people with and without a direct migration experience and is therefore known to be a controversial concept [85]. As the HCPs in the FGD used it almost exclusively for first generation migrants, the term seems dispensable at least for the purpose of this study. Furthermore, the HCPs often focused on patients of Turkish or Arabic descent. Most migrants living in Germany are of Turkish origin, and refugees from Syria and Iraq came to Germany in large numbers in recent years [86]. Although there are more people of Polish origin in Cologne than there are people of Iraqi, Syrian, Algerian, Moroccan, Libyan and Lebanese origin combined [87], not a single statement referred to persons of Polish origin. Migrants from Russia were only mentioned in connection with female health care representatives feeling rejected by male patients. It may be the case that the HCPs had only few encounters with patients of Polish origin, but this may also pose the question who is regarded as having a migrant background at all [88]. Additionally, only one of the HCPs was of Eastern European origin, but eight HCPs had roots in Turkey and Arab countries and reported to dealing with many patients from these regions, which may have contributed to focusing on these migrant groups during the FGD. Unsurprisingly, the term health literacy was rarely mentioned literally. Health literacy is a very broad concept; in real-life situations its determinants and processing steps may be observed rather than health literacy as a whole.

Regarding the health literacy model by Sørensen et al. [24] the allocation of statements to the processing steps was never a clear-cut decision, as these steps may overlap and interact. Our study partly questions the sequential nature of accessing, understanding, appraising and applying health-related information as proposed by Sørensen et al. [24]. From the perspective of the HCP, the negative appraisal of psychotherapy especially by migrant men prevented them from accessing information about this way of treatment. This is consistent with psychological research, which has shown the interrelatedness of perception and appraisal on multiple occasions [89,90]. Mutual understanding, improved by involving an interpreter, can eliminate false assumptions as in the case of the erroneously assumed role of a husband as a gatekeeper (see 3.2.1). This case also shows that understanding can also enable access. Furthermore, the health literacy of the HCP interacted with that of their migrant patients. A good example for this interaction is the processing step of understanding health information: By far the most statements in this regard were directed at reciprocal understanding. The ability to understand the patients and the ability of the patients to understand the HCP are mutually dependent. This emphasizes the social-relational nature of health literacy as well as its process character that already has been called "doing health literacy" [91].

By mapping real-life situations from the perspectives of HCPs to the integrated model of health literacy by Sørensen et al. [24], our research contributes to a deeper understanding of cross-cultural health care situations. Our findings suggest that challenges regarding the appraisal of health-related information may be connected to needs and solutions directed at a different processing step, namely understanding. To our knowledge, this is the first study exploring gender-specific aspects of health literacy of migrants from the perspective of HCP. A specific strength of our research lies in the application of the health literacy model by Sørensen et al. [24] to qualitative data with a concrete assignment of statements to the respective steps of health information processing. As far as we know, this has not yet been explored and can help to understand the complex relationships between systemic factors and gender aspects in the context of migration. Furthermore, our findings contribute to the further development of the concept of health literacy by (a) emphasizing the social-relational character of health literacy and (b) describing its processing steps as iterative rather than sequential elements. Another advantage of this research lies in the composition of the FGD. The participants were HCP from different professions, covering a wide range of ages and including first- and second-generation migrants as well as non-migrants.

There are several limitations to this study. First, it might be the case that the research question provoked generalizations about the diverse group of migrants. Asking the participants to refer to specific situations was aimed at preventing this. This may not have worked in every case, as relating to specific situations can mislead in regarding them as typical or representative for the migrant group mentioned. Second, the observations reported in this study may evoke stereotypes about persons of Islamic faith, a matter we intensely discussed within the research team. Although the participants of the FGD spoke with great empathy for migrants and more than 50% of them were first or second generation migrants themselves, it cannot be ruled out that stereotypes about persons of Islamic faith, for example about male Muslims [92,93] shaped some of their statements as well. With anti-immigration and anti-Islamic movements rising all over Europe [94,95], this is a delicate ethical matter, especially for researchers positioning themselves as favoring openness and equity. It is crucial not to see possible biases in their perceptions as personal deficits of the HCP. Stereotypes belong to the cognitive toolbox of all persons [96]. Overcoming them is especially difficult when acting under time pressure as it is the case in health care. The HCPs reported situations in which migrant women experienced serious health care disadvantages the HCP related to gender roles. We think these findings are important and should be reported. There may be situations that demand that HCPs act against perceived gender taboos in order to ensure adequate health care, especially for women, and there may be cases when doing so would do more harm than good. These difficult decisions have to be made by the HCP in every single case, and they clearly stated they need support in doing so. They strongly called for measures to improve mutual understanding with migrants. This indicates that they saw incomprehension and misunderstandings on both sides as the main causes of the challenges they perceived in interacting with migrants. Third, qualitative research is not aimed at representativeness [97]. This is also true for this study, as neither the participants are a representative selection of HCPs, nor the situations they described can be considered representative for the interaction with migrants. In most cases, gender-specific observations made by the HCP were limited to migrants from Turkey and Arab countries. Finally, it has to be mentioned that the FGD were held in the German language and translated into English. That may lead to a loss of information and/or bias in the meaning of the translated statements as they are presented in this manuscript.

Exploring the challenges, needs and applied solutions with regard to achieving optimal health care within different subpopulations of migrant men and women by letting them state their own perspective was outside the scope of this project. From our view, this would be the logical next step for further research in order to gain a more complete picture about gender-related aspects of health literacy in interactions with migrant patients.

5. Conclusions

Our research provides insights into the special role of gender in health literacy as perceived by HCPs when interacting with migrant patients mainly from Turkey and Arab countries. These results only represent the possibly biased or assumption-based perspectives of health care professionals on their migrant patients. From the HCPs' point of view, gender-specific challenges can result in consequences for the way in which health-related information is accessed, understood, and appraised in cross-cultural health care situations. It also shows that meeting these challenges by reducing time pressure and providing resources for improving communication may help HCPs to better understand the individual needs of their patients and prevent them from using heuristics that can be associated with stereotyping. This may be to the benefit of all actors within the health care sector—HCPs as well as persons of all genders and countries of origin. The results of our study can sensitize HCPs and policy makers to gender-specific challenges in the cross-cultural health care settings and show possible starting points for their solutions, especially at the level of mutual understanding of HCPs and migrants. Further research should focus on the perspective of the migrants themselves, considering the specific situations of different groups from different countries of origin.

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Appendix iii: Study III (Systematic review)

Baumeister A, Aldin A, Chakraverty D, Monsef I, Jakob T, Seven ÜS, Anapa G, Kalbe E, Skoetz N & Woopen C. (2019). Interventions for improving health literacy in migrants. *Cochrane Database of Systematic Reviews*, 11(11): CD013303. https://doi.org/10.1002/14651858.CD013303

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[Intervention Review]

Interventions for improving health literacy in migrants

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ABSTRACT

Background

Health literacy (HL) is a determinant of health and important for autonomous decision-making. Migrants are at high risk for limited HL. Improving HL is important for equitable promotion of migrants' health.

Objectives

To assess the effectiveness of interventions for improving HL in migrants. To assess whether female or male migrants respond differently to the identified interventions.

Search methods

We ran electronic searches to 2 February 2022 in CENTRAL, MEDLINE, Embase, PsycInfo and CINAHL. We also searched trial registries. We used a study filter for randomised controlled trials (RCTs) (RCT classifier).

Selection criteria

We included RCTs and cluster-RCTs addressing HL either as a concept or its components (access, understand, appraise, apply health information).

Data collection and analysis

We used the methodological procedures recommended by Cochrane and followed the PRISMA-E guidelines. Outcome categories were: a) HL, b) quality of life (QoL), c) knowledge, d) health outcomes, e) health behaviour, f) self-efficacy, g) health service use and h) adverse events. We conducted meta-analysis where possible, and reported the remaining results as a narrative synthesis.

Main results

We included 28 RCTs and six cluster-RCTs (8249 participants), all conducted in high-income countries. Participants were migrants with a wide range of conditions. All interventions were adapted to culture, language and literacy.

We did not find evidence that HL interventions cause harm, but only two studies assessed adverse events (e.g. anxiety). Many studies reported results for short-term assessments (less than six weeks after total programme completion), reported here. For several comparisons, there were also findings at later time points, which are presented in the review text.

Compared with no HL intervention (standard care/no intervention) or an unrelated HL intervention (similar intervention but different information topic)

Self-management programmes (SMP) probably improve self-efficacy slightly (standardised mean difference (SMD) 0.28, 95% confidence interval (CI) 0.06 to 0.50; 2 studies, 333 participants; moderate certainty). SMP may improve HIV-related HL (understanding (mean difference (MD) 4.25, 95% CI 1.32 to 7.18); recognition of HIV terms (MD 3.32, 95% CI 1.28 to 5.36)) (1 study, 69 participants). SMP may slightly improve health behaviours (3 studies, 514 participants), but may have little or no effect on knowledge (2 studies, 321 participants) or subjective health status (MD 0.38, 95% CI -0.13 to 0.89; 1 study, 69 participants) (low certainty). We are uncertain of the effects of SMP on QoL, health service use or adverse events due to a lack of evidence. ***HL skills building courses* (HLSBC)** may improve knowledge (MD 10.87, 95% CI 5.69 to 16.06; 2 studies, 111 participants) and any generic HL (SMD 0.48, 95% CI 0.20 to 0.75; 2 studies, 229 participants), but may have little or no effect on depression literacy (MD 0.17, 95% CI -1.28 to 1.62) or any health behaviour (2 studies, 229 participants) (low certainty). We are uncertain if HLSBC improve QoL, health outcomes, health service use, self-efficacy or adverse events, due to very low-certainty or a lack of evidence. ***Audio-/visual education without personal feedback (AVE)*** probably improves depression literacy (MD 8.62, 95% CI 7.51 to 9.73; 1 study, 202 participants) and health service use (MD -0.59, 95% CI -1.11 to -0.07; 1 study, 157 participants), but probably has little or no effect on health behaviour (risk ratio (RR) 1.07, 95% CI 0.91 to 1.25; 1 study, 135 participants) (moderate certainty). AVE may improve self-efficacy (MD 3.51, 95% CI 2.53 to 4.49; 1 study, 133 participants) and may slightly improve knowledge (MD 8.44, 95% CI -2.56 to 19.44; 2 studies, 293 participants) and intention to seek depression treatment (MD 1.8, 95% CI 0.43 to 3.17), with little or no effect on depression (SMD -0.15, 95% CI -0.40 to 0.10) (low certainty). No evidence was found for QoL and adverse events. ***Adapted medical instruction*** may improve understanding of health information (3 studies, 478 participants), with little or no effect on medication adherence (MD 0.5, 95% CI -0.1 to 1.1; 1 study, 200 participants) (low certainty). No evidence was found for QoL, health outcomes, knowledge, health service use, self-efficacy or adverse events.

Compared with written information on the same topic

SMP probably improves health numeracy slightly (MD 0.7, 95% CI 0.15 to 1.25) and probably improves print literacy (MD 9, 95% CI 2.9 to 15.1; 1 study, 209 participants) and self-efficacy (SMD 0.47, 95% CI 0.3 to 0.64; 4 studies, 552 participants) (moderate certainty). SMP may improve any disease-specific HL (SMD 0.67, 95% CI 0.27 to 1.07; 4 studies, 955 participants), knowledge (MD 11.45, 95% CI 4.75 to 18.15; 6 studies, 1101 participants) and some health behaviours (4 studies, 797 participants), with little or no effect on health information appraisal (MD 1.15, 95% CI -0.23 to 2.53; 1 study, 329 participants) (low certainty). We are uncertain whether SMP improves QoL, health outcomes, health service use or adverse events, due to a lack of evidence or low/very low-certainty evidence. ***AVE*** probably has little or no effect on diabetes HL (MD 2, 95% CI -0.15 to 4.15; 1 study, 240 participants), but probably improves information appraisal (MD -9.88, 95% CI -12.87 to -6.89) and application (RR 1.51, 95% CI 1.29 to 1.77) (1 study, 608 participants; moderate certainty). AVE may slightly improve knowledge (MD 8.35, 95% CI -0.32 to 17.02; low certainty). No short-term evidence was found for QoL, depression, health behaviour, self-efficacy, health service use or adverse events.

AVE compared with another AVE

We are uncertain whether narrative videos are superior to factual knowledge videos as the evidence is of very low certainty.

Gender differences

Female migrants' diabetes HL may improve slightly more than that of males, when receiving AVE (MD 5.00, 95% CI 0.62 to 9.38; 1 study, 118 participants), but we do not know whether female or male migrants benefit differently from other interventions due to very low-certainty or a lack of evidence.

Authors' conclusions

Adequately powered studies measuring long-term effects (more than six months) of HL interventions in female and male migrants are needed, using well-validated tools and representing various healthcare systems.

PLAIN LANGUAGE SUMMARY

What are the benefits and risks of health literacy interventions for migrants?

Health literacy (HL) means the knowledge, motivation and competencies (e.g. reading and writing abilities) that people need to find, understand, evaluate and use health information. Migrants are at risk for difficulties in HL (e.g. when they don't know the country's health system well).

'Generic' HL means that people can find, understand and use general health information to make health decisions. 'Disease-specific' HL means that people can find, understand and use information about a certain disease or that they know about the symptoms of a disease or understand treatment options.

Key messages

We have moderate to low confidence in these findings that some HL interventions have small to moderate positive effects on migrants' HL. This means that these interventions can help people improve their knowledge, recognition and understanding of medical terms, or use of health information.

There is a need for larger, well-designed studies that measure long-term effects of HL interventions in migrant women and men.

What did we want to find out?

Our main goal was to find out whether HL interventions can help migrants to improve their HL. We also wanted to find out if migrant women or migrant men benefit more from these interventions.

What did we do?

We searched for studies that looked at interventions for improving HL in migrants. These interventions were compared with 1) no HL intervention (e.g. standard care), 2) written information on the same health topic (e.g. brief brochure), 3) an unrelated HL intervention (participants received a similar intervention, but the information was on a *different* health topic), or 4) another HL intervention (participants received a different intervention, but the information was on the *same* health topic).

The included studies measured HL either as an overall concept or only components of it (e.g. understanding health information). We compared and summarised the results of studies and rated our confidence in the evidence, based on factors like study methods.

What did we find?

We found 34 studies that involved 8249 migrants with a wide range of health conditions. All studies were conducted in high-income countries. All interventions were adapted to the participants' culture, language and literacy level. None of the studies reported that HL interventions cause harm, but only two studies reported possible harms (anxiety). Many studies reported short-term results (up to six weeks after the intervention ended, the focus in this summary). There were also several findings at later time points (presented in the main review).

Compared with no or unrelated HL intervention:

Self-management programmes (SMP)*(long-term programmes including group education and personal support)* probably improve self-efficacy in managing one's disease slightly (which means that the participants had higher beliefs in their abilities to act on health information). SMP may also improve disease-specific HL and may slightly improve health behaviour, but may have little effect on knowledge or self-rated health. We do not know if SMP improves quality of life (QoL) or health service use.

HL skills building courses *(group education in which participants, for example, learn what to do to prevent a disease)* may improve knowledge and generic HL, but they may have little effect on depression literacy or health behaviour. We do not know if they improve QoL, health outcomes, health service use or self-efficacy.

Audio-/visual education without personal feedback (AVE)*(including video education, interactive computer education or printed educational photo stories)*probably improves depression literacy and health service use. AVE may improve self-efficacy and slightly improve knowledge and intention to seek depression treatment, but may have little effect on health behaviour or depression. No study reported on QoL.

Adapted medical instructions *(medical instructions that use simple language, illustrations or pictures)* may improve understanding health information, but may have little effect on medication adherence. No study reported on QoL, health outcomes, knowledge, health service use or self-efficacy.

Compared with written information:

SMP probably improves print literacy and self-efficacy, and health numeracy slightly. SMP may improve any disease-specific HL, knowledge and some health behaviours, but may have little effect on health information appraisal. We do not know whether SMP improves QoL, health outcomes or health service use.

AVEprobably has little effect on diabetes HL but probably improves information appraisal and application. AVE may slightly improve knowledge. No study reported on QoL, depression, health behaviour, self-efficacy or health service use.

AVE compared with another AVE:

We are uncertain if narrative videos are better than factual knowledge videos as the evidence was very uncertain.

Do migrant women or men benefit differently from HL interventions?

Migrant women's diabetes HL may improve slightly more than that of migrant men after receiving AVE. For other comparisons and outcomes we either did not find evidence, or we are uncertain about the results.

What are the limitations of the evidence?

It is possible that people in some studies knew which treatment they were getting. In addition, studies were done in different migrant groups, coming from different regions and with different health conditions, and some studies included few people.

How up-to-date is this evidence?

This review is up-to-date to 2 February 2022.

SUMMARY OF FINDINGS

Summary of findings 1. Culturally and literacy adapted self-management programme versus no health literacy intervention

Culturally and literacy adapted self-management programme versus no health literacy intervention

Patient or population: migrants
Setting: all settings
Intervention: culturally and literacy adapted self-management programme (programme length: 6 to 12 months)
Comparison: no health literacy intervention (usual care, placebo intervention or wait-list control)

Outcome category – outcome(s)*	**Anticipated absolute effects (95% CI)**		**Relative effect (95% CI)**	**№ of participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
	Risk with no health literacy intervention	**Risk with self-management programme**				
Health literacy – **Disease-specific health literacy** Assessed with: • functional HIV health literacy; understanding and recognition of HIV terms[1] (score range: 0 to 24, both scales) Higher scores are better Time point: short-term (immediately post-intervention)**	One RCT reported that the change from baseline score for understanding of HIV terms was 4.25 points higher (1.32 higher to 7.18 higher) and recognition of HIV terms was 3.32 points higher (1.28 higher to 5.36 higher) in the intervention group.		—	69 (1 RCT)	⊕⊕◯◯ Low[a]	Self-management programmes compared to no health literacy intervention may improve disease-specific health literacy (HIV health literacy) immediately post-intervention.
Quality of life	—		—	—	—	The effect of self-management programmes is unknown as there was no direct evidence identified.
Health-related knowledge – Multiple measures used: **(1)Diabetes knowledge**	**(1) Diabetes knowledge** One RCT (N = 252) reported that the mean diabetes knowledge score was 5.6 points higher (range = 2.2 higher to 9.0 higher) in the inter-		—	321 (2 RCTs)	⊕⊕◯◯ Low[b,c]	Self-management programmes compared to no health literacy intervention may have little or no effect on

- subset of ADKnowl, adapted version, score range: 0 to 104[2] **(2) HIV knowledge** 1. HIV global disease/treatment knowledge, true/false questionnaire (standardised on score 0 (no knowledge) to 100 (perfect knowledge) 2. Knowledge of risk of getting sicker without continuing HIV medication, 4 = very high risk, 1 = non-existent risk, higher score is better[3] Time point: short-term (immediately post-intervention)	vention group. The mean knowledge score in the control group was 68; P = 0.001. **(2) HIV knowledge** One RCT (N = 69) reported that the mean HIV global disease/treatment knowledge was 1.18% lower (9.23 lower to 6.87 higher) in the intervention group, but the CI encompassed values indicating both an improvement and a reduction in knowledge. The same study reported that the mean knowledge of the risk of getting sicker when stopping taking one's HIV medication was higher in the intervention group: 0.33 higher (-0.01 lower to 0.67 higher) but the CI also encompassed values indicating a null effect.				health-related knowledge immediately post-intervention. One cluster RCT (n = 230) was missing information about participant numbers but reported that the intervention increased breast cancer-related knowledge (MD 0.5, $P < 0.0001$) at 6 months post test (very low certainty)[d,e] One other RCT (N = 194) was missing data about the control group but reported that knowledge about heart health increased in the intervention group 3 months post-intervention.[4]
<u>Health outcome</u> – **Self-reported health status** Assessed with: - 1 item, perceived health status in past week, score range: 0 to 1 Higher score is better Time point: short-term (immediately post-intervention)	One RCT reported that the mean subjective health status in the past week was 0.38 points higher (0.13 lower to 0.89 higher) in the intervention group immediately post-intervention, but the CI encompassed both an improvement and a reduction in subjective health status.	—	69 (1 RCT)	⊕⊕⊝⊝ Low[f]	Self-management programmes compared to no health literacy intervention may have little or no effect on subjective health status immediately post-intervention.
<u>Health behaviour</u>[5]– ***Time point a: short-term (immediately post-intervention)*** Multiple outcomes assessed and multiple measures used: **(1) Blood glucose self-monitoring**	***Time point a: short-term*** **(1) Blood glucose self-monitoring:** One RCT (n = 252) reported higher odds of self-reported blood glucose self-monitoring in the intervention group immediately post-intervention (RR 1.30, 95% CI 1.11 to 1.52) **(2) Adherence to HIV medication:** One RCT (n = 69) reported that the proportion of participants who reported > 95% adherence	—	514 (3 RCTs)	⊕⊕⊝⊝ Low[g,h]	Self-management programmes compared to no health literacy interventions may slightly improve any health behaviour immediately post-intervention, but outcome measures and effects appear variable. One cluster-RCT was missing information about the number of participants ran-

- 24-hour recall, 3 questions on blood glucose self-monitoring behaviour **(2) Adherence to HIV medication** - 1 item from ACTG Adherence Baseline Questionnaire; proportion with > 95% adherence within last 4 days **(3) Physical activity** Assessed with: - Accelerometer data, average daily steps Higher scores are better	to HIV medication within the last 4 days was higher in the intervention group immediately post-intervention (IG change score: 1.71%, CG change score: -4.85%) **(3) Physical activity:** One RCT (n = 193) reported that the mean average daily steps was higher in the intervention group, but the CI encompassed both an improvement and a reduction in physical activity immediately post-intervention (MD 289 daily steps higher, 95% CI 601.41 lower to 1179.41 higher)					domised to each study group, as well as the intensity and length of the programme. In addition, data were not reported in a way in which they could be extracted for meta-analysis.
Self-efficacy – **Self-efficacy to manage one's disease** Multiple measures used: - LSESLD (score range: 17 to 68) - 1 item from ACTG Adherence Baseline Questionnaire (score range: 0 to 3) Higher score is better Time point: short-term (immediately post-intervention)	—	The mean score in the intervention group was 0.28 standard deviations higher (0.06 higher to 0.50 higher)	—	333 (2 RCTs)	⊕⊕⊕⊝ Moderate[g]	Self-management programmes compared to no health literacy interventions probably improve self-efficacy to manage one's disease slightly.
Health service use – not measured	—	—	—	—	—	The effect of self-management programmes on health service use is unknown as there was no direct evidence identified.
Adverse events – not reported	—	—	—	—	—	The effect of self-management programmes on adverse events is unknown as there

was no direct evidence identified.

*More detail on scoring and direction for each outcome measure is provided in Table 1; Table 2; Table 3; Table 4; Table 5; **Short-term: immediately up to 6 weeks after the total intervention programme was completed; medium-term: from 6 weeks up to and including 6 months after the total intervention programme was completed; long-term: longer than 6 months after the total intervention programme was completed.

ACTG: Adult AIDS Clinical Trials Group; **ADKnowl**: Audit of Diabetes Knowledge; **CG:** control group;**CI:** confidence interval;**IG:** intervention group; **LSESLD:** Lifestyle Self-Efficacy Scale for Latinos with Diabetes; **MD:** mean difference; **n.r.:** not reported; **RCT:** randomised controlled trial; **RR:** risk ratio; **REALM:** Rapid Estimate of Adult Literacy in Medicine

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[1] Results for understanding HIV terms and recognition of HIV terms were reported separately in the study, and only change scores were reported.

[2] The score range was taken from publications cited by the study authors (Rosal 2003; Speight 2001), as it was not reported in the published trial report (Rosal 2011).

[3] To improve the interpretation of results, we transformed the original scale, which had negative values indicating better performance, into a positive scale with higher values indicating better performance.

[4] GRADE was not used due to missing control group data.

[5] All outcomes except physical activity were assessed via self-report.

[a] Downgraded by -2 for imprecision: result was based on a single study with a small sample size (less than 100) and wide CI.

[b] Downgraded by -1 for imprecision: narrative synthesis conducted and the CI of one study encompassed values indicating both an improvement and a worsening in the outcome. In addition, the sample size was small.

[c] Downgraded by -1 for inconsistency: CI of one study indicated a small improvement in the outcome. The other study reported two measures of knowledge; results of the first measure indicated a reduction in knowledge with a CI encompassing values suggesting both an improvement and a worsening. The second measure indicated an improvement in knowledge with a CI encompassing an improvement and a null effect (lower CI -0.01).

[d] Downgraded by -2 for risk of bias: unclear risk of bias in several domains including random sequence generation and allocation concealment.

[e] Downgraded by -1 for imprecision: missing information about the number of participants in the intervention and control groups; the length and intensity of the programme and effect measures were not reported per study group.

[f] Downgraded by -2 for imprecision: result was based on a single study with a small sample size (less than 100) and the CI encompassed values indicating both an improvement and a worsening.

[g] Downgraded by -1 for risk of bias: high risk of bias for blinding in 2 out of 3 studies, unclear risk of bias for allocation concealment in one study.

[h] Downgraded by -1 for inconsistency: Two studies indicated an improvement in health behaviour, but the CI of one study indicated a worsening or an improvement in physical activity.

Summary of findings 2. Culturally and literacy adapted self-management programme versus written information on the same topic

Culturally and literacy adapted self-management programme versus written information on the same topic

Patient or population: migrants
Setting: all settings
Intervention: culturally and literacy adapted self-management programme
Comparison: written information on the same topic (standard brochure, or written pamphlet)

Outcome category – outcome(s)*	**Anticipated absolute effects** (95% CI)**		**Relative effect (95% CI)**	**№ of participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
	Risk with written information on the same topic	**Risk with self-management programme**				
Health literacy – ***Time point a: short-term (immediately post-intervention)******** **(1) Any generic health literacy** Multiple outcomes assessed and multiple measures used: • Health numeracy (NVS, score range: 0 to 5) • Print literacy (REALM, score range: 0 to 66) Higher score is better **(2) Any disease-specific health literacy** Multiple measures used: • Cancer screening health literacy (AHL-C, score range: 0 to 52) • Oral health literacy (TS-REALD, scaled score: 27 to 73) • High blood pressure health literacy (HBP Health Literacy Scale, score range: 0 to 43) • Diabetes health literacy (DM-REALM, score range: 0 to 82) Higher score is better **(3) Appraising health information**	***Time point a: short-term*** **(1) Any generic health literacy** One RCT reported that the intervention slightly increased health numeracy (NVS) immediately post-intervention (MD 0.7 points higher (0.15 higher to 1.25 higher)). The same RCT reported that the intervention increased generic print literacy (REALM) immediately post-intervention (MD 9.00 points higher (2.90 higher to 15.10 higher)).		—	209 (1 RCT)	⊕⊕⊕⊝ Moderate[a]	Self-management programmes compared to written information on the same topic probably improve health numeracy slightly and probably improve print literacy immediately post-intervention.
	(2) Any disease-specific health literacy The mean disease-specific health literacy score across intervention groups was 0.67 standard deviations higher (0.27 higher to 1.07 higher) immediately post-intervention.		—	955 (2 RCTs, 2 cluster-RCTs[1])	⊕⊕⊝⊝ Low[b,c]	Self-management programmes compared to written information on the same topic may improve any disease-specific health literacy immediately post-intervention.[2]
	(3) Appraising health information (decisional balance for using mammography or Pap testing) The mean decisional balance score in the intervention group was MD 1.15 points higher (0.23 lower to 2.53 higher) than in the control group immediately post-intervention.[3]		—	329 (1 cluster-RCT[1])	⊕⊕⊝⊝ Low[d,e]	Self-management programmes compared to written information may have little or no effect on the appraisal of health information (decisional balance) immediately post-intervention.
	Time point b: medium-term		—	(242) (1 cluster-RCT[1])	⊕⊕⊝⊝ Low[a,d]	Self-management programmes compared to written information

Assessed with: - Decisional balance measure (weighing pros and cons for mammography and Pap testing (5 pros and 9 cons, 5-point Likert scale) Higher score is better ***Time point b: medium-term (6 months post-intervention)*** **(1) Disease-specific health literacy** - High blood pressure health literacy (HBP Health Literacy Scale, score range: 0 to 43) Higher score is better	The mean high blood pressure health literacy in the control group was 25.3	The mean high blood pressure health literacy in the self-management group was MD 4.10 higher (0.97 higher to 7.23 higher) than in the control group				on the same topic may slightly improve high blood pressure health literacy 6 months after the programme was completed.
<u>Quality of life</u> – **Diabetes-related quality of life** standardised on score 0 (no quality of life) to 100 (perfect quality of life) Time point: short-term (immediately post-intervention)	The mean score for diabetes-related quality of life ranged from 66.5% to 96.2%	The mean diabetes-related quality of life score in the intervention groups was MD 9.06 points higher (2.85 higher to 15.27 higher)	—	288 (2 RCTs)[3]	⊕⊝⊝⊝ Very low[a,f,g]	We are uncertain whether self-management programmes compared to written information on the same topic improve diabetes-specific quality of life immediately post-intervention.
<u>Health-related knowledge</u> – ***Time point a: short-term (immediately post-intervention)*** **Any health-related knowledge** standardised on score 0 (no knowledge) to 100 (perfect knowledge)	***Time point a: short-term***		—	1101 (4 RCTs, 2 cluster-RCTs[1])	⊕⊕⊝⊝ Low[h,i]	Self-management programmes compared to written information on the same topic may improve health-related knowledge immediately post-intervention.
	The mean health-related knowledge score across control groups ranged from 24.4% to 74.2%	The mean score in the intervention groups was MD 11.45 points higher (4.75 higher to 18.15 higher)				
Time point b: medium-term (up to 6 months post-intervention) **Any health-related knowledge** standardised on score 0 (no knowledge) to 100 (perfect knowledge)	***Time point b: medium-term***		—	298 (2 RCTs)	⊕⊕⊝⊝ Low[d,e]	Self-management programmes compared to written information on the same topic may have little or no effect on health-related knowledge up to 6 months post-intervention.
	The mean health-related knowledge score across control groups was 73.7%	The mean knowledge score in the intervention groups was MD 3.87 points higher				

		(0.46 lower to 8.19 higher)				
Health outcome – **Any depression** ***Time point a: short-term (immediately post-intervention)*** Multiple measures used: - PHQ-9K (score range: 0 to 27) - KDSKA (score range: 0 to 75) - CES-D (score range: 0 to 60) Lower score is better ***Time point b: medium-term (up to 6 months post-intervention)*** Multiple measures used: - PHQ-9K (score range: 0 to 27) - CES-D (score range: 0 to 60) Lower score is better	***Time point a: short-term***		—	555 (3 RCTs, 1 cluster-RCT[1])	⊕⊝⊝⊝ Very low[j,k,l]	We are uncertain whether self-management programmes compared to written information on the same topic improve depression immediately post-intervention.
	—	The mean depression score in the intervention group was 0.19 standard deviations lower (0.62 lower to 0.23 higher)				
	Time point b: medium-term		—	267 (1 RCT, 1 cluster-RCT[1])	⊕⊕⊝⊝ Low[e,m]	Self-management programmes compared to written information on the same topic may have little or no effect on depression 6 months post-intervention.[2]
	—	The mean depression score in the intervention group was 0.32 standard deviations lower (0.90 lower to 0.27 higher)				
Health behaviour – Multiple outcomes assessed and multiple measures used ***Time point a: short-term (immediately post-intervention)*** **(1) Diabetes self-care activities** - SDSCA (score range: n.r.[4], higher score is better) **(2) Oral self-care behaviour** - Questionnaire (no further information), higher score is better **(3) Cervical/breast cancer screening adherence** - Medical record review	***Time point a: short-term*** **(1) Diabetes self-care activities** One RCT (n = 79) reported that the self-management programme improved diabetes self-care activities (MD 15 points higher (7.87 higher to 22.13 higher) **(2) Oral self-care behaviour** One RCT (n = 140) found that the intervention improved self-reported oral self-care behaviour (MD 3.1 points higher (2.5 higher to 3.7 higher) **(3) Cervical/breast cancer screening adherence** One cluster RCT (n = 336) that properly accounted for the cluster design, found that the intervention improved cervical/breast cancer		—	797 (2 RCTs, 2 cluster-RCTs)[6,7]	⊕⊕⊝⊝ Low[m,n]	Self-management programmes compared to written information on the same topic may improve health behaviour immediately post-intervention, but measures and sizes of effects appear variable.

(4) Non-adherence to blood pressure medication: - 24-hour recall, 3 questions on blood glucose self-monitoring behaviour, lower score is better ***Time point b: medium-term (up to 6 months post intervention)*** **(1) Non-adherence to blood pressure medication** - HB-MAS (score range: 8 to 32, lower score is better) **(2) Blood glucose self-monitoring:** - 24-hour recall, 3 questions on blood glucose self-monitoring behaviour	screening adherence (RR 7.17, 95% CI 3.96 to 12.99)[8] **(4) Non-adherence to blood pressure medication** One cluster-RCT (N = 242) reported that the mean non-adherence to blood pressure medication was 0.4 points lower (0.87 lower to 0.07 higher) in the intervention group. The mean non-adherence score in the control group was 9.2.					
	Time point b: medium-term **(1) Non-adherence to blood pressure medication** One cluster-RCT (n = 242) reported that the intervention had slightly lower scores on non-adherence to blood pressure medication (MD 0.40 points lower (0.78 lower to 0.02 lower)). The mean non-adherence score in the control group was 8.8. **(2) Blood glucose self-monitoring** One RCT (n = 23) reported greater self-reported blood glucose-self-monitoring in the intervention groups 4.5 months post-intervention (RR 1.96, 95% CI 0.76 to 5.03).		—	265 (1 RCT, 1 cluster-RCT[1])	⊕⊕⊝⊝ Low[l,o]	Self-management programmes compared to written information on the same topic may slightly improve health behaviour 6 months post-intervention, but outcome measures and size of effects appear variable.
Self-efficacy– **Self-efficacy to manage one's disease** ***Time point a: short-term (immediately post-intervention)*** Multiple measures used: - Adapted Stanford Chronic Disease Self-Efficacy Scale (score range: 0 to 80) - Questionnaire adapted from the HBP belief scale (score range: 8 to 32)	***Time point a: short-term***		—	552 (4 RCTs)	⊕⊕⊕⊝ Moderate[j]	Self-management programmes probably improve self-efficacy immediately post-intervention, when compared to written information on the same topic.[9]
	—	The mean self-efficacy score in the intervention group was 0.47 standard deviations higher (0.30 higher to 0.64 higher)				
	Time point b: medium-term		—	242 (1 cluster-RCT[1])	⊕⊕⊝⊝ Low[m,p]	Self-management programmes compared to written information may have little or no effect on high blood pressure self-
	The mean self-efficacy score in the	The mean self-efficacy score was MD 0.20 lower in the intervention				

- IMDSES (score range: 26 to 104) Higher score is better ***Time point b: medium-term (up to 6 months post-intervention)*** Self-efficacy to manage high blood pressure - Questionnaire adapted from the HBP belief scale (score range: 8 to 32) Higher score is better	control group was 26.1	group (1.16 lower to 0.76 higher) 6 months post-intervention				efficacy 6 months post-intervention.
Health service use – not reported	—	—	—	—	—	The effect of self-management programmes on health service use is unknown as there was no direct evidence identified.
Adverse events – not reported	—	—	—	—	—	The effect of self-management programmes on adverse events is unknown as there was no direct evidence identified.

* More detail on scoring and direction for each outcome measure is provided in Table 1; Table 6; Table 4; Table 7; Table 3; Table 5; Table 8; **The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI); ***Short-term: immediately up to 6 weeks after the total intervention programme was completed; medium-term: from 6 weeks up to and including 6 months after the total intervention programme was completed; long-term: longer than 6 months after the total intervention programme was completed.

ACTG: Adult AIDS Clinical Trials Group; **AHL-C:** Assessment of Health Literacy in Cancer Screening; **CG:** control group;**CI:** confidence interval;**DM-REALM:** Diabetes Mellitus-Rapid Estimate of Adult Literacy in Medicine; **GEE:** generalised estimating equations; **HB-MAS:** Hill-Bone Medication Adherence Scale; **HBP:** high blood pressure; **ICC:** intra-cluster correlation **IG:** intervention group; **IMDSES:** Insulin Management Self-Efficacy Scale; **KDSKA:** Kim Depression Scale for Korean Americans; **LSESLD:** Lifestyle Self-Efficacy Scale for Latinos with Diabetes; **MD:** mean difference; **NVS:** Newest Vital Sign; **PHQ:** Patient Health Questionnaire;**RCT:** randomised controlled trial; **REALM:** Rapid Estimate of Adult Literacy in Medicine; **RR:** risk ratio; **SDSCA:** Summary of Diabetes Self-Care Activities Scale; **TS-REALD:** Two Stage Rapid Estimate of Adult Literacy in Dentistry

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

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[1] Data have been re-analysed using the appropriate unit of analysis by considering the ICCs reported by Han 2017. For more details, see Unit of analysis issues.

[2] We applied the following rule of thumb to rate SMD effect sizes: 0.2 = small effect, SMD ≥ 0.5 = moderate effect, 0.8 = large effect; variation to this rule is SMD < 0.40 = small effect, SMD 0.4 to 0.7 = moderate effect, and SMD > 0.7 large effect (Higgins 2022). The effect size of this SMD was rated as being moderate. Although it was close to a 'large effect', the CI was wide with a lower CI indicating a possible small effect and an upper CI indicating a very large effect.

[3] Data for decisional balance of using mammography for breast cancer screening or Pap testing for cervical cancer screening were combined to create a single MD. Results for both scales are reported separately in Table 9.

[4] One RCT (n = 25) reported on diabetes-related quality of life but due to incomplete reporting, the direction and size of the effect was unclear.

[5] The validated SDSCA encompasses 11 core-items and 14 optional items (7-point Likert scale reflecting days per week) to assess self-reported diabetes-related self-care activities.

[6] Estimated from GEE model accounting for clustering within a church and adjusting for age, insurance, English proficiency, years in US, years of education, employment and family history of breast cancer; results for use of both tests are reported; results of separate analyses for breast cancer screening and cervical cancer screening are shown in Table 3.

[7] One RCT reported having assessed self-care activities, but did not report the results.

[8] The study also reported results for breast cancer screening adherence and cervical cancer screening adherence separately. Details are shown in additional Table 3.

[9] Effect size was rated as being moderate due to relatively narrow CI and an SMD near threshold (rule of thumb: 0.2 = small effect, SMD ≥ 0.5 = moderate effect, 0.8 = large effect; variation to this rule is SMD < 0.40 = small effect, SMD 0.4 to 0.7 = moderate effect and SMD > 0.7 = large effect; Higgins 2022).

[a] Downgraded by -1 for imprecision: result was based on a single study with a small sample size and/or CI was wide.

[b] Downgraded by -1 for risk of bias: unclear risk of bias for allocation concealment and/or random sequence generation in three out of four studies.

[c] Downgraded by -1 for inconsistency: considerable statistical heterogeneity ($I^2 > 75\%$).

[d] Downgraded by -1 for risk of bias: unclear risk of bias for random sequence generation and/or for allocation concealment.

[e] Downgraded by -1 for imprecision: result was based on two studies with a small sample size and the CIs encompassed values indicating both an improvement and a worsening in the outcome. In addition, the CI of one study was large.

[f] Downgraded by -1 for inconsistency: substantial statistical heterogeneity ($I^2 > 50\%$ to 75%), the direction of effect was generally consistent but one of the two CIs encompassed both an improvement and a worsening in this outcome.

[g] Downgraded by -1 for risk of bias: high risk of bias for blinding and outcomes were subjectively measured. One study was also at unclear risk of bias for allocation concealment.

[h] Downgraded by -1 for risk of bias: unclear risk of bias for random sequence generation and/or allocation concealment in five studies.

[i] Downgraded by -1 for inconsistency: substantial statistical heterogeneity ($I^2 > 90\%$). The direction of effect was generally consistent but CIs for two out of six effect estimates encompassed both an improvement and a worsening in knowledge.

[j] Downgraded by -1 for risk of bias: high risk of bias for blinding in all studies and outcome was subjectively measured, unclear risk of bias for allocation concealment and/or random sequence generation in three studies.

[k] Downgraded by -1 for inconsistency: substantial statistical heterogeneity ($I^2 = 79\%$), two out of four studies favoured written information (but CIs included both an improvement and a worsening in the outcome). The other two studies favoured the self-management programme.

[l] Downgraded by -1 for imprecision: CI encompassed values indicating both an improvement and a worsening in this outcome.

[m] Downgraded by -1 for risk of bias: unclear risk of bias for random sequence generation and/or allocation concealment, high risk of bias for blinding and outcome was subjectively measured.

[n] Downgraded by -1 for inconsistency: one study indicated little or no effect with a CI encompassing both an improvement and a small reduction in the outcome. The results of two studies indicated a large effect.

[o] Downgraded by -1 for imprecision: one CI encompassed both an improvement and a worsening in the outcome, the upper limit of the other CI was close to a null effect (-0.02).

[p] Downgraded by -1 for imprecision: the result was based on a single study with a small sample size and the CI encompassed values indicating both an improvement and a worsening.

Summary of findings 3. Culturally adapted health literacy skills building course versus no/unrelated health literacy intervention

Culturally adapted health literacy skills building course versus no/unrelated health literacy intervention

Patient or population: migrants
Setting: all settings
Intervention: culturally adapted health literacy skills building course
Comparison: no health literacy intervention (standard language course, or no additional intervention)/unrelated health literacy intervention (language course plus information on *different* health topic, or another skills building course plus information on *different* health topic)

Outcome category – outcome(s)*	**Anticipated absolute effects** (95% CI)**		**Relative effect (95% CI)**	**№ of participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
	Risk with no health literacy intervention	**Risk with health literacy skills building course**				
Health literacy – ***Time point a: short-term (up to 1 month post-intervention)****** **(1) Any generic functional health literacy** Multiple measures used: • TOFHLA (score range 0 to 100) • NVS (score range 0 to 6) Higher score is better **(2) Disease-specific health literacy** Depression literacy (i.e. depression knowledge) Assessed with: • D-Lit (score range: 0 to 22) Higher score is better ***Time point b: medium-term (6 months post-intervention*** **(1) Applying health information**	***Time point a: short-term (up to 1 month post-intervention)***		—	229 (2 RCTs)	⊕⊕⊝⊝ Low[a,b]	Health literacy skills building courses may improve any generic functional health literacy up to 1 month post-intervention, when compared to no or unrelated health literacy intervention.[1]
	—	The mean functional health literacy score in the intervention group was 0.48 SD higher (0.20 higher to 0.75 higher)				
	The mean depression literacy score in the control group was 12.89	The mean depression literacy score in the intervention group was 0.17 points higher (1.28 lower to 1.62 higher)	—	37 (1 RCT)	⊕⊕⊝⊝ Low[c]	Health literacy skills building courses may have little or no effect on depression literacy immediately post-intervention, when compared to no or unrelated health literacy intervention.[2]
	Time point b: medium-term (6 months post-intervention **(1) Applying health information** One cluster-RCT reported that the health literacy skills building course had little or no effect on the intention to change nutritional habits (MD 0.05, P > 0.05)		—	287 (1 RCT)	⊕⊝⊝⊝ Very low[d,e]	We are uncertain whether health literacy skills building courses improve the intention to change nutritional habits 6 months post-intervention, when compared to no or unrelated health literacy intervention.

Intention to change nutritional habits Assessed with: - 3 questions (score range: 1 to 3) Higher score is better						
Quality of life – not measured	—	—	—	—	—	The effect of the intervention on quality of life is unknown as there was no direct evidence identified.
Health-related knowledge – ***Time point a: short-term (up to 1 month post-intervention)*** **Any health-related knowledge** standardised on score 0 (no knowledge) to 100 (perfect knowledge) ***Time point b: medium-term (6 months post-intervention)*** Multiple measures used: **(1) Hepatitis b knowledge** - True/false questionnaire (score range: 0 to 5) **(2) Nutrition knowledge** - Nutrition knowledge test, true/false questionnaire (score range: 0 to 12) **(3) Colorectal cancer screening knowledge** - True/false questionnaire (5 items) Higher scores are better	***Time point a: short-term*** The mean knowledge score across the control groups was 57	The mean knowledge score was 69 (63 to 73) points out of 100 with the intervention (MD 10.87 (95% CI 5.69 to 16.06) immediately post-intervention[3]	—	111 (2 RCTs)	⊕⊕⊝⊝ Low[a,b]	Health literacy skills building courses may improve health-related knowledge immediately post-intervention, when compared to no or unrelated health literacy intervention.
	Time point b: medium-term **(1) Hepatitis b knowledge** One cluster-RCT (n = 168) reported that the mean knowledge score in the intervention group was 0.81 higher (0.43 higher to 1.18 higher)[4] **(2) Nutrition knowledge** One cluster-RCT (n = 291) reported that the intervention improved nutrition knowledge slightly (MD 0.79, P ≤ 0.001)[5] **(3) Colorectal cancer knowledge** One cluster-RCT (n = 329) that did not report a composite knowledge score (5 questions), found that the proportion of correct answers was higher in the intervention group in all 5 knowledge domains, with MDs ranging from 15.1% to		—	788 (3 cluster-RCTs)	⊕⊕⊝⊝ Low[f,g,h]	Health literacy skills building courses may slightly improve health-related knowledge 6 months post-intervention, when compared to no or unrelated health literacy intervention.

	36.8% and P values ranging from < 0.0001 to 0.012[6]					
Health outcome – not measured	—	—	—	—	—	The effect of the intervention on health outcomes is unknown as there was no direct evidence identified.
Health behaviour – ***Time point a: short-term (up to 1 month post-intervention)*** Multiple outcomes assessed and multiple measures used: **(1) Fat-related dietary habits** - Fat-Related Diet Habits Questionnaire (score range: 12 items, mean on a 4-point scale (rarely/never, sometimes, often, usually) **(2) Cardiovascular health behaviour** - CSC (score range: 34 to 136) Higher scores are better ***Time point b: medium-term (6 months post-intervention)*** **Any screening adherence** Multiple measures used: - Hepatitis B screening, medical record review - Up-to-date colorectal cancer screening, self-report of test receipt and when test was obtained	***Time point a: short-term*** **(1) Fat-related dietary habits** One RCT (n = 74) found little or no difference in self-reported fat-related dietary habits (MD 0.25 points higher (0.00 higher to 0.50 higher)) 1 month post-intervention **(2) Cardiovascular health behaviour** One RCT (n = 155) found little to no effect of the intervention on self-reported cardiovascular health behaviour (MD 1.2, P = 0.067)		—	229 (2 RCTs)	⊕⊕⊝⊝ Low[i,j]	Health literacy skills building courses may have little or no effect on any health behaviour up to 3 months post-intervention, when compared to no or unrelated health literacy intervention.
	Time point b: medium-term 259 per 1000	694 per 1000	RR 2.68 (0.33 to 21.83)	440 (2 cluster-RCTs)	⊕⊕⊝⊝ Low[k]	Health literacy skills building courses may improve or reduce screening adherence 6 months post-intervention, when compared to no or unrelated health literacy intervention; the effect sizes appear to vary considerably.
Self-efficacy– **Self-efficacy to change one's diet**	One cluster-RCT found that disease prevention and health literacy skills building courses had little to no effect on self-effi-		—	290 (1 RCT)	⊕⊝⊝⊝ Very low[d,e]	We are uncertain whether health literacy skills building courses improve self-efficacy

Assessed with: • 5 items (score range: 1 = low to 3 = high) Higher scores indicate higher levels of self-efficacy Time point: medium-term (6 months post-intervention)	cacy to change one's diet 6 months post-intervention (MD 0.03, P = 0.64).					to change one's diet 6 months post-intervention, compared to no or unrelated health literacy intervention.
Health service use – not reported	—		—	—	—	The effect of the intervention on health service use is unknown as there was no direct evidence identified.
Adverse events – not reported	—	—	—	—	—	The effect of the intervention on adverse events is unknown as there was no direct evidence identified.

*More detail on scoring and direction for each outcome measure is provided in Table 1; Table 4; Table 7; Table 3; Table 10; **The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI), ***Short-term: immediately up to 6 weeks after the total intervention programme was completed; medium-term: from 6 weeks up to and including 6 months after the total intervention programme was completed; long-term: longer than 6 months after the total intervention programme was completed.

AHL-C: Assessment of Health Literacy in Cancer Screening;**CI:** confidence interval; **CSC:** Cardiovascular Health Questionnaire; **D-Lit:** Depression Literacy Questionnaire; **GEE:** generalised estimating equations; **ICC:** intra-class correlation coefficient; **MD:** mean difference; **RCT:** randomised controlled trial; **RR:** risk ratio; TOFHLA: **TS-REALD:** Two Stage Rapid Estimate of Adult Literacy in Dentistry

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[1] The effect size was rated as being moderate as the SMD was near the threshold (rule of thumb: SMD ≥ 0.5 represents a moderate effect; variation to this rule is SMD 0.4 to 0.7 = moderate effect; Higgins 2022).

[2] We do not report the results of the 2-month follow-up assessment, as the data were not reported separately for the intervention groups in the identified publications.

[3] The knowledge score across control groups ranged from 48.1% to 61.8%.

[4] The results were adjusted for the cluster design by reducing the sample size by the design effect with the use of the ICC reported by Han 2017. Adjusted odds ratios estimated from GEE models are reported separately for each question in Table 2.

[5] Results reflect unadjusted values as we had insufficient information to re-analyse the data using the appropriate unit of analysis. According to the authors, the "intraclass correlations were negligible" (Elder 1998, p. 571).

[6] GEE models were used to account for clustering but only proportions of correct answers per item were reported. Thus, we do not know if the appropriate unit of analysis was used. Details are shown in Table 2.

[a] Downgraded by -1 for risk of bias: all studies at unclear risk of bias for random sequence generation, one study at unclear risk of bias for allocation concealment.

[b] Downgraded by -1 for imprecision: wide CI and small sample size.

[c] Downgraded by -2 for imprecision: result was based on a single study with a very small sample size (fewer than 50) and wide CI that encompassed values indicating both an improvement and a worsening in the outcome.

[d] Downgraded by -2 for risk of bias: unclear risk of bias for random sequence generation and allocation concealment, high risk of bias for blinding and outcome was subjectively measured, and the results were not adjusted for the cluster design, indicating a possible unit of analysis error.

[e] Downgraded by -1 for imprecision: result was based on a single study with a small sample size and data were not reported in a way in which an MD and a measure of spread could be calculated.

[f] Downgraded by -1 for risk of bias: unclear risk of bias for random sequence generation and allocation concealment in one study. In addition, in one study, the results were not adjusted to account for the cluster design and the information was insufficient to re-analyse the data, which indicates a unit of analysis error. For one study, we do not know whether the appropriate unit of analysis was used as only proportions of correct answers per item were reported.

[g] Downgraded by -1 for imprecision: pooling data was not possible. Two out of three studies did not report the data in a way in which an MD and a measure of spread could be calculated.

[h] Not downgraded for inconsistency: although two studies found little or no effect on knowledge scores, one study found a large effect, but there was consistency in the direction of effects.

[i] Downgraded by -1 for risk of bias: high risk of bias for blinding and outcomes were subjectively measured in all studies; all studies at unclear risk of bias for random sequence generation, one study at unclear risk of bias for allocation concealment.

[j] Downgraded by -1 for imprecision: data from one study are not reported in a way in which an MD and a measure of spread could be calculated. In addition, the sample size was small.

[k] Downgraded by -2 for imprecision: rare events in one study and the CI of the pooled effect estimate was very wide, including values indicating both a large improvement but also the possibility of a worsening in the outcome.

Summary of findings 4. Culturally and literacy adapted telephone education versus unrelated health literacy intervention

Culturally and literacy adapted telephone education versus unrelated health literacy intervention

Patient or population: migrants
Setting: participant's home
Intervention: culturally and literacy adapted telephone education
Comparison: unrelated health literacy intervention (telephone education on healthy nutrition)

Outcome category – outcome(s)*	**Anticipated absolute effects** (95% CI)**		**Relative effect (95% CI)**	**№ of participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
	Risk with unrelated health literacy intervention	**Risk with telephone education**				
Health literacy –	The mean decisional conflict in the con-	The mean decisional conflict in the interven-	—	431 (1 RCT)	⊕⊕⊕⊝ Moderate[a]	Culturally and literacy adapted telephone education compared to unrelated health literacy intervention probably

(1) Appraising health information Assessed with: - Decisional conflict scale, subscales informed decision, values clarity, support (1 out of 3 items), score range 0 to 100 Lower score is better	trol group was 39.89[1]	tion group was 5.70 points lower (10.24 lower to 1.16 lower)				improves appraising health information by reducing decisional conflict, when assessed 7 months post-intervention.
(2) Applying health information (prostate cancer screening intention) Assessed with: - self-report, 1 question assessing whether a decision for screening was made, yes/no Time point: long-term (approx. 7 months post-intervention post-intervention)***	806 per 1000	806 per 1000 (741 to 887)	RR 1.00 (0.92 to 1.10)	431 (1 RCT)	⊕⊕⊕⊝ Moderate[a]	Culturally and literacy adapted telephone education compared to unrelated health literacy intervention probably has little or no effect on applying health information (prostate cancer screening intention) 7 months post-intervention.
Quality of life – not measured	—	—	—	—	—	The effect of telephone education on quality of life is unknown as there was no direct evidence identified.
Health-related knowledge – **Prostate cancer knowledge** Standardised on score 0 (no knowledge) to 100 (perfect knowledge) Time point: long-term (approx. 7 months post-intervention)	The mean prostate cancer knowledge in the control group was 55%	The mean prostate cancer knowledge score was 62% (from 62 to 62) with the intervention (MD 6.9, 95% CI 6.88 to 6.92)	—	431 (1 RCT)	⊕⊕⊕⊝ Moderate[a]	Culturally and literacy adapted telephone education compared to unrelated health literacy intervention probably improves prostate cancer knowledge slightly 7 months post intervention.
Health outcome – not measured	—	—	—	—	—	The effect of telephone education on health outcomes is unknown as there was no direct evidence identified.

Health behaviour – **PSA testing** Assessed with: - medical record review Time point: long-term (2 years post-intervention)	671 per 1000	624 per 1000 (550 to 718)	RR 0.93 (0.82 to 1.07)	490 (1 RCT)	⊕⊕⊕⊝ Moderate[a]	Telephone education compared to an unrelated health literacy intervention probably has little or no effect on PSA testing 2 years post-intervention.
Self-efficacy – not measured	—	—	—	—	—	The effect of telephone education on self-efficacy is unknown as there was no direct evidence identified.
Health service use – not measured	—	—	—	—	—	The effect of telephone education on health service use is unknown as there was no direct evidence identified.
Adverse events – **Anxiety** Assessed with: - 7-item subscale of HADS, score range: 0 to 21 Lower score is better Time point: long-term (approx. 7 months post-intervention)	The mean anxiety score in the control group was 2.02[2]	The mean anxiety score in the intervention group was 0.14 points lower (0.55 lower to 0.27 higher)	—	431 (1 RCT)	⊕⊕⊕⊝ Moderate[a]	Telephone education compared to unrelated health literacy intervention probably has little or no effect on anxiety approximately 7 months post-intervention.

*More detail on scoring and direction for each outcome measure is provided in Table 6; Table 9; Table 3); **The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI); ***Short-term: immediately up to 6 weeks after the total intervention programme was completed; medium-term: from 6 weeks up to and including 6 months after the total intervention programme was completed; long-term: longer than 6 months after the total intervention programme was completed.

CI: confidence interval; **HADS:** Hospital Anxiety and Depression Scale; **RCT:** randomised controlled trial; **RR:** risk ratio; **PSA:** prostate-specific antigen

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[1] Scores ≤ 25 are associated with following through on decisions; scores > 37.5 are associated with delay in decision-making or feeling unsecure about its implementation (O'Connor 1993).

[2] Scores 0 to 7 represent no clinically meaningful anxiety or depression (Zigmond 1983).

[a] Downgraded by -1 for imprecision: result was based on a single study and/or the CI was wide or encompassed values indicating both an improvement and a worsening in the outcome.

Summary of findings 5. Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention

Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention

Patient or population: migrants
Setting: all settings
Intervention: culturally and literacy adapted audio-/visual education without personal feedback
Comparison: no health literacy intervention (usual care, wait-list control or placebo intervention)

Outcome category – outcome(s)*	Anticipated absolute effects** (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with no health literacy intervention	Risk with audio-/visual education				
Health literacy – **(1) Depression literacy** Assessed with: - D-Lit (score range: 0 to 22) Higher scores are better **(2) Applying health information** Multiple measures used: - Intent to seek treatment for depression scale (0 to 32) Higher scores are better Time point: short-term (immediately up to 1 week post-intervention)***	The mean depression literacy score in the control group was 8.22 points	The mean depression literacy score in the intervention group was 8.62 points higher (7.51 higher to 9.73 higher)	—	202 (1 RCT)	⊕⊕⊕⊝ Moderate[a]	Audio-/visual education without personal feedback compared to no health literacy intervention probably improves depression literacy 1 week post-intervention, when compared to no health literacy intervention.
	One study reported that the intervention improved the intention to seek treatment for depression (MD 1.8 points higher (0.43 higher to 3.17 higher))		—	120 (1 RCT)[1]	⊕⊕⊝⊝ Low[b,c]	Audio-/visual education without personal feedback may slightly improve the intention to seek treatment for depression immediately post-intervention, when compared to no health literacy intervention.

Quality of life – not measured	—	—	—	—	—	The effect of audio-/visual education without personal feedback on quality of life is unknown, as there was no direct evidence identified.
Health-related knowledge – **Any health-related knowledge** standardised on score 0 (no knowledge) to 100 (perfect knowledge) Time point: short-term (up to 1 month post-intervention)	The mean knowledge score across control groups ranged from 61.8% to 67.4%[2]	The mean knowledge score in the intervention groups was 8.44 higher (2.56 lower to 19.44 higher)	—	293 (2 RCTs)	⊕⊕⊝⊝ Low[d,e]	Audio-/visual education without personal feedback compared to no health literacy intervention may slightly improve health-related knowledge up to 1 month post-intervention, but the effect sizes appear to vary considerably.
Health outcome - **Depression** Multiple measures used: • PHQ-8 (score range: 0 to 24) • BDI-II (0 to 63) Lower score is better Time point: immediately up to 3 months post-intervention	—	The mean depression score in the intervention groups was 0.15 SMD lower (0.40 lower to 0.10 higher) than in the control groups	—	337 (2 RCTs)	⊕⊕⊝⊝ Low[f,g]	Audio-/visual education without personal feedback compared to no health literacy intervention may have little or no effect on any depression immediately up to 3 months post-intervention.
Health behaviour – **Child's up-to-date immunisation** Assessed with: • medical record review Time point: short-term (immediately up to 3 months post-intervention)	794 per 1000	849 per 1000 (722 to 992)	RR 1.07 (0.91 to 1.25)	135 (1 RCT)	⊕⊕⊕⊝ Moderate[a]	Audio-/visual education without personal feedback probably has little or no effect on child's up-to-date immunisation immediately up to 3 months post-intervention, when compared to no health literacy intervention.
Self-efficacy – **Self-efficacy to identify need for treatmentfor depression** Assessed with:	One RCT reported that audio-/visual education improved self-efficacy to identify the need for treatment for depression (MD 3.51 higher (2.53 higher to 4.49 higher)) immediately post-intervention		—	133 (1 RCT)	⊕⊕⊝⊝ Low[a,c]	Audio-/visual education without personal feedback may improve self-efficacy to identify the need for treatment for depression immediately post-intervention, when compared to no health literacy intervention.

- self-efficacy to identify need for treatment scale (score range: 0 to 15) Higher score is better Time point: short-term (immediately post-intervention)						
Health service use – **Child's emergency room visits** Assessed with: - medical record review Higher scores indicate higher levels of emergency room visits Time point: short--term (immediately up to 3 months post-intervention)	The mean rate of emergency room visits in the control group was 1.82	The mean rate of child's emergency room visits in the intervention group was 0.59 points lower (1.11 lower to 0.07 lower)	—	157 (1 RCT)	⊕⊕⊕⊝ Moderate[h]	Audio-/visual education without personal feedback compared to no health literacy intervention probably reduces child's emergency room visits up to 3 months post-intervention.
Adverse events – not measured	—	—	—	—	—	The effect of audio-/visual education without personal feedback on adverse events is unknown, as there was no direct evidence identified.

*More detail on scoring and direction for each outcome measure is provided in Table 1; Table 8; Table 2; Table 3; Table 4; Table 5; Table 10; **The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI), ***Short-term: immediately up to 6 weeks after the total intervention programme was completed; medium-term: from 6 weeks up to and including 6 months after the total intervention programme was completed; long-term: longer than 6 months after the total intervention programme was completed.

BDI-II: Beck Depression Inventory; **CI:** confidence interval; **D-Lit:** Depression Literacy Questionnaire; **FIT:** faecal immunochemical test; **PHQ-8:** Patient Health Questionnaire; **RCT:** randomised controlled trial; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

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[1] One additional RCT could not be included in the narrative synthesis due to missing data in the control group (Thompson 2012).
[2] Based on reported values from four studies included in the analysis, as one study reported change scores only (Unger 2013).
[a] Downgraded by -1 for imprecision: result was based on a single study with a small sample size.

[b] Downgraded by -2 for imprecision: wide CI and result was based on a single study with a small sample size.
[c] Downgraded by -1 for risk of bias: high risk of bias for blinding and outcome was subjectively measured; unclear risk of bias for allocation concealment.
[d] Downgraded by -1 for inconsistency: there was considerable statistical heterogeneity (> 75%). One study found a large effect whereas the other study found a small effect. However, the direction of effects appeared to be consistent.
[e] Downgraded by -1 for imprecision: small sample size and final SDs for one study were obtained from reported baseline scores, as post-intervention SDs were not reported.
[f] Downgraded by -1 for risk of bias: high risk of bias for blinding and outcome was subjectively measured.
[g] Downgraded by -1 for imprecision: small sample size and the CI encompassed values indicating both improvement and worsening in this outcome.
[h] Downgraded by -1 for imprecision: result was based on a single study with a small sample size and CI was wide, encompassing a large effect but also little or no effect.

Summary of findings 6. Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic

Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic

Patient or population: migrants
Setting: all settings
Intervention: culturally and literacy adapted audio-/visual education without personal feedback
Comparison: written information on the same topic (standard brochure, or literacy adapted pamphlet)

Outcome category – outcome(s)*	**Anticipated absolute effects** (95% CI)**		**Relative effect (95% CI)**	**№ of participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
	Risk with written information	**Risk with audio-/visual education**				
<u>**Health literacy**</u> – ***Time point a: short-term (up to 1 month post-intervention)****** **(1) Diabetes health literacy** Assessed with: - DHLS, standardised on score 0 (no health literacy) to 100 (perfect health literacy)[1] **(2) Appraising health information** Measured with: - Decisional conflict scale, subscales informed deci-	***Time point a: short-term***		—	240 (1 RCT)	⊕⊕⊕⊝ Moderate[a]	Audio-/visual education without personal feedback compared to written information on the same topic probably has little or no effect on diabetes health literacy.
	(1) Diabetes health literacy					
	The mean diabetes health literacy in the control group was 53%	The mean diabetes health literacy in the intervention group was 2.00 points higher (0.15 lower to 4.15 higher)				
	(2) Appraising health information		—	608 (1 RCT)	⊕⊕⊕⊝ Moderate[b]	Audio-/visual education without personal feedback compared to written information on the same topic probably improves the appraisal of health information (decisional conflict) 1 month post-intervention.
	The mean score in the intervention group was 31.3[2]	The mean decisional conflict score in the intervention group was 9.88 points lower (12.87 lower to				

sion, values clarity and support, score range 0 to 100 Lower score is better		6.89 lower) than in the control group				
(3) Applying health information Multiple measures used: • Made informed decision regarding HPV vaccination (composite variable of decision made/knowledge) Higher score is better	**(3) Applying health information** Made informed decision regarding HPV vaccination		RR 1.51 (1.29 to 1.77)	608 (1 RCT)[3]	⊕⊕⊕⊝ Moderate[b]	Audio-/visual education without personal feedback compared to written information on the same topic probably improves the application of health information (making an informed decision) 1 month post-intervention.
	415 per 1000	627 per 1000 (535 to 735)				
Time point b: medium-term (3 months post-intervention) **(1) Competencies (inhaler use technique)** • Checklist for correct use of an inhaler (standardised on score 0 to 10) Higher score is better	***Time point b: medium-term*** **(1) Competencies (inhaler use technique)**		—	176 (2 RCTs)	⊕⊕⊝⊝ Low[a,c]	Audio-/visual education without personal feedback compared to written information on the same topic may slightly improve competencies (inhaler use technique) 3 months post-intervention.
	The mean inhaler use technique in the control groups was 5.2 points[4]	The mean inhaler use technique in the intervention group was (0.98 points higher (0.26 higher to 1.70 higher)				
(2) Understanding health information Multiple measures used: • Understanding physician's instruction, open questions, score range: 0 to 3 • Understanding of pulmonary rehabilitation procedures, text passage and related questions, correct/incorrect (score range: n.r.) Higher scores are better	**(2) Understanding health information** One RCT (n = 85) reported that the mean understanding of physician's instruction in the intervention group was 0.04 higher (0.55 lower to 0.63 higher) than in the control group One RCT (n = 43) reported that the mean understanding of pulmonary rehabilitation procedures in the intervention group was 0.30 higher (0.76 lower to 1.36 higher) than in the control group.		—	128 (2 RCTs)	⊕⊕⊝⊝ Low[a,c]	Audio-/visual education without personal feedback compared to written information on the same topic may have little or no effect on understanding of health information 3 months post-intervention.
Quality of life – not measured	—	—	—	—	—	The effect of audio-/visual education without personal feedback on

						quality of life is unknown, as there was no direct evidence identified.
Health-related knowledge – ***Time point a: short-term (up to 1 month post-intervention)*** **Any health-related knowledge** Standardised on score 0 (no knowledge) to 100 (perfect knowledge)	***Time point a: short-term*** The mean health-related knowledge score ranged from 59.2% to 71.9%[5]	The mean knowledge score in the intervention group was 8.35 points higher (0.32 lower to 17.02 higher)	—	987 (3 RCTs)	⊕⊕⊝⊝ Low^{d,e}	Audio-/visual education without personal feedback compared to written information on the same topic may slightly improve health-related knowledge up to 1 month post-intervention.
Time point b: medium-term (up to 6 months post-intervention) **Any health-related knowledge** Standardised on score 0 (no knowledge) to 100 (perfect knowledge)	***Time point b: medium-term*** The mean cancer-related knowledge score across control groups ranged from 58% to 67%	The mean cancer-related knowledge score in the intervention groups was 7.30 points higher (3.73 lower to 18.32 higher)	—	979 (3 RCTs)	⊕⊝⊝⊝ Very low^{e,f,g}	We are uncertain whether audio-/visual education without personal feedback compared to written information on the same topic improves health-related knowledge up to 6 months post-intervention. One study (n = 85) did not report data in a way that could be extracted for meta-analysis but reported no difference in asthma knowledge; very low-certainty^{c,i}
Health outcome – **Depression** Assessed with: • PHQ-8, score range: 0 to 24 Lower score is better Time point: long-term (12 months post-intervention)	The mean depression score in the control group was 4.5	The mean depression score was 0.60 points lower (1.37 lower to 0.17 higher)	—	445 (1 RCT)	⊕⊕⊝⊝ Low^{h}	Audio-/visual education without personal feedback compared to written information on the same topic may have little or no effect on depression 12 months post-intervention.
Health behaviour – ***Time point a: medium-term (up to 6 months post-intervention)*** **Any cancer screening uptake**	***Time point a: medium-term*** **Any cancer screening uptake** 513 per 1000	549 per 1000 (487 to 616)	RR 1.07 (0.95 to 1.20)	803 (2 RCTs)	⊕⊕⊝⊝ Low^{e,f}	Audio-/visual education without personal feedback may have little or no effect on any cancer screening uptake up to six months post-intervention, when compared to written information on the same topic.

Assessed with: • Return of completed FIT kit within 90 days • Self-report of Pap test or appointment made ***Time point b: long-term (12 months post-intervention)*** **Documentation of new advance care planning** Assessed with: • Medical record review	***Time point b: long-term*** **Documentation of new advance care planning** 257 per 1000	382 per 1000 (290 to 506)	RR 1.49 (1.13 to 1.97)	445 (1 RCT)	⊕⊕⊕⊝ Moderate[j]	Audio-/visual education without personal feedback compared to written information on the same topic probably improves documentation of advance care planning 12 months post-intervention.
<u>**Self-efficacy**</u> – ***Time point a: short-term (immediately post-intervention)*** **Self-efficacy in accessing breast cancer-related advice or information** Assessed with: • 1 question (5-point scale, completely confident to not confident at all) **Any cancer-related self-efficacy** Multiple measures used **(1) Pooled findings:** • Self-efficacy for screening using FIT, score range: 6 to 30 • Self-efficacy in accessing breast cancer-related advice or information **(2) Unpooled finding:**	**Time point a: short-term** One RCT found little or no difference in self-efficacy in accessing breast cancer-related advice or information (MD 0.08 higher (0.02 lower to 0.18 higher))		—	240 (1 RCT)	⊕⊕⊝⊝ Low[j,k]	Audio-/visual education without personal feedback may have little or no effect on cancer-related self-efficacy immediately post-intervention, when compared to written information on the same topic.
	(1) Pooled findings The pooled analysis of 2 RCTs (N = 256) showed that the mean cancer-related self-efficacy in the intervention groups was 0.08 standard deviations higher (0.18 lower to 0.33 higher) three months post-intervention. **(2) Unpooled findings** One RCT (N = 727) found little or no difference in self-efficacy regarding Pap testing between the intervention and the control group (RR 1.02, 95% CI 0.98 to 1.06) 6 months post-intervention. One study (n = 43) that did not report data in a way in which an MD and a spread of scores could be calculated, found that the group receiving audio-/visual education had a slightly higher mean self-efficacy for managing COPD but the CIs encompassed		—	1026 (4 RCTs)	⊕⊕⊝⊝ Low[l,m]	Audio-/visual education without personal feedback may have little or no difference in cancer-related self-efficacy 3 months post-intervention, when compared to written information on the same topic.

- Self-efficacy regarding Pap testing for cervical cancer, 1 statement, yes/no, 1 question (5-point scale, completely confident to not confident at all) Higher score is better Time point: medium-term (up to 6 months post-intervention)	both an improvement and a reduction, indicating little or no difference in self-efficacy 3 months post-intervention					
Health service use – not measured	—	—	—	—	—	The effect of audio-/visual education without personal feedback on health service use is unknown, as there was no direct evidence identified.
Adverse events – **Anxiety** Assessed with GAD-7 (score range: 0 to 21) Lower scores are better Time point: long-term (12 months post-intervention)	The mean anxiety score in the control group was 3.7[6]	The mean anxiety score was 0.70 points lower (1.40 lower to 0.00 higher).	—	445 (1 RCT)	⊕⊕⊕⊝ Moderate[i]	Audio-/visual education without personal feedback probably has little or no effect on anxiety 12 months post-intervention.

*More detail on scoring and direction for each outcome measure is provided in Table 1; Table 6; Table 4; Table 2; Table 3; Table 5, **The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI), ***Short-term: immediately up to 6 weeks after the total intervention programme was completed; medium-term: up to and including 6 months after the total intervention programme was completed; long-term: longer than 6 months after the total intervention programme was completed.

CI: confidence interval; **DHLS:** Diabetes Health Literacy Survey; **GAD-7:** Generalised Anxiety Disorder-7; **n.r.:** not reported; **PHQ-8:** Patient Health Questionnaire; **RCT:** randomised controlled trial; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[1] Cut-off values for DHLS scores are as follows: inadequate, ≤ 59%; marginal, 60% to 74%; adequate, ≥ 75% (Calderón 2014).

[2] Scores ≤ 25 are associated with following through on decisions; scores > 37.5 are associated with delay in decision-making (O'Connor 1993).

[3] One RCT could not be included in the analysis due to missing effect measures for both the intervention and the control group (Unger 2013).

[4] Based on results reported in Poureslami 2016b, as there were inconsistencies in the reported final scores of Poureslami 2016a between the publications related to this study. Both studies had four intervention arms. Group 1, 2 and 3 watched different videos and group 4 read a pictorial pamphlet on the same topic. We combined group 1,2 and 3 to create a single pairwise comparison with group 4. The results of each study group are reported narratively in Table 11.

[5] Based on two out of the three studies included in the analysis, as one study reported change scores only (Unger 2013).

[6] Scores ranging from 0 to 7 represent no clinically meaningful anxiety or depression (Zigmond 1983).

[a] Downgraded by -1 for imprecision: small sample size and CI encompassed both benefit and harm.

[b] Downgraded by -1 for risk of bias: unclear allocation concealment and high risk of bias for blinding and outcome was either purely subjectively measured (for appraising health information) or a composite variable of self-reported decision and cut-off value on a knowledge scale (7 out of 12 correct).

[c] Downgraded by -1 for risk of bias: unclear risk or high risk for multiple domains including random sequence generation and allocation concealment in the included study/studies.

[d] Downgraded by -1 for inconsistency: considerable statistical heterogeneity (> 75%) due to inconsistent direction of effects.

[e] Downgraded by -1 for imprecision: CI was wide and/or encompassed values indicating both improvement and worsening in this outcome.

[f] Downgraded by -1 for risk of bias: unclear or high risk of bias for random sequence generation and allocation concealment in one study.

[g] Downgraded by -1 for inconsistency: considerable statistical heterogeneity (> 75%); two studies were in favour of audio-/visual education without feedback and one study was in favour of written information on the same topic.

[h] Downgraded by -2 for imprecision: result was based on a single study and the CI encompassed values indicating both an improvement and a worsening in the outcome.

[i] Downgraded by -2 for imprecision: result was based on a single study with a small sample size and four study arms, and the results were not reported in such a way that they could be extracted for meta-analysis. No composite score for three knowledge items was reported (the authors used a Likert scale but not a true/false questionnaire) and the score range was missing so that the results could not be standardised as scores on a scale ranging from 0 to 100.

[j] Downgraded -1 for imprecision: result was based on a single study and the CI encompassed values indicating a decrease in anxiety but also a null effect.

[k] Downraded by -1 for risk of bias: high risk of bis for blinding and the result was subjectively measured.

[l] Downgraded by -1 for imprecision: the CI of the pooled analysis and the CI of one study that reported a risk ratio were precise but encompassed values indicating both an improvement and a reduction in the outcome. The other study did not report a composite score, but subgroup analyses per study group (four groups) and per item (five items) only; three out of five CIs reported in this study encompassed both an improvement and a reduction. However, the point estimates of all four studies in this synthesis indicated little to no effect on self-efficacy, so that no further downgrading was conducted.

[m] Downgraded by -1 for risk of bias: unclear risk of bias for blinding in two studies and high risk of bias in one study, and the outcome was subjectively measured. In addition, there was unclear risk of bias for random sequence generation and/or allocation concealment in two studies.

Summary of findings 7. Culturally and literacy adapted audio-/visual education without personal feedback versus another culturally and literacy adapted audio-/visual education without personal feedback

Culturally and literacy adapted audio-/visual education without personal feedback versus another culturally and literacy adapted audio-/visual education without personal feedback

Patient or population: migrants
Setting: community
Intervention: audio-/visual education without personal feedback (narrative video)
Comparison: another audio-/visual education without personal feedback (factual knowledge video)

Outcome category – outcome(s)*	Anticipated absolute effects** (95% CI)	Relative effect (95% CI)	№ of participants	Certainty of the evidence	Comments

	Risk with factual knowledge video	Risk with narrative educational video		(studies)	(GRADE)	
Health literacy – **(1) Competencies (inhaler use technique)** Assessed with: • Checklist for correct use of an inhaler (standardised on score 0 to 10) Higher score is better	**1) Competences (inhaler use technique)**		—	91 (2 RCTs)	⊕⊝⊝⊝ Very low[a,b]	We are uncertain whether educational videos compared to factual knowledge videos improve competencies (inhaler use technique) 3 months post-intervention.
	The mean inhaler use technique score in the control group was 7 points	The mean inhaler use technique in the group who watched the narrative video was 0.89 lower (1.84 lower to 0.07 higher) than in the group who watched the knowledge video				
(2) Understanding health information (understanding physician's instruction) Assessed with: • Questionnaire, score range: 0 to 3 Higher score is better Time point: medium-term (3 months post-intervention)	**(2) Understanding health information** One RCT (n = 43) reported that the mean understanding of physician's instruction in the group who watched the narrative video was 0.15 lower (0.72 lower to 0.42 higher) than in the group who watched the knowledge video		—	43 (1 RCT)[1]	⊕⊝⊝⊝ Very low[a,b]	We are uncertain whether educational videos compared to factual knowledge videos improve the understanding of health information 3 months post-intervention.
(3) Applying health information (intention for cervical cancer screening using Pap test) Assessed with: • Self-report, appointment made Higher score is better Time point: medium-term (6 months post-intervention)	**(3) Applying health information**		RR 1.97 (0.83 to 4.69)	109 (1 RCT)	⊕⊝⊝⊝ Very low[a,b]	We are uncertain whether narrative educational videos compared to factual knowledge videos improve the application of health information 6 months post-intervention.
	125 per 1000	246 per 1000 (104 to 586)				
Quality of life – not measured	—	—	—	—	—	The effect of a narrative educational video compared to a factual knowledge video on quality of life is un-

						known as there was no direct evidence identified.
Health-related knowledge – **Any health-related knowledge** • Cervical cancer knowledge; standardised on score from 0 (no knowledge) to 100 (perfect knowledge) • Asthma knowledge, 3 items, 5-point Likert scale (score range: n.r.) Higher scores are better. Time point: medium-term (3 to 6 months post-intervention)	One RCT (n = 109) found that the mean heath-related knowledge score in the group who watched the narrative video was 1.12 points higher (4.63 lower to 6.87 higher). The mean cervical cancer knowledge score in the control group was 66%. One RCT (n = 43) found that the mean asthma knowledge score in the group who watched the narrative video was higher than in the group who watched the physician-led knowledge video (MD 0.85 higher (1.07 lower to 2.76 higher).[2]		—	152 (2 RCTs)	⊕⊝⊝⊝ Very low[a,b]	We are uncertain whether narrative educational videos compared to factual knowledge videos improve health-related knowledge up to 6 months post-intervention.
Health outcome – not measured	—	—	—	—	—	The effect of narrative educational videos compared to a factual knowledge video on health outcomes is unknown as there was no direct evidence identified.
Health behaviour – **Cervical cancer screening** Assessed with: • Self-report, 1 question, having had a Pap test (yes/no) Time point: medium-term (6 months post-intervention)	292 per 1000	376 per 1000 (219 to 651)	RR 1.29 (0.75 to 2.23)	109 (1 RCT)	⊕⊝⊝⊝ Very low[a,b]	We are uncertain whether narrative educational videos compared to factual knowledge videos improve cervical cancer screening behaviour 6 months post-intervention.
Self-efficacy – not measured	—	—	—	—	—	The effect of a narrative educational video compared to a factual knowledge video on self-efficacy is unknown as there was no direct evidence identified.

Health service use – not measured	—	—	—	—	—	The effect of a narrative educational video compared to a factual knowledge video on health service use is unknown as there was no direct evidence identified.
Adverse events – not measured	—	—	—	—	—	The effect of a narrative educational video compared to a factual knowledge video on adverse events is unknown as there was no direct evidence identified.

*We report on our predefined outcome categories and assigned all outcomes that we considered eligible for this review to one of these categories (see Types of outcome measures). More detail on scoring and direction for each outcome measure is provided in Table 4; Table 9; Table 3); **The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI); ***Short-term: immediately up to 6 weeks after the total intervention programme was completed; medium-term: from 6 weeks up to and including 6 months after the total intervention programme was completed; long-term: longer than 6 months after the total intervention programme was completed.

CI: confidence interval; **RCT:** randomised controlled trial; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[1] One RCT could not be included in the narrative synthesis as the participants who watched the narrative video and those who watched the knowledge video were not directly compared to each other, but both were compared to a control group who read a pictorial pamphlet (Poureslami 2016b). Details are shown in Table 12.

[2] No score range was reported, but subgroup analyses adjusted for age, gender, educational level and ethnicity per study group and knowledge item only. Therefore, we could not standardise the reported values on a scale ranging from 0 to 100. However, the three knowledge items were combined to calculate an MD across the items.

[a] Downgraded by -1 for risk of bias: unclear risk of bias for random sequence generation and/or allocation concealment in all studies.

[b] Downgraded by -2 for imprecision: small sample size and/or the results stemmed from a single study. In addition, the CI included values that encompassed both an improvement and a worsening.

Summary of findings 8. Culturally and literacy adapted medical instruction versus no health literacy intervention

Culturally and literacy adapted medical instruction versus no health literacy intervention

Patient or population: migrants
Setting: all settings
Intervention: culturally and literacy adapted medical instruction
Comparison: no health literacy intervention (usual care, standard written information + verbal instruction)

Outcome category – outcome(s)*	**Anticipated absolute effects** ** **(95% CI)**		**Relative effect (95% CI)**	**№ of participants (studies)**	**Certainty of the evidence (GRADE)**	**Comments**
	Risk with no health literacy intervention	**Risk with literacy adapted written information**				
Health literacy – **Medication understanding** Multiple measures used: - Demonstration by means of correct dosage in dosing tray (0 to 5) - Correct interpretation of label contents, 11 labels - MUQ (score range: 0 to 100) Higher scores are better Time point: short-term (up to 1 week post-intervention)***	Three RCTs reported on 3 health literacy outcomes related to the understanding of medical instructions. One RCT (n = 202) reported that health literacy informed medication instructions improved the correct dosage in the dosing tray immediately post-intervention (IG: median 4.0, IQR: 3.0 to 5.0; CG: median: 3.0, IQR: 2.0 to 4.0). Another RCT (n = 123) reported that pictograms plus verbal instruction improved the correct interpretation of label contents in 10 out of 11 medical instructions immediately post-intervention (no composite score reported). One RCT (n = 200) reported that a literacy adapted plain language text in combination with an illustrated medication list improved medication understanding assessed with MUQ at 1 week follow-up (10 points higher (5.70 higher to 14.30 higher)).		—	478 (3 RCTs)	⊕⊕⊝⊝ Low[a,b]	Culturally and literacy adapted medical instructions compared to no health literacy intervention may improve medication understanding up to 1 week post-intervention.
Quality of life – not measured	—	—	—	—	—	The effect of the intervention on quality of life is unknown as there was no direct evidence.
Health outcome – not measured	—	—	—	—	—	The effect of the intervention on health outcomes is unknown as there was no direct evidence.
Health-related knowledge – not measured	—	—	—	—	—	The effect of the intervention on health-related knowledge is unknown as there was no direct evidence.
Health behaviour – **Medication adherence**	The mean self-reported medication adherence in the	The mean medication adherence score in the intervention group was 0.5 points higher	—	200 (1 RCT)	⊕⊕⊝⊝ Low[c,d]	Culturally and literacy adapted medical instructions compared to no health literacy intervention may

Assessed with: - 8-item subscale of ARMS Time point: short-term (up to 1 week post-intervention)	control group was 9.9%	(0.1 lower to 1.1 higher)				have little or no effect on health behaviour.
Health service use – not measured	—	—	—	—	—	The effect of the intervention on health service use is unknown as there was no direct evidence.
Self-efficacy - not measured	—	—	—	—	—	The effect of the intervention on self-efficacy is unknown as there was no direct evidence.
Adverse events – not measured	—	—	—	—	—	The effect of the intervention on adverse events is unknown as there was no direct evidence.

*We report on our predefined outcome categories and assigned all outcomes that we considered eligible for this review to one of these categories (see Types of outcome measures). More detail on scoring and direction for each outcome measure is provided in Table 12; Table 3; **The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI); ***Short-term: immediately up to 6 weeks after the total intervention programme was completed; medium-term: from 6 weeks up to and including 6 months after the total intervention programme was completed; long-term: longer than 6 months after the total intervention programme was completed.

ARMS: Adherence to Refills and Medications Scale; **CG:** control group;**CI:** confidence interval; **IG:** intervention group; **IQR:** interquartile range; **MUQ:** Medication Understanding Questionnaire; **RCT:** randomised controlled trial; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a] Downgraded by -1 for risk of bias: one study was at high risk of bias for blinding; unclear allocation concealment in one other study.
[b] Downgraded by -1 for imprecision: data from two studies were not reported in a way that made it possible to calculate an MD.
[c] Downgraded by -1 for risk of bias: high risk of bias for blinding.
[d] Downgraded by -1 for imprecision: results were based on a single study with a small sample size and the CI encompassed both an improvement and a worsening.

Summary of findings 9. Female migrants' benefit of any health literacy intervention versus male migrants' benefit of any health literacy intervention

Female migrants' benefit of any health literacy intervention versus male migrants' benefit of any health literacy intervention

Patient or population: migrants

Settings: all settings

Intervention: any health literacy intervention

Comparison: no health literacy intervention, or written information on the same topic, or unrelated health literacy intervention

Outcome category–outcome(s)	Illustrative comparative risks** (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk for female migrants	Corresponding risk for male migrants				
Health literacy – Multiple outcomes and measures used: **(1) Generic health literacy** - Functional health literacy, TOFHLA (score range: 0 to 100) **(2) Disease-specific health literacy** - Diabetes health literacy DHLS, score range: 0 (no diabetes health literacy) to 100 (perfect diabetes health literacy) Higher scores are better	**(1) Generic functional health literacy** One RCT that compared a health literacy skills building course to no health literacy intervention reported that female migrants scored higher in functional health literacy immediately post-intervention (2.78 points higher (4.35 lower to 9.91 higher))		—	77 (1 RCT)	⊕⊝⊝⊝ Very low[a,b]	We are uncertain whether female migrants' generic functional health literacy improves more than that of male migrants when receiving health literacy skills building courses.
	(2) Disease-specific health literacy One RCT that compared audio-/visual education without personal feedback to written information on the same topic found that the intervention may improve diabetes health literacy in women more than in men (MD 5.00 higher (0.62 higher to 9.38 higher)). The mean diabetes health literacy score in men was 56%[1]		—	118 (1 RCT)	⊕⊕⊝⊝ Low[c]	Female migrants' diabetes-specific health literacy may improve slightly more than that of male migrants, when receiving audio-/visual education intervention.

Time point: short-term (immediately post-intervention)***					
Quality of life – not measured	—	—	—	—	The effect of any health literacy intervention on female compared to male migrants' quality of life is unknown as there was no direct evidence identified.
Health-related knowledge – not measured	—	—	—	—	The effect of any health literacy intervention on female compared to male migrants' health-related knowledge is unknown as there was no direct evidence identified.
Health outcome – not measured	—	—	—	—	The effect of any health literacy intervention on female compared to male migrants' health outcome is unknown as there was no direct evidence identified.
Health behaviour – ***Time point a: short-term (immediately post-intervention)*** **Cardiovascular health behaviour** - CSC (score range: 34 to 136) Higher score is better ***Time point b: long-term (approx. 12 months post-intervention*)** **New documentation of advance care planning** - Medical record review	***Time point a: short-term*** **Cardiovascular health behaviour** One RCT that compared a health literacy skills building course to no health literacy intervention (standard ESL course) found that women scored higher on the cardiovascular health behaviour questionnaire than men in the intervention group (MD 2.07 (5.04 lower to 9.18 higher))	—	77 (1 RCT)	⊕⊝⊝⊝ Very low[b,d]	We are uncertain whether female migrants' cardiovascular health behaviour improves more than that of male migrants when receiving health literacy skills building courses.
	Time point b: long-term **New documentation of advance care planning** One RCT that compared audio-/visual education without personal feedback to written information on the same topic found that health behaviour improved in both men and women in the intervention group. Female migrants were slightly more likely to have new documentation of advance care planning	—	219 (1 RCT)	⊕⊕⊝⊝ Low[c]	Audio-/visual education without personal feedback may have little or no effect on new documentation of advance care planning between female and male migrants 12 months post-intervention.

	than male migrants (RR 1.27, 95% CI 0.90 to 1.79) 12 months post-intervention.				
Health service use – not measured	—	—	—	—	The effect of any health literacy intervention on female compared to male migrants' health service use is unknown as there was no direct evidence identified.
Self-efficacy – not measured	—	—	—	—	The effect of any health literacy intervention on female compared to male migrants' self-efficacy is unknown as there was no direct evidence identified.
Adverse events – not measured	—	—	—	—	The effect of any health literacy intervention on adverse events for female compared to male migrants is unknown as there was no direct evidence identified.

*We report on our predefined outcome categories and assigned all outcomes that we considered eligible for this review to one of these categories (see Types of outcome measures). More detail on scoring and direction for each outcome measure is provided in Table 12 and Table 4; **The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI); ***Short-term: immediately up to 6 weeks after the total intervention programme was completed; medium-term: from 6 weeks up to and including 6 months after the total intervention programme was completed; long-term: longer than 6 months after the total intervention programme was completed.

CI: confidence interval; **CSC**: Cardiovascular Health Behaviour Questionnaire; **DHLS:** Diabetes Health Literacy Survey; **ESL:** English as a second language; **MD:** mean difference; **RCT:** randomised controlled trial; **RR:** risk ratio; **TOFHLA:** Test of Functional Health Literacy in Adults

GRADE Working Group grades of evidence
High quality: further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: we are very uncertain about the estimate.

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[1] Scoring of diabetes health literacy wasinadequate ≤ 59%, marginal 60% to 70% or adequate ≥ 75%.

[a] Downgraded by -1 for risk of bias: unclear risk of bias for random sequence generation and allocation concealment.

[b] Downgraded by -2 for imprecision: results were based on a single study with a small sample size (fewer than 100) and/or CIs encompassed values favouring either female or male migrants.

[c] Downgraded by -2 for imprecision: results were based on a single study with a small sample size and CIs were wide or encompassed values favouring either female or male migrants.

[d] Downgraded by -1 for risk of bias: unclear risk of bias for random sequence generation and allocation concealment, high risk of bias for blinding and outcome was subjectively measured.

BACKGROUND

International migration is a complex phenomenon of increasing importance in an era of rising globalisation. More than ever before, international migration touches all countries and affects all areas of daily living (IOM 2017). The growing presence of migrants, and refugees in particular, can have a complex impact on the healthcare systems of respective host countries, which face tremendous pressures in responding fast to new and increasing healthcare needs (Hunter 2016). However, evidence suggests persistent inequalities between migrants and non-migrants in accessing and using health information and healthcare services (Abbas 2018; Lebano 2020). In addition, the ongoing COVID-19 pandemic has shown that misinformation may exacerbate health-related inequalities in the context of migration, and even further highlighted the importance of individual and organisational health literacy (Sentell 2020).

Health literacy, understood as the ability to access, understand, appraise and apply health information (Sørensen 2012), has become a key contributor to effective disease management, improved health outcomes and the overall efficiency of health care. Furthermore, health literacy is an essential concept with regard to health-related autonomous decisions and health behaviour (Woopen 2015). Evidence suggests that the individual's perceived health literacy is not only associated with healthy lifestyle choices (e.g. physical activity), but also with one's general subjective health status and health-related quality of life (HLS19 Consortium 2021). In contrast, limitations in health literacy have been shown to be associated with higher rates of chronic diseases, more frequent hospitalisations and emergency treatments, higher healthcare expenditures, the reduced use of preventive measures, lower treatment adherence, and an increased risk of morbidity and mortality (Berkman 2011; Eichler 2009; HLS-EU Consortium 2012; HLS19 Consortium 2021; Paasche-Orlow 2007; Rasu 2015).

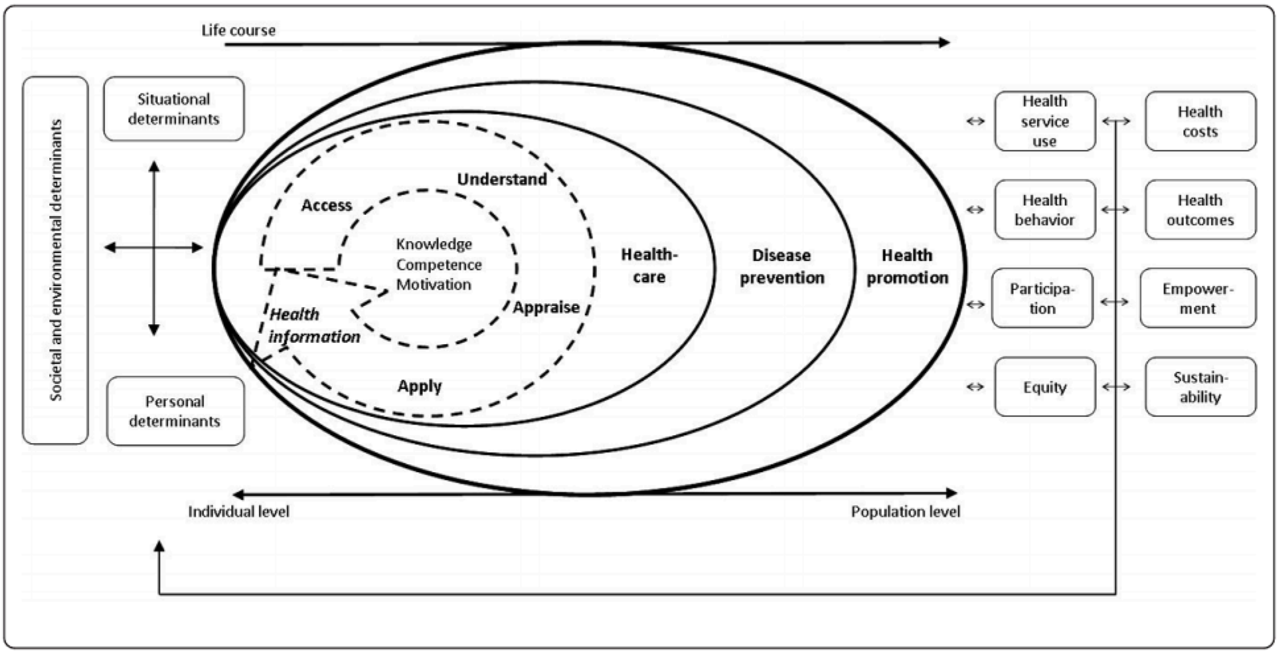
In studies conducted in Germany, migrants with low language proficiency and older people with a migrant background reported experiencing particular problems in understanding and processing health information, and in translating it into healthy choices (Berens 2022a; Quenzel 2016). These results are in line with studies from Australia, Canada and the USA that report ethnic minority status, limited language proficiency or having a migration experience as a risk factor for health literacy limitations (Beauchamp 2015; Christy 2017; Ng 2014; Sentell 2012). Similar critical evidence was found for the health literacy levels of refugees in Sweden (Wångdahl 2014). Although research on health literacy indicates that having a migrant background is not the sole issue (Berens 2022a; Ganahl 2016; HLS19 Consortium 2021), it seems likely to function as a multiplier in creating health inequalities. Health literacy has shown to be a social determinant of health (Nutbeam 2021; Pelikan 2018). It has a social gradient, including income, social status, education and age (Berkman 2011; HLS-EU Consortium 2012; HLS19 Consortium 2021), and some of these factors can be even more pronounced in the context of migration. Thus, improving health literacy, both at the individual and population level, is of crucial importance for a sustainable and equitable promotion of public health.

Description of the condition

Health literacy

The notion of health literacy was initially mentioned in the setting of school-based health education in the 1970s (Simonds 1974). In the medical context, the first definitions referred to health literacy as "the constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the healthcare environment" (AMA 1999). This rather passive understanding of the individual acting as a patient - today referred to as functional health literacy - has rapidly expanded to a more complex concept, including individual competencies and resources to take healthy choices and act on health information as an empowered consumer (Nutbeam 2000). In the European region, research on health literacy gained popularity among researchers and health policy-makers when the European Health Literacy Consortium presented its work in 2012, providing for the first time population-based data on citizens' health literacy in eight European countries (HLS-EU Consortium 2012). Based on a systematic review of existing definitions and conceptual frameworks, the researchers around Sørensen 2012 developed an integrated model of health literacy by systematically considering individual, social and systemic influencing factors, determinants and domains that can affect an individual's health literacy (see Figure 1). Referring to this underlying model, “health literacy is linked to literacy and entails people's knowledge, motivation and competencies to access, understand, appraise, and apply health information in order to make judgements and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course” (Sørensen 2012). A key component of this definition is the procedural character of health information processing, which is expressed in the following four steps:

Figure 1. Integrated model of health literacy (Sørensen 2012)



- access;
- understand;
- appraise; and
- apply.

Individual prerequisites such as knowledge, motivation and skills or competencies (e.g. reading and writing abilities) are necessary to pass through the four steps of health information processing. Applying these prerequisites, health literacy requires a person to search for and find relevant health information, to understand it sufficiently, to appraise it in the context of one's own value system and finally to apply the information, for example by making healthy choices. Thus, the individual's ability to process health information is closely linked to health-related behaviour (e.g. medication adherence), which can in turn influence health-related outcomes (e.g. progression of disease). However, important to note is that causes of limited health literacy are not limited exclusively to an individual. Health literacy is determined by individual abilities and resources on the one hand and structural, situational and political conditions on the other hand (Dodson 2015; Parker 2009). For example, a recent migrant might have sufficient health literacy skills to successfully navigate the healthcare system in the country of origin, but might be challenged by the demands and complexity of the healthcare system in the host country. Thus, the health literacy environment (e.g. clinicians with cultural competence or the type of access to health services and reliable health information) plays a crucial role in determining the specific health literacy-related challenges that migrants may encounter.

We applied the integrated model of health literacy as an umbrella framework in this review for assessing the effectiveness of health literacy interventions, focusing on the four steps of health information processing (access, understand, appraise and apply), and the involved cognitive, knowledge-based and motivational aspects that contribute to a person’s health literacy.

Disease-specific health literacy

A variety of context- and disease-specific definitions and models of health literacy have emerged within many medical disciplines, such as for psychiatry (mental health literacy), oncology (cancer literacy) or endocrinology (diabetes literacy) (Mackert 2015). Health literacy is hereby described with regard to the particular disease-specific demands concerning an individual, for instance the understanding of and adherence to a certain therapeutic regimen. Such disease-specific approaches often focus on the acquisition of knowledge about the related disease, implying the causal relationship between knowledge and the respective behaviour. Just to name one, the concept of mental health literacy, for instance, was initially defined as "knowledge and beliefs about mental disorders which aid their recognition, management or prevention" (Jorm 1997). It was later extended with the mental disorder-related knowledge that is necessary to benefit the mental health of oneself or others, referring thereby to the ability to recognise mental disorders, as well as to having the knowledge about their risk factors and causes, about effective self-help strategies, and adequate time to seek professional help or to help others (Jorm 2000). To date, several mental disorder-specific subcategories have emerged (e.g. depression literacy or suicide literacy) and new measurements evolve continuously.

Measurement of health literacy

To date, a broad variety of definitions and models have evolved around the world (Sørensen 2012). However, there is no uniformly applied definition of health literacy to date. Thus, measurements of health literacy are equally diverse, and depend on the underlying definition of health literacy (Altin 2014; Guzys 2015; Haun 2014), and on whether generic or disease-specific health literacy should be assessed. Generic health literacy can, for example, be assessed using performance-based or perception-based assessment tools. Two of the most widely used performance-based assessment tools are the Rapid Estimate of Adult Literacy in Medicine (REALM)

(Davis 1991) and the Test of Functional Health Literacy (TOFHLA) (Parker 1995). These tools measure reading and writing abilities in the medical context (REALM, in this review, is also referred to as print literacy) and text understanding or numeracy skills (TOFHLA, in this review, is also referred to as functional health literacy). Perception-based assessment tools such as the Health Literacy Questionnaire (HLQ) (Osborne 2013) or the European Health Literacy Questionnaire (HLS-EU-Q) (Sørensen 2013) measure self-reported health literacy, including, for instance, the assessment of self-perceived difficulties in processing health information with regard to health promotion, disease prevention and disease management (Sørensen 2013).

Disease-specific assessment tools often address certain aspects of health literacy, which are seen to be important in the respective disease-specific context (e.g. knowledge or attitudes towards professional help), others are based on established generic health literacy tools such as the TOFHLA or REALM, but use disease-specific words or phrases (e.g. HIV-specific terms) rather than general medical terminology. Knowledge is regarded as one of the major components of health literacy (Sørensen 2012), especially when it comes to applying it in certain (disease-specific) contexts. In health literacy research, knowledge is usually assessed by measures that assess declarative knowledge, which is explicit knowledge that can be verbalised by questionnaires (i.e. knowing facts about a certain skill domain). Procedural knowledge, however, is represented in procedures for performing a certain skill (i.e. knowing how to do things) (Anderson 1982). The latter is closely related to competencies such as reading and writing abilities or numeracy skills. Thus, these skills are often assessed by administering disease-specific health literacy measures that are based on established performance-based tools such as TOFHLA.

Migration

We use the term migration as defined by the International Organization for Migration (IOM), which states that migration is “the movement of a person or a group of persons, either across an international border, or within a state. It is a population movement, encompassing any kind of movement of people, whatever its length, composition and causes; it includes migration of refugees, displaced persons, economic migrants, and persons moving for other purposes, including family reunification” (IOM 2018). Voluntary migration is often accompanied by the hope for improved living conditions for oneself or family members, better working opportunities, or study purposes. Forced migration can include coercion or obligation to flee from natural or human-made disasters, extreme poverty, religious, sexual or political persecution, generalised violence, or armed conflicts such as civil war (IOM 2018; Moore 2004; Nuscheler 2013). However, making a clear-cut distinction between forced and voluntary migration is not always feasible as the complexity of individual experiences is often on a forced-voluntary continuum (Erdal 2018). As with health literacy, there is no uniformly applied definition of the term migrant at the international level. According to a recent definition proposed by the IOM, the term migrant can be used as an umbrella term that reflects the "common lay understanding of a person who moves away from his or her place of usual residence, whether within a country or across an international border, temporarily or permanently, and for a variety of reasons" (IOM 2019).

Independent of the reasons for peoples' movement, migration is a life-changing experience that affects an individual's biography, his or her family development, and shapes several following generations. Migration includes risks and opportunities in social and economic conditions, as well as health (Razum 2008). Poor socio-economic environments and living conditions, limited access to educational opportunities, and psychological stresses such as chronic work hazards are well examined causal factors leading to health inequalities (Marmot 2005). These factors can have a particularly strong impact on migrants' health because language barriers, racial discrimination or limited health systems knowledge are significant challenges to health improvement and preservation, and recovery from illness (Derose 2007; Harris 2006; Masseria 2010; Timmins 2002). Although migrants are often, at least initially, relatively healthy compared to most people in the host country, international studies indicate that immigrants and refugees tend to be vulnerable to poor mental health, certain communicable diseases such as tuberculosis and HIV/AIDS, and non-communicable diseases such as diabetes, injuries and maternal and child health problems (Goosen 2014; Kirmayer 2011; Lindert 2009; Rechel 2013; Yun 2012). Certain migration trajectories are linked to specific health adversities before, during and after migration. For example, among refugees escaping from civil war the migration process can be accompanied by violence, exploitation by human traffickers, hunger and infectious diseases (IOM 2013; United Nations 2017). Furthermore, accessing affordable high-quality health care in the host country can vary among healthcare systems and may depend on the legal status of the migrant (Bozorgmehr 2016; Rechel 2013; WHO 2010).

Gender

Gender is widely considered to describe roles, behaviours, identities and relations, whereas the terms sex typically refers to biological and physiological processes (Hammarström 2012). Given the behavioural and relational nature of the health literacy concept, we refer to differences between men's and women's health literacy as gender differences rather than sex differences (Sandford 1999). Therefore, we used the term gender to denote results concerning female and male migrants (and, had this been applicable, other genders).

Although differing in intensity, gender differences occur in all cultures and can be of critical importance at all stages of the migratory process (Malmusi 2010). Gender may influence both the reasons individuals migrate and the health outcomes they experience before, during and after migration. Thus, the process of migration is inherently gendered, influenced by gender roles, expectations and power dynamics. The intersectionality between gender, migration and their synergistic effects on health have been discussed in the scientific literature (Douki 2007; Malmusi 2010; Wandschneider 2020). Research shows, for example, that certain health risks are more common among women (e.g. sexual violence and abuse, human trafficking, or risks around childbirth and pregnancy), whereas accidents, physical stress or work hazards affect men more commonly (Douki 2007; Llácer 2007; Malmusi 2010; Schouler-Ocak 2017). Additionally, a systematic review of social epidemiological literature found that stronger adherence to traditional gender norms, higher levels of gender inequality, gender-based discrimination and gender-based violence were associated with adverse health outcomes among migrants (Wandschneider 2020). These circumstances can influence why people need health information, and affect how health information is accessed, processed and translated into health-related action.

Both gender and migration are factors that have received increased attention in relation to their roles as important determinants of health and health literacy (Svensson 2017). Simultaneously, there is a considerable lack of gender aggregated data in international migration research in general (Bircan 2022), and in health literacy research in particular (Aldin 2019; Chakraverty 2022). A recent review of 24 studies that included previously unpublished data from 15 studies found that men with a migrant background, although much less frequently examined, may have slightly lower health literacy than women. However, there was substantial heterogeneity between studies and the difference vanished when excluding studies with a high risk of bias (Chakraverty 2022). Nevertheless, to date it remains unclear how, and in which way, gender affects the health literacy of migrants or if female and male migrants perceive challenges regarding accessing, understanding, appraising and applying health information differently (Aldin 2019; Chakraverty 2020).

Considering equity in health literacy

A lack of evidence on equity has been described as a barrier to the use of systematic reviews by healthcare decision-makers (Welch 2015). Considering equity in systematic reviews on health literacy is therefore of high importance for the effective implementation of health literacy interventions. Health equity is defined as "the absence of avoidable and unfair inequalities in health" (Welch 2012; Whitehead 1992). The emphasis of this concept is on the avoidance of unfair differences in health and related outcomes among individuals in a population and among different population groups. Differences in health across certain socio-demographic characteristics, including age, sex and gender, or ethnicity, can be caused by discrimination or inadequate access to healthcare services, which hinders people from preserving and regaining health (Welch 2015).

The integrated model of health literacy developed by Sørensen 2012 (see Description of the condition) draws attention to the importance of equity in health literacy research across individuals and populations. The integrated model served as an equity model for this review because it includes relevant personal determinants such as gender and race, socio-economic status and education, situational variables (e.g. the current physical environment), and culture as societal and environmental determinants of health literacy. The term *race*, albeit a scientifically unjustifiable concept (Williams 1997), which is used inconsistently throughout the literature (Kaplan 2003; Williams 1994), is often applied to denote immigrant groups such as so-called Hispanics/Latinos/Latinas (López 2010). If this term was accompanied by information that the person who was categorised by race is a migrant, we would have used the term race (or the synonymous term 'ethnicity') as a personal determinant of health literacy. Thus, migration can be integrated in the model as a personal (i.e. race or ethnicity), situational (i.e. pre-, peri- and post-migration status), or societal and environmental factor (i.e. culture) to determine health literacy.

We followed the PRISMA-Equity (PRISMA-E) reporting guidelines for systematic reviews to acknowledge equity as an important determinant of health (Welch 2012; Welch 2015). We provided a strong rationale on gender and migration as important factors to be considered in health equity when discussing the improvement of health literacy. We formulated objectives that enabled the exploration of gender differences that may contribute to inequalities in health literacy. We applied an inclusive approach to the study population and ensured inclusion of different groups of migrants. Regarding data collection, we extracted and reported items related to equity using the PROGRESS-Plus framework. Moreover, we considered issues around equity in our synthesis and discussion of findings (Welch 2015).

Description of the intervention

This review assesses different interventions with the purpose of improving individual health literacy in migrants or one of the four steps of health information processing (access, understand, appraise or apply health information). These interventions may have included community-based health-related interventions, such as community education or schooling programmes, and individual-based health-related interventions such as online provision of information, personal (face-to-face) provision of information, or others. Interventions could have been delivered by any person involved in the health care or social work field and working closely with migrants and their descendants. Furthermore, the outcomes of these interventions should have been measured using either an established assessment tool for health literacy as a construct, or an assessment tool that is capable of measuring the outcomes that are targeted in the intervention and which are related to the respective processing step. Health literacy could have been assessed using remote (e.g. online, telephone) or face-to-face questionnaires or surveys. Interventions for improving health literacy that target healthcare providers, services or information materials rather than the consumer, would have been included only if the effects of such interventions were directly measured in female and male migrants (How the intervention might work). We focused on interventions targeting individual health literacy. Broader interventions that address the health literacy environment solely, such as health literacy toolkits for health systems (Dodson 2015), or approaches to creating health literate healthcare organisations, exist (Brach 2012) but were beyond the scope of this review.

How the intervention might work

Specific design features of interventions targeted for low-health-literacy populations (e.g. presenting essential information first, presenting information in simple language or formats, or substantiated by video or illustrated narratives) have been shown to be effective in terms of improving comprehension of information. Furthermore, multiple interventions such as intensive self- and disease-management or adherence interventions have shown promise in mitigating the effects of limited health literacy with regard to reduced emergency department visits and hospitalisations, and reduced disease prevalence (Berkman 2011; Sheridan 2011). A meta-analysis indicated that, on average, health literacy interventions significantly improved participants' health literacy (22%) and treatment adherence (16%) among those who participated in a health literacy intervention compared to those who did not. However, particular methodological and measurement moderators greatly affected the effect sizes of health literacy interventions on participants' level of health literacy. For instance, subjective health literacy measures showed higher effect sizes over objective measures and health literacy improvements were higher when participants self-assessed their health literacy compared to assessment by a clinician or other members of the clinical team (Miller 2016). Therefore, conclusions have to be drawn carefully, since the effects may be highly variable within the included studies.

Apart from interventions that aimed at improving health literacy in a general sense, we also included interventions that targeted at least one of the four steps of health information processing. Pathways for these interventions may have included empowering people by strengthening their skills in accessing, understanding, appraising or applying health information. For example, a web navigation training intervention (imparting knowledge) has been shown to improve health information search strategies of people living with HIV/AIDS, thereby focusing on the improved ability to search for and find online information (Kalichman 2006). Reproductive health knowledge was strengthened by a health education intervention that aimed to improve understanding of health information (Mbizvo 1997). The appraisal of such information was enhanced by matching content presentation to the health locus of control for recipients (Williams-Piehota 2004). Individually tailored information on behavioural change increased cholesterol screening rates and physical activity (Kreuter 1996).

A successful interaction with healthcare providers is dependent on the communication skills of the patient on the one hand (e.g. language proficiency) and those of the healthcare professionals on the other hand (e.g. use of plain language and taking time for explanation). Therefore, another pathway for improving migrants' health literacy could have included improving healthcare providers' communication skills, rather than educating the individual migrants themselves. Such interventions could have indirectly improved health literacy skills and, in turn, health-related outcomes through patient-provider communication that is respectful and tailored to the patient's health literacy needs. For instance, Tavakoly 2018 found that health provider communication skills training significantly improved patient communication skills, self-efficacy, adherence to medication and hypertension outcomes.

Beauchamp 2017 developed a three-step approach that identified health literacy issues of health professionals or consumers; developed appropriate interventions; and implemented, evaluated and improved these interventions by using Plan-Do-Study-Act (PDSA) cycles. Successful interventions involved one of the following four pathways: improvement of clinician skills and resources for health literacy, the active engagement of community volunteers to disseminate health promotion messages, the direct impact on consumers' health literacy and the redesign of existing healthcare services. Such studies indicate that an individual's health literacy can be improved through both direct and indirect means.

Why it is important to do this review

Research on migrants' health is highly relevant to gain a better understanding of migrants' specific healthcare needs, and how to respond best and most efficiently to these needs. Understanding the effectiveness of available interventions and pathways through which they have their effects is of great interest to decision-makers in healthcare systems, who face the challenge of rolling out interventions for improving health literacy across populations. Furthermore, it is important to identify effective approaches for improving access, understanding, appraisal and application of health information by migrants, since an appropriate response to healthcare needs entails the proper application of the health information found. However, people with limited health literacy skills face considerable barriers in accessing high-quality health information, and in understanding, appraising and applying the information for their own healthcare decisions and behaviours (Friis 2016; HLS-EU Consortium 2012; HLS19 Consortium 2021). These and other challenges should be considered in the research on migrants' health literacy to ensure equitable and humane healthcare systems on the one hand, and empowered individuals on the other hand.

There is no prior Cochrane effectiveness review on migrants' health literacy. There is a published Cochrane effectiveness review on interventions for improving consumers' online health literacy (Car 2011), and a published Cochrane protocol on interventions improving health literacy in people with kidney disease (Campbell 2016). However, we did not expect overlap between the reviews because health literacy is defined differently in each, and the phenomena and populations under study differ greatly.

Research on health literacy has the overarching aim of establishing a common understanding of health literacy, informing development of appropriate assessment tools, and effective interventions to improve health literacy. Health literacy measurement is evolving, and the majority of international research is targeted at assessing individuals' ability to function in the healthcare environment, mostly measuring functional aspects of health literacy (i.e. reading and writing abilities in the medical context) and neglecting procedural characteristics of the four health information processing steps in other than clinical settings (Guzys 2015; Haun 2014). In particular, a theory-driven approach of applying the integrated model of health literacy as an umbrella framework to assess the effectiveness of interventions that address the four health information processing steps has not yet been determined. This review can therefore contribute to a more profound understanding of health literacy as a multidimensional construct by identifying design features of interventions targeted to migrants that address the relevant health information processing steps sufficiently.

OBJECTIVES

- To assess the effectiveness of interventions for improving health literacy in migrants.
- To assess whether female or male migrants may respond differently to the identified interventions.

Such interventions must have addressed health literacy either as a comprehensive construct or at least one of its four health information processing steps (access, understand, appraise, apply). However, we did not aim to equate general health literacy interventions that include a range of activities targeted to all of the four health information processing steps with interventions that aim to improve only one step (e.g. understand). We aimed instead to create a comprehensive picture of the effect of health literacy interventions by applying the integrated model as an umbrella framework for a deductive analysis of the four steps of health information processing.

We did not restrict this review to specific settings or diseases because we aimed to provide an overview of available interventions for improving health literacy that address migrant populations.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (RCTs) and cluster-RCTs (trials in which groups of participants were randomised) (see Data collection and analysis). We planned to also include quasi-RCTs (trials in which randomisation was attempted but subject to potential manipulation, such as allocating participants by day of the week, date of birth or sequence of entry into trial), but no eligible quasi-RCTs were identified.

Types of participants

We included migrants, referring to immigrants, refugees, asylum seekers, wandering people and other individuals who have migrated (first-generation migrants). This corresponds with the definition by the International Organisation for Migration (IOM), which states that migration is the “the movement of a person or a group of persons, either across an international border, or within a state. It is a population movement, encompassing any kind of movement of people, whatever its length, composition and causes; it includes migration of refugees, displaced persons, economic migrants, and persons moving for other purposes, including family reunification” (IOM 2018). Thus, movement within a state was considered as migration only if it was embedded within the movement of a population.

We included adults aged 18 years or over. We applied no gender or ethnicity restrictions. We excluded trials if fewer than 80% of participants were adults, and if no subgroup data were available.

We excluded studies that included only extractable data for individuals of established ethnic minority communities (e.g. Latino Americans in the USA), defined as descendants of migrants who have settled in the respective country at least one generation ago. If data for subgroups who were explicitly designated as first-generation migrants could be extracted then we included the study. We included studies in which at least 80% of participants were migrants according to our definition. If no clear distinction could be made between ethnic minority group and migrant status according to our definition (e.g. when it was not stated which migrant generation was included), we excluded the study.

Types of interventions

We searched for studies that entailed, for instance, interventions that aimed to:

- improve health literacy in different settings (e.g. group-based education programmes for pregnant women on post-partum care in an immigrant community, or self-management programmes for improving disease management);
- improve health literacy in hard-to-reach groups (e.g. telephone interventions to improve patients' engagement in disease management);
- improve knowledge or understanding of information about health, disease or treatment (e.g. mitigate effects of limited language proficiency through the provision of information in different languages);
- affect the appraisal of health information (e.g. by individually tailoring the information provided); and
- improve understanding or use of medical information through culturally and literacy adapted medication labels.

We also searched for studies targeting health professionals' communication skills in consulting patients with low literacy skills (e.g. teach-back training, if the effect was measured in migrants) or studies that aimed to improve access to health information, e.g. through access to telemedicine in rural areas. However, we did not find any studies assessing the effects of either of these approaches.

We included health literacy interventions that were explicitly named as such, or interventions designed for individuals with low literacy skills without explicitly referring to the concept of health literacy, so long as the intervention's aims and outcomes could be assigned to health literacy as an umbrella concept. Such interventions could have addressed health literacy either as a general concept, or at a minimum, components of health literacy such as knowledge, or one of its four health information processing steps (access, understand, appraise and apply).

We excluded interventions that solely addressed the health literacy environment, i.e. interventions that focused on healthcare organisations or health systems without measuring the effect of these interventions on migrants' health literacy. We also excluded studies that could not be assigned to our umbrella framework of health literacy because the intervention was not designed to improve health literacy or even to mitigate the effects of low literacy. These studies were excluded even if they reported using a health literacy assessment tool.

At the protocol stage, we planned to conduct a main analysis including health literacy interventions that were explicitly named as such and a secondary deductive analysis including health literacy interventions that address at least one of the four health information processing steps (see description above). For example, if a study reported a 'health literacy intervention' as simply providing an information pamphlet on an available health service and reported a health literacy measure, we planned to include the study for the secondary analysis, assigning it to the processing step 'access', since the effect could not be assigned to health literacy as a general concept. We also planned to include such a study in the deductive analysis, if the pamphlet was targeted to individuals with limited language proficiency and the effect measured was the level of understanding that these individuals achieved regarding the information provided. In this case, the intervention was planned to be assigned to the processing step of 'understand' in the deductive analysis.

Due to the diversity of studies found, we were not able to conduct *one* main analysis, but rather identified several comparisons. We conducted meta-analyses where possible and deductively categorised the studies' outcomes to our umbrella framework of health literacy (see also Data synthesis). In addition, we decided to exclude studies that solely provided a publicly available pamphlet when the respective pamphlet was not adapted with regard to (health) literacy by the study authors.

Types of outcome measures

Outcome categories referred to empirically indicated associations of health literacy with the respective outcome category (Berkman 2011; HLS-EU Consortium 2012; Paasche-Orlow 2007; Paasche-Orlow 2005). Applied health literacy assessment tools could be either performance-based or perception-based (self-assessment) (see Description of the condition). Within studies, we prioritised validated assessment tools in preference to non-validated assessment tools. However, we did not exclude studies based on whether the assessment tool used had been validated or not.

If single trials reported more than one outcome that mapped to the same category, we listed all reported outcomes (see Characteristics of included studies), but reported effect measures of the prioritised outcomes only. If an outcome was measured in more than one way in a single trial (e.g. medical record review or self-report), we reported these outcomes narratively for each included study (see Effects of interventions, and Table 1 to Table 7), but prioritised objective outcome measures (e.g. medical record review) for inclusion in the meta-analysis in preference to subjective outcome measures (e.g. self-reported medication taking). If more than one outcome per category was measured in the same way, two review authors made a decision about which was clinically most important or which was the most appropriate measure of the outcome under focus (or both). For example, if a study reported the two objectively assessed outcome measures, 'children's emergency department encounters' and their 'attendance to well visits' for the category 'health service use', we presented the outcome 'emergency department encounters' as this was likely to have a greater clinical impact. We combined outcome data when a single trial measured the same outcome in the same way, but reported the results for subscales separately. For example, Han 2017 assessed breast cancer knowledge and cervical cancer knowledge. In this case, we did not prioritise one outcome over the other, but combined the data, as both knowledge tests reflected the intervention content.

For the category 'health literacy' we built subcategories, referring to them as 'generic health literacy', 'disease-specific health literacy' or 'components of health literacy'. Again, our aim was to provide an overview of available interventions that addressed health literacy either as a concept or one of its components, such as the four steps of health information processing. In addition, we believed that there are important conceptual distinctions to be made between generic health literacy and disease-specific health literacy. For example, one study reported five objective measures for assessing health literacy. One of these measures was not an established one, and we had insufficient information about how it was applied; one measure was the numeracy subscale of the TOFHLA (Parker 1995), but three measures were validated, full versions of a performance-based health literacy assessment tool (Kim 2020). Of these, one measure assessed disease-specific health literacy (diabetes health literacy; DM-REALM) (Kim 2020), the other two measures are widely used for assessing generic health literacy. One assesses health numeracy (NVS) (Weiss 2005); the other one is used to assess print literacy (REALM; also referred to as functional health literacy) (Davis 1991). We decided to report the results of the latter three measures as they all are validated tools that measure different aspects of health literacy, which we considered relevant for this review.

We conducted a meta-analysis when at least two studies, which we judged similar enough in terms of intervention features and comparator, measured the same outcome in the same way (see Data synthesis). If more than one outcome per category per trial was eligible for meta-analysis, we prioritised objective measures in preference to subjective measures to not double-count data for the same outcome category for the same population in one analysis. All outcomes reported in the included studies were assigned independently to the review's outcome categories. Any differences in categorisation were resolved by involving a third review author.

Primary outcomes

We aimed to include the following primary outcomes in this review:

- health literacy; and
- adverse events associated with the intervention (e.g. anxiety).

We also extracted outcomes that we considered as components of health literacy (a) knowledge; b) motivation; c) competencies; d) accessing health information; e) understanding health information; f) appraising health information; g) applying health information).

As prespecified in the protocol for this review, we reported on health-related knowledge separately in the summary of findings tables and in the results section. We assessed knowledge separately as empirical research strongly indicates that higher levels of (functional) health literacy are associated with higher levels of health-related knowledge (Berkman 2011; Osborn 2011; Paasche-Orlow 2005; Paasche-Orlow 2007; Sheridan 2011). In line with the integrated model, however, we considered knowledge to be one of the major components of health literacy. We planned to examine attitudes and beliefs as an outcome only if a knowledge measure was not applied in the respective study, because as proposed by Berkman 2011, we also believe that attitudes result from knowledge. However, none of the included studies assessed attitudes and beliefs without additionally reporting a separate knowledge measure.

Secondary outcomes

We aimed to include the following secondary outcomes, referring to these as 'outcomes related to health literacy':

- quality of life;
- health outcome (e.g. subjective health status, depression);
- health behaviour (e.g. use of preventive measures, medication adherence);
- health-related knowledge (e.g. disease-specific knowledge);
- health service use (e.g. use of emergency room services, hospitalisation rate);
- individual skills (e.g. self-efficacy, self-awareness); and
- health care costs.

At the protocol stage, we pre-specified the outcome category 'individual skills (e.g. self-efficacy, self-awareness)'. For the sake of clarity, and since self-efficacy has been shown in several studies to be associated with health literacy (Berens 2021; Berens 2022b; Guntzviller 2016; von Wagner 2009; Xu 2018), we decided to rename this category as 'self-efficacy', including the different forms of self-efficacy (e.g. self-efficacy to manage one's own disease, self-efficacy to use certain screening measures, or self-efficacy to identify a disease). We also planned to extract outcomes related to the prespecified category 'health care costs'. Health care costs as a secondary outcome was not assessed, as no data were available from the published main trial reports and due to a lack of resources we were not able to search for separate cost-effectiveness analyses.

We did not exclude studies based on the outcomes reported, but studies were excluded when it was not apparent that improving health literacy or mitigating the effects of low (health) literacy was an aim of the study.

We included the following main outcomesin the summary of findings tables:

- health literacy;
- adverse events associated with the intervention (e.g. anxiety);
- quality of life;
- health outcome (e.g. subjective health status, depression);
- health behaviour (e.g. use of preventive measures, exercising rate, medication adherence);
- health service use (e.g. use of emergency room services, hospitalisation rate);
- health-related knowledge (e.g. disease-specific knowledge); and
- self-efficacy.

Timing of outcome assessment

We reported all time points, starting from the earliest time point assessed after the total intervention programme was completed. This included short-term (up to six weeks from the start of the intervention and immediately after the intervention programme was completed), medium-term (from six weeks up to and including six months after the intervention programme was completed) and long-term outcomes (longer than six months after the intervention programme was completed).

Search methods for identification of studies

Electronic searches

We adapted the search strategies as suggested in Chapter 4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2022). The search strategy was developed by an Information Specialist (IM) in close consultation with the review authors. The concept of health literacy has evolved continuously since its first mention in 1974. Thus, we searched for studies that measured health literacy as a comprehensive concept, or one of its processing steps, even if these were not explicitly mentioned as such in the respective study. We included full-text articles and publications available as abstracts only if sufficient information was available on study design, characteristics of participants and interventions provided.

As a supplement to the protocol, the term 'health literacy' or 'literacy' had to be mentioned at full-text stage to avoid conceptual fraying. Accordingly, for studies to be included they had to either be designed to improve health literacy, or to mitigate the effects of lower literacy in the context of health.

Searches were run in the following databases from inception until 2 February 2022 (for a full overview, see Appendix 1).

- Cochrane Central Register of Controlled Trials (CENTRAL, Cochrane Library, all issues up to 2 February 2022);
- MEDLINE (OvidSP 1946 to 2 February 2022);
- EMBASE (OvidSP1974 up to 2 of February 2022);
- PsycINFO (OvidSP 1806 to 2 February 2022); and
- CINAHL (EBSCO 1982 to 2 February 2022).

No date, language or geographic restrictions were applied to the search.

Searching other resources

We searched for reference lists of the included studies and relevant systematic reviews. We also searched online trials registers for ongoing and recently completed studies from the inception of each trial register up to 2 February 2022:

- ClinicalTrials.gov; and
- WHO International Clinical Trials Registry Platform (ICTRP).

At the protocol stage, we planned to additionally handsearch for conference abstracts of certain conferences (e.g. migration conferences). We did not handsearch for conference abstracts due to a lack of resources and because our comprehensive search strategy most likely covered the published conference abstracts. We decided to search ClinicalTrials.gov and ICTRP as the other two clinical trial registries mentioned in the protocol (EU clinical trials register and DRKS) are already included in the ICTRP search portal.

Data collection and analysis

Selection of studies

We applied the following two components of Cochrane's Screen4Me workflow to reduce the number of references retrieved and to assess the search results:

1. Known assessments – a service that matches records in the search results to records that have already been screened in Cochrane Crowd and been labelled as 'a RCT' or as 'not a RCT'.
2. The RCT model - a machine learning RCT classifier (Wallace 2017), which is available in the Cochrane Register of Studies (CRS-Web). The RCT classifier assigns a probability of being a true RCT (from 0 to 100) to each citation. We assumed citations that were assigned a probability score below the cut-point at a recall of 99% to be non-RCTs. We manually dual screened those results that scored on or above the cut-point.

More information about Screen4Me and the evaluations that have been done is available at the Screen4Me website on the Cochrane Information Specialist's portal (see Marshall 2018; McDonald 2017; Noel-Storr 2018; Thomas 2017).

We did not use the third component, which would have consisted of consulting Cochrane Crowd, Cochrane's citizen science platform where the Crowd help to identify and describe health evidence, due to the relatively small number of references remaining.

Two review authors (AB, AAl) independently screened all titles and abstracts identified from searches to determine which met the inclusion criteria. The full text of any article identified as potentially relevant by at least one review author was retrieved. The same two review authors independently screened full-text articles for inclusion or exclusion, with discrepancies resolved by discussion and, if necessary, by consultation with a third author (DC) to reach a consensus (Higgins 2022). All potentially relevant articles excluded from the review at this stage are listed as excluded studies, with reasons provided in the Characteristics of excluded studies. The process of study selection is presented in a flow chart (Figure 2), as recommended by the PRISMA statement (Liberati 2009). Citation details and any available information about ongoing studies and of duplicate publications are also provided as each study (rather than each report) was the unit of interest in this review.

Figure 2. Study flow diagram

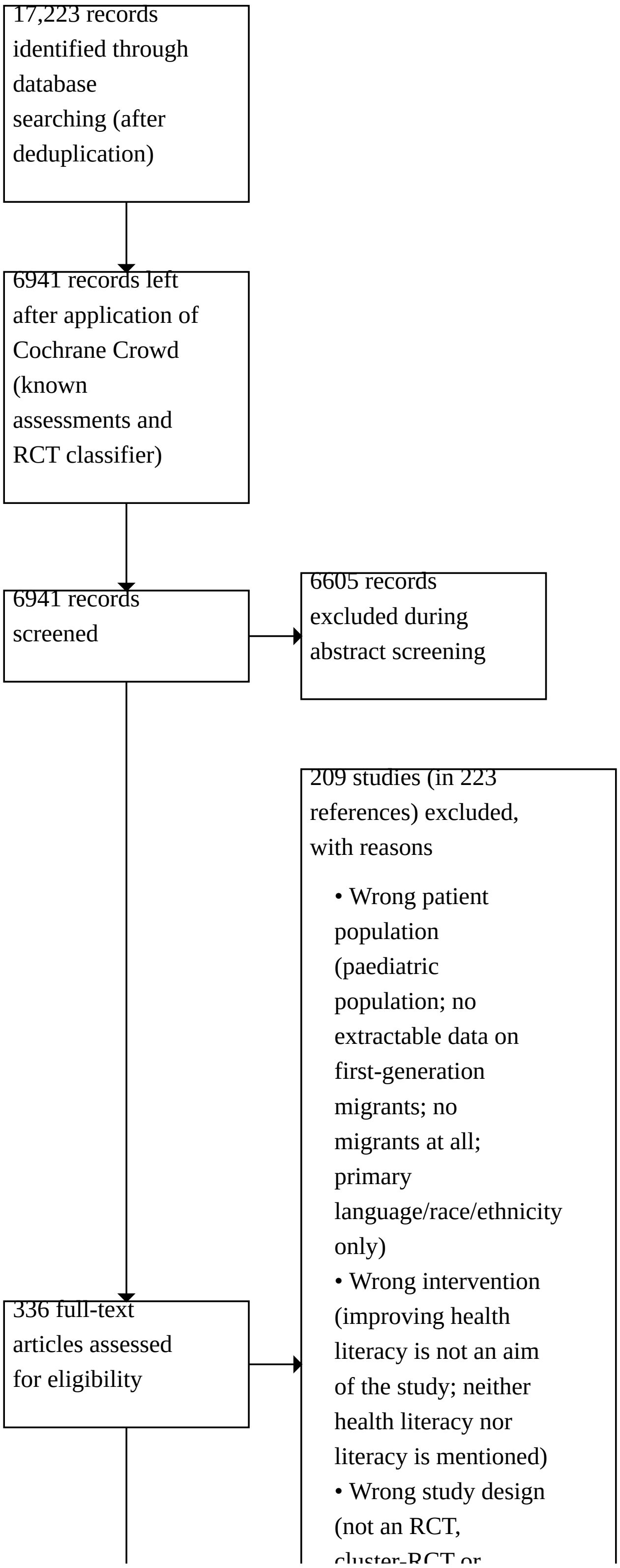
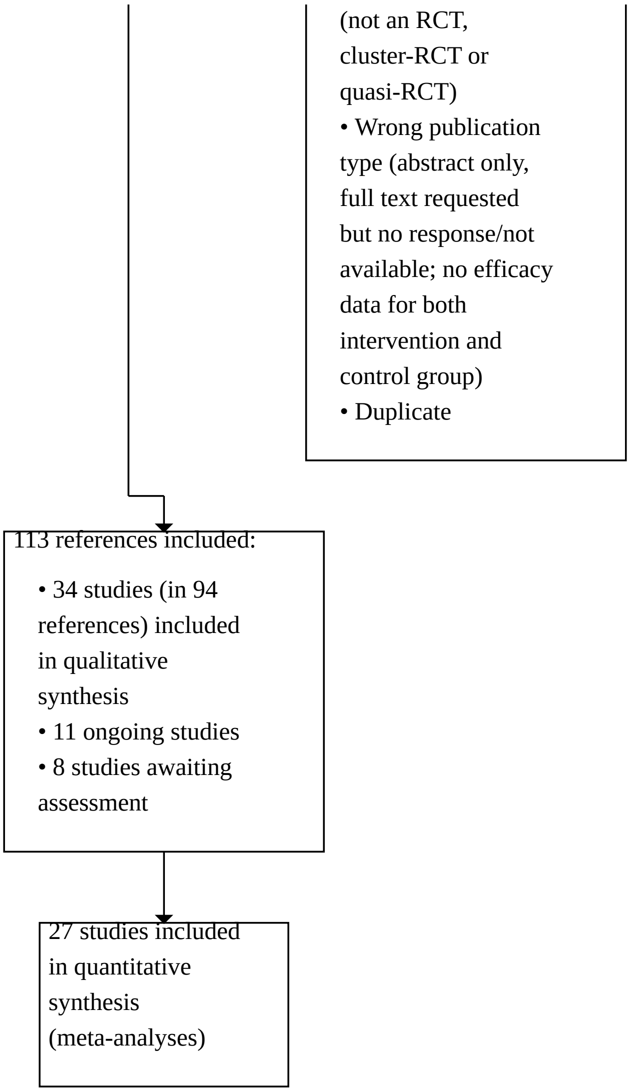


Figure 2. (Continued)



Data extraction and management

Two review authors (AB, CH) independently extracted data from the included studies. Any discrepancies were resolved by discussion until consensus was reached, or through consultation with a third author (AAl) whenever necessary. We developed and piloted a data extraction form on the basis of the Cochrane Consumers and Communication Data Extraction Template (available at: cccrg.cochrane.org/author-resources) and extended it to serve the specific aims of our review.

We extracted the following information:

- general information: author, title, source, publication date, country, language, duplicate publications;
- quality assessment (risk of bias): allocation concealment, blinding (participants, personnel, outcome assessors), incomplete outcome data, selective outcome reporting, selective recruitment of cluster participants, other sources of bias (e.g. methods of measurement or baseline imbalances between study groups);
- study characteristics: trial design, aim of the intervention, setting and dates, source of participants, inclusion/exclusion criteria, random sequence generation, selective recruitment of cluster participants, treatment, compliance with assigned intervention, length of follow-up, details of control group characteristics, e.g. recruitment and selection strategy, types of comparisons (e.g. waiting list control);
- participant characteristics: age, gender, ethnicity, number of participants recruited/allocated/evaluated, participants lost to follow-up, type of intervention;
- outcomes: primary outcome categories: health literacy and adverse events; secondary outcome categories: quality of life, health outcome, health behaviour, health-related knowledge, health service use, individual skills;
- data extraction by outcome: use of assessment tool, timing of outcome assessment; and

- funding: details of the funding source

Furthermore, because this is an equity-focused, theory-driven review, we extended the data extraction form with characteristics we considered relevant regarding health equity and health literacy. This concerned both the included studies and the participants. We used the PROGRESS-Plus concept (Place of residence, Race/ethnicity/culture, Occupation, Sex, Religion, Education, Socioeconomic status, Social capital, age, disability and sexual orientation) to capture equity-relevant data, as recommended in the PRISMA-Equity statement (Welch 2012; Welch 2015). We further extended the data extraction form with intervention features (e.g. language of delivery, cultural adaptation and consumer involvement, and characteristics of the participants (e.g. length of time living in host country) that we considered especially equity-relevant for migrant populations.

We extracted data on the definition of health literacy that guided the intervention and the assessment tool applied (e.g. a measure for disease-specific health literacy or generic health literacy). We used the integrated model by Sørensen 2012 to capture components of health literacy that were addressed by the interventions under study. We designated a component as being addressed when the authors explicitly stated that this certain aspect of health literacy was intended to be improved (e.g. through specific design features applied or the use of a certain outcome measure), the methods reported clearly referred to this component, or when the authors referred to an underlying framework or theory of health literacy that contains one of the following:

- prerequisites of health literacy (knowledge, motivation and competencies); and
- steps of health information processing (access, understand, appraise and apply).

For instance, we judged 'competencies' and 'understand' to be addressed by the intervention when the authors described methods such as learning words and phrases based on medical terminologies as being part of the intervention, or when a performance-based assessment tool for assessing (functional) health literacy was applied (e.g. TOFHLA) (Parker 1995).

We also extracted information on whether the interventions were developed on the basis of a theoretical framework that explicitly referred to health literacy (e.g. the integrated model of health literacy (Sørensen 2012)) or other established behavioural theories such as the theory of planned behaviour (Ajzen 1991), which might help explain causal pathways of the intervention effectiveness.

We extracted the following information for each health literacy intervention:

- theoretical framework underlying the intervention;
- procedure (including material provided);
- intervention provider (e.g. healthcare professional, trained lay health educators or researchers);
- delivery mode (delivered one-to-one or in groups, number and frequency of sessions, total duration of programme);
- delivery method (face-to-face, written, video-based, web-based);
- language of delivery (host country's language or language concordant/bilingual);
- format (individually tailored or standard format);
- setting/location (e.g. community setting, clinic, participants' home); and
- consumer involvement (e.g. in design and/or evaluation of intervention).

The data extraction form was pilot tested with the first five included studies, and refined throughout the review process. One review author entered all extracted data into RevMan 5 (Review Manager 2014), and a second review author checked for accuracy against the data extraction sheets. We contacted the authors of individual studies to ask for additional information whenever required.

Assessment of risk of bias in included studies

We assessed and reported the methodological risk of bias of included studies in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) and the Cochrane Consumers and Communication guidelines (Ryan 2013), which recommend the explicit reporting of the following individual elements for RCTs: random sequence generation; allocation sequence concealment; blinding (participants and personnel); blinding (outcome assessment); completeness of outcome data, selective outcome reporting; and other sources of bias, such as health literacy measurement (e.g. social desirability in self-assessment tools). We considered blinding separately for different outcomes where appropriate (for example, blinding may have the potential to affect objective versus subjective outcome measures differently). We judged each item as being at high, low or unclear risk of bias as set out in the criteria provided by Higgins 2011, and provided a quote from the study report and a justification for our judgement for each item in the risk of bias tables.

We deemed studies to be at the highest risk of bias if they scored as high or unclear risk of bias for either the sequence generation or allocation concealment domains, based on growing empirical evidence that these factors are particularly important potential sources of bias (Higgins 2022). For cluster-RCTs, we also assessed and reported the risk of bias associated with an additional domain: selective recruitment of cluster participants. In addition, we judged studies as being at high risk of bias in the domain 'other bias' when the reported data were not adjusted for the cluster design, and we were not able to re-analyse the data using the appropriate unit of analysis (i.e. when the necessary information such as the intra-cluster correlation coefficient (ICC), or the number of participants in each cluster, could not be obtained (see Unit of analysis issues)).

Two review authors (AB, AAl) independently assessed the risk of bias of included studies, with any disagreements resolved by discussion or involvement of a third author (DC) to reach a consensus. We contacted study authors for additional information about the included studies, or for clarification of the study methods as required. We incorporated the results of the risk of bias assessment into the review through standard tables, and systematic narrative description and commentary about each of the elements, leading to an overall assessment of the risk of bias of included studies and a judgement about the internal validity of the review's results.

Measures of treatment effect

For dichotomous outcomes, we analysed data based on the number of events (e.g. emergency room visits) and the number of people assessed in the intervention and comparison groups. We used these data to calculate the risk ratio (RR) and the corresponding 95% confidence interval (CI). Where continuous scales of measurement were used (e.g. health literacy measurement, knowledge scales), we analysed data based on the mean, standard deviation (SD) and number of people assessed in the intervention and comparison groups to calculate the mean difference (MD) and the corresponding 95% CI. If the MD was reported without individual group data, we used this to report the study results.

If more than one study measured the same outcome using different tools, we calculated the standardised mean difference (SMD) and 95% CI using the inverse variance method in RevMan 5 or standardised the scores to range from 0 to 100 points to facilitate pooling of data (e.g. for the outcome knowledge). When change from baseline scores and post-intervention scores were reported, we prioritised change scores over post-intervention scores, when repeated outcome measures were used in the studies. If not otherwise possible, we used both change scores and post-intervention scores to calculate the SMD. We refer to a study of 21 meta-analyses on osteoarthritis cited in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2022), which did not find a difference between combined SMDs based on post-intervention values and combined SMDs based on change scores (da Costa 2013). If results could not be summarised as point estimates with 95% CIs, we presented results narratively in tabular form for each outcome (see Table 1 to Table 7).

Unit of analysis issues

We checked for unit of analysis errors in the included cluster-RCTs. If errors were found, but sufficient information was available, we re-analysed the data using the appropriate unit of analysis by considering the intracluster correlation coefficient (ICC). We planned to obtain estimates of the ICC by contacting the authors of included studies, or to impute them using estimates from similar studies. We contacted all authors of studies that lacked information, but we could not obtain any additional information. However, one cluster-RCT provided sufficient information, including an ICC, to re-analyse the data in the trial report (Han 2017). One study reported in a secondary reference related to the trial that a cluster-design was used, but did not account for clustering in any analysis (Kim 2014). Four studies stated that they used generalised estimating equations (GEE) to account for clustering, but at least some of the data we used (e.g. for the outcome knowledge) were either not adjusted for the effective sample size (Han 2017; Taylor 2011), or the information was insufficient as only percentages were reported for our outcomes of interest (Bloom 2014; Tong 2017). For these outcomes, we used the ICC reported by Han 2017 to re-analyse the data. When we were not able to do so, we reported the unadjusted effect estimates and annotated them as (possible) unit of analysis error.

We used the most conservative ICC reported by Han 2017 for outcomes that have not been assessed by Han 2017, but by other studies to re-analyse the data. For example, the ICC for health literacy reported by Han 2017 was 0.03, but the ICC for cervical cancer knowledge was 0.02. We used an ICC of 0.03 for health literacy, self-efficacy and health behaviour, but 0.02 for high blood pressure knowledge to re-analyse the data reported by Kim 2014.

Dealing with missing data

We contacted study authors to obtain missing data (e.g. for participants, outcomes, effect values stratified by gender or summary data). We contacted the authors of 29 studies at least once, of whom 12 responded. Eight authors provided us with missing information or additional data. When authors responded but were not able to provide us with the missing data, or when we did not receive a response, we categorised these studies as 'Data sought but not used' (see Characteristics of included studies).

Where possible, we conducted all analyses based on the intention-to-treat principle. Otherwise, we analysed data as reported. We reported on losses to follow-up and assessed this as a source of potential bias (see Incomplete outcome data (attrition bias)).

For missing outcome or summary data, we imputed missing data where possible. If estimates for mean and standard deviations were missing, we calculated these statistics from reported data whenever possible, using the approaches described in Chapter 6 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2022a). When either the baseline or the post-intervention SD was not reported, we substituted it with the other, so long as we did not expect the intervention to alter the variability of the outcome measure, as recommended in Chapter 6.5.2.8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2022a). We aimed to investigate, through sensitivity analyses, the effects of any imputed data on pooled effect estimates. However, due to a lack of studies included in the respective pooled analyses (two studies each), we were not able to conduct any sensitivity analysis for imputed data.

Assessment of heterogeneity

Before we conducted any meta-analysis, we assessed studies for similarities in terms of setting, intervention, comparison and outcome measures. We then grouped studies according to the characteristics of the interventions (e.g. intervention components, mode and method of delivery), the comparison groups and the outcomes assessed. Where we detected substantial methodological heterogeneity across included studies, we used a narrative approach to data synthesis (see Data synthesis) and reported the results in additional tables where possible (see Table 1 to Table 7). As our aim was to assess the general effectiveness of health literacy interventions in migrants, we did not group studies according to the participants' clinical characteristics for the purposes of our analyses. We reported on the results of our synthesis as recommended by the reporting guideline for Synthesis Without Meta-Analysis (SWiM) in systematic reviews (Campbell 2020).

Where studies were considered to be similar enough to allow pooling of data in meta-analyses, we assessed the degree of heterogeneity by visual inspection of forest plots and by examining the Chi^2 test for heterogeneity. We quantified heterogeneity using the I^2 statistic. We considered an I^2 value of 50% or more to represent substantial heterogeneity. However, we interpreted this value in light of the size and direction of effects and the strength of the evidence for heterogeneity, based on the P value from the Chi^2 test (Higgins 2022); we considered the direction of effects and the variability in these rather than variability in the size of effects as a basis for our interpretation of heterogeneity. We considered this in our GRADE assessment in that we did not downgrade for inconsistency when the direction of effect was consistent across studies, despite some variability in the size of effects across individual studies (e.g. for the outcome health-related knowledge). We did, however, downgrade for inconsistency when there was high variability in measurement (e.g. when there was no gold standard measure for assessing a certain outcome) that added further uncertainty to the effects of health literacy interventions for this outcome.

Assessment of reporting biases

We assessed reporting bias qualitatively based on the characteristics of the included studies (e.g. if only small studies that indicated positive findings had been identified), and if information obtained from contacting study authors suggested that there were relevant unpublished studies.

We planned to investigate publication bias by using funnel plots if at least 10 studies were available for inclusion in the review. No meta-analysis included at least 10 studies, so we did not create funnel plots to assess reporting bias.

Data synthesis

We meta-analysed data based on whether the interventions in the included trials were similar enough in terms of setting, intervention, comparison and outcome measures to ensure meaningful conclusions from a statistically pooled result. We then pooled results across studies in cases where investigators used similar outcome measures, and we expected the effects to be independent of the type of health topic the participants received information on. We conducted a number of meta-analyses, as the heterogeneity of the included studies did not allow for pooling all studies that reported a single outcome together. When studies were judged sufficiently similar to be pooled together, but varied in the programme duration, we pooled the results with the most common timing of outcome assessment (e.g. immediately after the programme was completed) and conducted subgroup analyses by length of programme when appropriate (see Subgroup analysis and investigation of heterogeneity).

For inclusion in meta-analyses, we used the longest time point reported for each study and pooled the data together with studies reporting the same time point for the same outcome. For example, when one study assessed the same outcome two times within the same category (i.e. short-term, medium-term or long-term). However, we made one exception: for Unger 2013, we decided to pool only the shorter time point reported because the authors stated that "*the data collectors reported that several students shared their photonovel with students in the text pamphlet group after the posttest.*" (Unger 2013, p. 405). Thus, intervention fidelity was not assured, which might have introduced a bias concerning the assessment at one-month follow-up.

Due to the heterogeneity of included studies we used the random-effects model for all meta-analyses. We created forest plots to display individual study results, ordered by weight in ascending order. In addition, we narratively summarised all outcomes that met our inclusion criteria and presented them in additional tables (see Table 1 to Table 7).

We used a three-step approach to group the included studies and to examine possibilities for meta-analysis of the results within the prespecified outcome categories. The first author's (AB) grouping was independently reviewed by a second author (AAl or DC). The assessment of whether there was sufficient similarity for subordinating interventions, but also control groups, to one category was made by at least two review authors. All discrepancies were resolved by the involvement of a third review author.

Firstly, studies were grouped in terms of their main components with regard to content-related and methodological features. The categorisation of main intervention components was piloted with the first five studies and refined throughout the process of the data synthesis.

- Intense health education with direct provider contact, including:
  - multiple methods of knowledge transfer, provider delivered (e.g. multimedia presentations, interactive role-plays, discussions, evaluations).
- Simple health education without direct provider contact, including:
  - one or up to two methods of knowledge transfer, media delivered (e.g. written information, interactive online education, educational video, educational messages).
- Self-monitoring, including:
  - provision of take-home measuring instruments and supervision in order to manage, document and adapt one's own health or course of disease (e.g. blood pressure monitor).
- Role modelling, including:
  - information that was substantiated by illustrated narratives or the introduction of role modelling characters using audio- and/or visual formats (e.g. photonovel, narrative video).
- Motivational counselling, including:
  - provider and/or peer feedback on personal progress (e.g. with the use of motivational interviewing, phone calls, interactive messages).
- Redesign of written medical instructions, including:
  - (health) literacy adapted medication labels or written information (e.g. using (culturally adapted) plain language, pictograms).

Secondly, the main intervention components were set in relation to specific design features that we considered relevant for the intervention effect (e.g. interaction with the provider, number and frequency of educational sessions, total duration and intensity of the programme).

The following subcategories resulted from the first two steps of grouping:

- culturally and literacy adapted self-management programme;
- culturally adapted health literacy skill building course;
- culturally and literacy adapted telephone education;
- culturally and literacy adapted audio-/visual education without personal feedback; and
- culturally and literacy adapted medical instruction.

Thirdly, the study groups were ordered according to their comparator.

It was planned to include the following types of comparisons:

- health literacy intervention versus no intervention (including usual care); and
- health literacy intervention versus another health literacy intervention.

The following comparators were formed according to the trials identified:

- no health literacy intervention (i.e. attention placebo intervention, wait-list control or usual care/no intervention);
- unrelated health literacy intervention (i.e. same method or mode of delivery, but information on a *different* health topic);
- written information on the same health topic (i.e. written pamphlet/brochure, written pictogram); and
- another health literacy intervention (i.e. information on the *same* health topic in a different format, e.g. narrative video compared to factual knowledge video).

As the concept of health literacy is related to the processing of health information in different contexts, we referred to comparator interventions that provided information on a *different* health topic than that in the intervention as 'unrelated health literacy intervention' and reported the results together with comparators categorised as 'no health literacy intervention'. We referred to all comparators that did not fulfil our predefined criteria for health literacy interventions (see Types of interventions) as 'no health literacy intervention'.

For studies with more than two intervention groups, we used the following approaches: we extracted data from two groups, of which at least one applied a health literacy intervention, and provided the strongest contrast. If at least two groups referred to alternative variants of the same intervention, we combined the intervention groups to create a single pair-wise comparison, as recommended in Chapter 16.5 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2022). If the combination of intervention groups was not possible (e.g. due to a lack of information needed or when data were not presented in a way that they could be combined, see Poureslami 2016b), we extracted data from the two groups that provided the strongest contrast as described above.

The following comparisons resulted from the grouping procedure:

1. culturally and literacy adapted self-management programme versus no health literacy intervention;
2. culturally and literacy adapted self-management programme versus written information on the same topic;
3. culturally adapted health literacy skill building course versus no or unrelated health literacy intervention;
4. culturally and literacy adapted telephone education versus unrelated health literacy intervention;
5. culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention;
6. culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic;
7. culturally and literacy adapted audio-/visual education without personal feedback versus another culturally and literacy adapted audio-/visual education without personal feedback; and
8. culturally and literacy adapted medical instruction versus no health literacy intervention.

As our second aim was to assess whether female or male migrants benefit differently from any health literacy intervention, we formed a ninth comparison:

- female migrants' versus male migrants' benefit from any health literacy intervention.

Subgroup analysis and investigation of heterogeneity

We intended to conduct subgroup analyses for gender, ethnicity and health literacy assessment (if named as such) (see Objectives). Since health literacy can be defined and measured in different ways, we planned to conduct a subgroup analysis for perception-based versus performance-based measurement tools applied in the included studies. However, no self-assessment tool was used in the included studies. Therefore, it was not possible or meaningful to follow the protocol in terms of conducting subgroup analyses for perception-based versus performance-based health literacy assessment.

Due to high heterogeneity of the included interventions, participants and comparators and an insufficient number of studies in any of the meta-analyses, we were not able to conduct quantitative subgroup analyses for ethnicity or gender either. However, we were able to conduct separate analyses on outcomes for which we could obtain gender-separate scores from the study authors.

Contrary to the protocol, we conducted post hoc quantitative subgroup analyses for specific design features when we considered studies similar enough to be combined in a meta-analysis, but nevertheless design-specific heterogeneity needed to be considered. For example, when there was high variance in the programme duration, we conducted subgroup analyses by the length of the programme (e.g. up to six months versus up to 12 months) to investigate the reasons for heterogeneity.

Sensitivity analysis

We conducted sensitivity analyses for high risk of bias versus low risk of bias studies, when possible. In addition, we conducted sensitivity analyses when heterogeneity was unexplainably high. For example, the results of Kaur 2019 were noticeably better than the results of other studies included in the same meta-analysis, and we could not explain this with the study design or the participant characteristics.

Summary of findings and assessment of the certainty of the evidence

We presented the results of meta-analyses and narrative syntheses in summary of findings (SoF) tables for the major comparisons of the review. We provided a source and rationale for each assumed risk in the tables, and used the GRADE approach to assess the certainty in the evidence based on the methods described in Chapter 14 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2022). Furthermore, we used the GRADEpro GDT software for our assessments (GRADEpro GDT). Where meta-analyses were not possible, we presented results in a narrative format, taking into account the GRADE assessments (Ryan 2016).

We presented all time points for each key outcome in each study in the SoF tables, when the intervention effect on the respective outcome appeared to vary over time (e.g. for knowledge). We made one exception: for Koniak-Griffin 2015, we report the shorter time point (immediately post-intervention) because "there was a statistically significant decrease in the control group [at three-month follow-up], approaching a 1000-step decline, whereas intervention participants maintained their activity level." (p.82 f). Moreover, the number of average daily steps in the intervention group fell back to the baseline level (which was 8571 average daily steps (SD 3130)). Thus, the calculated MD does not reflect an actual improvement of the intervention group, so that reporting the results of the three-month follow-up assessment in the SoF table would have unintentionally overestimated the intervention effect.

Involvement of consumers

The involvement of consumers is important for obtaining a better understanding of the performance and effectiveness of health literacy interventions, particularly how they reach consumers. This effectiveness review and the linked QES were part of an overarching project on Gender-specific Health Literacy in Individuals with a Migration background (GLIM) that aimed to examine gender-specific aspects of health literacy in migrants by applying a mixed-methods approach. The project was funded by the Federal Ministry of Education and Research in Germany (grant number 01GL1723).

We involved consumers by conducting focus group discussions (FGDs) with female and male healthcare professionals (N = 31) in Germany, of whom more than 50% had a migrant background themselves. Our aim was to examine the perceived health literacy-related challenges and needs, as well as the applied solutions of healthcare professionals in Germany when engaging with persons with a migrant background (defined as first- or second-generation migrants). We particularly focused on personal factors such as gender, situational conditions such as the current workload, and societal and environmental factors such as system-related conditions that may impact the flow of information in transcultural treatment settings (Baumeister 2021a; Chakraverty 2020). We used the results of the FGDs to discuss and reflect on the findings of the current review (see Agreements and disagreements with other studies or reviews). Moreover, consumers were involved in the development of the review protocol as consumer referees provided written feedback on it. Consumer referees also read the results of the review and provided written feedback, as part of Cochrane's editorial processes.

At the protocol stage, we had planned to also involve consumers by conducting gender-separate focus group discussions (FGDs) with female and male migrants, as well as to conduct a final symposium with different stakeholders, such as experts from political and healthcare contexts, to discuss the impact and implications of our primary and secondary findings for healthcare decision-making at the political level, particularly in Germany. However, due to a lack of financial and human resources, this was not possible.

RESULTS

Description of studies

Results of the search

Our search yielded 17,223 results. After removal of duplicates and application of the RCT classifier, 6941 records were included for title and abstract screening (Figure 2). We assessed 336 possibly eligible references in full text. After reading the full texts, we excluded 223 references that did not fulfil our inclusion criteria.

Included studies

We included 34 studies (94 references) in this review (Figure 2). See the Characteristics of included studies for a full description of the included studies. In addition, eight references that we identified are still awaiting assessment (see Characteristics of studies awaiting classification), and 11 are ongoing (see Ongoing studies).

Study design

Of the 34 included studies, six were cluster-RCTs (Bloom 2014; Elder 1998; Han 2017; Kim 2014; Taylor 2011; Tong 2017), and 28 were RCTs. All were published in English.

Location

All studies were conducted in high-income countries, 27 of which were in the United States of America (USA). Four studies were conducted in Canada (Kaur 2019; Poureslami 2016a; Poureslami 2016b; Taylor 2011), two in Asia (Qatar and Singapore) (Kheir 2014; Wong 2020), and one study in Australia (Kiropoulos 2011).

Participants

We used the PROGRESS-Plus framework to assess equity-relevant data. A full description of participants is shown in Table 13.

The included studies recruited between 76 (Gwede 2019) and 943 participants (Valdez 2018). In total, 8249 participants were allocated to either an intervention or a control arm. According to the distribution of immigrant groups in the USA, most of the studies focused on participants who were born in Central and South America (19 studies; Calderón 2014; DeCamp 2020; Elder 1998; Gwede 2019; Hernandez 2013; Koniak-Griffin 2015; Lepore 2012; Mohan 2014; Ochoa 2020; Otilingam 2015; Payán 2020; Rosal 2005; Rosal 2011; Soto Mas 2018; Sudore 2018; Thompson 2012; Unger 2013; Valdez 2018; van Servellen 2005) or East and South Asia (13 studies; Bloom 2014; Bailey 2012; Han 2017; Kaur 2019; Kheir 2014; Kim 2009; Kim 2014; Kim 2020; Poureslami 2016a; Poureslami 2016b; Taylor 2011; Tong 2017; Wong 2020). One study included participants from both Central and South America and Asia (Valdez 2015), and one study included participants who had migrated from Europe (i.e. from Greece or Italy) to Australia (Kiropoulos 2011). The participants' time living in the host country was reported in 25 studies (Bailey 2012; DeCamp 2020; Elder 1998; Gwede 2019; Han 2017; Hernandez 2013; Kheir 2014; Kim 2009; Kim 2014; Kim 2020; Kiropoulos 2011; Koniak-Griffin 2015; Ochoa 2020; Otilingam 2015; Payán 2020; Poureslami 2016a; Poureslami 2016b; Soto Mas 2018; Sudore 2018; Taylor 2011; Thompson 2012; Tong 2017; Unger 2013; Valdez 2015; Valdez 2018); the average time since immigration ranged from less than one year up to 62 years.

Participants' occupational status was reported in 15 studies (Elder 1998; Gwede 2019; Han 2017; Hernandez 2013; Kaur 2019; Kheir 2014; Kim 2009; Kim 2020; Kiropoulos 2011; Koniak-Griffin 2015; Poureslami 2016a; Rosal 2005; Rosal 2011; Tong 2017; Wong 2020); two of these provided data on the type of occupation: these were migrant workers in the petrol industry (Kheir 2014), and migrant workers presumably working in Singaporean households (Wong 2020). All studies reported at least some information about the participants' formal education.

Twenty-one studies reported data related to social capital (e.g. number of children) (DeCamp 2020; Elder 1998; Gwede 2019; Han 2017; Hernandez 2013; Kim 2009; Kim 2020; Kiropoulos 2011;

Koniak-Griffin 2015; Lepore 2012; Ochoa 2020; Otilingam 2015; Payán 2020; Rosal 2011; Sudore 2018; Taylor 2011; Thompson 2012; Tong 2017; Valdez 2015; Valdez 2018; Wong 2020).

In total, 24 studies reported any information related to the participants' socioeconomic status such as income (seven studies; Bailey 2012; Elder 1998; Kheir 2014; Kim 2009; Otilingam 2015; Sudore 2018; van Servellen 2005), or health insurance (two studies; Kim 2014; Lepore 2012), and 15 studies reported information related to both (Calderón 2014; DeCamp 2020; Gwede 2019; Han 2017; Hernandez 2013; Kaur 2019; Kim 2020; Koniak-Griffin 2015; Ochoa 2020; Payán 2020; Rosal 2005; Rosal 2011; Thompson 2012; Tong 2017; Valdez 2018).

The mean age was reported in 24 studies (Bailey 2012; Calderón 2014; DeCamp 2020; Elder 1998; Gwede 2019; Han 2017; Kheir 2014; Kim 2009; Kim 2014; Kim 2020; Kiropoulos 2011; Koniak-Griffin 2015; Lepore 2012; Otilingam 2015; Payán 2020; Poureslami 2016a; Rosal 2005; Sudore 2018; Thompson 2012; Tong 2017; Unger 2013; Valdez 2015; Valdez 2018; Wong 2020) ranging from 28.7 years (Elder 1998) to 70.9 years (Kim 2014).

The least described PROGRESS-Plus domains were religion, sexual orientation and disability. Three studies provided concrete information on the participants' religion (Bloom 2014; Sudore 2018; Wong 2020), whereas one other study assessed how religious beliefs might influence medical-decision making (Gwede 2019). Four studies recruited their participants from churches (Han 2017; Kim 2009; Kim 2014; Kim 2020). One study reported data on the participants' sexual orientation (van Servellen 2005), whereas no study included participants with any mental or complex disability.

Most participants included in the studies were female (75.4%). Four studies did not provide data on the number of female and male participants randomly assigned to either the intervention or control arm (Elder 1998; Poureslami 2016a; Poureslami 2016b; Unger 2013). Ten studies had an all-female population (Bloom 2014; DeCamp 2020; Han 2017; Hernandez 2013; Koniak-Griffin 2015; Ochoa 2020; Otilingam 2015; Payán 2020; Valdez 2018; Wong 2020), and two studies included men only (Kheir 2014; Lepore 2012). Bloom 2014 also educated the husbands of women included in their study, but we had insufficient information to consider these data.

Health literacy

Nineteen studies reported baseline data on health literacy using a validated assessment tool. Of these, 12 additionally reported an outcome measure for health literacy (named as such) to assess the effectiveness of the intervention (Calderón 2014; Han 2017; Hernandez 2013; Kaur 2019; Kim 2014; Kim 2020; Kiropoulos 2011; Otilingam 2015; Soto Mas 2018; Unger 2013; van Servellen 2005; Wong 2020). Ten studies used a disease-specific assessment tool (Calderón 2014; Han 2017; Hernandez 2013; Kaur 2019; Kim 2014; Kim 2020; Kiropoulos 2011; Unger 2013; van Servellen 2005; Wong 2020). Two of these studies made use of both, a disease-specific and either one (Hernandez 2013) or more generic health literacy assessment tools (Kim 2020). Two studies reported results on generic functional health literacy (Soto Mas 2018) or health numeracy only (Otilingam 2015). Poureslami 2016a reported that they *"assessed patients' health literacy (as ability to access, understand, and use asthma-related information)"* but the results were not reported. A description of the assessment tools applied as well as the baseline scores of the participants in each study is shown in the Characteristics of included studies section.

Interventions

The identified interventions varied widely with regard to the design features such as methods and modes of delivery, the targeted populations, the health literacy components addressed and the outcomes assessed. An overview of the studies' grouping according to the main intervention components and the comparators is shown in Table 14 and in the Characteristics of included studies section.

In the following, the grouped interventions are described with regard to the intervention complexity in descending order.

1 Culturally and literacy adapted self-management programme

Studies categorised as culturally and literacy adapted self-management programmes aimed to improve self-care management in individuals with at least one chronic disease or a certain disease risk and low literacy skills and/or low language proficiency. Interventions were characterised by the following main intervention components: 1) a phase of intense one-to-one or group-based health education and 2) a maintenance phase of self-monitoring accompanied by 3) at least monthly individual motivational counselling up to a total programme duration of 12 months. The individual counselling sessions during the maintenance phase were usually delivered through telephone or face-to-face either by research staff (Kaur 2019; Rosal 2011), registered study nurses and/or trained lay community health workers (e.g. promotoras; lay Hispanic/Latinx community members who are trained to provide health education in the community) (Han 2017; Kim 2009; Kim 2014; Kim 2020; Koniak-Griffin 2015; Rosal 2005; van Servellen 2005). The counselling sessions were carried out to reinforce the lessons learned, to motivate to maintain self-care skills, and to provide normative feedback on the participants' progress. Participants included in these interventions were either (predominantly) male HIV-positive Latino immigrants (van Servellen 2005) or overweight Latinas at risk for developing a cardiovascular disease (Koniak-Griffin 2015), Korean or (Caribbean) Latinx immigrants with diabetes (Kim 2009; Kim 2020; Rosal 2005; Rosal 2011), Korean immigrants with high blood pressure (Kim 2014), or Korean immigrants at risk for breast or cervical cancer (Han 2017). One study aimed to improve oral health literacy in Punjabi immigrants by teaching correct dental hygiene and raising awareness of oral diseases such as gingivitis and dental plaque (Kaur 2019). All self-management interventions were individually tailored and facilitated by multidisciplinary teams except for one less complex intervention that was delivered by the lead researcher alone (Kaur 2019).

For one study, we only found an abstract describing a few results of the intervention's evaluation (Bloom 2014) and two publications describing the qualitative formative research to develop the intervention (Shirazi 2013; Shirazi 2015). Thus, the information about the intervention features is limited, but we assume that this intervention most likely fits into this grouping. Briefly, the study was based on extensive community-based participatory research and addressed Afghan Muslim women's breast health, of whom many have had a family history of breast cancer. It aimed to educate Afghan Muslim women about breast health and to improve mammography screening rates by means of culturally and literacy-sensitive, faith-based group education on a weekly basis (total duration is unclear), followed by the support of trained community health navigators to facilitate making and keeping appointments for mammography screening as needed. In addition, the male heads of the family were educated to convince them of the importance of educating their wives about breast health. Further details about the involvement of the participants' husbands, the intensity and total duration of the programme were not reported.

2 Culturally adapted health literacy skills building course

Interventions categorised as culturally adapted health literacy skill building courses were characterised by intense health education delivered in a group format, aiming to improve health literacy skills in the domain of disease prevention. These included multiple strategies of knowledge transfer such as risk communication, interactive role-plays to practise communication with healthcare providers, culture-sensitive narratives delivered through diverse multimedia formats (e.g. via video), and several other practices to improve health-related reading, writing and numeracy skills (e.g. writing short texts or calculating daily doses of calories). Three studies were conducted in the setting of adult language schools embedding face-to-face health literacy skills training related to a certain health topic in an existing English as a second language (ESL) course curriculum (Elder 1998; Soto Mas 2018; Taylor 2011). All of these interventions were delivered through trained ESL teachers. The mode of delivery for these courses ranged from one or two face-to-face group sessions lasting three hours (Taylor 2011), to more intense courses with 15 hours (Elder 1998), up to 42 hours of intense health literacy training delivered in 12 face-to-face group sessions (Soto Mas 2018). Two studies made use of two face-to-face group sessions lasting from 90 minutes (Tong 2017) to two hours (Otilingam 2015). In one study, the participants received additional telephone-based follow-up sessions that were delivered by trained lay community health workers (Tong 2017). Another study was delivered by trained bilingual research assistants (Otilingam 2015). The interventions were related to cardiovascular health behaviour in Latinx immigrants (Elder 1998; Soto Mas 2018), hepatitis B testing (Taylor 2011), colorectal cancer screening (Tong 2017) or depression (Wong 2020) in South and East Asian immigrants. One study with four arms and two intervention groups provided education about cardiovascular health only (intervention group 1) or cardiovascular health and brain health (intervention group 2) (Otilingam 2015).

3 Culturally and literacy adapted telephone education

One study provided information about prostate cancer through trained graduate-level health educators who delivered tailored telephone education (lasting 20 minutes) to immigrant men of African descent from the Caribbean (Lepore 2012). In addition, the participants received mailed health brochures on the topic. Participants in the control group received telephone education about healthy nutrition.

4 Culturally and literacy adapted audio-/visual education without personal feedback

Interventions categorised as culturally and literacy adapted audio-/visual education without personal feedback made use of simple health education delivered through diverse audio- and/or visual formats (e.g. via video, interactive touchscreen computer, websites and/or text messages, or via telephone calls). These studies aimed to improve knowledge and understanding of, and attitudes towards a certain disease or disease prevention service (e.g. screening, vaccines). They were designed to promote a specific health behaviour such as the correct medication dosing or to improve adequate health service use through educational messages embedded in culturally adapted narratives. Two studies aimed to improve the inhaler use in Asian immigrants either with asthma (Poureslami 2016a) or chronic obstructive pulmonary disease (COPD) (Poureslami 2016b). The information was either presented by a physician with the same ethnic background or through video-recorded role-plays conducted by peer patients or lay individuals of the community. Four studies made use of printed narratives (Payán 2020) and photonovels (in Spanish "fotonovela"; small comic books that tell a story of a person coping with a certain disorder or a health problem written at a low literacy reading level) (Hernandez 2013; Unger 2013). The included studies were related to depression (Hernandez 2013; Unger 2013), colorectal cancer (Gwede 2019) or breast cancer (Payán 2020). All four studies addressed Latinx immigrants. Payán 2020 and Hernandez 2013 delivered the printed photonovel verbally through a promotora, whereas Gwede 2019 provided an educational DVD in addition to the photonovel. Three other studies also used educational videos including narratives and role modelling elements either relating to diabetes (Calderón 2014), to cervical cancer (Ochoa 2020), or to child vaccinations and infant diseases (DeCamp 2020). Of these, one study additionally provided monthly interactive text messages (for 10 months) (DeCamp 2020). Two studies delivered health information about child nutrition (Thompson 2012) or cervical cancer (Valdez 2018) to Latinx immigrants through interactive touchscreen kiosks. Another two presented the information through interactive websites (Kiropoulos 2011; Sudore 2018), one study embedding case studies of individuals coping with depression in the "MIDonline" website, which was designed to educate Southern European immigrants living in Australia about depression (Kiropoulos 2011). The other study intended to increase engagement in advance care planning among elderly Latinos with chronic illnesses and to mitigate the effects of low literacy (Sudore 2018). The patient-directed interactive online advance care planning programme (PREPARE for your care) consisted of five modular skill-building steps including interactive online questions that generated an individual action plan and a summary of participants' individual wishes. Reminder calls by the research staff were carried out to remind the participants of talking about their wishes with their primary doctor (Sudore 2018).

Narratives in the form of photonovels or embedded in DVDs have also been used in other intervention studies as part of a broader main strategy such as group-based health education to foster adequate health service use or to model attitudinal change (Han 2017; Kaur 2019; Otilingam 2015; Rosal 2005; Rosal 2011; Soto Mas 2018; Taylor 2011).

5 Culturally and literacy adapted medical instruction

Three studies included a culturally and literacy-adapted presentation of written medical instructions as a single strategy using either pictograms, which were substantiated by verbal (Kheir 2014) or video instruction (Mohan 2014), or easily understandable, culturally adapted terminology (Bailey 2012). The primary aim of these studies was an improved medication understanding and use of prescribed medication without an additional component of disease-specific knowledge transfer. All studies were delivered in one session using a written format (Bailey 2012; Kheir 2014). One study additionally included a short video instruction (Mohan 2014). None of these studies were individually tailored.

Comparator

Twenty-nine studies were two-arm RCTs and five studies were multiple-arm RCTs (Kheir 2014; Otilingam 2015; Payán 2020; Poureslami 2016a; Poureslami 2016b). As recommended in Chapter 6.2.9 of the *Cochrane Handbook for Systematic Reviews of Interventions*, we created single pairwise comparisons for each trial (Higgins 2022a), resulting in two studies that were included in more than one comparison (Poureslami 2016a; Poureslami 2016b). An overview of the comparisons included in this review is shown in Table 14.

Health literacy interventions were compared with 'no health literacy intervention' including usual care and no additional intervention (Bailey 2012; DeCamp 2020; Kheir 2014; Mohan 2014; Rosal 2011; Soto Mas 2018; Thompson 2012; van Servellen 2005), placebo intervention (Hernandez 2013; Koniak-Griffin 2015; Kiropoulos 2011) and delayed intervention (Bloom 2014; Otilingam 2015; Wong 2020), or with 'unrelated health literacy intervention' (participants received the same intervention but information on a *different* health topic) (Elder 1998; Lepore 2012; Taylor 2011; Tong 2017). In 14 studies, a health literacy intervention was compared to 'written information on the same health topic' (Calderón 2014; Gwede 2019; Han 2017; Kaur 2019; Kim 2009; Kim 2014; Kim 2020; Han 2017; Payán 2020; Rosal 2005; Sudore 2018; Unger 2013; Valdez 2015; Valdez 2018). In four of these studies, participants in the control group received a brief brochure, but also a delayed intervention after the programme was completed (Han 2017; Kim 2009; Kim 2014; Kim 2020).

One study compared two variants of a health literacy intervention, which were a narrative educational video related to cervical cancer compared to a factual knowledge video on the same topic. We reported the results in *comparison 7* 'culturally and literacy adapted audio-/visual education without personal feedback versus another culturally and literacy adapted audio-/visual education without personal feedback' (Ochoa 2020).

Five studies were multiple-arm RCTs. Two of these studies, with four arms each, compared a (community) physician-led factual knowledge video (group 1) to a narrative, peer group role-played video (group 2), to a group who watched both videos (group 3), or to a control group who read a pictorial pamphlet on the same topic (group 4) (Poureslami 2016a; Poureslami 2016b). As we categorised more than one of these interventions as being a health literacy intervention, we reported these studies in two comparisons. Firstly, we combined groups 1, 2 and 3 to create a single pairwise comparison with group 4 and reported the results in *comparison 6.* Secondly, we reported the results for group 1 compared to group 2 in *comparison 7*. One other four-arm parallel trial compared two variants of the same intervention to two variants of wait-list control groups (Otilingam 2015). In this study, intervention group 1 consisted of a disease prevention and health literacy skills building course related to cardiovascular health, whereas intervention group 2 consisted of the same course extended by 20 to 30 minutes of education on brain health. The wait-list control groups differed in the timing of outcome assessments only. Control group 1 was assessed baseline, post-test and at one-month follow-up, whereas control group 2 was assessed post-test only. We pooled both intervention and control groups to create a single pairwise comparison for the post-test assessment. We compared the pooled intervention groups to control group 1 for the follow-up assessment. Another three-arm parallel trial compared a culturally and literacy adapted printed brochure about breast cancer to read oneself (group 1) to the same brochure, which was delivered by a community health worker (group 2) with a language concordant standard brochure about breast cancer (group 3, 'no health literacy intervention') (Payán 2020). We pooled group 1 and group 2, comparing it to group 3, which we refer to as the control group. Another study had two intervention arms split into three conditions for the analysis (Kheir 2014). Pictogram-only labels (group 1) were compared with pictogram labels with verbal instructions (group 2) to a standard text label with verbal instructions (group 3, here referred to as the control group). We included group 1 and group 3 only, as they built the greatest contrast.

Theories and frameworks guiding the interventions

Various health-related theories and frameworks were used to guide intervention development, implementation and/or evaluation. Table 15 presents an overview of the theoretical frameworks named by the study authors.

In summary, 19 established theories were applied in 21 studies, some of which referred to more than one theory guiding the intervention development, implementation and/or evaluation. Established theories and frameworks used referred to both theories of health promotion and health behaviour change, but also to behavioural theories in general. Most studies referred to Bandura's social-cognitive theory (Bandura 1977; Bandura 2002; Bandura 2004; Elder 1998; Hernandez 2013; Kim 2009; Rosal 2005; Rosal 2011; Soto Mas 2018; Sudore 2018; Tong 2017) or theories of self-efficacy (Bandura 1994; Bandura 1997; Hernandez 2013). Three studies informed their intervention with the transtheoretical model of health behaviour (Prochaska 1997; Sudore 2018; Tong 2017; Valdez 2018), three studies referred to the health belief model or its variations (Champion 2008; Janz 1984; Otilingam 2015; Payán 2020; Rosenstock 1988; Thompson 2012), and another three studies applied adult learning theory (Knowles 1984) or learning theories in general (Rosal 2011; Semple 2000; Smith 1999; Soto Mas 2018; Thompson 2012). The PRECEDE-PROCEED model (Green 1991) was used by Han 2017, Kim 2009 and Kim 2020. Unger 2013 and Valdez 2015 referred to the theory of reasoned action/planned behaviour (Ajzen 1991; Fishbein 1975).

Moreover, DeCamp 2020 referred to the behavioural skills model (Amico 2011), Gwede 2019 to the preventive health model (Aguado Loi 2020; Mc Queen 2008), Taylor 2011 used the health behaviour framework, which integrates various health- and behaviour-related theories and concepts including inter alia the social-cognitive theory or the transtheoretical model (Curry 1994), Sudore 2018 additionally referred to the interpersonal communication competence model (Spitzberg 1984; Street 1995; Street 2003), Kim 2014 used the self-help model of learned response to chronic illness experiences (Braden 1990b; Braden 1990a), Kaur 2019 informed the intervention with the behaviour change wheel (Michie 2011), Elder 1998 used operant conditioning (Skinner 1953), Payán 2020 additionally referred to the input output framework (McGuire 2015), Lepore 2012 to the Ottawa decision support framework (Doull 2006), and Hernandez 2013 referred to the model of culture-centric narratives (Larkey 2010). The intervention development of Bloom 2014 was guided by the cultural explanatory models (CEMs) framework (Rajaram 1998) and Chatman's theory of information seeking (Chatman 1996). All studies referenced empirical studies either related to (low) literacy or language proficiency, or health literacy in the context of health to emphasise the relevance and purpose of the intervention study.

Health literacy components addressed in the interventions

A description of the intervention components based on the integrated model of health literacy is shown in Table 16.

Most interventions were related to the domain of disease prevention (21/34) (Bloom 2014; DeCamp 2020; Elder 1998; Gwede 2019; Han 2017; Hernandez 2013; Kaur 2019; Kiropoulos 2011; Koniak-Griffin 2015; Lepore 2012; Ochoa 2020; Otilingam 2015; Payán 2020; Soto Mas 2018; Taylor 2011; Thompson 2012; Tong 2017; Unger 2013; Valdez 2015; Valdez 2018; Wong 2020). These interventions were usually designed to improve the knowledge of, and beliefs and attitudes towards, a certain disease, its treatment or a certain screening measure (e.g. cervical cancer screening). Thirteen interventions were related to the health care domain, aiming to improve participants' disease-specific self-management, their medication understanding or skills to navigate the health system. No study addressed the health promotion domain (Bailey 2012; Calderón 2014; Kheir 2014; Kim 2009; Kim 2014; Kim 2020; Mohan 2014; Poureslami 2016a; Poureslami 2016b; Rosal 2005; Rosal 2011; Sudore 2018; van Servellen 2005).

All but three interventions explicitly aimed at improving health-related knowledge or made use of at least one method of knowledge transfer (31/34) (Bailey 2012; Kheir 2014; Mohan 2014). Motivation was addressed by 23 interventions, including programmes that were, for example, designed to address motivational aspects of behaviour change. For six studies it was unclear if and how motivation was addressed (Bloom 2014; Calderón 2014; Kiropoulos 2011; Payán 2020; Valdez 2015; Valdez 2018) and three interventions did not address aspects of motivation (Bailey 2012; Kheir 2014; Mohan 2014). Seventeen studies aimed at improving competencies such as functional (health) literacy skills. Of these, 15 reported explicit methods for improving literacy or numeracy skills in the context of health (Elder 1998; Han 2017; Kaur 2019; Kim 2009; Kim 2014; Kim 2020; Koniak-Griffin 2015; Otilingam 2015; Rosal 2005; Rosal 2011; Soto Mas 2018; Taylor 2011; Tong 2017; van Servellen 2005; Wong 2020). Those interventions included, for example, learning medical terminology and health-related phrases or learning how to calculate nutrition values. Two interventions aimed at improving inhaler use technique for pulmonary diseases (Poureslami 2016a; Poureslami 2016b). For one study, we had insufficient information to permit judgement about whether competencies were addressed (Bloom 2014).

Regarding the four steps of health information processing, accessing health information was addressed by 22 interventions that explicitly or implicitly referred to this step by improving health care navigation skills or knowledge of the healthcare system, or by reducing barriers to accessing health care or health information (Bloom 2014; Calderón 2014; DeCamp 2020; Gwede 2019; Han 2017; Hernandez 2013; Kaur 2019; Kim 2009; Kim 2014; Kim 2020; Kiropoulos 2011; Koniak-Griffin 2015; Lepore 2012; Ochoa 2020; Rosal 2005; Rosal 2011; Soto Mas 2018; Tong 2017; Unger 2013; Valdez 2018; van Servellen 2005; Wong 2020).

Understanding health information was the most common addressed processing step; all interventions were designed to improve the understanding of health information or applied linguistically or literacy adapted information formats.

Appraising health information was addressed by 23 interventions (Calderón 2014; Han 2017; Hernandez 2013; Kaur 2019; Kim 2009; Kim 2014; Kim 2020; Kiropoulos 2011; Koniak-Griffin 2015; Lepore 2012; Payán 2020; Poureslami 2016a; Poureslami 2016b; Rosal 2005; Rosal 2011; Soto Mas 2018; Sudore 2018; Taylor 2011; Thompson 2012; Tong 2017; Unger 2013; Wong 2020). These interventions included, for example, components of knowledge transfer to improve trust in professional sources of health information or in healthcare providers. Others aimed at improving informed decision-making by improving the ability to weigh the pros and cons for a certain screening or treatment option. For eight studies, we do not know if and how the appraisal of health information was addressed (Bloom 2014; DeCamp 2020; Elder 1998; Gwede 2019; Ochoa 2020; Otilingam 2015; Valdez 2015; Valdez 2018). No intervention directly aimed at improving the participants' ability to filter, judge and evaluate whether information is of good quality, how to appraise whether a source of information is reliable (e.g. with regard to online information) or where to find good (online) health information.

All but Kheir 2014 addressed the application of health information. These studies either measured outcomes related to this step of information processing (e.g. behaviour intent or actual health behaviour) or referred to theories related to health literacy that imply a causal relationship between, for example, improved knowledge and a respective health behaviour.

Outcomes

A variety of outcomes, assessed with several measures, were reported in the included studies. We reported effect measures on all of our prespecified outcome categories prioritised as specified in Types of outcome measures. A full description of all outcomes assessed within the included studies is shown in the Characteristics of included studies. An overview of health literacy-related outcomes considered in this review, including measures applied and timing of outcome assessment, is shown in Table 17 and Table 18.

The following primary outcomes have been included in this review:

- Health literacy: a) generic health literacy (including functional health literacy, print literacy, health numeracy); b) disease-specific health literacy (including cancer screening health literacy, depression literacy, diabetes health literacy, high blood pressure health literacy, HIV health literacy, oral health literacy).
- Adverse events: associated with the intervention: anxiety.

The included secondary outcomes were as follows:

- Quality of life: diabetes-related quality of life.
- Health outcome: a) subjective health status (self-reported general health in past week); b) depression.
- Health behaviour: a) blood glucose self-monitoring; b) cardiovascular health behaviour; c) cancer screening behaviour (including breast cancer screening adherence, cervical cancer screening behaviour, colorectal cancer screening uptake, prostate cancer screening, up-to-date colorectal cancer screening); d) diabetes self-care activities; e) documentation of new advance care planning; f) hepatitis B testing; g) HIV medication adherence; h) oral hygiene self-care behaviour; i) fat-related diet habits; j) medication adherence (including adherence to asthma medication, medication adherence (non-

specific), non-adherence to blood pressure medication); k) physical activity; l) (child's) up-to-date immunisation.

- Health-related knowledge: a) asthma knowledge; b) cardiovascular disease (heart) knowledge; c) child health knowledge; d) cervical/breast cancer knowledge; e) colorectal cancer knowledge (including awareness of colorectal cancer and screening test); f) COPD knowledge; g) depression knowledge; h) diabetes knowledge; i) hepatitis B knowledge; j) high blood pressure knowledge; k) HIV knowledge; l) nutrition knowledge (including child nutrition and feeding knowledge); m) oral health knowledge; n) cognitive behaviour therapy knowledge; o) prostate cancer screening knowledge.
- Health service use: use of emergency room services.
- Self-efficacy (a) self-efficacy in managing one's disease (including diabetes and insulin management self-efficacy, self-efficacy in managing high blood pressure, medication adherence self-efficacy, COPD self-efficacy); b) cancer screening self-efficacy (including self-efficacy for colorectal cancer screening using faecal immunochemical test (FIT), self-efficacy for accessing breast cancer-related advice or information, self-efficacy for cervical cancer screening using pap testing); c) self-confidence in supporting individuals with depression; d) self-efficacy for identifying depression; e) self-efficacy to identify need for treatment (related to depression); f) self-efficacy to change one's diet).

Timing of outcome assessment

Participants were assessed at different time points and over varying follow-up periods. Many studies assessed participants at multiple time points. Thereby, follow-up periods with minimal provider contact (e.g. monthly telephone calls) were treated as being part of the intervention programme, since these contacts might have had an effect on our outcomes of interest (e.g. health behaviour). The majority of participants were assessed at short-term follow-up (up to six weeks from the start of the intervention and immediately after the intervention programme was completed) (Bailey 2012; Calderón 2014; Han 2017; Hernandez 2013; Kaur 2019; Kheir 2014; Kim 2009; Kim 2020; Kiropoulos 2011; Koniak-Griffin 2015; Mohan 2014; Ochoa 2020; Otilingam 2015; Payán 2020; Poureslami 2016a; Poureslami 2016b; Rosal 2011; Soto Mas 2018; Thompson 2012; Unger 2013; Valdez 2015; Wong 2020). In 12 studies, participants were assessed at medium-term follow-up (up to and including six months after the intervention programme was completed) (DeCamp 2020; Elder 1998; Gwede 2019; Kim 2014; Koniak-Griffin 2015; Poureslami 2016a; Poureslami 2016b; Rosal 2005; Taylor 2011; Tong 2017; Valdez 2018; van Servellen 2005). Two studies assessed participants longer than six months and up to two years after the intervention programme was completed (Lepore 2012; Sudore 2018).

In one study, the authors stated that participants were assessed six months post-intervention. However, the information about the design of the intervention and, thus, the total programme length including the supervised follow-up phase was insufficient to permit judgement about whether the outcomes were assessed short-term or medium-term (Bloom 2014).

Health literacy

Twelve studies explicitly stated to have measured either disease-specific or generic health literacy for assessing the intervention effectiveness. All the included studies assessed outcomes related to at least one of the four health information processing steps (access, understand, appraise and apply) or the prerequisites of health literacy (knowledge, motivation and competencies).

Eight studies reported outcomes on disease-specific health literacy. Three of these assessed primarily disease-specific knowledge and attitudes towards a certain disease or disease management. Two of these studies assessed depression literacy using either the original English version (Wong 2020) or an adapted and translated version of the validated Depression-Literacy questionnaire (D-Lit) by Griffiths 2004 (Kiropoulos 2011). One study assessed diabetes literacy using the Diabetes Health Literacy Survey (DHLS) (Calderón 2014). The questionnaire was developed and validated in the study and measured diabetes-related knowledge, knowledge application and cultural perceptions about diabetes management. Five studies made use of disease-specific health literacy assessment tools that were adapted from established generic measures for assessing functional health literacy, such as the Rapid Estimate of Adult Literacy in Medicine (REALM) (Davis 1991) or the Test of Functional Health Literacy in Adults (TOFHLA) (Parker 1995). One study reported a measure for high blood pressure health literacy using the High Blood Pressure-Health Literacy Scale (HBP-HLS) (Kim 2014). The scale was developed and validated by the study authors (Kim 2012). One study measured cancer screening literacy (Han 2017) using the Assessment of Health Literacy in Cancer Screening (AHL-C), also developed and validated by the study authors (Han 2014). One study reported a measure of HIV health literacy (van Servellen 2005) using an adapted version of the REALM developed by the study authors to assess recognition and understanding of HIV terms and, again, another study reported a measure of oral health literacy (Kaur 2019) using the validated two Stage Rapid Estimate of Adult Literacy in Dentistry (TS-REALD) (Stucky 2011). One study administered the diabetes-specific Rapid Estimate of Adult Literacy in Medicine (DM-REALM), developed and previously validated by the study authors (Kim 2020), referring to the outcome as *"health literacy knowledge"* (Kim 2020, p. 212). In addition, Kim 2020 administered three other established performance-based assessment tools for print literacy or health numeracy: the original REALM (Davis 1991), the numeracy subscale of the TOFHLA (Parker 1995) and the health numeracy test newest vital sign (NVS) (Weiss 2005). The NVS was also used by one other study (Otilingam 2015). One study administered the English version of the TOFHLA to assess functional health literacy (Soto Mas 2018). One study reported having assessed health literacy, but did not report the results (Poureslami 2016a).

All the assessment tools applied are performance-based measures that assess components of health literacy, such as disease-specific knowledge or functional health literacy, including subscales of print literacy (recognition of medical terms), functional literacy (understanding health-related phrases and terminology) or numeracy (performing minor mathematical tasks).

Prerequisites of health literacy

Knowledge

See outcome category 'health-related knowledge'.

Motivation

Two studies measured outcomes related to motivation. However, none of the results were included in our analysis, because the applied scales also addressed theoretical constructs other than motivation. Therefore, the results could not be subordinated to the construct of motivation. One study assessed *"Patient activation"*, which refers to the knowledge, skills and confidence the individuals need to manage their health and health care (DeCamp 2020). The measure captures aspects of motivation and engagement with health and self-management behaviour. Another study reported a measure that included motivation as a subscale of a broader behaviour change process scale including self-perceived knowledge, self-efficacy and readiness for behaviour change related to advance care planning (Sudore 2018).

Competencies (skills acquisition)

Two studies measured skills acquisition, such as correct use of metered dose inhaler by acting out the right steps of inhaler use measured through direct observation. Both studies used validated checklists to tick off the correct steps (Poureslami 2016a; Poureslami 2016b).

Steps of health information processing

Accessing health information

In the guiding health literacy framework (Figure 1), the first step of health information processing is *access* to health information, which refers to *"the ability to seek, find and obtain health information"* (Sørensen 2012).

None of the studies reported outcomes that were directly related to accessing health information.

Understanding health information

Understanding health information refers to *"the ability to comprehend the health information that is accessed"* (Sørensen 2012).

Five studies measured outcomes related to the understanding of health information. One study used the Medication Understanding Questionnaire (MUQ) to measure understanding of adapted medical instructions (Mohan 2014). One study assessed the level of comprehension of medical instructions by asking for the participant's interpretation of the medication label's content (Kheir 2014). Two studies measured outcomes related to the understanding of instructions for inhaler use. Of these, one study reported an outcome measure related to understanding of and adherence to physician's instructions for inhaler use for asthma by asking the participants to explain the instructions in their own words (Poureslami 2016a). The other study reported an outcome measure for the understanding of pulmonary rehabilitation by using a text passage and questions related to COPD, which was developed by the study authors (Poureslami 2016b). One study measured the understanding of medical instructions by means of a dosing tray, which was filled by the participants according to the respective instruction (Bailey 2012).

Appraising health information

Appraising health information is defined as *"the ability to interpret, filter, judge and evaluate the health information that has been accessed"* (Sørensen 2012). It was assessed in three studies, one reporting a measure on the decisional balance (i.e. the weighing of pros and cons) for the use of cancer screening measures after receiving an educational intervention related to breast and cervical cancer screening (Han 2017). The other two studies measured decisional conflict using the validated decisional conflict scale (O'Connor 1995), of which we report the results of the three subscales informed decision, values clarity and support. We do not report the results for the subscales uncertainty and effective decision as these subscales presume a full decision that reflects the processing step of *applying* health information rather than *the appraisal* of health information. One study measured decisional conflict related to human papillomavirus (HPV) vaccination (Valdez 2015) and the other study measured decisional conflict in the realm of prostate cancer screening (Lepore 2012).

Applying health information

Applying health information is defined as the *"ability to communicate and use the information"* (i.e. patient-provider interaction) and to make a decision that has a positive impact on one's health or the health of others (i.e. behaviour intent) (Sørensen 2012). Outcome categories such as 'health behaviour' or 'health service use' may not be directly subordinated to this step of health information processing, but can be seen as a consequence of the decisions made based on certain information and therefore are closely related to the processing step of applying health information. Two studies measured participants' behavioural intentions regarding the use of preventive measures, such as for cervical cancer (Ochoa 2020) or prostate cancer (Lepore 2012). One study measured participants' informed decision regarding the vaccination against HPV using the composite variable described above (see appraising health information) (Valdez 2015). Two studies reported an outcome measure that assessed participants' intention to change their diet (Elder 1998) or parents' planned behaviour changes with regard to the nutrition of their children (Thompson 2012). Two studies assessed the intention to seek professional help for a mental health problem (Hernandez 2013; Unger 2013), but Unger 2013 did not provide enough information to calculate a point estimate and a confidence interval.

Secondary outcomes related to health literacy

Quality of life

Two studies reported outcome measures on diabetes-related quality of life using the Diabetes Quality of Life Measure (DQOL) (Kim 2009; Kim 2020). One study also measured diabetes-related quality of life using an adapted version of the Audit of Diabetes Dependent Quality of Life (ADDQoL) (Rosal 2005).

Health-related knowledge

In total, 28 studies assessed health-related knowledge, including a variety of content-specific knowledge scales that tested the knowledge derived from the educational content conveyed in the study. Twenty-two studies measured disease-specific knowledge (DeCamp 2020; Gwede 2019; Han 2017; Hernandez 2013; Kim 2009; Kim 2014; Kim 2020; Koniak-Griffin 2015; Lepore 2012; Ochoa 2020; Otilingam 2015; Payán 2020; Poureslami 2016a; Poureslami 2016b; Rosal 2005; Rosal 2011; Taylor 2011; Tong 2017; Unger 2013; Valdez 2015; Valdez 2018; van Servellen 2005). Of these, one study measured parents' knowledge about infant diseases (DeCamp 2020). Seven studies assessed knowledge not directly related to a certain disease, but to another health-relevant topic. One of them assessed knowledge on cognitive behavioural therapy for depression (Wong 2020). Three studies made use of a nutrition knowledge measure (Elder 1998; Otilingam 2015; Thompson 2012), and, again, another study measured oral self-care knowledge (Kaur 2019). One study reported to have measured COPD-related knowledge, but did not report the results (Poureslami 2016b). One study reported data for the intervention group only (Koniak-Griffin 2015). One study measured knowledge, probably related to breast health or breast cancer as the intervention was related to these topics, but detailed information was not provided in the identified trial reports (Bloom 2014).

Nine studies explicitly referred to knowledge as a considerable component of the health literacy concept (Calderón 2014; Hernandez 2013; Kaur 2019; Kim 2014; Kim 2020; Kiropoulos 2011; Soto Mas 2018; Unger 2013; van Servellen 2005).

Health behaviour

Seventeen studies assessed outcomes that are related to the use of health information. Eight studies measured adherence to medication or therapeutic regimen through participants' self-report (Kim 2009; Kim 2014; Kim 2020; Otilingam 2015; Mohan 2014; Rosal 2005; Rosal 2011; van Servellen 2005). Of these, two studies reported to have used the Summary of Diabetes Self-Care Activities Scale (SDSCA) to assess adherence to a diabetes regimen (Kim 2009; Kim 2020), but one did not report the results (Kim 2020). Three studies assessed outcomes related to a healthy lifestyle, such as physical activity, which was measured through the use of objective accelerometer data (Koniak-Griffin 2015). Others assessed self-reported cardiovascular health behaviour (Soto Mas 2018) or self-reported oral hygiene behaviour (Kaur 2019). Four studies measured the use of preventive measures, one assessing the infant's up-to-date immunisation via electronic medical records (DeCamp 2020). Three other studies assessed the uptake of screening measures, one using self-report of colorectal cancer screening (Tong 2017) and one measuring self-report of breast cancer screening by mammography (Bloom 2014). The third study assessed return of a completed take home faecal immunochemical test kit (FIT kit) within 90 days using pre-stamped and self-addressed mailers for objective verification of screening completion (Gwede 2019). One study used medical records to verify cervical and breast cancer screening (Han 2017) and one study used medical records to verify self-reported hepatitis B screening (Taylor 2011). One study measured the documentation of new advance care planning forms by using a composite variable of legal forms and/or documented discussions about advance care planning with clinicians and/or surrogates (Sudore 2018).

Health outcomes

A total of eight studies assessed health outcomes. One study measured self-rated general health within the last week (van Servellen 2005). Seven studies reported outcome measures for depression using four different measures (Hernandez 2013; Kim 2009; Kim 2014; Kim 2020; Kiropoulos 2011; Rosal 2005; Sudore 2018). Four used the Patient Health Questionnaire (PHQ) either with eight items (PHQ-8) (DeCamp 2020; Sudore 2018) or with nine items (PHQ-9), respectively (Kim 2014; Kim 2020). One study used the Depression Scale for Korean Americans (KDSKA) (Kim 2009). Another study used the Beck Depression Inventory II (BDI-II) (Kiropoulos 2011), and the other two studies made use of the Center for Epidemiological Studies of Depression Scale (CES-D Scale) (Hernandez 2013; Rosal 2005). Sudore 2018 referred to depression as an adverse event related to the intervention.

Self-efficacy

Fourteen studies reported a variety of outcome measures related to self-efficacy. Seven studies measured self-efficacy in managing one's own disease or medication (Kim 2009; Kim 2014; Kim 2020; Rosal 2005; Rosal 2011; Poureslami 2016b; van Servellen 2005). Two studies used a measure to assess self-efficacy either for colorectal cancer screening using a faecal immunochemical test (Gwede 2019) or for cervical cancer using Pap testing (Valdez 2018). One study assessed self-efficacy in accessing breast cancer-related advice or information (Payán 2020). Two studies reported outcome measures on self-efficacy to identify depression or the need for treatment (Hernandez 2013; Unger 2013). One study assessed participants' self-confidence in supporting individuals with depression (Wong 2020) and another study measured self-efficacy in changing one's diet (Elder 1998).

Health service use

One study assessed the use of health services with the use of medical records to measure emergency room visits (DeCamp 2020).

Adverse events

Two studies reported adverse events related to the interventions. Both studies reported outcome measures for anxiety, whereas one study used the seven-item subscale of the Hospital Anxiety and Depression Scale (HADS) (Lepore 2012) and the other study made use of the Generalised Anxiety Disorder-7 questionnaire (GAD-7), referring to anxiety as an adverse event related to the intervention (Sudore 2018).

Gender

Ten studies included women only (Bloom 2014; DeCamp 2020; Han 2017; Hernandez 2013; Koniak-Griffin 2015; Ochoa 2020; Otilingam 2015; Payán 2020; Valdez 2018; Wong 2020); two studies included only men (Kheir 2014; Lepore 2012). Furthermore, some studies, despite having a gender-mixed study population, had a considerable disproportion of genders: five studies included predominantly women (80% or more, Calderón 2014; Rosal 2005; Soto Mas 2018; Thompson 2012; Valdez 2015), two of which even included more than 90% (Thompson 2012; Valdez 2015). Similarly, two studies included predominantly men (Poureslami 2016b; van Servellen 2005).

Studies awaiting assessment

Eight studies are awaiting assessment due to insufficient information to permit judgement for inclusion or exclusion. For four of these studies, we identified only abstracts indicating that health literacy or literacy in the context of health were addressed in the study design and at least a part of the participants were migrants, but we did not find a trial registry entry, a published protocol or a published final trial report to confirm the assumption (Erwin 2012; Essien 2017; Esquivel 2019; Glaser 2020). For the other studies we found either a study protocol, a trial report or a secondary analysis of the RCT, but the information was still insufficient to permit judgement about inclusion or exclusion (Gonzalez 2020; Joshi 2016; NCT04993326; Pekmezaris 2020).

For most studies, it was unclear if data (from ongoing studies) would be extractable separately for first-generation migrants or if at least 80% of the participants were first-generation migrants (Essien 2017; Gonzalez 2020; Joshi 2016; NCT04993326; Pekmezaris 2020). For one study, it was unclear which study design was used

(Glaser 2020). We contacted authors of studies for which a final trial report was available asking whether the participants were first-generation migrants, but did not receive a response. We also contacted authors to clarify the study design used, or to ask when a final trial report would probably be available and whether migrants will be included, but to date none of the final reports have actually been published.

Ongoing studies

We identified 11 ongoing studies from trial registries or during the electronic database searches (see Characteristics of ongoing studies and references to Ongoing studies).

Excluded studies

After screening titles and abstracts, we excluded 6605 references that did not match our inclusion criteria. In addition, we excluded a total of 209 studies (reported in 223 references) after full-text screening for the following reasons: duplicate, study used the wrong study design (neither a RCT nor a quasi-RCT or a cluster-RCT), study included the wrong study population (paediatric population, no separately extractable data on first-generation migrants, no migrants at all, or primary language/race/ethnicity/minority population only indicating that immigrants were not included), study evaluated the wrong intervention (improving health literacy was not an aim of the study, neither literacy nor health literacy was mentioned in the reference, or no outcome was related to health literacy). The details of relevant excluded trials are provided in the Characteristics of excluded studies.

Risk of bias in included studies

We assessed the risk of bias in the included studies according to the criteria defined at the protocol stage. Not applicable risk of bias domains are empty. Details of the risk of bias assessment for each of the included studies are shown in the risk of bias tables in the Characteristics of included studies, in Figure 3 and in Figure 4.

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

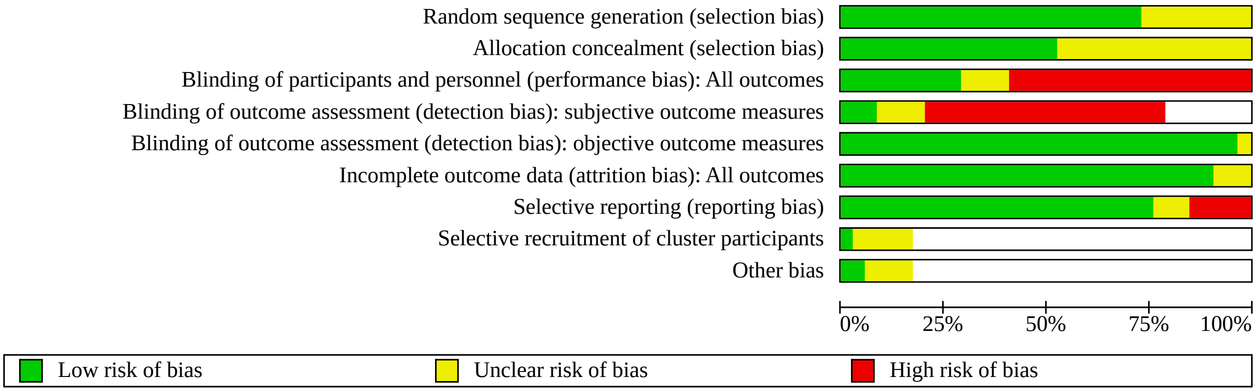
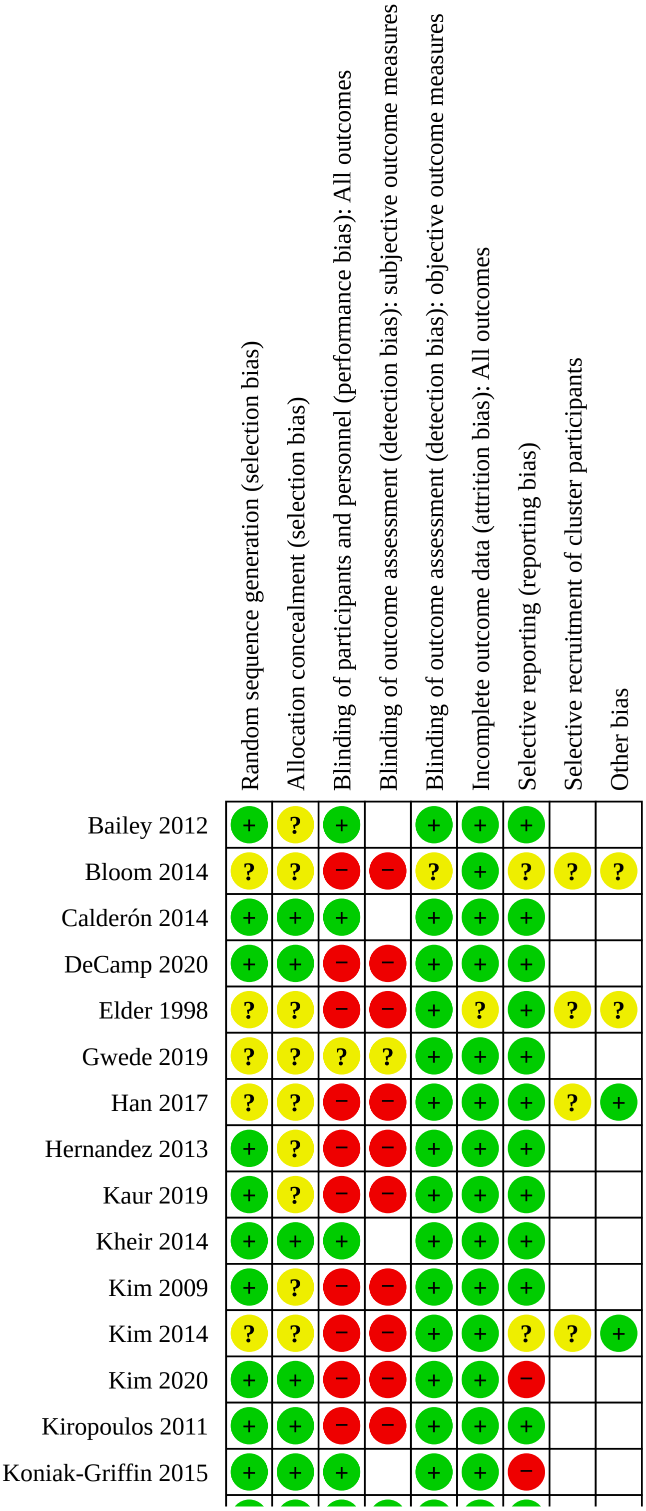


Figure 4. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias): All outcomes	Blinding of outcome assessment (detection bias): subjective outcome measures	Blinding of outcome assessment (detection bias): objective outcome measures	Incomplete outcome data (attrition bias): All outcomes	Selective reporting (reporting bias)	Selective recruitment of cluster participants	Other bias
Bailey 2012	+	?	+		+	+	+		
Bloom 2014	?	?	−	−	?	+	?	?	?
Calderón 2014	+	+	+		+	+	+		
DeCamp 2020	+	+	−	−	+	+	+		
Elder 1998	?	?	−	−	+	?	+	?	?
Gwede 2019	?	?	?	?	+	+	+		
Han 2017	?	?	−	−	+	+	+	?	+
Hernandez 2013	+	?	−	−	+	+	+		
Kaur 2019	+	?	−	−	+	+	+		
Kheir 2014	+	+	+		+	+	+		
Kim 2009	+	?	−	−	+	+	+		
Kim 2014	?	?	−	−	+	+	?	?	+
Kim 2020	+	+	−	−	+	+	−		
Kiropoulos 2011	+	+	−	−	+	+	+		
Koniak-Griffin 2015	+	+	+		+	+	−		

Figure 4. (Continued)

Koniak-Griffin 2015	+	+	+		+	+	−		
Lepore 2012	+	+	+	+	+	+	+		
Mohan 2014	+	+	−	−	+	+	+		
Ochoa 2020	?	?	+	+	+	+	+		
Otilingam 2015	?	+	−	−	+	+	+		
Payán 2020	+	+	−	−	+	+	+		
Poureslami 2016a	?	?	+		+	+	−		
Poureslami 2016b	+	?	−	−	+	+	−		
Rosal 2005	+	?	−	−	+	+	+		
Rosal 2011	+	?	−	−	+	+	+		
Soto Mas 2018	?	?	−	−	+	+	+		
Sudore 2018	+	+	+	+	+	+	?		
Taylor 2011	+	+	+		+	+	+	?	?
Thompson 2012	+	+	?	?	+	+	+		
Tong 2017	+	+	−	−	+	+	−	+	?
Unger 2013	+	+	−	−	+	+	+		
Valdez 2015	+	?	?	?	+	?	+		
Valdez 2018	+	+	?	?	+	?	+		
van Servellen 2005	+	+	−	−	+	+	+		
Wong 2020	+	+	+		+	+	+		

Allocation

Eighteen studies described adequate sequence generation and allocation concealment, and we assessed them as being of low risk of selection bias (Calderón 2014; DeCamp 2020; Kheir 2014; Kim 2020; Kiropoulos 2011; Koniak-Griffin 2015; Lepore 2012; Mohan 2014; Payán 2020; Sudore 2018; Taylor 2011; Thompson 2012; Tong 2017; Unger 2013; Valdez 2015; Valdez 2018; van Servellen 2005; Wong 2020). Eight trials reported adequate sequence generation, but the concealment of allocation was unclear (Bailey 2012; Hernandez 2013; Kaur 2019; Kim 2009; Poureslami 2016a; Poureslami 2016b; Rosal 2005; Rosal 2011). One study reported to have used sealed envelopes to inform participants about their random assignment, but did not provide information about how random assignment was generated (Otilingam 2015). We rated seven studies as being at unclear risk of bias for both random sequence generation and allocation concealment domains, as information was insufficient (Bloom 2014; Elder 1998; Gwede 2019; Han 2017; Kim 2014; Ochoa 2020; Soto Mas 2018).

Blinding

Performance bias

For most of the studies blinding of participants and personnel was not possible, despite best attempts to do so. However, we judged non-blinded studies to be at high risk of performance bias only when the outcomes assessed were self-reported or subject to interpretation, assuming that knowledge of participant's group assignment might have affected the results (e.g. for outcomes such as depression or self-efficacy). In total, we rated 20 studies as being at high risk of bias for this domain (Bloom 2014; DeCamp 2020; Elder 1998; Han 2017; Hernandez 2013; Kaur 2019; Kim 2009; Kim 2014; Kim 2020; Kiropoulos 2011; Mohan 2014; Otilingam 2015; Payán 2020; Poureslami 2016b; Rosal 2005; Rosal 2011; Soto Mas 2018; Tong 2017; Unger 2013; van Servellen 2005). In total, we rated 10 studies as being at low risk of performance bias (Bailey 2012; Calderón 2014; Kheir 2014; Koniak-Griffin 2015; Lepore 2012; Ochoa 2020; Poureslami 2016a; Sudore 2018; Taylor 2011; Wong 2020). We assessed two of these as being at low risk of performance bias, although some outcomes were subjectively measured (Ochoa 2020; Sudore 2018). One study compared audio-/visual education without personal feedback via a narrative video to audio-/visual education without personal feedback via a factual knowledge video. Thus, the intervention only differed in one aspect, so we assumed that this did not lead to substantial risk of bias (Ochoa 2020). In Sudore 2018, the intervention was delivered online and via telephone and the method for enhancing blinding of both the participants and the personnel was described in detail. For example, participants were told that they would review one of two guides on advance care planning but were blinded as to which guide was the active intervention and which was the active control (online programme and additional written advance directive versus written easy-to-read advance directive alone). We rated the other eight studies as being at low risk of performance bias as the outcomes considered in this review were objectively measured and not subject to interpretation or the participants were presumably not aware of the intervention received (Calderón 2014; Kheir 2014; Koniak-Griffin 2015; Lepore 2012; Ochoa 2020; Poureslami 2016a; Taylor 2011; Wong 2020). Therefore, we assumed that even non-blinding would not have affected the results. Four studies had an unclear risk of performance bias, as participants and personnel might have been blinded, but the information was insufficient to permit judgement. It remained unclear whether potential non-blinding might have affected the results of subjectively measured outcomes (Gwede 2019; Thompson 2012; Valdez 2015; Valdez 2018).

Detection bias

In concordance with the ratings for performance bias, we distinguished between subjective and objective outcome measures to assess the risk of detection bias, as blinding of group allocation and blinding of outcome assessors might have affected the risk of bias in this domain differently. Almost all studies reported primarily or exclusively subjectively measured outcomes that were dependent on the participants' judgement. Most of these studies made use of self-report questionnaires that were used repeatedly to assess the participants at different time points during the study period. We rated them as being at high risk of detection bias, when the participants were not, or presumably not, blinded to the intervention they received (Bloom 2014; DeCamp 2020; Elder 1998; Han 2017; Hernandez 2013; Kaur 2019; Kim 2009; Kim 2014; Kim 2020; Kiropoulos 2011; Mohan 2014; Otilingam 2015; Payán 2020; Poureslami 2016b; Rosal 2005; Rosal 2011; Soto Mas 2018; Tong 2017; Unger 2013; van Servellen 2005), and at unclear risk of bias when participants and personnel could have been blinded, but the information was insufficient to permit judgement of 'low risk' or 'high risk'(Gwede 2019; Thompson 2012; Valdez 2015; Valdez 2018). We rated three studies as being at low risk of bias for both subjective and objective outcomes, as the participants were presumably not fully aware of the intervention they received (Sudore 2018), or the interventions differed only very slightly. In one study, a narrative video about cervical cancer was compared to a non-narrative video on the same topic (Ochoa 2020), and in the other study the participants received telephone education on different health topics (Lepore 2012).

All 34 studies used observer-reported outcome measures. We rated all but one study, Bloom 2014, as being at low risk of bias, because the outcomes were measured by means of objective criteria without the involvement of the outcome assessors' judgement and/or outcome assessors were blinded.

We assessed Bloom 2014 as being at high risk for the domain 'subjective outcome measures' and at unclear risk of bias for the domain 'objective outcome measures' as participants and personnel were most likely not blinded due to the nature of the study, and health behaviour was measured via self-report. We do not know if knowledge was subjectively or objectively measured in the study. In the case that knowledge was also subjectively measured, the results for this outcome might also be biased.

Incomplete outcome data

In all studies, participants were analysed according to their original group assignment. Eight studies reported undertaking intention-to-treat analysis and provided details on the methods used, and we assessed them as being at low risk of bias (DeCamp 2020; Han 2017; Kaur 2019; Kheir 2014; Lepore 2012; Otilingam 2015; Sudore 2018; Wong 2020). We also assessed studies as being at low risk for attrition bias when outcome data were available for nearly all participants (Bailey 2012; Bloom 2014; Calderón 2014; Hernandez 2013; Kim 2009; Kiropoulos 2011; Lepore 2012; Mohan 2014; Poureslami 2016a; Poureslami 2016b; Rosal 2005; Rosal 2011; Soto Mas 2018; Thompson 2012), and studies had less than 15% differential loss of follow-up between intervention and control group and reported the reasons for dropouts per study arm (DeCamp 2020; Gwede 2019; Kim 2014; Kim 2020; Koniak-Griffin 2015; Payán 2020; Taylor 2011; Unger 2013; van Servellen 2005). We rated Ochoa 2020 as being at low risk of bias although the number of participants who dropped out was not reported separately per study arm, because the study compared two variants of the same intervention (narrative video versus knowledge video), indicating that neither of the interventions particularly led to the relatively high attrition rate of 47 out of 187 participants at six-month follow-up.

We rated three studies as being at unclear risk of bias in this domain. Of these, one study neither provided information on the numbers of participants that dropped out nor the reasons for attrition per study arm (Valdez 2018). One study reported considerable differences in the numbers of participants analysed between study groups. In total, 100 participants were not included in the analysis: 74 in the intervention group and 26 in the control group. It was unclear whether the participants did not complete pre- and/or post-test assessment or if they were excluded for other reasons (Valdez 2015). Another study reported attrition rates and results of a statistical attrition analysis, but due to lack of reporting of the total number of participants randomised to each arm as well as those who dropped out per arm, we also rated the risk of attrition bias as being unclear (Elder 1998).

Selective reporting

Fourteen study protocols or registered trial records were available to assess the risk of selective reporting. For the remaining 22 studies, we made decisions regarding the risk of reporting bias based on whether the results for each outcome listed in the methods section were present in the results of each published report. For one study, we found an abstract only. Thus, the information was insufficient to permit a judgement of 'low risk' or 'high risk' (Bloom 2014). We also assessed two other studies as being at unclear risk of bias. In one study, the registered trial record indicated that two additional outcomes, namely 'health care utilisation' and 'problem-solving and communication skills', should have been assessed additionally at six weeks, and month 6, 12, 18 and 24. The time points of outcome assessment reported in the primary cluster-RCT ranged up to 18 months, which indicates that another publication might follow (Kim 2014). In one study, the results for communication quality, satisfaction with communication, satisfaction with decision-making, care consistent with current goals, barriers to advance care planning (ACP) and attitudes about ACP were not reported. However, these measures were not pre-specified at clinicaltrials.gov, but in one of the two published study protocols (see secondary reference of Sudore 2018). It is unclear whether these measures were used as process variables or whether it was intended to assess these as outcome variables and whether the results are yet to be published (Sudore 2018).

We rated five studies as being at high risk for this domain. One of them indicated having assessed participants' health literacy at different time points (Poureslami 2016a), but results were not reported. Another study reported having assessed participants' knowledge of COPD, but did not report the results (Poureslami 2016b). In one study, all prespecified outcomes reported at clinicaltrials.gov were reported in the published reports, but the results of the control group's knowledge assessment were missing (Koniak-Griffin 2015). Another study indicated having assessed adherence to a diabetes regimen using the Diabetes Self-care Activities Scale, but also did not report the results (Kim 2020). Lastly, one study pre-specified colorectal cancer screening intention as an outcome measure in the trial registry, but the results are missing in the published trial report (Tong 2017).

Selective recruitment of cluster participants

We assessed potential bias resulting from selective recruitment of cluster participants in six cluster-RCTs. We assessed one study as being at low risk of recruitment bias (Tong 2017). For the other five studies, we did not have enough information to permit judgement of 'low risk' or 'high risk' (Bloom 2014; Elder 1998; Han 2017; Kim 2014; Taylor 2011).

Other potential sources of bias

No study applied a perception-based tool to measure health literacy. Therefore, in terms of health literacy assessment, social desirability was not a bias of concern in this review.

We rated most studies as being at low risk for other potential sources of bias (i.e. the domain was not applicable for these studies). We rated three cluster-RCTs as being at low risk of bias as they either properly accounted for the cluster-design in the analysis (Han 2017), or because we were able to re-analyse the data using the appropriate unit of analysis (Kim 2014; Taylor 2011). We rated three studies as being at unclear risk of bias in this domain due to insufficient information to permit judgement of 'low risk' or 'high risk' (Bloom 2014; Elder 1998; Tong 2017). We rated Tong 2017 as being at unclear risk of bias because, although the authors reported having accounted for clustering in the analyses, we were not able to verify whether it also accounted for those outcomes that we considered in this review, and due to insufficient information we were not able to re-analyse the data.

Effects of interventions

See: **Summary of findings 1** Culturally and literacy adapted self-management programme versus no health literacy intervention; **Summary of findings 2** Culturally and literacy adapted self-management programme versus written information on the same topic; **Summary of findings 3** Culturally adapted health literacy skills building course versus no/unrelated health literacy intervention; **Summary of findings 4** Culturally and literacy adapted telephone education versus unrelated health literacy intervention; **Summary of findings 5** Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention; **Summary of findings 6** Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic; **Summary of findings 7** Culturally and literacy adapted audio-/visual education without personal feedback versus another culturally and literacy adapted audio-/visual education without personal feedback; **Summary of findings 8** Culturally and literacy adapted medical instruction versus no health literacy intervention; **Summary of findings 9** Female migrants' benefit of any health literacy intervention versus male migrants' benefit of any health literacy intervention

Comparison 1: Culturally and literacy adapted self-management programme versus no health literacy intervention

We included four studies in this comparison. Of these, three were RCTs with a total programme length of six (van Servellen 2005) to 12 months (Koniak-Griffin 2015; Rosal 2011). For one cluster-RCT, we had limited information regarding the intensity and total length of the programme (Bloom 2014). Summary of findings 1 presents the evidence on the effect of culturally and literacy adapted self-management programmes, when compared to usual care or to no health literacy intervention. In addition, see Data and analyses for pooled data on this comparison and Table 1, Table 12, Table 3, Table 4 and Table 5 for data we did not pool.

Health literacy

One study with 69 participants assessed functional HIV health literacy and reported the results for understanding HIV terms and recognition of HIV terms separately (van Servellen 2005). Self-management programmes compared to no health literacy intervention may improve understanding of HIV terms (mean difference (MD) 4.25, 95% confidence interval (CI) 1.32 to 7.18; low-certainty evidence; Analysis 1.1) and recognition of HIV terms (MD 3.32, 95% CI 1.28 to 5.36; low-certainty evidence; Analysis 1.2) immediately post-intervention.

Quality of life

The effect of self-management programmes on quality of life is unknown when compared to no health literacy intervention, as there was no direct evidence.

Health-related knowledge

All four studies in this comparison assessed the effects of self-management programmes on knowledge immediately after the intervention programme was completed. The studies' knowledge tests were based on the interventions' content (i.e. diabetes mellitus, HIV, breast cancer or heart health). Due to differences in the scales used (Rosal 2011; van Servellen 2005), or missing information to calculate a mean difference and a measure of dispersion for each study group (Bloom 2014; Koniak-Griffin 2015), we narratively synthesised the results. We transformed the proportion of accurate responses to a percentage scale, ranging from 0% (no correct responses) to 100% (fully correct responses), whenever possible. Results for each outcome at each time point are presented in Table 2. The following results pertain to data that could not be pooled in a meta-analysis.

The narrative synthesis of two studies indicated that self-management programmes may make little or no difference to health-related knowledge immediately post-intervention, when compared to no health literacy intervention (low-certainty evidence) (Rosal 2011; van Servellen 2005). One randomised controlled trial (RCT) with 252 participants reported that the mean diabetes knowledge score was slightly higher in the intervention group (MD 5.6; range 2.2 to 9.0, details are shown in Table 2) (Rosal 2011). The mean knowledge score in the control group was 68. The other RCT with 69 participants reported that the mean

HIV global disease/treatment knowledge was slightly lower in the intervention group (MD -1.18%, 95% CI -9.23 to 6.87; Analysis 1.3), but the CI encompassed values that indicate both an improvement and a reduction in knowledge (van Servellen 2005). The same study, however, also reported that the mean knowledge of the risk of getting sicker when stopping taking one's HIV medication was slightly improved in the intervention group (MD 0.33, 95% CI -0.01 to 0.67; Analysis 1.4). However, the CI also encompassed values indicating a null effect.

One cluster-RCT was missing information about the number of participants randomised to each study group, and the intensity and length of the intervention programme. For example, we did not know if participants were assessed in the short term or medium term, as we also did not know for how long and at which intensity they received individual counselling. In addition, data were not reported in a way in which they could be extracted for meta-analysis (Bloom 2014). Briefly, Bloom 2014 reported that the intervention increased knowledge (MD 0.5, P < 0.0001) six months "post-test".

One other RCT with 194 participants was missing data for the control group but reported that knowledge about heart health increased in the intervention group three months post-intervention (Koniak-Griffin 2015); we did not grade the results due to missing data for the control group.

Self-management programmes may have little to no short-term effect on health-related knowledge. We are uncertain whether self-management programmes compared to no health literacy interventions improve knowledge in the medium term.

Health outcomes

There is low-certainty evidence from one RCT with 69 participants that self-management programmes compared to no health literacy intervention may lead to little or no difference in subjective health status within the past week when assessed immediately post-intervention (MD 0.38, 95% CI -0.13 to 0.89; Analysis 1.5) (van Servellen 2005).

Health behaviour

Three RCTs with 514 participants measured three health behaviour outcomes including self-reported blood glucose self-monitoring, self-reported adherence to HIV medication and physical activity assessed with an accelerometer. Results for each outcome at each time point assessed are presented in Table 4. The following results pertain to data that could not be pooled in a meta-analysis.

Rosal 2011 reported greater self-reported blood glucose-self-monitoring in the intervention group immediately post-intervention (RR 1.30, 95% CI 1.11 to 1.52; 252 participants; Analysis 1.6). van Servellen 2005 reported that the proportion of participants who reported > 95% adherence to HIV medication within the last four days was higher in the intervention group six months after randomisation (change score intervention group: 1.71%, change score control group: -4.85%, 69 participants). Koniak-Griffin 2015 reported that the mean physical activity (average daily steps) was higher in the intervention group immediately post-intervention (MD 289 daily steps, 95% CI -601.41 to 1179.41; 193 participants; Analysis 1.7).

One cluster-RCT was missing information about the number of participants randomised to each study group, and the intensity and length of the programme. The study reported that self-reported mammography screening was higher in the group who received the self-management programme compared to a wait-list control group (56% versus 10%; P < 0.0001; very low-certainty evidence) after six months (Bloom 2014). However, it was unclear whether the participants were supported by health navigators during the total follow-up time or not. Thus, we do not know whether participants were assessed in the short term or medium term. In addition, the information was insufficient to permit judgement for most risk of bias domains and the authors stated having used generalised estimating equations (GEE) models, but only reported the proportions of participants who self-reported that they have had a mammogram.

Unpooled findings indicate that self-management programmes may slightly improve health behaviour immediately post-intervention, when compared to no health literacy intervention (low-certainty evidence). However, the outcome measures and effects appear variable.

Koniak-Griffin 2015 also reported results for physical activity at three-month follow-up. The results indicated uncertainty about whether there is a medium-term effect on physical activity (MD 1336.00, 95% CI 540.86 to 2131.14; 193 participants; very low-certainty evidence; Analysis 1.8). The certainty of the evidence is very low as the control group had a more than 1000-step decline from immediately to three months post-intervention, whereas the number of average daily steps in the intervention group fell back to the baseline level (which was 8577 average daily steps (standard deviation (SD) 2872)). Thus, the calculated MD does not reflect an actual improvement in the intervention group.

Self-efficacy

Two RCTs measured self-efficacy to manage one's disease (Rosal 2011; van Servellen 2005). The pooled analysis with 333 participants indicated that self-management programmes compared to no health literacy interventions probably improve self-efficacy slightly immediately post-intervention (standardised mean difference (SMD) 0.28, 95% CI 0.06 to 0.50; Analysis 1.9).

Health service use

The effect of self-management programmes on health service use is unknown when compared to no health literacy intervention, as there was no direct evidence.

Adverse events

The effect of self-management programmes on health service use is unknown when compared to no health literacy intervention, as there was no direct evidence.

Comparison 2: Culturally and literacy adapted self-management programme versus written information on the same topic

We included six studies in this comparison with a total programme length of up to three (Rosal 2005; Kaur 2019), six (Han 2017; Kim 2009) and 12 months (Kim 2014; Kim 2020). The following results pertain to the short-term assessments (immediately after the programme was completed) unless otherwise described. One cluster-RCT reported additional results for six months after the programme was completed (Kim 2014). Summary of findings 2 presents the evidence relating to the effect of culturally and literacy adapted self-management programmes compared to written information on the same topic. In addition, see Data and analyses for pooled data on this comparison and Table 1, Table 9, Table 6, Table 2, Table 3, Table 4 and Table 5 for the data that we did not pool.

Health literacy

Four RCTs reported either measures for generic health literacy, including health numeracy (assessed with NVS) and print literacy (assessed with REALM) (Kim 2020), or for disease-specific health literacy, including cancer screening health literacy (assessed with AHL-C) (Han 2017), oral health literacy (assessed with TS-REALD) (Kaur 2019), high blood pressure health literacy (assessed with HBP Health Literacy Scale) (Kim 2014), or diabetes health literacy assessed with DM-REALM (Kim 2020).

Generic health literacy

There is moderate-certainty evidence from one RCT with 209 participants that self-management programmes compared to written information on the same topic probably improve health numeracy slightly (MD 0.7, 95% CI 0.15 to 1.25; Analysis 2.1) and that they probably improve print literacy immediately post-intervention (MD 9.00, 95% CI 2.90 to 15.10; Analysis 2.2) (Kim 2020).

Disease-specific health literacy

The pooled analysis of two RCTs (Kaur 2019; Kim 2020) and two cluster-RCTs (Han 2017; Kim 2014) with 955 participants indicated that self-management programmes compared to written information may improve disease-specific health literacy (SMD 0.67, 95% CI 0.27 to 1.07; I^2 = 89%; low-certainty evidence; Analysis 2.3). The test for subgroup differences by programme length was significant (Chi^2 = 4.89, df = 1, P = 0.03, I^2 = 79.2%; Analysis 2.4), revealing that participants who participated in shorter programmes (three to six months) and who were, thus, assessed after shorter follow-up periods (that were accompanied by at least monthly motivating telephone calls) had higher scores in disease-specific health literacy than those who participated in longer programmes of up to 12 months. Sensitivity analysis including only studies without high risk of bias (n = 2) showed a greater effect of self-management programmes compared to written information on the same topic, but the lower limit of the pooled CI included a value favouring written information on the same topic (SMD 0.87, 95% CI -0.05 to 1.78, I^2 = 94%; Analysis 2.5). Since the results of Kaur 2019 were noticeably better than the results of other studies, we conducted an additional sensitivity analysis for this outcome. Excluding Kaur 2019 from the analysis, however, did not considerably alter the interpretation of the results. The calculated standardised mean difference still indicated an important effect, but the statistical heterogeneity was reduced (SMD 0.47, 95% CI 0.19 to 0.76, I^2 = 76%; Analysis 2.6).

One cluster-RCT with 242 participants additionally reported on high blood pressure health literacy six months post-intervention. The self-management programme may improve high blood pressure health literacy slightly six months after the programme was completed (MD 4.10, 95% CI 0.97 to 7.23; low-certainty; Analysis 2.7) (Kim 2014).

Self-management programmes may improve any disease-specific health literacy immediately post-intervention, and they may improve high blood pressure health literacy slightly at six-month follow-up.

Steps of health information processing (appraising health information)

One cluster-RCT with 329 participants assessed decisional balance (i.e. weighing pros and cons) for using mammography or Pap testing for breast cancer screening or cervical cancer screening, respectively (Han 2017). The results indicated that self-management programmes compared to written information on the same topic may lead to little or no difference in decisional balance, when assessed immediately after the six-month programme was completed (MD 1.15, 95% CI -0.23 to 2.53; low-certainty evidence; Analysis 2.8).

Quality of life

The pooled analysis of two RCTs with 288 participants indicated uncertainty about whether self-management programmes improved diabetes-related quality of life immediately post-intervention (MD 9.06, 95% CI 2.85 to 15.27; I^2 = 60%; very low-certainty evidence; Analysis 2.9) (Kim 2020; Kim 2009).

One study with 25 participants reported on diabetes-related quality of life, but due to incomplete reporting, both the direction and the size of the effect was unclear (Rosal 2005). However, the reported CI encompassed both benefit and harm, indicating that the intervention makes little to no difference to quality of life. The certainty of the evidence was very low.

We are uncertain whether self-management programmes improve quality of life immediately post-intervention.

Health-related knowledge

Six studies assessed the effects of self-management programmes on knowledge (Han 2017; Kaur 2019; Kim 2009; Kim 2014; Kim 2020; Rosal 2005). The studies' knowledge tests were based on the interventions' content (i.e. heart health, diabetes mellitus and HIV). We transformed the proportion of accurate responses to a percentage scale ranging from 0% (no correct responses) to 100% (fully correct responses).

The pooled analysis of six studies indicated that self-management programmes may improve health-related knowledge (MD 11.45, 95% CI 4.75 to 18.15; I^2 = 92%; low-certainty evidence; Analysis 2.10). Due to the substantial statistical heterogeneity in this analysis, we conducted a subgroup analysis by programme length. It revealed that participants who participated in shorter programmes (three to six months), thus being assessed after shorter follow-up periods (supported by the study team), had slightly more correct answers than those who participated in longer programmes of up to 12 months with a longer maintenance phase. However, each subgroup's pooled CI remained wide and the test for subgroup differences was non-significant (Chi^2 = 0.02, df = 1, P = 0.89, I^2 = 0%; Analysis 2.11). Sensitivity analysis excluding studies with high risk of bias indicated that the effect of self-management programmes on health-related knowledge was even higher than indicated by the main analysis (MD 17.58, 95% CI 11.05 to 24.11, I^2 = 79%; 3 RCTs, 428 participants; Analysis 2.12). Since the results of Kaur 2019 were noticeably better than the results of other studies, we conducted an additional sensitivity analysis for this outcome. Excluding Kaur 2019 from the analysis, however, did not considerably alter the interpretation of the results. The calculated mean difference still indicated an important, but smaller, effect on knowledge (MD 8.76, 95% CI 3.57 to 13.96, I^2 = 82%; Analysis 2.13).

The pooled analysis of two studies with 298 participants indicated that self-management programmes may lead to little or no difference in health-related knowledge up to six months post-intervention (MD 3.87, 95% CI -0.46 to 8.19, I^2 = 30%; low-certainty evidence; Analysis 2.14) (Kim 2014; Rosal 2005).

Self-management programmes compared to written information on the same topic may improve health-related knowledge immediately post-intervention. However, the medium-term analysis indicated that they may lead to little or no difference in health-related knowledge up to six months post-intervention.

Health outcomes

The pooled analysis of four RCTs with 555 participants indicated uncertainty about whether self-management programmes have an effect on depression immediately post-intervention (SMD -0.19, 95% CI -0.62 to 0.23, I^2 = 79%; very low-certainty evidence; Analysis 2.15) (Kim 2009; Kim 2014; Kim 2020; Rosal 2005).

The pooled analysis of two studies with 267 participants indicated that self-management programmes compared to written information may lead to little or no difference in depression up to six months after the programme was completed (MD -0.32, 95% CI -0.90 to 0.27, I^2 = 53%; low-certainty evidence; Analysis 2.16) (Kim 2014; Rosal 2005).

We are uncertain whether self-management programmes improve depression either immediately or six months post-intervention.

Health behaviour

Five studies reported on five different health behaviour outcomes. In four studies, participants were assessed in the short term (immediately after the programme was completed) (Han 2017; Kaur 2019; Kim 2009; Kim 2014). In two studies, participants were assessed in the medium term (up to six months post-intervention) (Kim 2014; Rosal 2005). Outcome measures included diabetes self-care activities (Kim 2009), oral self-care behaviour (Kaur 2019), cervical/breast cancer screening adherence (Han 2017), non-adherence to blood pressure medication (Kim 2014), and blood glucose self-monitoring (Rosal 2005). The following results pertain to data that could not be pooled in a meta-analysis.

Kim 2009 reported that the self-management programme improved diabetes self-care activities post-intervention, when compared to written information on the same topic (MD 15, 95% CI 7.87 to 22.13; 79 participants; Analysis 2.17). Kaur 2019 found that the intervention improved self-reported oral self-care behaviour immediately post-intervention, when compared to written information on the same topic (MD 3.1, 95% CI 2.5 to 3.7; 140 participants; Analysis 2.18). One cluster-RCT with 336 participants reported that the intervention improved cervical and breast cancer screening adherence (risk ratio (RR) 7.17, 95% CI 3.96 to 12.99; Analysis 2.19) (Han 2017). Kim 2014 found little or no difference in non-adherence to blood pressure medication immediately post-intervention (MD -0.4, 95% CI -0.87 to 0.07; 1 cluster-RCT, 242 participants; Analysis 2.20), when compared to written information on the same topic.

Kim 2014 additionally reported results for non-adherence to blood pressure medication at six months after the programme was completed, indicating lower non-adherence scores in the intervention group (MD -0.40, 95%-CI -0.78 to -0.02; Analysis 2.21). Rosal 2005 reported greater self-reported blood glucose-self-monitoring in the intervention group four and a half months post-intervention, but the CI encompassed both a large improvement and a reduction in this outcome (RR 1.96, 95% CI 0.76 to 5.03; 23 participants; Analysis 2.22)

Kim 2020 stated having measured diabetes self-care activities but did not report the results.

The unpooled findings indicated that self-management programmes may improve some health behaviours immediately post-intervention (low-certainty evidence) and they may slightly improve some health behaviours up to six months post-intervention (low-certainty evidence). However, measures and effect sizes for both the short-term and the medium-term assessments appeared to be variable.

Self-efficacy

The pooled analysis of four studies with 552 participants showed that the mean score for self-efficacy to manage one's own disease was higher across the intervention groups (SMD 0.47, 95% CI 0.30 to 0.64; I^2 = 0%; moderate-certainty evidence; Analysis 2.23) (Kim 2009; Kim 2014; Kim 2020; Rosal 2005). The sensitivity analysis excluding studies at high risk of bias indicated a larger, but still moderate, effect on self-efficacy (SMD 0.58, 95% CI 0.34 to 0.81; I^2 = 0%; low-certainty evidence; Analysis 2.24).

One cluster-RCT with 242 participants also reported data for the six-month assessment, indicating that self-management programmes compared to written information may lead to little or no difference in high blood pressure self-efficacy six months post-intervention (MD -0.20, 95% CI -1.16 to 0.76; low-certainty evidence; Analysis 2.25) (Kim 2014).

Self-management programmes compared to written information on the same topic probably improve self-efficacy immediately post-intervention, but they may result in little or no effect on self-efficacy six months post-intervention.

Health service use

The effect of self-management programmes on health service use is unknown as there was no direct evidence.

Adverse events

The effect of self-management programmes on adverse events is unknown as there was no direct evidence.

Comparison 3: Culturally adapted health literacy skills building course versus no/unrelated health literacy intervention

We included three RCTs (Otilingam 2015; Soto Mas 2018; Wong 2020) and three cluster-RCTs (Elder 1998; Taylor 2011; Tong 2017) in this comparison. Participants were assessed in the short term (immediately post-intervention) and medium term (three to six months post-intervention). The following results pertain to the short-term assessments (immediately after the programme was completed) unless otherwise described. Summary of findings 3 presents the evidence relating to the effect of culturally adapted health literacy skills building courses compared to either no health literacy intervention or an unrelated health literacy intervention. In addition, see Data and analyses for pooled data on this comparison and Table 1, Table 8, Table 2, Table 4 and Table 5 for data that we did not pool.

Health literacy

Generic health literacy

Two RCTs measured generic functional health literacy using either the full version of the Test of Functional Health Literacy in Adults (TOFHLA) (Soto Mas 2018) or newest vital sign (NVS) (Otilingam 2015).

The pooled analysis of these two RCTs with 229 participants found that health literacy skills building courses may improve any generic functional health literacy up to one month post-intervention, when compared to no or unrelated health literacy intervention (SMD 0.48, 95% CI 0.20 to 0.75; $I^2 = 0\%$; low-certainty evidence; Analysis 3.1).

Disease-specific health literacy

One RCT with 37 participants indicated that health literacy skills building courses may lead to little or no difference in depression literacy immediately post-intervention, when compared to no or unrelated health literacy intervention (MD 0.17, 95% CI -1.28 to 1.62; low-certainty evidence; Analysis 3.2) (Wong 2020).

Steps of health information processing (applying health information)

One cluster-RCT with 287 participants indicated uncertainty about whether health literacy skills building courses improve the intention to change nutritional habits, when compared to no or unrelated health literacy intervention (MD 0.05; $P > 0.05$; very low-certainty evidence; see Table 8) (Elder 1998).

Quality of life

The effect of the intervention on quality of life is unknown as there was no direct evidence identified.

Health-related knowledge

The pooled analysis of two RCTs with 111 participants indicated that health literacy skills building courses may improve health-related knowledge immediately post-intervention, when compared to no or unrelated health literacy intervention (MD 10.87, 95% CI 5.69 to 16.06; $I^2 = 0\%$; low-certainty evidence; Analysis 3.3) (Otilingam 2015; Wong 2020). The knowledge score across control groups ranged from 48.1% to 61.8%. In absolute terms, this means that the group receiving no or unrelated health literacy intervention had, on average, 57 out of 100 answers correct whereas those in the self-management group had 68 answers correct on average (from 63 to 73 correct).

Three cluster-RCTs, which could not be pooled because most studies did not report the results in an extractable way for meta-analysis, measured health-related knowledge six months post-intervention (Elder 1998; Taylor 2011; Tong 2017). One cluster-RCT with 168 participants reported that the health literacy skills building course slightly improved hepatitis B knowledge six months post-intervention (MD 0.81, 95% CI 0.43 to 1.19; Analysis 3.4) (Taylor 2011). One cluster-RCT with 291 participants reported that the intervention slightly improved nutrition knowledge six months post-intervention (MD 0.79; $P \leq 0.001$) (Elder 1998). One cluster-RCT with 329 participants that did not report a composite knowledge score, but proportions of correct answers for five knowledge questions, found that the proportion of participants with correct answers was higher in the intervention group for all five knowledge domains with an MD ranging from 15.1% to 36.8% and P values ranging from < 0.0001 to 0.012 (Tong 2017). For more details on this outcome, see Table 2.

Health literacy skills building courses may slightly improve health-related knowledge six months post-intervention, when compared to no or unrelated health literacy intervention (low-certainty evidence).

Health outcomes

The effect of the intervention on health outcomes is unknown as there was no direct evidence identified.

Health behaviour

Two RCTs (Otilingam 2015; Soto Mas 2018) and two cluster-RCTs (Taylor 2011; Tong 2017) reported on three health behaviour outcomes. The following results pertain to data that could not be pooled in a meta-analysis.

Two RCTs reported on two health behaviour measures immediately post-intervention and indicated uncertainty about whether health literacy skills building courses improve health behaviour at this time point. One RCT with 74 participants found little or no difference in self-reported fat-related dietary habits one month post-intervention (MD 0.25, 95% CI 0.00 to 0.50; Analysis 3.5) (Otilingam 2015). One RCT with 155 participants also found little or no difference in self-reported cardiovascular health behaviour immediately post-intervention (MD 1.2; P value = 0.067, see Table 4) (Soto Mas 2018).

Two cluster-RCTs with 440 participants measured screening adherence six months post-intervention (Taylor 2011; Tong 2017). The pooled analysis indicated that health literacy skills building courses may improve or reduce screening adherence six months post-intervention, when compared to no or unrelated health literacy intervention (RR 2.68, 95% CI 0.33 to 21.83; low-certainty evidence; Analysis 3.6). The effect sizes appear to vary considerably, indicating an inconclusive result.

Health literacy skills building courses compared to no or unrelated health literacy intervention may lead to little or no difference in any health behaviour immediately post-intervention. When assessed at six-month follow-up, they may improve or reduce health behaviour (cancer screening adherence), but the importance of the effect is unclear as the effect sizes appeared to be variable.

Self-efficacy

One cluster-RCT with 290 participants indicated uncertainty about whether health literacy skills building courses improve self-efficacy to change one's diet six months post-intervention (MD 0.03; P = 0.64; very low-certainty evidence) (Elder 1998). For more details, see Table 5.

Health service use

The effect of the intervention on health service use is unknown as there was no direct evidence.

Adverse events

The effect of the intervention on adverse events is unknown as there was no direct evidence.

Comparison 4: Culturally and literacy adapted telephone education versus unrelated health literacy intervention

We included one RCT in this comparison. Lepore 2012 compared telephone education about prostate cancer to an unrelated health literacy intervention that came in the form of telephone education about nutrition. Participants were assessed in the long term (approximately seven months post-intervention for the outcomes decisional conflict (related to appraising health information), knowledge, prostate cancer screening intention and anxiety, and two years post-intervention for the outcome actual prostate-specific antigen (PSA) testing). Summary of findings 4 presents the evidence relating to the effect of culturally and literacy adapted telephone education compared to unrelated health literacy intervention. In addition, data related to this study are shown in Table 9, Table 8, Table 2, Table 4 and Table 7.

Steps of health information processing

Culturally and literacy adapted telephone education compared to unrelated health literacy intervention probably improves the appraisal of health information by reducing decisional conflict (-5.70, 95% CI -10.24 to -1.16; 431 participants; moderate-certainty evidence; Analysis 4.1), but probably leads to little or no difference in applying health information (prostate cancer screening intention) (RR 1.00, 95% CI 0.92 to 1.10; 431 participants; moderate-certainty evidence; Analysis 4.2), when assessed approximately seven months post-intervention.

Quality of life

The effect of telephone education on quality of life is unknown as there was no direct evidence.

Health-related knowledge

Culturally and literacy adapted telephone education compared to unrelated health literacy intervention probably improves prostate cancer knowledge slightly approximately seven months post-intervention (MD 6.9, 95% CI 6.88 to 6.92; 431 participants; moderate-certainty evidence; Analysis 4.3). In absolute terms, the group receiving unrelated telephone education had, on average, 55 out of 100 answers correct whereas those in the self-management group had 62 answers correct on average (from 62 to 62 correct).

Health outcomes

The effect of telephone education on health outcomes is unknown as there was no direct evidence.

Health behaviour

The data reported by Lepore 2012 indicated that telephone education compared to unrelated telephone education probably results in little or no difference in prostate cancer testing two years post-intervention (RR 0.93, 95% CI 0.82 to 1.07; 490 participants; moderate-certainty evidence; Analysis 4.4).

Self-efficacy

The effect of telephone education on self-efficacy is unknown as there was no direct evidence.

Health service use

The effect of telephone education on health service use is unknown as there was no direct evidence.

Adverse events

The data reported by Lepore 2012 indicated that telephone education compared to unrelated telephone education probably leads to little or no difference in anxiety (assessed with the seven-item subscale of the Hospital Anxiety and Depression Scale, HADS) approximately seven months post-intervention (MD -0.14, 95% CI -0.55 to 0.27; 431 participants; moderate-certainty evidence; Analysis 4.5).

Comparison 5: Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention

We included four RCTs in this comparison (DeCamp 2020; Hernandez 2013; Kiropoulos 2011; Thompson 2012). Summary of findings 5 presents the evidence relating to the effect of culturally and literacy adapted audio-/visual education compared to usual care, no health literacy intervention or unrelated health literacy intervention. In addition, see Data and analyses for pooled data on this comparison and Table 1, Table 8, Table 2, Table 3, Table 4, Table 5 and Table 10 for data we did not pool.

Health literacy

Disease-specific health literacy

One RCT with 202 participants reported results for depression literacy assessed with the Depression Literacy Questionnaire (D-Lit) (Kiropoulos 2011). Audio-/visual education without personal feedback compared to no health literacy intervention probably improves depression literacy one week post-intervention (MD 8.62, 95% CI 7.51 to 9.73; moderate-certainty evidence; Analysis 5.1).

Steps of health information processing (applying health information)

One RCT with 120 participants indicated that audio-/visual education without personal feedback may slightly improve the intention to seek treatment for depression immediately post-intervention (MD 1.8, 95% CI 0.43 to 3.17; low-certainty evidence; Analysis 5.2), when compared to no health literacy intervention (Hernandez 2013).

Quality of life

The effect of audio-/visual education without personal feedback on quality of life is unknown, as there was no direct evidence.

Health-related knowledge

Two studies assessed the effect of audio-/visual education compared to no health literacy intervention on health-related knowledge (DeCamp 2020; Hernandez 2013). The knowledge tests in the studies were based on the content of the interventions (i.e. child health and depression). We transformed the proportion of accurate responses to a percentage scale ranging from 0% (no correct responses) to 100% (fully correct responses).

The pooled analysis with 293 participants indicated that audio-/visual education without personal feedback compared to no health literacy intervention may slightly improve health-related knowledge up to one month post-intervention, but the effect sizes appear to vary considerably (MD 8.44, 95% CI -2.56 to 19.44; I^2 = 97%; low-certainty evidence; Analysis 5.3).

Health outcome

The pooled analysis of two RCTs with 337 participants indicated that audio-/visual education without personal feedback may lead to little or no difference in any depression immediately up to three months post-intervention (SMD -0.15, 95% CI -0.40 to 0.10; low-certainty evidence; Analysis 5.4), when compared to no health literacy intervention.

Health behaviour

One RCT with 135 participants assessed children's up-to-date immunisation immediately and up to three months post-intervention (participants were not assessed at the same time) (DeCamp 2020). The results of DeCamp 2020 (RR 1.07, 95% CI 0.91 to 1.25; moderate-certainty evidence; Analysis 5.5) indicated that audio-/visual education without personal feedback probably results in little or no difference in children's up-to-date immunisation immediately and up to three months post-intervention, when compared to no health literacy intervention.

Self-efficacy

The results of one RCT with 133 participants indicated that audio-/visual education without personal feedback may improve self-efficacy to identify the need for treatment of depression immediately post-intervention (MD 3.51, 95% CI 2.53 to 4.49; low-certainty evidence; Analysis 5.6), when compared to no health literacy intervention (Hernandez 2013).

Health service use

One RCT with 157 participants assessed children's emergency room visits immediately and up to three months post-intervention, indicating that audio-/visual education without personal feedback compared to no health literacy intervention probably reduces children's emergency room visits up to three months post-intervention (MD -0.59, 95% CI -1.11 to -0.07; moderate-certainty evidence; Analysis 5.7) (DeCamp 2020).

Adverse events

The effect of audio-/visual education without personal feedback on adverse events is unknown, as there was no direct evidence identified.

Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic

We included nine RCTs in this comparison (Calderón 2014; Gwede 2019; Payán 2020; Poureslami 2016a; Poureslami 2016b; Sudore 2018; Unger 2013; Valdez 2015; Valdez 2018). Participants were assessed in the short term immediately post-intervention up to 15 months after study enrolment. Summary of findings 6 presents the evidence relating to the effect of culturally and literacy adapted media interventions compared to another culturally and literacy adapted media intervention. In addition, see Data and analyses for pooled data on this comparison and Table 1, Table 11, Table 12, Table 9, Table 8, Table 2, Table 3, Table 4, Table 5 and Table 7 for data we did not pool.

Health literacy

Disease-specific health literacy

One RCT with 240 participants measured diabetes health literacy immediately post-intervention, indicating that audio-/visual education without personal feedback compared to written information on the same topic probably leads to little or no difference in diabetes health literacy (MD 2.00, 95% CI -0.15 to 4.15; moderate-certainty evidence; Analysis 6.1) (Calderón 2014).

Prerequisites and tools

The pooled analysis of two RCTs with 176 participants indicated that audio-/visual education without personal feedback compared to written information on the same topic may slightly improve competencies (inhaler use technique) three months post-intervention (MD 0.98, 95% CI 0.26 to 1.70; low-certainty evidence; Analysis 6.2) (Poureslami 2016a; Poureslami 2016b).

Steps of health information processing

Two RCTs with 128 participants reported results either for *understanding* physician's instruction (MD 0.04, 95% CI -0.55 to 0.63; 85 participants; Analysis 6.3) (Poureslami 2016a), or for *understanding* pulmonary rehabilitation procedures (MD 0.30, 95% CI -0.76 to 1.36; 43 participants) (Poureslami 2016b), both indicating that audio-/visual education without personal feedback compared to written information on the same topic may lead to little or no difference in understanding of health information three months post-intervention (low-certainty evidence). We found moderate-certainty evidence from one RCT with 608 participants, which reported results for *appraising* and *applying* health information (Valdez 2015). The study found that audio-/visual education without personal feedback compared to written information probably improves *appraising* health information by reducing decisional conflict, assessed with the three subscales 'informed decision', 'values clarity' and 'support' at one month post-intervention (MD -9.88, 95% CI -12.87 to -6.89; Analysis 6.4). This was also found for *applying* health information (making an informed decision regarding HPV vaccination) one month post-intervention (RR 1.51, 95% CI 1.29 to 1.77; Analysis 6.5).

Quality of life

The effect of audio-/visual education without personal feedback on quality of life is unknown, as there was no direct evidence.

Health-related knowledge

Six studies measured any health-related knowledge either immediately and up to one month post-intervention (Payán 2020; Unger 2013; Valdez 2015), or up to six months after the intervention was completed (Gwede 2019; Payán 2020; Poureslami 2016a; Valdez 2018). Poureslami 2016b stated having assessed COPD-related knowledge, but did not report the results. The knowledge tests in the studies were based on the content of the interventions (i.e. heart health, diabetes mellitus and HIV). We transformed the proportion of accurate responses to a percentage scale ranging from 0% (no correct responses) to 100% (fully correct responses).

The pooled analysis of three RCTs with 987 participants indicated that audio-/visual education without personal feedback compared to written information on the same topic may slightly improve health-related knowledge up to one-month post-intervention (MD 8.35, 95% CI -0.32 to 17.02; I^2 = 93%; low-certainty evidence;

Analysis 6.6) (Payán 2020; Unger 2013; Valdez 2015). Subgroup analysis revealed that the use of an audiovisual (multimedia) format (here an educational DVD) was more effective in improving health-related knowledge (MD 15.00, 95% CI 12.61 to 17.39; 1 study, 608 participants) than a printed visual format (here photonovels delivered either by community health workers or in a group session delivered by lay health workers) (MD 4.75, 95% CI -3.33 to 12.84; 2 studies, 379 participants). The test for subgroup differences was significant (Chi^2 = 5.68, df = 1, P = 0.02, I^2 = 82.4%; Analysis 6.7).

The pooled analysis of three RCTs with 979 participants indicated uncertainty about whether audio-/visual education without personal feedback compared to written information on the same topic improves cancer-related knowledge up to six months post-intervention (MD 7.30, 95% CI -3.73 to 18.32, I^2 = 90%; very low-certainty evidence; Analysis 6.8) (Gwede 2019; Payán 2020; Valdez 2018). The subgroup analysis showed that audiovisual (multimedia) formats (MD 12.27, 95% CI 8.28 to 16.26) were superior to printed visual formats (MD -2.80, 95% CI -8.00 to 2.40). The test for subgroup differences was significant (Chi^2 = 20.32, df = 1, P < 0.00001, I^2 = 95.1%; Analysis 6.9).

One study with 85 participants and four study arms could not be included in the pooled analysis as no composite score was reported (Poureslami 2016a). Only change scores and CIs per group and per item were reported. In addition, we had insufficient information about the score range, so combining the results of the knowledge items and pooling them with other data by calculating a standardised mean difference would have led to information loss. Briefly, the study found that audio-/visual education may make little or no difference to asthma knowledge three months post-intervention as almost all CIs were wide and included both benefit and harm (very low-certainty evidence). Results for all study groups are shown in Table 2.

Culturally and literacy adapted audio-/visual education without personal feedback may improve health-related knowledge in the short term, when compared with written information on the same topic. We do not know whether it has an effect on health-related knowledge in the medium term as the certainty of the evidence is very low.

Health outcome

One RCT with 445 participants measured depression 12 months post-intervention using the Patient Health Questionnaire (PHQ-8) (Sudore 2018). The results indicated that audio-/visual education without personal feedback compared to written information on the same topic may result in little or no difference in depression 12 months post-intervention (MD -0.60, 95% CI -1.37 to 0.17; low-certainty evidence; Analysis 6.10).

Health behaviour

Two RCTs measured cancer screening uptake either related to colorectal cancer (assessed via return of faecal immunochemical test) (Gwede 2019) or cervical cancer (assessed via self-reported Pap testing) (Valdez 2018). The pooled analysis with 803 participants indicated that audio-/visual education without personal feedback may lead to little or no difference in any cancer screening uptake up to six months post-intervention, when compared to written information on the same topic (RR 1.07, 95% CI 0.95 to 1.20, I^2 = 0%; low-certainty evidence; Analysis 6.11).

One RCT with 445 participants measured new documentation of advance care planning assessed via medical record (Sudore 2018). The results indicated that audio-/visual education without personal feedback compared to written information on the same topic probably improves documentation of advance care planning 12 months post-intervention (RR 1.49, 95% CI 1.13 to 1.97; moderate-certainty evidence; Analysis 6.12).

Self-efficacy

One RCT with 240 participants reported on self-efficacy in accessing breast cancer-related advice or information immediately post-intervention (Payán 2020) and indicated that audio-/visual education compared to written information on the same topic may result in little or no difference in self-efficacy in accessing breast cancer-related advice or information (MD 0.08, 95% CI -0.02 to 0.18; low-certainty evidence; Analysis 6.13).

Four studies measured self-efficacy three to six months post-intervention (Gwede 2019; Payán 2020; Poureslami 2016b; Valdez 2018). The results of two studies could be pooled. The following results pertain to the synthesis of the pooled analysis and the unpooled findings of the two other studies.

The pooled analysis of two RCTs with 256 participants found little or no effect of audio-/visual education without personal feedback on any cancer-related self-efficacy three months post-intervention (SMD 0.08, 95% CI -0.18 to 0.33, I^2 = 0%; Analysis 6.14) (Gwede 2019; Payán 2020). One study with 727 participants that could not be incorporated in the pooled analysis due to variance in the reported outcome data, also found that audio-/visual education made little or no difference to self-efficacy regarding Pap testing between the intervention groups (RR 1.02, 95% CI 0.98 to 1.06; Analysis 6.15) (Valdez 2018). One study with 43 participants and four study arms could not be incorporated in the pooled analysis as the data were not reported in a way that could be extracted for meta-analysis (Poureslami 2016b). The study found little or no effect on self-efficacy three months post-intervention. In this study no composite score was reported, but only subgroup analyses per intervention group compared to a control group and per item (five items). In addition, three out of the five CIs encompassed both an improvement and a reduction in self-efficacy. More details are shown in Table 5.

Audio-/visual education without personal feedback compared to written information on the same topic may have little or no effect on self-efficacy when assessed in the medium term.

Health service use

The effect of audio-/visual education without personal feedback on health service use is unknown as there was no direct evidence.

Adverse events

One RCT with 445 participants measured anxiety using the Generalised Anxiety Disorder Scale (GAD-7) (Sudore 2018). The results demonstrated that audio-/visual education without personal feedback probably leads to little or no difference in anxiety 12 months post-intervention (MD -0.70, 95% CI -1.40 to 0.00; moderate-certainty evidence; Analysis 6.16).

Comparison 7: Culturally and literacy adapted audio-/visual education without personal feedback versus another

culturally and literacy adapted audio-/visual education without personal feedback

We included three RCTs comparing a narrative video (here referred to as intervention) to a factual knowledge video (here referred to as control). One study aimed to improve knowledge about cervical cancer and cervical cancer screening behaviour in Spanish-speaking immigrants (Ochoa 2020). The other studies aimed to improve knowledge about asthma (Poureslami 2016a) or COPD (Poureslami 2016b) and its medication management in Asian immigrants. Participants were all assessed in the medium term, either three months (Poureslami 2016a; Poureslami 2016b) or six months post-intervention (Ochoa 2020). Poureslami 2016a and Poureslami 2016b stated that participants were also assessed six months post-intervention, but results were not reported. Summary of findings 7 presents the evidence relating to the effect of culturally and literacy adapted audio-/visual education without personal feedback (narrative video) versus another culturally and literacy adapted audio-/visual education without personal feedback (factual knowledge video). In addition, see Data and analyses for pooled data on this comparison and Table 11, Table 12, Table 8, Table 2 and Table 4 for data we did not pool.

Health literacy

Prerequisites and tools

The pooled analysis of two RCTs with 91 participants indicated uncertainty about whether educational (narrative) videos compared to factual knowledge videos improve competencies (inhaler use technique) three months post-intervention (MD -0.89, 95% CI -1.84 to 0.07; very low-certainty evidence; Analysis 7.1) (Poureslami 2016a; Poureslami 2016b).

Steps of health information processing

The results of one RCT with 43 participants indicated uncertainty about whether narrative videos compared to factual knowledge videos have an effect on *understanding* of physician's instruction three months post-intervention (MD -0.15, 95% CI -0.72 to 0.42; very low-certainty evidence; Analysis 7.2) (Poureslami 2016a). One study could not be included in the narrative synthesis as the participants who watched the narrative video and those who watched the knowledge video were not directly compared to each other, but both were compared to a control group who read a pictorial pamphlet (Poureslami 2016b). Details are shown in Table 12.

Ochoa 2020 reported results for intention to have cervical cancer screening (Pap testing) that indicated uncertainty about whether educational (narrative) videos compared to factual knowledge videos improve the application of health information (intention to have cervical cancer screening) six months post-intervention (RR 1.97, 95% CI 0.83 to 4.69; 109 participants; very low-certainty evidence; Analysis 7.3).

Quality of life

The effect of narrative videos compared to factual knowledge videos on quality of life is unknown, as there was no direct evidence identified.

Health-related knowledge

Two RCTs in this comparison reported results for health-related knowledge (Ochoa 2020; Poureslami 2016a). The knowledge tests in the studies were based on the content of the interventions (i.e. cervical cancer and asthma). We transformed the proportion of accurate responses to a percentage scale ranging from 0% (no correct responses) to 100% (fully correct responses) for the results of Ochoa 2020 only, as in Poureslami 2016a no score range was reported, but only subgroup analyses per study group and knowledge item. Therefore, we could not standardise the reported values on a scale ranging from 0 to 100. Nevertheless, the three knowledge items were combined to calculate an MD across the items.

The findings of Ochoa 2020 indicated uncertainty about whether watching a narrative video about cervical cancer has an effect on health-related knowledge, when compared to a factual knowledge video on the same topic (MD 1.12, 95% CI -4.63 to 6.87; 109 participants; Analysis 7.4) six months post-intervention. The mean cervical cancer knowledge score in the control group was 66%. However, there was an unclear risk of bias for random sequence generation and allocation concealment and the CI encompassed both an improvement and a worsening. The results of Poureslami 2016a also indicated uncertainty about the effect of watching a narrative video about asthma management on health-related knowledge when compared to a factual knowledge video on the same topic three months post-intervention (MD 0.85, 95% CI -1.07 to 2.76; 43 participants; Analysis 7.5).

We are uncertain whether narrative educational videos compared to factual knowledge videos improve health-related knowledge up to six months post intervention.

Health outcome

The effect of narrative educational videos compared to factual knowledge videos on health outcomes is unknown, as there was no direct evidence.

Health behaviour

The results of Ochoa 2020 indicated uncertainty about whether narrative educational videos compared to factual knowledge videos improve cervical cancer screening behaviour six months post-intervention (RR 1.29, 95% 0.75 to 2.23; 109 participants; very low-certainty evidence; Analysis 7.6).

Self-efficacy

The effect of narrative videos compared to factual knowledge videos on self-efficacy is unknown, as there was no direct evidence.

Adverse events

The effect of narrative videos compared to factual knowledge videos on adverse events is unknown, as there was no direct evidence.

Comparison 8: Culturally and literacy adapted medical instruction versus no health literacy intervention

We included three RCTs with 478 participants in this comparison (Bailey 2012; Kheir 2014; Mohan 2014). Participants were assessed up to one week post-intervention. Summary of findings 8 presents the evidence relating to the effect of culturally and literacy adapted medical instruction compared to another culturally and literacy adapted media intervention. In addition, see Data and analyses for data presented in forest plots and Table 12, and Table 4 for all data in this comparison.

Health literacy

Steps of health information processing (understanding health information)

One RCT with 202 participants reported that health literacy informed medication instructions improved the correct dosage in the dosing tray immediately post-intervention (intervention group: median 4.0, interquartile range (IQR) 3.0 to 5.0; control group: median 3.0, IQR 2.0 to 4.0) (Bailey 2012). Another RCT with 123 participants reported that pictograms plus verbal instruction improved the correct interpretation of label contents in 10 out of 11 medical instructions immediately post-intervention, when compared with standard text labels and verbal instruction (no composite score reported) (Kheir 2014). One RCT with 200 participants reported that a literacy adapted plain language text in combination with an illustrated medication list improved medication understanding assessed with the Medication Understanding Questionnaire (MUQ), with a score range of 0 (no knowledge) to 100 (perfect knowledge) at one-week follow-up (MD 10, 95% CI 5.70 to 14.30; Analysis 8.1) (Mohan 2014).

Culturally and literacy adapted medical instructions compared to no health literacy intervention may improve medication understanding up to one week post-intervention.

Quality of life

The effect of the intervention on quality of life is unknown as there was no direct evidence.

Health-related knowledge

The effect of the intervention on health-related knowledge is unknown as there was no direct evidence.

Health outcome

The effect of the intervention on health outcomes is unknown as there was no direct evidence.

Health behaviour

One RCT with 200 participants measured self-reported medication adherence at one week post-intervention (Mohan 2014), indicating that culturally and literacy adapted medical instructions compared to no health literacy intervention may result in little or no difference in health behaviour one week post-intervention (MD 0.5, 95% CI -0.1 to 1.1; low-certainty evidence).

Self-efficacy

The effect of the intervention on self-efficacy is unknown as there was no direct evidence.

Health service use

The effect of the intervention on health service use is unknown as there was no direct evidence.

Adverse events

The effect of the intervention on adverse events is unknown as there was no direct evidence.

Comparison 9: Female migrants' benefit of any health literacy intervention versus male migrants' benefit of any health literacy intervention

The study authors of three intervention studies provided gender-separate data upon request (Calderón 2014; Soto Mas 2018; Sudore 2018). Only Soto Mas 2018 reported gendered scores for functional health literacy in the published trial report. Nevertheless, the gendered scores for health behaviour were obligingly provided at our request. Summary of findings 9 presents the evidence relating to female and male migrants' benefits of any health literacy intervention.

Health literacy

Generic functional health literacy

One RCT with 77 participants in the intervention group that compared a health literacy skills building course to no health literacy intervention indicated uncertainty about whether female compared to male migrants' generic functional health literacy improves more immediately post-intervention (MD 2.78, 95% CI -4.35 to 9.91; very low-certainty evidence; Analysis 9.1) (Soto Mas 2018). Additional information on the findings related to this study are described in Comparison 3 (see also Summary of findings 3).

Disease-specific health literacy

The results of one RCT with 118 participants in the intervention group that compared audio-/visual education without personal feedback to written information on the same topic indicated that female migrants' diabetes health literacy may improve slightly more than that of male migrants (MD 5.00, 95% CI 0.62 to 9.38; low-certainty evidence; Analysis 9.2) (Calderón 2014).

Quality of life

The effect of any health literacy intervention on female compared to male migrants' quality of life is unknown as there was no direct evidence.

Health-related knowledge

The effect of any health literacy intervention on female compared to male migrants' health-related knowledge is unknown as there was no direct evidence.

Health outcome

The effect of any health literacy intervention on female compared to male migrants' health outcome is unknown as there was no direct evidence.

Health behaviour

The results of one RCT with 77 participants in the intervention group that compared a health literacy skills building course to no health literacy intervention (standard English as a second language (ESL) course) indicated uncertainty about whether female compared to male migrants' cardiovascular health behaviour improves more immediately post-intervention (MD 2.07, 95% CI -5.04 to 9.18; very low-certainty evidence; Analysis 9.3) (Soto Mas 2018). Additional information on the findings related to this study is described in Comparison 3 (see also Summary of findings 3).

The results of one other RCT with 219 participants in the intervention group indicated that audio-/visual education without personal feedback may lead to little or no difference in new documentation of advance care planning between female and male migrants 12 months post-intervention (RR 1.27, 95% CI 0.90 to 1.79; low-certainty evidence; Analysis 9.4) (Sudore 2018). Additional information on the findings related to this study is described in Comparison 6 (see also Summary of findings 6).

Self-efficacy

The effect of any health literacy intervention on female compared to male migrants' self-efficacy is unknown as there was no direct evidence.

Health service use

The effect of any health literacy intervention on female compared to male migrants' health service use is unknown as there was no direct evidence.

Adverse events

The effect of any health literacy intervention on adverse events for female compared to male migrants is unknown as there was no direct evidence.

DISCUSSION

Summary of main results

The primary objective of this review was to assess the effectiveness of interventions for improving health literacy in migrants. We included 34 studies in this review. Given our broad inclusion criteria regarding the interventions, participants and control groups, we expected heterogeneity between the identified studies. Additionally, there was great variation in the outcome measures and time points of assessment across studies. To address these factors appropriately, we grouped the included studies according to the main intervention components, the complexity of the intervention and the comparator, resulting in eight 'main comparisons'. In addition, we built a ninth comparison to address our second objective, which was to assess whether female and male migrants respond differently to any health literacy intervention.

Comparison 1: Culturally and literacy adapted self-management programme versus no health literacy intervention

See Summary of findings 1.

When compared to no health literacy intervention, self-management programmes may improve disease-specific HIV health literacy (understanding of HIV terms and recognition of HIV terms) in the short term. We found low-certainty evidence that self-management programmes may slightly improve any health behaviour, but the effects vary in size. Self-management programmes may lead to little or no difference in health-related knowledge or subjective health status immediately post-intervention, when compared to no health literacy intervention. We found moderate-certainty evidence that self-management programmes probably improve self-efficacy slightly immediately post-intervention.

We do not know whether self-management programmes have an effect on quality of life, or health service use, as the certainty of the evidence was either very low or we did not identify direct evidence for these outcomes. Adverse events related to the intervention were not reported in any of the included trials in this comparison.

Comparison 2: Culturally and literacy adapted self-management programme versus written information on the same topic

See Summary of findings 2.

When assessed in the short term, self-management programmes compared to written information on the same topic probably slightly improve health numeracy and probably improve generic print literacy. We found low-certainty evidence that self-management programmes may improve any disease-specific health literacy, when compared to written information on the same topic. The pooled analysis of six studies indicated that self-management programmes may improve health-related knowledge immediately post-intervention. We also found low-certainty evidence that they may improve any health behaviour immediately post-intervention, with variable effects. Moderate-certainty evidence indicated that self-management programmes compared to written information probably have a short-term effect on self-efficacy.

When assessed in the medium term, self-management programmes may slightly improve high blood pressure health literacy. With regard to the steps of health information processing, we found low-certainty evidence that self-management programmes may lead to little or no difference in the appraisal of health information (decisional balance for using mammography or Pap testing) in the medium term. The pooled analysis of two studies indicated that there may be little or no effect on health-related knowledge when assessed in the medium term. Self-management programmes may slightly improve some health behaviours, but both the outcome measures and size of effects appeared to be variable. Low-certainty evidence also indicated that there may be little or no medium-term effect on depression. Self-management programmes compared to written information on the same topic may result in little or no effect on high blood pressure self-efficacy six months post-intervention.

We do not know if self-management programmes improve quality of life, depression or health service use immediately post-intervention as our certainty in the evidence is either very low (quality of life, depression), or we did not find direct evidence for these outcomes (health service use). No study in this comparison reported adverse events (e.g. anxiety). We also do not know whether there are any long-term effects of self-management programmes compared to written information due to a lack of evidence.

Comparison 3: Culturally adapted health literacy skills building course versus no or unrelated health literacy intervention

See Summary of findings 3.

We found that health literacy skills building courses may improve any generic functional health literacy in the short term (up to one month post-intervention), when compared to no or an unrelated health literacy intervention. However, health literacy skills building courses may result in little or no difference in disease-specific health literacy (depression literacy) immediately post-intervention. We do not know if the intervention improves the intention to change nutritional habits (here referred to as applying health information) as the certainty of the evidence is very low. Health literacy skills building courses may improve health-related knowledge, but may have little or no effect on any health behaviour immediately post-intervention.

When assessed in the medium term (six months post-intervention), they may slightly improve knowledge, and they may improve or reduce health behaviour (cancer screening adherence); the measures and effect sizes appeared to vary considerably.

We are uncertain whether health literacy skills building courses improve quality of life, health outcomes or self-efficacy, due to a lack of evidence or a very low certainty of evidence. No study in this comparison reported adverse events (e.g. anxiety). We also do not know whether there are any long-term effects of health literacy courses due to a lack of evidence.

Comparison 4: Culturally and literacy adapted telephone education versus unrelated health literacy intervention

See Summary of findings 4.

We included only one study in this comparison. All participants were assessed in the long term (approximately seven months post-intervention up to two years follow-up (for health behaviour outcomes)). Culturally and literacy adapted telephone education compared to unrelated health literacy intervention probably has an important long-term effect on the appraisal of health information by decreasing decisional conflict, but probably results in little or no difference in prostate cancer screening intention or in actual prostate cancer testing (at two-year follow-up). The results of one study further suggest that telephone education probably slightly improves health-related knowledge approximately seven months post-intervention. Based on the results of this study, telephone education compared to unrelated telephone education probably does not cause harm as little or no long-term effect on anxiety has been found.

We do not know whether telephone education improves quality of life, health outcomes, self-efficacy or health service use, as we did not identify direct evidence for these outcomes. We also do not know whether there is any short- or medium-term effect of telephone education on health literacy outcomes due to a lack of evidence.

Comparison 5: Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention

See Summary of findings 5.

We found moderate-certainty evidence that audio-/visual education without personal feedback compared to no health literacy intervention probably improves depression literacy in the short term. We found low-certainty evidence indicating that it slightly improves the intention to seek treatment for depression (here referred to as applying health information), health-related knowledge and self-efficacy, but there may be little or no effect on any depression immediately in the short term.

We found moderate-certainty evidence indicating that audio-/visual education without personal feedback probably has little or no effect on health behaviour (children's up-to-date immunisation), but probably improves health service use (by reducing emergency room visits), both assessed immediately and up to three months post-intervention (short- to medium-term).

We do not know whether audio-/visual education without personal feedback has any effect on the participants' quality of life, or whether there are any adverse events related to this intervention, as we did not identify direct evidence for these outcomes.

Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic

See Summary of findings 6.

Audio-/visual education without personal feedback compared to written information on the same topic probably has little or no short-term effect on diabetes health literacy. However, we found moderate-certainty evidence indicating that audio-/visual education without personal feedback compared to written information probably has a short-term effect on *appraising* health information (by reducing decisional conflict) and on *applying* health information (making an informed decision regarding HPV vaccination). Audio-/visual education may slightly improve health-related knowledge in the short term, but we do not know whether this also improves at longer time points (six months) as our certainty in the evidence is very low.

We found low-certainty evidence that audio-/visual education may result in little or no difference in self-efficacy, when assessed either in the short term or medium term. When assessed in the medium term (three months post-intervention), audio-/visual education may slightly improve *competencies* (inhaler use technique). We found low-certainty evidence indicating that it may lead to little or no difference in *understanding* health information (understanding physician's instruction/pulmonary rehabilitation procedure) in the medium term.

When assessed in the long term, audio-/visual education without personal feedback compared to written information on the same topic may result in little or no difference in depression or any cancer screening uptake, but moderate-certainty evidence indicates that it probably improves new documentation of advance care planning in the long term.

We did not identify any direct evidence for quality of life or health service use. Therefore, the effect of the intervention on these outcomes is unknown. We found no evidence that audio-/visual education causes harm, but the results of one study indicated that there is probably little or no difference in anxiety 12 months post-intervention.

Comparison 7: Culturally and literacy adapted audio-/visual education without personal feedback versus another culturally and literacy adapted audio-/visual education without personal feedback

See Summary of findings 7.

We do not know whether narrative educational videos have an effect on either health literacy, quality of life, knowledge, health outcomes, self-efficacy, health service use or adverse events, as there was either no direct evidence (for the outcomes quality of life, health outcomes, self-efficacy, health service use and adverse events) or the certainty of the evidence is very low (for the outcomes health literacy, knowledge and health behaviour).

Comparison 8: Culturally and literacy adapted medical instruction versus no health literacy intervention

See Summary of findings 8.

We found low-certainty evidence indicating that culturally and literacy adapted medical instructions compared to no health literacy intervention may improve medication understanding and may lead to little or no difference in medication adherence up to one week post-intervention.

We do not know whether culturally and literacy adapted medical instructions have an effect on quality of life, health-related knowledge, health outcomes, health service use or self-efficacy. We also do not know if there are any adverse events related to the intervention due to a lack of evidence.

Comparison 9: Female migrants' versus male migrants' benefit of any health literacy intervention

See Summary of findings 9.

We found low-certainty evidence indicating that female migrants' diabetes health literacy may improve slightly more than that of male migrants when receiving audio-/visual education. However, one other study found that female migrants' health behaviour (new documentation of advance care planning) may be little or no different to that of male migrants 12 months post-intervention, when receiving audio-/visual education without personal feedback.

We do not know whether female or male migrants benefit differently from any health literacy intervention with regard to generic health literacy, quality of life, health-related knowledge, health outcomes, individual skills or health service use as there was no direct evidence or the certainty of the evidence is very low (health literacy, health behaviour). In addition, we do not know if there are any adverse events related to the interventions that may affect female migrants more or less than male migrants as none of the studies reported adverse events separately for female or male migrants.

Overview of intervention effects

The following Table 1 provides an overview of the review findings at the outcome level, presenting the results on intervention effects based on high-, moderate- or low-certainty evidence.

Table 1. Summary of intervention effects

Outcome category and outcomes	Interventions that *have* an effect on the outcome (high-certainty evidence)	Interventions that *probably have* an effect on the outcome (moderate-certainty evidence)	Interventions that *may have* an effect on the outcome (low-certainty evidence)	Female versus male migrants' benefits from any health literacy intervention
Health literacy 1) Generic health literacy 2) Disease-specific health literacy 3) Components of health literacy	—	**(1) Generic health literacy** ***Time point a: short-term**** Comp 2: SMP vs written information - Outcome 1: health numeracy; increase favours SMP, less important effect - Outcome 2: print literacy; increase favours SMP, important effect **2) Disease-specific health literacy** Comp 5: AVE w/o personal feedback vs no health literacy intervention - Outcome: depression literacy; increase favours SMP, important effect	**1) Generic health literacy** ***Time point a: short-term*** Comp 1: SMP vs no health literacy intervention - Outcome: HIV health literacy; increase favours SMP, important effect Comp 3: HL-SBC vs no/unrelated HL-SBC - Outcome: any generic health literacy; increase favours HL-SBC, important effect **2) Disease-specific health literacy** ***Time point a: short-term*** Comp 2: SMP vs written information - Outcome: any disease-specific health literacy; increase favours SMP, important effect Comp 3: HL-SBC vs no/unrelated HL-SBC - Outcome: depression literacy; little or no effect	**2) Disease-specific health literacy** ***Time point a: short-term*** Intervention: AVE w/o personal feedback - Outcome: diabetes health literacy; less important effect (low-certainty evidence)

		Comp 6: AVE w/o personal feedback vs written information • Outcome 1: diabetes-specific health literacy; increase favours AVE, little or no effect **3) Components of health literacy** ***Time point a: short-term*** Comp 6: AVE w/o personal feedback vs written information • Outcome 1: *appraising* health information (decisional conflict); decrease favours AVE, important effect • Outcome 2: *applying* health information (making informed decision); increase favours AVE, important effect ***Time point c: long-term*** Comp 4: Telephone education vs unrelated health literacy intervention • Outcome 1: *appraising* health information (decisional conflict); decrease favours telephone education, important effect • Outcome 2: *applying* health information (prostate cancer screening intention); little or no effect	***Time point b: medium-term*** Comp 2: SMP vs written information • Outcome: HBP health literacy; increase favours SMP, less important effect **3) Components of health literacy** ***Time point a: short-term*** Comp 8: AMI vs no health literacy intervention • Outcome: *understanding* health information; increase favours AMI, important effect Comp 2: SMP vs written information • Outcome: *appraising* health information (decisional balance for breast/cervical cancer screening); little or no effect Comp 5: AVE w/o personal feedback vs no health literacy intervention • Outcome: *applying* health information (intention to seek treatment for depression); increase favours AVE, less important effect ***Time point b: medium-term*** Comp 6: AVE w/o personal feedback vs written information • Outcome 1: *competencies* (inhaler use technique); increase favours AVE, less important effect • Outcome 2: *understanding* health information; little or no effect	
Quality of life	—	—	—	—
Health-related knowledge	—	***Time point c: long-term*** Comp 4: Telephone education vs unrelated health literacy intervention • Outcome: prostate cancer knowledge; increase favours telephone education, less important effect	***Time point a: short-term*** Comp 1: SMP vs no health literacy intervention • Outcome: any health-related knowledge; little or no effect Comp 2: SMP vs written information • Outcome: any health-related knowledge; increase favours SMP, important effect	—

			Comp 5: AVE w/o personal feedback vs no health literacy intervention • Outcome: any health-related knowledge; increase favours AVE, less important effect Comp 3: HL-SBC vs no/unrelated HL-SBC • Outcome: any health-related knowledge; increase favours HL-SBC, important effect Comp 6: AVE w/o personal feedback vs written information • Outcome: any health-related knowledge; increase favours AVE, less important effect ***Time point b: medium-term*** Comp 2: SMP vs written information • Outcome: any health-related knowledge; little or no effect Comp 3: HL-SBC vs no/unrelated HL-SBC • Outcome: any health-related knowledge; increase favours HL-SBC, less important effect	
Any health outcome	—	—	***Time point a: short-term*** Comp 1: SMP vs no health literacy intervention • Outcome: subjective health status; little or no effect ***Time point b: medium-term*** Comp 2: SMP vs written information • Outcome: depression; little or no effect Comp 5: AVE without personal feedback vs no health literacy intervention • Outcome: depression; little or no effect Comp 6: AVE without personal feedback vs written information • Outcome: depression; little or no effect	—
Any health behaviour	—	***Time point a: short-term*** Comp 5: AVE w/o personal feedback vs no health literacy intervention • Outcome: child's up-to-date immunisation; little or no effect	***Time point a: short-term*** Comp 1: SMP vs no health literacy intervention • Outcome: any health behaviour; increase favours SMP, less important effect	***Time point c: long-term*** Intervention: AVE w/o personal feedback • Outcome: new docu-

		Time point c: long-term Comp 4: Telephone education vs unrelated health literacy intervention • Outcome: prostate cancer screening; little or no effect Comp 6: AVE w/o personal feedback vs written information • Outcome: documentation of ACP; increase favours AVE, important effect	Comp 2 SMP vs written information • Outcome: any health behaviour; increase favours SMP, important effect Comp 3: HL-SBC vs no/unrelated HL-SBC • Outcome: any health behaviour; little or no effect Comp 8: AMI vs no health literacy intervention • Outcome: self-reported medication adherence; little or no effect ***Time point b: medium-term*** Comp 2 SMP vs written information • Outcome: any health behaviour; increase favours SMP, less important effect Comp 3: HL-SBC vs no/unrelated HL-SBC • Outcome: any cancer screening adherence (hepatitis B screening/colorectal cancer screening); increase favours HL-SBC, but unclear importance of this effect	mentation of ACP; little or no difference (low-certainty evidence)
Self-efficacy	—	***Time point a: short-term*** Comp 1: SMP vs no health literacy intervention • Outcome: self-efficacy to manage one's disease; increase favours SMP, less important effect Comp 2: SMP vs written information • Outcome: self-efficacy to manage one's disease; increase favours SMP, important effect	***Time point a: short-term*** Comp 5: AVE w/o personal feedback vs no health literacy intervention • Outcome: self-efficacy to identify need for treatment; increase favours AVE, important effect Comp 6: AVE w/o personal feedback vs written information • Outcome: self-efficacy for accessing breast cancer-related advice or information; little or no effect ***Time point b: medium-term*** Comp 2: SMP vs written information • Outcome: high blood pressure self-efficacy; little or no effect Comp 6: AVE w/o personal feedback vs written information • Outcome: any cancer-related self-efficacy; little or no effect	—
Health service use -	—	***Time point b: medium-term***	—	—

Child's emergency room visits		Comp 5: AVE w/o personal feedback vs no health literacy intervention • Outcome: child's emergency room visits; decrease favours AVE, important effect		
Adverse events - Anxiety	—	***Time point c: long-term*** Comp 4: Telephone education vs unrelated health literacy intervention • Outcome: anxiety; little or no effect Comp 6: AVE w/o personal feedback vs written information • Outcome: anxiety; little or no effect	—	—

*Short-term: immediately up to six weeks after the total intervention programme was completed; medium-term: up to and including six months after the total intervention programme was completed; long-term: longer than six months after the total intervention programme was completed.

ACP: advance care planning; **AMI:** adapted medical instruction;**AVE:** audio-/visual education; **Comp:** comparison; **HBP:** high blood pressure; **HL-SBC:** health literacy skills building course; **SMP:** self-management programme; **w/o**: without

Overall completeness and applicability of evidence

Due to the high degree of heterogeneity between the included studies in terms of the type and delivery of the interventions, the characteristics of the participants, the measured outcomes and the control groups, it was neither possible nor appropriate to pool all results and conduct meta-analyses with all studies for all outcomes. However, we were able to pool some results and conducted meta-analyses of studies we judged similar enough to be synthesised together (i.e. when at least two studies in one comparison measured the same outcome comparably). Nevertheless, despite strict grouping, there was considerable statistical heterogeneity in some analyses, reducing the extent to which we can draw firm conclusions from this review.

We investigated heterogeneity through post hoc subgroup analysis by specific design features such as programme length, and through sensitivity analysis excluding studies at high risk of bias. For example, we pooled data from interventions using multimedia formats such as educational DVDs or interactive touchscreen computers with those using print formats such as photonovel only; both were categorised as 'audio-/visual education without personal feedback'. Although we conducted subgroup analyses by such design features to investigate the reasons for heterogeneity, this should be taken into account when interpreting the results.

In addition, we did not restrict our inclusion criteria to a certain health context and included first-generation migrants with a range of different conditions, or those being at risk of developing certain conditions (e.g. certain types of cancer). Thus, the statistical heterogeneity may have reflected either differences across the clinically diverse studies and/or the heterogeneity of migrant groups, or variations in the interventions evaluated. Therefore, the pooled effect sizes and confidence intervals should be interpreted as a range across migrant groups and across conditions, which may not be applicable to a specific migrant group or a certain health condition in particular.

We planned to conduct quantitative subgroup analyses by ethnicity, gender and health literacy assessment tool (performance-based versus perception-based tool). However, no study made use of a perception-based tool to measure health literacy. Due to the studies' heterogeneity described above and an insufficient number of studies in any of the meta-analyses, we were not able to conduct quantitative subgroup analyses for ethnicity or gender either. In addition, many of the included studies only had small samples, and few also contained unclear reports or missing data that we had to impute, impeding the interpretation of the quantitative and qualitative synthesis. Moreover, the described heterogeneity also led us to pooling outcomes that did not assess exactly the same constructs or conditions. For example, the outcome self-efficacy for managing one's own disease was related to either diabetes, HIV, blood pressure or other conditions. In addition, and in the absence of a standardised measure that would have been applicable to all the studies, we did not restrict our synthesis to validated outcome measures, which may also lower the comparability and generalisability of our results.

Interpretation of the results was affected by heterogeneity in so far as decisions about whether there was an important effect or not were, at least for some outcomes, based on our subjective interpretation of the results. In some cases, we calculated standardised mean differences (SMD) to enable pooling and used rules of thumb for standardised effect measures as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2022). However, that was not possible for all outcome measures. Particularly when the measure was used by one study only, so that we could not calculate an SMD, or when we could not obtain a 'minimally important difference' for the respective outcome measure from the literature.

The studies included in this review were primarily of short- or medium-term duration; only a few outcome assessments were available at longer time points (i.e. longer than six months after completion of the intervention programme). Thus, for the majority of intervention types included, we do not know whether there are important long-term effects on health literacy or on health literacy-related outcomes. In addition, only two trials reported measuring unintended consequences or adverse events. Both audio-/visual education and telephone education probably have little or no long-term effect on anxiety. However, we do not know whether there are any adverse events or unintended consequences in the other interventions identified. Many studies included in this review were small and thus have likely been underpowered to detect adverse events. In addition, we found no evidence for an effect of any health literacy intervention on quality of life as we either did not identify direct evidence for this outcome (only three studies measured quality of life) or our certainty in the evidence is very low.

The majority of studies were based on established social-cognitive theories or models of health behaviour change. None of the included studies were guided by the integrated model of health literacy (Sørensen 2012). Other established health literacy models such as the three-level health literacy framework proposed by Nutbeam 2000 were also rather neglected. Only Kim 2020 developed a health literacy framework based on the definition of Ratzan 2000. Other studies that explicitly referred to the concept of health literacy primarily referenced empirical research that showed associations between limited health literacy or low literacy and the respective health problem under study without applying a certain health literacy framework or model for developing, implementing or evaluating the intervention.

We used the integrated model by Sørensen 2012 to guide the whole review process including data extraction, grouping of studies, data synthesis and interpretation of the results. To our knowledge, this is the first systematic review that uses such a comprehensive approach to synthesise evidence related to health literacy in the context of migration. Grouping health literacy intervention studies according to a set of cautiously developed criteria might help decision makers, future reviewers and other researchers to derive meaning from health literacy interventions. However, this review shows that applying the integrated model of health literacy and taking into account its components (i.e. knowledge, motivation, competencies and the four steps of health information processing) as a framework for assessing the effectiveness of health literacy interventions is, at least to date, limited.

We assume the following reasons for this finding: the interventions identified were primarily conducted in North America. None of the studies were conducted in Europe, where the integrated model of health literacy has its origin and is widely known. In addition, the more comprehensive approach of taking into account not only aspects of functional literacy or numeracy in the context of health, but also the procedural characteristics of health information processing, is quite young. Thus, the majority of the studies addressed literacy aspects and aimed to improve understanding or model health behaviour through mitigating the effects of low literacy and low language proficiency in the respective health context. However, implicitly, the studies' aims were often to improve either the accessing, understanding, appraising and/or applying of health information, even though the investigators did not use the concept of 'health literacy' to describe these aims. Hence, all studies implicitly (e.g. through methods used or theories applied) or explicitly (e.g. by mentioning this aspect in one of the published reports) addressed at least components of health literacy in the design or evaluation of the intervention.

Furthermore, it might not have been expedient on our side to subordinate the outcomes to the components of health literacy as this approach leaves space for interpretation. However, all decisions regarding the categorisation and priorisation of outcomes were made by at least two review authors. Furthermore, again, our aim was not to assess the effects of one specific intervention on migrants' health literacy assessed with established, validated tools only. We rather aimed to draw a comprehensive picture of those health literacy interventions available for migrants and assess at least components of the concept of health literacy (e.g. the four steps of health information processing). Therefore, it was not surprising that only 12 out of the 34 included studies reported an outcome measure for either generic or disease-specific health literacy to assess the intervention effectiveness.

The vast majority of studies reported a measure for health-related knowledge that was based on the intervention's content (27 studies). Empirical research strongly indicates that higher levels of (functional) health literacy are associated with higher levels of health-related knowledge (Berkman 2011; Osborn 2011; Paasche-Orlow 2007). In line with that, we considered knowledge to be one of the major components of health literacy. We found that health literacy interventions may have a short-term effect on health-related knowledge, ranging from less important to important effects. Some findings, however, seemed, at first sight, paradoxical. For example, we found that self-management programmes may lead to little or no difference in knowledge, when compared to no health literacy intervention (comparison 1), but they may have an important short-term effect on knowledge, when compared to written information on the same topic (comparison 2). This may be for the reason that there were only two studies included in the narrative synthesis of comparison 1, with one very small study (N = 69) reporting inconclusive results for knowledge and the other study (N = 252) reporting a mean difference of 5.6% in favour of the intervention. For both comparisons, however, our certainty in the evidence was low (i.e. the true effect may be substantially different from the estimate of the effect).

None of the included studies directly assessed the effects of health literacy interventions on motivation, but the majority of intervention studies made use of methods that targeted improved motivation and/or the interventions were guided by established behaviour change theories. Two studies reported on outcomes related to motivation. However, none of the results were reported in this review, as the applied scales also address theoretical constructs other than motivation (e.g. subjective knowledge or self-efficacy) and no subscale data were reported.

Outcome measures for competencies (e.g. reading and writing abilities or skills acquisition) were assessed in two studies, although it should be noted that all studies that reported an outcome measure for health literacy made use of established performance-based assessment tools such as REALM (Davis 1991) or TOFHLA (Parker 1995). These measures assess either reading and writing abilities (REALM), or understanding of text phrases and numeracy skills (TOFHLA) in the context of health. The disease-specific health literacy measures used were either also REALM- or TOFHLA-based, or they assessed disease-specific knowledge and/or beliefs (e.g. depression literacy assessed with the D-Lit by Griffiths 2004 or diabetes health literacy assessed with the DHLS by Calderón 2014). None of the studies used a self-assessment health literacy tool measuring self-perceived difficulties in accessing, understanding, appraising or applying health information in different health domains.

Regarding the four steps of health information processing, accessing health information was the only step not measured by any study to assess the intervention effectiveness. However, whether participants accessed health information was often implicitly addressed through outcome measures related to health behaviour or health service use (e.g. the use of preventive measures or rates of emergency department encounters). Five studies measured understanding of health information, which is closely related to functional health literacy, or how the construct is often assessed (see Description of the condition).

Only three studies assessed the appraisal of health information (i.e. the ability to filter, judge and evaluate the information received). This is noticeable, as in our understanding of health literacy, the ability to evaluate the information found not only in terms of its quality and trustworthiness, but also in light of one's own value system, is crucial for autonomous decision-making. Particularly regarding difficult health decisions (e.g. the use of certain, more or less invasive, screening measures or treatment options), it is important to recognise whether information is of high quality on the one hand and to thoughtfully outweigh the pros and cons (e.g. of a health service) on the other hand. According to European population studies, both migrants (Berens 2022a) and the majority population (HLS19 Consortium 2021) reported the greatest difficulties in appraising health information. In particular, judging different treatment options or judging the reliability of online information were perceived as challenging. The evidence we found regarding an effect of health literacy interventions on this processing step was either moderate- (two studies) or low-certainty (one study), but nevertheless based on only three studies. None of these studies measured the ability to judge whether an informational source or particular health information is trustworthy or reliable. However, all three studies measured decisional processes such as weighing pros and cons regarding cancer screening measures, indicating that health literacy interventions can have a positive impact on migrants' ability to make informed decisions that are congruent with one's value system.

Six studies measured behaviour intent, which is related to applying health information as it reflects a decision made. However, most studies measured health behaviour, which is widely regarded as an outcome of the health literacy process, as fully informed, autonomous decisions that are based on high-quality information may ultimately turn information into value congruent action.

We assessed the characteristics of study populations using the PROGRESS-Plus framework, thereby acknowledging equity as an important determinant of health. All studies were conducted in high-income countries, predominantly in North American, urban areas. Accordingly, we found a predominance of migrants who were born in Central and South America or East and South Asia in the studies, aged between 28.7 years to 70.9 years, and a 75% proportion of females. The average time since immigration ranged from less than one year up to 62 years, many of whom immigrated at least five years ago. All studies reported at least some information about the participants' education, whereas most studies included so-called "disadvantaged populations" of low (health) literacy and/or low socioeconomic status. The least described PROGRESS-Plus domains were religion, sexual orientation, disability and migrant status. However, three studies provided concrete information about the participant's religion, one study explored how participants' religious beliefs affected decision-making and four studies (including Korean Americans) recruited participants from religious communities. One study included Afghan Muslim women and described the intervention as being "faith-based". In total, 19 (56%) studies reported baseline data on health literacy using a validated assessment tool. Twelve studies additionally assessed health literacy (named as such) as an outcome. Most studies included primarily, or at least to a considerable part, participants with limited generic (functional) health literacy or disease-specific health literacy.

As this review aimed to assess the effectiveness of interventions for improving health literacy in migrants, and to assess whether female or male migrants benefit differently from these interventions, we included only studies that, at least implicitly, took into account health equity. Interestingly, a considerable proportion of the included studies neither defined health literacy or even literacy in the context of health, nor assessed health literacy (named as such). However, all studies shared the aim of either improving health literacy, or mitigating the effects of low literacy in migrants who were either low literate (partly even in their own language) or did not speak the host country's language well. In addition, all interventions were culturally tailored and linguistically or literacy adapted.

Migrants who are more comfortable and fluent in their native language may have better comprehension of health-related information when it is presented in their mother tongue. By using migrants' native language, health literacy interventions may better capture the nuances of the migrants' culture, beliefs and health practices and transfer these idiosyncrasies into the respective cultural context of the host country. This may be particularly important for the successful implementation of health literacy interventions designed for migrants, as health literacy is not only about understanding health information but also about appraising it against one’s set of values and applying it in the appropriate cultural context (Sørensen 2012). Thus, adapting a health literacy intervention culturally and linguistically may lead to an improved intervention experience, increased learning outcomes and more accurate assessments of the participants' health literacy levels. However, this review could not show which intervention components exactly increase the effectiveness of health literacy interventions, which in particular was due to the heterogeneity of the included studies. It is important to note, however, that a variety of intervention formats, besides classic written or oral approaches, have the potential to improve information transfer in migrants (see Effects of interventions). For example, short educational videos, group education or interactive online programmes may help to increase health literacy by considering the needs of people with low literacy skills, while carefully integrating cultural aspects identified as barriers for accessing, understanding, appraising or applying information on a certain health topic. A thorough investigation of which intervention components are most effective and appropriate for which migrant community may enhance the significance of future reviews and, thus, the design and implementation of future health literacy interventions.

The research strand on mental health literacy emerged from health literacy research, but has largely developed separately from it. What they have in common is that dealing successfully with one's own illness, navigating the health system and interacting with health professionals are essential concerns (Baumeister 2021b). Audio-/visual education such as web-based interventions including (inter-)active elements have shown to be a promising approach with regard to increasing mental health literacy and awareness for mental health problems such as depression (Brijnath 2016). Research has also shown that there are considerable cultural differences in beliefs about mental illness, particularly in relation to help-seeking beliefs (Altweck 2015; Jorm 2000; Jorm 2005). In addition, some migrant groups are particularly vulnerable to psychological distress compared to the majority population (Brijnath 2020), and can be confronted with additional stressors such as fear of deportation and discriminatory events (Valentín-Cortés 2020). In this review, only four studies aimed to improve mental health literacy (or knowledge about certain mental disorders, e.g. depression) in migrants, revealing that there is currently a substantial lack of intervention studies in this context and a need for developing and evaluating targeted, culture-sensitive interventions that aim to improve mental health literacy among migrants.

We were able to obtain gendered scores related to the intervention effects of only three studies and there was a disproportionate share of studies that included only, or predominantly, women. Twelve studies included either female (10 studies) or male migrants (two studies) only, another five studies included predominantly women (> 80%) and two studies included predominantly men. We contacted all authors with mixed-gender study populations asking for subgroup data, but received information from only three authors (Calderón 2014; Soto Mas 2018; Sudore 2018). As we intended to assess whether female or male migrants respond differently to either of the interventions, we included only those studies that reported gender-separate scores for the participants randomised to the intervention group in our gender-focused analyses. Thus, we ended up with results that were all based on single studies with very small sample sizes, impeding the degree to which we can draw conclusions from the evidence found for any gender differences.

We found low-certainty evidence from one study indicating that female migrants may benefit more from audio-/visual education without personal feedback with regard to diabetes-specific health literacy, when receiving audio-/visual education without personal feedback. One other study, evaluating a similar intervention type, found that there may be little or no difference in health behaviour between female and male migrants when receiving audio-/visual education. For the other predefined outcome categories, however, we either did not identify evidence assessing gender differences or our certainty in the evidence is very low. Thus, we cannot certainly tell whether female or male migrants benefit differently from the identified interventions or whether the needs regarding future health literacy interventions differ substantially between the genders.

Quality of the evidence

We conducted a GRADE assessment for each outcome included in this review. The certainty of the evidence for outcomes was predominantly rated as being low or very low, but we also found moderate-certainty evidence for some outcomes in different comparisons (e.g. for disease-specific health literacy or knowledge; see Effects of interventions). Across all comparisons, the most common reasons for downgrading were risk of bias for random sequence generation and/or allocation concealment or blinding, or the imprecision of effect estimates. These were often imprecise due to small sample sizes or wide confidence intervals with values indicating both an improvement or a worsening in the respective outcome. In addition, some studies did not report the results in such a way that they could be extracted for meta-analysis. For one cluster-RCT (Elder 1998), we were not able to re-calculate the data by using the appropriate unit of analysis. For two cluster-RCTs (Bloom 2014; Tong 2017), both of which reported having used GEE models to account for clustering, we were not sure if the appropriate unit of analysis was used as the data were reported as proportions only (e.g. proportion of participants who correctly answered questions regarding colorectal cancer).

Regarding the blinding of outcome assessors, most studies were rated at high risk of bias. This was due to the fact that we judged non-blinding to influence particularly the results of subjectively measured outcomes (e.g. depression, self-efficacy), meaning that participants also acted as their own outcome assessors. The nature of most studies, however, made blinding unfeasible, so we did not judge this to affect objectively measured outcomes such as knowledge. In addition, for 13 studies, we had insufficient information to permit judgement about low or high risk regarding random sequence generation and/or allocation concealment.

Potential biases in the review process

Health literacy is a multidimensional construct (Figure 1), which is defined and measured inconsistently (Mackert 2015), and so is migration. Thus, we used a correspondingly broad search strategy. However, although our searches were comprehensive, it is possible that not all potentially relevant studies were identified and screened for this review (this may be especially the case because health literacy is so variably described and the research is cross-disciplinary). We included first-generation migrants aged 18 years or over and did not restrict our search by health context, gender or participants' ethnicity. Nevertheless, it is possible that we have excluded studies in the abstract screening or at full-text stage that would have actually fitted into this review's objective. For example, to limit the amount of (heterogeneous) studies in this review, we decided during the screening process that either 'health literacy' or 'literacy' had to be mentioned in the published trial report. In addition, the intention to consider at least literacy-related aspects such as the use of literacy-adapted materials in the development, design and delivery of the intervention had to be evident. These studies did not have to describe themselves as 'health literacy intervention', but at least 'literacy' had to be mentioned as a concept and the outcomes had to be assignable to the integrated model of health literacy as an umbrella framework. This approach has its limitations in so far as it is possible that our understanding of health literacy influenced our view of potentially eligible studies. We might have excluded studies at full-text stage that actually evaluated interventions quite similar to those included in this review, but that missed explicitly stating that aspects of 'health literacy' or even 'literacy' were considered in the study. Thus, there may be other health literacy-relevant studies (according to our understanding based on Sørensen 2012), which could have contributed to the evidence base in this review.

For the reasons described above (see Summary of main results; Overall completeness and applicability of evidence), we anticipated the inclusion of a variety of studies that address certain aspects of health literacy in different settings, which have to be grouped according to their study features, thereby accepting at least some loss of information. We made efforts to group studies that fit together best according to the main intervention components, the intervention complexity and the comparators. However, this approach is limited as judgements of similarity between interventions and comparators depended on several aspects. Firstly, our subjective interpretation of what the concept of health literacy constitutes. Secondly, our judgement about to what extent certain intervention features (e.g. intense group education with active components or passive education through audio-/visual formats) affect the results of our predefined outcome categories. Thirdly, it depended on the quality of information that was reported in each trial, considering that some interventions were poorly described. In addition, the assignment of the interventions to one of the eight main comparisons was not always a clear-cut decision. For example, two interventions did not fit perfectly into the category 'culturally and literacy adapted self-management programme' as they had less intense phases of group education and/or less intense follow-up phases. In addition, both interventions were developed for individuals *at risk* of developing a certain disease, but not for individuals already affected. However, both programmes included self-management components such as breast self-examination (Han 2017) or practising good oral hygiene (Kaur 2019). These were compared to written information on the same topic.

Furthermore, we took these specific design features into account by conducting post hoc subgroup analyses for the length of the programme. We differentiated between studies that evaluated a less intense intervention programme with a shorter follow-up phase and studies that evaluated longer programmes. Thus, our grouping procedure may be somewhat biased. In addition, the interpretation of results could have been facilitated by combining control groups (e.g. written information and no health literacy intervention). In this way, more studies would have contributed to the evidence synthesis in each comparison. Thus, more general conclusions about whether a certain type of health literacy intervention (e.g. self-management programme) is effective when compared to a control group receiving no or minimal (written) information could have been made. However, again, we wanted to assess whether the processing of the respective health information delivered can be facilitated through the interventions identified. Thus, we think it is important to distinguish between control groups receiving information on a *different* health topic (than that of the intervention) or those receiving information on the *same* health topic, but to a minimal extent.

Trials with positive findings are more likely to be published, which might have influenced the selection of included studies in this review. In addition, the small number of studies for most outcomes did not allow for a quantitative analysis of publication bias and six out of the 34 studies were at unclear or high risk of selective outcome reporting, indicating that there may have been a bias arising from a failure to report all negative findings. However, efforts were made to overcome a potential publication bias through searching clinical trial registries for prospectively registered trials.

Agreements and disagreements with other studies or reviews

We found a prior review evaluating the effectiveness of health literacy interventions in immigrants, focusing on the role of nurses in the development and implementation of these interventions (Fernández-Gutiérrez 2018). The review included nine studies, two of which we also included in this review (Soto Mas 2018; van Servellen 2005), and found that the interventions were effective in improving functional health literacy and knowledge. However, only two studies were RCTs, the studies were not grouped according to intervention components and comparators, and no meta-analysis, only a narrative synthesis, was conducted. Thus, the comparability of results is limited.

We found one other review that aimed to evaluate the characteristics and the effectiveness of health literacy curricula incorporated in English as second language (ESL) courses (Chen 2015). The review concluded that these curricula are effective in terms of improving (functional) health literacy and knowledge. Three out of seven curricula evaluated in the review were also included in this current review, referring to these studies as 'health literacy skills building courses' (see Summary of findings 3). The findings do not differ considerably from ours, although we described our findings with more uncertainty. Chen 2015, however, did not conduct a systematic risk of bias assessment and four out of the seven curricula included in the review were evaluated using other than randomised controlled designs in the primary studies. We found low-certainty evidence indicating that health literacy skills building courses may improve generic (functional) health literacy and also knowledge slightly.

Stormacq 2020 assessed the effectiveness of health literacy interventions on health-related outcomes in socially disadvantaged adults living in a community, thereby including migrants in at least some studies. In this review, any health literacy interventions were compared to 1) standard care, no intervention or delayed intervention, or 2) minimal/alternative interventions. Three of the included studies were also included in this review (Kim 2009; Koniak-Griffin 2015; Mohan 2014). Stormacq 2020 found that 13 out of 22 studies were effective in improving a variety of health-related outcomes (mainly clinical outcomes), in preventive health practices and behaviours, and in health-promoting behaviours. In addition, the authors concluded that multi-faceted interventions appeared to be superior to single-modality interventions and identified some intervention components including cultural appropriateness, tailoring, skills building, goal setting and active discussions that contributed to the interventions' effectiveness. However, the authors' GRADE assessment judged the effects of health literacy interventions on all but one outcome, namely quality of life (low-certainty), to be of very low certainty. We found only very low-certainty evidence for an effect on quality of life that stemmed from three studies.

The review Fox 2022 aimed to characterise the research evaluating the effectiveness of health literacy interventions for refugees and migrants in high-income countries without systematically synthesising the results of each study in terms of health literacy-related outcomes. The review included 23 studies, 10 of which were also included in this review. The authors concluded that there was high heterogeneity between the intervention studies, the outcomes, as well as the outcome measures, impeding the comparison of the intervention effectiveness. These characteristics are similar to the findings of the current review.

We found no other systematic review that assessed whether women and men benefit differently from health literacy interventions, whether they are migrants or not. This is unsurprising considering that gender, or even sex differences, are highly neglected aspects in primary studies on health literacy of migrants. There is only one other systematic review on gender differences in the health literacy of migrants, which was also conducted by our review group (Chakraverty 2022). The results indicate that there are only marginal differences between female and male migrants' health literacy, when assessed with validated assessment tools. In addition, we found that studies on male migrants' health literacy in particular are sparse. However, as health literacy is a relational construct, which is dynamic and context-sensitive, we think that there are gender-specific aspects of health literacy that should be taken into account when designing, implementing and evaluating health literacy interventions.

In preparation for this review, and as part of an overarching project on gender-specific aspects of health literacy in individuals with a migrant background, we conducted focus group discussions (FGDs) with healthcare professionals in Germany. Of these, more than 50% were either first- or second-generation migrants themselves. The findings from the FGDs were analysed with a focus on organisational health literacy in the context of transcultural treatment settings (Baumeister 2021a), and in terms of the healthcare professionals' views on how gender as a personal determinant of health literacy may affect the interaction with their migrant patients (Chakraverty 2020). We found that there are certain gender-specific aspects of health literacy that affect how female and male migrants access, understand, appraise and apply health information. For example, we found that cultural and gender norms played a significant role for migrant women of Turkish or Arab origin with regard to accessing and understanding health information. This was expressed, for example, in a preference for access to female doctors (e.g. for personal reasons such as feelings of shame or humiliation when having to undress for a physical examination). Other findings were related to gender-specific aspects of language barriers, as some healthcare professionals stated that immigrant women of Turkish origin had limited language proficiency (i.e. German), more so than their male counterparts (Chakraverty 2020). Furthermore, gender may also be relevant in the realm of mental health literacy, as the participants of the FGDs reported a higher awareness of mental health issues in female migrants as compared to male migrants. The women's growing acceptance of psychotherapy was described as slowly spreading to the migrant men as well. It was not always clear, however, whether issues of understanding each other were foremost or solely grounded in a lack of language proficiency or due to low literacy skills. In addition, an omnipresent systemic lack of time and economic pressure was described by many healthcare professionals as one of the major barriers to an effective and satisfactory flow of information in transcultural treatment situations (Baumeister 2021a). In particular, time restrictions were perceived as hindering factors in adequately addressing female and male migrants' health literacy needs, including the healthcare professionals' response to potential gender-related issues. There are few, but some, other studies indicating that traditional gender roles, cultural norms and religious aspects do play a role in how female and male migrants access and process health information (e.g. Cherrington 2011; Shirazi 2013; Shirazi 2015). All these studies use qualitative study methods, indicating that exploring gender differences in the health literacy of migrants is, at least to date, more promising with the means of qualitative participatory research, than with quantitative measures only.

To sum up, the circumstance of our only finding very marginal differences in female and male migrants' benefit from health literacy interventions does not mean that there are not gender-specific aspects that need to be taken into account in the design, delivery and evaluation of health literacy interventions.

AUTHORS' CONCLUSIONS

Implications for practice

The degree of heterogeneity between the included studies was considerable and in some comparisons only a limited number of studies, partly with small sample sizes, were included. Therefore, the pooled effect sizes and confidence intervals should be interpreted as a range across migrant groups and across conditions, which may not be applicable to a specific migrant group or a certain health condition in particular.

We found moderate- to low-certainty evidence that some health literacy interventions can have small to moderate positive effects on health literacy. We also found moderate-certainty evidence for a short-term effect of self-management programmes on self-efficacy and moderate- to low-certainty evidence for a moderate (short-term) to small (medium-term) effect of self-management programmes and audio-/visual education without personal feedback on knowledge. We also found a small long-term effect of telephone education on knowledge (moderate-certainty). Results regarding the effects of health literacy interventions on health behaviour are mixed, as the measures and the effect sizes appear to vary considerably. Audio-/visual education without personal feedback probably has a positive effect on health service use but, nevertheless, the evidence stemmed from only one study. We do not know whether any health literacy intervention improves health-related quality of life in migrants, as we only identified very low-certainty evidence, or the outcome was not directly measured.

We found no evidence that health literacy interventions cause harm, but it is important to note that only two studies reported on adverse events such as anxiety. Both studies indicated that there are probably few or no negative long-term effects of audio-/visual or telephone-based education on anxiety.

We found only three studies reporting gender differences. Low-certainty evidence indicated that female migrants' diabetes health literacy may improve slightly more than that of male migrants when receiving audio-/visual education (AVE) without personal feedback, but there may be little or no difference between genders in health behaviour with AVE. For other intervention types and outcomes, the certainty of the evidence was either very low or no evidence was found. Thus, we cannot tell with any certainty whether the needs regarding future health literacy interventions differ substantially between female and male migrants.

Implications for research

There is a need for more high-quality studies, and adequately powered randomised controlled trials (RCTs) that explicitly aim to improve health literacy in migrants. There is a particular need for high-quality, long-term studies that measure comprehensive health literacy, for example, but not exclusively, based on the integrated model of health literacy (Sørensen 2012). This review shows that most intervention studies conducted in this area aimed to improve individuals' ability to function in the healthcare environment, mostly measuring functional health literacy (i.e. reading and writing abilities in the medical context) and neglecting the procedural characteristics of the four health information processing steps. Also, most studies were conducted in North America or other high-income countries, indicating a need to conduct studies worldwide, representing various countries and healthcare systems. In addition, comprehensive evaluations of health literacy interventions using robust and well-validated tools will improve this field.

There is a lack of studies that examine whether female and male migrants respond differently to health literacy interventions. In addition, there is a lack of intervention studies in this field that include male migrants only. In order to assess which components of health literacy should be addressed in future interventions, and to better understand which gender aspects should be considered in the development, implementation and evaluation of health literacy interventions, it is essential to take into account the perspectives and needs of female and male migrants, at best with the use of community-based participatory research methods. Future research should also provide thorough theoretical foundations for examining and improving health literacy in female and male migrants. This is necessary to explore the influence of migration, gender and its interactions with other factors such as education, social status and age in relation to health literacy, so that future interventions can consider aspects of health-related equity that are important for health information processing and, thus, for autonomous decisions regarding one's own health and the health of others.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Bailey 2012

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** 2 cities, San Francisco and Chicago, USA **Ethical approval:** yes **Recruitment setting:** 6 clinics and 3 community-based organisations (urban area) **Method of recruitment:** 1) approaching patients in waiting rooms, 2) having healthcare professionals direct patients to a research assistant of the study, 3) announcing the study or distributing flyers during group classes or clinic visits **Length of follow-up:** no follow-up **Dropouts:** 1 person did not complete the whole interview **A priori calculation of effect size/power?:** yes
Participants	**Description: low English proficient Chinese (Cantonese or Mandarin), Korean, Russian, Spanish or Vietnamese-speaking adults** **Health topic** • No specific (medication understanding) **Inclusion criteria** • 18 to 85 years of age, spoke either Chinese (Cantonese or Mandarin), Korean, Russian, Spanish or Vietnamese as their primary language, had basic reading skills and visual acuity, demonstrated by the ability to read 3 kindergarten-level words aloud, had taken a prescription medication in the past year and were limited English proficient (self-report) **Exclusion criteria** • Not reported **Intervention group** • Health literacy informed prescription instruction (102 randomised and analysed) **Control group** • Language concordant standard prescription instruction (100 randomised and analysed) Note: 1 was excluded after randomisation, did not complete the entire interview **PROGRESS-Plus** **P**lace of residence: urban, USA Time living in host country (years), mean (SD): 17.0 (0.7)

Bailey 2012 *(Continued)*

Race/ethnicity: Chinese, Korean, Russian, Spanish, Vietnamese

Gender

- Intervention: 55.4% female
- Control: 69.0% female

Education (years): 1% < 9 y, 14.4% 9 to 11 y, 29.2% 12 y or GED, 14.9% some college, 21.8% ≥ college graduate

Socioeconomic status/income: 44.7% USD 10,000, 36.7% USD 10,000 to 19,999, 18.6% ≥ USD 20,000

Age (years), mean (SD), range: 63.6 (0.91), 18 to 85

Health literacy (baseline)

Not measured

Interventions

Intervention: health literacy informed RX instructions

Theoretical framework: health literacy "best practices"

Description: concordant prescription instructions using health literacy ‘best practices’. The medication-taking was parted into 4 distinct time periods: morning, noon, evening and bedtime. Simple terms, lowercase and uppercase letters and numeric characters were used to facilitate patients’ understanding.

- Intervention provider: not applicable
- Delivery method/mode: written information
- Language of delivery: language concordant (by preference)
- Format: standard format
- Setting/location: clinic, hospital, participants' home
- Consumer involvement: no

Comparator

Type: no health literacy intervention

Description: standard instructions with typical terminology based upon those generated by a national chain pharmacy offering language assistance services.

Outcomes

Outcomes assessed in the study: medication understanding, regimen dosing, regimen consolidation

Outcomes considered in this review

- Health literacy
    - Understand (medication understanding)

Methods of assessing outcomes

- Medication understanding: demonstration by means of correct dosage in dosing tray (demonstrate correct dose, frequency and spacing; 0 to 5; 0 = incorrect, 1 = correct), numbers of instructions understood, RR, 95% CI

Note: a research assistant handed the participant the dosing tray and a Rx bottle and stated, “Using this tray, please show me when you would take this medicine over the course of one full day.” Research assistants recorded the number of pills the participant placed in each of the 24 compartments. Participants could refer to the Rx label throughout the exercise. The process was repeated for 5 individual medication labels.

Language of assessment: Spanish

Translation procedure: not applicable; bilingual research assistant

Bailey 2012 *(Continued)*

	Timing of outcome assessment: short-term (immediately post-intervention)
Health literacy	**Definition:** “capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” (IOM, 2004) **Health literacy components addressed by the intervention** Steps of information processing • Understand • Apply Health domain: health care
Notes	**Trial ID:** not reported **Funding:** funding was provided by the California Endowment.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Research assistants used a random number list, created by the study team, to assign participants to receive either standard or ConcordantRx instructions." There were more male participants in intervention arm 44.6% vs 31.0%, P < 0.05. However, the type of randomisation indicates that imbalances occurred by chance.
Allocation concealment (selection bias)	Unclear risk	Randomisation list was created by study team, but further description of allocation is not provided. This indicates an unclear risk of bias.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	No information on whether participants were aware of which group they were assigned to and whether personnel were aware of the assignment. However, the intervention consisted of a single exposure of two different medication labels and participants were assessed immediately with the use of objective criteria. Therefore, we assume that even non-blinding would not have affected the results.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	"1) Rx understanding, 2) regimen dosing and 3) regimen consolidation. Each was measured with a dosing tray, which consisted of 24 compartments, each labeled with one hour of the day. As some cultures use a 24 hour clock (i.e. 1400 vs. 2:00 pm) two different versions of trays were created. Participants were shown both and allowed to choose their preferred format. RAs demonstrated how to use the tray, then verified participant understanding of the tool." "Participants had to demonstrate the correct dose, frequency and spacing inferred by each instruction to be coded as ‘correct.’ Spacing criteria was developed by the research team with the assistance of two general internal medicine physicians." The outcome assessment is performance-based and was conducted immediately post-intervention. No statement was made on whether outcome assessors were blinded. However, even if the outcome assessors judged whether medication dosing was correct, it was objectively assessed and not dependent on a subjective judgement of either the interviewer or the participant.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"203 were randomised and initiated the study interview. 202 completed the entire interview and were included in analyses."

Bailey 2012 *(Continued)*

		One person dropped out: reason is provided, but not reported to which intervention the person was initially randomised to and no intention-to-treat analysis. However, the attrition rate indicates low risk of bias, since outcome data are available for nearly all participants randomised and the intervention only differed in type of Rx instruction provided.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported in the methods section are reported in the results of the paper.

Bloom 2014

Study characteristics	
Methods	**Study design:** cluster-RCT, 2 arms **Geographic location:** California, USA **Ethical approval:** not reported **Recruitment setting:** 17 Korean American churches and 3 senior centres **Method of recruitment:** not reported **Length of follow-up:** probably 6 months (unclear when programme ended) **Dropouts:** 2 women in the control group were lost to follow-up **A priori calculation of effect size/power?:** not reported
Participants	**Description: female Afghan Muslim refugees with low English proficiency** **Health topic** • Breast cancer screening; many of the participants have had a family history of breast cancer (not quantified for RCT population) **Inclusion criteria** • Afghan women with low English proficiency, ≥ 40 years **Exclusion criteria** • Not reported **Intervention group** • 'The Afghan Women's Breast Health Program' **Control group** • Wait-list control (delayed intervention) Note: 230 women were included in the study. Total numbers were not reported separately for each study group. Authors state that general linear models using generalised estimating equations (GEE) methods were used to account for clustering (sample and analysis), to adjust for baseline knowledge levels. **PROGRESS-Plus** **Baseline imbalances:** women in the intervention group had higher levels of knowledge **P**lace of residence: urban, USA

Bloom 2014 *(Continued)*

	Race/ethnicity: Afghan refugees Gender: 100% female Note: the women's husbands received education too, but details not reported. Education: limited English proficiency and low literacy; no further details reported **Health literacy (baseline)** Not measured
Interventions	**Intervention: 'The Afghan Women's Breast Health Program'** Theoretical framework: Cultural Explanatory Models (CEMs) framework (Rajaram 1998) and Chatman's Theory of Information Seeking (Chatman 1996) Description: following community-based participatory research methods (CBPR) a community advisory boards was formed and involved to design the study. Lay health educators (female and male) facilitated culturally and literacy sensitive faith-based group education for Afghan Muslim women about breast health using multiple methods of knowledge transfer (e.g. storytelling) and trained community health navigators/health advisors supported the women afterwards to facilitate making and keeping appointments as needed. • Intervention provider: lay health educators (female and male), community navigators • Delivery method/mode: weekly face-to-face group sessions with approx. 5 participants, support by community navigator afterwards • Language of delivery: language concordant (Farsi, Pashto) • Format: individually tailored • Setting/location: community • Consumer involvement: CBPR, formative research to inform the intervention Note: most of this information stems from the related formative research (Shirazi 2013; Shirazi 2015) and from a publicly available video (www.youtube.com/watch?v=v7YbebbMYi8). For example, the authors state that it was planned to use interactive methods and storytelling as a result of the interviews with 53 Afghan women that were conducted previously. In addition, an education programme for the male heads of the household was implemented "to turn potential gatekeepers into family health advocates"(Bloom 2014) through trustful relationships and education, but we could not find detailed information about this additional study component. **Comparator** Type: no health literacy intervention (wait-list control) Description: the control group received a delayed intervention.
Outcomes	Outcomes assessed in the study: breast cancer knowledge, mammography **Outcomes considered in this review** • Health-related knowledge (breast cancer knowledge) • Health behaviour (mammography) **Methods of assessing outcomes** • Methods of assessing outcomes not reported. Health behaviour (having had a mammogram) was assessed via self-report. Language of assessment: not reported **Timing of outcome assessment:** baseline, at 6-month follow-up (insufficient information to categorise into short-term or medium-term assessment as it is unclear for how long and at what intensity women were supported by the community health navigators after receiving group education).

Bloom 2014 *(Continued)*

Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools - Knowledge - Motivation (unclear) - Competences (unclear) Steps of information processing - Access - Understand - Appraise - Apply Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** National Institutes of Health, National Cancer Institute, USA. The Alameda County Program to Reduce Cancer Disparities (ANCP), U54 CA 153506 to the University of California, Berkeley, CA 94720-7360 and the Afghan Coalition of Fremont, California. **Additional notes:** we only found a conference abstract for the RCT; authors were contacted and asked for additional information but without success.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Cluster randomised design was used, but the information is insufficient to permit judgement about "low risk" or "high risk".
Allocation concealment (selection bias)	Unclear risk	The information is insufficient to permit judgement about "low risk" or "high risk".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel were most likely not blinded due to the nature of the study.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	"Women in the intervention group were more likely to report getting a mammogram between pre- and post-test" Participants and personnel were most likely not blinded due to the nature of the study and health behaviour was measured via self-report. In addition, we do not whether knowledge was subjectively or objectively measured in the study. If knowledge was subjectively measured, too. The results for knowledge might be biased as well.
Blinding of outcome assessment (detection bias) objective outcome measures	Unclear risk	We do not whether knowledge was subjectively or objectively measured in the study. Thus, the information is insufficient to permit judgement about "low risk" or "high risk".
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Retention from pre- to post-test was 99% (two women in the control group were lost to follow-up)."

Bloom 2014 *(Continued)*

		Low attrition rate and reasons provided.
Selective reporting (reporting bias)	Unclear risk	The information is insufficient to permit judgement about "low risk" or "high risk".
Selective recruitment of cluster participants	Unclear risk	The information is insufficient to permit judgement about "low risk" or "high risk".
Other bias	Unclear risk	Insufficient information to permit judgement of "low risk" or "high risk".

Calderón 2014

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** California, Los Angeles, USA **Ethical approval:** yes **Recruitment setting:** South Central Family Health Center (SCFHC), South Los Angeles **Method of recruitment:** a SCFHC's certified diabetes nurse screened information for new type 2 diabetes patients for study inclusion criteria; health navigator ("promotora") met with patients referred by the diabetes nurse and provided more information about the study. Flyers were distributed at the clinic and posted on billboards in waiting areas. **Length of follow-up:** no follow-up **Dropouts:** no dropouts **A priori calculation of effect size/power?:** not reported
Participants	**Description: economically disadvantaged Spanish-speaking Latino/Hispanics with type 2 diabetes** **Health topic** • Type 2 diabetes **Inclusion criteria** • Sought health care at the SCFHC, ≥ 18 years of age, diagnosed with type 2 diabetes, self-identified as Latino/Hispanic, Spanish speaking, had not received diabetes education or counselling from the diabetes nurse at the SCFHC **Exclusion criteria** • Not reported **Intervention group** • Animated video bilingual "¿Que es la Diabetes? / What Is Diabetes?" (118 randomised and analysed) **Control group** • Easy-to-read information about diabetes (122 randomised and analysed) **PROGRESS-Plus** **P**lace of residence: urban, USA

Calderón 2014 *(Continued)*

	Race/ethnicity: Latino **G**ender • Intervention: 78.8% female • Control: 84.4% female **E**ducation: 86.7% < high school, 13.3% ≥ high school **S**ocioeconomic status/ income: 75.6% < USD 10,000, 24.4% ≥ USD 10,000 Health insurance: 31.3% insured Age (years), range; distribution: 18 to > 60 y; 20.7% 18 to 39 y, 88.6% 40 to 60 y, 20.7% > 60 y **Health literacy (baseline)** Assessment tool, range (score): STOFHLA, 0 to 36, higher score is better (validated tool) • Intervention group: 62.0% inadequate HL (0 to 16), 8.0% marginal HL (17 to 21) 30.0% adequate HL (≥ 22) • Control group: 54.0% inadequate HL (0 to 16), 8.0% marginal HL (17 to 21) 38.0% adequate HL (≥ 22)
Interventions	**Intervention: animated video about diabetes ¿Que es la Diabetes?; What Is Diabetes?** Theoretical framework: not reported; reference to various programmes with animation-based teaching elements and to Doak 1996 Description: animated video whose icon "Corazon Quelate" (Heart that beats; Spanish version)/"Lotta Hart" (English version) describes typical characteristics of middle-aged Latinx/Hispanic/African American who are inclined to be overweight. One character is diagnosed with diabetes. The video covers 3 main topics about diabetes: (1) general information, (2) clinical management and (3) self-management. To explain more complex consequences of diabetes, the video resorts to animated illustrations. • Intervention provider: not applicable • Delivery method/mode: 1 individual video session lasting 13 minutes • Language of delivery: language concordant (bilingual) • Format: standard • Setting/location: SCFHC, South Los Angeles • Consumer involvement: culturally and linguistically adapted through involvement of the community of interest **Comparator** Type: written information on the same topic Description: 5 pages of easy-to-read diabetes information (5th grade reading level) available from the National Diabetes Information Clearinghouse of the National Institute of Diabetes and Digestive and Kidney diseases (NIDDK). In addition, information about diabetes definition, cause and risk factors, clinical management and self-management (accessed from the Spanish version of 'Your Guide to Diabetes: Type 1 and Type 2').
Outcomes	Outcomes assessed in the study: diabetes health literacy **Outcomes considered in this review** • Health literacy ◦ Diabetes health literacy **Methods of assessing outcomes** Interviewer administered questionnaire; show cards were used to display response options as the interviewer read survey questions.

Calderón 2014 *(Continued)*

	• Diabetes health literacy: Diabetes Health Literacy Survey (DHLS), developed for the study, 37 items measuring 4 constructs related to type 2 diabetes; (1) general type 2 diabetes information (16 items), (2) clinical management information (5 items), (3) self-management (6 items), and (4) ethnomedical (cultural) beliefs (10 items). The general information and clinical management information constructs measure type 2 diabetes knowledge (21 items combined). The self-management and ethnomedical belief constructs measure knowledge application and cultural perceptions about diabetes management (16 items combined). Language of assessment: Spanish and English Translation procedure: back-translation procedure Reliability/validity: validated in the study, coefficient α = 0.79 **Timing of outcome assessment:** baseline, short-term (immediately post- intervention)
Health literacy	**Definition:** “the degree to which individuals have the capacity to obtain, process and understand basic health information needed to make appropriate health decisions.” (AMA 1999, Nielson-Bohlman 2004) **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation (unclear) Steps of information processing • Access • Understand • Appraise • Apply Health domain: health care
Notes	**Trial ID:** not reported **Funding:** Agency for Healthcare Research and Quality (1R24-HS014022-01A1), the National Institute of Minority Health and Health Disparities (P20MD000182, P20MD000516, U54MD008149, MD000103), National Institute of Ageing (P30-AG021684), and National Center for Research Resources (UL1TR000124). **Additional notes:** unadjusted data and gender-separate scores for the outcome 'diabetes health literacy' were obtained from the study authors.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Random assignment was done via numbers concealed in sealed envelopes that were generated by the study statistician through randomization software."
Allocation concealment (selection bias)	Low risk	"Neither the SCFHC diabetes nurse educator who recruited patients nor Drew’s health navigator/promotora who tested participants knew the content of the envelopes (allocation concealment). Therefore, neither knew the group (animation or text) to which participants would be assigned (allocation status)." It can be strongly assumed that participants could not foresee assignment either.

Calderón 2014 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were most likely aware of the intervention they received due to the nature of the study. It is not clear whether the personnel who assessed the participants was blinded. However, outcomes measured were not subject to interpretation
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Diabetes health literacy was assessed with a questionnaire that predominantly measures factual knowledge. It was administered by an interviewer. It is not clear whether the interviewer was blinded, participants could not be blinded anyway. However, the outcome was assessed objectively and immediately post-intervention.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcome data are available for all participants, indicating a low risk of bias.
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the study.

DeCamp 2020

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** Maryland, USA **Ethical approval:** yes **Recruitment setting:** large urban, academic general paediatrics clinic **Method of recruitment:** review of the clinic schedule for completed initial newborn visits; potentially eligible parents were sent an informational letter about the study. A bilingual research assistant recruited potential participants either by follow-up phone call or during a subsequent newborn visit. **Length of follow-up:** length of programme: 10 months; follow-up survey at child age: 12 to 15 months, which was 1 to 3 months after the programme was completed **Dropouts:** 22 participants lost to follow-up (7 in the intervention group (5 moved or switched clinics, 2 were unable to be contacted) and 15 in the control group (4 moved or switched clinic, 5 were unable to be contacted and 6 declined) **A priori calculation of effect size/power?:** yes
Participants	**Description: immigrant parents or legal guardians of Latin descent with US-born infants < 2 months of age** **Health topic** • Child health **Inclusion criteria** • Parents or legal guardians of publicly insured, singleton US-born infants < 2 months of age, minimum parent age of ≥ 18 years, self-identification as Latino or Latina, preferred health care language of Spanish, 1 household cellular phone **Exclusion criteria** • Not reported

DeCamp 2020 *(Continued)*

	Intervention group • Salud al Día, Spanish-language interactive text messaging intervention (79 randomised and analysed for observer-reported outcomes, for participant-reported outcomes only 72 analysed) **Control group** • Usual care (78 randomised and analysed for observer-rated outcomes, for participant-reported outcomes only 63 analysed) Note: an intention-to-treat analysis was performed for primary outcomes (analysed via electronic medical record (EMR)); secondary outcomes that were not abstracted from the EMR included only individuals who finished follow-up survey. **PROGRESS-Plus** **P**lace of residence: urban, USA Time living in host country (years), mean (SD): 7.3 (5.3) **R**ace/ethnicity: Latinos **O**ccupation: 79.0% spouse or partner employed **G**ender: 100% female **E**ducation: 40.8% ≤ 8th grade, 26.1% some high school, 33.1% some high school or greater **S**ocioeconomic status/income (annual): 42.7% < USD 20,000, 24.2% USD 20,000 to 30,000, 7.6% > USD 30.000, 19.1% did not report or unknown Health insurance: all children publicly insured **S**ocial capital: 20.3% single, 79.6% spouse or partner Age (years), mean (SD): 29.3 (6.2) **Health literacy (baseline)** Assessment tool, range (score): Spanish-language version of the Newest Vital Sign (NVS), 6 items, 0 to 6, higher score is better (validated in English and Spanish) • Intervention group: 46.0% limited HL (0 to 1), 39.0% marginal HL (2 to 3) 15.0% adequate HL (4 to 6) • Control group: 51% limited HL (0 to 1), 37.0% marginal HL (2 to 3), 12.0% adequate HL (4 to 6) English proficiency was assessed using the US Census Bureau question, “How well do you speak English?” • Intervention group: 97.0% • Control group: 96.0%
Interventions	**Intervention: Salud al Día, an interactive text messaging intervention to reduce ED use and increase vaccine adherence** Theoretical framework: situated Information, Motivation, Behavioral Skills (sMIB) model (Amico 2011) Description: parents received interactive personalised text messages, push messages and watched an animated Spanish-language educational video. Sequences included appointment reminders, support for obtaining medicines, support for completing referrals, and illness care monitoring and education. Interactive text messages included reminders of flu vaccine or information on parent support programmes and public benefit programmes. Certain response records generated an email to a clinic nurse who contacted participants and offered further support. • Intervention provider: research staff, clinic staff

DeCamp 2020 *(Continued)*

	• Delivery method/mode: 1 individual video session lasting 9 min (plus take-home DVD at 2-month visit in clinic) and monthly interactive text messages for 10 months, if necessary email contact to clinic nurse • Language of delivery: language concordant (bilingual) • Format: tailored, algorithm-based interactive messages • Setting/location: academic general paediatrics clinic (video) • Consumer involvement: evaluated with members from the community of interest **Comparator** Type: no health literacy intervention (usual care/no additional intervention) Description: usual care for infants in the 1st year of life
Outcomes	Outcomes assessed in the study: infant health knowledge, up-to-date immunisations*, well visits, parent depression, emergency department use, parent experience of care rating, change in mean parent engagement, receipt of 2 doses of the influenza vaccine, well visit no-shows and cancellations, clinic visit provider continuity, number of sick care visits, speciality care referral completion, participant-generated telephone encounters, electronic medical record (EMR) patient portal (MyChart) status, Supplemental Nutrition Assistance programme (SNAP)/food stamp participation **Outcomes considered in this review** • Health-related knowledge (infant health knowledge) • Health behaviour (up-to-date immunisations) • Health outcome (parent depression) • Health service use (emergency department use) *Prioritised outcome in the category 'health behaviour' based on consensus opinion of the authors **Methods of assessing outcomes** Surveys were orally administered by bilingual research assistants, either in-person (enrolment and follow-up) or via telephone (midpoint). Responses were captured using a touchscreen tablet computer and Research Electronic Database Capture software. • Infant health knowledge: questionnaire based on intervention topics: (1) fever criteria, (2) public health insurance renewal, (3) right to interpretation during medical encounters, (4) obtaining an outside care report, (5) availability of after-hours clinic resources); 5 items, multiple choice, true/false questions, 1 point for each correct response, 0 to 5, higher score is better • Up-to-date immunisations: assessed via EMR • Parent depression: Patient Health Questionnaire (PHQ-8), 8 items, 0 to 24, cut-point ≥ 10 (moderate or severe depressive symptoms), lower score is better ◦ Reliability/validity: validated tool • Emergency department use: assessed via EMR Language of assessment: English, Spanish **Timing of outcome assessment:** baseline, short-term (at 11 to 14 months after randomisation, which was 1 to 3 months after the programme was completed)
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation Steps of information processing

DeCamp 2020 *(Continued)*

	- Access - Understand - Appraise (unclear) - Apply Health domain: disease prevention
Notes	**Trial ID:** NCT02647814 **Funding:** funding was provided by the Gordon and Betty Moore Foundation. **Additional notes:** authors provided additional information on request.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Random assignment was performed by computer random number generation in blocks of 10, with a 1:1 allocation ratio."
Allocation concealment (selection bias)	Low risk	Low risk of bias due to randomisation method used.
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Participants and research staff were not blinded to which intervention participants were allocated to. Clinical staff and providers were not aware of group assignment unless revealed by the participant." Personnel and participants were not blinded and some outcomes of interest were subjectively measured. Therefore, results of subjective outcomes might be bias
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	"All surveys were orally administered by bilingual research assistants. Survey responses were captured simultaneously with administration using a Touch-screen tablet computer and Research Electronic Database Capture software" Participants were aware of group assignment and depression was measured via self-reported questionnaire, which might have introduced a bias.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Participants and research staff were aware of group assignment. However, knowledge, health behaviour (child's up-to-date immunisation) and health service use (emergency department use) were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Analyses of primary outcomes were conducted per the intention-to-treat principle. Analyses of secondary and process outcomes that were not abstracted from the EMR included only those individuals with corresponding follow-up survey data." Authors report numbers and reasons of dropouts separately for each study arm using a CONSORT diagram. In total, 22 participants were lost to follow-up, n=7 (8.86%) in the intervention group and n=15 (19.23%) in the control group. The dropout rates are unbalanced. However, the differential loss between intervention and control arm is less than 15% (10.37%) and the reasons are reported transparently.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes are reported in the results.

Elder 1998

Study characteristics	
Methods	**Study design:** cluster-RCT, 2 arms **Geographic location:** California, USA **Ethical approval:** unclear **Recruitment setting:** recruited from 3 community college sites, which took place during a 1-week period at each site **Method of recruitment:** recruitment presentations **Length of follow-up:** 6 months **Dropouts:** 72% of those completing baseline surveys also completed 6-month follow-up surveys (294) Note: exact numbers of dropouts are not reported. **A priori calculation of effect size/power?:** not reported
Participants	**Description: adult students attending English as a Second Language (ESL) classes in the San Diego area** **Health topic** • Nutrition/cardiovascular health **Inclusion criteria** • Adult students, over > 18 years of age, attending ESL classes in the San Diego area **Exclusion criteria** • Not reported **Intervention group** • Educational intervention about heart health/nutrition (numbers randomised are not reported) **Control group** • Educational intervention about stress management topics (numbers randomised are not reported) Note: 408 participants took part in the study. Numbers randomised are not reported separately for each study arm, but total numbers of participants who were assessed at all 3 time points (baseline, post-intervention, 6-month follow-up, see 'additional tables'). **PROGRESS-Plus** **P**lace of residence: urban, USA Time living in host country (years): 45.0% < 3 y **R**ace/ethnicity: Latino, European, Asian, Others; Latino: 86.7% **G**ender: • 51.0% female (applies to the entire study population) Note: not reported per arm **E**ducation (years), mean (SD); distribution: 9.8 (3.7); 48.0% ≥ 9 y

Elder 1998 *(Continued)*

	Socioeconomic status: "(...) two-thirds of the group had monthly income less than $1099" (Elder 1998, p. 569). **S**ocial capital: "approximately one-third was married" (Elder 1998, p. 569) Age (years), mean (SD): 28.7 (9.8) **Health literacy (baseline)** Not measured
Interventions	**Intervention: 'Language for Health'** Theoretical framework: Social-cognitive Theory (Bandura 1977; Bandura 2002; Bandura 2004), Operant Conditioning (Skinner 1953) Description: educational intervention, which is incorporated in existing ESL course; classes about heart health/nutrition education. The classes included topics such as (1) understanding dietary fat and cholesterol, (2) classification of foods, (3) modifying eating habits, (4) reading food labels, (5) understanding blood pressure and its relationship to salt intake, (6) shopping for low fat and low-cholesterol foods, and (7) modifying recipes. Curricula conformed to statewide ESL guidelines, including several methods of knowledge transfer. • Intervention provider: trained ESL teacher • Delivery method/mode: as many as 5 face-to-face group sessions lasting 3 hours • Language of delivery: course adapted to low language proficient audience (including bilingual material) • Format: standard • Setting/location: usual setting (participants were already enrolled in ESL classes) • Consumer involvement: no **Comparator** Type: same method/mode of delivery, but information on a different health topic Description: same quantity of health-related information on stress management topics incorporated into the same standardised ESL course format.

Outcomes	Outcomes assessed in the study: nutrition-related knowledge, belief that change in diet leads to better health, intention to change one's diet, self-efficacy to change diet, blood pressure, cholesterol, waist and hip circumference/weight, fat avoidance score, stress knowledge (to test salience of attention-placebo manipulation)
	Outcomes considered in this review
	• Health literacy
	  ◦ Apply (self-reported intention to change nutritional habits)
	• Health-related knowledge (nutrition-related knowledge)
	• Self-efficacy (self-efficacy to change diet)
	Methods of assessing outcomes
	Paper-pencil questionnaires for patient-reported outcomes
	• Nutrition-related knowledge: nutrition knowledge test, 12 items, 0 to 12, higher score is better
	  ◦ Reliability/validity: validated in a following study by Elder 2000, α-coefficient reported = 0.60
	• Self-reported intention to change nutritional habits: 3 items, 1 to 3, higher score is better
	  ◦ Reliability/validity: validated within study sample, α-coefficient reported = 0.79
	• Self-efficacy to change diet: 5 items, 1 to 3, higher score is better
	  ◦ Reliability/validity: validated within study sample, α-coefficient reported = 0.80
	Language of assessment: bilingual (Spanish and English)

	Timing of outcome assessment: baseline, 3 months after randomisation (short-term) and at 6-month follow-up (medium-term)
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation • Competences Steps of information processing • Understand • Appraise (unclear) • Apply Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** funding was provided by the National Heart, Lung, and Blood Institute (no. 5R01 HL46776-02); no clinicaltrial.gov registration. **Additional notes:** authors were contacted and asked for additional information but provision was not possible (no longer access to data set).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Instructors were randomly assigned to teach one of the two educational programmes". It was stated that intervention and control groups "did not differ significantly on any baseline physiological, psychosocial, or demographic variable with one exception: Women constituted slightly more of the intervention group than the control group, c2 = 4.0, df=1, p < .05". Insufficient information to permit a judgement of "low risk" or "high risk"; no serious baseline differences reported.
Allocation concealment (selection bias)	Unclear risk	No statement on blinding of allocation concealment. Therefore, the information does not allow to permit judgement of "low risk" or "high risk" of bias
Blinding of participants and personnel (performance bias) All outcomes	High risk	Personnel and participants were most likely not blinded due to the natue of the study. This might have affected the results of subjectively measured outcomes.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	"Physiological assessments were usually conducted during class time in a designated room on campus. A comprehensive paper-pencil survey, available in English and Spanish, was administered in the classroom (...) Male and female research staff were available at physiological assessments and paper-pencil survey assessments." Participants were not blinded and subjective outcomes were measured using repeated questionnaires.

Elder 1998 *(Continued)*

Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Participants and research staff were aware of group assignment. However, knowledge was objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"For the most part, participants completing surveys also provided physiological measures at baseline (90t three month post-test (93%) and at the 6 month follow-up (86%). Seventy-two percent of those completing baseline surveys also completed 6 month follow-up surveys and 69% of those providing baseline physiological measures also provided these at the 6 month follow-up assessment. A thorough attrition analysis was conducted using procedures suggested by Biglan et al. (1991). No evidence was found for differences in the rate of attrition by condition (χ^2=0.06, d.f.=1, *p*=0.8). More importantly, ANOVAs showed that there was no differential attrition by condition with regard to demographic characteristics or any nutrition-related physiological or psychosocial measure." Attrition rates were reported and the statistical attrition analysis revealed no significant differences with regard to demographic characteristics. However, exact numbers of participants included in each study arm as well as numbers of dropouts per arm are not reported. Therefore, information is insufficient to permit judgement of "low risk" or "high risk".
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper.
Selective recruitment of cluster participants	Unclear risk	"Participants were adult students, over 18 years of age, attending ESL classes in the San Diego area. Participants were recruited from three community college sites. Recruitment at each site took place during a 1 week period. Because of the high percentage of native Spanish-speaking students in the targeted classes, classroom-recruitment presentations were conducted in English and in Spanish when necessary." Timing and sequence of cluster randomisation is unclear. Therefore, information is insufficient to permit judgement of "high risk" or "low risk".
Other bias	Unclear risk	"Results showed the intraclass correlations were negligible and so mixed model analysis of variance (ANOVA) procedures were conducted to test intervention effects." Results were not adjusted for the cluster-design. It is unclear how this affected the results, as the intracluster correlation coefficient is not reported and we had insufficient information to re-analyse the data.

Gwede 2019

Study characteristics	
Methods	**Study design:** RCT (pilot), 2 arms **Geographic location:** Southwest Florida, USA **Ethical approval:** yes **Recruitment setting:** 2 community clinics **Method of recruitment:** potential participants were selected from a community clinic, eligible participants were provided with further study information and written consent was obtained.

Length of follow-up: 3 months

Dropouts: 6 participants were lost to follow-up in the intervention group (reasons: more than 5 attempts, called second contact and contacted clinic for updated info but was unsuccessful); 2 participants discontinued intervention (reason: declined to further participate in study); 7 participants were lost to follow-up in the control group (reasons: more than 5 attempts, called second contact and contacted clinic for updated info but was unsuccessful); 2 participants discontinued intervention (reason: declined to further participate in study)

A priori calculation of effect size/power?: not reported

Participants

Description: patients of Latin/Hispanic descent, not up-to-date with colorectal cancer (CRC) screening guidelines at average risk of CRC

Health topic

- Colorectal cancer

Inclusion criteria

- Latin/Hispanic ethnicity (self-identified), receiving care at the participating clinics, ages 50 to 75 years, able to read, speak and understand Spanish, preferred to receive health information in Spanish, currently not up-to-date per CRC screening guidelines (never screened or previously screened but now overdue, at average risk for CRC (no symptoms of CRC, personal diagnosis of CRC or bowel diseases, and without family history of CRC)

Exclusion criteria

- Not reported

Intervention group

- 'Latinos Colorectal Cancer Awareness, Research, Education and Screening (LCARES)' (40 randomised and analysed for observer-reported outcomes, for participant-reported outcomes only 32 analysed)

Control group

- Standard Spanish-language booklet plus FIT (36 randomised and analysed for observer-reported outcomes, thereof 27 analysed for participant-reported outcomes)

PROGRESS-Plus

Place of residence: urban, USA

Time living in host country (years), mean (based on n = 71 participants who were not born in the US): 23.4

Race/ethnicity: Hispanics/Latino/as

Occupation (n = 75): 52.6% employed, 40.8% not employed, 4.0% retired, 1.0% student

Gender:

- Intervention: 65.0% female
- Control: 69.0% female

Education: 43.4% elementary or less, 18.4% some high school, 17.1% high school graduate, 21.0% > high school

Socioeconomic status/income (annual) (n = 70): 44.3% < USD 10,000, 55.1% ≥ USD 10,000

Health insurance: 25.5% insured

Social capital: 69.7% married/living together, 13.1% divorced/separated, 7.9% widowed, 9.2% never married/single

Gwede 2019 *(Continued)*

	Age (years), mean (SD), range: 57.2 (6.0), 50 to 74 **Health literacy (baseline)** Assessment tool, range (score): validated (Spanish) Single Item Literacy Screener (SILS), 2 single items assessing difficulties in reading written materials (1st question) and confidence in completing health forms by oneself (2nd question) 1st question: 0 to 5; 0 for ‘very confident’ to 3 for ‘almost always ask for help’, lower score is better 2nd question: 0 to 3; 0 for 'never' to 2 for 'always' • Intervention group: 19.0% always difficulties reading written materials, 21.0% not always difficulties reading written materials; 31.0% very confident in completing health forms, 9.0% less than very confident in completing health forms • Control group: 17.0% always difficulties reading written materials, 19.0% not always difficulties reading written materials; 26.0% very confident in completing health forms, 10.0% less than very confident in completing health forms
Interventions	**Intervention: Latinos Colorectal Cancer Awareness, Research, Education and Screening (LCARES)** Theoretical framework: Preventive Health Model (PHM) (Aguado Loi 2020; Mc Queen 2008) Description: the participants received a culture-sensitive photonovel booklet (here referred as fotonovela) and an educational DVD. The fotonovela contained stories with characters that represented a test-specific behaviour of the FIT screening while the DVD-storyline depicted characters that modelled the test-specific behaviour of a FIT screening. The participants watched the DVD in the clinic receiving a copy of it and the fotonovela to take home. In addition, participants received a FIT kit, written and oral user instructions, and a self-addressed stamped envelope to return the FIT kit. Email reminders were sent after 2 weeks. • Intervention provider: not applicable • Delivery method/mode: 1 individual video session plus printed fotonovela • Format: standard format • Setting/location: at 1 of the 2 community clinics • Consumer involvement: evaluated through involvement of members from the community of interest **Comparator** Type: written information on the same topic Description: standard Spanish-language booklet plus FIT, written and oral instructions to use FIT kit; reminder letters 2 weeks after study entry for participants who did not return FIT kit (like the intervention group)
Outcomes	Outcomes assessed in the study: awareness of CRC and screening tests, CRC screening uptake (return of a completed FIT kit within 90 days of intervention delivery), time to FIT kit return, Preventive Health Model (PHM) variables (i.a. self-efficacy for screening using FIT) **Outcomes considered in this review** • Health-related knowledge (awareness of CRC and screening tests) • Self-efficacy (self-efficacy for screening using FIT) • Health behaviour (screening uptake) **Methods of assessing outcomes** Bilingual study co-ordinators assessed measures at baseline (in-person) and by phone at 3-month follow-up. All questions were read aloud for all participants. • Awareness of CRC and screening tests: 3 questions from the NCI’s Health Information National Trends Survey (HINTS) and 3 questions derived from literature, 1 item (0 to 4), 2 items (0 to 2), 3 items were coded 0 for no and 1 for yes, 6 items in total, 0 to 11, higher score is better

Gwede 2019 *(Continued)*

	Note: items of the HINTS survey reflect subjective knowledge ("Have you heard about..."); other items not further described. • Self-efficacy for screening using FIT: 6 items on attitudes and confidence towards completing FIT, response scale for all items: 1 to 5 (1 = "strongly disagree" to 5 = "strongly agree"), 6 to 30, higher score is better • Screening uptake: return of a completed FIT kit within 90 days using pre-stamped and self-addressed mailers for objective verification of screening completion, coded as yes or no Language of assessment: Spanish Reliability/validity: not reported for awareness; validated Spanish version for self-efficacy **Timing of outcome assessment:** baseline, after 3 months (medium-term)
Health literacy	**Definition:** "Thus, an important feature in promoting screening behaviors is the provision of culturally, and linguistically salient information that is mindful of audiences at-risk of low-literacy (e.g. those who may have difficulty in obtaining, processing and understanding health information)" (Gwede 2019, p. 311). **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation Steps of information processing • Access • Understand • Appraise (unclear) • Apply Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** the study was supported by the Florida Department of Health's Biomedical Research Branch, Bankhead Coley [grant number: 4BB09]; no clinicaltrials.gov registration.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"After completion of baseline assessments, participants were randomized (1:1) to receive either the LCARES or comparison condition." Intervention group had a higher percentage identifying as 'other' race and an annual income less than $10.000", n= 21 (75%) versus n=10 (30%). The sample size is small, therefore imbalances might have occurred by chance. However, information is insufficient to permit judgement of "high risk" or "low risk", as the randomisation procedure is not clearly described.
Allocation concealment (selection bias)	Unclear risk	No statement on concealment of allocation. Therefore, information is insufficient to permit judgement of "low risk" or "high risk"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No statement about whether participants and personnel were blinded and the effect on subjectively measured outcomes is unclear.

Gwede 2019 *(Continued)*

Blinding of outcome assessment (detection bias) subjective outcome measures	Unclear risk	Subjective outcomes were measured with the use of repeated questionnaires and participants were probably not blinded to group allocation.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	"Screening uptake was evaluated by return of a completed FIT kit to the study team at the cancer center using pre-stamped and self-addressed mailers. This provided an objective verification of screening completion. The primary outcome was return of a completed FIT kit within 90 days of intervention delivery (coded as yes or no). Time to FIT kit return was a secondary outcome."
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Of the 76 enrolled, 40 were randomized to the LCARES intervention and 36 were randomized to the comparison condition. Accrual required 7 months. Fifty-nine participants completed the 3-month follow-up interview (32 in LCARES condition and 27 in the comparison condition). A total of 13 participants were considered lost to follow-up." Thirteen participants were excluded from analysis due to lost-to follow up (n=9 in intervention group and n=8 in control group, respectively). No intention-to-treat analysis was performed for subjective outcomes. However, authors transparently report on attrition rates per study arm including the reasons for dropouts (illustrated by a CONSORT diagram). Differential loss between intervention and control arm is less than 15%.
Selective reporting (reporting bias)	Low risk	All outcomes specified in the methods are reported in the results.

Han 2017

Study characteristics	
Methods	**Study design:** cluster-RCT, 2 arms **Geographic location:** Baltimore, Maryland–Washington, DC, USA **Ethical approval:** yes **Recruitment setting:** 23 Korean American churches **Method of recruitment:** 29 trained female community health workers (CHWs) from 23 ethnic churches recruited Korean American women from their respective churches. Trained bilingual research assistants visited the church, obtained written informed consent and collected data. **Length of follow-up:** 6 months (total programme duration) **Dropouts:** lost to follow-up at 3 months: 10 participants (reasons: 4 change of mind; 3 lack of time; 1 car accident; 1 moving out of state; 1 death); at 6 months: 7 participants (reasons: 4 no longer available; 2 change of mind; 1 out of contact) **A priori calculation of effect size/power?:** yes
Participants	**Description: Korean American women, who had not had either a mammogram or a Pap test within the past 24 months** **Health topic:** breast/cervical cancer; 5.4% had family history of breast cancer **Inclusion criteria** • Korean American women, 21 to 65 years of age, had not had either a mammogram (for women aged ≥ 40 years only) or a Pap test within the past 24 months, able to read and write Korean or English,

Han 2017 *(Continued)*

overdue on cancer screening at the time of enrolment (on the basis of the American Cancer Society's current cancer-screening guidelines)

Exclusion criteria

- Potential participants with a cancer diagnosis, an acute and/or terminal condition, psychiatric diagnosis (e.g. schizophrenia or cognitive impairment), or other conditions, women who have undergone hysterectomy

Intervention group

- CHW–led intervention to improve breast and cervical cancer screening health literacy (278 (from 11 churches) randomised and analysed)

Control group

- Publicly availably pamphlet and delayed intervention (282 (from 12 churches) randomised and analysed)

Note: intention-to-treat analysis was performed to account for missing data; methods reported.

PROGRESS-Plus

Place of residence: urban, USA

Time living in host country (years), mean (SD), range: 15.4 (9.7), 1 to 62

Race/ethnicity: Korean Americans

Occupation: 57.9% working full or part-time, 42.1% unemployed, retired or other

Gender:

- Intervention: 100% female
- Control: 100% female

Education: 35.2% high school graduate or less, 64.8% some college or more

Socioeconomic status/income: 26.4% very comfortable or comfortable, 34.5% just OK, 39.5% uncomfortable or very uncomfortable

Health insurance: 37.9% insured

Social capital: 85.5% married or partnered, 11.1% separated, widowed or divorced, 3.4% never married

Age (years), mean (SD): 46.1 (8.5)

Health literacy (baseline)

Assessment tool, range (score): Assessment of Health Literacy in Cancer screening (AHL-C), 0 to 53, higher score is better

- Intervention group, mean (SD): 19.9 (12.9)
- Control group, mean (SD): 21.9 (12.3)

Interventions

Intervention: CHW–led intervention to improve breast and cervical cancer screening literacy

Theoretical framework: Predisposing, Reinforcing, and Enabling Constructs in Education/environmental Diagnosis and Evaluation (PRECEDE)–Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development (PROCEED) model

Description: trained CHWs delivered health literacy skills training in group meetings. The components addressed participants' understanding of key medical terminology with regard to breast and cervical cancer screening, screening of relevant medical instructions, and knowledge of healthcare system navigation for obtaining screening. A DVD and a picture guidebook produced by the researchers were

Han 2017 *(Continued)*

handed out, too. In group meetings, key medical phrases in English and role-play scenarios presented in the DVD and guidebook were practised. In follow-up calls new skills and knowledge was reinforced.

- Intervention provider: trained CHW
- Delivery method/mode: 1 face-to-face group session (with 7 to 8 participants) lasting 1.5 to 2 hours, followed by 6 months of monthly telephone calls
- Language of delivery: language concordant (bilingual)
- Format: individually tailored
- Setting/location: variety of community sites (e.g. ethnic churches, the CHWs' homes, food courts in ethnic grocery stores, popular ethnic cafés)
- Consumer involvement: evaluated with CHWs and participants of the control group

Comparator

Type: written information on the same topic

Description: the wait-list control group received publicly available educational brochures related to breast and cervical cancer and a delayed intervention.

Outcomes

Outcomes assessed in the study: cancer screening health literacy, cancer knowledge (breast/cervical cancer), perceptions about cancer (decisional balance), adherence to age-appropriate screening guidelines

Outcomes considered in this review

- Health literacy
    - Cancer screening health literacy
    - Appraise (decisional balance)
- Health-related knowledge (cervical/breast cancer)
- Health behaviour (adherence age-appropriate screening)

Methods of assessing outcomes

Self-administered questionnaires for patient-reported outcomes, medical records for health service use.

- Cancer screening health literacy: AHL-C, 52 items, 0 to 52, higher score is better
    - Language of assessment: instructions in Korean, items in English
    - Reliability/validity: validated within study sample, α-coefficient reported = 0.70 (numeracy scale), α-coefficient reported = 0.96 (familiarity and total scales)

Note: The AHL-C is a performance-based measure that assesses print literacy, numeracy, and familiarity with and comprehension of cancer-specific words.

- Cervical, breast cancer knowledge: Breast Cancer Knowledge Test, 0 to 18, Cervical Cancer Knowledge Test; true/false questions, 0 to 20, higher score is better
    - Reliability/validity: the questionnaires are validated in Korean women, α-coefficient reported = 0.81 (breast cancer), α-coefficient reported = 0.80 to 0.89 (cervical cancer), respectively
- Decisional balance: Decisional Balance Measure (weighing pros and cons), 5 pros and 9 cons on 5-point Likert scale, higher score is better
    - Reliability/validity: validated within study sample, α-coefficient reported = 0.80 (mammogram), α-coefficient reported = 0.84 (Pap test)

Note: "The Cronbach a for the original scale ranged from 0.83 to 0.90, and α coefficients were 0.80 for mammogram and 0.84 for Pap testing in this sample."

- Adherence age-appropriate screening: assessed via medical record review, higher odds are better

Language of assessment: Korean (applies to knowledge and decisional balance)

Translation procedure (if necessary): validated tool (applies to knowledge and decisional balance)

	Timing of outcome assessment: baseline, short-term (at 3 months and at 6 months after randomisation)
Health literacy	**Definition:** "Health literacy - the degree to which individuals have the capacity to obtain, process, and understand basic health information and services to make appropriate health decisions" (Ratzan 2000) **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation • Competences Steps of information processing • Access • Understand • Appraise • Apply Health domain: disease prevention
Notes	**Trial ID:**NCT00857636 **Funding:** funding was provided by the National Cancer Institute (no. R01 CA129060).

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"We randomized the participating churches (intervention = 11; wait list control = 12) on the basis of their size and location. Insufficient information about the randomisation procedure and some minor baseline imbalances reported (subjective income (p=0.046) and English proficiency (p=0.046)).
Allocation concealment (selection bias)	Unclear risk	No statement on concealment of allocation. Therefore, the information is insufficient to permit judgement of "low risk" or "high risk".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Personnel and participants were not blinded to intervention allocation due to the nature of the study. Therefore, the results of subjectively measured outcomes might be biased.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	Participants were not blinded and 'decisional balance' was measured by repeated questionnaire. This might have introduced a bias.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Participants were not blinded but health literacy and knowledge were measured objectively and not subject to interpretation. Pap-Test use and mammography were assessed by self-report but additionally by medical record review, indicating a low risk of bias for this outcome.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Some incomplete data but not substantial. Reasons provided and sufficiently accounted for in the analysis; see consort diagram in appendix.

Han 2017 *(Continued)*

Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper.
Selective recruitment of cluster participants	Unclear risk	Timing and sequence of cluster randomisation is unclear. Therefore, information is insufficient to permit judgement of "high risk" or "low risk".
Other bias	Low risk	Authors sufficiently accounted for cluster-design in the analysis.

Hernandez 2013

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** California, USA **Ethical approval:** yes **Recruitment setting:** large multiservice community clinic **Method of recruitment:** through regularly offered health educational classes, at community events and other local services, snowball sampling **Length of follow-up:** no follow-up **Dropouts:** no dropouts; 3 in the intervention group were excluded from analysis (reasons: 2 participants had invalid measures due to missing responses and 1 due to wrong assignment) and 1 in the control group (reason: had invalid measures due to missing responses) **A priori calculation of effect size/power?:** not reported
Participants	**Description: Latinas at risk for depression** **Health topic** • Mental health (depression) **Inclusion criteria** • Spanish-speaking immigrant Latinas who are not currently in mental health treatment, but at high risk based on literature **Exclusion criteria** • Not reported **Intervention group** • Fotonovela "Secret Feelings" (78 randomised and 72 analysed for knowledge, 63 for intent to seek treatment for depression, and 70 for self-efficacy) **Control group** • Discussion of family communication (68 randomised and 64 analysed for knowledge, 57 for intent to seek treatment for depression, and 63 for self-efficacy) Note: 4 were excluded after randomisation, 3 in intervention group (2 had invalid measures due to missing responses, and 1 due to wrong assignment); 1 in control group (invalid measures due to missing responses). **PROGRESS-Plus**

Hernandez 2013 *(Continued)*

Place of residence: urban, USA

Time living in host country (years), distribution: 7.7% < 5 y, 34.0% 6 to 10 y, 57.7% > 10 y

Race/ethnicity: Latinas (78.8% Mexico, 21.1% other)

Occupation: 33.8% employed

Gender:

- Intervention: 100% female
- Control: 100% female

Education: 36.6% grade school, 25.3% middle school, 14.0% some high school, 10.5% high school or General Educational Development (GED), 10.5% some college or beyond

Socioeconomic status/income (annual): 69.7% < USD 19,000, 19.0% USD 20,000 to 30,000, 11.2% > USD 30,000

Health insurance: 45.0% insured

Social capital: 58.4% married, 24.6% living with partner, 7.7% never married, 9.1% divorced or widowed

Age (years), range: 18 to 55

Health literacy (baseline)

Assessment tool, range, level: Spanish version of Short Test of Functional Health Literacy in Adults (S-TOFHLA), 0 to 36; 23% inadequate HL (0 to 16); 16% marginal HL (17 to 22); 62.6% adequate HL (23 to 36)

- Intervention group: 21.3% inadequate, 16.0% marginal, 62.6% adequate
- Control group: 35.8% inadequate, 8.9% marginal, 55.2% adequate

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Interventions

Intervention: fotonovela "Secret Feelings", entertainment-education for populations with low health literacy

Theoretical framework: social-cognitive theory (Bandura 1977; Bandura 2002; Bandura 2004); culture-centric narrative (Larkey 2010)

Description: the intervention consisted of 1 session including 30 to 45 minutes pretest questionnaires, 20 to 30 minutes exposure to a photonovel (here referred as fotonovela) presenting a story of a depressed middle-aged Latina mother, 30 to 40 minutes post-test questionnaires. The storyline addressed adaptive illness perceptions, help-seeking behaviours, depression symptoms and treatment options, as well as common fears and misconceptions associated with treatment. The fotonovela was written at 4th grade reading level and read out loud with each literate participant taking turns.

- Intervention provider: experienced study site's promotoras
- Delivery method/mode: 1 face-to-face group session (printed fotonovela read out loud by literate participants)
- Language of delivery: language concordant
- Format: standard
- Setting/location: usual setting for educational classes offered regularly by the study site's promotoras, not clearly reported
- Consumer involvement: evaluated with participants of the experimental arm

Comparator

Type: no health literacy intervention

Description: discussion on family communication and intergenerational relationships developed by the study site's clinicians; first author delivered intervention and received training

Hernandez 2013 *(Continued)*

Outcomes	Outcomes assessed in the study: depression knowledge, intent to seek treatment, depression, self-efficacy to identify the need for treatment, stigma about mental health care, antidepressant stigma
	Outcomes considered in this review
	• Health literacy
	  ○ Apply (intent to seek treatment)
	• Health-related knowledge (depression knowledge)
	• Self-efficacy (self-efficacy to identify the need for treatment)
	Methods of assessing outcomes
	Self-administered questionnaires (supported by verbal instructions of interviewer); verbal administration to 11 participants who were illiterate or had difficulty completing the forms
	• Depression knowledge: Depression Knowledge Scale, 0 to 17, higher score is better
	  ○ Reliability/validity: translated and validated by Unger 2013.
	• Intent to seek treatment: modified Intent to Seek Treatment Scale, 4 items, 4-point Likert scale (1 = definitely not, 2 = probably not, 3 = probably yes, and 4 = definitely yes), 0 to 32, higher score is better
	  ○ Reliability/validity: translated Spanish version, Cronbach’s alpha reported α = 0.88
	• Self-efficacy: self-efficacy to identify the need for treatment scale, 3 items, 5-point Likert scale (1 = not sure to 5 = very sure, the midpoint 3 = neutral), 0 to 15, higher score is better
	  ○ Reliability/validity: translated Spanish version, Cronbach’s alpha α = 0.74
	Language of assessment: Spanish
	Translation procedure (if necessary): scales for intent to seek treatment and self-efficacy were translated into Spanish by a bilingual native speaker of Spanish and reviewed by 2 additional bilingual native speakers of Spanish. Feedback and edits were discussed until consensus was achieved.
	Timing of outcome assessment: baseline, short-term (immediately after intervention)

Health literacy	**Definition:** "Health literacy refers to health knowledge and health management skills influenced by reading fluency, prior health knowledge and experiences, as well as conceptual knowledge of health care" (Baker 2006). **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation Steps of information processing • Access • Understand • Appraise • Apply Health domain: disease prevention (depression)
Notes	**Trial ID:** not reported **Funding:** funding was provided by a grant from the Health Initiative of the Americas’ programme de Investigación de Migración y Salud (PIMSA). **Additional notes:** the intervention builds on the results of Unger 2013, exploring the fotonovela's compatibility with the promotora model of health education.

Risk of bias

Hernandez 2013 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Using STATA 11 software, those eligible for participation were randomly assigned to either the control or experimental group." Baseline differences in previous depression treatment reported. As the method of randomisation was appropriate imbalances probably occurred by chance.
Allocation concealment (selection bias)	Unclear risk	There is no mention of measures to conceal the allocation of participants to groups.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel were not blinded due to the nature of the study; subjectively measured outcomes might be biased.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	"Each group received verbal instructions for completion of the pretest and posttest that were verbally administered to 11 illiterate participants or to those with difficulty completing the forms." Outcome assessors were not blinded and subjective outcomes were measured by verbally administered questionnaires to participants who were not blinded to group allocation.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Participants and personnel were not blinded but depression knowledge was measured objectively and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	“One hundred forty-six women were recruited for this study. Three participants, one from the control group and two from the experimental group, had invalid measures due to several missing responses. One participant assigned to the experimental group reported being enrolled in counselling at the time of pretest and posttest administration, so her data were not used. Thus, a total of 142 participants were included: 67 in the control group and 75 in the experimental group.” Slightly imbalanced attrition rate (n = 3 vs n = 1). Reasons for exclusion of participants post randomisation are reported.
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section were reported in the results of the paper.

Kaur 2019

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** Montreal metropolitan areas, Canada **Ethical approval:** yes **Recruitment setting:** a community partner organisation, Punjabi community temples, community centres and grocery stores

Kaur 2019 *(Continued)*

	Method of recruitment: referrals from members of a community partner organisation, word of mouth, visits to Punjabi community temples, community centres and grocery stores **Length of follow-up:** 3 months (total duration of the programme) **Dropouts:** 21 (reasons: work schedules, lack of interest or unavailability) **A priori calculation of effect size/power?:** yes
Participants	**Description: Punjabi immigrants with good general health** **Health topic** • Oral health **Inclusion criteria** • Punjabi immigrants who were residing in Montreal, 18 to 60 years of age, in good general health, gave written informed consent **Exclusion criteria** • Non-permanent residents, use of orthodontic appliances, self-reporting of presence of any disease of soft/hard oral tissues, any systemic diseases, intake of medications such as anticonvulsants, calcium channel blockers and chemotherapy **Intervention group** • “Safeguard Your Smile” oral health literacy intervention (70 randomised and analysed) **Control group** • Conventional oral hygiene self-care pamphlet (70 randomised and analysed) **PROGRESS-Plus** **P**lace of residence: urban, Canada **R**ace/ethnicity: Punjabis **O**ccupation: 63.6% full-time workers (including 14.3% self-employed), 5.0% part-time workers, 1.4% occasional workers, 22.1% homemakers, 2.9% unemployed **G**ender: • Intervention: 68.6% female • Control: 51.4% female **E**ducation: 37.7% college/technical education, 26.8% university education, 35.5% high school or less **S**ocioeconomic status/income (annual): 52.1% CAD 0 to 49,999, 19.3% CAD 50,000 to 89,999, 6.4% CAD ≥ 90,000, 20.7% unknown Health insurance: 72.9% insured Age (years), range; distribution: 18 to 60; 26.4% 18 to 31 y, 46.4% 32 to 45 y, 27.1% 46 to 60 y **Health literacy (baseline)** Assessment tool, range, score: Two Stage Rapid Estimate of Adult Literacy in Dentistry (TS-REALD), 27 to 73, higher score is better • Intervention group, mean (SD): 35.06 (7.615) • Control group, mean (SD): 32.21 (7.190)
Interventions	**Intervention: “Safeguard Your Smile” (SYS) oral health literacy intervention**

Kaur 2019 *(Continued)*

Theoretical framework: Behavior Change Wheel (Michie 2011)

Description: participants received a 1-hour group intervention including 5 components: (1) reviewing a photonovel showing risk factors of dental plaque and gingivitis and benefits and risks of action/inaction, (2) a demonstration of tools and skills of oral hygiene and a teach-back of learned techniques (3) encouragement of participants to plan their dental hygiene and register a concrete plan and to track progress of a routine, and (4) a follow-up call to reinforce learned skills and motivate to maintain self-care behaviour.

- Intervention provider: lead researcher, no further training
- Delivery method/mode: 1 face-to-face group session (with 3 to 4 participants) lasting 1 hour; monthly phone calls within 3-month follow-up period
- Language of delivery: language concordant (bilingual)
- Format: partially tailored
- Setting/location: participant’s homes or to a suitable, quiet place mutually agreed upon by the participants
- Consumer involvement: culturally informed through involvement of members of a partner organisation representing the community of interest

Comparator

Type: written information on the same topic

Description: conventional English language oral hygiene self-care pamphlet

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Outcomes

Outcomes assessed in the study: oral health literacy, oral hygiene self-care knowledge, oral hygiene self-care behaviour, plaque index, gingival index

Outcomes considered in this review

- Health literacy
  - Oral health literacy
- Health-related knowledge (oral self-care knowledge)
- Health behaviour (oral self-care behaviour)

Methods of assessing outcomes

Self-administered questionnaires

- Oral health literacy: TS-REALD, scaled score, 27 to 73, higher score is better

Note: validated word recognition routing test; participants are asked to read a list of 5 dental words aloud, 1 point per correct pronunciation. Participants are categorised depending on their scores into 3 groups for further testing: (1) low literacy stage-2 (4-word test), (2) average literacy stage-2 (6-word test), (3) high literacy stage-2 (3-word test); score from routing test is added to the stage-2 score to produce a raw score, that is translated into a scaled score.

- Oral self-care knowledge: self-administered questionnaire, 15 items on oral self-hygiene knowledge, higher score is better
- Oral self-care behaviour: self-reported oral self-care behaviour, higher score is better

Note: the questionnaires were translated into Punjabi language and "provided to the participants who could not read or write in English".

Language of assessment: English for health literacy; Punjabi or English (applies to knowledge and behaviour)

Translation procedure: translated into the Punjabi language (applies to knowledge and behaviour)

Reliability/validity: validated tool (applies to health literacy)

Kaur 2019 *(Continued)*

	Timing of outcome assessment: baseline and 3 months after randomisation (immediately post-intervention)
Health literacy	**Definition:** "Oral health literacy refers to the "degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make oral health related decisions" (National Center for Health Statistics 2012). **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation • Competencies (reading/writing abilities, numeracy skills) Steps of information processing • Access • Understand • Appraise • Apply Health domain: disease prevention
Notes	**Trial ID:** NCT02521155 **Funding:** related to PhD thesis of first author Universté de Montréal; no additional funding declared **Additional notes:** authors were contacted and asked for additional information but without success; qualitative data related to the formative research are reported in the linked QES (Aldin 2019)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"After recruitment and obtaining free and informed consent, 140 participants were randomly assigned to the experimental or control group using a computer-generated random sequence provided by a statistician at the Université de Montréal, Canada." "Participants randomized into intervention and control groups differed as a function of age since females in the age group 32 to 45 years were over-represented in the intervention group compared to the control group." There was a baseline imbalance reported. However, the radnomisation method used indicates that they may have occured by chance. In addition, the samle size was small which can result in chance-based imbalances, too.
Allocation concealment (selection bias)	Unclear risk	There is no mention of measures to conceal the allocation of participants to groups.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Personnel and participants were not blinded to intervention allocation. It was explicitly stated that this was a non-blinded RCT. Therefore, results of subjectively measured outcomes might be biased.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	Outcome assessors were not blinded and health behaviour was measured with repeated questionnaires. This might have introduced a bias.

Kaur 2019 *(Continued)*

Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Outcome assessors were not blinded but health literacy and knowledge were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Initially 140 participants were recruited and consented to participate in the study. However, 21 people (15%) dropped out between pre-test and post-test primarily due to reasons such as work schedules, lack of interest or unavailability." "A sensitivity analysis was performed using the Worst Outcome Carried Forward (WOCF) to handle study dropouts and unanswered questionnaire items.The WOCF in this study consisted of using the pre-intervention values measured as observed data in the post-intervention. This strategy ensures that, even if the data is not missing at random, our results are robust to the worst-case scenario." Authors report reasons for dropouts, but not the numbers of dropouts per group. However, the attrition rate is moderate, the methods used to account for missing data are appropriate. Therefore, a low risk of bias is present.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported at clinicaltrials.gov are reported in the published reports.

Kheir 2014

Study characteristics	
Methods	**Study design:** RCT, 3 arms **Geographic location:** Doha, Qatar **Ethical approval:** yes **Recruitment setting:** at their workplace **Method of recruitment:** major contracting companies representing the main suppliers of workers to Qatar Petroleum (QP) were contacted; mid-level supervisors informed the workers and extended invitation **Length of follow-up:** no follow-up **Dropouts:** no dropouts **A priori calculation of effect size/power?:** yes
Participants	**Description: foreign workers with low literacy skills** **Health topic** • No specific (medication understanding) **Inclusion criteria** • Foreign employee of QP, 18 to 65 years of age, < 8 years of formal education, with poor English and Arabic language skills **Exclusion criteria** • Not reported

	Group 1 • Pictogram-only label (47 randomised and analysed) **Group 2** • Pictogram label with verbal instructions (36 randomised and analysed) **Group 3** • Standard text label with verbal instructions (40 randomised and analysed) Note: in this study all study arms were compared to each other. We created a single-pairwise comparison referring to group 2 as intervention group and to group 3 as control group as they built the greatest contrast. **PROGRESS-Plus** **P**lace of residence: urban **R**ace/ethnicity: Asians Time in Arab-speaking country (years), mean range: 4.6 to 6.1 y **O**ccupation: workers at QP company **G**ender: 100% male **E**ducation (years), mean (SD): 6.1 (3.4) **S**ocioeconomic status: each participant was compensated with QAR 50 (equivalent to about USD 14), which translates to about 2 to 3 days average wage Age (years), mean (SD): 32.1 (8.5) **Health literacy (baseline)** Not measured Note: all participants had low literacy skills. Inclusion criteria were less than 8 years of formal education and low English and Arabic language skills (self-assessed). The majority of the study population self-assessed themselves as poor in English (70.0%) and Arabic literacy (94.0%).
Interventions	**Intervention: pictogram label with verbal instructions (group 2)** Theoretical framework: not reported Description: the interviewer handed the pictogram-only labelled medication box to the participant and asked each participant to offer their interpretation of the label contents. This was repeated for all 11 of the medicine instructions (group 1 and 2). Current practice verbal instructions were given to participants. All verbal communication between the interviewers and the participants was conducted through an interpreter (group 2). • Intervention provider: research staff, interpreter • Delivery method/mode: written information, face-to-face instruction (1 session) • Language of delivery: language concordant • Format: standard • Setting/location: usual care setting, primary healthcare facility • Consumer involvement: culturally and linguistically informed through involvement of members of the population of interest as well as pharmacists **Comparator (group 3)** Type: no health literacy intervention

Kheir 2014 *(Continued)*

	Description: standard text label with verbal instructions (interpreted by interviewer fluent in respective language)
Outcomes	Outcomes assessed in the study: comprehension of medical instructions **Outcomes considered in this review** • Health literacy ○ Understand (comprehension of medical instructions) **Methods of assessing outcomes** • Comprehension of medical instructions: interpretation of label contents; level of comprehension, 11 items, 1 = no comprehension to 3 = full comprehension, 1 to 3, higher score is better Note: an appropriately labelled medication box was handed to participant by interviewer; participant was then asked to offer their interpretation of the label contents. The process was repeated for all 11 of the medicine instructions. Current practice verbal instructions (in English and Arabic) were given to participants in intervention group 1 and 2 only. Verbal communication between interviewer and participant was conducted through an interpreter. Each level of comprehension was pre-defined using guidelines for categorising the results to maximise consistency between the 2 interviewers. Language of assessment: English Translation procedure: the verbatim transcript of the entire discussions that were not in English were later translated **Timing of outcome assessment:** short-term (immediately post-intervention)
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Steps of information processing • Understand Health domain: health care
Notes	**Trial ID:** not reported **Funding:** funding was provided by a grant from Qatar National Research Fund under its Undergraduate Research Experience programme (no. UREP 10-111-3-026). **Additional information:** authors were contacted and asked for additional information but without success.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Participants were randomly assigned into three study arms using computer-generated random numbers" The randomisation procedure indicates a low risk of bias.
Allocation concealment (selection bias)	Low risk	"The interviewer handed the appropriately labelled medication box to the participant and asked each participant to offer their interpretation of the label contents." There is no statement whether the allocation was concealed. However, the randomisation was computer-generated and the participants were asked to interpret a labelled medication box directly afterwards. Even if the partici-

		pants had known the group they would be allocated to in advance, we do not think that it would have introduced a bias.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Personnel and participants were not blinded to intervention allocation but outcomes were objectively measured immediately post-intervention
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	"The interviewer handed the appropriately labeled medication box to the participant and asked each participant to offer their interpretation of the label contents. This was repeated for all 11 of the medicine instructions. Current practice verbal instructions (in English and Arabic) were given to participants in Groups A and C only. All verbal communication between the interviewers and the participants was conducted through an interpreter.The level of comprehension was determined as either 1 (no comprehension), 2 (partial comprehension) or 3 (full comprehension). To maximize consistency between the two interviewers, each level of comprehension was clearly defined and guidelines for categorizing the results were agreed upon as follows: full comprehension – complete understanding of the label leading to correct and safe use of the medicine; nil comprehension – total misunderstanding of the label leading to high risk for incorrect medicine usage; partial comprehension – indication of some comprehension with possible risk when taking the medicine." Outcome assessors were not blinded. However, as the participants were assessed immediately after the participant received the medication label and by means of predefined criteria including two interviewers, we assume a low risk for detection bias.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Participants were assessed immediately; hence, incomplete data due to lost to follow-up were not possible.
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section were reported in the results section of the paper.

Kim 2009

Study characteristics	
Methods	**Study design:** RCT (pilot), 2 arms **Geographic location:** Baltimore-Washington area, USA **Ethical approval:** yes **Recruitment setting:** Korean Resource Center (KRC), a community-based site in partnership with the research team **Method of recruitment:** multiple sources (list of participants in the authors' previous studies, ethnic media (e.g. newspapers, radio stations), ethnic Korean churches, Korean grocery stores) **Length of follow-up:** 30 weeks after randomisation (immediately after programme was completed) **Dropouts:** 4 lost to follow-up at 6 months after baseline, 1 in the intervention group and 3 in the control group (reason: lack of time) **A priori calculation of effect size/power?:** yes
Participants	**Description: Korean American immigrants with type 2 diabetes**

Kim 2009 *(Continued)*

Health topic

- Type 2 diabetes

Inclusion criteria

- Self-identification as Korean American immigrant, age ≥ 30 years, self-identification as having diabetes with an uncontrolled glucose level (A1C) ≥ 7.5% within the past 6 months, resident of the Baltimore-Washington area, able to give written consent to participate in the intervention study

Exclusion criteria

- Unable to give informed consent, physical or mental health conditions that could limit active participation in the study (e.g. blindness in both eyes, severe immobility, psychiatric diseases), haematological condition that would affect A1C assay, e.g. haemolytic anaemia, sickle cell anaemia

Intervention group

- Self-help intervention programme for type 2 diabetes management (SHIP-DM) (41 randomised and 40 analysed)

Control group

- Brief brochure and delayed intervention (42 randomised and 39 analysed)

PROGRESS-Plus

Place of residence: urban, USA

Time living in host country (years): 53.2% > 20 y

Race/ethnicity: Korean Americans

Occupation: 70.3% employed

Gender:

- Intervention: 37.5% female
- Control: 51.3% female

Education: 48.1% higher level of education

Socioeconomic status/income (annual family income): 59.2% > USD 40,000

Social capital: 87.3% married

Age (years), mean (SD): 56.4 (7.9)

Health literacy (baseline)

Not measured

Interventions

Intervention: SHIP-DM

Theoretical framework: theories of health literacy; PRECEDE–PROCEED model (Green 1991)

Description: community-based, multimodal behavioural SHIP-DM that consisted of 3 main intervention modes: (1) 6 weeks of behavioural group education programmes related to diabetes mellitus, (2) home glucose monitoring with tele transmission (HGMT) and (3) individual counselling. The weekly educational group sessions included features to increase knowledge about diabetes, psychological education and health literacy education. Participants were provided with a glucose monitor, an electronic BP monitor and an HGMT-system. Measurement data were transmitted and made accessible for nurse counsellors. Participants received monthly measurement reports through nurse counsellors. Monthly telephone counselling included data reviewing, reinforcement of lessons learned, discussion of issues related to diabetes self-management, assistance and emotional support.

Kim 2009 *(Continued)*

- Intervention provider: trained CHW and research nurses
- Delivery method/mode: 6 weekly face-to-face group sessions lasting 2 hours, followed by 6 months of self-monitoring and monthly telephone counselling (10 to 25 min)
- Language of delivery: language concordant (bilingual)
- Format: tailored
- Setting/location: KRC, participants' home
- Consumer involvement: culturally and linguistically informed through involvement of bilingual researchers, clinicians and members of the community of interest

Comparator

Type: written information on the same topic

Description: control group participants received a standard brochure about diabetes and a delayed intervention.

Outcomes

Outcomes assessed in the study: diabetes knowledge, self-efficacy, self-care activities, depression, diabetes-related quality of life, A1C level, fasting glucose, lipid batteries, blood pressure, height, weight (BMI), attitudes towards diabetes

Outcomes considered in this review

- Health-related knowledge (diabetes knowledge)
- Self-efficacy (diabetes self-efficacy)
- Health behaviour (diabetes self-care activities)
- Health outcomes (depression)
- Quality of life (diabetes-related quality of life)

Methods of assessing outcomes

All outcomes considered in this review were assessed with the use of structured questionnaires.

- Diabetes knowledge: Diabetes Knowledge Test (DKT), 2 components, (1) 14-item general test, 0 to 14, higher score is better (2) 9-item insulin-use sub-scale, higher score is better
    - Language of assessment: Korean translation of validated tool
    - Reliability/validity: validated within target population, Cronbach alpha for both components α ≥ 0.70
- Diabetes self-efficacy: adapted Stanford Chronic Disease Self-Efficacy Scale, 8 items, 10-point Likert scale, 1 = not confident at all, 4 = very confident, 0-80, higher score is better
    - Reliability/validity: validated within study sample, Cronbach alpha α = 0.85, test-retest reliability = 0.80
- Diabetes self-care activities: Summary of Diabetes Self-Care Activities (SDSCA), activities include dietary information, exercise, blood glucose testing, foot care and smoking, higher score is better
    - Reliability/validity: average inter-item correlations mean = 0.47, test-retest correlations mean = 0.40, correlations with other criterion measures mean = 0.23

Note: psychometric properties were obtained from a review of 5 randomised interventions and 2 observational studies (combined sample of 1988 people with diabetes) (Toobert 2000).

- Depression: Kim Depression Scale for Korean Americans (KDSKA), 21 items divided into 4 sub-scales (emotional, cognitive, behavioural and somatic); items are presented as declarative sentences related to 1 symptom of depression and a set of response options that measure frequency of depression symptoms in a 1-week period, 0 to 75, lower score is better
    - Translation procedure: validated Korean version
    - Reliability/validity (N = 303): Cronbach alpha α = 0.93
- Diabetes-related quality of life: translated and culturally adapted version of the Diabetes Quality of Life Measure (DQOL), 46 items, 4 dimensions (worries about future effects of diabetes (1), worries about social and vocational issues (2), impact of treatment (3), personal satisfaction with treatment (4)), lower score is better
    - Reliability/validity: Cronbach alpha α = 0.66 to 0.92, test-retest reliability r = 0.78 to 0.92

Kim 2009 *(Continued)*

	Language of assessment: Korean Translation procedure: back-translation procedure and panel consensus approach (applies to knowledge and self-efficacy) **Timing of outcome assessment:** baseline, at 18 weeks and at 30 weeks after randomisation (short-term). We report on the 30-week assessment only as this is the earliest time point after the intervention programme was completed.
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation • Competences Steps of information processing • Access • Understand • Appraise • Apply Health domain: health care
Notes	**Trial ID:** NCT00505960 **Funding:** funding was provided by the National Institutes of Health (NIDDK R34 DK071957), LifeScan, Inc (HCC002154), and the Johns Hopkins University School of Medicine General Clinical Research Center (M01-RR00052), from the National Center for Research Resources/National Institutes of Health. **Additional notes:** authors were contacted and asked for additional information (e.g. gender-separate scores) but without success.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"The 83 participants with confirmed eligibility were then randomly assigned to either the SHIP-DM intervention group (n = 41) or the control (delayed intervention) group (n = 42) by computer-automated random assignment."
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Because of the nature of this intervention and the design of the study, blinding of subjects to random assignment was not feasible." Non-blinding might have affected the results of subjectively measured outcomes.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	Personnel and participants were not blinded to study condition. Subjective outcomes were measured with repeated questionnaires.
Blinding of outcome assessment (detection bias)	Low risk	Outcome assessors were not blinded but knowledge was objectively measured and not subjective to interpretation.

Kim 2009 *(Continued)*

objective outcome measures		
Incomplete outcome data (attrition bias) All outcomes	Low risk	"One participant from the intervention group and 3 from the control group withdrew because of a lack of time (retention rate = 95.2%). Outcome data are available for almost all participants indicating a low risk of bias.
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods are reported in the results section.

Kim 2014

Study characteristics	
Methods	**Study design:** cluster-RCT, 2 arms **Geographic location:** Baltimore, Washington, USA **Ethical approval:** yes **Recruitment setting:** 17 Korean American churches and 3 senior centres **Method of recruitment:** 22 Korean American churches and senior centres were selected as intervention and control group sites; potential participants were screened, enroled and tested at each site **Length of follow-up:** 18 months (6 months after completion of the 1-year programme) **Dropouts:** 41 in the intervention group, thereof 34 after 6 months (15 refused classroom education, 16 with incomplete education, 3 did not conduct home blood pressure transmission, 3 did not receive telephone counselling), 4 after 12 months (1 Parkinson's disease, 1 lost contact, 1 visited Korea, 1 refused) and 3 after 18 months (1 deceased with fire, 1 lung cancer, 1 refused). 30 dropped out in the control group, thereof 23 after 6 months (3 returned to Korea, 18 refused, 2 lost contact) and 7 after 12 months (2 deceased, 2 refused, 1 moved out, 2 got sick) Note: reporting discrepancies with regard to attrition rates shown in the CONSORT diagram and in the text (38 vs 37 vs 34 in the intervention group after 6 months) **A priori calculation of effect size/power?:** not reported
Participants	**Description: Korean American seniors with high blood pressure (HBP)** **Health topic** • Hypertension (years), mean (SD): 9.6 (8.8); approximately 85.4% reported being on antihypertension medication, but less than half (46.3%) had successfully controlled hypertension (blood pressure) < 140/90 mm Hg or < 130/80 mm Hg for those with diabetes) **Inclusion criteria** • Korean American seniors who identified themselves as first-generation immigrants, ≥ 60 years old, had systolic blood pressure of ≥ 140 mm Hg and/or diastolic blood pressure of ≥ 90 mm Hg or were on antihypertensive medication **Exclusion criteria** • Not reported **Intervention group**

Kim 2014 *(Continued)*

- Multimodal self-help intervention on the control of high blood pressure (HBP) (225 randomised and 184 analysed)

Control group

- Brief educational brochure and abbreviated delayed intervention (215 randomised and 185 analysed)

Note: only participants who completed the study were included in the analysis.

PROGRESS-Plus

Place of residence: urban, USA

Time living in host country (years), mean (SD): 25.0 (11.0)

Race/ethnicity: Korean Americans

Gender:

- Intervention: 67.4% female
- Control: 72.4% female

Education: 37.4% ≤ middle school graduate, 28.2% high school graduate, 34.4% ≥ some college

Socioeconomic status, health insurance: 82.7% insured

Age (years), mean (SD), distribution: 70.9 (5.3), 42.0% ≤ 69 y, 51.5% 70 to 79 y, 6.5% ≥ 80 y

Health literacy (baseline)

Assessment tool, range, score: HBP health literacy scale, 0 to 43, higher score is better

- Intervention group, mean (SD): 24.7 (12.0)
- Control group, mean (SD): 24.5 (14.8)

Interventions

Intervention: multimodal SHIP on the control of HBP

Theoretical framework: Self-Help Model of Learned Response to Chronic Illness Experiences

Description: SHIP to control HBP; intervention consisted of (1) education and training, (2) blood pressure home monitoring and (3) telephone counselling. Weekly educational sessions over 6 weeks were delivered by trained registered nurses and nutritionists. Health literacy training included learning medical terminologies and practising communication with healthcare providers. Sessions also covered (1) HBP management, (2) complications of uncontrolled blood pressure, (3) diet and nutrition, (4) food labels and exercise, (5) medications and food-drug interactions and (6) problem-solving skills. For blood pressure home monitoring participants were equipped with a blood pressure monitor with tele-transmission. Participants were instructed to measure their blood pressure at home 2x/day with 3 readings at each measure and to transmit blood pressure data once a week to a contractor. The contractor set up a monthly report, which was used by counsellors and participants for goal setting. Trained bilingual CHWs undertook telephone counselling once a month for 12 months to strengthen healthy behaviours of the participants, deal with barriers and support.

- Intervention provider: trained research staff and research nurses
- Delivery method/mode: 6 weekly face-to-face group sessions (6 to 10 participants) lasting 2 hours, followed by 12 months of self-monitoring (including weekly submission of blood pressure to study website) and monthly telephone counselling
- Language of delivery: language concordant (bilingual)
- Format: individually tailored
- Setting/location: Korean American churches, senior centres, participants' home
- Consumer involvement: evaluated during conduct of the RCT with a sub-sample of participants

Comparator

Type: written information on the same topic

Kim 2014 *(Continued)*

	Description: participants received a brief educational brochure that also listed available resources in the community at baseline and an abbreviated educational session after all data were collected at 18 months.

Outcomes	Outcomes assessed in the study: HBP health literacy, HBP knowledge, self-efficacy in managing high blood pressure, medication adherence, depression, blood pressure
	Outcomes considered in this review
	- Health literacy
	  ◦ HBP health literacy
	- Health-related knowledge (HBP knowledge)
	- Self-efficacy (self-efficacy in managing HBP)
	- Health behaviour (medication adherence)
	- Health outcome (depression)
	Methods of assessing outcomes
	- HBP health literacy: validated HBP health literacy scale (Kim 2012), 43 items, 0 to 43, higher score is better
	  ◦ Language of assessment: instructions in Korean, items in English
	  ◦ Reliability/validity: validated in study sample, Kuder–Richardson coefficient = 0.98
	Note: the HBP health literacy scale covers 2 domains - print literacy and functional health literacy for HBP management. Items are scored as correct or incorrect and then summed.
	- HBP knowledge: HBP knowledge questionnaire, 0 to 26, higher score is better
	  ◦ Reliability/validity: validated previously, Kuder-Richardson coefficient = 0.62
	Note: combined measure of the 12-item Check Your HBPIQ instrument and 14 items based on literature review of study authors. It is unclear whether the scale underwent a translation process. Secondary publications indicate a back-to-back translation procedure (Han 2011).
	- Self-efficacy in managing HBP: questionnaire adapted from the HBP belief scale, 8 items, 4-point Likert scale, rate from 1 (not confident at all) to 4 (very confident), 8 to 32, higher score is better
	  ◦ Reliability/validity: Cronbach's α = 0.69
	- Medication adherence: Hill-Bone Medication Adherence Scale for Korean Americans (HB-MAS), 8 items, 4-point Likert scale to rate from 1 (none of the time) to 4 (all the time), 8 to 32, lower score is better
	  ◦ Reliability/validity: validated in study sample, Cronbach's α = 0.69
	Note: it is unclear whether the scale underwent a translation process. Secondary publications indicate a back-to-back translation procedure (Kim 2006).
	- Depression: Patient Health Questionnaire 9 (PHQ-9), assesses depressive symptoms over the past 2 weeks, 9 items, score 0 (not at all) to 3 (nearly every day, range 0 to 27, cutpoints are at 5 (mild), 10 (moderate), 15 (moderate severe), 20 (severe) depression, lower score is better
	  ◦ Reliability/validity: Cronbach's α = 0.81
	Note: researchers used a total score of ≥ 5 as cut-point for presence of depressive symptoms. It is unclear if the Korean version of the PHQ-9 was applied. Secondary publications indicate a back-to-back translation procedure (Kim 2015).
	Language of assessment: unclear for knowledge, self-efficacy, adherence and depression; PHQ-9 is validated in English and Korean
	Timing of outcome assessment: baseline, and at 6, 12 (short-term) and 18 months (long-term) after randomisation

Health literacy	**Definition:** "(...) 'The degree to which individuals have the capacity to obtain, process, and understand basic health information and services to make appropriate health decisions' (...) (Nielson-Bohlman 2004)" (Kim 2012, p. 2).

Kim 2014 *(Continued)*

	Health literacy components addressed by the intervention Prerequisites and tools • Knowledge • Motivation • Competences Steps of information processing • Access • Understand • Appraise • Apply Health domain: health care
Notes	**Trial ID:** NCT00406614 **Funding:** funding was provided by a grant from the National Heart, Lung, and Blood Institute (no. R01 HL085567). **Additional notes:** information on test instruments was extracted from multiple publications related to this study. For an overview of all publications, see Kim 2014. Authors were contacted for additional information but without success.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"we used a randomized clinical control trial with the intervention delayed for the control group. Using adaptive stratified randomization, we selected 22 Korean American churches and senior centers as intervention and control group sites, depending on size or location." "We used a cluster randomization using ethnic churches as the unit of random assignment in order to reduce the potential risk of treatment diffusion between participants." (Kim 2012, p.4) Insufficient information to permit judgement of "high risk" or "low risk".
Allocation concealment (selection bias)	Unclear risk	No statement on concealment of allocation. Therefore, information is insufficient to permit judgement of "low risk" or "high risk".
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the study, personnel and participants were not blinded to intervention allocation, results of subjectively measured outcomes might be biased.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	"After participants provided written informed consent, bilingual registered nurses (RNs) obtained 3 BP measurements, and trained bilingual research staff conducted face-to-face interviews for initial data collection. For both the intervention and control groups, data collection was repeated at 6, 12, and 18 months. Participants and personnel were not blinded and subjective outcomes were assessed by repeated questionnaires.
Blinding of outcome assessment (detection bias)	Low risk	Participants and personnel were not blinded but health literacy and knowledge were objectively measured and not subject to interpretation.

Kim 2014 *(Continued)*

objective outcome measures		
Incomplete outcome data (attrition bias) All outcomes	Low risk	"At 6, 12, and 18 months, the numbers of participants who stayed in the study were 379 (86.1%), 372 (84.5%), and 369 (83.9%); at 18 months, the distribution was nearly even (184 in the intervention group; 185 in the control group). Over the 18 months, 71 (16.1%) participants dropped out for reasons such as cessation of contact (phone disconnection, residence change), schedule conflict, personal problems, or physical conditions. Some dropped out because they thought their BP was not high enough to require rigorous management. There were no differences in sociodemographic characteristics between those who remained in the study and those who dropped out. Analysis included only those who completed the study." Authors transparently report on attrition rates per study arm including the reasons for dropouts (illustrated by a CONSORT diagram). Differential loss between intervention and control arm is less than 15%.
Selective reporting (reporting bias)	Unclear risk	All outcomes reported in the methods were reported in the results of the papers. However, study registration in clinicatrials.gov. indicates that 'health care utilization' and 'problem solving and communication skills' should have been assessed additionally at 6 weeks, month 6, 12, 18 and 24. Timepoints reported in the primary RCT range up to 18 month, which indicates the another publication might follow. Therefore, reporting bias is unclear.
Selective recruitment of cluster participants	Unclear risk	Information is insufficient to permit judgement of "high risk" or "low risk".
Other bias	Low risk	Data have been re-analysed using the appropriate unit of analysis (with the use of the ICC reported by Han 2017).

Kim 2020

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** Baltimore, Maryland, USA **Ethical approval:** yes **Recruitment setting:** natural community setting; 32 churches, 86 outreach to a supermarket, outreach to trade association meetings **Method of recruitment:** media campaigns, outreach to places populated or frequented by Korean Americans (e.g. ethnic churches, supermarkets, festivals), referrals by Korean healthcare providers **Length of follow-up:** 12 months (total duration of the programme) **Dropouts:** 15 in the intervention group, thereof 4 after 3 months (3 were too busy, 1 got enough), 4 after 6 months (1 was too busy, 2 due to cancer, 1 was out of contact), 2 after 9 months (1 due to family, 1 moved) and 5 after 12 months (2 were too tired, 1 was too busy, 1 stayed in Korea, 1 due to bankruptcy); 26 in the control group, thereof 17 after 3 months (2 visited Korea, 4 were too busy, 2 due to no ride, 1 due to language issue, 1 due to family, 1 due to cancer, 6 refused), 5 after 6 months (1 due to lymphoma, 2 were too busy, 1 refused, 1 due to mental issue), 2 after 9 months (1 due to cancer, 1 refused) and 2 after 12 months (1 was too busy, 1 refused) **A priori calculation of effect size/power?:** yes

Kim 2020 *(Continued)*

Participants	**Description: Korean Americans with type 2 diabetes** **Health topic** - Type 2 diabetes **Inclusion criteria** - Self-identification as a Korean American immigrant, age ≥ 35 years, physician-diagnosed DM, difficulty in managing glucose levels, as demonstrated by haemoglobin A1c (A1c) ≥ 7.0% (53 mmol/mol), ability to stay in the programme for at least 1 year **Exclusion criteria** - Unable to give informed consent, physical or mental health conditions that could limit active participation in the study (e.g. blindness in both eyes, severe immobility, psychiatric diseases), haematological condition that would affect A1C assay (e.g. haemolytic anaemia, sickle cell anaemia, past experience in diabetes group education) **Intervention group** - Self-help intervention programme for Diabetes Management (SHIP-DM) (120 randomised and 105 analysed) **Control group** - Brief educational brochure and abbreviated delayed intervention (130 randomised and 104 analysed) Note: only participants who completed the programme were included in the analysis. **PROGRESS-Plus** **P**lace of residence: urban, USA Time living in host country (years), mean (SD): 23.8 (11.0) **R**ace/ethnicity: Korean Americans **O**ccupation: 59.3% full/part-time **G**ender: - Intervention: 40.9% female - Control: 45.2% female **E**ducation (years), mean (SD): 13.4 (3.0) **S**ocioeconomic status/income (monthly), mean: USD 3780; 63.2% housing own, 67.7% comfortable living Health insurance: 50.2% insured **S**ocial capital: 89.5% married; family size (persons), mean (SD): 3.0 (1.2) Age (years), mean (SD): 58.7 (8.4) **Health literacy (baseline)** Print literacy (referred to as "health literacy knowledge"): assessment tool, range, score Rapid Estimated of Adult Literacy in Medicine (REALM), 66 medical terms, 0 to 66, higher score is better - Mean (SE) 32.1 (1.5), indicating 6th grade reading level Diabetes mellitus-specific Rapid Estimate of Adult Literacy in Medicine (DM-REALM), 82 diabetes-specific words, 0 to 88, higher score is better

Kim 2020 *(Continued)*

	• Mean: 51.3 (SE = 1.7), 7.3 points above the scale's midpoint Comprehension scale, 0 to 28, higher score is better • Mean (SE) 15.3 (0.6) Functional health literacy (health numeracy): Test of Functional Health Literacy in Adults (S-TOFHLA), numeracy subscale, 0 to 7, higher score is better • Mean (SE) 4.2 (0.2) Newest Vital Sign (NVS), 0 to 6, higher score is better • Mean (SE) 1.7 (0.1) Note: HL measures were correlated with each other: REALM and DM-REALM (r = 0.91, P value < 0.001), TOFHLA (r = 0.68, P value < 0.001) and NVS (r = 0.47, P value < 0.001)
Interventions	**Intervention: SHIP-DM** Theoretical framework: theories of health literacy, PRECEDE–PROCEED model (Green 1991) Description: the community-based, multimodal behavioural SHIP-DM that consisted of 3 main intervention modes: (1) 6 weeks behavioural education programmes, (2) self-monitoring and (3) individual counselling. (1) Weekly educational group sessions included features to enhance participants' knowledge of diabetes mellitus, psychological and health literacy education. (2) Participants were provided with a glucose monitor, strips and lancet(s) with instructions on how to use the equipment and registering measurements. Participants were requested to log their daily blood glucose levels twice a day for 12 months. (3) Telephone counselling was conducted once a month using motivational interviewing to counsel participants in disease-specific demands and to encourage them to maintain self-care skills and a healthy lifestyle. • Intervention provider: trained CHW and research nurses • Delivery method/mode: 6 weekly face-to-face group sessions lasting 2 hours, followed by 12 months of self-monitoring and monthly telephone counselling • Language of delivery: language concordant (bilingual) • Format: individually tailored • Setting/location: Korean Resource Centre, participants' home • Consumer involvement: culturally and linguistically informed through involvement of bilingual researchers, clinicians and members from the community of interest **Comparator** Type: written information on the same topic Description: participants received a brief educational brochure at baseline that highlighted the critical self-management principles of SHIP-DM; the brochure also contained available care and educational resources in the community. An abbreviated educational session was offered to control group members at 12 months.

Outcomes	Outcomes assessed in the study: functional health literacy, health numeracy, diabetes-specific health literacy, diabetes-specific knowledge, diabetes-specific self-efficacy, adherence to diabetes regimen*, depression, diabetes-related quality of life, comprehension**, social support*, dietary intake (using the 24-hour recall method)*, HbA1c, blood pressure, weight, cholesterol
	Outcomes considered in this review
	• Health literacy
	  ○ Functional health literacy
	  ○ Health numeracy
	  ○ Diabetes-specific health literacy

Kim 2020 *(Continued)*

- Quality of life (diabetes-related QoL)
- Health-related knowledge (diabetes knowledge)
- Health outcome (depression)
- Health behaviour (adherence to diabetes regimen)
- Self-efficacy (diabetes self-efficacy)

Notes: *results not reported in the identified publications; **comprehension was assessed via "comprehension scale" (it is not clear whether the comprehension scale was part of one of the health literacy assessment tools or whether it was used additionally; no additional explanations in the publications)

Methods of assessing outcomes

Health literacy was assessed with the use of 3 validated assessment tools on functional health literacy and health numeracy, respectively.

- Functional health literacy: REALM, 66 items, word recognition test of common medical terms, 0 to 66, higher score is better
    - Reliability/validity: validated tool
- Health numeracy: Test of Functional Health Literacy in Adults (TOFHLA), 7 items (numeracy sub-scale), 0 to 7, and NVS, 6 items, 0 to 6, higher score is better
    - Reliability/validity: Cronbach’s α = 0.84 and = 0.75, respectively
- Diabetes-specific health literacy: Diabetes-specific Rapid Estimate of Adult Literacy in Medicine (DM-REALM), 82 items (relevant words specifically important to diabetes mellitus, 3 levels of difficulty scale were developed by the research team), 0 to 82, higher score is better
    - Translation procedure: developed in 3 language versions by the research team
    - Reliability/validity: validated in pilot study, Cronbach's α = 0.9
- Diabetes knowledge: DKT, 14 items, 0 to 14 (general test) plus 9 items insulin sub-scale, 9 items, 0 to 9, higher score is better
    - Translation procedure: translated Korean version
    - Reliability/validity: validated tool, Cronbach's α = 0.70
- Diabetes self-efficacy: validated adapted Stanford Chronic Disease Self-Efficacy Scale, 8 items, 10-point Likert scale, 1 = not confident at all, 4 = very confident, 0 to 80, higher score is better
    - Translation procedure: translated into Korean language
    - Reliability/validity: validated tool, Cronbach's α = 0.85, test-retest validity = 0.80
- Depression: Korean version of the PHQ-9K, assesses depressive symptoms over the past 2 weeks, 9 items, score 0 (not at all) to 3 (nearly every day), cut-points are at 5 (mild), 10 (moderate), 15 (moderate severe), 20 (severe) depression, 0 to 27, lower score is better
    - Translation procedure: validated Korean version
    - Reliability/validity: validated tool
- Diabetes-related quality of life: DQOL, 15 items, 4 dimensions (concern about future effects of diabetes mellitus, concern about social and vocational issues, the impact of treatment, and personal satisfaction with treatment), 0 to 75, higher score is better
    - Validity/reliability: validated within the study sample, Cronbach's α = 0.84

Language of assessment: language of assessment is not reported for functional health literacy; other measures were assessed in Korean

Translation procedure: not reported for functional health literacy, health numeracy and quality of life

Timing of outcome assessment: baseline and at 3, 6, 9 and 12 months after randomisation (short-term, immediately after programme was completed)

Health literacy

Definition: "(...) HL is 'the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions' (Ratzan 2000, p. vi)".

Health literacy components addressed by the intervention

Prerequisites and tools

Kim 2020 *(Continued)*

	- Knowledge - Motivation - Competencies (reading/writing abilities, numeracy skills) Steps of information processing - Access - Understand - Appraise - Apply Health domain: health care
Notes	**Trial ID:** NCT01264796 **Funding:** funding was provided by a grant from the National Institute of Diabetes and Digestive and Kidney Diseases (no. R18 DK083936) with material support from LifeScan, including devices (OneTouch glucometer, OneTouch UltraSoft test strips, and OneTouch UltraSoft lancets) for study participants. In addition, the Johns Hopkins Institute for Clinical and Translational Research supported the cost of blood serum lab tests. **Additional notes:** the outcomes considered in this review are reported in two references. We have chosen the publication of the results on our primary outcome health literacy as the primary report, but we extracted data from all available reports related to this study. For an overview of all identified reports linked to this study, see Kim 2020. Authors were contacted and asked for additional information (e.g. gender-separate scores) but without success.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A total of 250 KA immigrants with uncontrolled T2DM were enrolled in our programme and randomized into either the intervention (n = 120) or the control (n = 130) group, with computer software ensuring equivalence between groups on key factors that might influence the primary outcome of A1C (e.g.., disease severity, age, body mass index, and gender)"
Allocation concealment (selection bias)	Low risk	Randomisation method indicated low risk of bias.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Personnel and participants were not blinded due to the nature of the intervention; results of subjectively measured outcomes might be biased.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	Participants were not blinded to study condition and subjective outcomes were measured with repeated questionnaires.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Participants were not blinded but health literacy and knowledge were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	“Analyses of changes in this study included only participants with complete follow-up data.” No intention-to-treat analysis, but completers only analysis was performed. Many dropouts in both arms (from 120 to 105 in intervention group (12.5%)

Kim 2020 *(Continued)*

		and 130 to 104 in control group (20%)). However, reasons are provided and similar across groups. Attrition rate does not exceed the recommended 20% for short-term follow-up according to Cochrane RoB guidance. Differential loss between intervention and control group is less than 15%.
Selective reporting (reporting bias)	High risk	Results on adherence to diabetes regimen assessed with the diabetes Selfcare Activities Scale, social support (no information on the tool used) and dietary intake (using a 24-hour recall) are not reported.

Kiropoulos 2011

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** Melbourne, Australia **Ethical approval:** yes **Recruitment setting:** Greek and Italian social welfare clubs, print and radio media directed at Greek- and Italian-speaking residents in Melbourne **Method of recruitment:** advertising in Greek and Italian social welfare clubs, print and radio media, participants who opted to take part in the study contacted researchers listed in advertisements **Length of follow-up:** 1 week after intervention **Dropouts:** no dropouts **A priori calculation of effect size/power?:** yes
Participants	**Description: Greek-born and Italian-born immigrants living in Australia** **Health topic** • Mental health (depression); 8.2% in intervention group and 13.0% in the control group currently receive psychological treatment **Inclusion criteria** • ≥ 45 years, born in Greece or Italy, living in Australia **Exclusion criteria** • Not reported **Intervention group** • Multicultural Information on Depression Online (MIDonline) website (110 randomised and analysed) **Control group** • Depression interview (92 randomised and analysed) **PROGRESS-Plus** **P**lace of residence: urban, Australia Time living in host country (years), mean (SD): 43.8 (9.0) **R**ace/ethnicity: Greeks and Italians

Kiropoulos 2011 *(Continued)*

Occupation: 5.0% never worked, 57.9% unskilled, 31.2% tradesperson/clerical, 4% manager/professional, 28.2% working now, 70.8% are not working now

Gender:

- Intervention: 69.1% female
- Control: 73.9% female

Education: 15.3% no/incomplete primary, 42.1% completed primary, 24.3% some secondary school, 9.9% all secondary school, 8.4% some/completed tertiary

Social capital: 28.2% married, 71.8% not married, 14.9% living with spouse, 52.0% living with children, 24.8% living with other relatives, 14.4% currently living alone, 85.6% not currently living alone

Age (years), mean (SD): 65.4 (8.57)

Health literacy (baseline)

Assessment tool, range, score: D-Lit scale, 22 items, 0 to 22, higher score is better

- Intervention group, mean (SD): 10.61 (3.28)
- Control group, mean (SD): 8.17 (4.29)

Interventions

Intervention: Multicultural Information on Depression Online (MIDonline) website

Theoretical framework: not reported

Description: for the MIDonline website the interviewer and participant sat together in front of the computer. In the first 10 minutes the interviewer explained the purpose of the website and instructed participants on how to use it. Participants were then given 1 hour to read through the online material by themselves. The MID online website provides culturally tailored multilingual information about depression designed for middle- to older-aged consumers who are not English-native speakers. The website incorporates (1) information about symptoms and case studies of depression, (2) how depression is diagnosed, (3) related disorders, (4) causes, (5) treatment options, (6) how to find a bilingual mental health professional and professional psychological care, (7) stigma related to mental illness and multilingual translated resources.

- Intervention provider: not applicable
- Delivery method/mode: 1 individual web-based session (interactive website)
- Language of delivery: language concordant (participant's language of choice)
- Format: standard
- Setting/location: consultation room located at Monash University
- Consumer involvement: no

Comparator

Type: placebo intervention; semi-structured interview about depression

Description: semi-structured interview with a bilingual interviewer who asked open-ended questions relating to the participant’s beliefs about depression including the causes, symptoms, course and development, treatments and outcomes of depression; no additional material

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Outcomes

Outcomes assessed in the study: depression literacy (depression knowledge), depression severity, depression stigma

Outcomes considered in this review

- Health literacy
    - Depression literacy
- Health outcome (depression)

Methods of assessing outcomes

	Face-to-face questionnaires administered by bilingual psychologists • Depression literacy: Adapted Depression Literacy Questionnaire (D-Lit), 22 items, true/false test of knowledge about depression, 0 to 22, higher score is better ○ Reliability/validity: validated within the study sample, α = 0.88 (Greek Version), α = 0.92 (Italian version) Note: 4 items of the original questionnaire were replaced to reflect the content of the MIDonline website. • Depression severity: validated Beck Depression Inventory-II (BDI-II), 21 items for measuring severity of depressive symptoms within "past two weeks, including today", 0 to 63, higher score is better ○ Reliability/validity: validated within the study sample, α = 0.90 (Greek version), α = 0.89 (Italian version) Language of assessment: language concordant Translation procedure (if necessary): all self-report scales were translated from English into Greek and Italian by the first author and other bilingual psychologists; all item translations were reconsidered by a second bilingual psychologist and researcher; more difficult or ambiguous items were examined for meaning with lay members of the Greek and Italian communities. Validity was checked by examining the psychometric properties of the scales after data were collected, preceding further analysis. **Timing of outcome assessment:** prior and immediately after intervention, 1-week follow-up (short term)
Health literacy	**Definition:** "depression literacy (also called depression knowledge)" (Kiropoulos 2011, p. 2), not further defined **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation (unclear) Steps of information processing • Access • Understand • Appraise • Apply Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** funding was provided by a major research grant from Beyondblue, the National Depression Initiative. **Additional notes:** authors were contacted and asked for additional information (e.g. gender-separate scores) but without success.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Participants were randomly assigned by the first author following a simple randomization procedure using a computerized list of random numbers to one of two intervention groups (either the MIDonline intervention (n = 110) or the control group (n = 92) using a 1:1 allocation with stratification at level of coun-

		try). The sequence of numbers was concealed until the intervention was assigned."
Allocation concealment (selection bias)	Low risk	"The sequence of numbers was concealed until the intervention was assigned."
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Interviewers and participants were not blinded to condition assignment" Non-blinding might have affected the results of subjectively measured outcomes.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	Outcome assessors were not blinded and depression was measured using a repeated questionnaire.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Participants and personnel were not blinded but depression literacy was objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	0% attrition rate. Therefore, a risk of attrition bias is not indicated.
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods are reported in the results of the paper.

Koniak-Griffin 2015

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** Los Angeles, California, USA **Ethical approval:** yes **Recruitment setting:** parent education centres, churches, laundromats, organisations providing basic services to children and families (e.g. ESL classes, job training, social services) **Method of recruitment:** recruitment was conducted in 4 consecutive intervention cycles. Trained recruiters gave small group and individual presentations providing an overview of study and programme announcements. **Length of follow-up:** 9 months (3 months after programme completion) **Dropouts:** 59 participants were lost to follow-up; 13 in the intervention group and 17 in the control group after 6 months and 11 in the intervention group and 18 in the control group after 9 months. **A priori calculation of effect size/power?:** yes
Participants	**Description: low-income Latina immigrants that are overweight** **Health topic** • Cardiovascular disease **Inclusion criteria**

Koniak-Griffin 2015 *(Continued)*

	- Self-identification as Latina, 35 to 64 years, Spanish- and/or English-speaking, overweight (BMI ≥ 25) **Exclusion criteria** - History of impaired physical mobility, type 1 diabetes, uncontrolled hypertension, heart attack, stroke, health clearance was required for participants with type 2 diabetes or hypertension controlled by diet and/or oral medications **Intervention group** - Lifestyle behaviour intervention, 'Mujeres Sanas y Precavidas (Healthy Women Prepared for Life)' (111 randomised and 98 analysed at 6-month follow-up, and 100 analysed at 9-month follow-up) **Control group** - Safety/disaster preparedness educational programme (112 randomised and 95 analysed at 6-month follow-up, and 94 at 9-month follow-up) Note: authors report having conducted a modified intention-to-treat analysis using mixed-effects models for repeated measures over time; 13 participants were excluded from physical activity analysis because they did not meet the accelerometer recording criteria. **PROGRESS-Plus** **P**lace of residence: urban Time living in host country (years), mean (SD), range (n = 204): 18.6 (8.3), 1 to 40 **R**ace/ethnicity: Latinas **O**ccupation: 74.6% unemployed **G**ender: female only **E**ducation (grade) (n = 220): 52.5% ≤ 8th grade, 33.6% 9th to 12th grade, 12.6% ≥ 13 years **S**ocioeconomic status/income (annual): ≤ USD 20,000 54.7%, USD 20,001 to 40,000 28.7%, USD 40,001 to 75,000 16.6% Health insurance: 31.8% insured **S**ocial capital: 72.2% married/living with a partner, 27.8% divorced/widowed/single Age (years), mean (SD), range: 44.6 (7.9), 35 to 64 **Health literacy (baseline)** Not measured
Interventions	**Intervention: lifestyle behaviour intervention "Mujeres Sanas y Precavidas"** Theoretical framework: community-based participatory research conceptual framework Description: the culturally targeted promotora-led programme included group education plus individual teaching and coaching units about healthy lifestyle behaviours to reduce cardiovascular disease risks. Promotoras presented standardised content in pairs and showed an instructor-led stretching and exercising DVD, produced by an official public health department. In coaching sessions, food and physical activity diaries of participants were discussed with promotors (inter alia). The intervention promoted four key messages: (1) healthy food choices, (2) portion control, (3) managing emotional eating and (4) increasing physical activity. Participants received a pedometer, a copy of the exercise video presented in the classes and culturally-appropriate recipes. - Intervention provider: trained promotoras - Delivery method/mode: 8 weekly face-to-face group sessions lasting 2 hours, followed by 4 months of individual teaching and coaching sessions (4 face-to-face sessions and 4 phone calls)

Koniak-Griffin 2015 *(Continued)*

	• Language of delivery: language concordant • Format: group-based, individually tailored • Setting/location: community setting, participants' home • Consumer involvement: evaluated with a smaller sample of intervention participants **Comparator** Type: no health literacy intervention (attention placebo control) Description: 6-month educational programme on safety and preparedness topics (e.g. in case of earthquakes) followed by the possibility of 8 individual teaching and coaching contacts where class content was reviewed in in-depth discussions. After completion of the study, participants were offered 2 classes on key information about a promotora-led health intervention ("Su Corazón, Su Vida").

Outcomes	Outcomes assessed in the study: knowledge of heart disease, physical activity*, dietary habits, body weight, height and waist circumference, blood pressure, blood lipids and glucose
	Outcomes considered in this review
	• Health related knowledge (heart disease knowledge)
	• Health behaviour (physical activity)
	Note: *prioritised outcome, category 'health behaviour'
	Methods of assessing outcomes
	• Heart disease knowledge: 10-item questionnaire adapted from a previous survey, true/false format (using statements, e.g. "Heart disease is the leading cause of death in woman"), 0 to 10, higher score is better
	  ○ Translation procedure: validated Spanish version
	  ○ Reliability/validity: α = 0.80
	Note: "Items also assessed prevention behaviours and awareness that early treatment exists."
	• Physical activity: Kenz Lifecorder Plus Accelerometer (Kenz, Nagoya, Japan), assesses vertical acceleration and counts of movement that are correlated with steady-state oxygen consumption; participants wore the accelerometer during waking hours for 7 consecutive days at each physical activity data collection period
	  ○ Reliability/validity: validated tool
	Note: "The Lifecorder activity counts were converted into METS (1 MET = 3.5 mL/kg min), thus enabling classification of intensity according to accepted standards as well as measurement of steps". Participants received verbal and written instructions with illustrations on the devices.
	Note: a bilingual research assistant, blinded to participant's group assignment, administered the questionnaires via face-to-face interviews.
	Language of assessment: Spanish
	Timing of outcome assessment: baseline, 6 months after randomisation (short-term, immediately after programme was completed) and 9 months after randomisation (medium-term, 3 months after programme was completed)

Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation Steps of information processing

Koniak-Griffin 2015 *(Continued)*

	- Understand - Appraise - Apply Health domain: prevention
Notes	**Trial ID:** NCT01333241 **Funding:** funding was obtained by the National Heart, Lung, and Blood Institute (R01 HL086931) and was part of a registered clinical trial. **Additional notes:** authors were contacted and asked for additional information (e.g. control groups' post-intervention knowledge scores) but provision of data was not possible.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Randomization was performed using a web-based programme custom-developed for this study. Participants were assigned to the Lifestyle Behavior Intervention or the control group in a 1:1 ratio using a block randomization procedure."
Allocation concealment (selection bias)	Low risk	The randomisation method indicates a low risk of bias.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Personnel and participants were not blinded due to the nature of the study. However, outcomes considered in this review were objectively measured.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Both physical activity and knowledge were objectively measured. No subjective judgement of personnel required.
Incomplete outcome data (attrition bias) All outcomes	Low risk	“Retention was 86.5% and 87.0% or the 6- and 9-month evaluations, respectively. (...) The retention rates across groups were not statistically different” The attrition rate is lower than 20% and the differential loss between study groups is not significant. A modified intention-to-treat-analysis was conducted for physical activity; a completers only analysis was performed for participant-reported outcomes.
Selective reporting (reporting bias)	High risk	All prespecified outcomes reported at clinicaltrials.gov are reported in the published reports. However, results of the control group's knowledge assessment were not reported.

Lepore 2012

Study characteristics

Methods	**Study design:** RCT, 2 arms **Geographic location:** New York, USA **Ethical approval:** yes

Lepore 2012 *(Continued)*

Recruitment setting: the sampling frame was constructed from the health insurance beneficiaries (~355,000) list of a large healthcare workers union in the New York City metropolitan area.

Method of recruitment: participants were drawn from the sampling frame and recruited via advance letters and reply cards.

Length of follow-up: 2 years for prostate-specific antigen (PSA) claims, self-report data were collected 8 months after randomisation (programme duration approx. 1 month).

Dropouts: 29 were lost to follow-up in the intervention group (reasons: 25 could not be reached for follow-up, 4 refused to complete the study); 30 were lost to follow-up in the control group (reasons: 25 could not be reached for follow-up, 4 refused to complete the study, 1 pulled from study); in the allocation process 15 did not receive allocated intervention (reasons: 11 could not be reached, 4 refused to complete, 0 pulled from study); 16 in the control group did not receive allocated intervention (reasons: 11 could not be reached, 4 refused to complete, 1 pulled from study)

A priori calculation of effect size/power?: yes

Participants

Description: black immigrant men from the Caribbean

Health topic

- Prostate cancer screening

Inclusion criteria

- Men who are accessible by telephone, have a primary care physician, 45 to 70 years, of black African descent

Exclusion criteria

- Prior diagnosis of prostate cancer or a prostate cancer test within the past 12 months

Intervention group

- Tailored telephone education intervention on prostate cancer (244 randomised and analysed for observer-reported outcomes, for participant-reported outcomes 215 analysed)

Control group

- Tailored telephone education intervention on fruit and vegetable consumption (246 randomised and analysed for observer-reported outcomes, for participant-reported outcomes 216 analysed)

Note: a partial intention-to-treat-analysis was performed; participants were included in analyses even if they did not receive the allocated intervention.

PROGRESS-Plus

Place of residence: urban, USA

Race/ethnicity: black men of African descent

Gender: 100% male

Education: 31.3% less than high school, 31.8% high school degree, 36.9% college education or degree

Socioeconomic status:

Health insurance: all had access to health insurance that covered prostate cancer tests

Social capital: 83.7% married

Age (years), mean (SD): 55.04 (6.29)

Health literacy (baseline)

Lepore 2012 *(Continued)*

	Not measured
Interventions	**Intervention: Tailored telephone education on prostate cancer** Theoretical framework: Ottawa Decision Support Framework (Doull 2006) Description: tailored telephone education about prostate cancer testing that included print education material, tailored and balanced information about prostate cancer risk and tests, and a values' clarification exercise. The intervention addressed participants' knowledge, values and decision conflict for prostate cancer screening, and aimed to increase their ability and motivation to talk with a physician about testing. Calls were audio-recorded and checked for fidelity. • Intervention provider: trained graduate-level health educator • Delivery method/mode: 2 individual phone calls within a 1-month period (median = 1 week) plus mailed brochure, 1 health education call lasting approx. 20 min and 1 follow-up call lasting approx. 5 min • Language of delivery: English • Format: tailored • Setting/location: participant's home • Cultural adaption: yes, theory/empirically informed • Consumer involvement: yes, but quantitatively evaluated **Comparator** Type: unrelated health literacy intervention (same methods but information on a different health topic) Description: print brochure on fruit and vegetable consumption and tailored telephone education including information about the recommended amounts of fruits and vegetables, appropriate serving size, and the importance of eating a colourful variety of fruits and vegetables.

Outcomes	Outcomes assessed in the study: knowledge on prostate cancer screening, testing intention, benefits-to-risk ratio of testing, and verified PSA testing, state of anxiety, decisional conflict, verified physician visit to discuss testing, congruence between intention and actual behaviour
	Outcomes considered in this review
	• Health literacy
	  ○ Appraise (decisional conflict*)
	  ○ Apply (testing intention)
	• Health-related knowledge (knowledge on prostate cancer screening)
	• Health behaviour (PSA testing)
	• Adverse events (anxiety)
	Note: We would have reported on the results of the following subscales: informed decision, values clarity and support. The subscales uncertainty and effective decision presume a completed decision, thus rather reflecting the processing step of applying health information. However, the authors report on the full subscales informed decision, values clarity and 1 item of the support subscale only justifying that with many participants (N = 81) having been still undecided after the intervention and reasons of reliability. These items "were dropped along with items 6 and 8 [subscale support] in order to bring reliability up to an acceptable level (Cronbach's alpha = .62)."
	Methods of assessing outcomes
	Questionnaires were telephone-administered by data collector blinded to group assignment.
	• Decisional conflict: subscales informed decision, values clarity and support (1 item), 0-100, lower score is better
	• Testing intention: participants were asked whether they had "decided to get tested in the future for prostate cancer" (0 = no, 1 = yes)

Lepore 2012 *(Continued)*

	• Knowledge on prostate cancer screening: 14 items (true/false) covered in the delivered pamphlet, 6 items on testing, 5 on risk factors and epidemiology, and 3 on treatment effectiveness and side effects (percent correct was used as the outcome measure), higher score ist better • PSA testing: medical claims scanned for PSA procedure codes using an expert system (0 = no, 1 = yes) • State of Anxiety: 7-item subscale of the Hospital Anxiety and Depression Scale (HADS), response options 0-3, 0-21, lower score is better Language of assessment: English Reliability/validity: only reported for state of anxiety, α = 0.66 pretest, 0.70 posttest **Timing of outcome assessment:** baseline (knowledge only), long-term (approx. 7 months follow-up for self-reported outcomes and at 1- and 2-year follow-up for PSA testing)
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation Steps of information processing • Access • Understand • Appraise • Apply Health domain: disease prevention
Notes	**Trial ID:** NCT01415375 **Funding:** funding was provided by the National Cancer Institute of the National Institutes of Health (grant R01 CA104223).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was conducted within three age strata (45–49, 50–54, and 55–70 years old) using the PLAN procedure of SAS (Cary, NC)." "The Principal Investigator used a computer generated randomization schedule to randomize the participant and emailed the randomization assignment to the interventionist."
Allocation concealment (selection bias)	Low risk	The randomisation procedure used indicates a low risk of selection bias.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Data collectors were blind to condition but the interventionists were not" Data collectors were blinded, but intervention providers were not. However, we assume that participants were unaware of the allocated intervention, as both the intervention and control group received telephone education.
Blinding of outcome assessment (detection bias) subjective outcome measures	Low risk	"Data collectors were blind to condition but the interventionists were not" Participants were presumably not aware of the intervention received

Lepore 2012 *(Continued)*

Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	"Data collectors were blind to condition but the interventionists were not" Knowledge and PSA testing were measured objectively and were not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Attrition was low (12%) and did not vary by condition. Most (93.6%) participants received their allocated intervention, but a few could not be reached by telephone. Medical claims data on prostate cancer testing and physician visits were 100% complete." Dropout rates are low and the differential loss between intervention and control group is 0.3%. Participants excluded from the analysis already had incomplete data at baseline stage. Questions were orally administered indicating that incomplete data did not result from participants' low literacy. An intention-to-treat analysis was conducted.
Selective reporting (reporting bias)	Low risk	All outcomes specified at clinicaltrials.gov are reported in the results.

Mohan 2014

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** Tennessee, USA **Ethical approval:** yes **Recruitment setting:** safety net clinic, Nashville **Method of recruitment:** research assistants screened patient charts and received referrals from clinic staff to identify patients with reported diabetes; patients were directly approached by research assistants in the clinic waiting room and other clinic areas. **Length of follow-up:** 1 week after intervention **Dropouts:** 2 in the intervention group were lost to follow-up, 1 in the control group were lost to follow-up **A priori calculation of effect size/power?:** not reported
Participants	**Description: Latinos with diabetes prescribed for at least 1 chronic medication** **Health topic** • Diabetes **Inclusion criteria** • ≥ 18 years, diagnosis of diabetes recorded in the medical chart, prescribed for at least 1 chronic medication **Exclusion criteria** • Unavailable list of their medications, corrected visual acuity > 20/50 using a Rosenbaum Pocket Screener, hearing deficit, dementia, psychosis, disorientation, belonging to a special human subjects population (e.g. pregnant or prisoner), being unable to communicate in English or Spanish, without a regular phone number

Mohan 2014 *(Continued)*

	Intervention group - PictureRx illustrated medication list (103 randomised and 99 analysed) **Control group** - Handwritten list of medications, but no illustrations (105 randomised and 101 analysed) Note: 4 participants were subsequently excluded from each arm for not meeting eligibility criteria. **PROGRESS-Plus** **P**lace of residence: urban, USA **R**ace/ethnicity: Latinos **G**ender: - Intervention: 61.6% female - Control: 77.2% female **E**ducation (years), mean: 8; 29.0% had at least high school education Age (years), mean: 50 **Health literacy (baseline)** Assessment tool, range, score: Brief Health Literacy Screen (BHLS), validated in Englisch and Spanish, 3 to 15, higher score is better - Intervention group, mean (SD): 10.5 (3.0) - Control group, mean (SD): 10.4 (3.3) 59% had limited health literacy
Interventions	**Intervention: PictureRx illustrated medication list** Theoretical framework: not reported Description: the participant's prescribed medication regimen was entered into a secure website by a research assistant to prepare and print a colour PictureRx illustrated medication schedule. It showed the full medication regimen, dosing of medication and included a picture of each medication to show its purpose. Medication instructions were printed in plain language (English and Spanish). The research assistant explained the PictureRx to the participant and showed a 2-minute video about it. Patients received a 1-page sheet with tips on how to use the PictureRx. - Intervention provider: research assistant - Delivery method/mode: written information, face-to-face instruction, 2-minute instruction video - Language of delivery: language concordant (bilingual) - Format: standard - Setting/location: safety net clinic - Consumer involvement: linguistically adapted through involvement of members from the community of interest **Comparator** Type: no health literacy intervention Description: usual care; the treating provider reviewed medication instructions with the patient and the patient received a handwritten list of medications in their preferred language, with instructions for use and the drug indications, but no illustrations.
Outcomes	Outcomes assessed in the study: medication understanding, medication adherence

Mohan 2014 *(Continued)*

Outcomes considered in this review

- Health literacy
    - Understand (medication understanding)
- Health behaviour (medication adherence)

Methods of assessing outcomes

Baseline questionnaire after enrolment in the study administered by research assistant, telephone administered follow-up interview (also by research assistant)

- Medication understanding: Medication Understanding Questionnaire (MUQ), 0 to 100 (representing percentage correct), higher score is better
    - Translation procedure: "MUQ was translated, checked for accuracy, and pilot-tested among a small population of Spanish-speaking patients." (Mohan 2014, p. e550)
    - Reliability/validity: validation within study sample unclear
- Medication adherence: 8-item sub-scale of the Spanish translation of Adherence to Refills and Medications Scale (ARMS), self-report measure that assesses patients' self-reported adherence under various circumstances (sub-scale is opposed to medication refills), 8 (most adherent) to 32 (least adherent), lower score is better
    - Translation procedure: translated Spanish version
    - Reliability/validity: validated Spanish version

Language of assessment: Spanish

Timing of outcome assessment: short-term (at 1-week follow-up)

Health literacy

Definition: "(…) evidence suggests that health literacy – or the constellation of skills needed to effectively function in the health care environment – plays an important role." (Mohan 2012, p. 2)

Timing of assessment: baseline

Health literacy components addressed by the intervention

Steps of information processing

- Understand
- Apply

Health domain: health care

Notes

Trial ID: not reported

Funding: funding was provided by Small Business Innovation Research award (no. R43 MD004048) (Riley/Boyington), from the HHS National Institute on Minority Health and Health Disparities (NIH) of the National Institutes of Health.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"The randomization codes were prepared in advance using a computer random number generator, in permuted blocks of varying size, and sealed individually in opaque envelopes to maintain concealment of treatment allocation." Participants in the intervention arm were more likely to be male (38% vs 23%; P = 0.017) and more likely to be white (98% vs 92%; P = 0.05). However, the type of randomisation indicates that imbalances occurred by chance.
Allocation concealment (selection bias)	Low risk	Allocation was concealed, indicating a low risk of bias.

Mohan 2014 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	"Research staff and patients were not blinded. Investigators and the biostatistician were blinded." Personnel and participants were not blinded to group allocation and medication adherence was measured subjectively.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	"Research staff and patients were not blinded. Investigators and the biostatistician were blinded." Outcome assessors were not blinded and medication adherence was measured via self-report, indicating a high risk of bias.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	No blinding of participants and personnel but medication understanding was objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"208 patients were randomized, 105 to usual care and 103 to the intervention. Upon further assessment, 4 patients were subsequently excluded from each arm for not meeting eligibility criteria, leaving 101 patients in the usual care arm and 99 in the intervention arm. Of those 200 patients, 197 (98.5%) completed the follow-up outcome assessment, including the medication understanding measure." "The primary analysis was an intention-to-treat comparison of medication understanding among patients randomized to receive the intervention versus patients randomized to usual care alone." Attrition rates are low and numbers and reasons for dropouts are reported in figure 2. An intention-to-treat-analysis was performed. Therefore, the risk of attrition bias is low.
Selective reporting (reporting bias)	Low risk	Both outcomes reported in the methods section are reported in the results of the paper.

Ochoa 2020

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** Los Angeles County, USA **Ethical approval:** not reported **Recruitment setting:** at participant's home via telephone **Method of recruitment:** participants were recruited via random digit dialling (RDD) procedures **Length of follow-up:** 6 months post-intervention **Dropouts:** in total, 191 dropped out; 113 did not complete post-test survey, 48 did not complete the survey at all (3) time points, another 31 were not included in the analysis, as they were born in the USA **A priori calculation of effect size/power?:** not reported
Participants	**Description: monolingual Spanish-speaking woman of Mexican origin** **Health topic**

- Cervical cancer

Inclusion criteria

- No pre-existing cervical cancer, 25 to 45 years, self-identified as fluent in Spanish, self-identified as being of Mexican origin, residing in Los Angeles County

Exclusion criteria

- Born in the USA

Note: participants born in the USA were excluded for analysis; authors indicate that "foreign-born and US-born Hispanics show differences of opinion in some key issues."

Intervention group

- "Tamale Lesson/Conversando entre Tamales", a narrative culturally tailored film (128 randomised and 61 analysed)

Control group

- "It's Time/Es Tiempo", a non-narrative film (104 randomised and 48 analysed)

PROGRESS-Plus

Place of residence: urban, USA

Time living in host country (years), mean: 25.12

Race/ethnicity: Hispanic, Mexican

Gender: 100% female

Education: 49.8% < high school, 31.25% high school, 19.0% some college degree

Socioeconomic status/income (annual): 41.6% < USD 20,000, 35.4% USD 20,000 to < 40,000, 16.05% USD 40,000 to < 60,000, 6.9% ≥ USD 60,000

Health insurance: 73.45% insured

Social capital: 78.95% married/living with partner, 10.7% separated/divorced/widowed, 10.35% never married (single)

Age (years), range: 25 to 45

Health literacy (baseline)

Not measured

Interventions

Intervention: narrative culturally tailored film about cervical cancer

Theoretical framework: not reported

Description: participants were exposed to a linguistically and culturally tailored narrative/story-telling film showing a Mexican-American family that prepares for the daughter's birthday party. One of the daughters tells her sister that she had an abnormal Pap test and has been diagnosed with the human papillomavirus infection (HPV). In the course of the film the daughter provides information about HPV, cervical cancer and the importance of Pap tests to detect cervical cancer while the older woman presented in the film recognise the benefits of testing for cervical cancer. At the end of the film the 3 main characters are going to the local clinic for the conducting of a Pap test.

- Intervention provider: not applicable
- Delivery method/mode: 1 (narrative) video session lasting 11 min
- Language of delivery: Spanish
- Format: standard format

Ochoa 2020 *(Continued)*

	- Setting/location: not reported - Consumer involvement: culturally informed through involvement of members from the community of interest **Comparator** Type: factual knowledge video on the same topic Description: Latina women featured film similar in length providing information via charts and figures. It also showed doctors and patients talking about cervical cancer, risk factors and their importance as well as the Pap testing procedure.
Outcomes	Outcomes assessed in the study: knowledge, attitudes towards Papanicolauou test (Pap test), behavioural intentions regarding cervical cancer, testing behaviour **Outcomes considered in this review** - Health literacy ○ Apply (behavioural intentions regarding cervical cancer) - Health-related knowledge (knowledge regarding Pap test and HPV) - Health behaviour (Pap testing behaviour) **Methods of assessing outcomes** Outcomes were assessed via questionnaires; no further information - Knowledge regarding Pap test and HPV: 8 items (open-ended questions, e.g. "Does a woman need a Pap test if she is not sexually active?"), correct/incorrect, 0 to 8, higher score is better - Attitudes towards Pap testing: questionnaire using "a series" of 10-point Likert-Scale ("1 = not at all" to "10 = extremely"), 4 questions measured how embarrassing, physically painful, important and expensive Pap tests were, higher score is better - Behavioural intentions regarding cervical cancer: 2 questions (1) "When did you have your most recent Pap test" at pretest and (2) "Since you saw the film, did you make an appointment for a Pap test?" post-intervention and follow-up, response options were "yes", "no" or "do not know" - Testing behaviour: 1 question ("Since you saw the film, have you had a Pap test?"), response options were "yes", "no" and "do not know" Note: as only monolingual Spanish-speaking Latinas were included, one can assume that the questionnaires were conducted in Spanish. **Timing of outcome assessment:** short-term and medium-term (knowledge was assessed baseline, post-intervention at 2 weeks and at 6-month follow-up, question (1) behavioural intention was assessed at baseline, question (2) was assessed at post-test and at 6-month follow-up, health behaviour was assessed at post-test and at 6-month follow-up)
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools - Knowledge - Motivation Steps of information processing - Access - Understand - Appraise (unclear) - Apply

Ochoa 2020 *(Continued)*

	Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** funding was provided by the National Cancer Institute (NCI) (grant no. RO1CA144052), the SC Clinical and Translation Science Institute at USC (CTSI) (award number UL1TR000130), and the Norris Comprehensive Cancer Center (NCCC) (NCI - P30CA014089).

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"... participants were randomly assigned to one of two experimental conditions: half of the participants were assigned to view the narrative film (Tamale Lesson/ Conversando entre Tamales), and the other half were assigned to view the nonnarrative film (It's Time/Es Tiempo)." "On average, women who were assigned to watch the narrative film reported longer length in the USA (26.6 vs 23.3; p = 0.005) compared with women who were assigned to the nonnarrative film." Insufficient information regarding the randomisation procedure to permit judgement of "high risk" or "low risk"; small sample size so that baseline imbalances might have occurred by chance.
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of high risk or low risk.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	It is not clear whether participants and personnel were blinded. However, interventions only differed in one aspect (narrative versus non-narrative video). We assume that this did not lead to bias.
Blinding of outcome assessment (detection bias) subjective outcome measures	Low risk	Subjective outcomes were measured by repeated questionnaires and participants were probably not blinded to group allocation. However, interventions only differed in one aspect (narrative versus non-narrative video). We assume that this did not lead to bias.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Unclear blinding but knowledge was objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Three hundred women were randomized, a total of 187 women completed the post-test survey, and 140 women completed the surveys at three points in time, of which 109 were included in this study (see Fig. 1). For analysis, we excluded participants who were born in the USA because it has been found that foreign-born and US-born Hispanics show differences of opinion on some key issues." A completers only analysis was conducted. Reasons for excluding US-born Latinas are provided, but numbers of dropouts and reasons for dropouts are not reported per study arm. However, the study compared a variant of the same intervention. Thus, we do not assume that one of the interventions led to a higher attrition rate to any particular degree than the other one.
Selective reporting (reporting bias)	Low risk	All outcomes specified in the methods section are reported in the results.

Otilingam 2015

Study characteristics	
Methods	**Study design:** RCT, 4 arms **Geographic location:** California, Los Angeles, USA **Ethical approval:** yes **Recruitment setting:** predominantly Mexican American community in Los Angeles County **Method of recruitment:** potentially eligible participants were invited via telephone to meet individually with a research assistant at the clinic. Invitations to participate in the nutrition study were issued to a series of random samples drawn from the parent study until a sufficient number of women agreed to participate. **Length of follow-up:** 1 month post-intervention **Dropouts:** 8 (2 in the heart plus brain condition and 3 in the heart only condition received only partial intervention and did not complete post-test); 3 (1 in each intervention group and 1 in the wait-list control group) were lost to follow-up. **A priori calculation of effect size/power?:** not reported
Participants	**Description: healthy Latinas** **Health topic** • Nutrition/heart and brain health **Inclusion criteria** • Being female and being a member of a longitudinal community-wide epidemiological study comprised of a representative sample of Latinos ≥ 40 years of age **Exclusion criteria** • Being on a special diet or already participating in another nutrition class or planning to move out of the area prior to the conclusion of the study **Intervention group 1** • Nutrition and heart health workshop (32 randomised and 29 analysed) **Intervention group 2** • Nutrition and heart health plus brain health workshop (33 randomised and 29 analysed) **Control group 1** • Waiting list control (17 randomised and 16 analysed) **Control group 2** • Post-intervention only waiting list control group (18 randomised and analysed) Note: an intention-to-treat-analysis was performed including all participants randomised; we used completers-only analysis for meta-analysis as final scores were reported for completers only. Results for both completers-only analysis and intention-to-treat-analysis (repeated measures analysis of variance for testing the difference between intervention and control groups) are reported in Table 1, Table 2 and Table 4. **PROGRESS-Plus**

Place of residence: urban, USA

Time living in host country (years), mean: 34.3

Race/ethnicity: Latinas

Gender

- 100% female

Education (highest level): 41.0% none or elementary, 35.0% high school, 10.0% community/technical college, 14.0% college

Socioeconomic status: 39.0% family income ≤ USD 20,000

Social capital (number of children living at home age < 17): mean 2.1

Age (years), mean, range: 58.95, 48 to 84

Health literacy (baseline)

Assessment tool, range, score: NVS, 6 items, 0 to 6, higher score is better

- Intervention group 1 (mean (SD)): 1.31 (1.71)
- Intervention group 2 (mean (SD)): 1.55 (1.60)
- Control group 1 (mean (SD)): 1.25 (1.24)
- Control group 2: not applicable

Interventions

Interventions Nutrition and heart health plus brain health workshop (group 1) and Nutrition and heart health workshop (group 2)*

Theoretical framework: Social Learning Theory and health belief model (Rosenstock 1988); theories/empirical evidence related to literacy in the context of health and limited language proficiency

Description: two workshops with the first one conducted one week after pretest. The workshops included culturally tailored nutrition education techniques. Photographs and other visual aids were featured to circumvent potential concerns of low reading literacy. Both intervention groups received the nutrition education. The additional "Brain Connection" module content was delivered to intervention group 2 only during the first workshop (20 to 30 min). It incorporated research findings about the relationship between metabolic syndrome and increased risk for dementia, a visual representation in which a non-pathological brain was compared with the brain of someone with Alzheimer's disease, research findings about the relationship between saturated fat consumption and increased risk of cardiovascular as well as cerebrovascular diseases, and knowledge about dementia.

- Intervention provider: trained bilingual research assistants
- Delivery method/mode: 2 face-to-face group sessions with up to 7 participants) lasting 2.5 hours (1 week apart)
- Language of delivery: language concordant (74% of the sessions were held in Spanish, the others in English)
- Format: standard
- Setting/location: community clinic
- Consumer involvement: culturally informed and adapted through involvement of members from the community of interest

Comparator

Type (group 3, 4): no health literacy intervention

Description: participants in control group 1 and in control group 2 were offered an invitation to participate in two 2-hour workshops based on materials given to participants in the heart plus brain health condition after the intervention was completed.

Otilingam 2015 *(Continued)*

	*Intervention groups were combined to create a single-pairwise comparison with group 3 for the 1-month follow-up assessment (results for control group 4 were reported post-test only and we used the 1-month assessment for meta-analysis).
Outcomes	Outcomes assessed in the study: health numeracy, dietary fat knowledge, behaviours to reduce dietary fat **Outcomes considered in this review** • Health literacy ◦ Health numeracy • Health-related knowledge (dietary fat knowledge) • Health behaviour (behaviours to reduce dietary fat) **Methods of assessing outcomes** Participants were administered materials orally in Spanish or English per preference; no further information. • Health numeracy: NVS, 6 items to assess reading and numeracy skills, 0 to 6, higher score is better ◦ Reliability/validity: validated in English and Spanish • Dietary fat knowledge: 9 items from the US Department of Agriculture's Diet and Health Knowledge Survey reflecting the learning content, 0 to 9, higher score is better • Behaviours to reduce dietary fat: Fat-Related Diet Habits Questionnaire, 12 items on self-reported frequency of behaviours to reduce fat consumption, mean of 4-point Likert scale (rarely, never, sometimes, often, usually), 1 to 4, higher score is better Language of assessment: per preference (Spanish or English) **Timing of outcome assessment:** baseline, immediately after intervention and at 1-month follow-up (short-term)
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation • Competences Steps of information processing • Understand • Appraise (unclear) • Apply Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** the authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was partially supported by NIH Grants P50 AG005142 (principal investigator [PI]: Helena Chui), R25 MH071544 (PIs: Barry Lebowitz, Jilip Jeste), U10EY11753 (PI: Rohit Varma), a Wallis Annenberg Fellowship (Poorni Otilingam), and an unrestricted grant from Research to Prevent Blindness, New York (Rohit Varma). **Additional notes:** leader manuals and all handouts and posters on the brain condition are available at dornsife.usc.edu/labs/scrap/usc-alzheimers-disease/. Authors provided additional information (e.g. score range for Dietary Fat Habits Questionnaire) on request.

Otilingam 2015 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"The study comprised a randomized controlled trial" "All potentially eligible participants were invited by telephone to meet individually with a research assistant at the clinic to complete the informed consent and to be given a sealed envelope with their random assignment to a study condition (so that research assistants were blind to condition until the envelope was opened)." There is only a statement that the participants were randomised, but no information on the randomisation procedure used. Therefore, information is insufficient to permit judgement of high risk or low risk of bias.
Allocation concealment (selection bias)	Low risk	"All potentially eligible participants were invited by telephone to meet individually with a research assistant at the clinic to complete the informed consent and to be given a sealed envelope with their random assignment to a study condition (so that research assistants were blind to condition until the envelope was opened)."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were not blinded to group allocation due to the nature of the study and health behaviour was subjectively measured. This might have introduced bias.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	Health behaviour was measured via self-report and participants were not blinded to group allocation. This might have introduced bias.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Participants were not blinded but health numeracy and knowledge were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"A total of 100 individuals were randomized to the four conditions, with 92% completing all times of measurement for their condition. Two members of the heart plus brain condition and three members of the heart only condition received only a partial intervention and did not complete the posttest, and another one participant from each intervention condition was lost at follow-up. One member of the wait list control group was lost at follow-up." "PROC MIXED allowed for including all participants, even if they discontinued after providing 1 or 2 times of measurement, or if they were in the posttest only wait list control group." The attrition rate is low and reasons for loss to follow-up are transparently reported, indicating a low risk of bias. An intention-to-treat analysis was performed.
Selective reporting (reporting bias)	Low risk	All outcomes specified in the methods section are reported in the results.

Payán 2020

Study characteristics	
Methods	**Study design:** RCT, 3 arms **Geographic location:** California, USA **Ethical approval:** yes **Recruitment setting:** outpatient clinic waiting rooms in a large public hospital providing care for underserved populations **Method of recruitment:** bilingual, bicultural and trained Latina research staff, approached woman for recruitment and to assess eligibility **Length of follow-up:** 3 months **Dropouts:** completion rate was 100% for the first 2 time points of outcome assessment (baseline and post-intervention); 80.4% completed the 3-month follow-up assessment. In total, 47 did not complete the 3-month follow-up (12 in group 1, 18 in group 2 and 17 in the control group). **A priori calculation of effect size/power?:** not reported
Participants	**Description: low-income Latinas** **Health topic** • Breast cancer **Inclusion criteria** • ≥ 35 years, Spanish-speaking, not pregnant (or desiring to be pregnant in the near future), no prior/current breast cancer diagnosis or use of chemoprevention medications (Tamoxifen, Raloxifene, Tibolone or Arimidex) **Exclusion criteria** • Not reported **Group 1** • CUIDARSE ("taking care of oneself") brochure on breast cancer (79 randomised and 67 analysed at 3-month follow-up) **Group 2** • CUIDARSE ("taking care of oneself") brochure on breast cancer delivered by CHWs (79 randomised and analysed immediately after intervention, at 3-month follow-up 61 analysed) **Group 3** • Spanish-language guide on breast cancer (82 randomised and analysed immediately after intervention, at 3-month follow-up 65 analysed) Note: in this study all study arms are compared to each other. We created a single pair-wise comparison by combining group 1 and 2 and referring to them as the intervention group. We refer to group 3 as the control group. **PROGRESS-Plus** **P**lace of residence: urban, USA Time living in host country (years) (n = 240): 69.9% ≥ 15 y **R**ace/ethnicity: Latinas

Payán 2020 *(Continued)*

	Gender: 100% female **E**ducation: 64.2% ≥ 6th grade level of education Socioeconomic status/ income (annual household income): 93.4% < USD 30,000 Health insurance: 79.6% **S**ocial capital: 46.8% married, 30.5% separated, 22.7% single Age (years), mean (SD), range: 52.3 (8.8), 35 to 72 **Health literacy (baseline)** Not measured
Interventions	**Interventions:CUIDARSE brochure (group 1), CHW-delivered CUIDARSE brochure (group 2)*** Theoretical framework: input-output framework (McGuire 2015), Health Belief Model (Champion 2008) Description: the brochure CUIDARSE contained four fictional narratives describing Latinas with different risk levels for developing breast cancer. The content incorporated information on basic prevention, the risks, advantages and disadvantages of preventive actions and modifiables well as non-modifiable risk factors for developing breast cancer (group 1, 2). The brochure was orally administered by trained CHWs without additional support (group 2). • Intervention provider: trained bilingual CHWs • Delivery method/mode: 1 face-to-face session lasting 15 min (printed brochure orally administered) (unclear whether delivered in group or individually) • Language of delivery: language concordant (bilingual) • Format: standard format • Setting/location: public hospital • Consumer involvement: culturally and linguistically adapted through involvement of members from the community of interest **Comparator** Type: no health literacy intervention (standard brochure) Description: participants in group 3 received a Spanish-language consumer guide on reducing breast cancer risk from the Agency for Healthcare Research and Quality (AHRQ). *Groups were combined to create a single pair-wise comparison.
Outcomes	Outcomes assessed in the study: breast cancer risk knowledge, self-efficacy to access breast cancer-related advice or information, perceived breast cancer susceptibility **Outcomes considered in this review** • Health-related knowledge (breast cancer risk knowledge) • Self-efficacy (self-efficacy to access breast cancer-related advice or information) **Methods of assessing outcomes** Outcomes were assessed via questionnaires, 3-month follow-up assessments were telephone-administered by trained bilingual, bicultural research staff. • Breast cancer risk knowledge: 16 items, including 2 items from the breast cancer knowledge test (breast self-examination and screening knowledge), 1 item on breastfeeding as risk factor and 11 items on risk factors from the intervention brochure, true/false response options, 0 to 16, higher score is better • Self-efficacy to access breast cancer-related advice or information: adapted item from a cancer confidence question in the 2012 Health Information National Trends Survey ("Overall, how confident are

	you that you could get advice or information about breast cancer if you needed it?”), 5-point Likert scale ranging from "completely confident" to "not confident at all", higher score is better Language of assessment: English or Spanish Translation procedure: back-to-back translation, translation discrepancies were resolved by a bilingual committee (principal investigator, project coordinator, and other bilingual and bicultural staff) Reliability/validity: adapted from validated tools, no further information reported **Timing of outcome assessment:** baseline, short-term (immediately post-intervention) and medium-term (at 3-month follow-up)
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation (unclear) Steps of information processing • Understand • Appraise • Apply Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** funding was provided by the AHRQ, Grant No. R18HS019264. **Additional notes:** authors provided additional information (related to intervention delivery and language of assessments) and data (unadjusted mean (SD) for knowledge and self-efficacy) upon request.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Randomization was stratified by recruitment clinic and individual level of education (≥6 or <6 years of education) to prevent imbalanced group assignment due to possible confounders." "The control group had fewer participants born in El Salvador compared to Groups 1 and 2 (13.4% vs. 25.3% vs. 29.1%). The control group also had fewer participants with higher acculturation levels (≥15 years in the United States) compared to Groups 1 and 2 (58.5% vs. 74.7% vs. 75.9%)" Baseline differences were reported for two variables. However, the sample size was small and there is no evidence that there was a problem in the randomisation process.
Allocation concealment (selection bias)	Low risk	"All participants completed a baseline survey before being randomized to one of three study arms using sealed randomization envelopes. Data collectors were blind to the study condition up until this point." Concealment of allocation was ensured through the use of "sealed randomization envelopes", indicating a low risk of bias.

Payán 2020 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel were most likely not blinded to group allocation due to the nature of the study and self-efficacy was subjectively measured. This might have introduced bias.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	Self-efficacy was measured via questionnaire and participants were not blinded to group allocation. This might have introduced bias.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Knowledge was objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"The response rate was 100% at baseline and postintervention (n = 240) and decreased to 80.4% (n = 193) after 3 months." No intention-to-treat analysis was performed. In total, 47 participants did not complete the 3-month follow-up (n = 12 in group 1, n = 18 in group 2 and n = 17 in the control groups) and no reasons are given for the loss to follow-up. However, the differential loss between intervention and control groups is less than 15%, indicating that the reasons for dropouts were not caused by the nature of the intervention.
Selective reporting (reporting bias)	Low risk	All outcomes specified in the methods section are reported in the results.

Poureslami 2016a

Study characteristics	
Methods	**Study design:** RCT, 4 arms **Geographic location:** Vancouver, Canada **Ethical approval:** yes **Recruitment setting:** collaborating physicians' clinics **Method of recruitment:** convenience sampling method: physicians identified participants for the qualitative and quantitative study from the community **Length of follow-up:** 6 months*, outcomes reported were assessed at 3-month follow-up **Dropouts:** 2 (1 Punjabi, 1 Chinese) did not complete 3-month follow-up and were excluded from analysis **A priori calculation of effect size/power?** yes *Inconsistencies in length of intervention in 2 study reports (9-month vs 10-month). However, the intervention was a single exposure to 1 of 2 educational videos or both videos, respectively, or a brief pamphlet (control group). Follow-up tests were conducted immediately post-intervention (1 month after baseline assessment) and at 3-month follow-up. In addition, authors report that a short telephone-based follow-up was conducted at 6-month follow-up, but did not report the results. Figure 1 also indicates a 9-month follow-up assessment that is not reported in the text either.
Participants	**Description: Chinese or Punjabi immigrants with physician-diagnosed asthma using asthma medications daily**

Poureslami 2016a *(Continued)*

Health topic

- All participants had physician-diagnosed asthma

Inclusion criteria

- Physician diagnosis of asthma, used asthma medications daily, ≥ 21 years of age, immigrated to Canada within the past 5 years, resided in Vancouver during the study period, spoke Mandarin, Cantonese or Punjabi

Exclusion criteria

- Not reported

Intervention groups

- **Group 1:** Physician-led video (22 randomised and analysed)
- **Group 2:** Community video (21 randomised and analysed)
- **Group 3:** Physician-led and community videos (20 randomised and analysed)
- **Group 4:** Educational pamphlet (24 randomised and 22 analysed)

Note: according to the flow diagrams shown in the published trial reports (Poureslami 2016a), 21 participants watched the physician-led video (vs 22 according to texts and tables). We used the numbers displayed in texts and tables, assuming that the numbers displayed in the flow diagrams might be wrong.

PROGRESS-Plus

Place of residence: urban, Canada

Time living in host country: participants had immigrated to Canada within the past 5 years

Race/ethnicity: Chinese and Punjabi

Occupation: 21.2% employed, 29.4% unemployed, 43.5% retired, 5.9% volunteer job

- **G**ender: 50.6% female (applies to the entire study population)

Education: 17.6% never attended formal school, 24.7% completed elementary school, 34.1% completed high school, 23.5% post-high-school education

Age (years), mean (SD), range: 62.9 (15.3), 21 to 87

Health literacy (baseline)

Not reported

Interventions

Theoretical framework: theories of health literacy; formative research to inform intervention development

Comparison 1: audio-/visual education without personal feedback versus written information on the same topic

Intervention: clinical, knowledge video, narrative community video or both (groups 1,2, and 3)*

Description: participants watched either one or two educational videos at the clinic or at home. The knowledge video provided clinical information about asthma symptoms, medication techniques and self-management strategies. The correct method of inhaler use was demonstrated by a well-known physician from the same ethnic background as the participants. In the community video, participants and caregivers role-played a scenario, offering opinions and narratives about asthma and its management in short videos. The contents of both videos were similar, showing cultural beliefs and practices from 3 target ethnic communities. The correct way of using inhalers was performed by respiratory educators from the target communities at the end of both the physician-led and community videos.

- Intervention provider: not applicable

- Delivery method/mode: 1 individual video session (either 1 or 2 videos: 1 factual knowledge video (25 minutes) and 1 peer-led (community) video, 12 to 14 minutes)
- Language of delivery: language concordant (all materials were provided in Mandarin and Cantonese (referred to as the "Chinese" group), and Punjabi
- Format: standard
- Setting/location: clinic or home (per preference)
- Consumer involvement: evaluated with participants of the intervention

Comparator

Type: (written information on the same topic

Description: culturally and literacy adapted pictorial pamphlets containing the same information in written format; developed by the research team using a community-based participatory approach.

Comparison 2: culturally and literacy adapted audio-/visual education without personal feedback versus another culturally and literacy adapted audio-/visual education without personal feedback

Intervention: narrative, community video (group 2)

Description: participants watched the narrative, community video (see description above)

Comparator: physician-led, knowledge video (group 1)

Description: participants watched the physician-led, knowledge video (see description above)

*From this study, we have formed two comparisons: firstly, we combined group 1, 2 and 3 to create a single-pairwise comparison with group 4 reporting the results in the comparison 'culturally and literacy adapted audio-/visual education without personal feedback versus written information om the same topic'. Secondly, we compared the results of group 1 with those of group 2, reporting them in the comparison 'culturally and literacy adapted audio-/visual education without personal feedback versus another culturally and literacy adapted audio-/visual education without personal feedback'.

Outcomes

Outcomes assessed in the study: asthma-related knowledge, inhaler use technique, understanding physician's instructions, asthma-related knowledge (knowledge of symptoms, triggers and factors that make asthma worse), qualitative open-ended questions on patients' overall beliefs and concerns about asthma and its management

In addition, authors state that they "added some questions to assess patients’ health literacy" but the results are not reported.

Outcome measures considered in this review:

- Health literacy
  - Competences (inhaler use technique)
  - Understand physician's instruction (i.e. understanding of and adherence to physician's instructions about inhaler use)
- Health-related knowledge (asthma-related knowledge)

Methods of assessing outcomes:

Outcomes were assessed face-to-face (at 3 months) and via telephone by trained bilingual facilitators

- Inhaler use skills acquisition: inhaler use technique: verified by 2 observers (the facilitator and study co-ordinator), participants demonstrated correct use and had to describe each step, 1 point for appropriate use per step, 0 to 9 standard checklist, higher score is better
  - Reliability/validity: not applicable

Note: checklist for inhaler use technique included the following steps: (1) shake device (metered-dose inhaler); (2) load the inhaler; (3) breathe out away from inhaler; (4) put the inhaler in mouth behind teeth; (5) breathe in deeply; (6) hold breath for 5 to 10 seconds; (7) breathe out from nose; (8) wait for 60 seconds before taking the second puff, if needed; and (9) recap and rinse mouth, if needed.

Poureslami 2016a *(Continued)*

	• Understanding of and adherence to physician's instructions: 5 items, asking participants to explain the instruction in their own words, 0 = incorrect, 1 = correct, higher score is better ◦ Language of assessment: Chinese, Punjabi ◦ Reliability/validity: psychometric properties not reported • Asthma related knowledge: functional knowledge of asthma symptoms, triggers, and factors that could make asthma worse, 5-point Likert scale, no score range reported, higher score is better • Language of assessment: Chinese, Punjabi ◦ Reliability/validity: developed by study authors and validated previously within target population, psychometric properties not reported Translation procedure: professional translators translated the written materials to the 3 target languages and provided back-translation **Timing of outcome assessment**: baseline, medium-term (at 3-month follow-up), results of 6-month assessment are not reported
Health literacy	**Definition:** health literacy as "ability to access, understand, and use asthma-related information" (Poureslami 2012, p. 544) **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation Steps of information processing • Understand • Appraise • Apply Health domain: health care
Notes	**Trial ID:** NCT01474928 **Funding:** funding was provided by the Canadian Institutes of Health Research (CIHR) and partly by the Centre for Lung Health at the University of British Columbia. **Additional notes:** authors were contacted and asked for additional information (e.g. with regard to the health literacy assessment) but without success. Data have been extracted from multiple trial reports (see all references related to Poureslami 2016a).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Eighty-seven subjects were randomized into the intervention, and 85 completed the study" Insufficient information to permit judgement of low risk or high risk because there is no information on the method used for randomisation.
Allocation concealment (selection bias)	Unclear risk	No statement on concealment of allocation and whether investigators or participants could foresee assignment. Therefore, the information is insufficient to permit judgement of low risk or high risk.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"The study team was not blind to the subject group assignment. We also involved a family member who normally took care of the subject at home (the immediate caregiver at the home) in the interviews and learning process across the study groups."

Poureslami 2016a *(Continued)*

		According to the study register (clinicaltrials.gov) this was a single-blind study in which only the participants were masked to the group they were assigned to. However, due to the nature of the study, it is unclear whether blinding of the participants was effective. Personnel could have been blinded, but the authors state that they were not. However, the outcomes considered in this review were objectively measured. Thus, we do not assume that non-blinding affected the results.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	"We interviewed each patient alone in their native language to ensure confidentiality. The interviews were facilitated by bilingual and bicultural experienced moderators from the same community who were not aware of the study hypothesis. The facilitators signed an agreement to keep the information confidential." Although it is unclear whether blinding to study hypothesis also includes blinding to the intervention allocation, knowledge, understanding of physician's instruction and inhaler technique acquisition were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Eighty-seven subjects were randomized into the intervention, and 85 completed the study (42 Chinese and 43 Punjabi, age 21–87 y [mean SD 62.9 15.3 y], 42 males and 43 females) (Table 1)." The attrition rate is presented in a CONSORT diagram; the number of dropouts per arm is not explicitly reported in the text. When comparing all numbers across the publications, one could assume that the participants dropped out from the control group. Only 2 participants dropped out in total and reasons are provided, indicating a low risk of bias.
Selective reporting (reporting bias)	High risk	"We assessed patients' functional knowledge, health literacy, and health practices (as explained in the section “Measurement”) related to asthma at the baseline interview (pretest). We then conducted our intervention 1 month immediately after the pretest, and then had a further follow up 3 months post-intervention. Furthermore, 6 months after the post-intervention, the patients were invited to participate in a telephone follow-up survey to assess their self-reported use of the peak flow meter, whether they followed their action plans, and whether they used their prescribed medications regularly." An outcome measure for health literacy is reported in the methods section but not in the result section of the paper. In addition, in the report of time point a (Poureslami 2012), an additional telephone follow-up was conducted to assess medication adherence, but results are not reported in any of the publications.

Poureslami 2016b

Study characteristics	
Methods	**Study design:** RCT, 4 arms **Geographic location:** Vancouver, Canada **Ethical approval:** yes **Recruitment setting:** outpatient respiratory clinics **Method of recruitment:** collaborating physicians identified and referred potential candidates, bilingual facilitators contacted candidates **Length of follow-up:** 3 months*

	Dropouts: no dropouts **A priori calculation of effect size/power?:** yes *Inconsistencies between text and figure 1; according to figure 1 follow-ups should have been conducted at 3, 6 and 9 months after intervention. Quote: "All outcomes were measured at baseline, then at 4 weeks and 3 months after intervention (...) Data were collected over a 4-month period through 3 in-person assessments. The baseline assessment preceded the intervention; the post-intervention assessment occurred immediately following the intervention (4 weeks after baseline); a follow-up assessment occurred 3 months following intervention."
Participants	**Description: Chinese immigrants with chronic obstructive pulmonary disease (COPD)** **Health topic** • All participants had diagnosed COPD by spirometry **Inclusion criteria** • Confirmed COPD diagnosis by spirometry, being symptomatic, an immigrant to Canada within past 20 years, residing in Vancouver, speaking Mandarin or Cantonese **Exclusion criteria** • Self-reported patients, persons < 21 years old, persons who live in a nursing home, unwilling to participate in the study **Intervention groups** • **Group 1:** clinical knowledge video (22 randomised and analysed) • **Group 2:** narrative, community video (26 randomised and analysed) • **Group 3:** clinical and community video (29 randomised and analysed) • **Group 4:** pictorial pamphlet (14 randomised and analysed) Note: according to figure 1, 29 participants watched the clinical video (vs 22 according to the text and to table 1) and 22 participants watched both videos (vs 29 according to text and to table 1). We used the numbers displayed in the text and in table 1, assuming that the numbers displayed in figure 1 might be wrong. **PROGRESS-Plus** **P**lace of residence: urban, Canada Time living in host country: participants had immigrated to Canada within the past 12 years **R**ace/ethnicity: Chinese **G**ender: • 21.9% female (applies to the entire study population) Note: not reported per arm **E**ducation: 46.2% low education, 53.8% high education Age (years), median; distribution: 75; 40.7% ≤ 75, 59.3% > 75 **Health literacy (baseline)** Not measured
Interventions	Theoretical framework: theories of health literacy **Comparison 1: audio-/visual education without personal feedback versus written information on the same topic**

Poureslami 2016b *(Continued)*

Intervention: clinical, knowledge video, narrative community video or both (groups 1, 2 and 3)*

Description: participants watched either a physician-led, knowledge video (group 1), a narrative, community video (group 2) related to COPD management. The researchers used the same content to develop the lay videos and the clinical videos in the 2 languages. In the last scene of both videos, an experienced respiratory educator from the same language group as the participants demonstrated the correct use of different inhalers. The “clinician video” was a 20-minute physician-led video, providing clinical information about COPD symptoms and self-management strategies. In the “lay video,” peer patients role-played a scenario offering opinions and narratives about COPD self-management in a 12-minute video clip. 2 lay videos with similar content in Mandarin and Cantonese languages were developed.

- Intervention provider: not applicable
- Delivery method/mode: 1 individual video session (2 videos: 1 physician-led, factual knowledge video and 1 peer-led (role-played) video
- Language of delivery: language concordant
- Format: standard
- Setting/location: clinic or home
- Consumer involvement: culturally and linguistically adapted through involvement of members from the community of interest

Comparator

Description: easy-to-understand pictorial self-management pamphlet at grade 5 literacy level using the same content from the active intervention in a printed format, translated and back-translated in Cantonese and Mandarin.

Comparison 2: culturally and literacy adapted audio-/visual education without personal feedback versus another culturally and literacy adapted audio-/visual education without personal feedback

Intervention: narrative, community video (group 2)

Description: participants watched the narrative, community video (see description above)

Comparator: physician-led, knowledge video (group 1)

Description: participants watched the physician-led, knowledge video (see description above)

*From this study, we have formed two comparisons: firstly, we combined group 1, 2 and 3 to create a single-pairwise comparison with group 4 reporting the results in comparison 6 'culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic'. Secondly, we compared the results of group 1 with those of group 2, reporting them in comparison 7 'culturally and literacy adapted audio-/visual education without personal feedback versus another culturally and literacy adapted audio-/visual education without personal feedback'.

Outcomes

Outcomes assessed in the study: COPD knowledge**, inhaler technique, understanding of pulmonary rehabilitation procedure*, understanding of steps to manage COPD, self-efficacy for COPD self-management

Outcomes considered in this review

- Health literacy
    - Competences (inhaler use technique)
    - Understand (understanding pulmonary rehabilitation procedure)
- Self-efficacy (self-efficacy for COPD self-management)

*Prioritised outcome in category 'health literacy - understand', as it was unclear how 'understanding of steps to manage COPD was assessed'

**Authors state that "some questions of BRISTOL COPD Knowledge Questionnaire [BCKQ]" (knowledge and actions needed to prevent or treat COPD exacerbation) were used, but the results are not reported.

Poureslami 2016b *(Continued)*

	Methods of assessing outcomes Trained bilingual facilitators assessed outcomes face-to-face. • Inhaler use technique: measured in 2 steps, i.e. (1) participants' ability to correctly use an inhaler and (2) to differentiate between different inhalers (reliever or preventer therapy), participants received a pass/fail score; participants demonstrated correct use and had to describe each step, 1 point for appropriate use per step, validated checklist, direct observation through 2 community facilitators, 0 to 10, higher score is better • Understanding of pulmonary rehabilitation procedure: based on Canadian Thoracic Society COPD assessment guidelines, the team developed a text passage and participants were asked to answer related questions in the checklist to determine their grasp of pulmonary rehabilitation procedures; responses were scored correct = 1 or incorrect = 0, higher score is better • Self-efficacy for COPD self-management: validated COPD Self-Efficacy Scale, short version, 5 items, 5-point Likert scale to rate from 1 (not at all confident) to 5 (totally confident), higher score is better Language of assessment: Cantonese, Mandarin Translation procedure: professional translators translated the written materials and provided back-translation. In addition, translations were reviewed and commented by COPD patients during initial focus groups. Reliability/validity: for self-efficacy, a validated tool was used. **Timing of outcome assessment:** baseline, short-term (at 4 weeks after randomisation; results not reported) and medium-term (at 3-month follow-up)
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation Steps of information processing • Understand • Appraise • Apply Health domain: health care
Notes	**Trial ID:** NCT01474707 **Funding:** funding was provided by an operating grant from CIHR. **Additional notes:** data were extracted from study report and from information collected at clinicaltrials.gov. Authors were contacted and asked for additional information (e.g. with regard to the knowledge assessments) but without success.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Block randomization was applied to assign patients into the study groups, including three experimental groups and one control group. Because of our previous knowledge regarding the re-effectiveness of educational pamphlets on disease management, we applied an unequal randomization approach to deliberately assign more participants in intervention groups. Our aim was to ensure enrolling adequate numbers of participants in the intervention groups to

Poureslami 2016b *(Continued)*

		detect the effect of educational interventions on attainment of self-management skills. It is a helpful approach, particularly when a 2:1 ratio is employed, and we managed our random allocation close to a 2:1 ratio for each intervention/control pairing."
Allocation concealment (selection bias)	Unclear risk	No statement on concealment of allocation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	"Data collection was conducted by trained bilingual facilitators, blinded throughout the study, as was the data analyst." Personnel were blinded throughout the study. However, due to the nature of the study, participants were most likely aware of the intervention to which they were allocated. This might have affected the results of subjectively measured outcomes.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	"Data collection was conducted by trained bilingual facilitators, blinded throughout the study, as was the data analyst. An identical questionnaire was used in the three different assessments." Outcome assessors were blinded. However, self-efficacy was measured subjectively with the use of repeated questionnaires.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	No blinding of participants but understanding of pulmonary rehabilitation procedures was objectively measured and inhaler technique acquisition was assessed objectively by two blinded outcome assessors by means of a checklist indicating a low risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No dropouts, therefore the risk of bias is low.
Selective reporting (reporting bias)	High risk	"Given the lack of an existing COPD self-management questionnaire in Chinese language, the study assessment tool also included some questions developed by the research team using the Bristol COPD Knowledge Questionnaire regarding disease-related knowledge and actions needed to prevent or treat a COPD exacerbation." The results on knowledge were not reported.

Rosal 2005

Study characteristics	
Methods	**Study design:** RCT (pilot), 2 arms **Geographic location:** Massachusetts, USA **Ethical approval:** yes **Recruitment setting:** community health centre (CHC), elder health service (affiliated to the CHC) and online (community-wide database) **Method of recruitment:** participants were randomly recruited by each recruitment site; the director of each site chose 1 of every 5 individuals from a list ordered by a record number. **Length of follow-up:** 6 months after randomisation

Rosal 2005 *(Continued)*

	Dropouts: "Assessment completion rates were 100% at baseline (95% CI = 86%, 100%) and 92% (95% CI = 74%, 99%) at the 3- and the 6-month assessments." No further details reported. **A priori calculation of effect size/power?:** not reported
Participants	**Description: low-income Spanish-speaking individuals with type 2 diabetes** **Health topic** • Diabetes type 2 **Inclusion criteria** • Having a healthcare provider, having a doctor-confirmed diagnosis of type 2 diabetes, ≥ 18 years of age, having a home phone, having a doctor's approval to participate in the physical activity component of the intervention, being able to provide informed consent in English or Spanish **Exclusion criteria** • History of diabetic ketoacidosis, having current gestational diabetes, planning to move out of the area within the study period, using steroids for short periods during the previous year, having had a cardiovascular event within the previous 6 months **Intervention group** • Self-management intervention for metabolic self-control in individuals with type 2 diabetes (15 randomised and analysed) **Control group** • Usual care (no intervention) (10 randomised and analysed) **PROGRESS-Plus** **P**lace of residence: urban, USA **R**ace/ethnicity: Hispanic, Puerto Rican **O**ccupation: 24.0% housewife, 20.0% disabled, 4.0% unemployed, 4.0% never worked, 48.0% pension **G**ender: • Intervention: 80.0% female • Control: 80.0% female **E**ducation: 50.0% ≤ 5th grade, 24.0% 6th to 8th grade, 24.0% 9th to 12th grade **S**ocioeconomic status/income (annual): 84.0% ≤ USD 10,000, 16.0% USD 10,001 to 20,000 Health insurance: 40.0% Medicaid only, 60.0% Medicaid and supplemental Age (years), mean (SD), range: 62.6 (8.6), 45 to 82 **Health literacy (baseline)** Not measured
Interventions	**Intervention: self-management intervention for metabolic self-control in individuals with type 2 diabetes** Theoretical framework: Social Cognitive Theory, intervention delivery was guided by the patient-centred counselling model Description: the intervention consisted of an initial 1-hour individual session, followed by 10 weekly 2.5- to 3-hour group sessions and 2 15-minute individual sessions during the 10-week period immediately prior to the group sessions. The programme was designed to improve diabetes knowledge, atti-

Rosal 2005 *(Continued)*

tudes and self-management skills. For the intervention purpose, a soap opera was read aloud in the group session, which conveyed diabetes-related cues in the context of a love story, as well as self-management and successful coping strategies regarding barriers to diabetes self-management. To enhance the intervention effect, pauses were made during the reading to discuss and emphasise certain aspects. In addition, the intervention used a traffic light system developed with the participants to visually depict educational messages.

- Intervention provider: diabetes nurse, nutritionist and research assistant (known to community residents)
- Delivery method/mode: 1 initial face-to-face individual session lasting 1 hour, 10 weekly face-to-face group sessions lasting 2.5- to 3 hours and 2 individual sessions lasting 15 minutes (immediately prior to group sessions within 10-week period)
- Language of delivery: Spanish
- Format: tailored format
- Setting/location: community room, known to the residents, located near the recruitment sites
- Consumer involvement: culturally adapted through involvement of members from the community of interest

Comparator

Type: written information (simple booklet)

Description: control group participants and intervention group participants received a simple booklet describing the importance of lifestyle factors regarding diabetes management and providing recommendations for diet, physical activity and self-monitoring of blood glucose (SMBG).

Note: the control condition was included to provide data on the feasibility of conducting a future RCT with the target population.

Outcomes

Outcomes assessed in the study: psychosocial variables (diabetes knowledge, self-efficacy for diet, exercise, self-monitoring, oral glycaemic agents, insulin, depression, diabetes-related quality of life), physiological variables (HbA1c, percentage in HbA1c, total cholesterol, high-density/low-density lipoprotein, triglycerides, Log (triglycerides), BMI, waist circumference, systolic/diastolic blood pressure), behavioural variables (physical activity, blood glucose self-monitoring*, dietary intake in total kcal, total fat, saturated fat, total carbohydrates, fibre (no composite score reported))

Outcomes considered in this review

- Quality of life (diabetes-related quality of life)
- Health-related knowledge (diabetes knowledge)
- Self-efficacy (self-efficacy for diet, exercise, self-monitoring, oral glycaemic agents, insulin)
- Health outcome (depression)
- Health behaviour (blood-glucose self-monitoring)

*Prioritised outcome in the category 'health behaviour' based on consensus opinion of the authors

Methods of assessing outcomes

Assessments were telephone administered by a trained, native-Spanish-speaking dietitian (only health behaviour) or interviewer, respectively.

- Diabetes knowledge: Audit of Diabetes Knowledge Scale (ADKnowl), adapted by authors, 23 item-sets (104 items) on various diabetes-related topics, true/false/"don't know", 2 item-sets (7 items) are intended for individuals using insulin and 2 item-sets (9 items) are intended for individual who treat their diabetes with tablets, higher score is better
    - Reliability/validity: internal consistency K-R 20 = 0.78 (n = 41), test-retest reliability r = 0.79 (n = 19)
- Self-efficacy: Insulin Management Self-Efficacy Scale (IMDSES), adapted by study authors, 26 items, 4-point Likert-scale, 1 = "low confidence" to 4 = "high confidence", 26 to 104, higher score is better
    - Reliability/validity: Cronbach's α = 0.84 (n = 48), test-retest reliability = 0.90 (n = 19)

Rosal 2005 *(Continued)*

- Blood glucose self-monitoring: 24-hour recall of self-monitoring blood glucose by asking individuals whether they had checked their blood sugar level in the previous 24 hours, at what time and what value was obtained, lower score is better
- Depression: Center for Epidemiological Studies-Depression Scale (CES-D), adapted by study authors, 20 items, 0 to 60, lower score is better
    - Reliability/validity: Cronbach's α = 0.87 (n = 45), test-retest reliability = 0.64 (n = 16)
- Diabetes-related quality of life: Audit of Diabetes Dependent Quality of Life (ADDQOL), adapted and translated version

Note: details of the tools were taken from various publications, cited by the study authors (ADKnowl: Speight 2001, IMDSES: Bernal 2000, CES-D: Sawyer-Radloff 1977). It is unclear whether the information also applies to the adapted versions. Psychometric properties originate, according to study authors, from "preliminary psychometric data of the adapted scales". Adaption of the tools included the (1) modification for telephone administration by an interviewer and (2) qualitative analysis utilising cognitive interviewing to assess clarity, understanding of instructions and wording of the items for the target population.

Language of assessment: Spanish

Timing of outcome assessment: short-term (3 months after randomisation, which was 2 weeks after the programme was completed), and medium-term (6 months after randomisation)

Health literacy

Definition: not reported

Health literacy components addressed by the intervention

Prerequisites and tools

- Knowledge
- Motivation
- Competences

Steps of information processing

- Access
- Understand
- Appraise
- Apply

Health domain: health care

Notes

Trial ID: not reported

Funding: the study was supported by an American Diabetes Association Innovation Awards supported in part by Novo Nordisk Pharmaceuticals.

Additional notes: authors were contacted and asked for additional information (e.g. gendered scores) but provision was not possible (no longer access to data set).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A list of individuals with type 2 diabetes was randomly generated by each recruitment site (all individuals with a diagnosis of type 2 diabetes at each site had an equal chance of being selected to be in the list), with the director of each site choosing one of every five individuals from a list ordered by record number (...) Upon recruitment and attainment of baseline information, individuals were randomized into either an intervention or a control condition (...) Participants were grouped as closely as possible by age, gender, and insulin

Rosal 2005 *(Continued)*

		status (whether or not they used insulin) and randomized to intervention or control in a 3:2 ratio." Some minor baseline differences for some variables are reported. However, the sample size is very small and the randomisation procedure indicates that these imbalances probably occurred by chance.
Allocation concealment (selection bias)	Unclear risk	Insufficient information to permit judgement of low risk or high risk.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the study, personnel and participants were not blinded; results of subjectively measured outcomes might be biased.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	"In addition, psychosocial measures were previously adapted for use with this population, and assessments were conducted by interviewers who were blind to treatment condition." Interviewers were blinded to study condition, but participants were not. Subjective outcomes were measured with repeated questionnaires.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Interviewers were blinded to study condition, but participants were not. However, knowledge was objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Assessment completion rates were 100% at baseline (95% CI = 86%, 100%) and 92% (95% CI = 74%, 99%) at the 3- and the 6-month assessments." It is unclear if there were any imbalances in the dropout rates between intervention and control group. However, the overall attrition rate is low, indicating a low risk of attrition bias.
Selective reporting (reporting bias)	Low risk	All outcomes specified in the methods section are reported in the results.

Rosal 2011

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** Massachusetts, USA **Ethical approval:** yes **Recruitment setting:** 5 CHCs **Method of recruitment:** research co-ordinators screened participants and obtained primary care providers' (PCP) approval for participation of screened patients; the co-ordinators sent letters signed by PCPs informing patients about the study and then contacted the patients; eligible and interested individuals were scheduled for a recruitment visit where consent procedures were implemented. **Length of follow-up:** 12 months (total programme duration) **Dropouts:** no dropouts **A priori calculation of effect size/power?:** yes

Rosal 2011 *(Continued)*

Participants

Description: low-income Latinos with type 2 diabetes

Health topic

- Type 2 diabetes, last HbA1c (previous 7 months) ≥ 7.5%

Inclusion criteria

- Latino ethnicity, age ≥ 18 years of age, documented diagnosis of type 2 diabetes, last HbA1c (previous 7 months) ≥ 7.5%, ability to walk, no type 1 diabetes or history of ketoacidosis, no medical contraindications to participation, no use of glucocorticoid therapy within the prior 3 months, not currently participating in a cardiac rehabilitation or formal weight loss programme, no plans to move out of the area within the 12-month study period, access to a telephone, ability and willingness to provide informed consent (English or Spanish), physician approval to participate

Exclusion criteria

- Inability to understand and provide informed consent (English or Spanish) to participate, a medical condition that precluded adherence to study dietary recommendations (e.g. Crohn's disease, ulcerative colitis, end-stage renal disease), a cognitive/mental (documented dementia, psychiatric hospitalisation or suicidality within the prior five years) or physical condition (diagnosis of AIDS or hepatitis C) that precluded participation, no telephone or access to one, plans to move out of the area within the 12-month study period, intermittent use of glucocorticoid therapy within the prior 3 months, acute coronary event (myocardial infarction or unstable angina) within the prior 6 months

Intervention group

- Diabetes self-management intervention "Latinos en Control" (124 randomised and analysed)

Control group

- Usual care (no intervention) (128 randomised and analysed)

PROGRESS-Plus

Place of residence: urban, USA

Race/ethnicity: (Caribbean) Latinos

Occupation (n = 230): 11.3% working full or part-time, 3.5% unemployed/looking for a job, 61.7% disabled, 10.9% retired, 12.6% housewife

Gender:

- Intervention: 78.2% female
- Control: 75% female

Education (n = 250): 28.0% ≤ 4th grade, 28.0% 5th to 8th grade, 19.2% 9th to 12th grade (not high school graduate), 24.8% ≥ high school

Socioeconomic status/income (annual) (n = 217): 55.3% < USD 10,000

Health insurance: 89.3% public insurance, 6.0% commercial insurance, 2.8% free care, 2.0% no insurance

Social capital: 25.8% married or living with partner, 39.0% divorced/widowed/separated, 25.2% never married

Age (years): 16.3% 18 to 44 y, 29.8% 45 to 54 y, 32.9% 55 to 64 y, 21.0% ≥ 65 y

Health literacy (baseline)

Not measured

Rosal 2011 *(Continued)*

	Note: literacy was assessed by self-reported education (56% of participants had a formal education ≤ 8th grade).
Interventions	**Intervention: diabetes self-management intervention "Latinos en Control"** Theoretical framework: Social-cognitive Theory, Adult Learning Theory Description: 1-year diabetes self-management programme consisting of an intense phase and a follow-up phase of face-to-face group sessions. In the first session, participants received a 1-hour personalised counselling and cooking. In addition, participants were provided with a pedometer to self-monitor health-related behaviour and physical indicators. The intervention sessions concerned healthy nutrition and food preparation. During group sessions, each participant spent about 10 min in a one-on-one discussion with research staff to talk about behavioural goals, assess progress, feedback and facilitating improvements. Each session, participant's received feedback on their blood glucose variability and their self-management behaviour. • Intervention provider: trained team of 2 leaders and an assistant (either nutritionist or health educator and trained lay individuals or 3 lay individuals supervised by 2 investigators) • Delivery method/mode: 12 weekly face-to-face group sessions lasting 2.5 hours and 8 monthly face-to-face group sessions. First session: 1st hour personalised counselling • Language of delivery: language concordant (bilingual, bicultural) • Format: individually tailored • Setting/location: 1st session as individual 1-hour meeting in the participant's home, the remaining sessions in groups at centrally located community settings (e.g. a Latino centre, a senior centre, a Young Men Christians Association (YMCA) site) • Consumer involvement: culturally adapted through involvement of members from the community of interest **Comparator** Type: usual care (no additional intervention) Description: usual care
Outcomes	Outcomes assessed in the study: diabetes knowledge, self-efficacy in diabetes management, physical activity, blood glucose self-monitoring, HbA1c, dietary intake, diet Note: no composite score for dietary intake and diet reported. **Outcome measures considered in this review** • Health-related knowledge (diabetes knowledge) • Self-efficacy (self-efficacy in diabetes management) • Health behaviour (blood glucose self-monitoring)* *Prioritised outcome in the category 'health behaviour' based on consensus opinion of the authors. **Methods of assessing outcomes** • Diabetes knowledge: subset of ADKnowl, adapted by authors, *presumably* 23 item-sets (104 items) on various diabetes-related topics, true/false/"don't know", 2 item-sets (7 items) are intended for individuals using insulin and 2 item-sets (9 items) are intended for individuals who treat their diabetes with tablets, higher score is better Note: details of the tool have been taken from publications cited by the study authors (Rosal 2003; Speight 2001). It is unclear whether the information also applies to the adapted version and whether the 104-item subset was used. Psychometric properties originate according to study authors from "preliminary psychometric data of the adapted scales". Adaption of the tools included the (1) modification for telephone administration by an interviewer and (2) qualitative analysis utilising cognitive interviewing to assess clarity, understanding of instructions and wording of the items for the target population. The ADKnowl was translated and cross-checked in several stages by several professional English- and Spanish-native translators.

	- Self-efficacy in diabetes management: Lifestyle Self-Efficacy Scale for Latinos with Diabetes (LSESLD), 17 items, 17 to 68, higher score is better Note: the tool has been previously developed and validated by study authors; to be found in Wang 2013. - Blood glucose self-monitoring: unannounced phone calls, 3 recalls per time point (oral assessment including 3 questions on self-monitoring of blood glucose), higher score is better Language of assessment: bilingual (English or Spanish) Translation procedure: translated, validated versions Reliability/validity: self-efficacy: Cronbach's α = 0.85; not reported for knowledge **Timing of outcome assessment:** short-term (12 months after randomisation, immediately after completion of the intervention programme) **Results stratified according to gender:** no
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools - Knowledge - Motivation - Competences Steps of information processing - Access - Understand - Appraise - Apply Health domain: health care
Notes	**Trial ID:** not reported **Funding:** funding was provided by the National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases Grant (no. R18-DK-65985) and a grant from the Robert Wood Johnson Foundation and Novo Nordisk Pharmaceutical (to Milagros C. Rosal). **Additional notes:** authors were contacted and asked for additional information (e.g. gendered scores) but provision was not possible.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	“Randomization was at the individual level and stratified by site, sex, HbA1c level, and insurance status. Within each strata, subjects were randomized in randomly allocated blocks.”
Allocation concealment (selection bias)	Unclear risk	“Given the nature of the study, we could not blind participants’ PCPs; however, providers were not informed of their patients’ study assignments.” Not clearly stated whether blinding refers to concealed allocation.

Rosal 2011 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the study, personnel and participants could not be blinded, indicating a high risk of bias for subjectively measured outcomes.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	Subjective outcomes were measured with the use of repeated questionnaires and participants were not blinded to group allocation. This might have introduced bias.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Knowledge was objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"A total of 252 patients were enrolled and participated in the study, with 128 randomized to the control condition and 124 randomized to the intervention condition." Follow-up data are reported for 252 participants, so it can be concluded that the outcome data are complete, indicating a low risk of bias.
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods section are reported in the results of the paper.

Soto Mas 2018

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** Texas, USA **Ethical approval:** yes **Recruitment setting:** general population **Method of recruitment:** local Spanish radio and television stations announced study **Length of follow-up:** no follow-up **Dropouts:** 18 in the intervention group and 8 in the control group were excluded from analysis (completed less than 75.0% of sessions) **A priori calculation of effect size/power?:** not reported
Participants	**Description: Spanish-speaking adults with low to intermediate English proficiency** **Health topic:** • Cardiovascular health, no specific health problems of participants reported **Inclusion criteria** • Ability to read and write Spanish, ≥ 21 years of age, no previous participation in formal health/cardiovascular education/prevention programme, low to intermediate level of English proficiency, ability to read, write and speak English at a basic level **Exclusion criteria**

- Not reported

Intervention group

- Health Literacy and ESL Curriculum (95 randomised and 77 analysed)

Control group

- Conventional ESL Curriculum (86 randomised and 78 analysed)

Note: only participants who completed more than 75% of the sessions were included in the final analysis.

PROGRESS-Plus

Place of residence: urban, USA

Time living in host country (years) (n = 145): 2.2% < 1 y, 12.7% 1 to 3 y, 8.3% 4 to 7 y, 70.2% 8 y or more, 6.6% missing

Race/ethnicity: Latinos

Gender:

- Intervention: 76.6% female
- Control: 84.6% female

Education (n = 154): 5.2% elementary school, 11.7% middle school, 40.9% high school, 18.8% associate/technical degree, 20.1% bachelor's degree, 1.9% master's degree, 1.3% doctoral degree

Age (years): 9.0% 20 to 30 y, 38.7% 31 45 y, 52.3% ≥ 46 y

Note: complete data provided only for n = 155 analysed participants.

Health literacy (baseline)

Assessment tool, range, level: English TOFHLA (full version) 0 to 100, ≤ 59 inadequate, 60 to 74 marginal, 75 ≤ adequate

- Intervention group, mean (95% CI): 65.5 (62.1 to 68.9)
- Control group, mean (95% CI): 59.9 (56.1 to 63.8)

Interventions

Intervention: Health literacy and ESL curriculum

Theoretical framework: theories of health literacy and health behaviour, sociocultural approaches to literacy and communication, Adult Learning Theory

Description: the intervention consisted of a conventional ESL course, which was extended by health literacy-related content and skills development. It focused on improving English proficiency in listening, speaking, reading and writing while developing health literacy and cardiovascular disease prevention knowledge skills. The health literacy curriculum consisted of 12 separate units that opened with a vignette in Spanish language describing the experiences with health and the healthcare system of a recently arrived immigrant family. The content addressed the development of skills related to prose, documents, numeracy, clinical practices, preventive practices and navigation of the health care system.

- Intervention provider: trained ESL teacher
- Delivery method/mode: 12 face-to-face, group sessions lasting 3.5 hours (total of 42 hours) delivered over a period of 6 weeks
- Language of delivery: English/Spanish
- Format: standard
- Setting/location: 3 community colleges
- Consumer involvement: evaluated with participants of the intervention

Comparator

Soto Mas 2018 *(Continued)*

	Type: usual care (standard ESL course without additional information) Description: a second teacher delivered conventional curriculum to all control groups, the conventional ESL programme is not specific to health literacy but, it includes content related to civic and life skills (e.g. make an appointment, use community resources, communicate schedule information) and maths (e.g. complete a bar graph, calculate net pay), in addition, 2 units are related to health “ailments and injuries,” and “food and nutrition.” Note: standard ESL curriculum already includes health related topics. Therefore, control group assignment might not be accurate.
Outcomes	Outcomes assessed in the study: functional health literacy, cardiovascular health behaviour **Outcomes considered in this review** • Health literacy ○ Functional health literacy • Health behaviour (cardiovascular health behaviour) **Methods of assessing outcomes** Self-administered questionnaires, health literacy assessment, but in group setting; general completion instructions were read out loud to the group. • Functional health literacy: English version of TOFHLA, 0 to 100, ≤ 59 inadequate, 60 to 74 marginal, 75 ≤ adequate, higher score is better • Cardiovascular health behaviour: Cardiovascular Health Questionnaire (CSC), 34 to 136, higher score is better Language of assessment: English (health literacy) and Spanish (health behaviour) Translation procedure: the CRC was a translated version; not reported for health literacy Reliability/validity: validated tools **Timing of outcome assessment:** baseline and short-term (immediately after intervention at 6 weeks after first session)
Health literacy	**Definition:** “The degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions.” (Ratzan 2000, pp. v-vi) **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation • Competences Steps of information processing • Access • Understand • Appraise • Apply Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** funding was provided by the National Heart, Lung, and Blood Institute, National Institutes of Health (Title: Health Literacy and ESL: Integrating Community-Based Models for the U.S.-Mexico Border Region. No. 1R21 HL091820-01A2. PI: Francisco Soto Mas).

Soto Mas 2018 *(Continued)*

	Additional notes: the study was reported in multiple publications. For an overview of the included reports linked to this study, see (Soto Mas 2018). Gendered scores for health behaviour were provided by the study authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Those who met all requirements were randomly assigned to either the intervention or control group. When more than one family member or relative qualified, only one person per household was selected for the study." "Years in the US (P=0.024) and level of education (P=0.022) were the only demographic variable unbalanced between intervention and control at baseline with controls more likely to have lived in the US longer and more likely to have less than high school education. The intervention group had higher TOFHLA and higher numeracy scores at baseline compared to controls." Insufficient information to permit judgement of low risk or high risk, as the method of randomisation is not reported.
Allocation concealment (selection bias)	Unclear risk	No statement on allocation concealment. Therefore, information is insufficient to permit judgement of low risk or high risk.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the study, blinding of participants and personnel was not possible and cardiovascular health behaviour was subjectively measured.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	Cardiovascular health behaviour was measured via self-report and participants were not blinded to group allocation. This might have introduced bias.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Participants and personnel were not blinded but health literacy was objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"All participants who attended the last session completed the posttest. Only participants who completed more than 75% of the sessions were included in the final analysis." The dropout rate was higher for the intervention group compared to the control group (N = 18 vs N = 10); no intention-to-treat analysis was performed, but a completers only analysis was done. However, reasons for dropouts were transparently given, and intervention and control only differed in their content, so that the imbalanced dropout rate was presumably not caused by the intervention.
Selective reporting (reporting bias)	Low risk	All outcomes reported in the methods were reported in the results of the publications.

Sudore 2018

Study characteristics

Methods	**Study design:** RCT, 2 arms

Sudore 2018 *(Continued)*

	Geographic location: California, USA **Ethical approval:** yes **Recruitment setting:** 4 primary care clinics within the San Francisco Health Network **Method of recruitment:** a Health Insurance Portability and Accountability Act (HIPAA) waiver was obtained to identify individuals who met inclusion criteria and exclusion criteria and had upcoming primary care appointments. After receiving clinician approval, recruitment letters were sent, written at a 5th-grade reading level in English or Spanish. If patients did not opt out, staff called them to assess interest and eligibility. **Length of follow-up:** 15 months after randomisation (12 months post-intervention) **Dropouts:** 29 withdrew from intervention group (7 lost interest, 1 was too sick, 9 took study too long, 4 found study upsetting, 3 were too busy, 5 other reasons, not further described); 21 withdrew from control group (5 lost interest, 2 were too sick, 3 took study too long, 1 found study upsetting, 2 were too busy, 8 other reasons, not further described) Note: dropouts are reported for both English and Spanish-speaking participants separately in a supplement file (eTable1). **A priori calculation of effect size/power?:** yes
Participants	**Description: chronically or seriously ill elderly Latinos** **Health topic** • Chronic or serious illnesses; 57.1% reported fair to poor self-rated health **Inclusion criteria** • ≥ 55 years, spoke Spanish well or very well, had 2 or more chronic medical conditions by medical record review, 2 or more visits with a primary care provider (e.g. established care), 2 or more additional outpatient, inpatient or emergency department visits in the past year (e.g. marker of illness) **Exclusion criteria** • Dementia, moderate to severe cognitive impairment, blindness, deafness, delirium, psychosis, active drug or alcohol abuse (determined by their clinician, *International Classification of Diseases, Ninth Revision* codes, medical record review, or in-person screening), lack of a telephone, inability to answer consent teach-back questions within 3 attempts **Intervention group** • Advance care planning program “PREPARE” and easy-to-read Advance Directive (AD) intervention (219 randomised and analysed) **Control group** • Easy-to-read AD-Only intervention (226 randomised and analysed) Note: intention-to-treat analysis was performed to account for missing data. **PROGRESS-Plus** **P**lace of residence: urban, USA Time living in host country (years), mean: 26 **R**ace/ethnicity: White Latino or Hispanic (98.9%), White non-Latino or Hispanic, Multiethnic or other **G**ender: • Intervention: 71.7% female

Sudore 2018 *(Continued)*

	- Control: 72.1% female **R**eligion: 49.9% fairly to extremely religious, 59.6% fairly to extremely spiritual **E**ducation: 83.6% ≤ high school **S**ocioeconomic status/income: 27.4% not enough to make ends meet **S**ocial capital (measure of total support score): 36.7; 37.5% in a marriage or long-term relationship, 88.8% have adult children, 98.0% have a potential surrogate Age (years), mean (SD): intervention group: 64 (6.8); control group: 64 (7.2) **Health literacy (baseline)** Assessment tool, range, level: S-TOFHLA, 0 to 36, 0 to 22 limited, 23 to 36 adequate - Intervention group: 58.9% limited health literacy - Control group: 62.8% limited health literacy Note: BHLS in Spanish and English was used for block randomisation (inadequate vs adequate); C-index = 0.82, (0.77 to 0.87) for inadequate health literacy
Interventions	**Intervention: advance care planning programme “PREPARE” and AD intervention** Theoretical framework: Social-cognitive Theory (Bandura 1977; Bandura 2002; Bandura 2004), Transtheoretical Model (Prochaska 1997), interpersonal communication competence model (Spitzberg 1984; Street 1995; Street 2003) Description: the intervention consisted of a patient-directed, online-advance care planning programme written at 5th grade reading level that participants read in English or Spanish; voice-overs of texts and closed-captioning of videos were provided (www.prepareforyourcare.org). The website consisted of 5 modular skill-building steps and personal values questions about the participant's medical care, the creation of an action plan and participants’ individual wishes. Additionally, participants received an easy-to-read written Advance Directive (AD) to take home alongside the summary of wishes, PREPARE information in pamphlet, booklet and DVD format and the website login. Before the doctor’s visit, participants were reminded to talk to their physician about the PREPARE materials. - Intervention provider: trained research staff - Delivery method/mode: 1 web-based session (interactive website), ongoing access to website, plus literacy adapted printed AD, reminder phone call 1 to 3 days prior to primary care visit - Language of delivery: language concordant (bilingual) - Format: tailored (algorithm-based) - Setting/location: primary care clinic/regular setting (at home) - Consumer involvement: adapted through involvement of members from the community of interest **Comparator** Type: written information on the same topic Description: easy-to-read AD in English or Spanish to read in research offices and to take home.
Outcomes	Outcomes assessed in the study: documentation of new advance care planning (ACP), depression, anxiety, ACP behaviour change and action processes, ease of use and satisfaction with PREPARE, communication quality*, satisfaction with communication*, satisfaction with decision-making*, care consistent with current goals*, barriers to ACP*, attitudes about ACP* **Outcomes considered in this review** - Health outcome (depression) - Health behaviour (documentation of new ACP) - Adverse events (anxiety)

Sudore 2018 *(Continued)*

* results are not reported.

Methods of assessing outcomes

Face-to-face or phone-based assessment by blinded interviewer.

- Documentation of new ACPs: composite variable of legal forms (ADs durable power of attorney for health care, Physicians Orders for Life Sustaining treatment) and/or documented discussions (documentation of oral directives or goals of care noted in medical record)

Notes: all notes in the medical record were handsearched; forms and discussions were assessed separately; 2 independent, blinded reviewers double-coded primary outcomes.

- Depression: Patient Health Questionnaire (PHQ-8), 8 items, 0 to 24, cut-point ≥ 10 (moderate or severe depressive symptoms), lower score is better

Note: authors refer to depression and anxiety as adverse events. According to our pre-defined outcome categories, we report only anxiety as a potential adverse event related to the intervention.

- Anxiety: Generalised Anxiety Disorder-7 (GAD-7) questionnaire, 7 items asking the frequency of anxiety symptoms in the last 2 weeks, Likert scale ranging from 0 (not at all) to 3 (nearly every day), 0 to 21, lower score is better

Language of assessment: Spanish

Reliability/validity: validated tools

Timing of outcome assessment: long-term (15 months after randomisation, which was at 12-month follow-up)

Adverse events: adjusted mean depression and anxiety scores did not differ between study arms.

Health literacy

Definition: not reported

Health literacy components addressed by the intervention

Prerequisites and tools

- Knowledge
- Motivation

Steps of information processing

- Understand
- Appraise
- Apply

Health domain: health care

Notes

Trial ID: NCT01990235

Funding: funding was provided by grant from the National Institutes of Health (NIH) National Institute on Aging (NIA) (no. R01 AG045043) and a Patient-Centered Outcomes Research Institute (PCORI) Award (CDR-1306-01500). Funding was obtained by Rebecca L. Sudore.

Additional notes: the trial is reported in multiple publications including results of qualitative formative research. We have chosen the publication in which the results of the primary outcomes are reported. For a full overview of included publications related to this study, see Sudore 2018 [https://revman.cochrane.org/#/296117111501030413/dashboard/htmlView/1.203.173?revertEnabled=false&versionWithProductionChanges=false#STD-Sudore-2018].

Baseline characteristics and results for both Spanish-speaking and English-speaking participants were reported separately. We only used the data available for Spanish-speaking participants and calculated relative numbers, when necessary, based on the reported information. Gendered scores for the outcome documentation of ACP planning were obtained from the study authors.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A statistician not involved in recruitment or data collection uses a computer-based random number generator to create a randomisation scheme using block randomisation by health literacy (adequate health literacy vs limited health literacy, as determined by a validated question concerning confidence with medical forms). Random block sizes of 4, 6 and 8 are used to ensure an equal number of patients with limited health literacy in each group. Randomisation information is associated with a unique patient identification number and is kept separate from other patient data." Higher rate of prior documentation of ACP among Spanish speakers in the AD-only arm compared with Spanish speakers in the PREPARE arm. However, the type of randomisation indicates random imbalances.
Allocation concealment (selection bias)	Low risk	"Clinicians were blinded. Participants could not be blinded but were told during consent there was a “50-50 chance” of getting 1 of 2 ACP interventions, and the nonassigned intervention was not described." This method of randomisation reduces foreknowledge of group allocation, indicating a low risk of bias.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	"Participants are told that each research participant will review one of two guides, but study participants are blinded as to which guide is the active intervention and which is the active control. Since each group obtains ACP materials, such as the easy-to-read advance directive, blinding is enhanced." Besides best attempts to blind the participants, the nature of these interventions does not allow for complete blinding of the participants. However, since participants only knew that they would review one of two ACP materials, the risk of bias is reduced to a low to moderate level.
Blinding of outcome assessment (detection bias) subjective outcome measures	Low risk	"Participants are told that each research participant will review one of two guides, but study participants are blinded as to which guide is the active intervention and which is the active control. Since each group obtains ACP materials, such as the easy-to-read advance directive, blinding is enhanced. To ensure blinding of all outcome assessments, research staff who conduct follow-up interviews are never the same staff member who completed the baseline interview and randomisation for that participant. At the start of all follow-up interviews, participants are reminded not to discuss the study materials they reviewed. If, however, during the follow-up interview, the research assistant becomes unblinded (eg, the participant mentions the PREPARE website), this information is noted in our database, and the participant is assigned to a new blinded research assistant for all subsequent interviews." See comment above.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	"All primary outcome data were double-coded by 2 independent, blinded reviewers as described in the trial protocol in Supplement 1". Personnel were blinded for outcome assessment. ACP documentation is an objective outcome, as it does not require subjective judgement.

Sudore 2018 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	The authors report the numbers of participants lost to follow-up in a CONSORT diagram and provide reasons for dropouts. An intention-to-treat-analysis was performed, indicating a low risk of bias.
Selective reporting (reporting bias)	Unclear risk	Results for the outcomes communication quality, satisfaction with communication, satisfaction with decision-making, care consistent with current goals, barriers to ACP and attitudes about ACP are not reported. However, these measures were not pre-specified at clinicaltrials.gov, but in one of the two published study protocols (see secondary reference, Sudore 2016). It is unclear whether these measures were used as process variables or whether it was intended to assess these as outcome variables, and whether the results for these outcomes are yet to be published.

Taylor 2011

Study characteristics	
Methods	**Study design:** cluster-RCT, 2 arms **Geographic location:** British Columbia, Canada **Ethical approval:** yes **Recruitment setting:** 6 community-based organisations that provide ELSA education **Method of recruitment:** a regular ESL-class teacher and a project teacher collaborated for recruitment; a regular teacher explained the purpose and eligibility criteria for the study, but all students could attend the health education class. Project staff then distributed Chinese language recruitment flyers (which provided detailed information about the project) and answered questions. **Length of follow-up:** 6 months **Dropouts:** 38 refused to complete a follow-up survey, could not be contacted after multiple attempts or had disconnected phones and/or email addresses. Thereof, 15 in the intervention group and 23 in the control group. Note: dropout rates are not displayed per study arm. **A priori calculation of effect size/power?:** not reported
Participants	**Description: Asian immigrants visiting ESL class** **Health topic** • Hepatitis B prevention, no specific health problems of participants reported **Inclusion criteria** • No testing for hepatitis B, of Asian descent, speaking Cantonese, Farsi, Korean, Mandarin or Punjabi **Exclusion criteria** • Not reported **Intervention group** • ESL curriculum addressing hepatitis B (95 randomised and 80 analysed) **Control group** • ESL curriculum addressing physical activity (123 randomised and 100 analysed)

Taylor 2011 *(Continued)*

	Note: 40 classes were randomised to hepatitis B curriculum and 40 classes were randomised to physical activity curriculum; 218 fulfilled inclusion criteria. Analysis included only the participants who provided follow-up data (180). Generalised estimating equations were used to account for cluster-randomisation. **PROGRESS-Plus** **P**lace of residence: urban, Canada Time living in host country (years): 45.0% < 2 y, 55.0% ≥ 2 y **R**ace/ethnicity: Asian **G**ender: - Intervention: 66.0% female - Control: 70.0% female **E**ducation (years): 65.0% < 16 y, 35.0% ≥ 16 y **S**ocial capital: 86.0% currently married, 14.0% not currently married Age (years): 46.0% < 40 y, 54.0% ≥ 40 y Note: data are provided only for analysed participants. **Health literacy (baseline)** Not measured
Interventions	**Intervention: ESL Curriculum addressing Hepatitis B** Theoretical framework: Health Behavior Framework (Curry 1994) Description: the ESL curriculum consisted of partner exercises and group exercises related to hepatitis B including information about the high rate of HBV infection in Chinese-Canadian communities, the ways in which hepatitis B can be transmitted from one person to another and potential consequences of hepatitis B infection. At the end of the ESL classes, students received a pamphlet (with Chinese and English text) entailing key learning points. - Intervention provider: trained ESL teacher - Delivery method/mode: 1 face-to-face, group session lasting 3 hours - Language of delivery: course adapted to low language proficient audience (including trilingual material) - Format: standard - Setting/location: community setting (regular classrooms) - Consumer involvement: informed through involvement of members from the community of interest **Comparator** Type: unrelated health literacy intervention Description: 3-hour ESL curriculum about physical activity
Outcomes	Outcomes assessed in the study: hepatitis-B-related knowledge, hepatitis B testing **Outcomes considered in this review** - Health-related knowledge (hepatitis B knowledge) - Health behaviour (hepatitis B testing) **Methods of assessing outcomes** An interviewer conducted a telephone interview at 6-month follow-up.

Taylor 2011 *(Continued)*

	• Hepatitis B knowledge: questionnaire with 5 items, true/false questions (e.g. whether immigrants are more likely to be infected with hepatitis B than people who were born in Canada; hepatitis B can be spread during childbirth, during sexual intercourse and by sharing razors; and hepatitis B infection can cause liver cancer), 0 to 5, higher score is better • Hepatitis B testing: medical record, participants who indicated he/she had been tested for HBV in the time of follow-up, HBV testing records from the healthcare provider (participants signed a medical release form giving project staff permission to request medical record) Language of assessment: Chinese, Farsi, Korean, Punjabi Translation procedure: study material (e.g. consent form and questionnaires) was translated into Chinese, Farsi, Korean and Punjabi using forward-translation, back-translation and reconciliation. Reliability/validity: not reported **Timing of outcome assessment**: only post-intervention assessment, medium-term (at 6-month follow-up)
Health literacy	**Definition**: not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation • Competences Steps of information processing • Access • Understand • Appraise • Apply Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** funding was provided by grant (no. R01-CA-113663) from the US National Cancer Institute. One of the authors (Dr. C. Bajdik) is the recipient of a Scholar Award from the Michael Smith Foundation for Health Research. **Additional notes:** authors were contacted and asked for additional information (e.g. knowledge scores) but without success (study too old, authors no longer have access to the data).

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"A blocked randomization scheme was used whereby classes from each of the six participating community organizations formed a stratum and were randomized within the stratum. Students who had never received serologic testing for HBV were identified from a self-administered baseline survey. Each student who attended a project class and indicated he/she had never been tested for HBV was asked to complete an interviewer-administered follow-up survey six months after attending his/her project class."
Allocation concealment (selection bias)	Low risk	"Certified ESL teachers with experience in teaching ELSA level three classes were hired and trained (in either the HBV or physical activity curriculum). Different teachers delivered education to the experimental and control group

Taylor 2011 *(Continued)*

		classes." Project staff collaborated with the regular teacher and project teacher for each class to schedule recruitment and associated project classes. Project classes were generally scheduled within one week of recruitment classes. At each recruitment class, the regular teacher explained that the study would see if health education in English classes can improve immigrants' health; a guest speaker would be coming to the class to provide instruction about a health topic; and only students who spoke Cantonese, Farsi, Korean, Mandarin, and Punjabi were being invited to be part of the study (but all students could attend the health education class). Project staff then distributed recruitment flyers in the study languages (that provided detailed information about the project) and answered questions." The intervention was delivered by externally hired teachers, whereas the project staff and regular teachers informed the participants about the study without mentioning the content of the intervention. Therefore, foreknowledge of group allocation is unlikely for both intervention provider and participants.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Personnel and participants were not blinded to group allocation due to the nature of the study, but outcomes were objectively measured and not subject to interpretation.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Participants and personnel were not blinded. However, knowledge was objectively measured by a true/false questionnaire and HBV testing was objectively assessed by verifying self-reported HBV testing through medical record review.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Follow-up surveys were completed by 180 (83%) of the 218 students who had no history of hepatitis B testing. (The other 38 students refused to complete a follow-up survey, could not be contacted after multiple attempts or had disconnected phones and/or email addresses). Therefore, our analysis included 180 students." N = 38 refused to complete a follow-up survey (n = 15 in the intervention group and n = 23 in the control group). The authors report attrition rates per group and provide reasons for loss to follow-up. Differential loss between the intervention and control group is less than 15%.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported in the methods are reported in the results of the paper.
Selective recruitment of cluster participants	Unclear risk	No information about the time point when participants were recruited and enrolled.
Other bias	Unclear risk	"Because the study randomization was by group rather than by individual, Generalized Estimating Equations (GEE) were also used for the evaluation. Our multivariable GEE analyses adjusted for the following variables: ESL organization, class time (day versus evening), country of origin (China, India, Iran, or other Asian country), years since immigration (<2 versus ≥2), gender, age in years (<40 versus ≥40), years of education (<16 versus ≥16), and marital status (currently married versus not currently married)." The authors state that they accounted for clustering in the analysis. This does not relate to the data we considered in the meta-analysis, but we re-analysed the data with the use of the ICC reported by Han 2017. Therefore, we assume a low risk of bias in this domain.

Thompson 2012

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** Maryland, USA **Ethical approval:** yes **Recruitment setting:** urban hospital-based academic paediatric clinic **Method of recruitment:** 2 trained bilingual, bicultural research assistants recruited parents in the clinic waiting room; interested parents were consented by the use of an oral consent process. **Length of follow-up:** no follow-up **Dropouts:** no dropouts **A priori calculation of effect size/power?:** yes
Participants	**Description: low-income Spanish-speaking parents of infants and toddlers** **Health topic** • Child nutrition and feeding **Inclusion criteria** • Spanish-speaking self-reported Latino adults who were the primary caregiver to a child < 3 years **Exclusion criteria** • Parents who had a child < 3 years with significant medical issues requiring special nutritional or feeding needs **Intervention group** • Nutrition education via touchscreen (80 randomised and analysed) **Control group** • Usual care (80 randomised and analysed*) Note: 2 participants in the control group were excluded from the analysis because they were missing any responses to the knowledge questionnaire. However, these participants were included in the analysis for the secondary outcome 'planned changes in behaviour'. **PROGRESS-Plus** **P**lace of residence: urban, USA Time living in host country (years), mean (n = 158): 6.02 **R**ace/ethnicity: Latinos/Latinas **G**ender (n = 148): • Intervention: 94.0% female • Control: 91.0% female **E**ducation (years) (n = 159): 41.0% 6 y or less, 51.0% 7 to 12 y, 8.0% some or all of university degree **S**ocioeconomic status/income: "low-income" population (Thompson 2012) Health insurance: "More than 95% of clinic patients are publicly insured" (Thompson 2012, p. 413) **S**ocial capital (number of children), mean: 2.3

Thompson 2012 *(Continued)*

	Age (years), mean: 27.55 **Health literacy (baseline)** Not measured
Interventions	**Intervention: nutrition education via touchscreen** Theoretical framework: behavioural, cognitive and humanistic learning theories, Health Belief Model, cultural targeting strategies Description: the intervention group members viewed 5 culturally and linguistically adapted modules on nutrition and feeding presented on an interactive platform using a touchscreen computer. The modules contained a series of short educational messages and included text, pictures and audio material that accounted for the educational levels and health literacy of the participants. The modules were interactive, meaning questions requiring participants' responses with feedback given. Content was partly tailored based upon these responses. • Intervention provider: not applicable • Delivery method/mode: 1 individual web-based session (interactive touchscreen computer, 5 modules of 2 to 8 min, total duration approximately 25 min) • Language of delivery: language concordant • Format: partly tailored (algorithm-based) • Setting/location: semi-private office setting • Consumer involvement: no **Comparator** Type: usual care (no additional intervention) Description: participants in the control group did not receive any intervention.
Outcomes	Outcomes assessed in the study: parental nutrition and feeding knowledge, planned changes in behaviour **Outcomes considered in this review** • Health literacy ○ Apply (behaviour intent) (planned changes in behaviour) • Health-related knowledge (parental nutrition and feeding knowledge) **Methods of assessing outcomes** Face-to-face orally administered questionnaires by trained bilingual research assistants • Parental nutrition and feeding knowledge: 19 questions including 12 true/false questions and 7 multiple choice questions (4 options) related to breastfeeding (5 questions), formula (3 questions), solid foods (3 questions), milk (4 questions) and juice (4 questions), 0 to 19, higher score is better • Planned changes in behaviour: 3 questions including 1 question related to planned changes in behaviour on the basis of the lessons learned ("yes"/"perhaps"/"no"), 1 open-ended question on exactly what behaviours participants want to change, and 1 question on plans about talking to the child's doctor, family or friends about the information (yes, probably, no) Language of assessment: language concordant Translation procedure (if necessary): back-translation technique Reliability/validity: developed for the study, no psychometric properties reported **Timing of outcome assessment:** baseline, short-term (immediately after intervention)
Health literacy	**Definition:** not reported

	Health literacy components addressed by the intervention Prerequisites and tools • Knowledge • Motivation Steps of information processing • Understand • Appraise • Apply Health domain: disease prevention (prevent childhood diseases through nutritional failure)
Notes	**Trial ID:** NCT01272492 **Funding:** funding was provided by Johns Hopkins University.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Participants were randomized by the use of a block randomization process. We used block randomization, 10-per-block, to prevent sample size imbalances which could affect the study's power. At the start of the trial, an opaque container was filled with 10 envelopes with equal representation of intervention and control assignments. The research assistant removed an envelope from this container to determine each participant's group assignment. After ten participants, she repeated the process."
Allocation concealment (selection bias)	Low risk	The randomisation procedure used indicates a low risk of selection bias.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of participants and personnel was not reported and behaviour intent was subjectively measured. It is unclear whether the results were affected.
Blinding of outcome assessment (detection bias) subjective outcome measures	Unclear risk	Participants were probably not blinded to group allocation and behaviour intent was assessed using a verbally administered questionnaire.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Unclear blinding but knowledge was objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Only 2 participants were missing any responses to the knowledge questions.These individuals were not included in the analyses for the total summed knowledge score and the breastfeeding domain-specific summed knowledge score." No participant was lost to follow-up and only 2 participants were excluded from the analysis due to missing responses.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported at clinicaltrials.gov are reported in the published reports.

Tong 2017

Study characteristics	
Methods	**Study design:** cluster-RCT, 2 arms **Geographic location:** California, USA **Ethical approval:** yes **Recruitment setting:** community, community-based organisations (e.g. Hmong Women's Heritage Association (HWHA)) **Method of recruitment:** lay health educators (LHE) were recruited through Hmong radio and HWHA clients. After receiving training on participant recruitment, LHEs recruited participants through their own social networks. Participants were recruited through radio announcements and HWHA clients, each LHE recruited 12 to 15 participants. **Length of follow-up:** 6 months after first session (3 months after intervention programme was completed) **Dropouts:** 1 in the intervention group (could not be contacted), 4 in the control group (could not be contacted) **A priori calculation of effect size/power?:** yes
Participants	**Description: Hmong Americans without personal history of CRC** **Health topic** • Colorectal cancer (CRC), no specific health problem of participants reported **Inclusion criteria** • For LHEs: to be Hmong, ≥ 50 years of age, similar to trial participants, but due to recruitment problems, the lower age cut-off was changed to 18 years (starting in wave 2) • For participants: 50 to 75 years, self-identifying as Hmong, speaking Hmong or English, living and intending to stay in the area for at least 6 months, having no personal history of CRC, having no medical problems preventing them from attending sessions, being willing to participate in a study about CRC screening or nutrition and physical activity (NPA) Note: randomisation was conducted on the level of LHE. The intervention was implemented in 3 time periods (waves). Each LHE participated only in 1 wave. 29 Hmong LHEs (aged 21 to 55, 82.7% women, 14 in the intervention group) were recruited. One LHE in the control group dropped out before study activities began, and that LHE's 2 participants were assigned to another control group LHE. **Exclusion criteria** • Personal history of CRC, medical problems that may prevent them from attending 2 educational sessions **Intervention group** • CRC education (161 randomised and analysed) **Control group** • NPA education (168 randomised and analysed) **PROGRESS-Plus** **P**lace of residence: urban, USA

Tong 2017 *(Continued)*

	Time living in host country (years), mean (SD), range; distribution: 15.4 (9.7), 1 to 62; 83.6% > 10 y, 16.4% ≤ 10 y **R**ace/ethnicity: Hmong Americans (born in Laos) **O**ccupation: 90.9% not employed **G**ender: • Intervention: 73.9% female • Control: 74.4% female **E**ducation: 88.8% no formal education **S**ocioeconomic status/income (annual): 53.8% < USD 20,000, 4.0% USD 20,000 or more, 42.2% don't know/missing Health insurance: 95.1% insured **S**ocial capital: 65.3% married or living with a partner Age (years), mean; distribution: 60.4, 73.3% 50 to 64 y, 26.7% 65 to 75 y **Health literacy (baseline)** 88.8% of participants had no formal education, indicating low literacy even in their native language.
Interventions	**Intervention: CRC education** Theoretical framework: Social-cognitive Theory (Bandura 1977; Bandura 2002; Bandura 2004), Transtheoretical Model (Prochaska 1997) Description: LHEs were trained to deliver CRC prevention information. The intervention addressed (1) knowledge of CRC risk and prevention, (2) expectations about CRC screening, (3) self-efficacy and (4) intention (motivation and readiness to obtain screening). A CRC flip chart was supposed to encourage CRC screening by describing needs and benefits of screening, screening frequency and barriers to screening. For the flip chart, cultural images and translation were adapted. • Intervention provider: trained LHE • Delivery method/mode: 2 face-to-face group sessions lasting approximately 90 min, separated by 2 months, 2 follow-up phone calls 1 month after each session • Language of delivery: language concordant (bilingual) • Format: standard • Setting/location: not reported • Consumer involvement: informed by a qualitative study with another study population (with a different ethnic background) **Comparator** Type: unrelated health literacy intervention Description: 2 lectures on healthy nutrition for cardiovascular health and diabetes prevention delivered by health educators. The follow-up telephone calls for the control group were conducted by NPA LHEs who asked participants about their diet.
Outcomes	Outcomes assessed in the study: CRC awareness, CRC knowledge**, CRC ever screening, up-to-date CRC screening* **Outcomes considered in this review** • Health-related knowledge (CRC knowledge) • Health behaviour (up-to-date CRC screening)

Tong 2017 *(Continued)*

	*Prioritised outcome measure based on consensus decision of the authors; **We only report the results of CRC knowledge as awareness reflects subjective rather than objective knowledge of colorectal screening measures. **Methods of assessing outcomes** • Knowledge about CRC screening: 5 questions, (1) heard of colon polyps, (2 to 4) frequency of testing for FOBT (yearly), sigmoidoscopy (every 5 years) and colonoscopy (every 10 years), and (5) age of screening starts at 50, 0 to 5, higher score is better • Up-to-date CRC screening: self-reported up-to-date CRC screening (FOBT at 1 year, sigmoidoscopy at 5 years, or colonoscopy at 10 years) Language of assessment: bilingual (Hmong and English) Note: translation procedure and reliability/validity were not reported. **Timing of outcome assessment:** medium-term (6 months after first session)
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation • Competences Steps of information processing • Access • Understand • Appraise • Apply Health domain: disease prevention
Notes	**Trial ID:** NCT01904890 **Funding:** funding was provided by the National Cancer Institute (no. U54 CA153499). Tung T. Nyguyen, Susan Stewart and Moon S. Chen, Jr. contributed funding acquisition. **Additional notes:** We would have included CRC screening intention (reported as an outcome measure at clinicalTrials.gov) in our analysis as an outcome measure for "apply" health information, but results are not reported. Authors were contacted and asked for additional information (e.g. gendered scores) but without success.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"We used a two-arm cluster randomized controlled trial (RCT), with clustering at the level of the LHEs, who were recruited through Hmong radio and HWHA clients. After receiving training on participant recruitment, LHEs recruited participants through their own social networks. Some participants were recruited through radio announcements and HWHA clients. LHEs were randomized by a computer programme to either the intervention or control arm after completing recruitment." Randomisation was conducted at the level of the LHE. The LHE recruited the participants on their own. However, since the LHE educators were randomised

Tong 2017 *(Continued)*

		after completing the recruitment, the risk of selective recruitment of cluster participants is low.
Allocation concealment (selection bias)	Low risk	"The LHEs were trained on protection of human subjects in recruitment and participation but did not administer consent. Following the training, each LHE recruited 12–15 participants using a script describing the purpose of the project and scope of participant involvement. After completing recruitment and being randomized, the intervention LHEs received a second training session to conduct small group sessions and deliver CRC information. The control LHEs did not receive a second training session as the HWHA staff delivered the NPA information." "Third, it is possible that LHEs may choose participants who may be more likely to get screening, but we attempted to deal with this selection bias by blinding LHEs and participants to study arm assignment until after recruitment was completed.”
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding was not possible due to the nature of the study and CRC screening was assessed via self-report.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	CRC screening was assessed via self-report and participants were not blinded to their allocated group, which might have introduced bias.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	No blinding but knowledge was objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"The retention rate at 6-month follow-up was 98%, with 5 participants who could not be contacted." "All participants were included in analyses regardless of prior CRC screening history. Generalized estimating equations (GEE) were used in all models to account for clustering by LHE. Analyses were conducted on an intention-to-treat basis, with baseline values carried forward for dropouts. All analyses were conducted with SAS software, version 9.3 (SAS Institute, Inc., Cary, NC); statistical significance was assessed at the 0.05 level (2-sided)." N = 1 in the intervention group and N = 4 in the control group dropped out, with reasons provided. The attrition rate indicates a low risk of bias, as outcome data are available for nearly all participants randomised.
Selective reporting (reporting bias)	High risk	CRC screening intention was pre-specified as an outcome measure at clinicaltrials.gov, but the results are not reported.
Selective recruitment of cluster participants	Low risk	Participants were recruited prior to randomisation of the LHE, indicating a low risk of recruitment bias.
Other bias	Unclear risk	"Generalized estimating equations (GEE) were used in all models to account for clustering by LHE. Analyses were conducted on an intention-to-treat basis, with baseline values carried forward for dropouts. All analyses were conducted with SAS software, version 9.3 (SAS Institute, Inc., Cary, NC); statistical significance was assessed at the 0.05 level (2-sided)." The authors accounted for clustering by LHE. We re-analysed the data for the outcome 'up-to-date colorectal cancer screening', but the results for the outcome 'knowledge' were not reported in a way in which we could verify if ad-

	justed values were reported (proportions of correct answers were reported only) and the data could not be re-analysed. Thus, we do not know if a unit of analysis error is present for the outcome 'knowledge'.

Unger 2013

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** California, USA **Ethical approval:** not reported **Recruitment setting:** 3 community adult schools **Method of recruitment:** students enrolled in all classes were invited, except for classes related to medical education (e.g. medical assistant) **Length of follow-up:** 1 month **Dropouts:** no dropouts **A priori calculation of effect size/power?:** not reported
Participants	**Description: healthy immigrant Latinos currently enrolled in community adult schools** **Health topic** • No specific **Inclusion criteria** • Not reported **Exclusion criteria** • Not reported **Intervention group** • Fotonovela "Secret Feelings” (83 randomised and 69 analysed) **Control group** • Text pamphlet on depression (84 randomised and 70 analysed) Note: 185 participants were randomised either to intervention or control group, 135 were analysed. 18 were excluded from the analysis because they did not self-identify as Hispanic/Latino (3 were White, 3 were African American, 1 was "Other" and 11 did not answer the question). Authors provided numbers of participants randomised and analysed on request. **PROGRESS-Plus** **P**lace of residence: urban, USA Time living in host country (years): 43.2% 11 y or more, 18.7% 6 to 10 y, 13.7% 1 to 5 y, 5.8% less than 1 y, 2.9% missing **R**ace/ethnicity: Hispanics/Latinos **G**ender:

Unger 2013 *(Continued)*

	- 47.5% female (applies to the entire study population) Note: not reported per arm **E**ducation: 62.6% less than high school, 37.4% high school or more Age (years), mean (SD), range; distribution: 35.8 (12.9), 18 to 90; 34.5% 18 to 29, 25.2% 30 to 39, 20.9% 40 to 49, 13.7% 50 to 59, 2.9% 60 to 90, 2.9% missing **Health literacy (baseline)** Not measured
Interventions	**Intervention: fotonovela "Secret Feelings"** Theoretical framework: Theory of Planned Behavior, Theory of Reasoned Action (Ajzen 1991; Fishbein 1975) Description: participants read the fotonovela "Secret Feelings", a 30-page comic book-sized fotonovela, printed in Spanish and English at 4th grade reading level. The fotonovela was about a Latino family coping with depression. The main educational messages embedded in the narrative are that (1) depression is a real and serious medical condition that affects a person's functioning, (2) people with depression should seek professional help and (3) treatment for depression is available and effective. - Intervention provider: 1 data collector, no further information - Delivery method/mode: 1 face-to-face group session lasting 20 to 30 min (printed fotonovela read by oneself) - Language of delivery: language concordant (bilingual) - Format: standard - Setting/location: usual setting for educational classes - Consumer involvement: evaluated within another study population (see Hernandez 2013) **Comparator** Type: written information on the same topic Description: participants received an evidence-based text pamphlet "Depression" by the National Institute of Mental Health (NIH publication 08 3561), which conveys similar information in a non-narrative format, 26 pages, targeted to low literacy audience, publicly available in Spanish and English, language according to preference.

Outcomes	Outcomes assessed in the study: depression knowledge, willingness to seek help for depression, self-efficacy to identify depression, stigma about mental health care, antidepressant stigma, dissemination of fotonovela through social networks
	Outcomes considered in this review
	- Health literacy
	  ◦ Apply (willingness to seek help for depression)
	- Health-related knowledge (depression knowledge)
	- Self-efficacy (self-efficacy to identify depression)
	Methods of assessing outcomes
	Self-administered questionnaires
	- Willingness to seek help for depression: modified items from intention to seek depression care scale (Cabassa 2007), 1 = no 2 = yes, 4 items, higher score is better
	  ◦ Translation procedure: translated version
	  ◦ Reliability/validity: validated Spanish version, Cronbach's α = 0.70
	- Depression knowledge: Depression Knowledge Scale: 10 items on 'symptom recognition' (5 depression symptoms according to Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV), 5 non-

Unger 2013 *(Continued)*

	- depressive symptoms, and 10 items on 'treatment knowledge' (adapted from D-Lit by Griffiths 2004), 0 to 17, higher score is better
	  - Reliability/validity: validated within study sample
	- Self-efficacy: self-efficacy to identify depression, 2 items adapted from Lorig 1996, 1 = "not confident at all" to 10 = "very confident", 2 items, higher score is better
	  - Reliability/validity: Cronbach's α = 0.72
	Language of assessment: Spanish and English according to preference (each question was shown in both languages)
	Translation procedure: back-translation technique (applies to literacy and self-efficacy)
	Timing of outcome assessment: immediately before and after intervention, and at 1-month follow-up

Health literacy	**Definition(s):** "Health literacy is the degree to which people have the capacity to obtain, process, and understand health information to make appropriate health decisions" (Kutner 2006). "Mental health literacy (knowledge about mental health disorders and treatments); stigmatization of depression; attribution of depression to non-medical causes including *nervios* (nerves), *fallo mental* (mental deficiency or failure), and *locura* (craziness); reluctance to discuss emotional problems with strangers, and reluctance to take antidepressant medication" (Unger 2013, p. 399). **Health literacy components addressed by the intervention** Prerequisites and tools - Knowledge - Motivation Steps of information processing - Access - Understand - Appraise - Apply Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** not reported **Additional notes:** we only report on the results of time point 1, which was immediately after the intervention, as "several students shared their fotonovelas with students in the text pamphlet group after the posttest." (Unger 2013, p. 405). Therefore, results of the 1-month follow-up might be biased. Authors provided information on numbers randomised to each study arm on request.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The data collector gave each participant an envelope containing a pretest survey, a Fotonovela or text pamphlet, and a posttest survey. The envelopes were shuffled randomly prior to the data collection so that assignment of students to experimental condition would be random." This randomisation method introduces a low risk of bias. Baseline imbalances were not reported.
Allocation concealment (selection bias)	Low risk	"Participants were instructed to open their envelopes and fill out the pretest survey."

Unger 2013 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the study, blinding of participants and personnel was most likely not possible. Therefore, the results of subjective outcomes are possibly biased.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	Participants were not blinded to group allocation and subjective outcomes were assessed with repeated questionnaires.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Knowledge was measured objectively and was not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Pretest and posttest data were collected from 185 students. Of those, 157 (85 %) completed the 1-month follow-up. Of those, 18 were excluded from the analysis because they did not self-identify as Hispanic/Latino (3 were White, 3 were African American, 1 was ‘‘Other’’, and 11 did not answer the question). The remaining 139 students were included in the analytic sample." The authors provided additional information on the total numbers randomised on request; differential loss between the intervention and control group is less than 15%. No intention-to-treat analysis was performed, but a completers only analysis was done.
Selective reporting (reporting bias)	Low risk	All outcomes reported int the methods were reported in the results of the paper.

Valdez 2015

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** Santa Clara County, CA, USA; Los Angeles, CA, USA **Ethical approval:** yes **Recruitment setting:** Latino study population was recruited in Santa Clara County, CA, USA, Korean study population was recruited in Los Angeles, CA, USA; no further information reported **Method of recruitment:** participants were recruited by a trained, bicultural, research assistant in their respective region. **Length of follow-up:** 4 weeks after intervention **Dropouts:** in total, 100 participants were not included in the analysis, 74 in the intervention group and 26 in the control group. It is unclear, whether the participants did not complete pre- and/or post-intervention assessment or if they were excluded for other reasons. **A priori calculation of effect size/power?:** yes
Participants	**Description: Latino and Korean American parents** **Health topic** • Cervical cancer

Valdez 2015 *(Continued)*

Inclusion criteria

- Self-identified member of either Korean or Latino communities, either a parent/guardian of an unvaccinated child aged 11 to 12 years, or an unvaccinated adolescent aged 13 to 17 years, telephone access to permit participation in a post-intervention interview

Exclusion criteria

- Not reported

Intervention group

- Educational Intervention (DVD) on HPV vaccine (364 randomised and 290 analysed)

Control group

- Language-appropriate Centers for Disease Control and Prevention (CDC) flyer on the HPV vaccine (344 randomised and 318 analysed)

Note: from the intervention group 167 participants were located in Los Angeles and 197 were located in San Jose. From the control group 153 were located in Los Angeles and 191 were located in San Jose.

PROGRESS-Plus

Place of residence: urban, USA

Time living in host country (years), mean; distribution: 14.3; 93.6% foreign-born, (n = 700) 14.9% < 5 y, 18.9% 6 to 10 y, 28.4% 11 to 15 y, 37.9% 16+ y

Race/ethnicity: Latino and Korean American

Gender (n = 707):

- Intervention (n = 365): 90.9% female
- Control: 93.6% female

Education (years of formal education): 19.6% < 6, 16.7% 7 to 11 y, 18.5% 12 y, 9.9% 13 to 15 y, 35.3% 16+ y

Social capital (number of children (mean; distribution); marital status): 2.8; 52.3% 1 to 2, 39.4% 3 to 4, 8.3% 5+; 72.7% married/living together

Age (years), mean; distribution (n = 691): 41.7; 12.3% < 35 y, 22.3% 35 to 39 y, 34.6% 40 to 44 y, 17.2% y, 11.2% 50+ y

Health literacy (baseline)

Not measured

Interventions

Intervention: educational intervention for HPV vaccine

Theoretical framework: Theory of Planned Behaviour (Ajzen 1991)

Description: the intervention consisted of an educational DVD that delivered evidence-based information about cervical cancer. DVD content addressed 3 main topics: (1) HPV, (2) the association between HPV infection and cervical cancer, and (3) key aspects of HPV vaccine. Participants watched the DVD in privacy in their homes at an individually convenient time.

- Intervention provider: not applicable
- Delivery method/mode: 1 individual video session (DVD watched at home at individually convenient time)
- Language of delivery: Spanish, Korean or English (participants' preferred language)
- Format: standard
- Setting/location: at participants' homes

Valdez 2015 *(Continued)*

	• Consumer involvement: culturally and linguistically adapted through involvement of members from the communities of interest **Comparator** Type: written information on the same topic Description: participants in the control arm received a language-appropriate CDC flyer on HPV vaccine.

Outcomes	Outcomes assessed in the study: HPV and cervical cancer knowledge, decisional conflict, made informed decision regarding HPV vaccination
	Outcomes considered in this review
	• Health literacy
	  ○ Appraise (decisional conflict*)
	  ○ Apply (made informed HPV vaccination decision**)
	• Health-related knowledge (HPV and cervical cancer knowledge)
	*We report on the results of the following subscales: informed decision, values clarity and support. The subscales uncertainty and effective decision presume a completed decision, thus rather reflecting the processing step of applying health information; **Prioritised outcome for the category 'health literacy - applying health information' based on consensus decision of the authors.
	Methods of assessing outcomes
	Outcomes were assessed via telephone interview.
	• Decisional conflict: Decisional Conflict Scale, subscales informed decision, values clarity, support, 0 to 100 (each scale), lower score is better
	  ○ Reliability/validity: Decisional Conflict Scale is validated in English and Spanish
	• Made informed decision: 3 criteria: (1) making a vaccination choice, (2) affirming that the decision was an informed choice and (3) having a knowledge score of at least 7 out of 12 knowledge items, higher score is better
	• HPV and cervical cancer knowledge: 12 items on HPV knowledge and awareness derived from scales used in the 2007 Health Information National Trends Survey (HINTS) and the 2007 California Health Information Survey (CHIS), additional questions related to the intervention content were integrated, true/false, 0 to 12, higher score is better
	  ○ Reliability/validity: not reported
	Language of assessment: per preference
	Translation procedure: HINTS was available in English and Spanish, CHIS was also available in Korean; content-specific questions were developed for the study.
	Timing of outcome assessment: baseline, at 1-month follow-up

Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation (unclear) Steps of information processing • Understand • Appraise (unclear) • Apply

Valdez 2015 *(Continued)*

	Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** funding was provided by the National Institute on Minority Health and Health Disparities Grant No. 2R44MD005198-03A1.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Participants were then randomized, stratified by study site (Los Angeles or San Jose), using a programmed algorithm on the laptop computer and assigned to an intervention or control study arm."
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No statement about whether participants or personnel were blinded. Participants in the control group received a CDC flyer, which was most likely publicly available. It is unclear whether the results of subjectively measured outcomes are biased.
Blinding of outcome assessment (detection bias) subjective outcome measures	Unclear risk	Subjective outcome was measured with the use of repeated questionnaires administered via telephone interview. It is unclear whether the interviewer and participants were blinded.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Knowledge was objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There are considerable differences in the numbers of participants analysed between study groups. In total, N = 100 participants were not included in the analysis, n = 74 in the intervention group and n = 26 in the control group. It is unclear whether the participants did not complete pre- and/or post-test assessment or if they were excluded for other reasons. Therefore, the information is insufficient to permit judgement.
Selective reporting (reporting bias)	Low risk	All outcomes specified in the methods section are reported in the results.

Valdez 2018

Study characteristics

Methods	**Study design:** RCT, 2 arms **Geographic location:** Los Angeles, San Jose and Fresno, USA **Ethical approval:** yes **Recruitment setting:** community clinics at 3 sites in California **Method of recruitment:** participants who visited the community clinics were recruited by bilingual, bicultural female research assistants; a verbally administered screening questionnaire determined eligibility.

Valdez 2018 *(Continued)*

	Length of follow-up: 6 months post-intervention **Dropouts:** attrition rate was 12.8% in Fresno, 18.9% in San Jose and 35.4% in Los Angeles; overall attrition rate was 22.9% (216) Note: 29 participants reported at baseline that they had received a Pap test within the past 2 years (they did not meet the inclusion criteria). The authors included these women in the analysis as being in the contemplation stage ("plans to have a pap test in the next 12 months" (Valdez 2018, p. 223). **A priori calculation of effect size/power?:** not reported
Participants	**Description: low-income Latinas** **Health topic** • Cervical cancer **Inclusion criteria** • 21 to 69 years of age, self-identified Latina, annual household income of ≤ USD 24,680, no prior cervical cancer diagnosis, no prior hysterectomy, no Pap test within the past 2 years **Exclusion criteria** • Not reported **Intervention group** • One-time Cervical Cancer Education Programme via interactive touchscreen kiosk (480 randomised and 383 analysed) **Control group** • Usual care (publicly available brochure in Spanish or English) (463 randomised and 344 analysed) Note: participants were analysed as randomised, but complete cases only. **PROGRESS-Plus** **P**lace of residence: urban, USA Time living in host country (years); distribution: 80.0% foreign born, 26.0% 1 to 5 y, 18.0% 6 to 10 y, 20.0% 11 to 15 y, 36.0% 16+ y **R**ace/ethnicity: Latina **G**ender: 100% female **E**ducation (years of formal education), mean (SD); distribution: 8.2 (3.8); 39.0% 1 to 6 y, 34.0% 7 to 11 y, 21.0% 12 y, 6.0% 13+ y **S**ocioeconomic status/ income: criteria for inclusion was annual household income of ≤ USD 24,680 Health insurance: 51.0% insured **S**ocial capital (martial status; number of children (mean (SD); distribution): 21.0% single, 43.0% married, 15.0% living together, 15.0% divorced/separated, 5.0% widowed; 3.0 (2.2) children; 10.0% no children, 14.0% 1 child, 21.0% 2 children, 22.0% 3 children, 15.0% 4 children, 18.0% 5+ children Age (years), mean (SD), range: 39.1 (11.8), 21 to 69 **Health literacy (baseline)** Not measured
Interventions	**Intervention:** Cervical Cancer Education Programme

Valdez 2018 *(Continued)*

Theoretical framework: transtheoretical model (Prochaska 1997)

Description: the intervention included a one-time education programme delivered through interactive, multimedia touchscreen kiosks. Participants received on-screen prompts, individualised according to language and age group. The age-tailored features included behavioural models and multimedia elements to create cultural, linguistic and literacy-adapted features. The programme incorporated 8 interactive modules. Module content comprised various information on cervical cancer, HPV and Pap testing and how health resources in a treatment setting can be claimed.

- Intervention provider: not applicable
- Delivery method/mode: 1 individual web-based session lasting 20 to 30 min (interactive, multimedia touchscreen kiosk)
- Language of delivery: English or Spanish
- Format: tailored (algorithm-based)
- Setting/location: not reported
- Consumer involvement: culturally adapted through involvement of members from the community of interest

Comparator

Type: written information on the same topic

Description: participants in the control arm received an 8-panel, 2 colour brochure developed by the Office of Woman's Health of the California Department of Health Services on gynaecological cancers provided in English and Spanish. The procedure corresponds to usual care.

Outcomes

Outcomes assessed in the study: cervical cancer knowledge, attitudes towards cervical cancer and Pap testing, self-reported screening behaviour, self-efficacy regarding Pap testing

Outcomes considered in this review

- Health-related knowledge (cervical cancer knowledge)
- Health behaviour (self-reported screening behaviour)
- Self-efficacy (self-efficacy regarding pap smear)*

*Self-efficacy was assessed with three statements. We only report on the results of the statement "Can get a pap smear if needed" as "Every woman should get pap smear" and "Pap smears can save our lives" reflect attitudes and beliefs rather than self-efficacy; **Health behaviour was assessed with three items: We included one question to assess screening behaviour reported in the study, as"Kiosk main reason for getting a pap test" and "Kiosk information especially influenced decision to get a pap test" do not directly ask for participants' screening behaviour.

Methods of assessing outcomes

Baseline assessments were delivered through touchscreen kiosk deployed in waiting rooms at the collaborating clinics. Post-intervention assessments were conducted via structured, language concordant, telephone interviews by bilingual, bicultural, female interviewers. Study used adapted scales from the Pathfinders intervention study conducted by the Northern California Cancer Center (Zapka 2004).

- Cervical cancer knowledge: 5 items, yes/no, higher score is better
- Self-reported screening behaviour: 1 item (having had a Pap test or made an appointment in the interval between before the intervention and post-intervention), yes/no
- Self-efficacy regarding pap smear: one statement, "Can get a pap smear if needed", yes/no

Language of assessment: language concordant (knowledge), Spanish/English per preference (behaviour)

Translation procedure: back-to-back translation

Reliability/validity: added questions were examined for face validity by subject-matter experts and assessed for clarity and comprehension through individual cognitive interviewing with 10 Latinas.

Valdez 2018 *(Continued)*

	Timing of outcome assessment: baseline, medium-term (at 6-month follow-up)
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Motivation (unclear) Steps of information processing • Access • Understand • Appraise (unclear) • Apply Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** funding was provided by the National Cancer Institute, Grant No. 5R44CA093110-3.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"The kiosks were programmemed with an algorithm that used a random number generator to randomly assign participants to study arms. Upon completion of a pretest survey conducted on the kiosks, participants were randomly assigned to either an intervention or control condition with equal probability, stratified by study site and kiosk."
Allocation concealment (selection bias)	Low risk	The method used in the randomisation process indicates a low risk of bias.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Personnel were blinded; there is no information on whether participants were blinded. It is unclear whether subjectively measured outcomes were affected.
Blinding of outcome assessment (detection bias) subjective outcome measures	Unclear risk	"Participants in both conditions were reassessed at 6 months from baseline through a structured, language concordant, telephone interview by bilingual-bicultural, female interviewers who were blinded to participants’ group assignment." Health behaviour was measured with the use of questionnaires that were administered via telephone and participants were most likely aware of the intervention they received. It is unclear whether this might have affected the results.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	"Participants in both conditions were reassessed at 6 months from baseline through a structured, language concordant, telephone interview by bilingual-bicultural, female interviewers who were blinded to participants’ group assignment." Participants were most likely not blinded, but knowledge was objectively measured and not subject to interpretation.

Valdez 2018 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Attrition rates at post-test were 12.8 % in Fresno, 18.9 % in San Jose, and 35.4 % in Los Angeles, with an overall attrition rate of 22.9 %." Distribution of dropouts between study groups is not reported and reasons for attrition are not provided. The authors state having performed an intention-to-treat analysis, but present results for completers only. It is unclear whether the risk of attrition bias is high or low.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported.

van Servellen 2005

Study characteristics	
Methods	**Study design:** RCT (pilot), 2 arms **Geographic location:** California, USA **Ethical approval:** yes **Recruitment setting:** 2 administratively linked HIV community-based not-for-profit clinics **Method of recruitment:** clinical trial staff screened medical records of the clinic and approached eligible patients by phone and/or letter. **Length of follow-up:** 6 months (total programme duration) **Dropouts:** 9 in the intervention group, thereof 2 after 6 weeks (reason: unable to be reached initially after the instructional component of the programme) and 7 after 6 months; 7 in the control group, thereof 2 after 6 weeks (reason: unable to be reached initially after the instructional component of the programme) and 5 after 6 months **A priori calculation of effect size/power?:** yes
Participants	**Description: Latinos with HIV-infection** **Health topic** • HIV **Inclusion criteria** • Male or female, ≥ 18 years of age, Spanish speaking, detectable viral load, stated problem with adherence, taking antiretroviral medications for at least 3 months **Exclusion criteria** • Adherence problems with undetectable viral loads **Intervention group** • HIV treatment adherence enhancement programme “Es por la vida” (43 randomised and 41 analysed at 6 weeks and 34 analysed at 6 months) **Control group** • Standard clinic care (42 randomised and 40 analysed at 6 weeks and 35 analysed at 6 months) Note: 93 participants were randomised either to intervention or control group. Authors did not provide numbers on participants randomised to different treatment groups.

van Servellen 2005 *(Continued)*

	PROGRESS-Plus **P**lace of residence: urban, USA **R**ace/ethnicity: Latinos **G**ender: • Intervention: 11.6% female • Control: 7.1% female **E**ducation (years): 81.0% < 12 y **S**ocioeconomic status/income (per month): 41.0% ≤ USD 500 Age (years), mean, range: 40.7, 21 to 78 **Health literacy (baseline)** Assessment tool, range, level: modified REALM (24 additional HIV-relevant medical terms), higher score is better • Intervention group, mean: 17.07 (recognition), 12.49 (understand) • Control group, mean: 18.64 (recognition), 13.62 (understand)
Interventions	**Intervention: HIV treatment adherence enhancement programme "Es por la vida"** Theoretical framework: no specific Description: the intervention consisted of modular group sessions including (1) basic HIV/AIDS information, (2) barriers and facilitators of adherence management, (3) maintaining quality of life and controlling illness-related stress, (4) reducing risks related to transmitting HIV and management of substance use (5) and communication skills with healthcare providers and maintaining effective family and community support systems. All materials were read and discussed. There were additional follow-up phone calls and face-to-face conversations with a nurse practitioner focussing on barriers to HIV treatment adherence and strategies to reduce those barriers. Problem-solving and motivational interviewing strategies were used by reviewing content that has not been fully understood and identifying ways to lower barriers of adherence management, or to identify support systems. • Intervention provider: nurse practitioner and health educator; trained foreign medical student (only assessment) • Delivery method/mode: 5 weekly face-to-face group sessions (with 3 to 7 participants), 6 months of telephone or face-to-face counselling • Language of delivery: language concordant (bilingual) • Format: individually tailored • Setting/location: 2 administratively linked clinics • Consumer involvement: indicated, but missing information **Comparator** Type: no health literacy intervention Description: standard clinic care, no additional intervention
Outcomes	Outcomes assessed in the study: functional HIV health literacy, HIV-related knowledge, adherence self-efficacy, medication adherence (self-report), general health status (self-report), viral load, relationship and communication with healthcare provider **Outcomes considered in this review** • Health literacy ◦ Functional HIV health literacy (recognition and understanding of HIV-related terms) • Health-related knowledge (HIV-related knowledge)

van Servellen 2005 *(Continued)*

- Health outcome (general health status)
- Health behaviour (medication adherence)
- Self-efficacy (adherence self-efficacy)

Methods of assessing outcomes

Questionnaires administered by a bilingual foreign medical

- HIV health literacy: modified REALM, 24 additional HIV-relevant medical terms (recognition of terms and understanding of HIV terms), higher score is better
    - Reliability/validity: validated within study sample, Cronbach's α = 0.81 (recognition scale, baseline), 0.82 (6 weeks), and 0.74 (6 months); Cronbach's α = 0.79 (understanding scale, baseline), 0.84 (6 weeks), and 0.79 (6 months)

Note: health literacy measures and questions were designed by clinic staff in collaboration with the study team. 24 HIV terms were added to the original set of medical terms of the REALM by keeping with the original format. For example, terms ranged from HIV, virus and symptoms (lower level of difficulty) to terms such as viral replication, protease inhibitors, HIV-resistant strains (higher level difficulty). Participants were asked first if they had heard these terms (global recognition) and second, whether they could explain them (global understanding).

- HIV-related knowledge: HIV illness and treatment knowledge and misconceptions scale, 17 items, 0 to 17, higher score is better
    - Reliability/validity: validated within target population
- Adherence self-efficacy: 1 item from the Adult AIDS Clinical Trials Group (ACTG) Adherence Baseline Questionnaire, 3-point Likert scale, (0 = not at all sure to 3 = extremely sure), higher score is better
- Medication adherence: ACTG Adherence behaviours Adherence Baseline Questionnaire (self-report), dichotomous variables were created for those who had greater than 90.0% and greater than 95.0% adherence to their antiretroviral medication regimen in the past 4 days

Note: we prioritised the variable '95% adherence to antiretroviral medication regimen in the past 4 days' over '90.0% adherence in the past 4 days'.

- General health status: 1 item assessing perceived level of general health status in the past week, range of score and direction of score is not reported

Note: "Most measures were already translated into Spanish but were reviewed again by the bilingual research assistant to ensure proper translation of ideas and concepts. Questions not previously translated were submitted for translation by an independent linguistic and cultural consultant who used the standard multi-step forward/backward translation with additional evaluation by our bilingual research staff." (van Servellen 2003, p. 288)

Language of assessment: Spanish

Translation procedure (if necessary): not reported

Reliability/validity: no psychometric properties reported (applies to adherence self-efficacy, medication adherence and health status)

Timing of outcome assessment: baseline, at 6 weeks (after group sessions) and at 6 months (short-term) after randomisation

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Health literacy

Definition: "According to various reports, the accepted distinguishing characteristics of health-literate individuals include the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (IOM, 2004) Furthermore, individuals' health literacy skills and capacities are influenced by their education, culture, and language (Adams, 2003). It follows that HIV-related health literacy would include those skills and knowledge to obtain, process, and understand HIV-related information, and that these skills and knowledge are influenced by the particular educational level, culture, and language of the group in question." (van Servellen 2005, p. 747)

Health literacy components addressed by the intervention

Prerequisites and tools

van Servellen 2005 *(Continued)*

	- Knowledge - Motivation - Competences Steps of information processing - Access - Understand - Appraise - Apply Health domain: health care
Notes	**Trial ID:** not reported **Funding:** funding was provided by a grant from the University-wide AIDS Research programme and State Office of AIDS (no. R00-LA-112). **Additional notes:** we tried to contact the authors to ask for additional information but without success.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	“Upon enrollment, all participants received a code number from a published table of random numbers and assigned to either the pilot intervention group or comparison group.”
Allocation concealment (selection bias)	Low risk	The method of randomisation indicates a low risk of bias.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Due to the nature of the study, participants and personnel were not blinded; results of subjectively measured outcomes might be biased.
Blinding of outcome assessment (detection bias) subjective outcome measures	High risk	Subjective outcomes were measured with repeated questionnaires and participants were not blinded to group allocation.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Participants and personnel were not blinded but health literacy and knowledge were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Baseline and 6 weeks (immediately after instructional modular programme) data were available for 41 intervention and 40 comparison group patients. From 6 weeks to 6 months, an additional 5 participants in the comparison group and 7 participants in the pilot group were lost to follow-up, for an attrition rate of 21% for the intervention group and 17% for the comparison group. Analysis of the characteristics of these 16 patients revealed that they had a poorer understanding of HIV terms (11.00 versus 13.38) [F(1,82) 3.96, p 0.05] and a statistically significant higher viral load than those who remained (99,328 versus 36,973) [F(1,83) 4.34, p 0.04]. They were also less apt to take part in decisions about their care (1.88 versus 2.41) [F(1,82) 4.62, p 0.03].

van Servellen 2005 *(Continued)*

		The numbers of and reasons for participants lost to follow-up are reported and equal for both the control and intervention group.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported in the methods section are reported in the results of the paper.

Wong 2020

Study characteristics	
Methods	**Study design:** RCT, 2 arms **Geographic location:** Singapore, Southeast Asia **Ethical approval:** yes **Recruitment setting:** office of the Humanitarian Organization for Migration Economics (HOME), a non-governmental organisation located in Singapore **Method of recruitment:** through social media and HOME **Length of follow-up:** 2-month follow-up **Dropouts:** 2 in the intervention group, thereof 1 post-intervention (reason: repatriated back to the Philippines) and 1 at 2-month follow-up (reason: lost to follow-up), 5 in the control group, thereof 1 post wait-list measurement (reason: work schedule problem) and 4 at 2-month follow-up (reason: lost to follow-up, not in town, repatriated back to the Philippines) **A priori calculation of effect size/power?:** yes
Participants	**Description: Filipino domestic workers** **Health topic** • Mental health (depression) **Inclusion criteria** • Filipina domestic workers, female, 23 ≤ years (legal age of working in Singapore), able to travel to the training site 4 consecutive weeks, literate in English, at least 9 years of formal education **Exclusion criteria** • Not reported **Intervention group** • Cognitive Behavioural Therapy (CBT)-based paraprofessional training programme (19 randomised and 18 analysed) **Control group** • Wait-list control (20 randomised and 19 analysed) Note: the control group attended the programme following completion of the programme by the intervention group. **PROGRESS-Plus** **P**lace of residence: urban, Southeast Asia Time living in host country (years) (time working in Singapore), mean, range: 9.45, 1 to 24

Wong 2020 *(Continued)*

	Race/ethnicity: Filipino **O**ccupation: working in Singaporean households; number of days off in current job: 58.95% 1/week and public holidays, 66.8% 1/week, 2.5% 2/month, 5.15% 3/month **G**ender: 100% female **R**eligion: 71.85% Roman Catholic, 28.15% other Christian faith **E**ducation (n = 38): 72.0% completed high school (secondary) 4 years, 28.0% completed university Note: 9 ≤ years of formal education was an inclusion criterion. **S**ocial capital (n = 38): 48.4% were single or never married, 25.8% were married, 25.8% were separated, divorced or widowed Age (years), mean (SD): 38.6 (6.3) **Health literacy (baseline)** Assessment tool, range (score): Depression Literacy Questionnaire (D-Lit, here referred to as "DLQ"), 22 items, true/false questions, 0 to 22, higher score is better (validated tool) • Intervention group, mean (SD): 10.65 (2.47) • Control group, mean (SD): 11.45 (2.65)
Interventions	**Intervention: CBT-based paraprofessional training** programme Theoretical framework: formative research to inform intervention development Description: participants received a CBT-based paraprofessional group training following a manual from another CBT-based training that has been previously developed for refugees from Burma in North Carolina (USA). The manual was a version adapted to the needs of foreign domestic workers (FDWs) in Singapore. Participants in the training group attended in HOMEs office 4 weekly English language sessions, held by 2 masters' level clinical psychology trainees. Participants received session handouts and homework practices. The training sessions aimed to support skills regarding depression via didactics, discussions and role-plays. Training addressed (1) recognition of signs and symptoms of depression, (2) improving attitudes towards treatment-seeking for depression and (3) provision of basic CBT skills to be able to support peers and to increase awareness of available resources in the community. • Intervention provider: master's level clinical psychology trainees • Delivery method/mode: 4 weekly face-to-face, group sessions lasting 3 hours with homework exercises • Language of delivery: English • Format: standard • Setting/location: office of HOME • Consumer involvement: a questionnaire was used at the end of the training to receive participants' feedback. **Comparator** Type: no health literacy intervention (delayed intervention) Description: the wait-list control group received a delayed intervention immediately after the training group's programme completion.
Outcomes	Outcomes assessed in the study: depression literacy, CBT knowledge, attitudes towards seeking professional help, self-confidence in supporting individuals with depression, depression-related stigma **Outcomes considered in this review** • Health literacy ◦ Depression literacy

Wong 2020 *(Continued)*

	◦ CBT knowledge **Methods of assessing outcomes** Outcomes were assessed via questionnaires • Depression literacy: Depression Literacy Questionnaire (D-Lit/DLQ), 22 items, true/false questions, 0 to 22, higher score is better ◦ Reliability/validity: internal consistency α = 0.70 • CBT knowledge: knowledge of CBT questionnaire (Knowledge CBT-Q), 9 items, multiple choice questions, higher score is better ◦ Reliability/validity: psychometric properties not reported Language of assessment: English **Timing of outcome assessment:** baseline, short-term (immediately after intervention) and at 2-month follow-up (both groups combined) Note: intervention and control group were both assessed at 2-month follow-up. The waiting list control group received the training programme immediately after the intervention group's completion (between post-intervention assessment and follow-up assessment) and were also assessed at 2-month follow-up. The results for the follow-up assessment are reported for the combined groups only. Therefore, these results could not be incorporated in the analysis (see Table 1 and Table 2) Adverse events: "No participants reported any unintended effects or harms resulting from attending the training program." (Wong 2020, p. 577)
Health literacy	**Definition:** not reported **Health literacy components addressed by the intervention** Prerequisites and tools • Knowledge • Competences Steps of information processing • Access • Understand • Appraise • Apply Health domain: disease prevention
Notes	**Trial ID:** not reported **Funding:** funding was obtained by a start-up Grant awarded to Dr. Shian-Ling Keng by the Faculty of Arts and Social Sciences in National University of Singapore (NUS) and to Marian Wong as a master's thesis grant by the Department of Psychology at NUS (R-581-000-153-133).

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	"Forty FDWs were randomized in blocks to either the training group or the WL group based on computer-generated random numbers (www.randomizer.org)."
Allocation concealment (selection bias)	Low risk	"The generation of random numbers and allocation were conducted by an independent research assistant (who was not involved in the recruitment or da-

Wong 2020 *(Continued)*

		ta collection procedure of the study) based on the sequence of participants' enrolment into the study."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Due to the nature of the study, personnel and participants were not blinded, but outcomes were objectively measured.
Blinding of outcome assessment (detection bias) objective outcome measures	Low risk	Participants were not blinded to study condition, but depression literacy and CBT knowledge were objectively measured and not subject to interpretation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	In total, n = 2 in the intervention group dropped out, of which n = 1 post-intervention (repatriated back to the Philippines) and n = 1 at 2-month follow-up (lost to follow-up); n = 5 in the control group, of which n = 1 post wait-list measurement (work schedule problem) and n = 4 at 2-month follow-up (lost to follow-up, not in town, repatriated back to the Philippines). Dropout rates differed only slightly between the intervention and control group, indicating a low risk of bias.
Selective reporting (reporting bias)	Low risk	All outcomes specified in the methods section are reported in the results.

Abbreviations used:
ACP: advance care planning; ACTG: Adult AIDS Clinical Trials Group; AD: advance directive; ADKnowl: Audit of Diabetes Knowledge Scale; AHL-C: Assessment of Health Literacy in Cancer screening; AHRQ: Agency for Healthcare Research and Quality; ARMS: Adherence to Refills and Medications Scale; ATSPH-SF: Attitudes Towards Seeking Professional Psychological Help-Short Form; BCKQ: Bristol COPD Knowledge Questionnaire; BDI-II: Beck Depression Inventory-II; BHLS: Brief Health Literacy Screen; BMI: body mass index; CBT: Cognitive Behavioural Therapy; CBPR: community based participatory research; CDC: Centers for Disease Control and Prevention; CES-D: Center for Epidemiological Studies-Depression Scale; CHC: community health centre; CHIS: California Health Information Survey; CHW: trained community health workers; CI: confidence interval; CIHR: Canadian Institutes of Health Research; COPD: chronic obstructive pulmonary disease; CRC: colorectal cancer; CSC: Cardiovascular Health Questionnaire; D-Lit/DLQ: Depression Literacy Questionnaire; DHLS: Diabetes Health Literacy Survey; DKT: Diabetes Knowledge Test; DM-REALM: Diabetes-specific Rapid Estimate of Adult Literacy in Medicine; DQOL: Diabetes Quality of Life Measure; DSM: Diagnostic and Statistical Manual of Mental Disorders; ED: emergency department; EMR: Electronic Medical Record; ESL: English as a second language; FDW: foreign domestic workers; FGD: focus group discussion; FIT: faecal immunochemical test; FOBT: faecal occult blood test; GED: general educational development; GEE: generalized estimating equations; HADS: Hospital Anxiety and Depression Scale; HB-MAS: Hill-Bone Medication Adherence Scale; HbA1c: haemoglobin A1c; HBP: high blood pressure; HBV: hepatitis B Virus; HGMT: home glucose monitoring with teletransmission; HINTS: Health Information National Trends Survey; HIPAA: Health Insurance Portability and Accountability Act; HL: health literacy; HLS: health literacy scale; HOME: Humanitarian Organization for Migration Economics; HPV: human papilloma virus; HWHA: Hmong Women's Heritage Association; ICC: intra-cluster correlation coefficient; ICER: Incremental Cost-Effectiveness Ratio; IMDSES: Insulin Management Self-Efficacy Scale; IOM: Institute of Medicine; KDSKA: Kim Depression Scale for Korean Americans; Knowledge CBT-Q: Knowledge of CBT questionnaire; KRC: Korean Resource Center; LHE: lay health educators; LSESLD: Lifestyle Self-Efficacy Scale for Latinos with Diabetes; MET: metabolic equivalents; MIDonline: Multicultural Information on Depression online; MUQ: Medication Understanding Questionnaire; NCI: National Cancer Institute; NIA: National Institute on Aging; NIDDK: National Institute of Diabetes and Digestive and Kidney diseases; NIH: National Institutes of Health; NIMHD: National Institute on Minority Health and Health Disparities; NPA: nutrition and physical activity; NVS: newest vital sign; Pap test: Papanicolaou test; PCORI: Patient-Centered Outcomes Research Institute; PCP: primary care providers; PHM: Preventive Health Model; PHQ-9K: Korean version of PHQ-9; PHQ: Patient Health Questionnaire; PRECEDE: Predisposing, Reinforcing, and Enabling Constructs in Education/environmental Diagnosis and Evaluation; PROCEED: Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development; PSA: prostate-specific antigen; QES: qualitative evidence synthesis; QoL: quality of life; QP: Qatar Petroleum; RCT: randomised controlled trial; RDD: random digit dialling; REALM: Rapid Estimated of Adult Literacy in Medicine; RoB: risk of bias; RR: risk ratio; Rx: prescription; S-TOFHLA: Spanish version of Short Test of Functional Health Literacy in Adults; SCFHC: South Central Family Health Center; SD: standard deviation; SDSCA: Summary of Diabetes Self-Care Activities; SE: standard error; SHIP-DM: Self-Help Intervention programme for type 2 Diabetes Management; SHIP: Self-Help Intervention Programme; SILS: Single Item Literacy Screener; SMBG: self-monitoring of blood glucose; sMIB: Behavioral Skills model; SNAP: Supplemental Nutrition Assistance programme; SYS: Safeguard your Smile; TOFHLA: Test of Functional Health Literacy in Adults; TS-REALD: Two Stage Rapid Estimate of Adult Literacy in Dentistry; y: years

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Ahmad 2012	Wrong intervention
Albright 2005	Wrong population
Alcala 2016	Wrong study design
Alegria 2014	Wrong population
Alegria 2019	Wrong intervention
Apter 2015	Wrong patient population
Aragones 2010	Wrong intervention
Arnold 2019	Wrong population
Athavale 2016	Wrong population
Bahromov 2011	Wrong intervention
Baker 2013	Wrong study design
Banna 2011	Wrong study design, wrong intervention, wrong patient population
Bastani 2010	Wrong intervention
Bastani 2015	Wong intervention
Beauchamp 2020	Wrong intervention
Bermejo 2013	Wrong patient population, wrong intervention
Brenner 2015	Wrong patient population
Brenner 2016	Wrong patient population
Calderón-Mora 2020	Wrong intervention
Carrasquillo 2012	Wrong intervention
Carrasquillo 2014	Wrong population
Carrasquillo 2015	Wrong population
Carrasquillo 2017	Wrong intervention
Carrasquillo 2018	Wrong population
Castejon 2013	Wrong intervention
Chai 2018	Wrong population

Study	Reason for exclusion
Chakkalakal 2017	Wrong population
Chalela 2015	Wrong population
Chan 2014	Wrong population
Chan 2015	Wrong population
Christy 2019	Wrong population
Cohan 2009	Wrong population
Collado 2014	Wrong intervention
Dancel 2013	Wrong population
Davis 2017	Wrong population
Del 2017	Wrong population
DeStephano 2010	Wrong study design
Dietrich 2006	Wrong population
Diez 2018	Wrong population, wrong intervention
Drieling 2011	Wrong patient population, wrong intervention
Drks 2019	Wrong intervention
Dueweke 2017	Wrong intervention
Duggan 2012	Wrong intervention, wrong population
Dwight-Johnson 2010	Wrong intervention
Elder 2016	Wrong publication type, wrong intervention
Ell 2007	Wrong intervention
Ell 2017	Wrong intervention
Erenoğlu 2020	Wrong intervention
Esquivel 2014	Wrong population
Eylem 2015	Wrong intervention
Fang 2019	Wrong intervention
Fehniger 2014	Wrong population
Felicitas-Perkins 2017	Wrong intervention
Field 2009	Wrong population

Study	Reason for exclusion
Field 2010	Wrong intervention
Fischer 2013	Wrong intervention
Fischer 2015	Wrong population
Fortmann 2015	Wrong intervention
Frosch 2011	Wrong patient population, wrong intervention
Gademan 2012	Wrong population
Gany 2007	Wrong intervention
Garbers 2012	Wrong population
Garland 2007	Wrong intervention
Gelberg 2019	Wrong intervention
Goel 2016	Wrong population, wrong intervention
Golchert 2019	Wrong intervention
Gold 2014	Wrong intervention
Gonzales 2014	Wrong intervention
Gonzales 2016	Wrong study design
Gonzales 2020	Wrong patient population
Goodyer 2006	Wrong population
Gordon 2014	Wrong population
Gordon 2016	Wrong population
Greenhalgh 2005	Wrong patient population
Greenhalgh 2011	Wrong population
Gustafsson 2015	Wrong intervention
Gwadz 2017	Wrong patient population, wrong intervention
Gwynn 2016	Wrong population
Hahn 2015	Wrong study design
Han 2010	Wrong population, wrong intervention
Handley 2008	Wrong population
Harmsen 2005	Wrong population

Study	Reason for exclusion
Helland-Kigen 2013	Wrong population
Helland-Kigen 2013a	Duplicate
Hernandez 2015	Duplicate
Hijazi 2013	Wrong intervention
Hijazi 2014	Wrong intervention
Holzel 2014	Wrong population
Holzel 2016	Wrong intervention
Horowitz 2011	Wrong population
Howell 2011	Wrong population
Howie-Esquivel 2014	Wrong population
Howie-Esquivel 2014a	Duplicate
Interian 2013	Wrong study design
Jacobson 2016	Wrong study design
Jang 2018	Wrong intervention
Jerant 2014	Wrong population
Jerant 2014a	Duplicate
Jervelund 2018	Wrong study design
Jih 2016	Wrong population
Jihyun 2018	Wrong intervention
Jimenez 2015	Wrong intervention
Jimenez 2017	Wrong intervention
Juarez 2013	Wrong population, wrong intervention
Juarez-Carrillo 2012	Wrong intervention
Juon 2016	Wrong intervention
Kandula 2014	Wrong intervention
Kandula 2020	Wrong intervention
Kendall 2017	Wrong population, wrong intervention
Kepka 2011	Wrong intervention

Study	Reason for exclusion
Kieffer 2013	Wrong intervention
Kieffer 2013a	Duplicate
Kim 2010	Wrong intervention
Kim 2014a	Wrong intervention
Kim 2019	Wrong population
Kiropoulos 2011a	Duplicate
Ko 2017	Wrong publication type
Kocken 2008	Wrong intervention
Kohlstadt 2016	Wrong population
Koniak-Griffin 2011	Wrong population
Kurth 2016	Wrong population
Kurtovich 2010	Duplicate
Kwon 2015	Wrong intervention
Kwong 2013	Wrong intervention
Ladley 2018	Wrong population
Lam 2003	Wrong intervention
Lasser 2010	Duplicate
Lee 2014	Wrong population
Lee 2014a	Wrong intervention
Lee 2017	Wrong intervention
Lee-Lin 2016	Wrong intervention
Li 2014	Wrong population
Lindberg 2020	Wrong intervention
Lood 2015	Wrong intervention
Ma 2017	Wrong intervention
Ma 2018	Wrong intervention/wrong patient population
Ma 2019	Wrong intervention
Macabasco-O'Connell 2011	Wrong population

Study	Reason for exclusion
Macabasco-O'Connell 2011a	Duplicate
Makoul 2009	Wrong study design
Makoul 2011	Wrong population
Marcus 2015	Wrong intervention
Medina-Ramirez 2019	Wrong intervention
Meredith 2014	Wrong population
Millan-Ferro 2017	Wrong population
Miranda 2019	Wrong study design
Mitchell 2015	Wrong intervention
Moore 2016	Wrong intervention
Myers 2018	Wrong intervention
Møen 2020	Wrong population
Navarro 1995	Wrong intervention
NCT00857636	Duplicate
NCT03980808	Wrong patient population, wrong intervention
NCT04831463	Wrong intervention
Nedjat-Haiem 2012	Wrong study design, wrong intervention
Nguyen 2009	Wrong population, wrong intervention
Nickell 2019	Wrong intervention
O'Connor 2014	Wrong population
O'Connor 2020	Wrong intervention
Oh 2017	Wrong intervention, wrong study design
Patel 2019	Wrong population
Pekmezi 2009	Wrong intervention
Pekmezi 2012	Wrong intervention
Peragallo 2005	Wrong intervention
Percac-Lima 2016	Wrong population
Poureslami 2011a	Duplicate

Study	Reason for exclusion
Poureslami 2011b	Wrong study design, wrong population
Qi 2011	Wrong intervention
Radlick 2020	Wrong intervention
Reddy 2014	Wrong intervention
Reijneveld 2003	Wrong intervention
Reuland 2017	Wrong population
Rhodes 2011	Wrong intervention
Ridgeway 2021	Wrong intervention
Rosas 2015	Wrong intervention
Saha 2013	Wrong intervention
Saha 2018	Wrong intervention
Salazar 2012	Wrong population
Schensul 2009	Wrong population, wrong intervention
Schillinger 2008	Wrong patient population
Schlumbrecht 2016	Wrong study design
Siddiqui 2017	Wrong intervention
Silvani 2015	Wrong intervention
Spalluto 2019	Wrong intervention
Sundquist 2010	Wrong intervention
Sußkind 2019	Wrong intervention
Swerissen 2006	Wrong intervention
Taylor 2002	Wrong intervention
Taylor 2009b	Wrong population
Thom 2018	Wrong population
Tsai 2018	Wrong study design
Tu 2006	Wrong population, wrong intervention
Tuot 2015	Wrong population
Turner 2018	Wrong population

Study	Reason for exclusion
Unlu 2010	Wrong intervention
Uygun 2020	Wrong intervention
Vargas 2010	Wrong population
Vincent 2014	Wrong population
Vlaar 2017	Wrong intervention
Walker 2007	Wrong study design, wrong intervention
Walker 2012	Wrong population
Wang 2015	Wrong intervention
Wells 2011	Wrong population
Wieland 2018	Wrong population
Wong 2008	Wrong intervention
Wong 2021	Wrong intervention
Wu 2015	Wrong intervention
Yun 2016	Wrong study design
Zhang 2013	Wrong intervention

Characteristics of studies awaiting classification *[ordered by study ID]*

Erwin 2012

Methods	RCT
Participants	Latinx
Interventions	Cancer education versus diabetes education
Outcomes	—
Notes	Abstract only, insufficient information to permit judgement

Esquivel 2019

Methods	Pilot RCT
Participants	US Latinos with heart failure
Interventions	Educational intervention versus usual care

Esquivel 2019 *(Continued)*

Outcomes	Acceptability and appropriateness of a culturally tailored educational intervention
Notes	Abstract of feasibility study only, no trial ID

Essien 2017

Methods	RCT
Participants	Spanish-speaking participants
Interventions	Peer mentorship in diabetes versus unknown
Outcomes	Unknown
Notes	Conference abstract only, no trial ID, unclear if data are extractable for first-generation migrants

Glaser 2020

Methods	Unclear, probably cluster-RCT
Participants	Non-English speaking population
Interventions	Culturally tailored education about colorectal cancer
Outcomes	Colorectal cancer screening
Notes	Conference abstract only, unclear study design

Gonzalez 2020

Methods	RCT
Participants	Ethnically diverse and socio-economically disadvantaged patients
Interventions	Telephone education about diabetes mellitus versus enhanced usual care
Outcomes	Depression, medication adherence, self-efficacy
Notes	Study protocol, unclear if data on first-generation migrants are extractable

Joshi 2016

Methods	Quasi-RCT
Participants	Hispanic women
Interventions	Computer-based bilingual breastfeeding educational programme

Joshi 2016 *(Continued)*

Outcomes	Knowledge, self-efficacy and intent to breastfeed
Notes	Unclear if participants are first-generation migrants (at least 80%); additional information requested from author but not provided

NCT04993326

Methods	RCT
Participants	African Americans
Interventions	Online diabetes self-management education and support along with COVID-19 prevention and protection (vaccination) education and resource information versus usual care
Outcomes	Understanding of diabetes self-management, understanding of COVID-19 risks
Notes	Unclear if data are extractable for first-generation migrants; clinicaltrials.gov identifier: NCT04993326

Pekmezaris 2020

Methods	Diabetes management programme for Hispanic/Latino
Participants	
Interventions	Diabetes telemonitoring versus comprehensive outpatient management
Outcomes	
Notes	Ongoing study; unclear if data are extractable for first-generation migrants; clinicaltrials.gov identifier: NCT03960424

RCT: randomised controlled trial

Characteristics of ongoing studies *[ordered by study ID]*

ACTRN12619001019190

Study name	The Strong Families Trial: Randomised controlled trial of a family strengthening program to prevent unhealthy weight gain among 5- to 11-year old children from at risk families
Methods	RCT
Participants	Parents
Interventions	Face-to-face behavioural parenting and lifestyle (BPL) intervention
Outcomes	Usual care
Starting date	23 February 2023 (recruitment)

ACTRN12619001019190 *(Continued)*

Contact information	andre.renzaho@westernsydney.edu.au
Notes	

Blashill 2021

Study name	Pilot randomised controlled trial of a patient navigation intervention to enhance engagement in the PrEP continuum among young Latino MSM
Methods	Pilot RCT
Participants	Latino men
Interventions	Patient navigation intervention versus usual care plus written information
Outcomes	Knowledge, self-efficacy, attitudes and beliefs, adherence
Starting date	2019
Contact information	kwells@mail.sdsu.edu
Notes	Clinicaltrials.gov identifier: NCT04048382

Castro 2013

Study name	Design of a randomized controlled trial for multiple cancer risk behaviors among Spanish-speaking Mexican-origin smokers
Methods	RCT
Participants	High-risk Mexican-origin smokers who are overweight/obese
Interventions	Health education (HE) versus motivation and problem-solving (MAPS) intervention
Outcomes	Smoking status, servings of fruits and vegetables, and both self-reported and objectively measured physical activity
Starting date	—
Contact information	—
Notes	Study protocol only; NCT01504919

NCT03726619

Study name	e-CHEC-uP: Scaling up an Efficacious Cancer Screening Intervention for Women With Limited English
Methods	RCT

NCT03726619 *(Continued)*

Participants	Korean American Women
Interventions	One-time online-based education followed by phone counselling over 6 months versus one-time face-to-face education followed by phone counselling over 6 months
Outcomes	Breast and cervical cancer screening measures, health literacy, breast and cervical cancer knowledge, cancer screening-related self-efficacy
Starting date	14 July 2019
Contact information	
Notes	

NCT03909347

Study name	PLAN: dementia Literacy Education and Navigation for Korean Elders With Probable Dementia and Their Caregivers
Methods	RCT
Participants	288 self-identified first-generation Korean Americans
Interventions	Dementia literacy education and navigation versus usual care
Outcomes	Dementia literacy
Starting date	July 2020
Contact information	hhan3@jhu.edu
Notes	Clinicaltrials.gov identifier: NCT03909347

NCT04125680

Study name	English as Second Language Health Literacy programme
Methods	RCT, 2 arms
Participants	Hispanic adult learners
Interventions	ESL curriculum that focuses on using pedagogies for health literacy as a practice
Outcomes	Prevention behaviours, prevention knowledge, health literacy, health service use
Starting date	February 2020
Contact information	feuerher@umich.edu
Notes	—

NCT04319458

Study name	Testing Mediators and Moderators of a Fotonovela for Depression to Promote Help-seeking Behavior
Methods	RCT
Participants	Latinx/Hispanics
Interventions	Secret feelings fotonovela versus NIH Brochure: Depression: What You Need to Know
Outcomes	Help-seeking behaviour
Starting date	—
Contact information	—
Notes	clinicaltrials.gov identifier: NCT04319458

NCT04564209

Study name	Information Visualizations to Facilitate Clinician-patient Communication in HIV Care (Info Viz: HIV)
Methods	RCT
Participants	Latinx
Interventions	Infographic intervention
Outcomes	Standard care
Starting date	18 August 2021
Contact information	—
Notes	—

NCT04905030

Study name	Education, Immigration and HPV Vaccination: an Informational Randomized Trial
Methods	Informational RCT
Participants	Immigrant women in Sweden
Interventions	Three types of HPV vaccination information
Outcomes	Decision to vaccinate child against HPV, posterior beliefs about false risks of the HPV vaccine
Starting date	2021
Contact information	—

NCT04905030 *(Continued)*

Notes	ClinicalTrials.gov identifier: NCT04905030

Waterman 2019

Study name	Working Within an Integrated Learning Healthcare System to Improve Living Kidney Donation Knowledge Across the CKD Continuum for All Racial Groups
Methods	RCT
Participants	English and Spanish-speaking adults
Interventions	ET@Home education versus usual care
Outcomes	Knowledge, ability to make an informed decision about transplant, self-efficacy
Starting date	2017
Contact information	—
Notes	Clinicaltrials.gov identifier: NCT03389932

Weise 2021

Study name	Low-threshold, culturally-sensitive group psychoeducation programme for asylum seekers (LoPe)
Methods	RCT
Participants	Asylum seekers
Interventions	Culturally sensitive, low-threshold psychoeducation versus wait-list control
Outcomes	Knowledge, changes in mental distress, openness towards psychotherapy and resilience
Starting date	2020
Contact information	—
Notes	Trial registration identifier: DRKS00020564

ESL: English as a second language; HPV: human papillomavirus; NIH: National Institutes of Health; RCT: randomised controlled trial

DATA AND ANALYSES

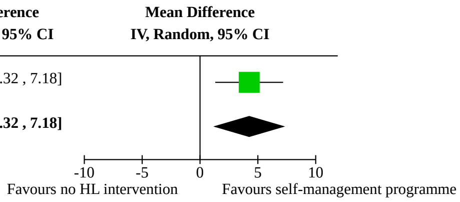
Comparison 1. Culturally and literacy adapted self-management programme versus no HL intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 HIV health literacy: understanding HIV terms (short-term: immediately post-intervention)	1	69	Mean Difference (IV, Random, 95% CI)	4.25 [1.32, 7.18]
1.2 HIV health literacy: recognition of HIV terms (short-term: immediately post-intervention)	1	69	Mean Difference (IV, Random, 95% CI)	3.32 [1.28, 5.36]
1.3 Health-related knowledge: HIV global disease/treatment knowledge, 0 to 100 (short-term: immediately post-intervention)	1	69	Mean Difference (IV, Random, 95% CI)	-1.18 [-9.23, 6.87]
1.4 Health-related knowledge: HIV knowledge, risk of getting sicker (short-term: immediately post-intervention)	1	69	Mean Difference (IV, Random, 95% CI)	0.33 [-0.01, 0.67]
1.5 Health outcomes: subjective health status (short-term: immediately post-intervention)	1	69	Mean Difference (IV, Random, 95% CI)	0.38 [-0.13, 0.89]
1.6 Health behaviour: blood glucose self-monitoring 2 times per day (capped at 2), self-report (short-term: immediately post-intervention)	1	252	Risk Ratio (M-H, Random, 95% CI)	1.30 [1.11, 1.52]
1.7 Health behaviour: physical activity, average daily steps (short-term: immediately post-intervention)	1	193	Mean Difference (IV, Random, 95% CI)	289.00 [-601.41, 1179.41]
1.8 Health behaviour: physical activity, average daily steps (short-term: three months post-intervention)	1	193	Mean Difference (IV, Random, 95% CI)	1336.00 [540.86, 2131.14]
1.9 Self-efficacy to manage one's disease (short-term: immediately post-intervention)	2	333	Std. Mean Difference (IV, Random, 95% CI)	0.28 [0.06, 0.50]

Analysis 1.1. Comparison 1: Culturally and literacy adapted self-management programme versus no HL intervention, Outcome 1: HIV health literacy: understanding HIV terms (short-term: immediately post-intervention)

	Self-management programme			No HL intervention				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
van Servellen 2005 (1)	6.16	7.97	34	1.91	3.6	35	100.0%	4.25 [1.32 , 7.18]
Total (95% CI)			**34**			**35**	**100.0%**	**4.25 [1.32 , 7.18]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.84 (P = 0.005)
Test for subgroup differences: Not applicable

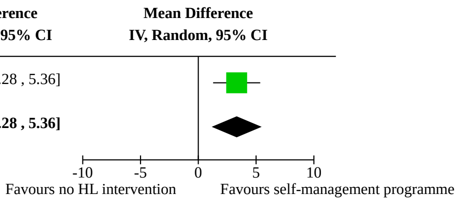


Footnotes
(1) Change scores.

Analysis 1.2. Comparison 1: Culturally and literacy adapted self-management programme versus no HL intervention, Outcome 2: HIV health literacy: recognition of HIV terms (short-term: immediately post-intervention)

	Self-management programme			No HL intervention				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
van Servellen 2005 (1)	4.66	4.8	34	1.34	3.76	35	100.0%	3.32 [1.28 , 5.36]
Total (95% CI)			**34**			**35**	**100.0%**	**3.32 [1.28 , 5.36]**

Heterogeneity: Not applicable
Test for overall effect: Z = 3.19 (P = 0.001)
Test for subgroup differences: Not applicable

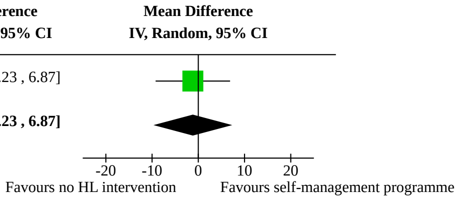


Footnotes
(1) Change scores.

Analysis 1.3. Comparison 1: Culturally and literacy adapted self-management programme versus no HL intervention, Outcome 3: Health-related knowledge: HIV global disease/treatment knowledge, 0 to 100 (short-term: immediately post-intervention)

	Self-management programme			No HL intervention				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
van Servellen 2005 (1)	7.06	18.67	34	8.24	15.24	35	100.0%	-1.18 [-9.23 , 6.87]
Total (95% CI)			**34**			**35**	**100.0%**	**-1.18 [-9.23 , 6.87]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.29 (P = 0.77)
Test for subgroup differences: Not applicable

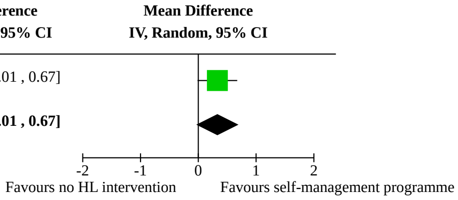


Footnotes
(1) Change scores.

Analysis 1.4. Comparison 1: Culturally and literacy adapted self-management programme versus no HL intervention, Outcome 4: Health-related knowledge: HIV knowledge, risk of getting sicker (short-term: immediately post-intervention)

	Self-management programme			No HL intervention				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
van Servellen 2005 (1)	0.24	0.78	34	-0.09	0.67	35	100.0%	0.33 [-0.01 , 0.67]
Total (95% CI)			**34**			**35**	**100.0%**	**0.33 [-0.01 , 0.67]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.88 (P = 0.06)
Test for subgroup differences: Not applicable

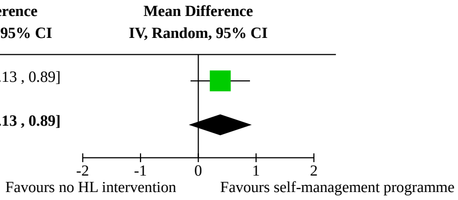


Footnotes
(1) Knowledge of risk of getting sicker without continuing HIV medication; change scores.

Analysis 1.5. Comparison 1: Culturally and literacy adapted self-management programme versus no HL intervention, Outcome 5: Health outcomes: subjective health status (short-term: immediately post-intervention)

	Self-management programme			No HL intervention				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
van Servellen 2005 (1)	0.47	1.21	34	0.09	0.95	35	100.0%	0.38 [-0.13 , 0.89]
Total (95% CI)			**34**			**35**	**100.0%**	**0.38 [-0.13 , 0.89]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.45 (P = 0.15)
Test for subgroup differences: Not applicable

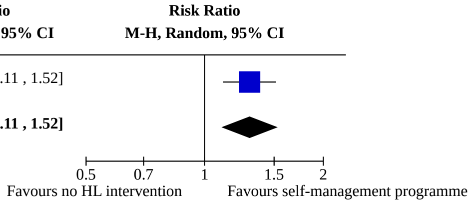


Footnotes
(1) Change scores.

Analysis 1.6. Comparison 1: Culturally and literacy adapted self-management programme versus no HL intervention, Outcome 6: Health behaviour: blood glucose self-monitoring 2 times per day (capped at 2), self-report (short-term: immediately post-intervention)

	Self-management programme		No HL intervention			Risk Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Random, 95% CI**
Rosal 2011	102	124	81	128	100.0%	1.30 [1.11 , 1.52]
Total (95% CI)		**124**		**128**	**100.0%**	**1.30 [1.11 , 1.52]**
Total events:	102		81			

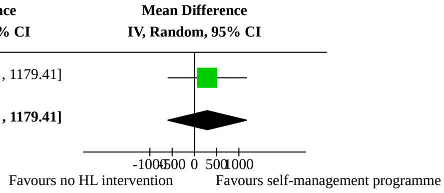
Heterogeneity: Not applicable
Test for overall effect: Z = 3.31 (P = 0.0009)
Test for subgroup differences: Not applicable



Analysis 1.7. Comparison 1: Culturally and literacy adapted self-management programme versus no HL intervention, Outcome 7: Health behaviour: physical activity, average daily steps (short-term: immediately post-intervention)

	Self-management programme			No HL intervention				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Koniak-Griffin 2015	8769	2747	98	8480	3506	95	100.0%	289.00 [-601.41 , 1179.41]
Total (95% CI)			**98**			**95**	**100.0%**	**289.00 [-601.41 , 1179.41]**

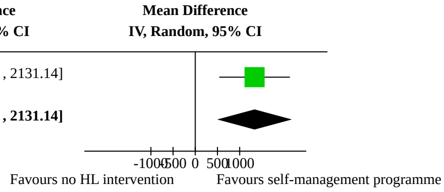
Heterogeneity: Not applicable
Test for overall effect: Z = 0.64 (P = 0.52)
Test for subgroup differences: Not applicable



Analysis 1.8. Comparison 1: Culturally and literacy adapted self-management programme versus no HL intervention, Outcome 8: Health behaviour: physical activity, average daily steps (short-term: three months post-intervention)

	Self-management programme			No HL intervention				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Koniak-Griffin 2015 (1)	8577	2872	98	7241	2764	95	100.0%	1336.00 [540.86 , 2131.14]
Total (95% CI)			**98**			**95**	**100.0%**	**1336.00 [540.86 , 2131.14]**

Heterogeneity: Not applicable
Test for overall effect: Z = 3.29 (P = 0.0010)
Test for subgroup differences: Not applicable

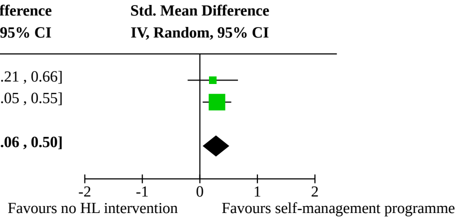


Footnotes
(1) "[T]here was a statistically significant decrease in the control group, approaching a 1000-step decline, whereas intervention participants maintained their activity level." (p. 82 f)

Analysis 1.9. Comparison 1: Culturally and literacy adapted self-management programme versus no HL intervention, Outcome 9: Self-efficacy to manage one's disease (short-term: immediately post-intervention)

	Self-management programme			No HL intervention				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
van Servellen 2005	0.12	0.95	41	-0.06	0.59	40	24.4%	0.22 [-0.21 , 0.66]
Rosal 2011 (1)	3.238	0.5	124	3.073	0.6	128	75.6%	0.30 [0.05 , 0.55]
Total (95% CI)			**165**			**168**	**100.0%**	**0.28 [0.06 , 0.50]**

Heterogeneity: Tau² = 0.00; Chi² = 0.08, df = 1 (P = 0.78); I² = 0%
Test for overall effect: Z = 2.54 (P = 0.01)
Test for subgroup differences: Not applicable



Footnotes
(1) Standard deviations of final scores were taken from reported baseline values, as neither final standard deviations nor other values indicating the spread of scores were reported.

Comparison 2. Culturally and literacy adapted self-management programme versus written information

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Generic health literacy: health numeracy, NVS (short-term: immediately post-intervention)	1	209	Mean Difference (IV, Random, 95% CI)	0.70 [0.15, 1.25]
2.2 Generic health literacy: print literacy, REALM (short-term: immediately post-intervention)	1	250	Mean Difference (IV, Random, 95% CI)	9.00 [2.90, 15.10]
2.3 Any disease-specific health literacy (short-term: immediately post-intervention) - all studies	4	955	Std. Mean Difference (IV, Random, 95% CI)	0.67 [0.27, 1.07]
2.4 Any disease-specific health literacy (short-term: immediately post-intervention - by subgroup length of programme)	4	955	Std. Mean Difference (IV, Random, 95% CI)	0.67 [0.27, 1.07]
2.4.1 Up to 6 months	2	463	Std. Mean Difference (IV, Random, 95% CI)	1.02 [0.43, 1.62]
2.4.2 12 months	2	492	Std. Mean Difference (IV, Random, 95% CI)	0.33 [0.16, 0.51]
2.5 Any disease-specific health literacy (short-term: immediately post-intervention) - studies without high risk of bias	2	390	Std. Mean Difference (IV, Random, 95% CI)	0.87 [-0.05, 1.78]
2.6 Any disease-specific health literacy (short-term: immediately post-intervention) - without Kaur 2019	3	815	Std. Mean Difference (IV, Random, 95% CI)	0.47 [0.19, 0.76]
2.7 High blood pressure health literacy, HBP health literacy scale (medium-term: 6 months post-intervention)	1	242	Mean Difference (IV, Random, 95% CI)	4.10 [0.97, 7.23]
2.8 Health literacy - appraise: decisional balance for using mammography and Pap testing (short-term: immediately post-intervention)	1	329	Mean Difference (IV, Random, 95% CI)	1.15 [-0.23, 2.53]
2.9 Diabetes-related quality of life, DQOL (short-term: immediately post-intervention) - all studies	2	288	Mean Difference (IV, Random, 95% CI)	9.06 [2.85, 15.27]
2.10 Any health-related knowledge, 0 to 100 (short-term: immediately post-intervention) - all studies	6	1101	Mean Difference (IV, Random, 95% CI)	11.45 [4.75, 18.15]
2.11 Any health-related knowledge, 0 to 100 (short-term: immediately post-intervention) - by subgroup length of programme	6	1101	Mean Difference (IV, Random, 95% CI)	11.37 [4.74, 18.01]
2.11.1 Up to 6 months	4	619	Mean Difference (IV, Random, 95% CI)	11.68 [0.72, 22.65]

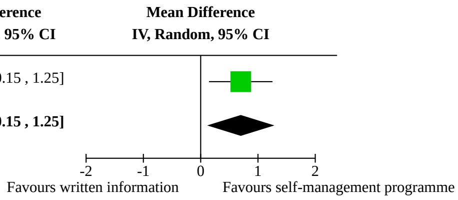
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.11.2 12 months	2	482	Mean Difference (IV, Random, 95% CI)	10.65 [0.90, 20.40]
2.12 Any health-related knowledge, 0 to 100 (short-term: immediately post-intervention) - studies without high risk of bias	3	428	Mean Difference (IV, Random, 95% CI)	17.58 [11.05, 24.11]
2.13 Any health-related knowledge, 0 to 100 (short-term: immediately post-intervention) - without Kaur 2019	5	961	Mean Difference (IV, Random, 95% CI)	8.76 [3.57, 13.96]
2.14 Any health-related knowledge, 0 to 100 (medium-term: up to 6 months post-intervention)	2	298	Mean Difference (IV, Random, 95% CI)	3.87 [-0.46, 8.19]
2.15 Health outcome: any depression (short-term: immediately post-intervention)	4	555	Std. Mean Difference (IV, Random, 95% CI)	-0.19 [-0.62, 0.23]
2.16 Health outcome: any depression (medium-term: up to 6 months post-intervention)	2	267	Std. Mean Difference (IV, Random, 95% CI)	-0.32 [-0.90, 0.27]
2.17 Health behaviour: diabetes self-care activities (short-term: immediately post-intervention)	1	79	Mean Difference (IV, Random, 95% CI)	15.00 [7.87, 22.13]
2.18 Health behaviour: oral hygiene self-care behaviour (short-term: immediately post-intervention)	1	140	Mean Difference (IV, Random, 95% CI)	3.10 [2.50, 3.70]
2.19 Health behaviour: screening adherence (mammogram and Pap test), medical record review (short-term: immediately post-intervention)	1	336	Risk Ratio (M-H, Random, 95% CI)	7.17 [3.96, 12.99]
2.20 Health behaviour: non-adherence to blood pressure medication (short-term: immediately post-intervention)	1	242	Mean Difference (IV, Random, 95% CI)	-0.40 [-0.87, 0.07]
2.21 Health behaviour: non-adherence to blood pressure medication (medium-term: 6 months post-intervention)	1	242	Mean Difference (IV, Random, 95% CI)	-0.40 [-0.78, -0.02]
2.22 Health behaviour: blood glucose self-monitoring 2 times per day (capped at 2), self-report (medium-term: 4 1/2 months post-intervention)	1	23	Risk Ratio (M-H, Random, 95% CI)	1.96 [0.76, 5.03]
2.23 Self-efficacy to manage one's disease (short-term: immediately post-intervention) - all studies	4	552	Std. Mean Difference (IV, Random, 95% CI)	0.47 [0.30, 0.64]
2.24 Self-efficacy to manage one's disease (short-term: immediately post-intervention) - studies without high risk of bias	2	285	Std. Mean Difference (IV, Random, 95% CI)	0.58 [0.34, 0.81]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.25 Self-efficacy to manage one's disease (medium-term: 6 months post-intervention)	1	242	Mean Difference (IV, Random, 95% CI)	-0.20 [-1.16, 0.76]

Analysis 2.1. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 1: Generic health literacy: health numeracy, NVS (short-term: immediately post-intervention)

	Self-management programme			Written information				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Kim 2020	3.1	2.04939	105	2.4	2.039608	104	100.0%	0.70 [0.15 , 1.25]
Total (95% CI)			**105**			**104**	**100.0%**	**0.70 [0.15 , 1.25]**

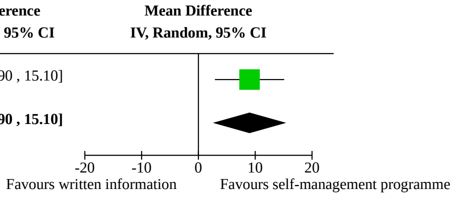
Heterogeneity: Not applicable
Test for overall effect: Z = 2.47 (P = 0.01)
Test for subgroup differences: Not applicable



Analysis 2.2. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 2: Generic health literacy: print literacy, REALM (short-term: immediately post-intervention)

	Self-management programme			Written information				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Kim 2020	40.5	24.099793	120	31.5	25.083859	130	100.0%	9.00 [2.90 , 15.10]
Total (95% CI)			**120**			**130**	**100.0%**	**9.00 [2.90 , 15.10]**

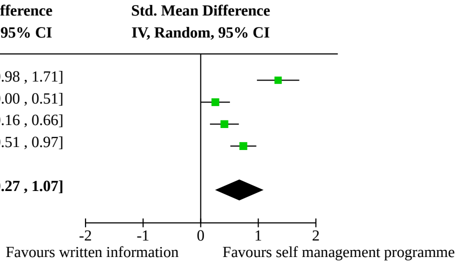
Heterogeneity: Not applicable
Test for overall effect: Z = 2.89 (P = 0.004)
Test for subgroup differences: Not applicable



Analysis 2.3. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 3: Any disease-specific health literacy (short-term: immediately post-intervention) - all studies

	Self-management programme			Written information				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Kaur 2019 (1)	6.51	3.8534	70	1.41	3.691	70	22.9%	1.34 [0.98 , 1.71]
Kim 2014 (2)	28.2	12.1	121	24.9	13.7	121	25.5%	0.25 [0.00 , 0.51]
Kim 2020 (3)	8.4	16.43	120	2.4	12.54	130	25.6%	0.41 [0.16 , 0.66]
Han 2017 (4)	12.2	9.3	160	5.3	9.3	163	26.1%	0.74 [0.51 , 0.97]
Total (95% CI)			**471**			**484**	**100.0%**	**0.67 [0.27 , 1.07]**

Heterogeneity: Tau² = 0.14; Chi² = 26.55, df = 3 (P < 0.00001); I² = 89%
Test for overall effect: Z = 3.31 (P = 0.0009)
Test for subgroup differences: Not applicable

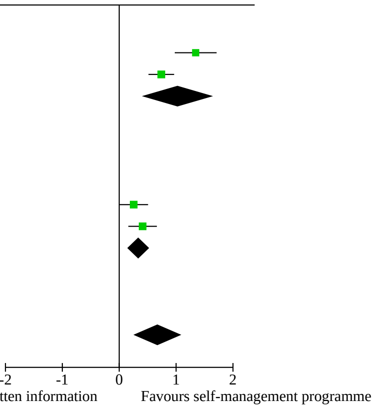


Footnotes
(1) Change scores, calculated from reported linear mixed model analysis.
(2) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.
(3) Change scores.
(4) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis; data represent MD of change scores adjusted for baseline health literacy and participant characteristics.

Analysis 2.4. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 4: Any disease-specific health literacy (short-term: immediately post-intervention - by subgroup length of programme)

	Self-management programme			Written information				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
2.4.1 Up to 6 months								
Kaur 2019 (1)	6.51	3.8534	70	1.41	3.691	70	22.9%	1.34 [0.98 , 1.71]
Han 2017 (2)	12.2	9.3	160	5.3	9.3	163	26.1%	0.74 [0.51 , 0.97]
Subtotal (95% CI)			**230**			**233**	**48.9%**	**1.02 [0.43 , 1.62]**
Heterogeneity: Tau^2 = 0.16; Chi^2 = 7.53, df = 1 (P = 0.006); I^2 = 87%								
Test for overall effect: Z = 3.40 (P = 0.0007)								
2.4.2 12 months								
Kim 2014 (3)	28.2	12.1	121	24.9	13.7	121	25.5%	0.25 [0.00 , 0.51]
Kim 2020 (4)	8.4	16.431677	120	2.4	12.54193	130	25.6%	0.41 [0.16 , 0.66]
Subtotal (95% CI)			**241**			**251**	**51.1%**	**0.33 [0.16 , 0.51]**
Heterogeneity: Tau^2 = 0.00; Chi^2 = 0.75, df = 1 (P = 0.39); I^2 = 0%								
Test for overall effect: Z = 3.67 (P = 0.0002)								
Total (95% CI)			**471**			**484**	**100.0%**	**0.67 [0.27 , 1.07]**
Heterogeneity: Tau^2 = 0.14; Chi^2 = 26.55, df = 3 (P < 0.00001); I^2 = 89%								
Test for overall effect: Z = 3.31 (P = 0.0009)								
Test for subgroup differences: Chi^2 = 4.81, df = 1 (P = 0.03), I^2 = 79.2%								

Std. Mean Difference
IV, Random, 95% CI

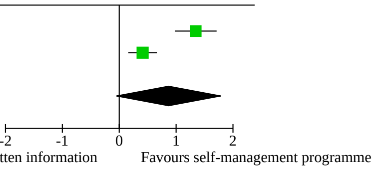


Footnotes
(1) Scores calculated from linear mixed model analysis.
(2) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis; data represent MD of change scores adjusted for baseline health literacy and participant characteristics.
(3) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.
(4) Change scores.

Analysis 2.5. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 5: Any disease-specific health literacy (short-term: immediately post-intervention) - studies without high risk of bias

	Self-management programme			Written information				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Kaur 2019 (1)	6.51	3.8534	70	1.41	3.691	70	48.9%	1.34 [0.98 , 1.71]
Kim 2020 (2)	8.4	16.431677	120	2.4	12.54193	130	51.1%	0.41 [0.16 , 0.66]
Total (95% CI)			**190**			**200**	**100.0%**	**0.87 [-0.05 , 1.78]**
Heterogeneity: Tau^2 = 0.41; Chi^2 = 16.87, df = 1 (P < 0.0001); I^2 = 94%								
Test for overall effect: Z = 1.86 (P = 0.06)								
Test for subgroup differences: Not applicable								

Std. Mean Difference
IV, Random, 95% CI

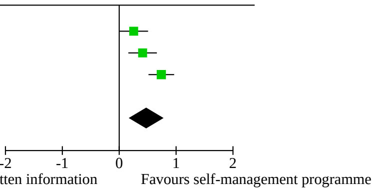


Footnotes
(1) Change scores, calculated from linear mixed model analysis.
(2) Change scores.

Analysis 2.6. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 6: Any disease-specific health literacy (short-term: immediately post-intervention) - without Kaur 2019

	Self-management programme			Written information				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Kim 2014 (1)	28.2	12.1	121	24.9	13.7	121	32.7%	0.25 [0.00 , 0.51]
Kim 2020 (2)	8.4	16.431677	120	2.4	12.54193	130	32.8%	0.41 [0.16 , 0.66]
Han 2017 (3)	12.2	9.3	160	5.3	9.3	163	34.5%	0.74 [0.51 , 0.97]
Total (95% CI)			**401**			**414**	**100.0%**	**0.47 [0.19 , 0.76]**
Heterogeneity: Tau^2 = 0.05; Chi^2 = 8.43, df = 2 (P = 0.01); I^2 = 76%								
Test for overall effect: Z = 3.22 (P = 0.001)								
Test for subgroup differences: Not applicable								

Std. Mean Difference
IV, Random, 95% CI

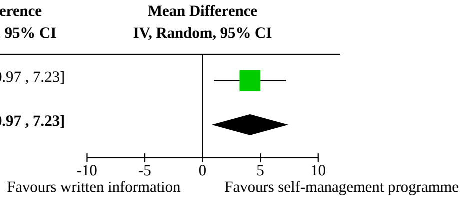


Footnotes
(1) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.
(2) Change scores.
(3) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis; data represent MD of change scores adjusted for baseline health literacy and participant characteristics.

Analysis 2.7. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 7: High blood pressure health literacy, HBP health literacy scale (medium-term: 6 months post-intervention)

	Self-management programme			Written information				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Kim 2014 (1)	29.4	11.4	121	25.3	13.4	121	100.0%	4.10 [0.97 , 7.23]
Total (95% CI)			**121**			**121**	**100.0%**	**4.10 [0.97 , 7.23]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.56 (P = 0.01)
Test for subgroup differences: Not applicable



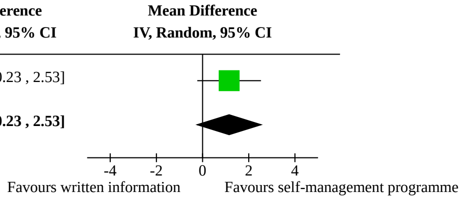
Footnotes

(1) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.

Analysis 2.8. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 8: Health literacy - appraise: decisional balance for using mammography and Pap testing (short-term: immediately post-intervention)

	Self-management programme			Written information				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Han 2017 (1)	52.2	6.43	163	51.05	6.33	166	100.0%	1.15 [-0.23 , 2.53]
Total (95% CI)			**163**			**166**	**100.0%**	**1.15 [-0.23 , 2.53]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.63 (P = 0.10)
Test for subgroup differences: Not applicable



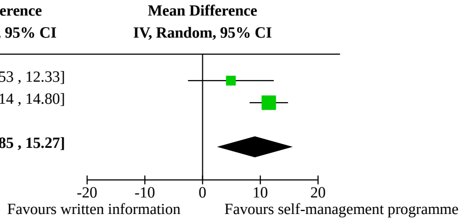
Footnotes

(1) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis; data represent pooled change scores of decisional balance subscales.

Analysis 2.9. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 9: Diabetes-related quality of life, DQOL (short-term: immediately post-intervention) - all studies

	Self-management programme			Written information				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Kim 2009	4.6	17.3	40	-0.3	16.4	39	36.7%	4.90 [-2.53 , 12.33]
Kim 2020	10	12.3	105	-1.47	12.24	104	63.3%	11.47 [8.14 , 14.80]
Total (95% CI)			**145**			**143**	**100.0%**	**9.06 [2.85 , 15.27]**

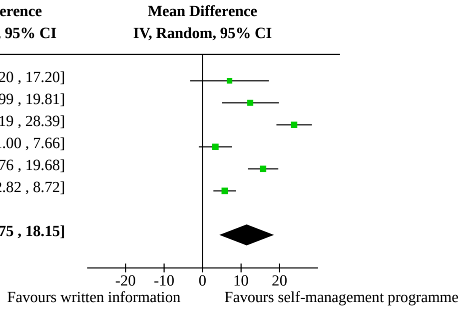
Heterogeneity: Tau² = 12.95; Chi² = 2.50, df = 1 (P = 0.11); I² = 60%
Test for overall effect: Z = 2.86 (P = 0.004)
Test for subgroup differences: Not applicable



Analysis 2.10. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 10: Any health-related knowledge, 0 to 100 (short-term: immediately post-intervention) - all studies

	Self-management programme			Written information				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Rosal 2005 (1)	5	15	15	-2	11	10	13.2%	7.00 [-3.20 , 17.20]
Kim 2009 (1)	17.4	16.43	40	5	17.14	39	15.4%	12.40 [4.99 , 19.81]
Kaur 2019 (2)	29.26	14.33	70	5.47	13.42	70	17.5%	23.79 [19.19 , 28.39]
Han 2017 (3)	61.11	21.67	186	57.78	21.11	189	17.6%	3.33 [-1.00 , 7.66]
Kim 2020 (1)	19.29	14.65	105	3.57	14.58	104	17.9%	15.72 [11.76 , 19.68]
Kim 2014 (4)	80	10.38	136	74.23	14.23	137	18.4%	5.77 [2.82 , 8.72]
Total (95% CI)			**552**			**549**	**100.0%**	**11.45 [4.75 , 18.15]**

Heterogeneity: Tau² = 61.30; Chi² = 59.81, df = 5 (P < 0.00001); I² = 92%
Test for overall effect: Z = 3.35 (P = 0.0008)
Test for subgroup differences: Not applicable

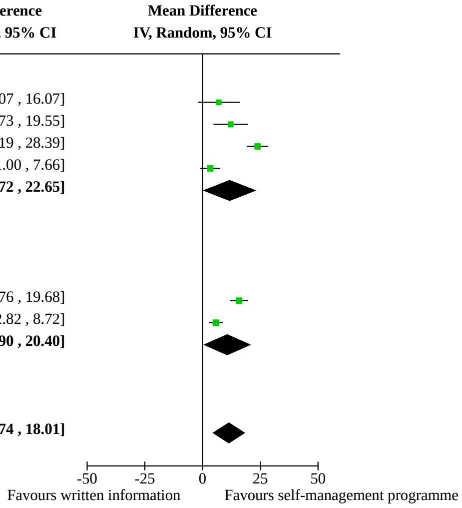


Footnotes
(1) Change scores.
(2) Change scores, calculated from reported linear mixed model analysis.
(3) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis; data represent pooled change scores for cervical and breast cancer knowledge.
(4) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.

Analysis 2.11. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 11: Any health-related knowledge, 0 to 100 (short-term: immediately post-intervention) - by subgroup length of programme

	Self-management programme			Written information				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
2.11.1 Up to 6 months								
Rosal 2005 (1)	5	15	15	-2	8	10	14.0%	7.00 [-2.07 , 16.07]
Kim 2009 (1)	17.14	16.43	40	5	17.14	39	15.3%	12.14 [4.73 , 19.55]
Kaur 2019 (2)	29.26	14.33	70	5.47	13.42	70	17.3%	23.79 [19.19 , 28.39]
Han 2017 (3)	61.11	21.67	186	57.78	21.11	189	17.5%	3.33 [-1.00 , 7.66]
Subtotal (95% CI)			**311**			**308**	**64.1%**	**11.68 [0.72 , 22.65]**
Heterogeneity: Tau² = 113.97; Chi² = 41.77, df = 3 (P < 0.00001); I² = 93%								
Test for overall effect: Z = 2.09 (P = 0.04)								
2.11.2 12 months								
Kim 2020 (1)	19.29	14.65	105	3.57	14.58	104	17.7%	15.72 [11.76 , 19.68]
Kim 2014 (4)	80	10.38	136	74.23	14.23	137	18.2%	5.77 [2.82 , 8.72]
Subtotal (95% CI)			**241**			**241**	**35.9%**	**10.65 [0.90 , 20.40]**
Heterogeneity: Tau² = 46.32; Chi² = 15.57, df = 1 (P < 0.0001); I² = 94%								
Test for overall effect: Z = 2.14 (P = 0.03)								
Total (95% CI)			**552**			**549**	**100.0%**	**11.37 [4.74 , 18.01]**

Heterogeneity: Tau² = 60.60; Chi² = 59.88, df = 5 (P < 0.00001); I² = 92%
Test for overall effect: Z = 3.36 (P = 0.0008)
Test for subgroup differences: Chi² = 0.02, df = 1 (P = 0.89), I² = 0%

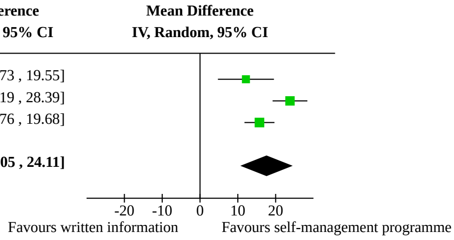


Footnotes
(1) Change scores.
(2) Change scores, calculated from reported linear mixed model analysis.
(3) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis; data represent pooled change scores for cervical and breast cancer knowledge.
(4) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.

Analysis 2.12. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 12: Any health-related knowledge, 0 to 100 (short-term: immediately post-intervention) - studies without high risk of bias

	Self-management programme			Written information				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Kim 2009 (1)	17.14	16.43	40	5	17.14	39	27.6%	12.14 [4.73 , 19.55]
Kaur 2019 (2)	29.26	14.33	70	5.47	13.42	70	35.4%	23.79 [19.19 , 28.39]
Kim 2020 (1)	19.29	14.65314	105	3.57	14.583196	104	37.0%	15.72 [11.76 , 19.68]
Total (95% CI)			**215**			**213**	**100.0%**	**17.58 [11.05 , 24.11]**

Heterogeneity: Tau² = 25.89; Chi² = 9.75, df = 2 (P = 0.008); I² = 79%
Test for overall effect: Z = 5.28 (P < 0.00001)
Test for subgroup differences: Not applicable

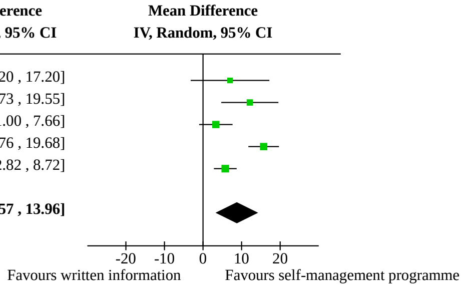


Footnotes
(1) Change scores.
(2) Change scores, calculated from reported linear mixed model analysis.

Analysis 2.13. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 13: Any health-related knowledge, 0 to 100 (short-term: immediately post-intervention) - without Kaur 2019

	Self-management programme			Written information				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Rosal 2005 (1)	5	15	15	-2	11	10	13.1%	7.00 [-3.20 , 17.20]
Kim 2009 (1)	17.14	16.43	40	5	17.14	39	17.2%	12.14 [4.73 , 19.55]
Han 2017 (2)	61.11	21.67	186	57.78	21.11	189	22.4%	3.33 [-1.00 , 7.66]
Kim 2020 (1)	19.29	14.65	105	3.57	14.58	104	22.9%	15.72 [11.76 , 19.68]
Kim 2014 (3)	80	10.38	136	74.23	14.23	137	24.4%	5.77 [2.82 , 8.72]
Total (95% CI)			**482**			**479**	**100.0%**	**8.76 [3.57 , 13.96]**

Heterogeneity: Tau² = 26.57; Chi² = 22.43, df = 4 (P = 0.0002); I² = 82%
Test for overall effect: Z = 3.31 (P = 0.0009)
Test for subgroup differences: Not applicable

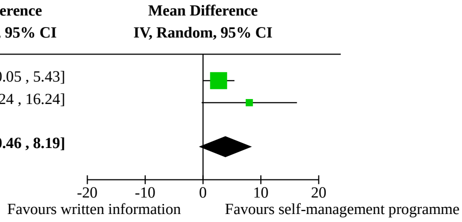


Footnotes
(1) Change scores.
(2) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis; data represent pooled change scores for cervical and breast cancer knowledge.
(3) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.

Analysis 2.14. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 14: Any health-related knowledge, 0 to 100 (medium-term: up to 6 months post-intervention)

	Self-management programme			Written information				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Kim 2014 (1)	80	10.77	136	77.31	12.31	137	77.9%	2.69 [-0.05 , 5.43]
Rosal 2005 (2)	5	13	15	-3	8	10	22.1%	8.00 [-0.24 , 16.24]
Total (95% CI)			**151**			**147**	**100.0%**	**3.87 [-0.46 , 8.19]**

Heterogeneity: Tau² = 4.29; Chi² = 1.44, df = 1 (P = 0.23); I² = 30%
Test for overall effect: Z = 1.75 (P = 0.08)
Test for subgroup differences: Not applicable

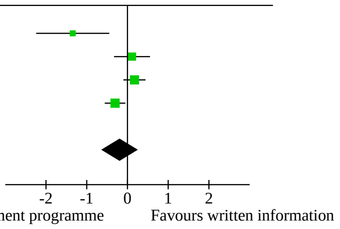


Footnotes
(1) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.
(2) Change scores.

Analysis 2.15. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 15: Health outcome: any depression (short-term: immediately post-intervention)

	Self-management programme			Written information				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Rosal 2005	-3.7	7.6	15	7.6	8.9	10	13.5%	-1.34 [-2.24 , -0.45]
Kim 2009 (1)	-0.5	4.5	40	-1	4.3	39	25.2%	0.11 [-0.33 , 0.55]
Kim 2020 (1)	-0.5	5.12	105	-1.3	4.08	104	30.4%	0.17 [-0.10 , 0.44]
Kim 2014 (2)	2.1	2.9	121	3	3	121	30.9%	-0.30 [-0.56 , -0.05]
Total (95% CI)			**281**			**274**	**100.0%**	**-0.19 [-0.62 , 0.23]**

Heterogeneity: Tau² = 0.13; Chi² = 14.61, df = 3 (P = 0.002); I² = 79%
Test for overall effect: Z = 0.91 (P = 0.37)
Test for subgroup differences: Not applicable

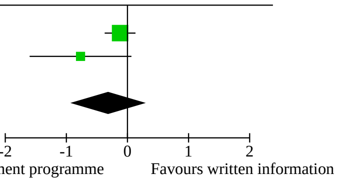


Footnotes
(1) Change scores.
(2) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.

Analysis 2.16. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 16: Health outcome: any depression (medium-term: up to 6 months post-intervention)

	Self-management programme			Written information				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Kim 2014 (1)	2.5	3.3	121	2.9	3.3	121	69.6%	-0.12 [-0.37 , 0.13]
Rosal 2005 (2)	1.4	9.8	15	9.57	11	10	30.4%	-0.77 [-1.60 , 0.07]
Total (95% CI)			**136**			**131**	**100.0%**	**-0.32 [-0.90 , 0.27]**

Heterogeneity: Tau² = 0.11; Chi² = 2.12, df = 1 (P = 0.15); I² = 53%
Test for overall effect: Z = 1.07 (P = 0.29)
Test for subgroup differences: Not applicable

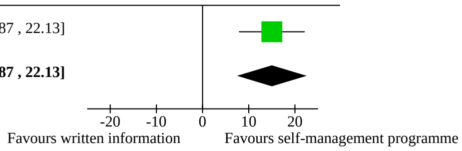


Footnotes
(1) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.
(2) Change scores.

Analysis 2.17. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 17: Health behaviour: diabetes self-care activities (short-term: immediately post-intervention)

	Self-management programme			Written information				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Kim 2009	17.5	16.9	40	2.5	15.4	39	100.0%	15.00 [7.87 , 22.13]
Total (95% CI)			**40**			**39**	**100.0%**	**15.00 [7.87 , 22.13]**

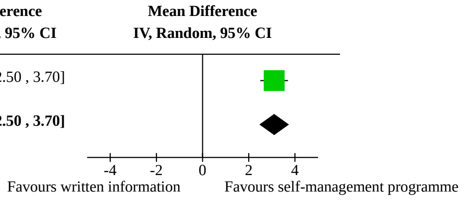
Heterogeneity: Not applicable
Test for overall effect: Z = 4.13 (P < 0.0001)
Test for subgroup differences: Not applicable



Analysis 2.18. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 18: Health behaviour: oral hygiene self-care behaviour (short-term: immediately post-intervention)

	Self-management programme			Written information				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Kaur 2019 (1)	3.58	1.8982	70	0.48	1.7195	70	100.0%	3.10 [2.50 , 3.70]
Total (95% CI)			**70**			**70**	**100.0%**	**3.10 [2.50 , 3.70]**

Heterogeneity: Not applicable
Test for overall effect: Z = 10.13 (P < 0.00001)
Test for subgroup differences: Not applicable

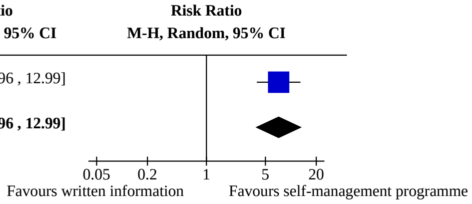


Footnotes
(1) Change scores, calculated from linear mixed model repeated measure analysis.

Analysis 2.19. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 19: Health behaviour: screening adherence (mammogram and Pap test), medical record review (short-term: immediately post-intervention)

	Self-management programme		Written information			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI
Han 2017 (1)	77	166	11	170	100.0%	7.17 [3.96 , 12.99]
Total (95% CI)		**166**		**170**	**100.0%**	**7.17 [3.96 , 12.99]**
Total events:	77		11			

Heterogeneity: Not applicable
Test for overall effect: Z = 6.49 (P < 0.00001)
Test for subgroup differences: Not applicable

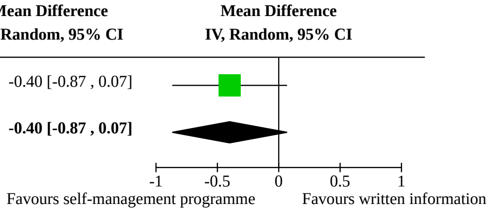


Footnotes
(1) Cluster-RCT, estimated from generalised estimating equations model accounting for clustering and baseline characteristics.

Analysis 2.20. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 20: Health behaviour: non-adherence to blood pressure medication (short-term: immediately post-intervention)

	Self-management programme			Written information				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Kim 2014 (1)	9.1	1.7	121	9.5	2	121	100.0%	-0.40 [-0.87 , 0.07]
Total (95% CI)			**121**			**121**	**100.0%**	**-0.40 [-0.87 , 0.07]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.68 (P = 0.09)
Test for subgroup differences: Not applicable

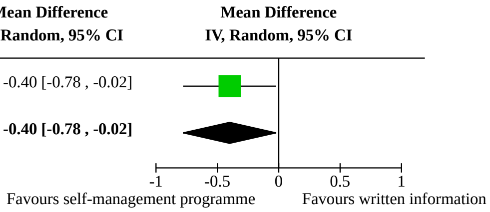


Footnotes
(1) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.

Analysis 2.21. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 21: Health behaviour: non-adherence to blood pressure medication (medium-term: 6 months post-intervention)

Study or Subgroup	Self-management programme Mean	SD	Total	Written information Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Kim 2014 (1)	8.8	1.4	121	9.2	1.6	121	100.0%	-0.40 [-0.78 , -0.02]
Total (95% CI)			**121**			**121**	**100.0%**	**-0.40 [-0.78 , -0.02]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.07 (P = 0.04)
Test for subgroup differences: Not applicable

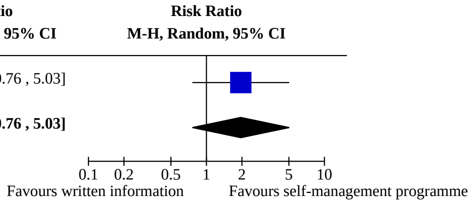


Footnotes
(1) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.

Analysis 2.22. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 22: Health behaviour: blood glucose self-monitoring 2 times per day (capped at 2), self-report (medium-term: 4 1/2 months post-intervention)

Study or Subgroup	Self-management programme Events	Total	Written information Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Rosal 2005	11	15	3	8	100.0%	1.96 [0.76 , 5.03]
Total (95% CI)		**15**		**8**	**100.0%**	**1.96 [0.76 , 5.03]**
Total events:	11		3			

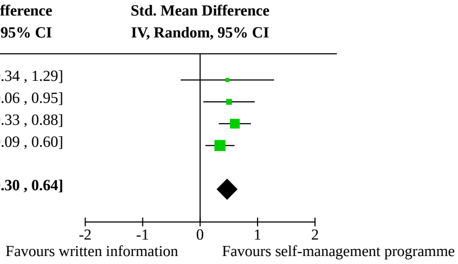
Heterogeneity: Not applicable
Test for overall effect: Z = 1.39 (P = 0.16)
Test for subgroup differences: Not applicable



Analysis 2.23. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 23: Self-efficacy to manage one's disease (short-term: immediately post-intervention) - all studies

Study or Subgroup	Self-management programme Mean	SD	Total	Written information Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Rosal 2005 (1)	0.06	0.58	15	-0.21	0.5	10	4.3%	0.47 [-0.34 , 1.29]
Kim 2009 (1)	6.6	14.4	40	-0.9	15.1	39	14.3%	0.50 [0.06 , 0.95]
Kim 2020 (1)	9.5	12.2963	105	1.8	13.0648	101	36.8%	0.61 [0.33 , 0.88]
Kim 2014 (2)	26.6	3.2	121	25.4	3.7	121	44.6%	0.35 [0.09 , 0.60]
Total (95% CI)			**281**			**271**	**100.0%**	**0.47 [0.30 , 0.64]**

Heterogeneity: Tau² = 0.00; Chi² = 1.84, df = 3 (P = 0.61); I² = 0%
Test for overall effect: Z = 5.43 (P < 0.00001)
Test for subgroup differences: Not applicable

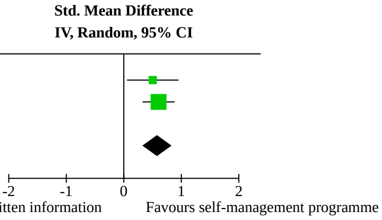


Footnotes
(1) Change scores.
(2) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.

Analysis 2.24. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 24: Self-efficacy to manage one's disease (short-term: immediately post-intervention) - studies without high risk of bias

	Self-management programme			Written information				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Kim 2009 (1)	6.6	14.4	40	-0.9	15.1	39	28.0%	0.50 [0.06 , 0.95]
Kim 2020 (1)	9.5	12.2963	105	1.8	13.0648	101	72.0%	0.61 [0.33 , 0.88]
Total (95% CI)			**145**			**140**	**100.0%**	**0.58 [0.34 , 0.81]**

Heterogeneity: Tau² = 0.00; Chi² = 0.14, df = 1 (P = 0.71); I² = 0%
Test for overall effect: Z = 4.77 (P < 0.00001)
Test for subgroup differences: Not applicable

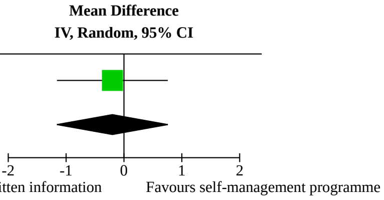


Footnotes
(1) Change scores.

Analysis 2.25. Comparison 2: Culturally and literacy adapted self-management programme versus written information, Outcome 25: Self-efficacy to manage one's disease (medium-term: 6 months post-intervention)

	Self-management programme			Written information				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Kim 2014 (1)	25.9	3.7	121	26.1	3.9	121	100.0%	-0.20 [-1.16 , 0.76]
Total (95% CI)			**121**			**121**	**100.0%**	**-0.20 [-1.16 , 0.76]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.41 (P = 0.68)
Test for subgroup differences: Not applicable



Footnotes
(1) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.

Comparison 3. Culturally adapted health literacy skills building course versus no/unrelated health literacy intervention

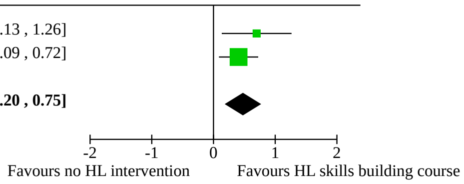
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Any generic health literacy (short-term: up to 1 month post-intervention)	2	229	Std. Mean Difference (IV, Random, 95% CI)	0.48 [0.20, 0.75]
3.2 Depression literacy, D-Lit (short-term: outcome assessment immediately post-intervention)	1	37	Mean Difference (IV, Random, 95% CI)	0.17 [-1.28, 1.62]
3.3 Any health-related knowledge, 0 to 100 (short-term: up to 1 month post-intervention) - all studies	2	111	Mean Difference (IV, Random, 95% CI)	10.87 [5.69, 16.06]
3.4 Hepatitis B knowledge (medium-term: 6 months post-intervention)	1	168	Mean Difference (IV, Random, 95% CI)	0.81 [0.43, 1.19]
3.5 Health behaviour: fat-related dietary habits, self-report (short-term: 1-month post-intervention)	1	74	Mean Difference (IV, Random, 95% CI)	0.25 [0.00, 0.50]
3.6 Health behaviour: any screening adherence, odds ratio short-/medium-term: up to 6 months post-intervention)	2	440	Risk Ratio (IV, Random, 95% CI)	2.68 [0.33, 21.83]

Analysis 3.1. Comparison 3: Culturally adapted health literacy skills building course versus no/unrelated health literacy intervention, Outcome 1: Any generic health literacy (short-term: up to 1 month post-intervention)

	HL skills building course			No HL intervention				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Otilingam 2015 (1)	2.57	1.72	58	1.38	1.54	16	24.0%	0.70 [0.13 , 1.26]
Soto Mas 2018 (2)	12.9	11.01	77	8.2	11.98	78	76.0%	0.41 [0.09 , 0.72]
Total (95% CI)			**135**			**94**	**100.0%**	**0.48 [0.20 , 0.75]**

Heterogeneity: Tau^2 = 0.00; Chi^2 = 0.78, df = 1 (P = 0.38); I^2 = 0%
Test for overall effect: Z = 3.37 (P = 0.0008)
Test for subgroup differences: Not applicable

Std. Mean Difference
IV, Random, 95% CI



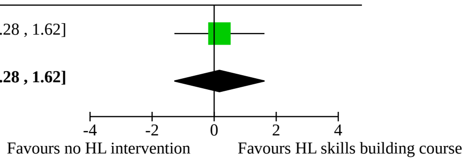
Footnotes
(1) Intervention groups were merged to create a single pairwise comparison.
(2) Change scores.

Analysis 3.2. Comparison 3: Culturally adapted health literacy skills building course versus no/unrelated health literacy intervention, Outcome 2: Depression literacy, D-Lit (short-term: outcome assessment immediately post-intervention)

	HL skills building course			No HL intervention				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Wong 2020	13.06	2.1	18	12.89	2.4	19	100.0%	0.17 [-1.28 , 1.62]
Total (95% CI)			**18**			**19**	**100.0%**	**0.17 [-1.28 , 1.62]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.23 (P = 0.82)
Test for subgroup differences: Not applicable

Mean Difference
IV, Random, 95% CI

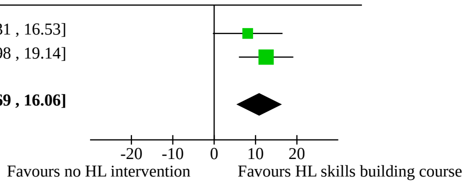


Analysis 3.3. Comparison 3: Culturally adapted health literacy skills building course versus no/unrelated health literacy intervention, Outcome 3: Any health-related knowledge, 0 to 100 (short-term: up to 1 month post-intervention) - all studies

	HL skills building course			No HL intervention				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Wong 2020 (1)	56.22	12.33	18	48.11	13.78	19	37.9%	8.11 [-0.31 , 16.53]
Otilingam 2015 (2)	74.34	13.49	58	61.78	11.4	16	62.1%	12.56 [5.98 , 19.14]
Total (95% CI)			**76**			**35**	**100.0%**	**10.87 [5.69 , 16.06]**

Heterogeneity: Tau^2 = 0.00; Chi^2 = 0.67, df = 1 (P = 0.41); I^2 = 0%
Test for overall effect: Z = 4.11 (P < 0.0001)
Test for subgroup differences: Not applicable

Mean Difference
IV, Random, 95% CI

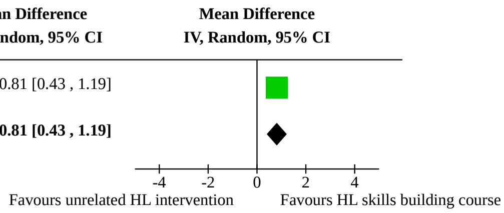


Footnotes
(1) Baseline SD was taken for intervention group's effects due to uncertainty in the reported post SD.
(2) Intervention groups were merged to create a single pairwise comparison.

Analysis 3.4. Comparison 3: Culturally adapted health literacy skills building course versus no/unrelated health literacy intervention, Outcome 4: Hepatitis B knowledge (medium-term: 6 months post-intervention)

	HL skills building course			Unrelated HL intervention				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Taylor 2011 (1)	3.68	1.12	75	2.87	1.38	93	100.0%	0.81 [0.43 , 1.19]
Total (95% CI)			**75**			**93**	**100.0%**	**0.81 [0.43 , 1.19]**

Heterogeneity: Not applicable
Test for overall effect: Z = 4.20 (P < 0.0001)
Test for subgroup differences: Not applicable

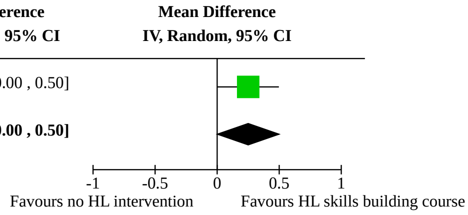


Footnotes
(1) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.

Analysis 3.5. Comparison 3: Culturally adapted health literacy skills building course versus no/unrelated health literacy intervention, Outcome 5: Health behaviour: fat-related dietary habits, self-report (short-term: 1-month post-intervention)

	HL skills building course			No HL intervention				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Otilingam 2015 (1)	3.41	0.35	58	3.16	0.47	16	100.0%	0.25 [0.00 , 0.50]
Total (95% CI)			**58**			**16**	**100.0%**	**0.25 [0.00 , 0.50]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.98 (P = 0.05)
Test for subgroup differences: Not applicable

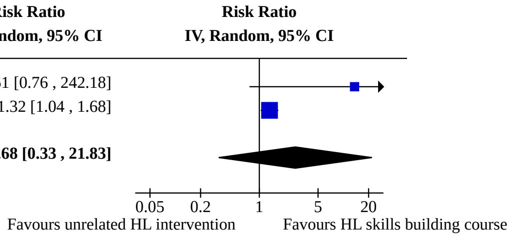


Footnotes
(1) Intervention groups were merged to create a single pairwise comparison.

Analysis 3.6. Comparison 3: Culturally adapted health literacy skills building course versus no/unrelated health literacy intervention, Outcome 6: Health behaviour: any screening adherence, odds ratio short-/medium-term: up to 6 months post-intervention)

	HL skills building course		Unrelated HL intervention			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	IV, Random, 95% CI
Taylor 2011 (1)	5	75	0	93	30.3%	13.61 [0.76 , 242.18]
Tong 2017 (1)	76	133	60	139	69.7%	1.32 [1.04 , 1.68]
Total (95% CI)		**208**		**232**	**100.0%**	**2.68 [0.33 , 21.83]**
Total events:	81		60			

Heterogeneity: Tau^2 = 1.63; Chi^2 = 2.50, df = 1 (P = 0.11); I^2 = 60%
Test for overall effect: Z = 0.92 (P = 0.36)
Test for subgroup differences: Not applicable



Footnotes
(1) Cluster-RCT; data have been re-analysed using the appropriate unit of analysis.

Comparison 4. Culturally and literacy adapted telephone education versus unrelated health literacy intervention

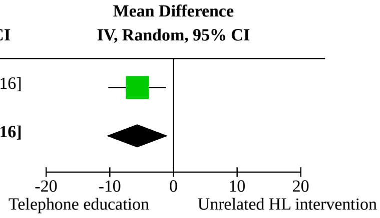
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Health literacy - appraise: decisional conflict (long-term: approx. 7 months post-intervention)	1	431	Mean Difference (IV, Random, 95% CI)	-5.70 [-10.24, -1.16]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.2 Health literacy - apply: prostate cancer screening intention (long-term: approx. 7 months post-intervention)	1	431	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.92, 1.10]
4.3 Prostate cancer knowledge, 0 to 100 (long-term: approx. 7 months post-intervention)	1	431	Mean Difference (IV, Random, 95% CI)	6.90 [6.88, 6.92]
4.4 Health behaviour: prostate cancer testing (long-term: 2 years post-intervention)	1	490	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.82, 1.07]
4.5 Adverse events: anxiety (long-term: approx. 7 months post-intervention)	1	431	Mean Difference (IV, Random, 95% CI)	-0.14 [-0.55, 0.27]

Analysis 4.1. Comparison 4: Culturally and literacy adapted telephone education versus unrelated health literacy intervention, Outcome 1: Health literacy - appraise: decisional conflict (long-term: approx. 7 months post-intervention)

Study or Subgroup	Telephone education Mean	SD	Total	Unrelated HL intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Lepore 2012 (1)	34.15	24.03	215	39.85	24.04	216	100.0%	-5.70 [-10.24 , -1.16]
Total (95% CI)			**215**			**216**	**100.0%**	**-5.70 [-10.24 , -1.16]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.46 (P = 0.01)
Test for subgroup differences: Not applicable

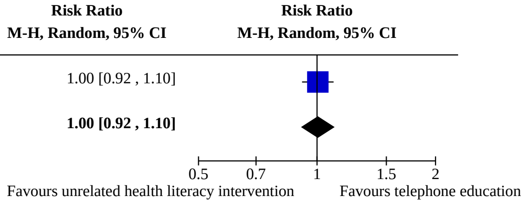


Footnotes
(1) Adjusted for education and any PSA claim prior to pretest.

Analysis 4.2. Comparison 4: Culturally and literacy adapted telephone education versus unrelated health literacy intervention, Outcome 2: Health literacy - apply: prostate cancer screening intention (long-term: approx. 7 months post-intervention)

Study or Subgroup	Telephone education Events	Total	Unrelated health literacy intervention Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Lepore 2012	174	215	174	216	100.0%	1.00 [0.92 , 1.10]
Total (95% CI)		**215**		**216**	**100.0%**	**1.00 [0.92 , 1.10]**
Total events:	174		174			

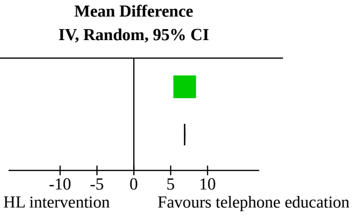
Heterogeneity: Not applicable
Test for overall effect: Z = 0.10 (P = 0.92)
Test for subgroup differences: Not applicable



Analysis 4.3. Comparison 4: Culturally and literacy adapted telephone education versus unrelated health literacy intervention, Outcome 3: Prostate cancer knowledge, 0 to 100 (long-term: approx. 7 months post-intervention)

	Telephone education			Unrelated HL intervention				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Lepore 2012 (1)	61.6	0.13	215	54.7	0.13	216	100.0%	6.90 [6.88 , 6.92]
Total (95% CI)			**215**			**216**	**100.0%**	**6.90 [6.88 , 6.92]**

Heterogeneity: Not applicable
Test for overall effect: Z = 550.95 (P < 0.00001)
Test for subgroup differences: Not applicable

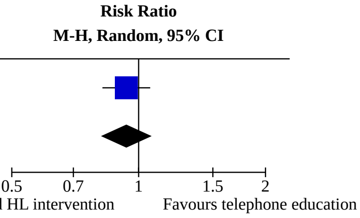


Footnotes
(1) Adjusted for education, any PSA claim prior to pretest and percentage correct on knowledge index at pretest.

Analysis 4.4. Comparison 4: Culturally and literacy adapted telephone education versus unrelated health literacy intervention, Outcome 4: Health behaviour: prostate cancer testing (long-term: 2 years post-intervention)

	Telephone education		Unrelated HL intervention			Risk Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Random, 95% CI**
Lepore 2012	153	244	165	246	100.0%	0.93 [0.82 , 1.07]
Total (95% CI)		**244**		**246**	**100.0%**	**0.93 [0.82 , 1.07]**
Total events:	153		165			

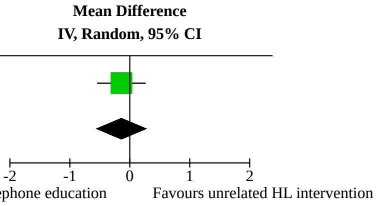
Heterogeneity: Not applicable
Test for overall effect: Z = 1.01 (P = 0.31)
Test for subgroup differences: Not applicable



Analysis 4.5. Comparison 4: Culturally and literacy adapted telephone education versus unrelated health literacy intervention, Outcome 5: Adverse events: anxiety (long-term: approx. 7 months post-intervention)

	Telephone education			Unrelated HL intervention				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Lepore 2012	2.02	2.155443	215	2.16	2.145753	216	100.0%	-0.14 [-0.55 , 0.27]
Total (95% CI)			**215**			**216**	**100.0%**	**-0.14 [-0.55 , 0.27]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.68 (P = 0.50)
Test for subgroup differences: Not applicable



Comparison 5. Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention

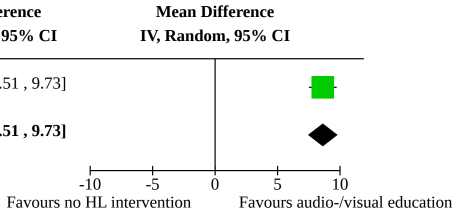
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Health literacy: depression literacy, D-Lit (short-term: at 1-week post-intervention)	1	202	Mean Difference (IV, Random, 95% CI)	8.62 [7.51, 9.73]
5.2 Health literacy: apply - intent to seek treatment (short-term: immediately post-intervention)	1	120	Mean Difference (IV, Random, 95% CI)	1.80 [0.43, 3.17]
5.3 Any health-related knowledge, 0 to 100 (short-term: immediately up to 3 months post-intervention)	2	293	Mean Difference (IV, Random, 95% CI)	8.44 [-2.56, 19.44]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.4 Health outcome: any depression (short-term: up to 1 week post-intervention)	2	337	Std. Mean Difference (IV, Random, 95% CI)	-0.15 [-0.40, 0.10]
5.5 Health behaviour: child's up-to-date immunisation (short-term: immediately up to 3 months post-intervention)	1	135	Risk Ratio (IV, Random, 95% CI)	1.07 [0.91, 1.25]
5.6 Self-efficacy to identify need for treatment (short-term: immediately post-intervention)	1	133	Mean Difference (IV, Random, 95% CI)	3.51 [2.53, 4.49]
5.7 Health service use: emergency room visits, medical record review (short-term: immediately up to 3 months post-intervention)	1	157	Mean Difference (IV, Random, 95% CI)	-0.59 [-1.11, -0.07]

Analysis 5.1. Comparison 5: Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention, Outcome 1: Health literacy: depression literacy, D-Lit (short-term: at 1-week post-intervention)

Study or Subgroup	Audio-/visual education Mean	SD	Total	No HL intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Kiropoulos 2011	16.84	3.58	110	8.22	4.33	92	100.0%	8.62 [7.51 , 9.73]
Total (95% CI)			**110**			**92**	**100.0%**	**8.62 [7.51 , 9.73]**

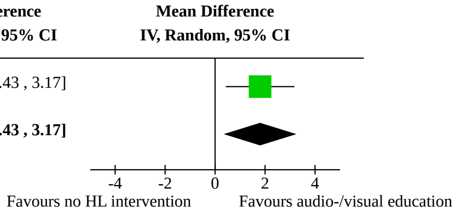
Heterogeneity: Not applicable
Test for overall effect: Z = 15.23 (P < 0.00001)
Test for subgroup differences: Not applicable



Analysis 5.2. Comparison 5: Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention, Outcome 2: Health literacy: apply - intent to seek treatment (short-term: immediately post-intervention)

Study or Subgroup	Audio-/visual education Mean	SD	Total	No HL intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Hernandez 2013 (1)	1.1	2.99	63	-0.7	4.46	57	100.0%	1.80 [0.43 , 3.17]
Total (95% CI)			**63**			**57**	**100.0%**	**1.80 [0.43 , 3.17]**

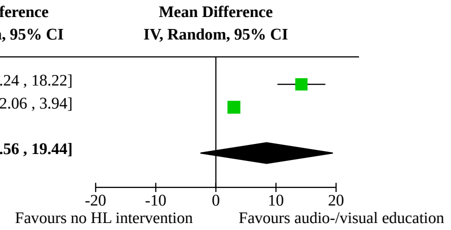
Heterogeneity: Not applicable
Test for overall effect: Z = 2.57 (P = 0.01)
Test for subgroup differences: Not applicable



Footnotes
(1) Change scores.

Analysis 5.3. Comparison 5: Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention, Outcome 3: Any health-related knowledge, 0 to 100 (short-term: immediately up to 3 months post-intervention)

	Audio-/visual education			No/unrelated HL intervention				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Hernandez 2013 (1)	14.35	13.17	72	0.12	10.53	64	48.4%	14.23 [10.24 , 18.22]
DeCamp 2020 (1)	13.4	3	79	10.4	3	78	51.6%	3.00 [2.06 , 3.94]
Total (95% CI)			**151**			**142**	**100.0%**	**8.44 [-2.56 , 19.44]**

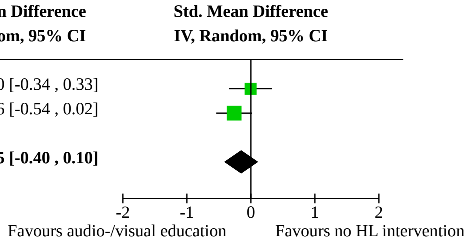


Heterogeneity: Tau² = 60.87; Chi² = 28.85, df = 1 (P < 0.00001); I² = 97%
Test for overall effect: Z = 1.50 (P = 0.13)
Test for subgroup differences: Not applicable

Footnotes
(1) Change scores.

Analysis 5.4. Comparison 5: Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention, Outcome 4: Health outcome: any depression (short-term: up to 1 week post-intervention)

	Audio-/visual education			No HL intervention				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
DeCamp 2020 (1)	0.68	3.82	72	0.7	4.18	63	42.7%	-0.00 [-0.34 , 0.33]
Kiropoulos 2011	6.36	6.6	110	8.26	7.88	92	57.3%	-0.26 [-0.54 , 0.02]
Total (95% CI)			**182**			**155**	**100.0%**	**-0.15 [-0.40 , 0.10]**

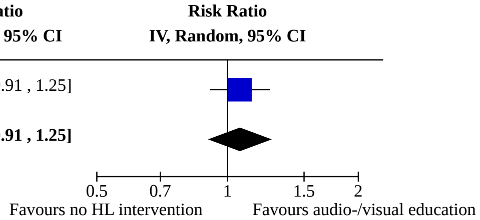


Heterogeneity: Tau² = 0.01; Chi² = 1.33, df = 1 (P = 0.25); I² = 25%
Test for overall effect: Z = 1.20 (P = 0.23)
Test for subgroup differences: Not applicable

Footnotes
(1) Change scores.

Analysis 5.5. Comparison 5: Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention, Outcome 5: Health behaviour: child's up-to-date immunisation (short-term: immediately up to 3 months post-intervention)

	Audio-/visual education		No HL intervention			Risk Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**IV, Random, 95% CI**
DeCamp 2020	61	72	50	63	100.0%	1.07 [0.91 , 1.25]
Total (95% CI)		**72**		**63**	**100.0%**	**1.07 [0.91 , 1.25]**
Total events:	61		50			

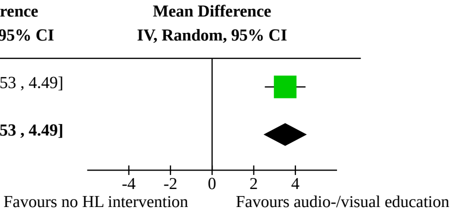


Heterogeneity: Not applicable
Test for overall effect: Z = 0.80 (P = 0.42)
Test for subgroup differences: Not applicable

Analysis 5.6. Comparison 5: Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention, Outcome 6: Self-efficacy to identify need for treatment (short-term: immediately post-intervention)

	Audio-/visual education			No HL intervention				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Hernandez 2013 (1)	3.64	3.36	70	0.13	2.35	63	100.0%	3.51 [2.53 , 4.49]
Total (95% CI)			**70**			**63**	**100.0%**	**3.51 [2.53 , 4.49]**

Heterogeneity: Not applicable
Test for overall effect: Z = 7.03 (P < 0.00001)
Test for subgroup differences: Not applicable

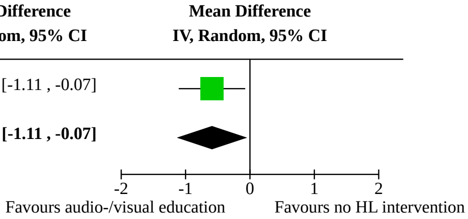


Footnotes
(1) Change scores.

Analysis 5.7. Comparison 5: Culturally and literacy adapted audio-/visual education without personal feedback versus no health literacy intervention, Outcome 7: Health service use: emergency room visits, medical record review (short-term: immediately up to 3 months post-intervention)

	Audio-/visual education			No HL intervention				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
DeCamp 2020 (1)	1.23	1.66	79	1.82	1.64	78	100.0%	-0.59 [-1.11 , -0.07]
Total (95% CI)			**79**			**78**	**100.0%**	**-0.59 [-1.11 , -0.07]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.24 (P = 0.03)
Test for subgroup differences: Not applicable



Footnotes
(1) Change scores.

Comparison 6. Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic

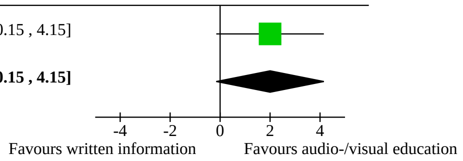
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 Diabetes health literacy, DHLS (short-term: immediately post-intervention)	1	240	Mean Difference (IV, Random, 95% CI)	2.00 [-0.15, 4.15]
6.2 Health literacy - competencies: inhaler use technique, checklist 0 to 10 (medium-term: 3 months post-intervention)	2	176	Mean Difference (IV, Random, 95% CI)	0.98 [0.26, 1.70]
6.3 Health literacy - understanding physician's instructions (medium-term: 3 months post-intervention)	1	85	Mean Difference (IV, Random, 95% CI)	0.04 [-0.55, 0.63]
6.4 Health literacy - appraise: decisional conflict (short-term: 1 month post-intervention)	1	608	Mean Difference (IV, Random, 95% CI)	-9.88 [-12.87, -6.89]
6.5 Health literacy - apply: informed decision against HPV vaccination (short-term: 1 month post-intervention)	1	608	Risk Ratio (M-H, Random, 95% CI)	1.51 [1.29, 1.77]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.6 Any health-related knowledge, 0 to 100 (short-term: up to 1 month post-intervention) - all studies	3	987	Mean Difference (IV, Random, 95% CI)	8.35 [-0.32, 17.02]
6.7 Any health-related knowledge, 0 to 100 (short-term: up to 1 month post-intervention) - by subgroup audiovisual (multimedia)/visual (print only)	3	987	Mean Difference (IV, Random, 95% CI)	8.35 [-0.32, 17.02]
6.7.1 Audiovisual format (multimedia)	1	608	Mean Difference (IV, Random, 95% CI)	15.00 [12.61, 17.39]
6.7.2 Visual format (print only)	2	379	Mean Difference (IV, Random, 95% CI)	4.75 [-3.33, 12.84]
6.8 Any health-related knowledge, 0 to 100 (medium-term: 3 to 6 months post-intervention) - all studies	3	979	Mean Difference (IV, Random, 95% CI)	7.30 [-3.73, 18.32]
6.9 Any health-related knowledge, 0 to 100 (medium-term: 3 to 6 months post-intervention) - by subgroup audiovisual (multimedia)/visual (print only)	3	979	Mean Difference (IV, Random, 95% CI)	7.30 [-3.73, 18.32]
6.9.1 Audiovisual format (multimedia)	2	786	Mean Difference (IV, Random, 95% CI)	12.27 [8.28, 16.26]
6.9.2 Visual format (print only)	1	193	Mean Difference (IV, Random, 95% CI)	-2.80 [-8.00, 2.40]
6.10 Health outcome: depression, PHQ-8 (long-term: 12 months post-intervention)	1	445	Mean Difference (IV, Random, 95% CI)	-0.60 [-1.37, 0.17]
6.11 Health behaviour: any cancer screening uptake (medium-term: up to 6-month follow-up)	2	803	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.95, 1.20]
6.12 Health behaviour: new documentation of advance care planning (long-term: 12 months post-intervention)	1	445	Risk Ratio (M-H, Random, 95% CI)	1.49 [1.13, 1.97]
6.13 Breast cancer self-efficacy (short-term: immediately post-intervention)	1	240	Mean Difference (IV, Random, 95% CI)	0.08 [-0.02, 0.18]
6.14 Cancer-related self-efficacy (medium-term: at 3-month follow-up)	2	256	Std. Mean Difference (IV, Random, 95% CI)	0.08 [-0.18, 0.33]
6.15 Self-efficacy regarding Pap testing (medium-term: at 6-month follow-up)	1	727	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.98, 1.06]
6.16 Adverse event: anxiety, GAD-7 (long-term: 12 months post-intervention)	1	445	Mean Difference (IV, Random, 95% CI)	-0.70 [-1.40, 0.00]

Analysis 6.1. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 1: Diabetes health literacy, DHLS (short-term: immediately post-intervention)

	Audio-/visual education			Written information				Mean Difference	Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**	**IV, Random, 95% CI**
Calderón 2014 (1)	55	8	118	53	9	122	100.0%	2.00 [-0.15 , 4.15]	
Total (95% CI)			**118**			**122**	**100.0%**	**2.00 [-0.15 , 4.15]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 1.82 (P = 0.07)
Test for subgroup differences: Not applicable

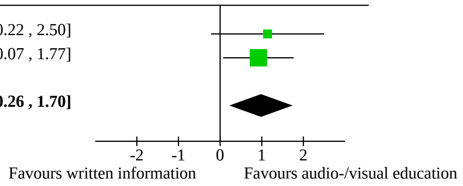


Footnotes
(1) Data represent unadjusted values obtained from study authors.

Analysis 6.2. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 2: Health literacy - competencies: inhaler use technique, checklist 0 to 10 (medium-term: 3 months post-intervention)

	Audio-/visual education			Written information				Mean Difference	Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**	**IV, Random, 95% CI**
Poureslami 2016a (1)	2.31	2.98	63	1.17	2.73	22	28.0%	1.14 [-0.22 , 2.50]	
Poureslami 2016b (2)	6.12	1.89	77	5.2	1.4	14	72.0%	0.92 [0.07 , 1.77]	
Total (95% CI)			**140**			**36**	**100.0%**	**0.98 [0.26 , 1.70]**	

Heterogeneity: Tau² = 0.00; Chi² = 0.07, df = 1 (P = 0.79); I² = 0%
Test for overall effect: Z = 2.68 (P = 0.007)
Test for subgroup differences: Not applicable

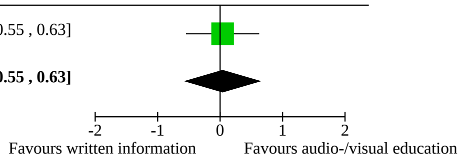


Footnotes
(1) Change scores; group 1, 2 and 3 were combined to create a single pairwise comparison with group 4; results adjusted for age, gender, educational level and ethnicity.
(2) Group 1, 2 and 3 were combined to create a single pairwise comparison with group 4.

Analysis 6.3. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 3: Health literacy - understanding physician's instructions (medium-term: 3 months post-intervention)

	Audio-/visual education			Written information				Mean Difference	Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**	**IV, Random, 95% CI**
Poureslami 2016a (1)	0.39	0.93	63	0.35	1.29	22	100.0%	0.04 [-0.55 , 0.63]	
Total (95% CI)			**63**			**22**	**100.0%**	**0.04 [-0.55 , 0.63]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 0.13 (P = 0.89)
Test for subgroup differences: Not applicable

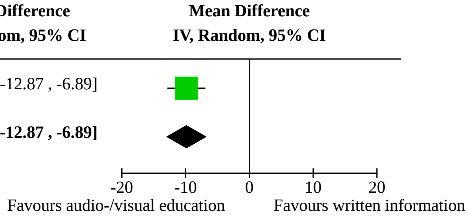


Footnotes
(1) Change scores; group 1, 2 and 3 were combined to create a single pairwise comparison with group 4; results adjusted for age, gender, educational level and ethnicity.

Analysis 6.4. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 4: Health literacy - appraise: decisional conflict (short-term: 1 month post-intervention)

	Audio-/visual education			Written infromation				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Valdez 2015 (1)	21.4	16.34	290	31.28	21.1	318	100.0%	-9.88 [-12.87 , -6.89]
Total (95% CI)			**290**			**318**	**100.0%**	**-9.88 [-12.87 , -6.89]**

Heterogeneity: Not applicable
Test for overall effect: Z = 6.49 (P < 0.00001)
Test for subgroup differences: Not applicable

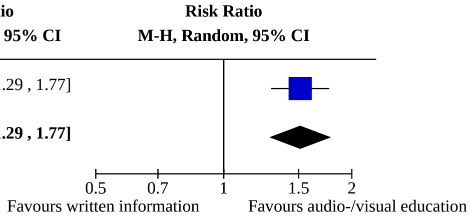


Footnotes
(1) Decisional conflict scale; subscales informed decision, values clarity and support were merged to create a single score.

Analysis 6.5. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 5: Health literacy - apply: informed decision against HPV vaccination (short-term: 1 month post-intervention)

	Audio-/visual education		Written information			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI
Valdez 2015	182	290	132	318	100.0%	1.51 [1.29 , 1.77]
Total (95% CI)		**290**		**318**	**100.0%**	**1.51 [1.29 , 1.77]**
Total events:	182		132			

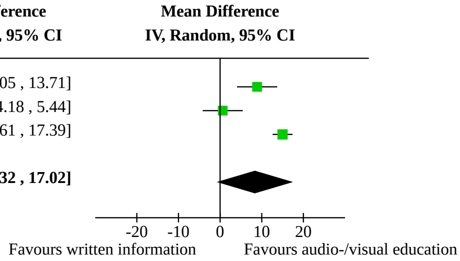
Heterogeneity: Not applicable
Test for overall effect: Z = 5.14 (P < 0.00001)
Test for subgroup differences: Not applicable



Analysis 6.6. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 6: Any health-related knowledge, 0 to 100 (short-term: up to 1 month post-intervention) - all studies

	Audio-/visual education			Written information				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Unger 2013 (1)	13.94	15.65	69	5.06	13.29	70	32.4%	8.88 [4.05 , 13.71]
Payán 2020 (2)	72.51	16.53	158	71.88	18.75	82	32.5%	0.63 [-4.18 , 5.44]
Valdez 2015	74.17	13.33	290	59.17	16.67	318	35.1%	15.00 [12.61 , 17.39]
Total (95% CI)			**517**			**470**	**100.0%**	**8.35 [-0.32 , 17.02]**

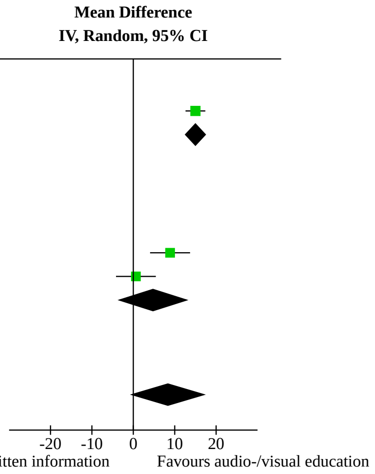
Heterogeneity: Tau² = 54.20; Chi² = 29.00, df = 2 (P < 0.00001); I² = 93%
Test for overall effect: Z = 1.89 (P = 0.06)
Test for subgroup differences: Not applicable



Footnotes
(1) SDs were calculated from SEs (declared as SDs), t-values and P values reported for in-between group changes.
(2) Intervention groups 1 and 2 were combined to create a single pairwise comparison; SDs were obtained from study authors.

Analysis 6.7. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 7: Any health-related knowledge, 0 to 100 (short-term: up to 1 month post-intervention) - by subgroup audiovisual (multimedia)/visual (print only)

Study or Subgroup	Audio-/visual education Mean	SD	Total	Written information Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
6.7.1 Audiovisual format (multimedia)								
Valdez 2015	74.17	13.33	290	59.17	16.67	318	35.1%	15.00 [12.61 , 17.39]
Subtotal (95% CI)			**290**			**318**	**35.1%**	**15.00 [12.61 , 17.39]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 12.30 (P < 0.00001)								
6.7.2 Visual format (print only)								
Unger 2013 (1)	13.94	15.65	69	5.06	13.29	70	32.4%	8.88 [4.05 , 13.71]
Payán 2020 (2)	72.51	16.53	158	71.88	18.75	82	32.5%	0.63 [-4.18 , 5.44]
Subtotal (95% CI)			**227**			**152**	**64.9%**	**4.75 [-3.33 , 12.84]**
Heterogeneity: Tau^2 = 27.99; Chi^2 = 5.63, df = 1 (P = 0.02); I^2 = 82%								
Test for overall effect: Z = 1.15 (P = 0.25)								
Total (95% CI)			**517**			**470**	**100.0%**	**8.35 [-0.32 , 17.02]**
Heterogeneity: Tau^2 = 54.20; Chi^2 = 29.00, df = 2 (P < 0.00001); I^2 = 93%								
Test for overall effect: Z = 1.89 (P = 0.06)								
Test for subgroup differences: Chi^2 = 5.68, df = 1 (P = 0.02), I^2 = 82.4%								



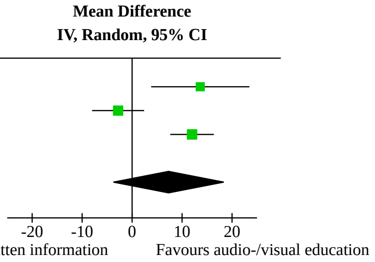
Footnotes

(1) Change scores; SDs were calculated from SEs (declared as SDs), t-values and p values reported for in-between group changes.

(2) Intervention groups 1 and 2 were combined to create a single pair-wise comparison; SDs were obtained from study authors.

Analysis 6.8. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 8: Any health-related knowledge, 0 to 100 (medium-term: 3 to 6 months post-intervention) - all studies

Study or Subgroup	Audio-/visual education Mean	SD	Total	Written information Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Gwede 2019	71.82	18.18	32	58.18	20	27	29.2%	13.64 [3.81 , 23.47]
Payán 2020 (1)	64.08	18.44	128	66.88	16.88	65	35.0%	-2.80 [-8.00 , 2.40]
Valdez 2018	74	32	383	62	28	344	35.8%	12.00 [7.64 , 16.36]
Total (95% CI)			**543**			**436**	**100.0%**	**7.30 [-3.73 , 18.32]**
Heterogeneity: Tau^2 = 83.37; Chi^2 = 20.41, df = 2 (P < 0.0001); I^2 = 90%								
Test for overall effect: Z = 1.30 (P = 0.19)								
Test for subgroup differences: Not applicable								

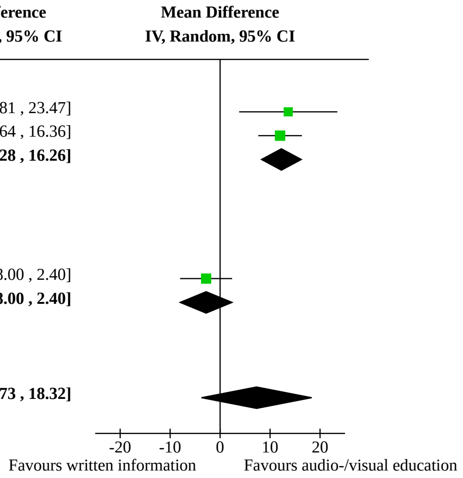


Footnotes

(1) Intervention groups 1 and 2 were combined to create a single pairwise comparison; SDs were obtained from study authors.

Analysis 6.9. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 9: Any health-related knowledge, 0 to 100 (medium-term: 3 to 6 months post-intervention) - by subgroup audiovisual (multimedia)/visual (print only)

Study or Subgroup	Audio-/visual education Mean	SD	Total	Written information Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
6.9.1 Audiovisual format (multimedia)								
Gwede 2019	71.82	18.18	32	58.18	20	27	29.2%	13.64 [3.81 , 23.47]
Valdez 2018	74	32	383	62	28	344	35.8%	12.00 [7.64 , 16.36]
Subtotal (95% CI)			**415**			**371**	**65.0%**	**12.27 [8.28 , 16.26]**
Heterogeneity: Tau² = 0.00; Chi² = 0.09, df = 1 (P = 0.76); I² = 0%								
Test for overall effect: Z = 6.03 (P < 0.00001)								
6.9.2 Visual format (print only)								
Payán 2020 (1)	64.08	18.44	128	66.88	16.88	65	35.0%	-2.80 [-8.00 , 2.40]
Subtotal (95% CI)			**128**			**65**	**35.0%**	**-2.80 [-8.00 , 2.40]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.06 (P = 0.29)								
Total (95% CI)			**543**			**436**	**100.0%**	**7.30 [-3.73 , 18.32]**
Heterogeneity: Tau² = 83.37; Chi² = 20.41, df = 2 (P < 0.0001); I² = 90%								
Test for overall effect: Z = 1.30 (P = 0.19)								
Test for subgroup differences: Chi² = 20.32, df = 1 (P < 0.00001), I² = 95.1%								

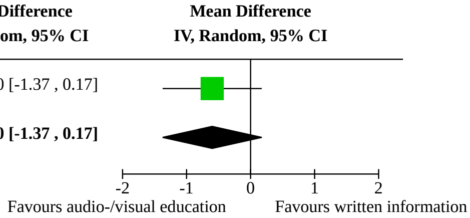


Footnotes

(1) Intervention groups 1 and 2 were combined to create a single pair-wise comparison; SDs were obtained from study authors.

Analysis 6.10. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 10: Health outcome: depression, PHQ-8 (long-term: 12 months post-intervention)

Study or Subgroup	Audio-/visual education Mean	SD	Total	Written information Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Sudore 2018 (1)	3.9	4.13	219	4.5	4.2	226	100.0%	-0.60 [-1.37 , 0.17]
Total (95% CI)			**219**			**226**	**100.0%**	**-0.60 [-1.37 , 0.17]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.52 (P = 0.13)								
Test for subgroup differences: Not applicable								

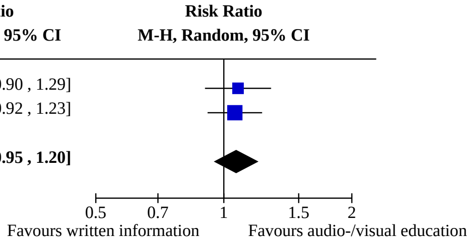


Footnotes

(1) Adjusted for baseline depression and anxiety scores.

Analysis 6.11. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 11: Health behaviour: any cancer screening uptake (medium-term: up to 6-month follow-up)

Study or Subgroup	Audio-/visual education Events	Total	Written information Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Gwede 2019 (1)	36	40	30	36	40.5%	1.08 [0.90 , 1.29]
Valdez 2018 (2)	195	383	165	344	59.5%	1.06 [0.92 , 1.23]
Total (95% CI)		**423**		**380**	**100.0%**	**1.07 [0.95 , 1.20]**
Total events:	231		195			
Heterogeneity: Tau² = 0.00; Chi² = 0.03, df = 1 (P = 0.87); I² = 0%						
Test for overall effect: Z = 1.15 (P = 0.25)						
Test for subgroup differences: Not applicable						



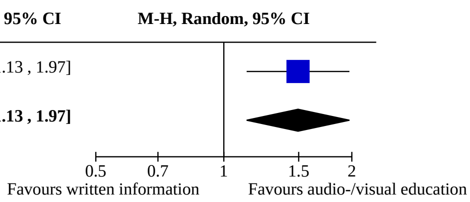
Footnotes

(1) Assessed via faecal immunochemical test (FIT) kit return.

(2) Assessed via self-report.

Analysis 6.12. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 12: Health behaviour: new documentation of advance care planning (long-term: 12 months post-intervention)

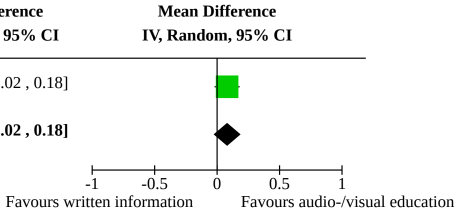
	Audio-/visual education		Written information			Risk Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Random, 95% CI**
Sudore 2018	84	219	58	226	100.0%	1.49 [1.13 , 1.97]
Total (95% CI)		**219**		**226**	**100.0%**	**1.49 [1.13 , 1.97]**
Total events:	84		58			



Heterogeneity: Not applicable
Test for overall effect: Z = 2.83 (P = 0.005)
Test for subgroup differences: Not applicable

Analysis 6.13. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 13: Breast cancer self-efficacy (short-term: immediately post-intervention)

	Audio-/visual education			Written information				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Payán 2020 (1)	0.88	0.33	158	0.8	0.4	82	100.0%	0.08 [-0.02 , 0.18]
Total (95% CI)			**158**			**82**	**100.0%**	**0.08 [-0.02 , 0.18]**

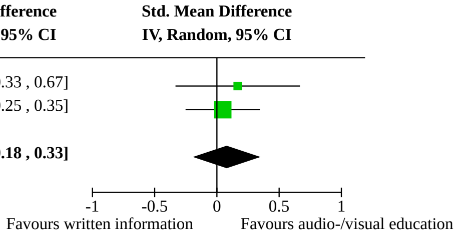


Heterogeneity: Not applicable
Test for overall effect: Z = 1.56 (P = 0.12)
Test for subgroup differences: Not applicable

Footnotes
(1) Intervention groups 1 and 2 were combined to create a single pairwise comparison; data were obtained from the study authors.

Analysis 6.14. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 14: Cancer-related self-efficacy (medium-term: at 3-month follow-up)

	Audio-/visual education			Written information				Std. Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Gwede 2019	29.7	1	27	29.5	1.3	36	26.3%	0.17 [-0.33 , 0.67]
Payán 2020 (1)	0.77	0.42	128	0.75	0.44	65	73.7%	0.05 [-0.25 , 0.35]
Total (95% CI)			**155**			**101**	**100.0%**	**0.08 [-0.18 , 0.33]**



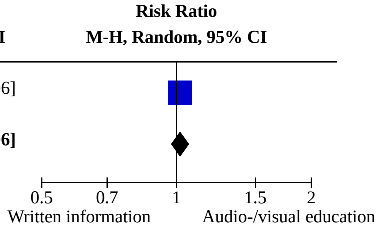
Heterogeneity: Tau² = 0.00; Chi² = 0.16, df = 1 (P = 0.68); I² = 0%
Test for overall effect: Z = 0.60 (P = 0.55)
Test for subgroup differences: Not applicable

Footnotes
(1) Intervention groups 1 and 2 were combined to create a single pairwise comparison; unadjusted values were obtained from study authors.

Analysis 6.15. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 15: Self-efficacy regarding Pap testing (medium-term: at 6-month follow-up)

Study or Subgroup	Audio-/visual education Events	Audio-/visual education Total	Written information Events	Written information Total	Weight	Risk Ratio M-H, Random, 95% CI
Valdez 2018 (1)	356	383	314	344	100.0%	1.02 [0.98 , 1.06]
Total (95% CI)		**383**		**344**	**100.0%**	**1.02 [0.98 , 1.06]**
Total events:	356		314			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.83 (P = 0.41)
Test for subgroup differences: Not applicable

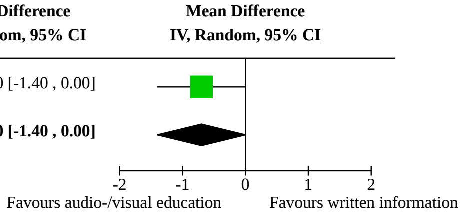


Footnotes
(1) "Can get pap smear if needed", yes

Analysis 6.16. Comparison 6: Culturally and literacy adapted audio-/visual education without personal feedback versus written information on the same topic, Outcome 16: Adverse event: anxiety, GAD-7 (long-term: 12 months post-intervention)

Study or Subgroup	Audio-/visual education Mean	Audio-/visual education SD	Audio-/visual education Total	Written information Mean	Written information SD	Written information Total	Weight	Mean Difference IV, Random, 95% CI
Sudore 2018 (1)	3	3.754276	219	3.7	3.814467	226	100.0%	-0.70 [-1.40 , 0.00]
Total (95% CI)			**219**			**226**	**100.0%**	**-0.70 [-1.40 , 0.00]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.95 (P = 0.05)
Test for subgroup differences: Not applicable



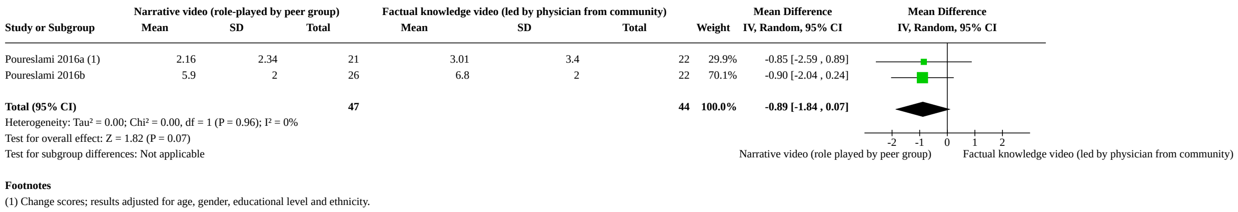
Footnotes
(1) Adjusted for baseline depression and anxiety scores.

Comparison 7. Culturally and literacy adapted audio-/visual education without personal feedback versus another audio-/visual education without personal feedback

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.1 Health literacy - competencies: inhaler use technique, checklist 0 to 10 (medium-term: 3 months post-intervention)	2	91	Mean Difference (IV, Random, 95% CI)	-0.89 [-1.84, 0.07]
7.2 Health literacy - understanding physician's instruction (medium-term: 3 months post-intervention)	1	43	Mean Difference (IV, Random, 95% CI)	-0.15 [-0.72, 0.42]
7.3 Health literacy - apply: Pap testing intention, self-report (medium-term: 6 months post-intervention)	1	109	Risk Ratio (M-H, Random, 95% CI)	1.97 [0.83, 4.69]
7.4 Cervical cancer knowledge, 0 to 100 (medium-term: 6 months post-intervention)	1	109	Mean Difference (IV, Random, 95% CI)	1.12 [-4.63, 6.87]
7.5 Asthma knowledge (medium-term: 3 months post-intervention)	1	43	Mean Difference (IV, Random, 95% CI)	0.85 [-1.07, 2.76]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.6 Health behaviour: cervical cancer screening (medium-term: at 6-month follow-up)	1	109	Risk Ratio (M-H, Random, 95% CI)	1.29 [0.75, 2.23]

Analysis 7.1. Comparison 7: Culturally and literacy adapted audio-/visual education without personal feedback versus another audio-/visual education without personal feedback, Outcome 1: Health literacy - competencies: inhaler use technique, checklist 0 to 10 (medium-term: 3 months post-intervention)



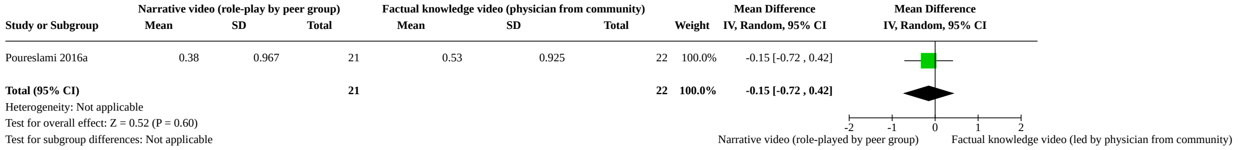
	Narrative video (role-played by peer group)			Factual knowledge video (led by physician from community)				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Poureslami 2016a (1)	2.16	2.34	21	3.01	3.4	22	29.9%	-0.85 [-2.59 , 0.89]
Poureslami 2016b	5.9	2	26	6.8	2	22	70.1%	-0.90 [-2.04 , 0.24]
Total (95% CI)			**47**			**44**	**100.0%**	**-0.89 [-1.84 , 0.07]**

Heterogeneity: Tau² = 0.00; Chi² = 0.00, df = 1 (P = 0.96); I² = 0%
Test for overall effect: Z = 1.82 (P = 0.07)
Test for subgroup differences: Not applicable

Footnotes

(1) Change scores; results adjusted for age, gender, educational level and ethnicity.

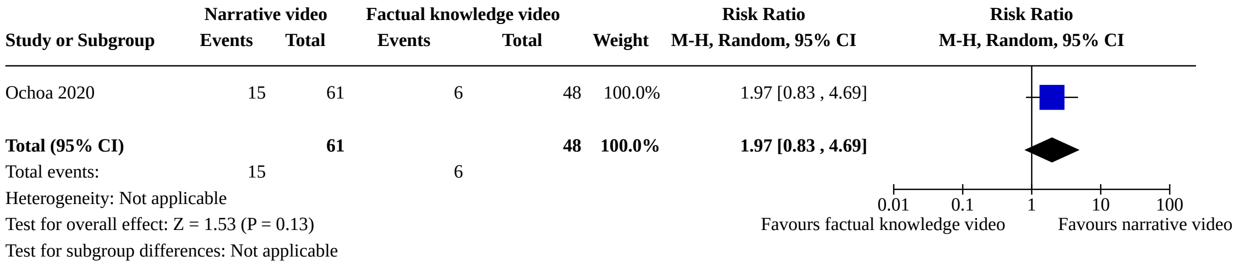
Analysis 7.2. Comparison 7: Culturally and literacy adapted audio-/visual education without personal feedback versus another audio-/visual education without personal feedback, Outcome 2: Health literacy - understanding physician's instruction (medium-term: 3 months post-intervention)



	Narrative video (role-play by peer group)			Factual knowledge video (physician from community)				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Poureslami 2016a	0.38	0.967	21	0.53	0.925	22	100.0%	-0.15 [-0.72 , 0.42]
Total (95% CI)			**21**			**22**	**100.0%**	**-0.15 [-0.72 , 0.42]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.52 (P = 0.60)
Test for subgroup differences: Not applicable

Analysis 7.3. Comparison 7: Culturally and literacy adapted audio-/visual education without personal feedback versus another audio-/visual education without personal feedback, Outcome 3: Health literacy - apply: Pap testing intention, self-report (medium-term: 6 months post-intervention)



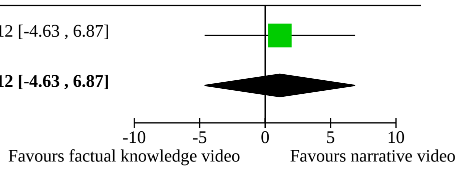
	Narrative video		Factual knowledge video			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI
Ochoa 2020	15	61	6	48	100.0%	1.97 [0.83 , 4.69]
Total (95% CI)		**61**		**48**	**100.0%**	**1.97 [0.83 , 4.69]**
Total events:	15		6			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.53 (P = 0.13)
Test for subgroup differences: Not applicable

Analysis 7.4. Comparison 7: Culturally and literacy adapted audio-/visual education without personal feedback versus another audio-/visual education without personal feedback, Outcome 4: Cervical cancer knowledge, 0 to 100 (medium-term: 6 months post-intervention)

	Narrative video			Factual knowledge video				Mean Difference	Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**	**IV, Random, 95% CI**
Ochoa 2020	67.25	15.88	61	66.13	14.63	48	100.0%	1.12 [-4.63 , 6.87]	
Total (95% CI)			**61**			**48**	**100.0%**	**1.12 [-4.63 , 6.87]**	

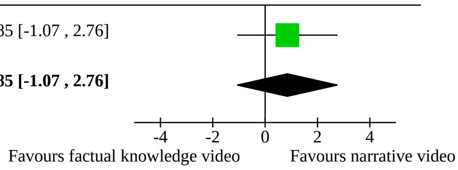
Heterogeneity: Not applicable
Test for overall effect: Z = 0.38 (P = 0.70)
Test for subgroup differences: Not applicable



Analysis 7.5. Comparison 7: Culturally and literacy adapted audio-/visual education without personal feedback versus another audio-/visual education without personal feedback, Outcome 5: Asthma knowledge (medium-term: 3 months post-intervention)

	Narrative video			Factual knowledge video				Mean Difference	Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**	**IV, Random, 95% CI**
Poureslami 2016a (1)	0.835	2.612	21	-0.013	3.723	22	100.0%	0.85 [-1.07 , 2.76]	
Total (95% CI)			**21**			**22**	**100.0%**	**0.85 [-1.07 , 2.76]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 0.87 (P = 0.39)
Test for subgroup differences: Not applicable



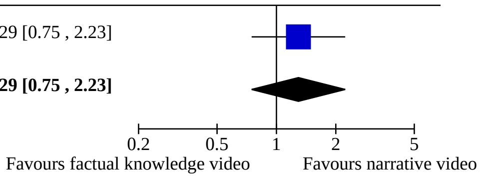
Footnotes

(1) Results of three knowledge questions were combined to create a composite score.

Analysis 7.6. Comparison 7: Culturally and literacy adapted audio-/visual education without personal feedback versus another audio-/visual education without personal feedback, Outcome 6: Health behaviour: cervical cancer screening (medium-term: at 6-month follow-up)

	Narrative video		Factual knowledge video			Risk Ratio	Risk Ratio
Study or Subgroup	**Events**	**Total**	**Events**	**Total**	**Weight**	**M-H, Random, 95% CI**	**M-H, Random, 95% CI**
Ochoa 2020 (1)	23	61	14	48	100.0%	1.29 [0.75 , 2.23]	
Total (95% CI)		**61**		**48**	**100.0%**	**1.29 [0.75 , 2.23]**	
Total events:	23		14				

Heterogeneity: Not applicable
Test for overall effect: Z = 0.92 (P = 0.36)
Test for subgroup differences: Not applicable



Footnotes

(1) Calculated from reported percentages.

Comparison 8. Culturally and literacy adapted medical instruction versus no health literacy intervention

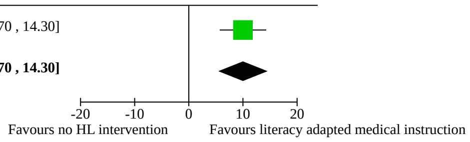
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 Understand: medication understanding (short-term: immediately post-intervention)	1	200	Mean Difference (IV, Random, 95% CI)	10.00 [5.70, 14.30]

Analysis 8.1. Comparison 8: Culturally and literacy adapted medical instruction versus no health literacy intervention, Outcome 1: Understand: medication understanding (short-term: immediately post-intervention)

Study or Subgroup	Literacy adapted medical instruction Mean	SD	Total	No HL intervention Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Mohan 2014	86.4	12.6	99	76.4	18	101	100.0%	10.00 [5.70 , 14.30]
Total (95% CI)			**99**			**101**	**100.0%**	**10.00 [5.70 , 14.30]**

Heterogeneity: Not applicable
Test for overall effect: Z = 4.56 (P < 0.00001)
Test for subgroup differences: Not applicable

Mean Difference
IV, Random, 95% CI



Comparison 9. Female migrants' benefit of any health literacy intervention versus male migrants' benefit of any health literacy intervention

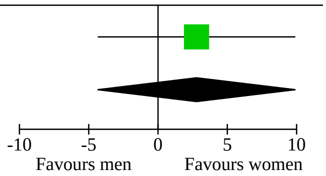
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
9.1 Generic health literacy, TOFHLA (short-term: immediately post-intervention)	1	77	Mean Difference (IV, Random, 95% CI)	2.78 [-4.35, 9.91]
9.2 Diabetes health literacy, DHLS (short-term: immediately post-intervention)	1	118	Mean Difference (IV, Random, 95% CI)	5.00 [0.62, 9.38]
9.3 Cardiovascular health behaviour (short-term: immediately post-intervention)	1	77	Mean Difference (IV, Random, 95% CI)	2.07 [-5.04, 9.18]
9.4 Health behaviour: new documentation of advance care planning (long-term: approx. 12 months post-intervention)	1	219	Risk Ratio (M-H, Random, 95% CI)	1.27 [0.90, 1.79]

Analysis 9.1. Comparison 9: Female migrants' benefit of any health literacy intervention versus male migrants' benefit of any health literacy intervention, Outcome 1: Generic health literacy, TOFHLA (short-term: immediately post-intervention)

Study or Subgroup	Women Mean	SD	Total	Men Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Soto Mas 2018	73.78	11.97	59	71	13.95	18	100.0%	2.78 [-4.35 , 9.91]
Total (95% CI)			**59**			**18**	**100.0%**	**2.78 [-4.35 , 9.91]**

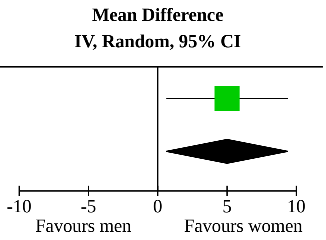
Heterogeneity: Not applicable
Test for overall effect: Z = 0.76 (P = 0.44)
Test for subgroup differences: Not applicable

Mean Difference
IV, Random, 95% CI



Analysis 9.2. Comparison 9: Female migrants' benefit of any health literacy intervention versus male migrants' benefit of any health literacy intervention, Outcome 2: Diabetes health literacy, DHLS (short-term: immediately post-intervention)

	Women			Men				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Calderón 2014 (1)	56	9.64	93	51	10	25	100.0%	5.00 [0.62 , 9.38]
Total (95% CI)			**93**			**25**	**100.0%**	**5.00 [0.62 , 9.38]**

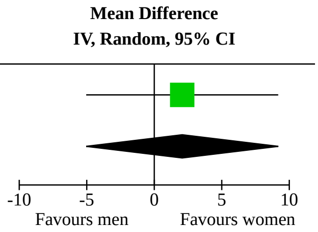


Heterogeneity: Not applicable
Test for overall effect: Z = 2.24 (P = 0.03)
Test for subgroup differences: Not applicable

Footnotes
(1) Unadjusted values were obtained from the study authors.

Analysis 9.3. Comparison 9: Female migrants' benefit of any health literacy intervention versus male migrants' benefit of any health literacy intervention, Outcome 3: Cardiovascular health behaviour (short-term: immediately post-intervention)

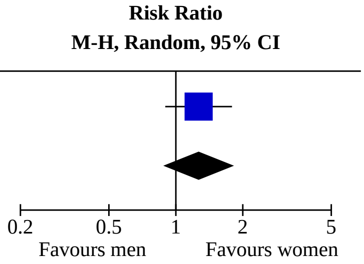
	Women			Men				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Soto Mas 2018	59.63	4.374163	59	57.56	15.200987	18	100.0%	2.07 [-5.04 , 9.18]
Total (95% CI)			**59**			**18**	**100.0%**	**2.07 [-5.04 , 9.18]**



Heterogeneity: Not applicable
Test for overall effect: Z = 0.57 (P = 0.57)
Test for subgroup differences: Not applicable

Analysis 9.4. Comparison 9: Female migrants' benefit of any health literacy intervention versus male migrants' benefit of any health literacy intervention, Outcome 4: Health behaviour: new documentation of advance care planning (long-term: approx. 12 months post-intervention)

	Men		Women			Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI
Sudore 2018	28	62	56	157	100.0%	1.27 [0.90 , 1.79]
Total (95% CI)		**62**		**157**	**100.0%**	**1.27 [0.90 , 1.79]**
Total events:	28		56			



Heterogeneity: Not applicable
Test for overall effect: Z = 1.34 (P = 0.18)
Test for subgroup differences: Not applicable

ADDITIONAL TABLES

Table 1. Outcome category: (disease-specific) health literacy

Study ID	Health topic	Measure	No. of participants	Time point(s)	Intervention arm(s) Mean (SD)*	Control arm(s) Mean (SD)	Notes
1 Culturally and literacy adapted self-management programme vs no health literacy intervention							
van Servellen 2005	HIV	HIV health literacy Print literacy (recognition of HIV terms): modified REALM, 0 to 24, higher score is better Functional health literacy (understanding HIV terms): participants had to explain HIV-relevant terms, 0 to 24, higher score is better	IG: 34 CG: 35	6 months after randomisation (immediately post-intervention)	4.66 (4.80) (recognition) 6.16 (7.97) (understanding)	1.34 (3.76) (recognition) 1.91 (3.60) (understanding)	Change scores are reported Intervention group: P < 0.001 (both time points)
2 Culturally and literacy adapted self-management programme vs written information on the same topic							
Han 2017	Breast/cervical cancer	Cancer screening health literacy AHL-C, 52 items, 0 to 52, higher score is better	IG: 278 CG: 282	6 months after randomisation (immediately post-intervention)	32.1 (12.7)	27.2 (13.0)	Cluster-RCT; data have been re-analysed for meta-analysis using the appropriate unit of analysis with the use of the ICC reported by Han 2017 (see Analysis 2.3; Analysis 2.4; Analysis 2.6)
Kaur 2019	Oral health	Oral health literacy TS-REALD, 27 to 73, higher score is better	IG: 70 CG: 70	3 months after randomisation (immediately post-intervention)	6.51 (3.85)	1.41 (3.69)	Change scores, calculated from reported linear mixed model analysis. MD 5.10 (95% CI 3.85 to 6.34) Group x time P < 0.0001
Kim 2014	High blood pressure	HBP health literacy HBP health literacy scale, 0 to 43, higher score is better	IG: 184 CG: 185	12 months after randomisation (immediately post-intervention)	28.2 (12.1)	24.9 (13.7)	Cluster-RCT; data have been re-analysed for meta-analysis using the appropriate unit of analysis with the use of the ICC

Table 1. Outcome category: (disease-specific) health literacy *(Continued)*

				18 months after randomisation (6-month follow-up)	29.4 (11.4)	25.3 (13.4)	reported by Han 2017 (see Analysis 2.3; Analysis 2.4; Analysis 2.6)
Kim 2020	Type 2 diabetes	Print literacy REALM, 0 to 66, higher score is better	IG: 105 CG: 104	12 months after randomisation (immediately post-intervention)	40.5 (SE 2.2)	31.5 (SE 2.2)	P < 0.01 (all time points)
		Diabetes-specific print literacy DM-REALM, 0 to 82, higher score is better		12 months after randomisation (immediately post-intervention)	62.9 (SE 2.1)	50.8 (SE 2.7)	P < 0.001 (all time points)
		Functional health literacy TOFHLA, 0 to 7, higher score is better		12 months after randomisation (immediately post-intervention)	4.9 (SE 0.2)	4.4 (SE 0.3)	No difference
		Health numeracy NVS, 0 to 6, higher score is better		12 months after randomisation (immediately post-intervention)	3.1 (SE 0.2)	2.4 (SE 0.2)	P < 0.05
3 Culturally adapted health literacy skills building course vs no/unrelated health literacy intervention							
Otilingam 2015	Nutrition/heart and brain health	Health numeracy NVS, 0 to 6, higher score is better	IG 1: 29 IG 2: 29 CG 1: 16 CG 2: 18	Immediately post-intervention	IG 1: 2.59 (1.92) IG 2: 2.34 (1.99)	CG: 1.00 (1.63) CG 2: 1.61 (1.79)	Both IG and both CG were combined for meta-analysis (see Analysis 3.1). CG 2 was assessed immediately post-intervention only. Group x time P = 0.0103
				At 1-month follow-up	IG 1: 2.59 (1.76) IG 2: 2.55 (1.70) Combined: 2.57 (1.72)	CG 1: 1.38 (1.54)	
Soto Mas 2018	Cardiovascular health	Functional health literacy	IG: 77	Immediately post-intervention	72.8	73.7	P = 0.012

Table 1. Outcome category: (disease-specific) health literacy *(Continued)*

		TOFHLA, 0 to 100, higher score is better	CG: 78		Mean change post-pre (95% CI): 12.9 (10.4 to 15.3)	Mean change post-pre (95% CI): 8.2 (5.5 to 10.9)	
				6 weeks after first session	—	—	
Wong 2020	Mental health (depression)	Depression literacy D-Lit, 0 to 22, higher score is better	IG: 18 CG: 19	Immediately post-intervention	13.06 (2.10)	12.89 (2.40)	P = 0.36
				At 2-month follow-up	13.38 (2.12) (combined sample)	—	
5 Culturally and literacy adapted media education without personal feedback vs no health literacy intervention							
Kiropoulos 2011	Mental health (depression)	Depression literacy D-Lit, 0 to 22, higher score is better	IG: 110 CG: 92	Immediately post-intervention	17.43 (3.99)	8.03 (4.33)	P < 0.001
				At 1-week follow-up	16.84 (3.58)	8.22 (4.33)	Pre-intervention measure of the variable as a covariate P < 0.001 Post-intervention measure of the variable as a covariate P < 0.01
6 Culturally and literacy adapted media intervention without personal feedback vs literacy adapted written information							
Calderón 2014	Type 2 diabetes	Diabetes literacy DHLS, 37 items on type 2 diabetes knowledge (21 items) and knowledge application and cultural perceptions about diabetes management (16 items)	IG: 118 CG: 122	Immediately post-intervention	0.55 (0.08)	0.53 (0.09)	Unadjusted values were obtained from study authors

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* Unadjusted mean (SD) if not otherwise reported.

AHL-C: Assessment of Health Literacy in Cancer Screening; CG: control group; CI: confidence interval; DHLS: Diabetes Health Literacy Survey; D-Lit: Depression Literacy Questionnaire; DM-REALM: Diabetes Mellitus-Rapid Estimate of Adult Literacy in Medicine; HBP: high blood pressure; IG: intervention group; MD: mean difference; NVS: newest vital sign; RCT: randomised controlled trial; REALM: Rapid Estimate of Adult Literacy in Medicine; SD: standard deviation; SE: standard error; TOFHLA: Test of Functional Health Literacy in Adults; TS-REALD: Two Stage Rapid Estimate of Adult Literacy in Dentistry

Table 2. Outcome category: health-related knowledge

Study ID	Health topic	Measure	No. of participants	Time point(s)	Intervention arm(s) Mean (SD)*	Control arm(s) Mean (SD)*	Notes
1 Culturally and literacy adapted self-management programme vs no health literacy intervention							
Bloom 2014	Breast health/ breast cancer	Not reported	N: 230	6 months post-intervention	—	—	MD 0.5 (P < 0.0001) Cluster-RCT; "GEE were used to account for clustering (sample and analysis)" (Bloom 2014) Increased knowledge did not increase mammography
Koniak-Griffin 2015	Cardiovascular disease	Heart knowledge questionnaire, adapted from a previous survey by Mosca et al (2004) (10 items, true/false format, 0 to 10, higher score is better)	IG: 98 CG: 95	6 months after randomisation (immediately post-intervention)	7.9 (2.6)	Not reported	—
			IG: 100 CG: 94	9 months after randomisation (at 3-month follow-up)	9.4 (1.9)		
Rosal 2011	Type 2 diabetes	ADKnowl, adapted version (23 item-sets (104 items), 0 to 104, higher score is better)	IG: 124 CG: 128	12 months after randomisation (immediately post-intervention)	0.089 (range -0.065 to 0.113)	0.033 (range 0.009 to 0.057)	Intervention effect 0.056 (0.022 to 0.090) P = 0.001
van Servellen 2005	HIV	(1) HIV Illness and Treatment Knowledge	IG: 34	6 months after randomi-	(1) 1.20 (3.19)	(1) 1.40 (2.59)	Change scores are reported

Table 2. Outcome category: health-related knowledge *(Continued)*

		and Misconceptions Scale (17 items, 0 to 17, higher score is better) (2) Knowledge of risk of getting sicker 1 item, 1 = very high risk to 4 = nonexistent risk, lower score is better	CG: 35	sation (immediately post-intervention)	(2) -0.24 (0.78)	(2) 0.09 (0.67)	To improve the interpretation of results, the original scale has been transformed into a positive scale with higher values indicating better performance (see Analysis 1.4)
2 Culturally and literacy adapted self-management programme vs written information on the same topic							
Han 2017	Cervical/breast cancer	Breast Cancer Knowledge Test (0 to 18, higher score is better)	IG: 278 CG: 282	6 months after randomisation (immediately post-intervention)	11.0 (3.9)	10.4 (3.8)	Cluster-RCT; data have been reanalysed for meta-analyses using the appropriate unit of analysis with the use of the ICC reported by Han 2017. In addition, combined scores for breast cancer knowledge and cervical cancer knowledge were calculated (see Analysis 2.10; Analysis 2.11). Estimated MD 0.7 (95% CI -0.1 to 1.6) MD estimated from linear mixed-effects models adjusted for baseline knowledge, age, insurance, English proficiency, years of US residence, years of education, employment and family history of breast cancer.
		Cervical Cancer Knowledge Test (0 to 20, higher score is better)			5.6 (2.4)	5.3 (2.6)	Estimated MD –0.1 (95% CI –0.3 to 0.1)
Kaur 2019	Oral health	Questionnaire on oral self-care knowledge and oral self-care behaviour	IG: 70 CG: 70	3 months after randomisation	4.389 (2.15)	0.82 (2.013) (95% CI 0.34 to 1.31)	MD 3.57 (2.88 to 4.26) Group x time P < 0.0001

Table 2. Outcome category: health-related knowledge *(Continued)*

		(0 to 15, higher score is better)					Mean (SD) was calculated from reported linear mixed model analysis
Kim 2009	Type 2 diabetes	DKT (14 items, 0 to 14 (general test, knowledge I), 9 items insulin subscale (knowledge II)[1], higher score is better)	IG: 40 CG: 39	30 weeks after randomisation	Knowledge (I) 2.4 (2.3) Knowledge (II) 0.3 (3.7)[1]	Knowledge (I) 0.7 (2.4) Knowledge (II) 0.4 (0.8)[1]	Change scores are reported Knowledge (I) P = 0.00 Knowledge (II) P = 0.27
Kim 2014	High blood pressure	HBP knowledge questionnaire (0 to 26, higher score is better)	IG: 184 CG: 185	12 months after randomisation	20.8 (2.7)	19.3 (3.7)	Cluster-RCT; data have been reanalysed for meta-analysis using the appropriate unit of analysis with the use of the ICC reported by Han 2017. Group x time P = 0.001 (see Analysis 2.10; Analysis 2.11; Analysis 2.14; Analysis 2.13)
				18 months after randomisation (6-month follow-up)	20.8 (2.8)	20.1 (3.2)	
Kim 2020	Type 2 diabetes	DKT (14 items, 0 to 14 (general test), 9 items insulin subscale (results not reported), higher score is better)	IG: 105 CG: 104	12 months after randomisation	10.3 (SE 0.2)	8.3 (SE 0.3)	Group P < 0.001
Rosal 2005	Type 2 diabetes	ADKnowl, adapted version (23 item-sets (104 items), 0 to 104), higher score is better	IG: 15 CG: 10	3 months after randomisation (immediately post-intervention)	0.05 (0.15)	-0.02 (0.11)	Change scores are reported Group x time P = 0.27
				6 months after randomisation (4.5 months post-intervention)	0.05 (0.13)	-0.03 (0.08)	
3 Culturally adapted health literacy skills building course vs no/unrelated health literacy intervention							

Table 2. Outcome category: health-related knowledge *(Continued)*

Elder 1998	Nutrition/cardiovascular health	Nutrition knowledge test (0 to 12, higher score is better)	IG: 134 CG: 157	3 months after randomisation (immediately post-intervention)	6.76	6.04	Cluster-RCT; unadjusted values are reported Group x time P ≤ 0.001
				At 6-month follow-up	6.90	6.11	
Otilingam 2015	Nutrition/heart and brain health	US Department of Agriculture's Diet and Health Knowledge Survey (0 to 9, higher score is better)	IG 1: 32 IG 2: 33 CG 1: 16 CG 2: 18	Immediately post-intervention	IG 1: 6.86 (1.27) IG 2: 7.03 (0.91) Combined: 6.95 (1.10)	CG 1: 5.94 (1.12) CG 2: 6.22 (0.94) Combined: 6.09 (1.02)	Group x time P = 0.0293 (combined IGs vs CG 1) Both IGs and CGs were combined for meta-analyses (see Analysis 3.3) CG 2 was assessed post-test only
			IG 1: 29 IG 2: 29 CG 1: 16 CG 2: 18	At 1-month follow-up	IG 1: 6.72 (1.33) IG 2: 6.66 (1.11) IG 1, 2*: 6.69 (1.21)	CG 1: 5.56 (1.71)	
Taylor 2011	Hepatitis B prevention, no specific health problem of participants reported	Questionnaire (0 to 5, higher score is better)	IG: 80 CG: 100	At 6-month follow-up	3.68 (1.12)	2.87 (1.38)	Cluster-RCT; data have been reanalysed for meta-analysis using the appropriate unit of analysis with the use of the ICC reported by Han 2017.
					Immigrants are more likely to be infected with HBV AOR 2.12 (1.12 to 4.03) HBV can be spread during childbirth AOR 2.10 (0.96 to 4.62) HBV can be spread during sexual intercourse AOR 2.58 (1.29 to 5.15) HBV can be spread by sharing razors AOR 5.42 (1.91 to 15.39)		AOR estimated through GEE models were used to account for clustering; adjusted for ESL organisation, class time, country of origin, years since immigration, gender, age group, years of education and marital status

Table 2. Outcome category: health-related knowledge *(Continued)*

					HBV infection can cause liver cancer AOR 2.08 (1.08 to 4.02		
Tong 2017	Colorectal cancer	Questionnaire (0 to 5, higher score is better)	IG: 161 CG: 168	6 months after first session (at 3-month follow-up)	Knowledge of colon polyps: 23.6% to 78.3%, MD 54.7% Screening start age at 50 years: 14.3% to 36.0%, MD 21.7% FOBT yearly: 10.6% to 38.5%, MD 27.9% Sigmoidoscopy every 5 years: 3.7% to 24.2%, MD 20.5% Colonoscopy every 10 years: 2.5% to 20.5%, MD 18%	Knowledge of colon polyps: 19.6% to 37.5%, MD 17.9% Screening start age at 50 years: 11.9% to 14.3%, MD 2.4% FOBT yearly: 11.9% to 17.3%, 5.4% Sigmoidoscopy every 5 years: 1.2% to 4.2%, MD 3% Colonoscopy every 10 years: 3.6% to 6.5%, MD 2.9%	MD 36.8%, P < 0.0001 MD 19.3%, P = 0.0056 MD 22.5%, P = 0.0001 MD 17.5%, P < 0.0001 MD 15.1%, P = 0.012 Cluster-RCT. No composite score reported. Authors state that GEE models were used to account for clustering. "For every point increase on the knowledge score (0-5), the odds of ever-screening and being up to date with screening were significantly increased, supporting knowledge as a mediator of the intervention effect." (Tong 2017
Wong 2020	Mental health (depression)	CBT-Q (0 to 9, higher score is better)	IG: 18 CG: 19	Immediately post-intervention	5.06 (0.10)	4.33 (1.24)	P = 0.07
				At 2-month follow-up	—		
4 Culturally and literacy adapted telephone education vs unrelated culturally and literacy adapted telephone education							
Lepore 2012	Prostate cancer screening	Questionnaire (0 to 14, higher score is better)	IG: 215 CG: 216	Approx. 7 months post-intervention	61.6 (SE 0.009)	54.7 (SE 0.009)	P < 0.001 Adjusted for education, any PSA claim prior to pretest, and percent correct on knowledge index at pretest
5 Culturally and literacy adapted audio-/visual education**without personal feedback vs no health literacy intervention**							

Table 2. Outcome category: health-related knowledge *(Continued)*

DeCamp 2020	Child health	Questionnaire (0 to 5, higher score is better)	IG: 72 CG: 63	10 to 13 months after randomisation (immediately to 3 months post-intervention)	0.67 (0.15)	0.52 (0.15)	Change scores are reported P = 0.52
Hernandez 2013	Depression	Depression Knowledge Scale (0 to 17, higher score is better)	IG: 72 CG: 64	Immediately post-intervention	2.44 (2.24)	0.02 (1.79)	Change scores are reported
Thompson 2012	Child nutrition and feeding	Questionnaire (0 to 19, higher score is better)	IG: 80 CG: 78	Immediately post-intervention	17.25 (1.7) 90.8 (9)	13.7 (2.1) 72.3 (11.2)	P < 0.001
6 Culturally and literacy adapted audio-/visual education without personal feedback vs written information on the same topic							
Gwede 2019	Colorectal cancer	Awareness of colorectal cancer and screening tests (Questionnaire based on NCI's Health Information National Trends Survey and on literature, 0 to 11, higher score is better)	IG: 32 CG: 27	At 3-month follow-up	7.9 (2.0)	6.4 (2.2)	—
Payán 2020	Breast cancer	Questionnaire (0 to 16, higher score is better)	IG 1: 79 (Cuidarse brochure) IG 2: 79 (Cuidarse brochure, CHW delivered) CG: 82 (standard brochure)	Immediately post-intervention	IG 1: 11.7 (2.7) IG 2: 11.5 (2.6) IG 1, 2: 11.6 (2.64)	CG: 11.5 (3.0)	10 to 13 months after randomisation; and IGs were combined for meta-analysis (see, Analysis 6.6; Analysis 6.7; Analysis 6.8; Analysis 6.9)

Table 2. Outcome category: health-related knowledge *(Continued)*

			IG 1: 67 IG 2: 61 CG: 65	At 3-month follow-up	IG 1: 10.3 (3.1) IG 2: 10.2 (2.8) IG 1, 2: 10.25 (2.95)	CG: 10.7 (2.7)	
Poureslami 2016a	Asthma	Functional knowledge of asthma symptoms, triggers and factors that could make asthma worse (5-point Likert scale, range not reported, higher score is better)	Group 1: 22 Group 2: 21 Group 3: 20 Group 4: 22	At 3-month follow-up	Knowledge of asthma symptoms Group 1: -0.19, 95% CI -0.78 to 0.40 Group 2: 0.33, 95% CI -0.30 to 0.97 Group 3: 0.88, 95% CI -0.02 to 1.79 Knowledge of asthma triggers Group 1: 0.50, 95% CI -0.62 to 1.62 Group 2: 1.29, 95% CI -0.03 to 2.54) Group 3: 0.29, 95% CI -0.99 to 1.58 Knowledge of triggers that could make asthma worse Group 1: -0.18, 95% CI -2.37 to 2.01	Knowledge of asthma symptoms Group 4: 0.17, 95% CI -0.62 to 0.95 Knowledge of asthma triggers Group 4: 1.22, 95% CI 0.38 to 2.07 Knowledge of triggers that could make asthma worse Group 4: 0.45, 95% CI -1.41 to 2.31	6-month assessment not reported No composite score reported, data were not combined as no score range was reported; the scale could not be standardised on a scale ranging from 0 to 100 Results reported are adjusted for age, gender, educational level and ethnicity Data have been extracted from the secondary reference (see Poureslami 2016a for all trial reports related to this study)

Table 2. Outcome category: health-related knowledge *(Continued)*

					Group 2: 0.86, 95% CI -0.51 to 2.22 Group 3: 0.35, 95% CI -1.12 to 1.94		
Poureslami 2016b	COPD	"Some" questions of BCKQ	—				
Unger 2013	Depression	Depression Knowledge Scale (0 to 17, higher score is better)	IG: 69 CG: 70	Immediately post-intervention	2.37 (SE 0.32)	0.86 (SE=0.27)	
				1-month follow-up	t = 5.09, P < 0.05	t = 2.64, P < 0.05	"[T]he data collectors reported that several students shared their photonovel with students in the text pamphlet group after the posttest." (Unger 2013, p. 405)
Valdez 2015	Cervical cancer	Questionnaire (0 to 12, higher score is better)	IG: 290 CG: 318	At 1-month follow-up	8.9 (1.6)	7.1 (2.0)	P < 0.0001
Valdez 2018	Cervical Cancer	Questionnaire (0 to 5, higher score is better)	IG: 383 CG: 344	At 6-month follow-up	3.7 (1.6)	3.1 (1.4)	P < 0.0001
7 Culturally and literacy adapted audio-/visual education**without personal feedback vs another culturally and literacy adapted** audio-/visual education**without personal feedback**							
Ochoa 2020	Cervical cancer	Questionnaire (0 to 8, higher score is better)	IG: 61 CG: 48	At 2-week follow-up	5.10 (1.45)	4.44 (1.15)	P = 0.011
				At 6-month follow-up	5.38 (1.27)	5.29 (1.17)	P = 0.718
Poureslami 2016a	Asthma	Functional knowledge of asthma symptoms, triggers, and factors that could make asthma worse	Group 1 (physician-led knowledge video): 22	At 3-month follow-up	Knowledge of asthma symptoms	Knowledge of asthma symptoms	6-month assessment not reported No composite score reported Results are adjusted for age, gender, educational level and ethnicity

Table 2. Outcome category: health-related knowledge *(Continued)*

		(5-point Likert scale, range not reported, higher score is better)	Group 2 (narrative, peer-led video): 21		Group 1: -0.19, 95% CI -0.78 to 0.40 Knowledge of asthma triggers Group 1: 0.50, 95% CI -0.62 to 1.62 Knowledge of triggers that could make asthma worse Group 1: -0.18, 95% CI -2.37 to 2.01	Group 2: 0.33, 95% CI -0.30 to 0.97 Knowledge of asthma triggers Group 2: 1.29, 95% CI -0.03 to 2.54) Knowledge of triggers that could make asthma worse Group 2: 0.86, 95% CI -0.51 to 2.22
Poureslami 2016b	COPD	"Some" questions from BCKQ	A 3-month follow-up	—		

*Unadjusted mean (SD) if not otherwise reported.

[1] Assessed only for those injecting insulin (intervention, n = 5; control, n = 7). Data were not included in the meta-analyses.

ADKnowl: Audit of Diabetes Knowledge; AOR: adjusted odds ratio; BCKQ: Bristol COPD Knowledge Questionnaire; CBT: cognitive behavioural therapy; CBT-Q: Knowledge of CBT questionnaire; CG: control group; CI: confidence interval; COPD: chronic obstructive pulmonary disease; DKT: Diabetes Knowledge Test; ESL: English as a second language; GEE: generalised estimating equations; HBP: high blood pressure; HBV: hepatitis B virus; IG: intervention group; NCI: National Cancer Institute; OR: odds ratio; PSA: prostate-specific antigen; SD: standard deviation; SE: standard error

Table 3. Outcome category: health outcomes

Study ID	Health topic	Measure	No. of participants	Time point(s)	Intervention arm Mean (SD)*	Control arm Mean (SD)*	Notes
1 Culturally and literacy adapted self-management programme vs no health literacy intervention							
van Servellen 2005	HIV	Self-reported health status (1 item assessing general health status in the past week)	IG: 34 CG: 35	6 months after randomisation (immediately post-intervention)	0.47 (1.21)	0.09 (0.95)	Change scores are reported

Table 3. Outcome category: health outcomes *(Continued)*

							No differences between study groups
2 Culturally and literacy adapted self-management programme vs written information on the same topic							
Kim 2009	Depression	KDSKA (21 items with 4 subscales, 0 to 75, lower score is better)	IG: 40 CG: 39	30 weeks after randomisation	-0.5 (4.5)	-1.0 (4.3)	P = 0.70
Kim 2014	Depression	PHQ-9 (9 items, 0 to 27, lower score is better)	IG: 184 CG: 185	12 months after randomisation	2.1 (2.9)	3.0 (3.0)	Group x time P = 0.04
				18 months after randomisation (at 6-month follow-up)	2.5 (3.3)	2.9 (3.3)	
Kim 2020	Depression	PHQ-9K (9 items, 0 to 27, lower score is better)	IG: 105 CG: 104	12 months after randomisation	4.8 (SE 0.5)	4.1 (SE 0.4)	—
Rosal 2005	Depression	CES-D (20 items, 0 to 60, lower score is better)	IG: 15 CG: 10	3 months after randomisation (immediately post-intervention)	-3.7 (7.6)	7.6 (8.9)	Change scores are reported
				6 months after randomisation (4.5 months post-intervention)	1.4 (9.8)	9.57 (11.0)	Group x time P = 0.03
5 Culturally and literacy adapted audio-/visual education**without personal feedback vs no health literacy intervention**							
DeCamp 2020	(Parent) depression	PHQ-8 (8 items, 0 to 24, lower score is better)	IG: 72 CG: 63	Immediately to 3 months post-intervention (10 to 13 months after randomisation)	0.68 (3.82)	0.70 (4.18)	P = 0.97
Kiropoulos 2011	Depression	BDI-II (0 to 63, lower score is better)	IG: 110 CG: 92	Immediately post-intervention	7.26 (7.64)	8.13 (7.53)	P = 0.87
				1 week post-intervention	6.36 (6.60)	8.26 (7.88)	P = 0.18[1] P = 0.19[2]
6 Culturally and literacy adapted audio-/visual education without personal feedback vs written information on the same topic							
Sudore 2018	Depression	PHQ-8	IG: 219	At 12-month follow-up	3.9 (95% CI 3.3 to 4.4)	4.5 (95% CI 4.0 to 5.1)	P = 0.10

Table 3. Outcome category: health outcomes *(Continued)*

		(0 to 24) referred to as adverse events, lower score is better	CG: 226				Adjusted for baseline depression and anxiety scores

*Unadjusted mean (SD) if not otherwise reported.

[1] ANCOVA employed the pre-intervention measure of the variable as a covariate.

[2] ANCOVA employed the postintervention measure of the variable as a covariate.

BDI-II: Beck Depression Inventory-II; CES-D: Center for Epidemiological Studies-Depression Scale; CG: control group; IG: intervention group; KDSKA: Kim Depression Scale for Korean Americans; PHQ-8: Patient Health Questionnaire-8; PHQ-9: Patient Health Questionnaire-9; PHQ-9K: Korean version of PHQ-9; SD: standard deviation; SE: standard error

Table 4. Outcome category: health behaviour

Study ID	Health topic	Measure	No. of participants	Time point(s)	Intervention arm Mean (SD)*	Control arm Mean (SD)	Notes
1 Culturally and literacy adapted self-management programme vs no health literacy intervention							
Bloom 2014	Breast health/ breast cancer	Self-report, mammography	N: 230	6 months after randomisation (no further details)	56%	10%	P < 0.0001 Cluster-RCT; authors state that general linear models with GEE used to account for clustering (sample and analysis)
Koniak-Griffin 2015	Cardiovascular health	Physical activity; Lenz Lifecorder Plus Accelerometer, assesses vertical acceleration and counts movements that are correlated with steady-state oxygen consumption	IG: 98 CG: 95	6 months after randomisation (immediately post-intervention)	8769 (2747)	8480 (3506)	Number of average daily steps is reported "[T]here was a statistically significant decrease in the control group, approaching a 1000-step decline, whereas intervention participants maintained their activity level." (Koniak-Griffin 2015, p.82 f)
			IG: 100 CG: 94	9 months after randomisation (at 3-month follow-up)	8577 (2872)	7241 (2764)	
Rosal 2011	Diabetes type 2	Self-monitoring of blood glucose	IG: 124 CG: 128	12 months after randomisation (immediate-	102/124; 81.5%	81/128; 63.6%	P = 0.023 Values reflect blood glucose self-monitoring 2 or more

Table 4. Outcome category: health behaviour *(Continued)*

		3 recalls per time point (oral assessment), 3 questions on physical activity and 3 questions on self-monitoring of blood glucose, higher score is better		ly post-intervention)			times per day; absolute numbers were calculated from reported percentages
van Servellen 2005	HIV	HIV medication adherence, adherence behaviours baseline questionnaire (Proportion of > 95% adherence within last 4 days)	IG: 34 CG: 35	6 months after randomisation (immediately post-intervention)	1.71%	-4.85%	Change scores are reported
2 Culturally and literacy adapted self-management programme vs written information on the same topic							
Han 2017	Breast cancer	Adherence to mammogram, pap test, or both tests (Medical record review)	Mammogram[a] IG: 198 CG: 201	6 months after randomisation (immediately post-intervention)	n: 111 (56.1%)[b]	n: 20 (10.0%)[b]	Cluster-RCT AOR (95% CI)[b] (1) 18.5 (9.2 to 37.4) (2) 13.3 (7.9 to 22.3) (3) 17.4 (7.5 to 40.3) [a]Women who were missing screening status were assumed to have not undergone screening [b]Estimated from GEE model accounting for clustering, adjusted for age, insurance, English proficiency, years in US, years of education, employment and family history of breast cancer
			Pap test[a] IG: 246 CG: 251	Immediately post-intervention	n: 134 (54.5%)[b]	n: 23 (9.2%)[b]	
			Both tests[a] IG: 166 CG: 170	Immediately post-intervention	77/166 (46.4%)[b]	11/170 (6.5%)[b]	
Kaur 2019	Oral hygiene	Questionnaire on oral self-care behaviour (higher score is better)	IG: 70 CG: 70	3 months after randomisation (immediately post-intervention)	3.10 (95% CI 2.50 to 3.69)		Group x time P < 0.0001

Table 4. Outcome category: health behaviour *(Continued)*

Kim 2009	Diabetes type 2	Diabetes self-care activities, SDSCA (higher score is better)	IG: 40 CG:39	30 weeks after randomisation (immediately post-intervention)	17.5 (16.9)	2.5 (15.4)	Change scores are reported P = 0.00
Kim 2014	High blood pressure	Non-adherence to blood pressure medication, HB-MAS (8 items, 4-point Likert-scale, 1 = none of the time to 4 = all of the time, 8 to 32, lower score is better)	IG: 184 CG: 185	12 months after randomisation	9.1 (1.7)	9.5 (2.0)	Cluster-RCT; data have been re-analysed for meta-analyses using the appropriate unit of analysis with the use of the ICC reported by Han 2017
				18 months after randomisation (at 6-month follow-up)	8.8 (1.4)	9.2 (1.6)	
Rosal 2005	Diabetes type 2	Blood glucose self-monitoring; 24-hour recall of self-monitoring of blood glucose by asking individuals whether they had checked their blood sugar level in the previous 24 hours, at what time, and the value, higher score is better	IG: 15 CG: 8	3 months after randomisation (immediately post-intervention)	No./day capped at 2; 2/day both calls 0.63 (0.26); 12/15 (80%)	No./day capped at 2; 2/day both calls 0.19 (0.35); 4/8 (50%)	No difference
				6 months after randomisation (4.5 months post-intervention)	No./day capped at 2; 2/day both calls 0.63 (0.24); 11/15 (74%)	No./day capped at 2; 2/day both calls 0.06 (0.27); 3/8 (38%)	
3 Culturally adapted health literacy skill building course vs no/unrelated health literacy intervention							
Otilingam 2015	Behaviours to reduce dietary fat	Fat-Related Diet Habits Questionnaire (12 items, 4-point Likert scale, rarely/never, sometimes, often, usually, 1 to 4, higher score is better)	IG 1: 32 IG 2: 33 CG 1: 16 CG 2: 18	Immediately post-intervention	IG 1: 3.18 (0.46) IG 2: 3.25 (0.27)	CG 1: 3.16 (0.39) CG 2: 3.12 (0.50)	IGs were combined to create a single score (see Analysis 3.5). CG 2 was assessed immediately post-intervention only. Group x time P = 0.0140
				At 1-month follow-up	IG 1: 3.43 (0.40) IG 2: 3.38 (0.30)	CG 1: 3.16 (0.47)	

Table 4. Outcome category: health behaviour *(Continued)*

					Combined: 3.41 (0.35)		
Taylor 2011	Hepatitis B	Medical record of HBV testing	IG: 80 CG: 100	At 6-month follow-up	5/80 (6.25%)	0/100 (0%)	Cluster-RCT; data have been re-analysed for meta-analyses using the appropriate unit of analysis with the use of the ICC reported by Han 2017 (see Analysis 3.6)
Tong 2017	Colorectal cancer	Up-to-date colorectal cancer screening* FOBT, S/C; self-report of test receipt and when the test was obtained	IG: 161 CG: 168	6 months after first intervention session	92/161 (57.1%)	73/168 (43.5%)	Cluster-RCT. Unadjusted values are reported.
Soto Mas 2018	Cardiovascular health	Cardiovascular health behaviour; CSC (34 items, 4-point Likert scale, 1 = never to 4 = always, 34 to 136, higher score is better)	IG: 77 CG: 78	Immediately post-intervention	59.1	57.9	P = 0.067
4 Culturally and literacy adapted telephone education vs unrelated culturally and literacy adapted telephone education							
Lepore 2012	Prostate cancer	Prostate cancer screening behaviour; verified PSA test (Medical claims scanned for PSA procedure codes using an expert system, 0 = no, 1 = yes)	IG: 244 CG: 246	1-year follow-up 2-year follow-up	110/244 (45.1%) 153/244 (62.7%)	113/246 (45.9%) 165/246 (66.7%)	Absolute numbers were calculated from reported percentages
5 Culturally and literacy adapted audio-/visual education**without personal feedback vs no health literacy intervention**							
DeCamp 2020	Child's health	Prostate cancer screening behaviour; electronic medical record	IG: 72 CG: 63	3 months post-intervention (15 months after child's birth)	n: 61 (85%)	n: 50 (79%)	No difference Percentages-only are reported
6 Culturally and literacy adapted audio-/visual education**without personal feedback vs written information on the same topic**							
Gwede 2019	Colorectal cancer	Colorectal cancer screening uptake; Return of completed FIT kit within 90 days of intervention delivery, yes/no	IG: 40 CG: 36	3 months post-intervention	n: 36 (90%)	n: 30 (83%)	P = 0.379 Percentages-only are reported

Table 4. Outcome category: health behaviour *(Continued)*

Sudore 2018	Advance care planning, no specific	Documentation of new advance care planning (Legal forms and documented discussions with clinicians and/or surrogates)	IG: 219 CG: 226	At 12-month follow-up	84/219	58/226	—
Valdez 2018	Cervical cancer	Pap test screening behaviour (Self-report, having had a Pap test or made an appointment in the interval between pre-test and post-test, yes/no)	IG: 383 CG: 344	At 6-month follow-up	n: 195 (51%)	n: 165 (48%)	Absolute numbers were calculated from reported percentages
7 Culturally and literacy adapted audio-/visual education**without personal feedback vs another culturally and literacy adapted** audio-/visual education**without personal feedback**							
Ochoa 2020	Cervical cancer	Pap testing behaviour (1 item, "Since you saw the film, have you had a Pap test?", yes/no/do not know)	IG: 61 CG: 48	At 6-month follow-up	n: 23 (37.9%)	n: 14 (29.2%)	Absolute numbers were calculated from reported percentages Results of the 2-week post-intervention assessment are not reported
8 Culturally and literacy adapted medical instruction vs no health literacy intervention							
Mohan 2014	No specific	Medication adherence; ARMS, patients' self-reported adherence under various circumstances (sub-scale to medication refills) (8 items, 8 to 32, lower, score is better)	IG: 99 CG: 101	At 1-week follow-up	10.3	9.9	No variance per study group reported, but MD of change scores: MD 0.5 (95% CI -0.1 to 1.1) "Each 1-point increase in BHLS score was associated with a decrease of 0.1 (95% CI, –0.2 to 0.0) in the ARMS score." (Mohan 2014)

*Results are unadjusted mean (SD) if not otherwise reported.
AOR: adjusted odds ratio; ARMS: Adherence to Refills and Medications Scale; CI: confidence interval; CSC: Cardiovascular Health Questionnaire; EMR: Electronic Medical Record; FOBT: faecal occult blood test; GEE: generalised estimating equations; HB-MAS: Hill-Bone Medication Adherence Scale; HBV: hepatitis B virus; MD: mean difference; OR: odds ratio; Pap test: Papanicolaou test; PSA: prostate-specific antigen; S/C: sigmoidoscopy or colonoscopy; SD: standard deviation; SDSCA: Summary of Diabetes Self-Care Activities

Table 5. Outcome category: self-efficacy

Study ID	Health topic	Measure	No. of participants	Time point(s)	Intervention arm Mean (SD)*	Control arm Mean (SD)*	Notes
1 Culturally and literacy adapted self-management programme vs no health literacy intervention							
Rosal 2011	Diabetes type 2	Self-efficacy in diabetes management; LSESLD (17 items, 17 to 68, higher score is better)	IG: 124 CG: 128	4 months after randomisation	0.448 (0.362 to 0.534)	0.132 (0.040 to 0.219)	Mean (range) is reported P < 0.001 For meta-analysis, the final SD was substituted with the reported baseline SD (Analysis 1.9)
				12 months after randomisation	0.448 (0.0348 to 0.548)	0.213 (0.113 to 0.313)	P = 0.001
van Servellen 2005	HIV	Self-efficacy for HIV medication adherence; adherence behaviours baseline questionnaire (item from the ACTG) (1 question on certainty to take medications correctly, 0 = not at all sure to 3 = extremely sure, higher scores are better)	IG: 41 CG: 40	At 6 weeks after randomisation	0.27 (0.92)	-0.08 (0.92)	Intervention group: P ≥ 0.10 Change scores are reported
			IG: 34 CG: 35	At 6 months after randomisation	0.12 (0.95)	-0.06 (0.59)	Change scores are reported
2 Culturally and literacy adapted self-management programme vs written information on the same topic							
Kim 2009	Diabetes type 2	Adapted Stanford Chronic Disease Self-Efficacy Scale (8 x 10-point Likert items, 0 to 80, 1 = not confident at all, 4 = very confident, higher scores are better)	IG: 40 CG: 39	18 weeks after randomisation	8.7 (11.4)	2.6 (15.0)	Change scores are reported P = 0.02
				30 weeks after randomisation	6.6 (14.4)	-0.9 (15.1)	Change scores are reported P = 0.01

Table 5.   **Outcome category: self-efficacy** *(Continued)*

Kim 2014	HBP	Self-efficacy in managing high blood pressure; questionnaire adapted from the HBP belief scale (8 items, 4-point Likert scale, 1 = not confident at all, 4 = very confident, 8 to 32, higher scores are better)	IG: 184 CG: 185	12 months after randomisation (immediately post-intervention)	26.6 (3.2)	25.4 (3.7)	Cluster-RCT; data have been reanalysed for meta-analysis using the appropriate unit of analysis with the use of the ICC reported by Han 2017 (see Analysis 2.23; Analysis 2.25) Group x time P = 0.001 (at 12 months)
				18 months after randomisation (6-month follow-up)	25.9 (3.7)	26.1 (3.9)	
Kim 2020	Diabetes type 2	Adapted Stanford Chronic Disease Self-Efficacy Scale (8 items, 10-point Likert scale, 0 to 80, 1 = not confident at all, 4 = very confident, higher scores are better)	IG: 105 CG: 104	12 months after randomisation	58.6 (SE 1.2)	46.5 (SE 1.6)	P < 0.001
Rosal 2005	Diabetes type 2	IMDSES (26 items, 4-point Likert-scale, 1 = "low confidence" to 4 = "high confidence", 26 to 104, higher scores are better)	IG: 15 CG: 10	3 months after randomisation (immediately post-intervention)	Self-efficacy for (1) Diet 0.03 (0.4) (2) Exercise 0.11 (0.9) (3) Self-monitoring 0.3 (1.0) (4) Oral glycaemic agents -0.1 (0.3) (5) Insulin -0.14 (1.3)	Self-efficacy for (1) Diet 0.44 (0.3)* (2) Exercise 0.24 (0.6) (3) Self-monitoring –0.3 (0.7) (4) Oral glycaemic agents 0 (0) (5) Insulin –0.2 (0.5)	Change scores are reported No composite score reported. For meta-analysis, a single score was calculated (see Analysis 2.23)
				6 months after randomisation (4.5 months post-intervention)	(1) Diet 0.10 (0.6) (2) Exercise 0.04 (0.6) (3) Self-monitoring 0.30 (1.0)	(1) Diet 0.13 (0.4) (2)Exercise –0.14 (1.0)	

Table 5. Outcome category: self-efficacy *(Continued)*

					(4) Oral glycaemic agents 0.04 (0.1) (5) Insulin 0.01 (0.6)	(3) Self-monitoring –0.07 (0.7) (4) Oral glycaemic agents –0.25 (0.5) (5) Insulin –0.27 (0.4)	
3 Culturally adapted health literacy skills building course vs unrelated health literacy intervention							
Elder 1998	Nutrition/cardiovascular health	Self-efficacy to change one's diet (5 items, 1 to 3, higher score is better)	IG: 133 CG: 157	3 months post-intervention	2.29	2.25	No difference Cluster-RCT; unadjusted values are reported
				At 6-month follow-up	2.30	2.27	
5 Culturally and literacy adapted audio-/visual education**without personal feedback vs no health literacy intervention**							
Hernandez 2013	Depression	Self-efficacy to identify the need for treatment scale (3 items, 5-point Likert scale, 1 = not sure, 5 = very sure, 0 to 15, higher scores are better)	IG: 70 CG: 63	Immediately post-intervention	3.64 (3.36)	0.13 (2.35)	Change scores are reported P < 0.001
6 Culturally and literacy adapted audio-/visual education**without personal feedback vs written information on the same topic**							
Gwede 2019	Colorectal cancer	Self-efficacy for screening using FIT (6 items, 6 to 30, higher scores indicating higher levels of self-efficacy)	IG: 27 CG: 36	At 3-month follow-up	29.7 (1.0)	29.5 (1.3)	P = 0.039
Poureslami 2016b (4-arms, COPD)	COPD	COPD Self-Efficacy Scale (short version) (5 items, 5-point Likert-scale, 1 = not at all confident to 5 = totally confident, higher scores are better)	Group 3: 29 Group 4: 14	3 months post-intervention	(1) Prepared to manage COPD Group 3 vs Group 4 0.87 (0.04 to 1.71), P < 0.05 (2) Perception of being informed about COPD Group 3 vs Group 4 0.12 (-0.65 to 0.90), P < 0.05		No composite score reported MD (95% CI), P values are reported No difference between female and male participants

Table 5. Outcome category: self-efficacy *(Continued)*

					(3) Remain calm when facing a worsening of COPD Group 3 vs Group 4 0.28 (-0.54 to 1.11), N/S (4) Ability to achieve goals in managing COPD Group 3 vs Group 4 1.05 (0.08 to 2.02), P < 0.05 (5) Ability to self-manage COPD symptoms Group 3 vs Group 4 0.38 (-1.18 to 0.41), P < 0.05		
Payán 2020	Breast cancer	Self-efficacy in accessing breast cancer-related advice or information (1 item, "Overall, how confident are you that you could get advice or information about breast cancer if you needed it?", 5-point Likert scale 1 = "completely confident" to 3 = "not confident at all" (3), higher scores are better)	IG 1: 79 IG 2: 79 CG: 82	Immediately post-intervention	IG 1: 0.87 (0.34) IG 2: 0.89 (0.32) IG 1, 2: 0.88 (0.33)	0.80 (0.40)	Final values were obtained from study authors IG 1 and IG 2 were combined to create a single pairwise comparison
			IG 1: 67 IG 2: 61 CG: 65	At 3-month follow-up	IG 1: 0.67 (0.47) IG 2: 0.88 (0.33) IG 1, 2: 0.77 (0.42)	0.75 (0.44)	
Unger 2013	Depression	Self-efficacy to identify depression (2 items, 10-point Likert scale, 1 = "not at all confident" to 10 = "very confident", higher scores are better)	IG: 69 CG: 70	Immediately post-intervention	t = 4.54, P < 0.05	t = 3.16, P < 0.05	—
				At 1-month follow-up	t = 3.31, P < 0.05	t = 3.00, P < 0.05	"[T]he data collectors reported that several students shared their photonovel with students in the text pamphlet group after the posttest." (Unger 2013, p. 405).

Table 5. Outcome category: self-efficacy *(Continued)*

Valdez 2018	Cervical cancer/Pap testing	Self-efficacy regarding Pap smear (1 item, "Can get a pap smear if needed", yes/no)	IG: 383 CG: 344	6-month follow-up	n: 356, 93 %	n: 314, 91 %	P = 0.40

* Unadjusted mean (SD) if not otherwise reported.

ACTG: Adult AIDS Clinical Trials Group; CG: control group; COPD: chronic obstructive pulmonary disease; FIT: faecal immunochemical test; HBP: high blood pressure; IG: intervention group; IMDSES: Insulin Management Self-Efficacy Scale; LSESLD: Lifestyle Self-Efficacy Scale for Latinos with Diabetes; MD (95% CI): mean difference (95% confidence interval); N/S: not significant; SD: standard deviation; SE: standard error ; Pap: Papanicolaou

Table 6. Outcome category: quality of life

Study ID	Health topic	Measure	No. of participants	Time point(s)	Intervention arm Mean (SD)*	Control arm Mean (SD)	Notes
2 Culturally and literacy adapted self-management programme vs written information on the same topic							
Kim 2009	Diabetes-related quality of life	DQOL, modified version (4 dimensions of QOL, 46 items, lower score is better)	IG: 40 CG: 39	30 weeks after randomisation (immediately post-intervention)	84 -4.6 (16.5)	96.8 0.3 (16.4)	P = 0.03
Kim 2020	Diabetes-related quality of life	DQOL (4 dimensions of QOL, 15 items, 0 to 75, higher score indicates higher level of quality of life)	IG: 105 CG: 104	12 months after randomisation	57.6 (SE 1.0) Change from baseline: 7.5 (SE 0.9)	49.9 (SE 1.0) Change from baseline: -1.1 (0.9)	P < 0.001 P < 0.001
Rosal 2005	Diabetes-related quality of life	ADDQoL, adapted version, modified for telephone administration (13 items)	IG: 15 CG: 10	3 months after randomisation (immediately post-intervention)	-0.35 (1.4)	-0.8 (1.0)	No differences between study groups
				6 months after randomisation (4.5 months post-intervention)	-2.4 (2.0)	-1.3 (2.3)	We do not know which effect indicates a higher level of quality of life

*Unadjusted mean (SD) if not otherwise reported.

ADDQoL: Audit of Diabetes Dependent Quality of Life; CG: control group; DQOL: Diabetes Quality of Life measure; IG: intervention group; SD: standard deviation; SE: standard error

Table 7. Outcome category: adverse events

Study ID	Health topic	Measure	No. of participants	Time point(s)	Intervention arm Mean (SD)*	Control arm-Mean (SD)	Notes
4 Culturally and literacy adapted telephone education vs unrelated culturally and literacy adapted telephone education							
Lepore 2012	Prostate cancer	Anxiety HADS, 7 items subscale for assessing anxiety, 0 to 21, lower score is better	IG: 215 CG: 216	Approx. 7 months post-intervention	2.02 (SE 0.147)	2.16 (SE 0.146)	P = 0.42 Adjusted for education, any PSA claim prior to pretest and state anxiety level at pretest
6 Culturally and literacy adapted audio-/visual education without personal feedback vs written information on the same topic							
Sudore 2018	Advance care planning, no specific	Anxiety GAD-7, 0 to 21, cut-point > 10 (moderate anxiety), lower score is better	IG: 219 CG: 226	At 12-month follow-up	3.0 (95% CI 2.5 to 3.5)	3.7 (95% CI 3.2 to 4.2)	P = 0.05 Adjusted for baseline depression and anxiety scores

*Unadjusted mean (SD) if not otherwise reported.
CI: confidence interval; CG: control group; GAD-7: Generalised Anxiety Disorder-7; HADS: Hospital Anxiety and Depression Scale; IG: intervention group; SD: standard deviation; SE: standard error

Table 8. Outcome category: health literacy - applying health information

Study ID	Health topic	Measure	No. of participants	Time point(s)	Intervention arm Mean (SD)*	Control arm Mean (SD)*	Notes
3 Culturally adapted health literacy skills building course vs no/unrelated health literacy							
Elder 1998	Cardiovascular health/nutrition	Intention to change nutritional habits, questionnaire (3 items, 1 to 3, higher score is better)	IG: 131 CG: 156	Immediately post-intervention	2.71	2.69	Condition x time: P = 0.06 Cluster-RCT "Results showed the intraclass correlations were negligible and so mixed model analysis of variance
				At 6-month follow-up	2.71	2.66	

Table 8. Outcome category: health literacy - applying health information *(Continued)*

							(ANOVA) procedures were conducted to test intervention effects."
4 Culturally and literacy adapted telephone education vs unrelated health literacy intervention							
Lepore 2012	Testing intention	Testing intention for prostate cancer (Participants were asked whether they had "decided to get tested in the future for prostate cancer", 0 = no, 1 = yes)	IG: 215 CG: 216	Approx. 7 months post-intervention	n = 215 80.9%	n = 216 81.0%	(95% CI 0.614 to 1.610) Adjusted for education level and claims-verified PSA test prior to pretest
5 Culturally and literacy adapted audio-/visual education**without personal feedback vs no health literacy intervention**							
Hernandez 2013	Depression	Intention to seek treatment for depression Intention to seek treatment for depression scale, 0 to 32, higher score is better	IG: 63 CG: 57	Immediately post-intervention	1.10 (2.99)	-0.70 (4.46)	Change scores are reported P = 0.012 "[...] groups' mean increase in intent to seek treatment, [...] used to control for alpha inflation, yielded a more conservative a-level of.01, rendering the above p value marginally significant in favour of greater intention to seek treatment on the part of experimental participants exposed to the fotonovela"
Thompson 2012	Behaviour intent/behaviour change	Planned changes in behaviour, questionnaire (3 questions on behaviour change based on what was learned through programme)	IG: 80 CG: 78	Immediately post-intervention	Planned behaviour change (1) 71% Planned to talk to child's doctor 80% Planned to talk to family or friends	—	Data available for intervention group only 50.9% of those who planned to change behaviour planned to change something related to the milk module

Table 8. Outcome category: health literacy - applying health information *(Continued)*

					100%		
6 Culturally and literacy adapted audio-/visual education without personal feedback vs written information on the same topic							
Unger 2013	Depression	Willingness to seek help for depression Modified intention to seek help for depression care scale (4 items, 1 = no, 2 = yes, higher score is better)	IG: 69 CG: 70	Immediately post-intervention	"76 % of the respondents (...) answered "yes" to all of the questions in this scale at baseline, (...) this increased to 83 % at posttest and 86 % at 1-month follow-up"	"There were no significant differences between the fotonovela group and the text pamphlet group in willingness to seek help for depression at baseline, posttest, or follow-up, and neither group changed significantly on this variable."	"[T]he data collectors reported that several students shared their photonovel with students in the text pamphlet group after the posttest." (Unger 2013, p. 405).
Valdez 2015	Informed decision regarding HPV vaccination	Made informed decision regarding HPV vaccination ((1) making a vaccination choice, (2) affirming that the decision was an informed choice, and (3) having a knowledge score of at least 7 out of 12 knowledge items, higher score is better)	IG: 290 CG: 318	At 1-month follow-up	182/290 (62.8%)	132/318 (41.5%)	P < 0.0001
7 Culturally and literacy adapted audio-/visual education without personal feedback vs another culturally and literacy adapted audio-/visual education without personal feedback							
Ochoa 2020	Behavioural intentions regarding cervical cancer	Pap testing intention ("Since you saw the film, did you make an appointment for a Pap test?", "yes", "no" or "do not know")	IG: 61 CG: 48	2 weeks post-intervention	Not reported	Not reported	There "was no statistical difference in behavioural intentions at 2 weeks based on the film condition; however, there were trends that the narrative film had a greater effect." (Ochoa 2020, p. 739)

Table 8. Outcome category: health literacy - applying health information *(Continued)*

				At 6-month follow-up	15/61 (24.1%)	6/48 (12.5%)	Absolute numbers were calculated from reported percentages

* Unadjusted mean (SD) if not otherwise reported.
CG: control group; CI: confidence interval; HPV: human papillomavirus; IG: intervention group; PSA: prostate-specific antigen; RCT: randomised controlled trial; SD: standard deviation

Table 9. Outcome category: health literacy - appraising health information

Study ID	Domain	Measure	No. of participants	Time point(s)	Intervention arm Mean (SD)*	Control arm Mean (SD)*	Notes
2 Culturally and literacy adapted self-management programme vs written information on the same topic							
Han 2017	Cervical/breast cancer	Decisional balance measure (weighing pros and cons for mammography and Pap testing) (5 pros and 9 cons on 5-point Likert scale)	Breast cancer IG: 278 CG: 282	At 6 months after randomisation (immediately post-intervention)	50.0 (6.0)	49.0 (6.0)	Cluster-RCT; data have been re-analysed for meta-analysis using the appropriate unit of analysis with the use of the ICC reported by Han 2017. In addition, outcome data for decisional balance for mammography and decisional balance for Pap testing were combined to create a single score (see Analysis 2.8) Estimated MD 1.3 (95% CI 0.4 to 2.1) Estimated MD adjusted for baseline decisional balance, age, insurance, English proficiency, years of US residence, years of education, employment and family history of breast cancer
			Cervical cancer IG: 278 CG: 282		54.4 (6.1)	53.1 (6.0)	Estimated MD 1.1 (95% CI 0.5 to 1.6) Estimated MD adjusted for baseline decisional balance, age, insurance, English proficiency, years of US residence, years of education, employment and family history of breast cancer.
3 Culturally adapted health literacy skills building course vs no health literacy intervention							

Table 9. Outcome category: health literacy - appraising health information *(Continued)*

Valdez 2015	Cervical cancer/HPV vaccine	Decisional Conflict Scale (Subscales (1) informed decision, (2) values clarity, (3) support, 0 to 100 (each scale), lower score is better)	IG: 290 CG: 318	1 month post-intervention	(1) 19.7 (15.8) (2) 20.3 (15.1) (3) 22.8 (17.1)	(1) 32.3 (21.4) (2) 32.8 (22.1) (3) 30.0 (20.4)	Difference between intervention and control in pre-post change (1) P < 0.0001 (2) P < 0.0001 (3) P = 0.0023
4 Culturally adapted telephone education vs unrelated culturally adapted telephone education							
Lepore 2012	Prostate cancer	Decisional Conflict Scale (Subscales (1) informed decision, (2) values clarity, (3) support (1 out of 3 items), 0 to 100, lower score is better)	IG: 215 CG: 216	Approximately 7 months post-intervention	34.15 (SE 1.639)	39.85 (SE 1.636)	P = 0.14 Measured post-test only Adjusted for education and any PSA claim prior to pretest

* Unadjusted mean (SD) if not otherwise reported.
CG: control group; ICC: intraclass correlation; IG: intervention group; MD: mean difference; PSA: prostate-specific antigen; SD: standard deviation

Table 10. Outcome category: health service use

Study ID	Health topic	Measure	No. of participants	Time point(s)	Intervention arm Mean (SD)*	Control arm Mean (SD)	Notes
5 Culturally and literacy adapted audio-/visual education**without personal feedback vs no health literacy intervention**							
DeCamp 2020	Child health	Emergency department visits (EMR)	IG: 79 CG: 78	1 to 3 months post-intervention (12 to 15 months after child's birth)	1.23 (1.66)	1.82 (1.64)	P = 0.03

*Results are unadjusted mean (SD) if not otherwise reported.
CG: control group; CI: confidence interval; EMR: electronic medical record; ER: emergency room; GEE: generalised estimating equations; IG: intervention group; RR: risk ratio; SD: standard deviation

Table 11. Outcome category: health literacy - competencies

Study ID	Health topic	Measure	No. of participants	Time point(s)	Intervention arm Mean (SD)*	Control arm Mean (SD)*	Notes
6 Culturally and literacy adapted audio-/visual education without personal feedback vs written information on the same topic							
Poureslami 2016a (4 study arms)	Asthma medication management	Inhaler use technique; direct observation (2 observers) (Participants demonstrated correct use and had to describe each step, 1 point for appropriate use per step, standard checklist, 0 to 9, higher score is better)	Group 1 (physician-led knowledge video): 22 Group 2 (narrative, peer-led video): 21 Group 3 (both videos): 20 Group 4 (pamphlet): 22	At 3-month follow-up	Group 1: 2.71, 95% CI 1.35 to 4.06 Group 2: 1.95, 95% CI 0.99 to 2.91) Group 3: 1.53, 95% CI 0.66 to 2.40	Group 4: 1.05 (-0.10 to 2.20)	Change scores are reported Results adjusted for age, gender, educational level and ethnicity
Poureslami 2016b (4 study arms)	COPD medication management	Inhaler use technique; direct observation (2 observers) (Participants demonstrated correct use and had to describe each step, 10-item-validated inhaler-specific checklist, standard checklist, 0 to 9, higher score is better)	Group 1 (physician-led knowledge video): 22 Group 2 (narrative, peer-led video): 26 Group 3 (both videos): 29 Group 4 (pamphlet): 14	At 3-month follow-up	Group 1: 6.8 (2.0) Group 2: 5.9 (2.0) Group 3: 5.8 (1.6)	Group 4: 5.2 (1.4)	—
7 Culturally and literacy adapted audio-/visual education without personal feedback vs another culturally adapted audio-/visual education without personal feedback							
Poureslami 2016a	Asthma medication management	Inhaler use technique; direct observation (2 observers) (Participants demonstrated correct use and had to describe each step, 1 point for appropriate use per step, standard checklist, 0 to 9, higher score is better)	Group 1 (physician-led knowledge video): 22 Group 2 (narrative. peer-led video): 21	At 3-month follow-up	Group 1: 2.71, 95% CI 1.35 to 4.06	Group 2: 1.95, 95% CI 0.99 to 2.91)	Change scores are reported Results adjusted for age, gender, educational level and ethnicity
Poureslami 2016b	COPD medication management	Inhaler use technique; direct observation (2 observers)	Group 1 (physician-led knowledge video): 22	At 3-month follow-up	Group 1: 6.8 (2.0)	Group 2: 5.9 (2.0)	—

Table 11. Outcome category: health literacy - competencies *(Continued)*

		(Participants demonstrated correct use and had to describe each step, 10-item-validated inhaler-specific checklist, standard checklist, 0 to 9, higher score is better)	Group 2 (narrative. peer-led video): 26

*Unadjusted mean (SD) if not otherwise reported.

CG: control group; CI: confidence interval; COPD: chronic obstructive pulmonary disease; IG: intervention group; SD: standard deviation

Table 12. Outcome category: health literacy - understanding health information

Study ID	Health topic	Measure	No. of participants	Time point(s)	Intervention arm Mean (SD)*	Control arm Mean (SD)*	Notes
6 Culturally and literacy adapted audio-/visual education without personal feedback vs written information on the same topic							
Poureslami 2016a (4 study arms)	Asthma	Understanding of and adherence to physician's instructions (5 items, 0 to 5, higher score is better)	Group 1 (physician-led knowledge video): 22 Group 2 (narrative, peer-led video): 21 Group 3 (both videos): 20 Group 4 (pamphlet): 22	3 months post-intervention	Group 1: 0.53, 95% CI 0.12 to 0.94 Group 2: 0.38, 95% CI -0.06 to 0.82 Group 3: 0.24, 95% CI -0.19 to 0.66	Group 4: 0.35, 95% CI -0.22 to 0.92	Change scores are reported Adjusted for age, gender, educational level and ethnicity
Poureslami 2016b (4 study arms)	COPD	Understanding pulmonary rehabilitation procedures Questionnaire; text passage based on Canadian Thoracic Society COPD assessment guidelines, developed by the research team and related questions answered by participants (Correct/incorrect, higher score is better)	Group 1 (physician-led knowledge video): 22 Group 2 (narrative, peer-led video): 26 Group 3 (both videos): 29 Group 4 (pamphlet): 14	3 months post-intervention	—		Change scores are reported; adjusted for age, gender, educational level and disease severity Group 1 vs group 4: MD 2.14 (95% CI 0.73 to 3.16) Group 2 vs group 4: MD 2.22 (95% CI0.86 to 3.30) Group 3 vs group 4: MD 0.30 (95% CI -0.76 to 1.36)

Table 12. Outcome category: health literacy - understanding health information *(Continued)*

7 Culturally and literacy adapted audio-/visual education without personal feedback vs another culturally and literacy adapted audio-/visual education without personal feedback							
Poureslami 2016a	—	Understanding of and adherence to physician's instructions (5 items, 0 to 5, higher score is better)	Group 1 (physician-led knowledge video): 22 Group 2 (narrative peer-led video): 21	3 months post-intervention	Group 1: 0.53, 95% CI 0.12 to 0.94	Group 2: 0.38, 95% CI -0.06 to 0.82	Change scores are reported Adjusted for age, gender, educational level and ethnicity
Poureslami 2016b	—	Understanding pulmonary rehabilitation procedures Questionnaire; text passage based on Canadian Thoracic Society COPD assessment guidelines, developed by the research team and related questions answered by participants (Correct/incorrect, higher score is better)	Group 1 (physician-led knowledge video): 22 Group 2 (narrative peer-led video): 26	3 months post-intervention	—		Change scores are reported; adjusted for age, gender, educational level and disease severity Group 2 vs group 4 (pamphlet): 2.22, 95% CI 0.86 to 3.30, P < 0.05 Group 1 vs group 4 (pamphlet): 2.14, 95% CI 0.73 to 3.16
8 Culturally and literacy adapted medical instruction vs no health literacy intervention							
Bailey 2012	Medication understanding	Demonstration by means of correct dosage in dosing tray (5 items, frequency and spacing, 0 to 5, higher score is better)	IG: 102 CG: 100	Immediately post-intervention	Median: 4.0 (IQR 3.0 to 5.0)	Median: 3.0 (IQR 2.0 to 4.0)	P < 0.0001
Kheir 2014 (3 study arms)	Medication understanding	Interpretation of label contents (11 medicine labels, 1 = no comprehension to 3 = full comprehension, 1 to 3, higher score is better)	Group 1 (standard text labels + verbal instructions): 40 Group 2 (pictogram-only): 47 Group 3 (pictogram + verbal instructions): 36	Immediately post-intervention	—	—	For 10 of the 11 medicine instructions, participants in group 3 (pictogram + verbal instructions) consistently scored higher than participants in group 1 (standard text labels + verbal instructions), while group 1 had higher scores than group 2 (pictogram-only) for 8 of the 11 labels.

Table 12. Outcome category: health literacy - understanding health information *(Continued)*

Mohan 2014	Medication understanding	MUQ (0 to 100, higher score is better)	IG: 99 CG: 101	At 1-week follow-up	86.4 (12.6)	76.4 (18.0)	Adjusted difference P < 0.001

*Unadjusted mean (SD) if not otherwise reported.
CG: control group; CI: confidence interval; COPD: chronic obstructive pulmonary disease; IG: intervention group; IQR: interquartile range; MD: mean difference; MUQ: Medication Understanding Questionnaire

Table 13. PROGRESS-plus framework

PROGRESS								**Plus**	**Health literacy**
Study[1]	**Place of residence; time living in host country**	**Race/ethnicity/culture/language**	**Occupation**	**Gender**	**Religion**	**Education**	**Socioeconomic status, social capital**	**Age, sexual orientation, disability, migrant status**	**Assessment tool, range**
Bailey 2012 (No. analysed = 202)	• Urban, USA • 17 (0.7)*	• Chinese, Korean, Russian, Spanish, Vietnamese • Primary languages: Chinese, Korean, Russian, Spanish, Vietnamese	—	• 62.2% female	—	• 19.8% < 9 years, 14.4% 9 to 11 years, 29.2% 12 years or GED, 14.9% some college, 21.8% ≥ college graduate	• Annual income: 44.7% < USD 10,000, 36.7% USD 10,000 to USD 19,999, 18.6% ≥ USD 20,000	• 63.6 (0.91)*, range 18 to 85 • The sample included participants with prescribed medication in the past year; medication use 4.5 (0.2)*	—
Bloom 2014 Total N = 230	• Urban, USA	• Afghan • Farsi, Pashto	—	• 100% female	• Muslim	• Low literacy, no further details	—	• ≥40 years • Many with family history of breast cancer	—
Calderón 2014	• Urban, USA	• Latino	—	• 81.7% female	—	• 86.7% < high school,	• Annual income: 75.6% < USD 10,000, 24.4% ≥ USD 10,000	• 20.7% 18 to 39 years,	• S-TOFH-

Table 13. PROGRESS-plus framework *(Continued)*

(Total N = 240)		- Spanish				13.3% ≥ high school	- Health insurance: 31.3% insured	88.6% 40 to 60 years, 20.7% > 60 years - Participants sought health care at a clinic; 79% self-reported fair or poor general health status	LA, 0 to 36; 58.0% 0 to 16 (inadequate HL), 8.0% 17 to 21 (marginal HL), 34.0% 22 to 36 (adequate HL)
DeCamp 2020 (Total N = 157)	- Urban, USA - 7.3 (5.3)*	- Latino - Spanish	- 79.0% spouse or partner employed	—	—	- 40.8% ≤ 8th grade, 26.1% some high school, 33.1% high school or greater	- Annual income: 42.7% < USD 20.000, 24.2% USD 20.000 to USD 30.000, 7.6% > USD 30.000, 19.1% did not report or unknown - Health insurance: all children publicly insured - 20.3% single, 79.6% spouse or partner	- 29.3 (6.2)*	- NVS, 0 to 6; 48.4% 0 to 1 (limited HL), 38.2% 2 to 3 (marginal HL), 13.4% 4 to 6 (adequate HL) - English proficiency was assessed using the US Census Bureau question

Table 13. PROGRESS-plus framework *(Continued)*

									"How well do you speak English?", overall results not reported
Elder 1998 (No. only Latinos = 341)	• Urban, USA • 45.0% < 3 y	• Latino (86.7%), European, Asian, others • Spanish	• Students in English as second language classes	• 51.0% female	—	• 48.0% ≥ 9 y, 9.8 (3.7)*	• Monthly income: 66.7% < USD 1099 • 33.3% married	• 28.7 (9.8)*	—
Gwede 2019 (Total N = 76)	• Urban, USA • 23.4* for those born outside the USA (n = 71)	• Hispanic/Latino • Spanish	n = 75 • 52.6% employed, 40.8% not employed, 4.0% retired, 1.0% student	• 67.1% female	—	• 43.4% elementary or less, 18.4% some high school, 17.1% high school graduate, > 21.0% high school	n = 70 • Annual income: 44.3% < USD 10,000, 55.1% ≥ USD 10,000 • Health insurance: 25.5% insured • 69.7% married/living together, 13.1% divorced/separated, 7.9% widowed, 9.2% never married/single	• 57.2 (6.0)*, range 50 to 74 • Participants received care at a clinic	• SILS, 0 to 5; 47.4% always difficult reading written materials, 52.6% not always difficult reading written materials, 75.0% very confident in completing health forms,

Table 13. **PROGRESS-plus framework** *(Continued)*

									25.0% less than very confident in completing health forms
Han 2017 (Total N = 560)	- Urban, USA - 15.4 (9.7)*, range 1 to 62	- Korean Americans - English proficiency: 40.5% not at all or poor, 36.1% fair, 23.4% fluent	- 57.9% working full/part-time, 42.1% unemployed, retired or other	- 100% female	—	- 35.2% high school graduate or less, 64.8% some college or more	- 26.4% very comfortable or comfortable, 34.5% just OK, 39.5% uncomfortable or very uncomfortable - Health insurance: 37.9% insured - 85.5% married or partnered, 11.1% separated, widowed or divorced, 3.4% never married	- 46.1 (8.5)* - 5.4% family history of breast cancer	- AHL-C, 0 to 52; 20.9*
Hernandez 2013 (Total N = 146)	- Urban, USA - 7.7% < 5 y; 34.0% 6 to 10 y, 57.7% > 10 y	- Latinas (78.8% Mexican, 21.1% other) - 82.3% not bilingual	- 33.8% employed	- 100% female	—	- 36.6% grade school, 25.3% middle school, 14.0% some high school, 10.5% high school or GED, 10.5% some college or beyond	- Annual income: 69.7% < USD 19,000, 19.0% USD 20,000 to USD 30,000, 11.2% > USD 30,000 - Health insurance: 45.0% insured - 58.4% married, 24.6% living with partner, 7.7% never married, 9.1% divorced or widowed	- Range 18 to 55 - At risk for depression	- S-TOFHLA, 0 to 36; 28.1% 0 to 16 (inadequate HL), 12.6% 17 to 21 (marginal HL), 59.1% 22 to 36 (adequate HL)
Kaur 2019	- Urban, Canada	- Punjabs - Punjabi	- 63.6% full-time	- 60.0% female	—	- 37.7% college/technical educa-	- Annual income: 52.1% CAD 0 to 49,999, 19.3% CAD 50,000	- 26.4% 18 to 31 y, 46.4% 32 to 45 y,	- TS-REALD

Table 13. PROGRESS-plus framework *(Continued)*

(Total N = 140)			workers (including 14.3% self-employed), 5.0% part-time workers, 1.4% occasional workers, 22.1% homemakers, 2.9% unemployed			tion, 26.8% university education; 35.5% high school or less	to 89,999, 6.4% CAD 90,000+, 20.7% unknown • Health insurance: 72.9% insured	27.1% 46 to 60 y; range 18 to 60	
Kheir 2014 (Total N = 123)	• Urban, Qatar • Time in Arabic speaking country: 4.6 to 6.1 y	• Asians • 0.8% Malayalam, 16.3% Nepal, 1.6% Urdu, 8.9% Tagalog, 22.8% Bangla, 49.6% other • Level of English: 13.8% good, 16.3% average, 94.3% poor	• Workers at Qatar Petroleum Company	• 100% male	—	• Years of schooling: 6.1 (3.4)*	• Each participant received QR 50 (equivalent to about USD 14), translating to 2 to 3 days average wage	• 32.1 (8.5)*	—

Table 13. PROGRESS-plus framework *(Continued)*

Kim 2009 (No. analysed = 79)	• Urban, USA • 53.2% > 20 y	• Korean Americans • Korean	• 70.3% employed	• 44.3% female	—	• 48.1% higher level of education	• Annual income: 59.2% > USD 40.000 • 87.3% married	• 56.4 (7.9)* • Type 2 diabetes	—
Kim 2014 (No. analysed = 369)	• Urban, USA • 25.0 (11.0)*	• Korean Americans • Korean	—	• 69.9% female	—	• 37.4% ≤ middle school graduate, 28.2% high school graduate, 34.4% ≥ some college	• Health insurance: 82.7% insured	• 70.9 (5.3)* • Diagnosed with hypertension for 9.6 (8.8)* years; 85.4% reported being on antihypertension; 46.3% had successfully controlled hypertension (BP < 140/90 mmHg or < 130/80 mmHg for diabetes patients)	• HBP-HLS, 0 to 43; 24.6*
Kim 2020 (No. analysed = 209)	• Urban, USA • 23.8 (11.0)*	• Korean Americans • Korean	• 59.3% working full/part-time	• 43.1% female	—	• Years of education: 13.4 (3.0)*	• Monthly income, mean (SD): USD 3780 (3411)*, 63.2% own housing, 67.7% comfortable living • Health insurance: 50.2% insured • 89.5% married, family size, persons: 3.0 (1.2)*	• 58.7 (8.4)* • Type 2 diabetes	• REALM, 0 to 66; 32.1 (1.5)***, indicating 6th grade reading level • DM-REALM, 0 to 88; 51.3 (1.7)***, 7.3 points above the

Table 13. PROGRESS-plus framework *(Continued)*

									scale's midpoint - Comprehension scale, 0 to 28; 15.3 (0.6)*** - S-TOFHLA, numeracy subscale, 0 to 7; 4.2 (0.2)*** - NVS, 0-6; 1.7 (0.1)***
Kiropoulos 2011 (Total N = 202)	- Urban, Australia - 43.8 (9.0)*	- Greeks and Italians - Participants rated their English proficiency "good" for simple situations and "poor/ fair" for more difficult situations	- 5.0% never worked, 57.9% unskilled, 31.2% tradesperson/clerical, 4.0% manager/professional, 28.2% working now, 70.8% are not	- 71.3% female	—	- 15.3% no/incomplete primary, 42.1% completed primary, 24.3% some secondary school, 9.9% all secondary school, 8.4% some/ completed tertiary	- 28.2% married,71.8% not married, 14.9% living with spouse, 52.0% living with children, 24.8% living with other relatives, 14.4% currently living alone, 85.6% not currently living alone	- 65.4 (8.57)* - Depression	- D-Lit, 0 to 22; 9.5*

Table 13. PROGRESS-plus framework *(Continued)*

			working now						
Koniak-Griffin 2015 (Total N = 223)	• Urban, USA • 18.6 (8.3)*	• Latinas • Spanish	• 74.6% unemployed	• 100% female	—	• 52.5% ≤ 8th grade, 33.6% 9th to 12th grade, 12.6% ≥ 13 years	• Annual income: 54.7% ≤ USD 20,000, 28.7% USD 20,001 to 40,.000, 16.6% USD 40,001 to 75,000 • Health insurance: 31.8% insured • 72.2% married/living with a partner, 27.8% divorced/widowed/single	• 44.6 (7.9)* • 6.3% diabetes (clinical data), 12.1% hypertension ((BP ≥ 140/90, self-report); 25% felt depressed or "bothered by loss of interest", 22.0% both	—
Lepore 2012 (No. analysed = 431 for survey data, N = 490 for medical claims data)	• Urban, USA	• Black African descent (77.4% Caribbean)	—	• 100% male	—	N = 490 • 31.3% < high school degree, 31.8% high school degree, 36.9% college education or degree	• "all had a primary care physician and access to health insurance that covered prostate cancer tests." • 83.7% married	• 55.04 (6.29)*	—
Mohan 2014 (No. analysed = 200)	• Urban, USA	• Latinos • 99.5% of patients identified Spanish as their primary language spoken at home	—	• 69.5% female	—	• 29% at least high school education, years of education: 8*	—	• 50* • Diagnosis of diabetes in the medical chart; prescription of at least 1 chronic medication	• BHLS, 3 to 15; 10.4*
Ochoa 2020	• Urban, USA • 25.12*	• Latinas • English-speaking profi-	—	• 100% female	—	N = 232 • 49.8% < high school,	N = 232 • Annual income: 41.6% < USD 20,000, 35.4% USD 20,000 to	• Range 25 to 45 • Health status: 1.4%	—

Table 13. PROGRESS-plus framework *(Continued)*

(No. analysed = 109)		ciency: 29.4% very well/well, 70.6% not very well/ not at all; English reading proficiency: 35.6% very well/ well, 64.4% not very well/not at all; English writing proficiency: 31.0% very well/well, 69.0% not very well/ not at all				31.25% high school, 19.0% some college degree	< 40,000, 16.05% USD 40,000 to < 60,000, 6.9% ≥ USD 60,000 • Health insurance: 73.45% insured • 78.95% married/living with partner, 10.7% separated/divorced/widowed, 10.35% never married (single)	very poor or poor, 13.2% fair, 3.8% good, 17.65% very good, 30.9% excellent	
Otilingam 2015 (Total N = 100)	• Urban, USA • 34.3*	• Latinas • Language preference Spanish: 78.0%	—	• 100% female	—	• (Highest degree): 41.0% none or elementary, 35.0% high school, 10.0% community/technical college, 14.0% college	• Annual family income: 39.0% < USD 20,000/year • Number of children living at home < age 17: 2.1*	• 58.9*, range 48 to 84	n = 73 • NVS, 0 to 6; 1.39* (wait-list control II post-test only)
Payán 2020 (No. analysed = 193)	• Urban, USA • 69.9% ≥ 15 y (N = 240)	• Latinas • English proficiency: 4.2% very well, 13.8% well, 31.3% not well, 28.3% almost	—	• 100% female	—	N = 240 • 64.2% ≥ 6th grade level of education	N = 240 • Annual household income: 93.4% < USD 30,000 • Health insurance: 79.6% insured • 46.8% married, 30.5% separated, 22.7% single	• 52.3 (8.8)*, range 35 to 72	—

Table 13. PROGRESS-plus framework *(Continued)*

		none, 22.5% not at all well (N = 240)							
Poureslami 2016a (No. analysed = 85)	• Urban, Canada • Participants had immigrated to Canada within the past 5 y	• Chinese and Punjabs • 49.0% Chinese; 51.0% Punjabi	• 21.2% employed, 29.4% unemployed, 43.5% retired, 5.9% volunteer job	• 50.6% female	—	• 17.6% never attended formal school, 24.7% completed elementary school, 34.1% completed high school, 23.5% post-high school education	—	• 62.9 (15.3)*, range 21 to 87 • Asthma	—
Poureslami 2016b (Total N = 91)	• Urban, Canada • Participants immigrated within the past 12 y at the time of the study (inclusion criterion)	• Chinese • 19.8% Mandarin, 80.2% Cantonese	—	• 21.9% female	—	• 46.2% low education, 53.8% high education	—	• 40.7% ≤ 75 years, 59.3% > 75 years; 75** • Chronic obstructive pulmonary disease (COPD)	—
Rosal 2005 (No. analysed = 25)	• Urban, USA	• Hispanic (Puerto Rican) • 95% spoke Spanish only	• 24.0% housewife, 20.0% disabled, 4.0% unemployed,	• 80.0% female	—	• 50.0% ≤ 5th grade, 24.0% 6th to 8th grade, 24.0% 9th to 12th grade	• Annual income: 84.0% ≤ USD 10,000/per year, 16.0% USD 10,001 to 20,000 • Health insurance: 40.0% Medicaid only, 60.0% Medicaid and supplemental	• 62.6 (8.6)*, range 45 to 82 • Type 2 diabetes; perceived health: 4.0% excellent, 4.0% very	—

Table 13. PROGRESS-plus framework *(Continued)*

			4.0% never worked, 48.0% pension					good, 8.0% good, 72.0% fair, 12.0% poor; years with diagnosed diabetes 8.2 (5.8)*, 16.0% diabetes related complications, 84.0% 1 complication, 84.0% ≥ 1 family member with diabetes	
Rosal 2011 (Total N = 252)	• Urban, USA	• (Caribbean) Latinos • 93.3% monolingual Spanish; language chosen for assessment Spanish 100%	n = 230 11.3% working full or part-time, 3.5% unemployed/looking for a job, 61.7% disabled, 10.9% retired, 12.6% housewife	• 76.6% female	—	• 28.0% ≤ 4th grade, 28.0% 5th to 8th grade, 19.2% 9th to 12th grade (not high school graduate), 24.8% ≥ high school	• Annual income: 55.3% < USD 10,000 • Health insurance: 89.3% public insurance, 6.0% commercial insurance, 2.8% free care, 2.0% no insurance • 25.8% married or living with partner, 39.0% divorced/widowed/separated, 25.2% never married	• 16.3% 18 to 44 y, 29.8% 45 to 54 y, 32.9% 55 to 64 y, 21.0% ≥ 65 y • Documented diagnosis of type 2 diabetes; HbA1c (previous 7 months) ≥ 7.5%	—
Soto Mas 2018 (Total N = 181)	• Urban, USA • 2.2% < 1 y (n = 4); 12.7% 1 to 3 y (n = 23); 8.3% 4 to 7 y	• Latino • Spanish	—	• 79.0% female	—	n = 155 • 5.2% elementary school, 11.7% middle school, 40.9% high school, 18.8% associate/techni-	—	n = 155 • 9.0% 20 to 30 years, 38.7% 31 to 45 years, 52.3% ≥ 46	n = 155 • TOFHLA, 0 to 100; 62.7*

Table 13. PROGRESS-plus framework *(Continued)*

	(n = 15); 70.2% 8 y or more (n = 127); 6.6% missing (n = 12)					cal degree, 20.1% bachelor's degree, 1.9% master's degree, 1.3% doctoral degree			
Sudore 2018 (No. of Spanish-speaking participants = 445)	• Urban, USA • 26*	• 98.9% White Latino or Hispanic, 0.2% White non-Latino or Hispanic, 0.9% Multiethnic or other • Spanish	—	• 72.0% female	49.9% fairly to extremely religious, 59.6% fairly to extremely spiritual	• 83.6% ≤ high school	• 27.4% not enough to make ends meet, financial social standing (1 to 10 score): 5.6* • Measure of social support score (total, 11 to 55): 36.7*, 37.5% in a marriage or long-term relationship, 88.8% have adult children, 98.0% have a potential surrogate	• 64* • Self-rated health: 57.1% reported fair to poor health	• S-TOFHLA, 0 to 36; 60.9% limited HL
Taylor 2011 (Total N = 180)	• Urban, Canada • Years since immigration: 45.0% < 2 y; 55.0% ≥ 2	• Asian • Cantonese, Farsi, Korean, Mandarin, Punjabi	—	• 68.0% female	—	• 65.0% < 16 years, 35.0% ≥ 16 years	• 86.0% currently married, 14.0% not currently married	• Age: 46.0% < 40 years, 54.0% ≥ 40 years	—
Thompson 2012 (Total N = 170)	• Urban, USA • 6.05* (n = 158)	• Latinos • Spanish	—	• 92.5% female	—	n = 159 • 41.0% < 6 y, 51.0% 7 to 12 y, 8.0% some or all of university degree	• Income: "low-income" population • Health insurance: "More than 95% of clinic patients are publicly insured"	• 27.55*	—
Tong 2017 (Total N = 329)	• Urban, USA • 15.4 (9.7)*,	• Hmong Americans (born in Laos)	• 90.9% not employed	• 74.2% female	—	• 88.8% no formal education	• Annual income: 53.8% < USD 20,000, 4.0% USD 20,000 or more, 42.2% don't know/missing	• 60.4*	—

Table 13. PROGRESS-plus framework *(Continued)*

	range 1 to 62, 83.6% > 10 years, 16.4% ≤ 10 years	- 89.4% speak only Hmong at home, 70.5% speak English poorly or not at all					- Health insurance: 95.1% insured - 65.3% married or living with a partner		
Unger 2013 (No. analysed = 139)	- Urban, USA - 43.2% 11 y or more, 18.7% 6 to 10 y, 13.7% 1 to 5 y, 5.8% less than 1 y, missing 2.9%	- Hispanics/Latinos - Language spoken at home: 28.1% only Spanish, 38.1% mostly Spanish, 27.3% English and Spanish equally, 4.3% mostly English, 1.4% only English, 0.7% missing	—	- 47.5% female	—	- 62.6% less than high school, 37.4% high school or more	—	- 35.8 (12.9)*, range 18 to 90	—
Valdez 2015 (Total N = 708)	- Urban, USA - 93.6% foreign-born); 14.9% < 5 y, 18.9% 6 to 10 y, 28.4% 11 to 15 y, 37.9% 16+ y	- Latinos and Koreans - 49.7% Spanish, 43.8% Korean, 6.5% English	—	n = 707 - 92.2% female	—	- 19.6% < 6, 16.7% 7 to 11 years, 18.5% 12 years, 9.9% 13 to 15 years, 35.3% 16+	n = 707 - 83.9% child has regular doctor - Number of children: 2.8*; 52.3% 1 to 2, 39.4% 3 to 4, 8.3% 5+; 72.7% married/living together	n = 691 - 41.7*; 12.3% < 35 years, 22.3% 35 to 39 years, 34.6% 40 to 44 years, 17.2% 45 to 49 years, 11.2% 50+ years	—

Table 13. **PROGRESS-plus framework** *(Continued)*

Valdez 2018 (No. analysed = 727)	• Urban, USA • 80.0% foreign-born; 26.0% 1 to 5 y, 18.0% 6 to 10 y, 20.0% 11 to 15 y, 36.0% 16+ y (N = 943)	• Latinas • Language of pre-test: 73.0% Spanish, 7.0% English (N = 943)	—	• 100% female	—	N = 943 • 8.2 (3.8)*, 39.0% 1 to 6 years, 34.0% 7 to 11 years, 21.0% 12 years, 6.0% 13+ years	• Inclusion criteria: annual household income of ≤ USD 24,680 • Health insurance: 51.0% insured (N = 943) • 21.0% single, 43.0% married, 15.0% living together, 15.0% divorced/separated, 5.0% widowed; number of children: 3.0 (2.2)*; 10.0% no children, 14.0% one child, 21.0% two children, 22.0% three children, 15.0% four children, 18.0% 5+ children (n = 943)	• 39.1 (11.8)* • Participants were recruited from a community clinic, where they had a clinic appointment independently from the study	—
van Servellen 2005 (No. analysed = 85)	• Urban, USA	• Latinos • Language spoken at home: 75.25% Spanish	—	• 9.4% female	—	• 81.0% < 12 years	• Monthly income: 41.0% ≤ USD 500	• 40.7*, range 21 to 78 • 49.4% male-to-male sex risk factor • HIV	• Modified REALM, 0 to 24; global recognition score 17.9*, global understanding score 13.1* (n = 81)
Wong 2020 (No. analysed = 39)	• Urban, Singapore • Note: time working in Singapore: 9.45* (range 1	• Filipino	• 100% foreign domestic workers	• 100% female	n = 38 • 71.85% Roman Catholic, 28.15% other Christian faith	n = 38 • 72.0% completed high school (secondary) 4 years, 28.0% completed university	n = 38 • 48.4% were single or never married, 25.8% were married, 25.8% were separated, divorced or widowed	• 38.6 (6.3)* • At risk for depression • Foreign domestic workers, not protected under the Singaporean Employment Act	n = 37 • DLQ, 22-item, true/false questions, 0 to 22 (validated

Table 13. PROGRESS-plus framework *(Continued)*

to 24 years)	tool) Intervention group, mean: 11.06*

[1] Not all studies reported numbers on all participants randomised to either the intervention or control arm. Here we report the number of participants randomised, if not otherwise stated.

*Mean (SD), **Median (SD), ***Mean (SE)

Abbreviations:

AHL-C: Assessment of Health Literacy in Cancer screening; BHLS: Brief Health Literacy Screen; BP: blood pressure; D-Lit/DLQ: Depression Literacy Questionnaire; DM-REALM: Diabetes-specific Rapid Estimate of Adult Literacy in Medicine; GED: general educational development; HBP-HLS: high blood pressure health literacy scale; HL: health literacy; NVS: newest vital sign; QR: Qatari riyal; REALM: Rapid Estimated of Adult Literacy in Medicine; SD: standard deviation; SILS: Single Item Literacy Screener; TOFHLA: Test of Functional Health Literacy in Adults; TS-REALD: Two Stage Rapid Estimate of Adult Literacy in Dentistry; y: years

Table 14. Grouping of studies according to main intervention components and comparator

Study ID	Health topic	Description of intervention arm(s)	Main intervention component	Additional intervention components	Intervention delivery method/mode	Intervention provider	Comparator
1 Culturally and literacy adapted self-management programme vs no health literacy intervention							
Bloom 2014	Breast cancer	Multimodal educational intervention "Afghan women's breast health program"	Intense health education (multiple methods of knowledge transfer/skills training, personal interaction with provider)	Individual motivational counselling	Weekly face-to-face group sessions, followed by individual motivational counselling through health navigators (total programme duration, number and length of group sessions and counselling not reported)	Trained LHE/ health navigators	Wait-list control (delayed intervention)
Koniak-Griffin 2015	Cardiovascular disease	Multimodal lifestyle behaviour intervention, "Mujeres Sanas y Precavidas"	Intense health education (multiple methods of knowledge transfer/skills training, personal interaction with provider)	Individual motivational counselling, self-monitoring	8 weekly face-to-face group sessions lasting 2 hours, followed by 4 months of individual teaching and coaching sessions (4 face-to-face sessions and 4 phone calls)	Trained promotoras	Attention placebo control; same quantity, but information on safety and preparedness

Table 14. Grouping of studies according to main intervention components and comparator *(Continued)*

Rosal 2011	Type 2 diabetes	Multimodal Diabetes Self-Management intervention programme “Latinos en Control”	Intense health education (multiple methods of knowledge transfer/skills training, role modelling, personal interaction with provider)	Individual motivational counselling, self-monitoring	12 weekly face-to-face group sessions lasting 2.5 hours and 8 monthly face-to-face group sessions. First session: 1st hour personalised counselling and cooking; remaining time: group protocol and meal	Trained team of 2 leaders and an assistant (either nutritionist or health educator and trained lay individuals or 3 lay individuals supervised by 2 investigators)	Usual care (no additional intervention)
van Servellen 2005	HIV	Multimodal HIV treatment adherence enhancement program “Es por la vida”	Intense health education (multiple methods of knowledge transfer/skills training, personal interaction with provider)	Individual motivational counselling, self-monitoring	5 weekly face-to-face group sessions (of 3 to 7 participants), followed by 6 months of telephone counselling or face-to-face encounters	Nurse practitioner and health educator; trained foreign medical student (only assessment)	Usual care (no additional intervention)
2 Culturally and literacy adapted self-management programme vs written information on the same topic							
Han 2017	Breast/cervical cancer	CHW-led breast and cervical cancer health literacy skills training	Intense health education (multiple methods of knowledge transfer/skills training, role modelling, personal interaction with provider)	Individual motivational counselling, self-monitoring	1 face-to-face group session (of 7 to 8 women) lasting 1.5 to 2 hours, followed by 6 months of monthly telephone calls	Trained CHW	Wait-list control/standard brochure
Kaur 2019	Oral health	“Safeguard Your Smile” oral health literacy intervention	Intense health education (multiple methods of knowledge transfer/skills training, role modelling, personal interaction with provider)	Individual motivational counselling, self-monitoring	1 face-to-face group session (of 3 to 4 participants) lasting 1 hour; monthly phone calls within a 3-month follow-up period	Lead researcher, no further training	Standard brochure
Kim 2009	Type 2 diabetes	Community based, multimodal behavioural Self-Help Intervention Programme for Di-	Intense health education (multiple methods of knowledge transfer/skills training, personal interaction with provider)	Individual motivational counselling, self-monitoring	6 weekly face-to-face group sessions lasting 2 hours followed by 6 months of self-monitoring	Trained CHW and research nurses	Wait-list control/standard brochure

Table 14. Grouping of studies according to main intervention components and comparator *(Continued)*

		abetes Management (SHIP-DM, pilot study)			and monthly telephone counselling (10 to 25 min)		
Kim 2014	High blood pressure (HBP)	Multimodal self-help intervention programme on the control of high blood pressure	Intense health education (multiple methods of knowledge transfer/skills training, personal interaction with provider)	Individual motivational counselling, self-monitoring	6 weekly face-to-face group sessions (of 6 to 10 participants) lasting 2 hours, followed by 12 months of self-monitoring (including weekly submission of BP to study website) and monthly telephone counselling	Trained research staff and research nurses	Wait-list control/standard brochure
Kim 2020	Type 2 diabetes	Community based, multimodal behavioural Self-Help Intervention Programme for Diabetes Management (SHIP-DM)	Intense health education (multiple methods of knowledge transfer/skills training, personal interaction with provider)	Individual motivational counselling, self-monitoring	6 weekly face-to-face group sessions lasting 2 hours, followed by 12 months of self-monitoring and monthly telephone counselling	Trained CHW and research nurses	Wait-list control/standard brochure
Rosal 2005	Type 2 diabetes	Multimodal self-management intervention programme for metabolic self-control in individuals with type 2 diabetes	Intense health education (multiple methods of knowledge transfer/skills training, role modelling, personal interaction with provider)	Individual motivational counselling, self-monitoring	1 initial face-to-face individual session lasting 1 hour, 10 weekly face-to-face group sessions lasting 2.5 to 3 hours and 2 individual sessions lasting 15 min (immediately prior to group sessions within 10 weeks period)	Diabetes nurse, nutritionist and research assistant (known to community residents)	Standard brochure
3 Culturally adapted health literacy skills building course vs no/unrelated health literacy intervention							
Elder 1998	Nutrition/cardiovascular health	Health literacy skills training embedded in language course	Intense health education (multiple methods of knowledge transfer/skills training incorporated in existing English as a second language (ESL) course, personal interaction with provider)	—	As many as 5 face-to-face group sessions lasting 3 hours	Trained ESL teacher	Same method/mode of delivery, but information on a different health topic
Otilingam 2015	Nutrition/heart	Group 1: Workshop on nutrition and heart health	Group 1, 2 (combined)**: Intense health education (multiple methods of	—	2 face-to-face group sessions (of up to 7 partici-	Trained bilingual research assistants	Group 3, 4**: wait-list control

Table 14. Grouping of studies according to main intervention components and comparator *(Continued)*

	and brain health	Group 2: Workshop on nutrition and heart health plus brain health Group 3: Wait-list control Group 4: Post-test only wait-list control	knowledge transfer/skills training, role modelling, personal interaction with provider)		pants) lasting 2 hours (1 week apart)		
Soto Mas 2018	Cardiovascular health	Health literacy skills training embedded in language course	Intense health education (multiple methods of knowledge transfer/skills training incorporated in existing ESL course, role modelling, personal interaction with provider)	—	12 face-to-face, group sessions lasting 3.5 hours (total of 42 hours) delivered over a period of 6 weeks	Trained ESL teacher	Usual care (standard ESL course without additional information)[1]
Taylor 2011	Hepatitis B	Health literacy skills training embedded in language course	Intense health education (multiple methods of knowledge transfer/skills training incorporate in existing ESL course, role modelling, personal interaction with provider)	—	1 face-to-face, group session lasting 3 hours	Trained ESL teacher	Same method/mode of delivery, but information on a different health topic
Tong 2017	Colorectal cancer (CRC)	LHE-led CRC group education	Intense health education (multiple methods of knowledge transfer/skills training, personal interaction with provider)	Individual motivational counselling	2 face-to-face group sessions lasting approx. 90 min, separated by 2 months 2 follow-up phone calls 1 month after each session	Trained LHE	Same method/mode of delivery, but information on a different health topic
Wong 2020	Mental health (depression)	Cognitive behavioural therapy (CBT)-based paraprofessional training programme	Intense health education (multiple methods of knowledge transfer/skills training, personal interaction with provider)	—	4 weekly face-to-face, group sessions lasting 3 hours, homework exercises	Master's level clinical psychology trainees	Wait-list control
4 Culturally adapted telephone education vs unrelated culturally adapted telephone education							

Table 14. Grouping of studies according to main intervention components and comparator *(Continued)*

Lepore 2012	Prostate cancer	Tailored telephone education intervention on prostate cancer	Simple health education (2 methods of knowledge transfer: telephone education plus educational pamphlet), personal interaction with provider	Decision support	2 individual phone calls within a 1-month period (median = 1 week) plus mailed brochure, 1 health education call lasting approx. 20 min and 1 follow-up call lasting approx. 5 min	Trained graduate-level health educator	Same method/ mode of delivery, but information on a different health topic
5 Culturally and literacy adapted audio-/visual education without personal feedback vs no health literacy intervention							
DeCamp 2020	Child health	"Salud al Día", Spanish-language interactive text messaging intervention	Simple health education (2 methods of knowledge transfer: factual information, role modelling)	Motivational interactive text/push messages and automated feedback	1 individual video session lasting 9 min (plus take-home DVD at 2-month visit in clinic) and monthly interactive text messages for 10 months, if necessary email contact to clinic nurse	Research staff, clinic staff	Usual care (no additional intervention)
Hernandez 2013	Mental health (depression)	Fotonovela "Secret Feelings"	Simple health education (1 method of knowledge transfer: role modelling), extent of personal interaction with provider unclear	—	1 face-to-face group session (printed fotonovela read out loud by literate participants)	Experienced study site's promotoras	Placebo intervention (group discussion on family communication)
Kiropoulos 2011	Depression	Multicultural Information on Depression Online (MIDonline) website	Simple health education (2 methods of knowledge transfer, role modelling, multiple interactive online modules)	—	1 individual web-based session (interactive website)	Not applicable	Placebo intervention (semi-structured interview about depression)
Thompson 2012	Child nutrition and feeding	Nutrition education via interactive touchscreen	Simple health education (1 method of knowledge transfer: multiple interactive online modules)	Algorithm-based automated feedback	1 individual web-based session (interactive touchscreen computer, 5 modules of 2 to 8 min, total duration approx. 25 min)	Not applicable	Usual care (no additional intervention)
6 Culturally and literacy adapted audio-/visual education without personal feedback vs written information on the same topic							

Table 14. Grouping of studies according to main intervention components and comparator *(Continued)*

Calderón 2014	Type 2 diabetes	Animated bilingual video "¿Que es la Diabetes?/What Is Diabetes?"	Simple health education (1 method of knowledge transfer: role modelling)	—	1 individual video session lasting 13 min	Not applicable	Easy-to-read information on diabetes (language concordant)
Gwede 2019	Colorectal cancer	“LCARES” fotonovela booklet and DVD intervention plus faecal immunochemical test (FIT)	Simple health education (2 methods of knowledge transfer: factual information, role modelling)	Reminder letters	1 individual video session plus printed fotonovela	Not applicable	Standard brochure
Payán 2020	Breast cancer	Group 1: CUIDARSE ("taking care of oneself") brochure on breast cancer Group 2: CHW-delivered CUIDARSE ("taking care of oneself") brochure on breast cancer Group 3*: usual care (standard brochure)	Group 1, 2** (combined): simple health education (1 method of knowledge transfer: role modelling), personal contact, but no additional support or information (oral administration of adapted written information)	—	1 face-to-face session lasting 15 min (printed brochure verbally administered) (unclear whether delivered in group or individually)	Trained bilingual CHW	Group 3*: usual care (standard brochure)
Poureslami 2016a	Asthma	Group 1: physician-led video Group 2: community video Group 3: both physician-led and community videos Group 4: literacy adapted pictorial pamphlet (language concordant)	Group 3*: simple health education (2 methods of knowledge transfer: factual information, role modelling)	—	1 individual video session (2 videos: 1 factual knowledge video and 1 peer-led (community) video)	Not applicable	Group 4*: easy-to-read pictorial pamphlet on asthma
Poureslami 2016b	COPD	Group 1: physician-led video Group 2: community video Group 3: both	Group 3*: simple health education (2 methods of knowledge transfer: factual information, role modelling)	—	1 individual video session (2 videos: 1 physician-led, factual knowledge video and 1 peer-led (role-played) video	Not applicable	Group 4*: easy-to-read pictorial pamphlet on COPD

Table 14. **Grouping of studies according to main intervention components and comparator** *(Continued)*

		physician-led and community videos Group 4: literacy adapted pictorial pamphlet (language concordant)					
Sudore 2018	No specific (advance care planning)	Interactive online advance care planning programme “PREPARE” and AD intervention	Simple health education (2 methods of knowledge transfer: multiple interactive online modules, skills training), personal interaction with provider via telephone	Algorithm-based automated feedback	1 web-based session (interactive website), ongoing access to website, plus literacy adapted printed Advance Directive (AD), reminder phone call 1 to 3 days prior to primary care visit	Trained research staff	Written advance directive
Unger 2013	Mental health (depression)	Fotonovela "Secret Feelings"	Simple health education (1 method of knowledge transfer: role modelling), personal interaction with provider unclear	—	1 face-to-face group session lasting 20 to 30 min (printed fotonovela read by oneself)	One data collector, no further information	Standard brochure
Valdez 2015	Cervical cancer	Educational DVD on human HPV vaccine	Simple health education (2 methods of knowledge transfer: role modelling, factual information)	—	1 individual video session (DVD watched at home at individually convenient time)	Not applicable	Usual care (standard brochure)
Valdez 2018	Cervical cancer	Cervical cancer education via interactive touchscreen	Simple health education (1 method of knowledge transfer: multiple interactive online modules)	Algorithm-based automated feedback	1 individual web-based session lasting 20 to 30 min (interactive, multimedia touchscreen kiosk)	Not applicable	Standard brochure
7 Culturally and literacy adapted audio-/visual education without personal feedback vs another culturally and literacy adapted audio-/visual education without personal feedback							
Ochoa 2020	Cervical cancer	Tamale Lesson/Conversando entre Tamales", a narrative culturally tailored film on prevention of cervical cancer	Simple health education (1 method of knowledge transfer: role modelling)	—	1 narrative/story telling video session lasting 11 min	Not applicable	Factual knowledge video
Poureslami 2016a	Asthma	Group 1: physician-led video	Group 2*: simple health education (1 method of knowl-	—	1 narrative/story telling video session (peer-played	Not applicable	Group 1*: (Community)

Table 14. Grouping of studies according to main intervention components and comparator *(Continued)*

		Group 2: community video Group 3: both physician-led and community videos Group 4: literacy adapted pictorial pamphlet (language concordant)	edge transfer: role modelling)				physician-led, factual knowledge video
Poureslami 2016b	COPD	Group 1: physician-led video Group 2: community video Group 3: both physician-led and community videos Group 4: literacy adapted pictorial pamphlet (language concordant)	Group 2*: simple health education (1 method of knowledge transfer: role modelling)	—	1 narrative video session (peer-played)	Not applicable	Group 1*: (Community) physician-led, factual knowledge video
8 Culturally and literacy adapted medical instruction vs no health literacy intervention							
Bailey 2012	No specific (medication understanding)	Health literacy informed Rx bottles	Adapted written medical instructions (health literacy informed medication label)	—	Written information	Not applicable	Language concordant standard text labels
Kheir 2014	No specific (medication understanding)	Group 1: pictogram-only label Group 2: pictogram label with verbal instructions Group 3: standard text label with translated verbal instructions	Group 2*: adapted written medical instructions (pictogram labels) plus translated verbal instructions	—	Written information, face-to-face instruction (1 session)	Research staff, interpreter	Group 3*: standard text label with translated verbal instructions

Table 14. Grouping of studies according to main intervention components and comparator *(Continued)*

Mohan 2014	Diabetes (medication understanding)	PictureRx illustrated medication list	Adapted written information (illustrated medication list + plain language bilingual text), personal contact with provider	—	Written information, face-to-face instruction, 2-min instruction video	Research assistant	Language concordant standard text labels

AD: advance directive; BP: blood pressure; CHW: community health worker; COPD: chronic obstructive pulmonary disease; CRC: colorectal cancer; ESL: English as a second language; LHE: lay health educator; Rx: prescription; SHIP-DM: Self-Help Intervention programme for type 2 Diabetes Management

* Prioritised intervention group to create a single pairwise comparison; ** Groups were combined to create a single pairwise comparison

[1] Standard ESL curriculum already includes health-related topics. Therefore, control group assignment might not be accurate.

Table 15. Theoretical frameworks used to guide the intervention development

Theoretical framework	Study
Behavior Change Wheel (Michie 2011)	Kaur 2019
Behavioral Skills Model (Amico 2011)	DeCamp 2020
Health Behavior Framework[1] (Curry 1994)	Taylor 2011
Health Belief Model (Janz 1984)	Thompson 2012
Health Belief Model, Social Learning Theory and self-efficacy (Rosenstock 1988)	Otilingam 2015
Health Belief Model (perceived barriers and benefits, perceived susceptibility, self-efficacy and cues to action) (Champion 2008)	Payán 2020
Input-Output Framework (McGuire 2015)	Payán 2020
Adult learning theory (Knowles 1984)	Soto Mas 2018; Rosal 2011
Learning theories (Smith 1999; Semple 2000)	Thompson 2012
Model of culture-centric narratives (Larkey 2010)	Hernandez 2013
Operant conditioning (Skinner 1953)	Elder 1998
Ottawa Decision Support Framework (Doull 2006)	Lepore 2012
Preventive Health Model (Mc Queen 2008)	Gwede 2019
PRECEDE-PROCEED model[2] (Green 1991[3])	Kim 2009; Kim 2020; Han 2017
Self-Help Model (Braden 1990b; Braden 1990a)	Kim 2014
Social-Cognitive Theory (Bandura 1977; Bandura 2002; Bandura 2004)	Elder 1998; Hernandez 2013; Kim 2009; Rosal 2005; Rosal 2011; Sudore 2018; Soto Mas 2018; Tong 2017
The Interpersonal Communication Competence Model (Spitzberg 1984; Street 2003)	Sudore 2018
Theory of Reasoned Action/Planned Behaviour (Ajzen 1991; Fishbein 1975[4])	Unger 2013; Valdez 2015
Transtheoretical Model of Health Behavior (Prochaska 1997)	Sudore 2018; Tong 2017; Valdez 2018
Theories about self-efficacy (Bandura 1994)	Hernandez 2013

[1] Authors mentioned explicitly the *Health Belief Model*, the *Theory of Reasoned Action/Planned Behavior*, the *PRECEDE* model and *Social influence theory,* which are integrated in the *Health Behavior Framework.*

[2] Authors mentioned explicitly premises of the self-help model (Braden 1990b; Braden 1990a), which is integrated in the *PRECEDE-PROCEED* model.

[3] Green developed *PRECEDE* in 1974 and Kreuter added *PROCEED* in 1991.

[4] The *Theory of Reasoned Action* was originally developed by Fishbein & Ajzen (1975) (Fishbein 1975); Ajzen complemented it in 1991 (Ajzen 1991).

Table 16. Health literacy components addressed by the intervention

Study ID	Health domain[1]	Prerequisites/tools[1]			Processing steps[1]			
		Knowledge	Motivation	Competencies	Access	Understand	Appraise	Apply
No./total +	**Health care 13/34** **Disease prevention 21/34** **Health promotion 0/34**	**31/34**	**25/34**	**15/34**	**22/34**	**34/34**	**23/34**	**33/34**
1 Culturally and literacy adapted self-management programme vs no health literacy intervention								
Bloom 2014	Disease prevention	+	u	u	+	+	u	+
Koniak-Griffin 2015	Disease prevention	+	+	+	+	+	+	+
Rosal 2011	Health care	+	+	+	+	+	+	+
van Servellen 2005	Health care	+	+	+	+	+	+	+
2 Culturally and literacy adapted self-management programme vs written information on the same topic								
Han 2017	Disease prevention	+	+	+	+	+	+	+
Kaur 2019	Disease prevention	+	+	+	+	+	+	+
Kim 2009	Health care	+	+	+	+	+	+	+
Kim 2014	Health care	+	+	+	+	+	+	+
Kim 2020	Health care	+	+	+	+	+	+	+
Rosal 2005	Health care	+	+	+	+	+	+	+
3 Culturally adapted health literacy skills building course vs no/unrelated health literacy intervention								
Elder 1998	Disease prevention	+	+	+	-	+	u	+
Otilingam 2015	Disease prevention	+	+	+	-	+	u	+
Soto Mas 2018	Disease prevention	+	+	+	+	+	+	+

Table 16. Health literacy components addressed by the intervention *(Continued)*

Taylor 2011	Disease prevention	+	+	+	-	+	+	+
Tong 2017	Disease prevention	+	+	+	+	+	+	+
Wong 2020	Disease prevention	+	+	+	+	+	+	+
4 Culturally and literacy adapted telephone education vs unrelated culturally and literacy adapted telephone education								
Lepore 2012	Disease prevention	+	+	-	+	+	+	+
5 Culturally and literacy adapted audio-/visual education without personal feedback vs no health literacy intervention								
DeCamp 2020	Disease prevention	+	+	-	+	+	u	+
Hernandez 2013	Disease prevention	+	+	-	+	+	+	+
Kiropoulos 2011	Disease prevention	+	u	-	+	+	+	+
Thompson 2012	Disease prevention	+	+	-	-	+	+	+
6 Culturally and literacy adapted audio-/visual education**without personal feedback vs written information on the same topic**								
Calderón 2014	Health care	+	u	-	+	+	+	+
Gwede 2019	Disease prevention	+	+	-	+	+	u	+
Payán 2020	Disease prevention	+	u	-	-	+	+	+
Poureslami 2016a	Health care	+	+	-	-	+	+	+
Poureslami 2016b	Health care	+	+	-	-	+	+	+
Sudore 2018	Health care	+	+	-	-	+	+	+
Unger 2013	Disease prevention	+	+	-	+	+	+	+
Valdez 2015	Disease prevention	+	u	-	-	+	u	+
Valdez 2018	Disease prevention	+	u	-	+	+	u	+
7 Culturally and literacy adapted audio-/visual education**without personal feedback vs another culturally and literacy adapted** audio-/visual education**without personal feedback**								

Table 16. Health literacy components addressed by the intervention *(Continued)*

Ochoa 2020	Disease prevention	+	+	-	+	+	u	+
8 Culturally and literacy adapted medical instruction vs no health literacy intervention								
Bailey 2012	Health care	-	-	-	-	+	-	+
Kheir 2014	Health care	-	-	-	-	+	-	-
Mohan 2014	Health care	-	-	-	-	+	-	+

[1] = review authors' assignment; + = addressed (either explicitly stated/measured or implicitly through theory used or methods applied); u = unclear whether health literacy component was addressed; - = health literacy component was not addressed

Table 17. Outcomes considered in this review - components of health literacy

Study ID	(Disease-specific) health literacy*	Prerequisites**		Steps of health information processing			Timing of outcome assessment considered
		Knowledge***	Competencies	Understand	Appraise	Apply	
1 Culturally and literacy adapted self-management programme vs no health literacy intervention							
Bloom 2014	—	Breast health/breast cancer knowledge, not specified, no further details reported	—	—	—	—	After 6 months[1]
Koniak-Griffin 2015	—	Heart disease knowledge; 10-items adapted from previous survey (true/false), 0 to 10	—	—	—	—	Short-term, immediately post-intervention, medium-term (3 months post-intervention)
Rosal 2011	—	Diabetes knowledge; Audit of Diabetes Knowledge (ADK) (subset of 25 items, true/false), no range of score reported	—	—	—	—	Short-term (immediately post-intervention)
van Servellen 2005	HIV health literacy;	HIV knowledge;	—	—	—	—	Short-term (immediately post-intervention)

Table 17. Outcomes considered in this review - components of health literacy *(Continued)*

	modified REALM (24 additional HIV-relevant medical terms); 0 to 24 (recognition of terms); 0 to 24 (understand (explain) terms)	HIV Illness and Treatment Knowledge and Misconceptions measure (0 to 17)					
2 Culturally and literacy adapted self-management programme vs written information on the same topic							
Han 2017	Cancer health literacy; AHL-C; sub-scales on print literacy and functional health literacy, 0 to 53	Cervical and breast cancer knowledge; Breast Cancer Knowledge Test (0 to 18); Cervical Cancer Knowledge Test (0 to 20)	—	—	Decisional balance measure (weighing pros and cons), 5 pros and 9 cons on 5-point Likert scale	—	Short-term (immediately post-intervention)
Kaur 2019	Oral health literacy; TS-REALD; word recognition test, 27 to 73	Oral hygiene self-care knowledge; no range of scores reported	—	—	—	—	Short-term (immediately post-intervention)
Kim 2009	—	Diabetes knowledge; Diabetes Knowledge Test (DKT) (0 to 14)	—	—	—	—	Short-term (immediately post-intervention)
Kim 2014	HBP health literacy; HBP Health Literacy Scale, sub-scales of print/func-	HBP knowledge; HBP knowledge questionnaire (0 to 26)	—	—	—	—	Short-term and medium-term (immediately post-intervention and at 6-month follow-up)

Table 17. Outcomes considered in this review - components of health literacy *(Continued)*

	tional literacy and numeracy, 0 to 43						
Kim 2020	(1) Print literacy: REALM, 0 to 66 (2) Diabetes-specific literacy: DM-REALM, 0 to 83 (3) Health numeracy: TOFHLA, 7-item numeracy subscale (NVS), 0 to 6	Diabetes knowledge; Diabetes Knowledge Test (DKT) (0 to 14)	—	—	—	—	Short-term (immediately post-intervention)
Rosal 2005	—	Diabetes knowledge; Audit of Diabetes Knowledge Scale (ADKnowl), 23 item-sets (104 items) on various diabetes-related topics, true/false/"don't know", no range of score reported	—	—	—	—	Short-term (2 weeks post-intervention) and medium-term (4.5 months after programme completion)
4 Culturally adapted health literacy skills building course vs no/unrelated health literacy intervention							
Otilingam 2015	Health numeracy; NVS, 0 to 6	Dietary fat knowledge, 9 items (0 to 9)	—	—	—	—	Short-term (at 1 month post intervention)
Soto Mas 2018	Functional health literacy; TOFHLA, 0 to 100	—	—	—	—	—	Short-term (immediately post- intervention)
Wong 2020	Depression literacy; D-Lit, 0 to 22	Knowledge on cognitive behavioural therapy (CBT); 9 items (multiple choice)	—	—	—	—	Short-term (immediately post-intervention and at 2-month follow-up)

Table 17. Outcomes considered in this review - components of health literacy *(Continued)*

Elder 1998	—	Nutrition-related knowledge; nutrition knowledge test, 12 items (0 to 12)	—	—		Intention to change nutritional habits (questionnaire: 3 items (1 to 3))	Medium-term (6-month follow-up)
Taylor 2011	—	Hepatitis B knowledge; questionnaire, 5 items (0 to 5)	—	—	—	—	Medium-term (at 6-month follow-up)
Tong 2017	—	Colorectal cancer knowledge; questionnaire, 5 items (0 to 5)	—	—	—	—	Medium-term (at 3-month follow-up)
5 Culturally and literacy adapted telephone education vs unrelated culturally and literacy adapted telephone education							
Lepore 2012	—	Knowledge on prostate cancer screening; 14 items (true/false), percent correct	—	—	—	Testing intention; decision made to get tested for prostate cancer (yes/no)	Long-term (8 months after randomisation, approx 7 months post-intervention)
6 Culturally and literacy adapted audio-/visual education without personal feedback vs no health literacy intervention							
DeCamp 2020	—	Infant health knowledge; true/false, (0 to 5)	—	—	—	—	Short-term (immediately up to 3 months post-intervention)[2]
Hernandez 2013	—	Depression knowledge; Depression Knowledge Scale (0 to 17)	—	—	—	Intention to seek treatment for depression; intention to seek treatment for depression scale (0 to 32)	Short-term (immediately post-intervention)
Kiropoulos 2011	Depression literacy; D-Lit, 0 to 22	—	—	—	—	—	Short-term (1 week post-intervention)
Thompson 2012	—	Parental nutrition and feeding knowledge 12-item true/false questions and 7 multiple choice questions (4 options), 0 to 19	—	—	—	Planned changes in behaviour: 3 questions; 1 question related to planned	Short-term (immediately post-intervention)

Table 17. Outcomes considered in this review - components of health literacy *(Continued)*

						changes in behaviour (yes, perhaps, no), 1 open-ended question on exactly what behaviours they want to change, and 1 question on plans about talking to the child's doctor, family or friends about the information (yes, probably, no), no score reported	
6 Culturally and literacy adapted audio-/visual education without personal feedback vs written information on the same topic							
Calderón 2014	Diabetes Health Literacy; DHLS, 37 items on 4 constructs related to diabetes type; 21 items on knowledge and 16 items on knowledge and cultural perceptions	—	—	—	—	—	Short-term (immediately post- intervention)
Gwede 2019	—	Awareness of colorectal cancer and screening tests; 6 items (0 to 11)	—	—	—	—	Medium-term (at 3-month follow-up)
Payán 2020	—	Breast cancer risk knowledge; questionnaire, true/false (0 to 16)	—	—	—	—	Short-term (immediately post-intervention) and medium-term (at 3-month follow-up)
Poureslami 2016a	—	Asthma-related knowledge, questionnaire, 5-point Likert	Inhaler use technique; di-	Understanding of and adher-	—	—	Short-term (immediately post- intervention)

Table 17. Outcomes considered in this review - components of health literacy *(Continued)*

		scale, range of scores not reported	rect observation (2 observers); participants demonstrated correct use and had to describe each step (0 to 9 standard checklist), higher score is better	ence to physician's instructions: 5 items, asking participants to explain the instruction in their own words, 0 = incorrect, 1 = correct, higher score is better			and medium-term (at 3-month follow-up)[3]
Poureslami 2016b	—	—	Inhaler use technique; direct observation (2 observers); participants demonstrated correct use and had to describe each step; 0 to 10, validated checklist, higher score is better	Understanding of pulmonary rehabilitation; text passage based on Canadian Thoracic Society COPD assessment guidelines, developed by the research team and related questions answered by participants. (correct = 1 or incorrect = 0), higher score is better	—	—	Short-term (at 4 weeks (immediately post-intervention and medium-term (at 3- month follow-up)
Sudore 2018	—	—	—	—	—	Engagement in ACP actions; subscale of ACP Engagement survey, 0 to 25, higher score is better	Long-term (15 months after enrolment)
Unger 2013	—	Depression knowledge; depression knowledge scale (0 to 17)	—	—	—	Willingness to seek help for depression; modi-	Short-term (immediately post-intervention)

Table 17. Outcomes considered in this review - components of health literacy *(Continued)*

						fied intention to seek depression care scale (4 to 8)	
Valdez 2015	—	HPV and cervical cancer knowledge; 12 items on HPV knowledge and awareness, and additional questions related to the intervention content (0 to 12)	—	—	Decisional Conflict Scale, subscales informed decision, values clarity, support, 0 to 100 (each scale), lower score is better	Made informed decision; 3 criteria, composite score: (1) making a vaccination choice, (2) affirming that the decision was an informed choice and (3) having a knowledge score of at least 7 out of 12 knowledge items, higher score is better	Short-term (at 1- month follow-up)
Valdez 2018	—	Knowledge on cervical cancer, human papillomavirus (HPV) and Pap testing: adapted scale from Pathfinder intervention study, 5 items, yes/no	—	—	—	—	Medium-term (at 6-month follow-up)
7 Culturally and literacy adapted audio-/visual education without personal feedback vs another culturally and literacy adapted audio-/visual education without personal feedback							
Ochoa 2020	—	Knowledge regarding Pap test, HPV and cervical cancer; 8 open-ended questions summed to knowledge score	—	—	—	Cervical cancer screening intention; 2 questions: (1) "When did you have your most recent Pap test" and (2) "Since you saw the film, did you make an appointment for a Pap test?" (yes/no, do not know)	Short-term and medium-term (knowledge at 2-weeks post-test and at 6-month follow-up), behavioural intentions at 22 weeks post-test and at 6-month follow-up
8 Culturally and literacy adapted medical instruction vs no health literacy intervention							

Table 17. Outcomes considered in this review - components of health literacy *(Continued)*

Bailey 2012	—	—	—	Comprehension of medical instruction; demonstration by means of correct dosage in dosing tray (demonstrate correct dose, frequency and spacing; 0 to 5; 0 = incorrect, 1 = correct), numbers of instructions understood, RR, 95% CI	—	—	Short-term (immediately post-intervention)
Kheir 2014	—	—	—	Comprehension of medical instructions through interpretation of label contents; level of comprehension (1 to 3; 1 no comprehension to 3 full comprehension)	—	—	Short-term (immediately post-intervention)
Mohan 2014	—	—	—	Medication understanding: Medication Understanding Questionnaire (MUQ), 0 to 100 (0 to 3 for each medication), higher score is better	—	—	Short-term (1 week post-intervention)

*Outcomes to be considered in this review; see Characteristics of included studies for an overview of all outcomes assessed within the included studies.
**No study reported a measure for assessing either motivation or the step of accessing health information.

***Results for the outcome category 'health-related knowledge' were reported separately in the results section as well as in the summary of findings tables.

[1] Not enough information to categorise into short-, medium- or long-term assessment.

[2] Participants were not all assessed at one time point (immediately post intervention up to three months post-intervention). We report the results as short-term outcomes.

[3] Authors only report results of a 3-month follow-up assessment.

ACP: advance care planning; ADK: Audit of Diabetes Knowledge; ADKnowl: Audit of Diabetes Knowledge Scale; AHL-C: Assessment of Health lIteracy in Cancer; CI: confidence interval; COPD: chronic obstructive pulmonary disease; DHLS: Diabetes Health Literacy Survey; DKT: Diabetes Knowledge Test; D-Lit/DLQ: Depression Literacy Questionnaire; DM-REALM: Diabetes-specific Rapid Estimate of Adult Literacy in Medicine; HBP: high blood pressure; HPV: human papillomavirus; MUQ: Medication Understanding Questionnaire; NVS: Newest Vital Sign; REALM: Rapid Estimate of Adult Literacy in Medicine; RR: risk ratio; TOFHLA: Test of Functional Health Literacy in Adults; TS-REALD: Two Stage Rapid Estimate of Adult Literacy in Dentistry

Table 18. Outcomes considered in this review - additional outcomes related to health literacy

Study ID	Quality of* life	Health outcomes	Health behaviour	Self-efficacy	Health service use	Adverse events	Timing of outcome assessment considered
1 Culturally and literacy adapted self-management programme vs no health literacy intervention							
Bloom 2014	—	—	Mammography: self-report, no further details reported	—	—	—	After 6 months[1]
Koniak-Griffin 2015	—	—	Physical activity*: accelerometer data (worn during walking hours for 7 consecutive days)	—	—	—	Short-term (immediately post-intervention), medium-term (3 months post-intervention)
Rosal 2011	—	—	Blood glucose self-monitoring*: unannounced phone calls (3 recalls per time point (oral assessment, 3 questions on blood glucose self-monitoring, higher score is better	Self-efficacy in diabetes management; self-efficacy for dietary and physical activity change (Lifestyle Self-Efficacy Scale for Latinos with Diabetes (LSESLD); 17 items)	—	—	Short-term (immediately post-intervention)
van Servellen 2005	—	Self-reported general health status, 1 item on perceived level of general health in past week*	HIV medication adherence ACTG Adherence behaviours Baseline Questionnaire (self-report), proportion of those with > 95% adherence within last 4 days	Medication adherence self-efficacy Certainty to master medication regimen; 1 item of ACTG Adherence Baseline Questionnaire (3-point Likert scale), higher score is better	—	—	Short-term (immediately post-intervention)

Table 18. Outcomes considered in this review - additional outcomes related to health literacy *(Continued)*

2 Culturally and literacy adapted self-management programme vs written information on the same topic

Han 2017	—	—	Adherence to age-appropriate screening (medical record review)	—	—	—	Short-term (immediately post-intervention)
Kaur 2019	—	—	Health behaviour (oral hygiene self-care behaviour) Questionnaire on oral self-care knowledge and oral self-care behaviour, no total score provided	—	—	—	Short-term (immediately post-intervention)
Kim 2009	Quality of life (diabetes-related QoL) Diabetes Quality of Life Measure (DQOL, 14 items) (0 to 75)	Depression; KDSKA (0 to 21), lower score is better	Adherence to diabetes regimen Diabetes Self-Care Activities scale, no range reported	Diabetes self-efficacy; adapted Stanford Chronic Disease Self-Efficacy Scale, 8 items, 10-point Likert scale, 0 to 80, higher score is better	—	—	Short-term (immediately post-intervention)
Kim 2014	—	Depression; PHQ-9 (0 to 27), lower score is better	Self-reported medication adherence HB-MAS (8 items, 4-point Likert scale, 1 (none of the time) to 4 (all of the time), 8 to 32, higher score is better	Self-efficacy in managing high blood pressure; 8-item questionnaire adapted from the HBP belief scale (4-point Likert scale (1 to 4))	—	—	Short-term and medium-term (immediately post-intervention and at 6-month follow-up)
Kim 2020	Quality of life (diabetes-related QoL) Diabetes Quality of Life Measure (DQOL, 14 items) (0 to 75)	Depression; Korean Patient Health Questionnaire 9 (PHQ-9K) (0 to 27), lower score is better	—	Diabetes self-efficacy; adapted Stanford Chronic Disease Self-Efficacy Scale, 8 items, 10-point Likert scale, 0 to 80, higher score is better	—	—	Short-term (immediately post-intervention)
Rosal 2005	Diabetes-related quality of life, adapted ADDQoL,	Depression; Center for Epidemiological Studies-Depression Scale	Blood-glucose self-monitoring*: 24-hour recall of self-monitoring blood glucose by asking individuals whether they had checked their blood sugar level in the pre-	IMDSES, 26-item, 4-point Likert-scale ranging from 1 ("low confidence") to 4 ("high con-	—	—	Short-term (2 weeks post-intervention) and medium-term (4.5 months after pro-

Table 18. Outcomes considered in this review - additional outcomes related to health literacy *(Continued)*

	score range not reported	(CES-D), 0 to 60, lower score is better	vious 24 hours, at what time, and what value was obtained, lower score is better	fidence"), 26 to 104, higher score is better			gramme completion)
2 Culturally adapted health literacy skills building course vs no/unrelated health literacy intervention							
Otilingam 2015	—	—	Fat-Related Diet Habits Questionnaire, 12 items, mean on 4-point scale; (1 to 4), higher score is better	—	—	—	Short-term (at 1 month follow-up)
Soto Mas 2018	—	—	Cardiovascular health behaviour; CSC (34 to 136)	—	—	—	Short-term (immediately post-intervention)
Wong 2020	—	—	—	—	—	—	Short-term (immediately post-intervention and at 2-month follow-up)
Elder 1998	—	—	—	Self-efficacy to change one's diet; questionnaire: 5 items on self-efficacy: score 1 (low) to 3 (high)	—	—	Medium-term (at 6-month follow-up)
Taylor 2011	—	—	Hepatitis B testing (self-report and verification through medical records)	—	—	—	Medium-term (6-month follow-up)[2]
Tong 2017	—	—	Up-to-date colorectal cancer screening* including faecal occult blood test (FOBT), sigmoidoscopy or colonoscopy (S/C)) (self-report of test receipt and when the test was obtained)	—	—	—	Medium-term (at 3-month follow-up)
4 Culturally and literacy adapted telephone education vs unrelated culturally and literacy adapted telephone education							
Lepore 2012	—	—	PSA testing; medical claims records (0 = no, 1 = yes)	—	—	State Anxiety; 7-item sub-scale of the HADS (0	Long-term (8 months after randomisation (anxiety), 2 years af-

Table 18. Outcomes considered in this review - additional outcomes related to health literacy *(Continued)*

						to 21), lower score is better	ter randomisation (PSA testing))
5 Culturally and literacy adapted audio-/visual education without personal feedback vs no health literacy intervention							
DeCamp 2020	—	Parent depression; PHQ-8, 8 items (0 to 24), lower score is better	Up-to-date immunisation assessed via EMR	—	ER visits assessed via EMR*	—	Short-term (immediately up to 3 months post-intervention)[3]
Hernandez 2013	—	—	—	Self-efficacy to identify need for treatment; Self-Efficacy to identify the Need for Treatment Scale (0 to 15)	—	—	Short-term (immediately post- intervention)
Kiropoulos 2011	—	Depression; BDI-II (0 to 63), lower score is better	—	—	—	—	Short-term (1 week post-intervention)
Thompson 2012	—	—	—	—	—	—	NA
6 Culturally and literacy adapted audio-/visual education**without personal feedback vs written information on the same topic**							
Calderón 2014	—	—	—	—	—	—	NA
Gwede 2019	—	—	Screening for colorectal cancer; return of a completed FIT kit within 90 days of intervention	Self-efficacy for screening using FIT	—	—	Medium-term (at 3-month follow-up)
Payán 2020	—	—	—	Self-efficacy in accessing breast cancer-related advice or information: one item adapted from a cancer confidence question in the 2012 Health Information National Trends Survey; the item asked "Overall, how confident are you that you	—	—	Short-term (immediately post-intervention and 3-month follow-up)

Table 18. Outcomes considered in this review - additional outcomes related to health literacy *(Continued)*

				could get advice or information about breast cancer if you needed it?", 5-point scale ranging from "completely confident" to "not confident at all"			
Poureslami 2016a	—	—	—	—	—	—	Medium-term (at 3-month follow-up)[4]
Poureslami 2016b	—	—	—	COPD self-efficacy; validated COPD Self-Efficacy Scale (short version, 5 items), 5-point Likert scale	—	—	Medium-term (at 3 month follow-up)
Sudore 2018	—	Depression*; PHQ-8, (0 to 24) referred to as adverse events, lower score is better	Documentation of new Advance Care Planning (legal forms and documented discussions with clinicians and/or surrogates)	—	—	Anxiety (GAD-7 questionnaire (0 to 21), referred to as adverse events, lower score is better	Long-term (at 12-month follow-up)
Unger 2013	—	—	—	Self-efficacy to identify depression, 2 items adapted from Lorig et al; 10-point scale ranging from 1 = "not at all confident" to 10 = "very confident" (mean (SD); range not reported)	—	—	Short-term (immediately post-intervention)
Valdez 2015	—	—	—	—	—	—	NA
Valdez 2018	—	—	Screening behaviour (Pap testing): adapted scale from the Pathfinder intervention study, yes/no (e.g. "Obtained a pap test or made appointment"); further information not reported	Self-efficacy (Pap testing): adapted scale from the Pathfinder intervention study, binary items (yes/no) (e.g. "Can get a pap smear if needed");	—	—	Medium-term (at 6-month follow-up)

Table 18. Outcomes considered in this review - additional outcomes related to health literacy *(Continued)*

				further information not reported			
7 Culturally and literacy adapted audio-/visual education**without personal feedback vs another culturally and literacy adapted** audio-/visual education**without personal feedback**							
Ochoa 2020	—	—	Pap testing behaviour, self-report, 1 question: "Since you saw the film, have you had a Pap test?" with response options "yes", "no" and "do not know"	—	—	—	Short-term (at 2 week post-test) and mid-term (at 6-month follow-up)
8 Culturally and literacy adapted medical instruction vs no health literacy intervention							
Bailey 2012	—	—	—	—	—	—	NA
Kheir 2014	—	—	—	—	—	—	NA
Mohan 2014	—	—	Medication adherence: 8 item sub-scale of Spanish translation of ARMS, patients' self-reported adherence under various circumstances (sub-scale to medication refills), 8 (most adherent to 32 (least adherent), lower score is better	—	—	—	Short-term (1 week)

*Prioritised outcome to be considered in this review; see Characteristics of included studies for a full description of outcomes assessed in the respective study.

[1] Not enough information to categorise into short-, medium- or long-term assessment.

[2] Post-test assessment only.

[3] Participants were not all assessed at one time point (immediately post intervention up to three month post intervention). We report the results as short-term outcomes.

[4] Authors report that a short telephone-based outcome assessment was conducted at 6-month follow-up, assessing subjective medication adherence, but results are not reported.

ACTG: Adult AIDS Clinical Trials Group; ARMS: Adherence to Refills and Medications Scale; BDI-II: Beck Depression Inventory-II; COPD: chronic obstructive pulmonary disease; CSC: Cardiovascular Health Questionnaire; DQOL: Diabetes Quality of Life Measure; EMR: electronic medical record; ER: emergency room; FIT: faecal immunochemical test; FOBT: faecal occult blood test ; GAD-7: Generalised Anxiety Disorder-7; HADS: Hospital Anxiety and Depression Scale; HB-MAS: Hill-Bone Medication Adherence Scale; HBP: high blood pressure; IMDSES: Insulin Management Self-Efficacy Scale; KDSKA: Kim Depression Scale for Korean Americans; LSESLD: Lifestyle Self-Efficacy Scale for Latinos with Diabetes; NA: not applicable; PHQ: Patient Health Questionnaire; PSA: prostate-specific antigen; QoL: quality of life; SD: standard deviation

APPENDICES

Appendix 1. Search strategies

Cochrane Central Register of Controlled Trials (via Cochrane Library)

ID Search

#1 MeSH descriptor: [Multilingualism] explode all trees

#2 multilingualism*:ti,ab,kw

#3 "as a second language":ti,ab,kw

#4 bilingual*:ti,ab,kw

#5 (second language):ti,ab,kw

#6 (foreign language):ti,ab,kw

#7 (proficiency and language):ti,ab,kw

#8 MeSH descriptor: [Communication Barriers] explode all trees

#9 (barrier near/7 language):ti,ab,kw

#10 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9

#11 MeSH descriptor: [Transients and Migrants] explode all trees

#12 migrant*:ti,ab,kw

#13 (migration* near/3 (background* or human*)):ti,ab,kw

#14 MeSH descriptor: [Emigrants and Immigrants] explode all trees

#15 MeSH descriptor: [Undocumented Immigrants] explode all trees

#16 MeSH descriptor: [Emigration and Immigration] explode all trees

#17 (immigrant* or immigrat*):ti,ab,kw

#18 (emigrant* or emigrat*):ti,ab,kw

#19 (minorit* near/3 (population* or group*)):ti,ab,kw

#20 (ethnic* near/3 (population* or group* or patient* or background* or specific* or minorit* or identit*)):ti,ab,kw

#21 (displaced and (people or person*)):ti,ab,kw

#22 MeSH descriptor: [Vulnerable Populations] explode all trees

#23 MeSH descriptor: [Refugees] explode all trees

#24 (foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn):ti,ab,kw

#25 (cultur* near/5 (differences* or cross* or background*)):ti,ab,kw

#26 (linguisticall* near/5 (differences* or cross* or background*)):ti,ab,kw

#27 (border* and crossing):ti,ab,kw

#28 #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27

#29 MeSH descriptor: [Access to Information] explode all trees

#30 ((access or gain access or obtain or seek out or find or indentify) near/5 (information* or health*)):ti,ab,kw

#31 MeSH descriptor: [Comprehension] explode all trees

#32 (understand or comprehend or comprehension):ti,ab,kw

#33 (appraise or evaluate or process or interpret or assess):ti,ab,kw

#34 "assessment of information":ti,ab,kw

#35 (apply or decide):ti,ab,kw

#36 (use* near/3 (information* or health)):ti,ab,kw

#37 MeSH descriptor: [Decision Making] explode all trees

#38 ((make or making or made or take) near/4 decision*):ti,ab,kw

#39 (acting or act or action):ti,ab,kw

#40 judge*:ti,ab,kw

#41 #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40

#42 MeSH descriptor: [Consumer Health Information] explode all trees

#43 MeSH descriptor: [Information Literacy] explode all trees

#44 MeSH descriptor: [Health Literacy] explode all trees

#45 (information* near/3 health*):ti,ab,kw

#46 (health* near/3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)):ti,ab,kw

#47 #42 or #43 or #44 or #45 or #46

#48 MeSH descriptor: [Health Education] explode all trees

#49 MeSH descriptor: [Educational Status] explode all trees

#50 (health* near/3 education*):ti,ab,kw

#51 MeSH descriptor: [Health Services Accessibility] explode all trees

#52 #48 or #49 or #50 or #51

#53 #41 and (#47 or #52)

#54 health litera*:ti,ab,kw

#55 medical literacy:ti,ab,kw

#56 (health and literacy):ti

#57 (functional and health and literacy):ti,ab,kw

#58 low-litera*:ti,ab,kw

#59 (litera* or illitera*):ti,ab,kw

#60 (read or comprehen*):ti,ab,kw

#61 MeSH descriptor: [Reading] explode all trees

#62 MeSH descriptor: [Comprehension] explode all trees

#63 MeSH descriptor: [Health Promotion] explode all trees

#64 MeSH descriptor: [Health Education] explode all trees

#65 MeSH descriptor: [Patient Education as Topic] explode all trees

#66 MeSH descriptor: [Communication Barriers] explode all trees

#67 MeSH descriptor: [Communication] explode all trees

#68 MeSH descriptor: [Attitude to Health] explode all trees

#69 MeSH descriptor: [Comprehension] explode all trees

#70 MeSH descriptor: [Educational Status] explode all trees

#71 #69 and #70

#72 (family and literacy):ti,ab,kw

#73 drug labeling:ti,ab,kw

#74 MeSH descriptor: [Drug Prescriptions] explode all trees

#75 comprehension:ti,ab,kw

#76 ((cancer or diabetes or genetics) and (literacy or comprehension))

#77 (adult and (educational status or (educational and status) or literacy))

#78 (limited and (educational status or (educational and status) or literacy))

#79 (patient* and (educational status or (educational and status) or literacy))

#80 (patient* and (comprehension or understanding))

#81 #54 or #55 or #56 or #57 or #58 or #59 or #60 or #61 or #62

#82 #63 or #64 or #65 or #66 or #67 or #68 or #69 or #70 or #71 or #72 or #73 or #74 or #75 or #76 or #77 or #78 or #79 or #80 or #81

#83 #81 and #82

MEDLINE (via Ovid)

Searches

1 "Transients and Migrants"/

2 migrant*.tw,kf,ot.

3 (migration* adj3 (background* or human*)).tw,kf,ot.

4 exp "Emigrants and Immigrants"/

5 Undocumented immigrants/

6 "Emigration and Immigration"/

7 (immigrant* or immigrat*).tw,kf,ot.

8 (emigrant* or emigrat*).tw,kf,ot.

9 (minorit* adj3 (population* or group*)).tw,kf,ot.

10 (ethnic* adj3 (population* or group* or patient* or background* or specific* or minorit* or identit*)).tw,kf,ot.

11 (displaced and (people or person$1)).tw.

12 Vulnerable populations/

13 Refugees/

14 (foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn).tw,kf,ot.

15 (cultur* adj5 (differences* or cross* or background*)).tw,kf,ot.

16 (border* and crossing).tw.

17 ((culturall* or linguisticall*) adj3 (diverse* or patient* or parent* or communit* or background* or student* or wom?n or famil*)).tw,kf,ot.

18 or/1-17

19 multilingualism/

20 multilingualism*.tw,kf,ot.

21 "as a second language".tw,kf,ot.

22 bilingual.tw,kf,ot.

23 second language.tw.

24 foreign language.tw.

25 (proficiency and language).tw.

26 communication barriers/

27 (barrier adj3 language).tw,kf,ot.

28 or/19-27

29 18 or 28

30 Access to Information/

31 ((access or gain access or obtain or seek out or find or identify) adj5 (information* or health*)).tw.

32 Comprehension/

33 (understand or comprehend or comprehension).tw.

34 (appraise or evaluate or process or interpret or assess).tw.

35 assessment of information.tw.

36 (apply or decide).tw.

37 (use* adj3 (information* or health)).tw.

38 (capacit* adj4 health).tw.

39 accept*.tw,kf,ot.

40 Decision Making/

41 ((make or making or made or take) adj4 decision*).tw.

42 ("behavior change" or "behaviour change").tw,kf,ot.

43 (acting or act or action).tw.

44 judge*.tw.

45 or/30-44

46 exp Consumer Health Information/ or Information literacy/

47 Health Literacy/

48 (information* adj3 health*).tw.

49 (health* adj3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)).tw.

50 or/46-49

51 Health Education/ or Educational Status/

52 (health* adj3 education*).tw.

53 Health Services Accessibility/sn [Statistics & Numerical Data]

54 or/51-53

55 45 and (50 or 54)

56 health litera$2.af.

57 medical literacy.af.

58 (health and literacy).ti.

59 (functional and health and literacy).tw.

60 low-litera$2.ti.

61 litera$2.ti.

62 illitera$2.ti.

63 reading/ or comprehension/

64 (read* or comprehen*).tw,kf.

65 health promotion/

66 health education/

67 patient education/

68 communication barriers/

69 communication/

70 health knowledge,attitudes,practice/

71 attitude to health/

72 comprehension/ and *educational status/

73 (family and literacy).ti.

74 (drug labeling.af. or Drug Prescriptions/) and comprehension.af.

75 ((cancer or diabetes or genetics) and (literacy or comprehension)).ti.

76 (adult and (educational status or (educational and status) or literacy)).af.

77 (limited and (educational status or (educational and status) or literacy)).af.

78 (patient$1 and (educational status or (educational and status) or literacy)).af.

79 (patient$1 and (comprehension or understanding)).ti.

80 or/56-64

81 or/65-79

82 80 and 81

83 randomized controlled trial.pt.

84 controlled clinical trial.pt.

85 randomi?ed.ab.

86 placebo.ab.

87 drug therapy.fs.

88 randomly.ab.

89 trial.ab.

90 groups.ab.

91 or/83-90

92 exp animals/ not humans/

93 91 not 92

94 29 and (55 or 82) and 93

Embase (via Ovid)
Searches

1 exp migrant/

2 migrant*.tw,kw.

3 (migration* adj3 (background* or human*)).tw,kw.

4 (emigrant* or immigrant*).tw,kw.

5 (undocumented* adj3 immigrant*).tw,kw.

6 (ethnic* adj3 (population* or group* or patient* or background* or specific* or minorit* or identit*)).tw,kw.

7 (displaced and (people or person$1)).tw.

8 (low* adj3 income*).ti,ab.

9 (minorit* adj3 (population* or group*)).tw,kw.

10 exp refugee/

11 Vulnerable population/

12 (foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn).tw,kw.

13 (cultur* adj5 (differences* or cross* or background*)).tw,kw.

14 (border* and crossing).tw.

15 ((culturall* or linguisticall*) adj3 (tailor* or diverse* or patient* or parent* or communit* or background* or student* or wom?n or famil*)).tw,kw.

16 "cultural factor"/

17 or/1-16

18 multilingualism/

19 multilingualism*.tw,kw.

20 "as a second language".tw,kw.

21 bilingual.tw,kw.

22 second language.tw.

23 foreign language.tw.

24 (proficiency and language).tw.

25 communication barriers/

26 (barrier adj3 language).tw,kw.

27 or/18-26

28 17 or 27

29 access to information/

30 ((access or gain access or obtain or seek out or find or identify) adj5 (information* or health*)).tw.

31 comprehension/

32 (understand or comprehend or comprehension).tw.

33 (appraise or evaluate or process or interpret or assess).tw.

34 judge*.tw.

35 assessment of information.tw.

36 (apply or decide).tw.

37 (use* adj3 (information* or health)).tw.

38 (capacit* adj4 health).tw.

39 accept*.tw.

40 decision making/

41 ((make or making or made or take) adj4 decision*).tw.

42 ("behavior change" or "behaviour change").tw.

43 (acting or act or action).tw.

44 or/29-43

45 consumer health information/

46 information literacy/

47 health literacy/

48 (information* adj3 health*).tw.

49 (health* adj3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)).tw.

50 health education/

51 educational status/

52 (health* adj3 education*).tw.

53 exp health care delivery/

54 or/45-53

55 44 and 54

56 health litera$2.mp.

57 medical literacy.mp.

58 (health and literacy).ti.

59 (functional and health and literacy).tw.

60 low-litera$2.ti.

61 litera$2.ti.

62 illitera$2.ti.

63 reading/ or comprehension/

64 (read* or comprehen*).tw,kw.

65 or/56-64

66 *health promotion/

67 *health education/

68 *patient education/

69 *communication barriers/

70 *communication/

71 *health knowledge, attitudes, practice/

72 *attitude to health/

73 *comprehension/ and *educational status/

74 (family and literacy).ti.

75 (drug labeling.mp. or Prescription/) and comprehension.mp.

76 ((cancer or diabetes or genetics) and (literacy or comprehension)).ti.

77 (adult and (educational status or (educational and status) or literacy)).mp.

78 (limited and (educational status or (educational and status) or literacy)).mp.

79 (patient$1 and (educational status or (educational and status) or literacy)).mp.

80 (patient$1 and (comprehension or understanding)).ti.

81 or/66-80

82 65 and 81

83 55 or 82

84 randomized controlled trial/

85 controlled clinical trial/

86 single blind procedure/ or double blind procedure/

87 crossover procedure/

88 random*.tw.

89 placebo*.tw.

90 ((singl* or doubl*) adj (blind* or mask*)).tw.

91 (crossover or cross over or factorial* or latin square).tw.

92 (assign* or allocat* or volunteer*).tw.

93 or/84-92

94 28 and 83 and 93

CINAHL (via EBSCO)

Query

S84 S82 AND S83

S83 (DE "Placebo" OR ((random* OR controlled) AND trial*) OR randomly OR randomized OR placebo* OR double-blind)

S82 (S10 or S28) and (S54 or S81)

S81 S79 and S80

S80 S64 or S65 or S66 or S67 or S68 or S69 or S70 or S71 or S72 or S73 or S74 or S75 or S76 or S77 or S78

S79 S55 or S56 or S57 or S58 or S59 or S60 or S61 or S62 or S63

S78 TI (patient* and (comprehension or understanding))

S77 SU (patient* and (educational status or (educational and status) or literacy))

S76 SU (limited and (educational status or (educational and status) or literacy))

S75 SU (adult and (educational status or (educational and status) or literacy))

S74 TI (cancer or diabetes or genetics) and (literacy or comprehension)

S73 SU (drug labeling or prescriptions, drugs) and comprehension

S72 TX family and literacy

S71 MA COMPREHENSION AND MA EDUCATIONAL STATUS

S70 MA "Health Personnel Attitudes"

S69 DE "Health Attitudes"

S68 DE "Health Knowledge" OR DE "Health Behavior"

S67 DE COMMUNICATION

S66 DE COMMUNICATION BARRIERS

S65 DE HEALTH EDUCATION

S64 DE HEALTH PROMOTION

S63 DE COMPREHENSION

S62 DE READING

S61 TX illitera* OR TX literac*

S60 TX read* OR TX comprehen*

S59 TX low-litera*

S58 TX functional and health and literacy

S57 TX health and literacy

S56 TX medical literacy

S55 TX health litera*

S54 S44 and (S49 or S53)

S53 S50 or S51 or S52

S52 MA HEALTH SERVICES ACCESSIBILITY

S51 TX health* N3 education*

S50 DE HEALTH EDUCATION OR (DE EDUCATION AND DE STATUS)

S49 S45 or S46 or S47 or S48

S48 TX health* N3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)

S47 TX information* N3 health*

S46 DE HEALTH LITERACY

S45 MA CONSUMER HEALTH INFORMATION OR DE INFORMATION LITERACY

S44 S29 or S30 or S31 or S32 or S33 or S34 or S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or S43

S43 TX judge*

S42 TX acting or act or action

S41 TX "behavior change" or "behaviour change"

S40 TX ((make or making or made or take) N4 decision*)

S39 DE DECISION MAKING

S38 TX accept*

S37 TX capacit* N4 health

S36 TX use* N3 (information* or health)

S35 TX apply or decide

S34 TX assessment of information

S33 TX appraise or evaluate or process or interpret or assess

S32 TX (understand or comprehend or comprehension)

S31 DE COMPREHENSION

S30 TX (access or gain access or obtain or seek out or find or indentify) N5 (information* or health*)

S29 MA "ACCESS TO INFORMATION"

S28 S11 or S12 or S13 Or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27

S27 TX (culturall* or linguisticall*) N3 (diverse* or patient* or parent* or communit* or background* or student* or woman or women or famil*)

S26 TX border* and crossing

S25 TX cultur* N3 (differences* or cross* or background*)

S24 TX (foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn)

S23 (DE REFUGEES OR DE ASYLUM SEEKING OR DE POLITICAL ASYLUM)

S22 MA VULNERABLE POPULATIONS

S21 TX (displaced and (people or person*))

S20 TX ethnic* N2 (population* or group* or patient* or background* or specific* or minorit* or identit*)

S19 TX minorit* N2 (population* or group*)

S18 TX emigrant* OR TX emigrat*

S17 TX immigrant* OR TX immigrat*

S16 DE IMMIGRATION

S15 DE HUMAN MIGRATION

S14 MA "EMIGRANTS AND IMMIGRANTS"

S13 TX migration* N3 (background* or human*)

S12 TX migrant*

S11 MA "TRANSIENTS AND MIGRANTS"

S10 (S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9)

S9 TX (barrier N3 language)

S8 (DE "Communication Barriers")

S7 TX (proficiency and language)

S6 TX foreign language

S5 TX second language

S4 TX "as a second language"

S3 TX multilingualism*

S2 TX bilingual

S1 (DE "Multilingualism" OR DE "Bilingualism" OR DE "Bilingual Education" OR DE "English as Second Language") PsycINFO (via EBSCO)

PsycINFO (via OVID)

Searches

1 Multilingualism/ or Bilingualism/ or "Bilingual Education"/ or "English as Second Language"/

2 (bilingual* or multilingual* or "second language" or "foreign language").tw.

3 (proficiency and language).tw.

4 "Communication Barriers"/

5 (barrier adj3 language).tw.

6 IMMIGRATION/ or exp HUMAN MIGRATION/

7 (migrant* or immigrant* or immigrat* or emigrant* or emigrat*).tw.

8 (migration* adj3 (background* or human*)).tw.

9 (minorit* adj2 (population* or group*)).tw.

10 (ethnic* adj2 (population* or group* or patient* or background* or specific* or minorit* or identit*)).tw.

11 (displaced and (people or person*)).tw.

12 exp At Risk Populations/

13 asylum seeking/ or political asylum/ or refugees/

14 (foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn).tw.

15 (cultur* adj3 (difference* or cross* or background*)).tw.

16 (border* and crossing).tw.

17 ((culturall* or linguisticall*) adj3 (diverse* or patient* or parent* or communit* or background* or student* or woman or women or famil*)).tw.

18 or/1-17

19 information specialists/

20 ((access or gain access or obtain or seek out or find or indentify) adj5 (information* or health*)).tw.

21 exp Comprehension/

22 (understand or comprehend or comprehension or appraise or evaluate or process or interpret or assess or "assessment of information" or apply or decide or accept*).tw.

23 (use* adj3 (information* or health)).tw.

24 (capacit* adj4 health).tw.

25 exp Decision Making/

26 ((make or making or made or take) adj4 decision*).tw.

27 ("behavior change" or "behaviour change" or acting or act or action or judge*).tw.

28 or/19-27

29 health information/ or information literacy/ or exp health literacy/

30 (information* adj3 health*).tw.

31 (health* adj3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)).tw.

32 or/29-31

33 exp Health Education/

34 EDUCATION/ and STATUS/

35 (health* adj3 education*).tw.

36 exp Health Care Access/

37 or/33-36

38 28 and (32 or 37)

39 exp Health Literacy/

40 (health litera* or medical literacy or read* or comprehen* or literac* or low-litera* or illitera*).tw.

41 (health and literacy).tw.

42 exp Reading/

43 exp Comprehension/

44 or/39-43

45 Health Promotion/ or Health Education/ or Communication Barriers/ or Health Knowledge/ or Health Behavior/ or Health Attitudes/ or Health Personnel Attitudes/

46 exp Educational Attainment Level/

47 Comprehension/ and exp Educational Attainment Level/

48 (family and literacy).tw.

49 exp Prescription Drugs/

50 Comprehension/ and exp Prescription Drugs/

51 ((cancer or diabetes or genetics) and (literacy or comprehension)).ti.

52 (adult and (educational status or (educational and status) or literacy)).tw.

53 (limited and (educational status or (educational and status) or literacy)).tw.

54 (patient* and (educational status or (educational and status) or literacy)).tw.

55 (patient* and (comprehension or understanding)).ti.

56 or/45-55

57 44 and 56

58 18 and (38 or 57)

59 (control: or random:).tw. or exp treatment/

60 clinical trials/ or "treatment outcome clinical trial".md. or ((randomi?ed adj7 trial*) or ((single or doubl* or tripl* or treb*) and (blind* or mask*)) or (controlled adj3 trial*) or (clinical adj2 trial*)).ti,ab,id.

61 59 or 60

62 58 and 61

HISTORY

Protocol first published: Issue 4, 2019

CONTRIBUTIONS OF AUTHORS

Annika Baumeister (AB) developed the protocol and wrote the review (study screening and selection, data extraction, study quality assessment, data synthesis, interpretation of findings, GRADE assessment, creation of summary of findings (SoF) tables and evidence profiles, writing the text of the review).

Angela Aldin (AAl) assisted in the development of this review (study screening and selection, data synthesis and interpretation of findings, study quality assessment, GRADE assessment), proofread and commented on the draft. She was in constant exchange with Annika Bameister due to the parallel development of the qualitative evidence synthesis linked to this effectiveness review.

Digo Chakraverty (DC) assisted in the study selection and data synthesis (grouping of studies), proofread and commented on the draft.

Constanze Hübner (CH) assisted in study screening and data extraction, proofread and commented on the draft.

Anne Adams (AAd) provided statistical expertise, proofread and commented on the review draft.

Ina Monsef (IM) developed the search strategies and conducted electronic searches, proofread and commented on the review draft.

Nicole Skoetz (NS) provided methodological advice, proofread and commented on the review draft.

Elke Kalbe (EK) provided content expertise, proofread and commented on the review draft.

Christiane Woopen (CW) provided content expertise, proofread and commented on the review draft.

DECLARATIONS OF INTEREST

Annika Baumeister (AB): award of the grant from the Federal Ministry of Education and Research for the University Hospital of Cologne to perform this systematic review does not lead to a conflict of interest.

Angela Aldin (AAl): award of the grant from the Federal Ministry of Education and Research for the University Hospital of Cologne to perform this systematic review does not lead to a conflict of interest.

Digo Chakraverty (DC): award of the grant from the Federal Ministry of Education and Research for the University Hospital of Cologne to perform this systematic review does not lead to a conflict of interest.

Constanze Huebner (CH): none known.

Anne Adams (AAd): none known. She is an editor with Cochrane, but was not involved in the editorial process for this review.

Ina Monsef (IM): none known. She is the Information Specialist for Cochrane Haematology, but was not involved in the editorial process for this review.

Nicole Skoetz (NS): award of the grant from the Federal Ministry of Education and Research for the University Hospital of Cologne to perform this systematic review does not lead to a conflict of interest; she is Co-ordinating Editor of Cochrane Haematology, but was not involved in the editorial process for this review.

Elke Kalbe (EK): award of the grant from the Federal Ministry of Education and Research for the University Hospital of Cologne to perform this systematic review does not lead to a conflict of interest.

Christiane Woopen (CW): award of the grant from the Federal Ministry of Education and Research for the University Hospital of Cologne to perform this systematic review does not lead to a conflict of interest.

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Internal sources

- Research Unit Ethics, Institute for the History and Ethics of Medicine, University of Cologne, Faculty of Medicine and University Hospital Cologne, Germany

  Provision of the offices, including technical equipment.

External sources

- German Federal Ministry of Education and Research, Germany

  This review is funded by the German Federal Ministry of Education and Research, grant number 01GL1723.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Extending this review with a qualitative evidence synthesis

The author team of this effectiveness review aimed to conduct a qualitative evidence synthesis (QES) in parallel: *Gender differences in health literacy of migrants: a synthesis of qualitative evidence* (protocol) (Aldin 2019). The QES aimed to add to this effectiveness review by exploring whether gender differences in the health literacy of migrants exist, and which factors underlie these differences in the four health information processing steps. Additionally, it attempted to identify factors associated with gender and migration that may play a role in the design, delivery and effectiveness of health literacy interventions for female and male migrants. The QES has not yet been completed. At the time of publication, the possibility of the companion QES being completed to complement the current review is being explored.

Criteria for considering studies for this review

Types of interventions

At the protocol stage (Baumeister 2019), we planned to conduct a main analysis including health literacy interventions that were explicitly named as such and a secondary deductive analysis including health literacy interventions that address at least one of the four health information processing steps (see "description of the condition" section). For example, if a study reported a 'health literacy intervention' as simply providing an information pamphlet on an available health service and reported a health literacy measure, we planned to include the study for the secondary analysis, assigning it to the processing step 'access', since the effect cannot be assigned to health literacy as a general concept. We also planned to include such a study in the deductive analysis, if the pamphlet was targeted to individuals with limited language proficiency and the effect measured was the level of understanding that these individuals achieve regarding the information provided. In this case, the intervention was planned to be assigned to the processing step of 'understand' in the deductive analysis.

Due to the diversity of studies found, we were not able to conduct *one* main analysis, but rather conducted meta-analyses where possible and deductively categorised the studies' outcomes to our umbrella framework of health literacy (see also Data synthesis). In addition, we decided to exclude studies that solely provided a publicly available pamphlet when the respective pamphlet was not adapted with regard to (health) literacy by the study authors.

Types of outcome measures

Secondary outcomes

At the protocol stage, we pre-specified the outcome category 'individual skills (e.g. self-efficacy, self-awareness)'. For the sake of clarity, and since self-efficacy has been shown in several studies to be associated with health literacy (Berens 2021; Berens 2022b; Guntzviller 2016; von Wagner 2009; Xu 2018), we decided to rename this category of outcomes as 'self-efficacy', including the different forms of self-efficacy (e.g. self-efficacy to manage one's own disease, self-efficacy to use certain screening measures or self-efficacy to identify a disease). We also planned to extract outcomes related to the prespecified category 'Healthcare costs'. Healthcare costs as a secondary outcome was not assessed as no data were available from the published main trial reports and due to a lack of resources we were not able to search for separate cost-effectiveness analyses.

Search methods for identification of studies

Searching other resources

At the protocol stage, we planned to additionally handsearch for conference abstracts of certain conferences (e.g. migration conferences). We did not handsearch for conference abstracts due to a lack of resources and because our comprehensive search strategy most likely covered the published conference abstracts. We decided to search ClinicalTrials.gov and ICTRP as the other two clinical trial registries mentioned in the protocol (the EU clinical trials register and DRKS) are already included in the ICTRP search portal.

Data collection and analysis

Subgroup analysis

We intended to conduct subgroup analyses for gender, ethnicity and health literacy assessment (if named as such) (Objectives). Since health literacy can be defined and measured in different ways, we planned to conduct a subgroup analysis for different measurement tools applied in the included studies (performance-based versus self-assessment tools).

No self-assessment health literacy tool was applied in the included studies, therefore it was not possible or meaningful to follow the protocol in terms of conducting subgroup analyses for self-reported versus performance-based health literacy assessment. Due to the high heterogeneity of studies in terms of interventions, participants and comparators, and an insufficient number of studies in any of the meta-analyses, we were not able to conduct a quantitative subgroup analysis for gender or ethnicity either. However, we conducted separate analysis by gender, where possible.

Contrary to the protocol, we conducted post hoc quantitative subgroup analyses for specific design features when we considered studies similar enough to be combined in a meta-analysis, but nevertheless design-specific heterogeneity needed to be considered. For example, when there was high variance in the programme duration, we conducted subgroup analyses by length of the programme (e.g. up to six months versus up to 12 months) to investigate the reasons for heterogeneity.

Involvement of consumers

At the protocol stage, we had planned to also involve consumers by conducting gender-separate focus group discussions (FGDs) with female and male migrants, as well as to conduct a final symposium with different stakeholders, such as experts from political and healthcare contexts, to discuss the impact and implications of our primary and secondary findings for healthcare decision-making at the political level, particularly in Germany. However, due to a lack of financial and human resources, this was not possible.

NOTES

This review is based on guidance provided by Cochrane Consumers and Communication (CCCG 2016).

This review was developed in parallel with the linked Cochrane qualitative evidence synthesis (QES) (Aldin 2019), through continuous exchange between Annika Baumeister (first author of this review) and Angela Aldin (first author of the linked QES).

Appendix iv: Study III (Protocol of systematic review)

Baumeister A, Aldin A, Chakraverty D, Hübner C, Adams A, Monsef I, Skoetz N, Kalbe E & Woopen C. (2019). Interventions for improving health literacy in migrants [protocol]. *Cochrane Database of Systematic Reviews*, (4): CD013303. https://doi.org/10.1002/14651858.CD0133

Cochrane Library

Cochrane Database of Systematic Reviews

Interventions for improving health literacy in migrants (Protocol)

Baumeister A, Aldin A, Chakraverty D, Monsef I, Jakob T, Seven ÜS, Anapa G, Kalbe E, Skoetz N, Woopen C

Baumeister A, Aldin A, Chakraverty D, Monsef I, Jakob T, Seven ÜS, Anapa G, Kalbe E, Skoetz N, Woopen C.
Interventions for improving health literacy in migrants.
Cochrane Database of Systematic Reviews 2019, Issue 4. Art. No.: CD013303.
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[Intervention Protocol]

Interventions for improving health literacy in migrants

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

- To assess the effectiveness of interventions for improving health literacy in migrants.
- To assess whether female or male migrants may respond differently to the identified interventions.

Such interventions must address health literacy either as a comprehensive construct or at least one of its four health information processing steps (access, understand, appraise, apply). However, we do not aim to equate general health literacy interventions that include a range of activities targeted to all of the four health information processing steps with interventions that aim to improve only one step (e.g. understand). We aim instead to create a comprehensive picture of the effect of health literacy interventions by applying the integrated model as an umbrella framework for a deductive analysis of the four steps of health information processing.

We will not restrict this review to specific settings or diseases because we aim to provide an overview of all available interventions for improving health literacy addressing migrant populations.

Extending this review with a qualitative evidence synthesis

The author team of this effectiveness review will conduct a qualitative evidence synthesis (QES) in parallel: *Gender differences in health literacy of migrants: a synthesis of qualitative evidence* (Aldin 2019). Since we expect that relatively few studies will explicitly aim to explore if female and male migrants respond differently to a selected health literacy intervention, or even contain data on female and male migrants that can be extracted separately, the QES will supplement the effectiveness review in terms of gender-specific aspects that can affect the health information processing steps. Additionally, it will attempt to identify factors associated with gender and migration that may play a role in the design, delivery and effectiveness of health literacy interventions for female and male migrants,

as it may be able to identify other relevant determinants that cannot be explored by quantitative methods. The QES will be linked to the effectiveness review by using the conceptual framework of health literacy developed by Sørensen 2012. The synthesised evidence from the effectiveness review and the linked QES will ultimately validate the applicability of the integrated model by Sørensen 2012 in interventions for improving health literacy in migrants. On the basis of the joint results, we will develop a logic model that includes the identified factors that must to be taken into account in the development and delivery of health literacy interventions for female and male migrants. The author teams will continuously exchange on methodological issues and support each other within the review process.

BACKGROUND

International migration is a complex phenomenon of increasing importance in an era of rising globalisation. More than ever before, international migration touches all countries and affects all areas of daily living (IOM 2018). The growing presence of migrants, and refugees in particular, can have a complex impact on health care systems of respective host countries that face tremendous pressures of responding fast to new and increasing health care needs (Hunter 2016).

Health literacy has become a key contributor to effective disease management, improved health outcomes and the overall efficiency of health care. Furthermore health literacy is an essential concept with regard to health-related autonomous decisions and behaviour (Woopen 2015). Limitations in health literacy are associated with more frequent hospitalisations and emergency treatments, higher health care expenditures, the reduced use of preventive measures, lower treatment adherence, and an increased risk of morbidity and mortality (Berkman 2011; Eichler 2009; HLS-EU Consortium 2012; Paasche-Orlow 2007; Rasu 2015).

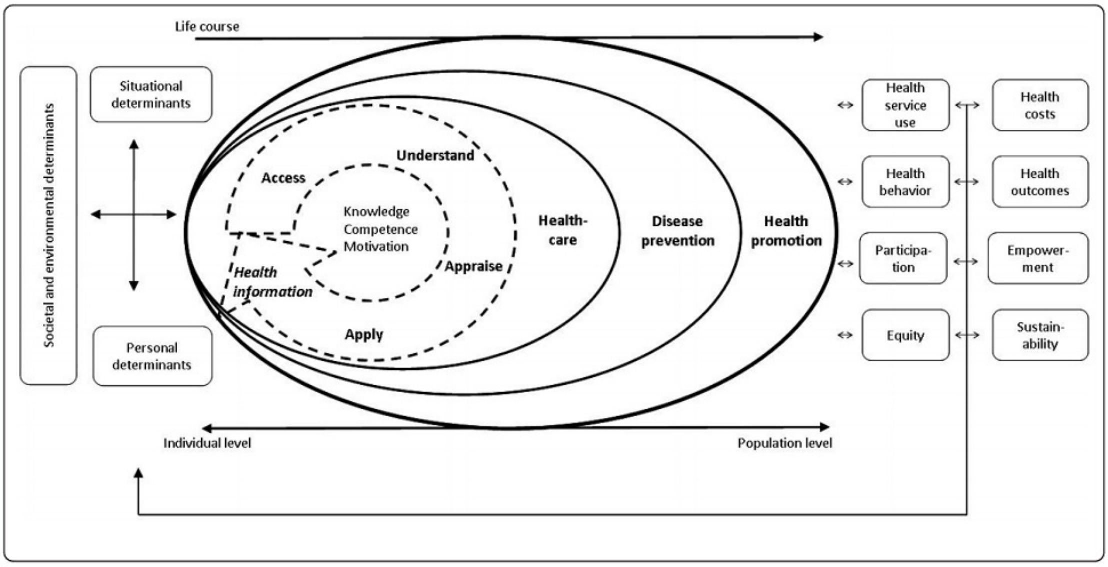
Extensive research exists at the population level among different European countries, suggesting that 47% of the European population have limited or inadequate subjective health literacy (HLS-EU Consortium 2012). Although exact numbers vary across the different countries, all of the results point to a call for action with regard to improving individuals' health literacy (Friis 2016; Pelikan 2013; Schaeffer 2017; van der Heide 2013). Additionally, a recent population study from Germany identified migrants as a high-risk group for limited health literacy, with 71% reporting substantial difficulties in processing health information and translating it into health promoting behaviour (Schaeffer 2017; Quenzel 2016). These results are in line with studies from Australia and the USA that report ethnic minority status as a risk factor for limited health literacy (Adams 2009; Christy 2017; Kutner 2006). Similar critical evidence was found for the health literacy levels of refugees in Sweden (Wångdahl 2014). Thus, improving health literacy, both at the individual and population level, is of crucial importance for a sustainable and equitable promotion of public health.

Description of the condition

Health literacy

The notion of health literacy was initially mentioned in the setting of school-based health education in the 1970s (Simonds 1974). In the medical context, the first definitions referred to health literacy as "the constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the healthcare environment" (AMA 1999). This rather passive understanding of the individual acting as a patient - today referred to as functional health literacy - has rapidly expanded to a more complex concept, including individual competencies and resources to take healthy choices and act on health information as an empowered consumer (Nutbeam 2000). To date, a broad variety of definitions and models have evolved around the world (Sørensen 2012). However, until now there is no uniformly applied definition of health literacy. There is little consensus on which combination of individual skills and capabilities constitutes health literacy, or on the areas of life in which these capabilities are applied. Thus, measurements of health literacy are equally diverse, and depend on the underlying definition of health literacy (Altin 2014; Guzys 2015; Haun 2014). Based on a systematic review of existing definitions and conceptual frameworks, Sørensen 2012 developed an integrated model of health literacy by systematically considering individual, social and systemic influencing factors, determinants and domains that can affect individual's health literacy (see Figure 1). Referring to this underlying model, "health literacy is linked to literacy and entails people's knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course" (Sørensen 2012). A key component of this definition is the procedural character of health information processing, which is expressed in the following four steps:

Figure 1. Integrated model of health literacy Sørensen 2012



- access;
- understand;
- appraise; and
- apply.

Individual prerequisites such as knowledge, motivation and skills or competencies (e.g. reading and writing abilities) are necessary to pass through the four steps of health information processing. Applying these prerequisites, health literacy requires a person to search for and find relevant health information, to understand it sufficiently, to appraise it in the context of one's own value system, and finally to apply the information, for example, by making healthy choices. Thus, the individual's ability to process health information is closely linked to health-related behaviour (e.g. medication adherence), which can in turn influence health-related outcomes (e.g. progression of disease). However, it is important to note that causes for limited health literacy are not limited exclusively to the individual. Health literacy is determined by individual abilities and resources on the one hand and structural, situational and political conditions on the other hand (Dodson 2015; Parker 2009). For example, a recent migrant might have sufficient health literacy skills to successfully navigate the health care system in the country of origin, but might be challenged by the demands and complexity of the health care system in the host country. Thus, the health literacy environment (e.g. clinicians with intercultural competence or the type of access to health services) plays a crucial role in determining the specific health literacy-related challenges that migrants may encounter.

We will apply the integrated model of health literacy as an umbrella framework for assessing the effectiveness of health literacy interventions, focusing on the four steps of health information processing (access, understand, appraise and apply), and the involved cognitive, knowledge-based and motivational aspects that contribute to a person's health literacy.

Migration

We use the term migration as defined by the International Organization for Migration (IOM), which states that migration is "the movement of a person or a group of persons, either across an international border, or within a state. It is a population movement, encompassing any kind of movement of people, whatever its length, composition and causes; it includes migration of refugees, displaced persons, economic migrants, and persons moving for other purposes, including family reunification" (IOM 2018a). Voluntary migration is often accompanied by the hope for improved living conditions for oneself or family members, better working opportunities, or study purposes. Forced migration can include coercion or obligation to flee from natural or human-made disasters, extreme poverty, religious, sexual or political persecution, generalised violence, or armed conflicts such as civil war (IOM 2018a; Moore 2004; Nuscheler 2013; Schouler-Ocak 2017). However, making a clear-cut distinction between forced and voluntary migration is not always feasible, since the complexity of individual experiences are often on a forced-voluntary continuum (Erdal 2018).

Independent from reasons for peoples' movement, migration is a life-changing experience that affects individual biographies, his or her family development, and shapes several following generations.

Migration includes risks and opportunities in social and economic conditions, as well as health (Razum 2008). Poor socio-economic environments and living conditions, limited access to educational opportunities, and psychological stresses such as chronic work hazards are well examined causal factors leading to health inequalities (Marmot 2005). These factors can have a particularly strong impact on migrants' health because language barriers, racial discrimination or limited health systems knowledge are significant challenges to health improvement and preservation, and recovery from illness (Derose 2007; Harris 2006; Masseria 2010; Timmins 2002). Although migrants are often, at least initially, relatively healthy compared to most people in the host country, international studies indicate that immigrants and refugees tend to be vulnerable to poor mental health, certain communicable diseases such as tuberculosis and HIV/AIDS, and non-communicable diseases such as diabetes, injuries and maternal and child health problems (Goosen 2014; Kirmayer 2011; Lindert 2009; Rechel 2013; Yun 2012). Certain migration trajectories are linked to specific health adversities and rates of health care experienced before, during, and after migration. For example, among refugees escaping from civil war the migration process can be accompanied by violence, exploitation by human traffickers, hunger, and infectious diseases (IOM 2013; United Nations 2017). Furthermore, accessing affordable high-quality healthcare in the host country can vary among health care systems and may depend on the legal status of the migrant (Bozorgmehr 2016; Rechel 2013; WHO 2010).

Although differing in intensity, gender differences occur in all cultures and can be of critical importance at all stages of the migratory process. However, certain health risks are more common among women (e.g. sexual violence and abuse, human trafficking, or risks around childbirth and pregnancy), whereas accidents, physical stress or work hazards affect men more commonly (Douki 2007; Llácer 2007; Malmusi 2010; Schouler-Ocak 2017). These circumstances can influence why people need health information, and affect how health information is accessed, processed and translated into health-related action.

Research on health literacy indicates that having a migrant background might not be the sole issue (Ganahl 2016), but seems likely to function as a multiplier in creating health inequalities. Health literacy has a social gradient, including social status, education, income, and age (Berkman 2011; HLS-EU Consortium 2012; Schaeffer 2017; Quenzel 2016). Some of these factors can be even more pronounced in the context of migration. However, generalising assumptions on migrants' health literacy should be avoided, as people differ in their experiences, educational background, socioeconomic resources, and in their health status.

Considering equity in health literacy

A lack of evidence on equity has been described as a barrier to use of systematic reviews by health-decision makers (Welch 2015). Considering equity in systematic reviews on health literacy is therefore of high importance for the effective implementation of health literacy interventions. Equity is defined as "the absence of avoidable and unfair inequalities in health" (Welch 2012; Whitehead 1992). The emphasis of this concept is on the avoidance of unfair differences in health and related outcomes among individuals in a population and among different population groups. Differences in health across certain socio-demographic characteristics, including age, sex and gender, or ethnicity, can be caused by discrimination or inadequate access to health care services, which hinders people from preserving and regaining health (Welch 2015).

The integrated model of health literacy developed by Sørensen 2012 (see Description of the condition) draws attention to the importance of equity in health literacy research across individuals and populations. The integrated model will serve as an equity model for this review because it includes relevant personal determinants such as gender and race, socio-economic status and education, situational variables (e.g. the current physical environment), and culture as societal and environmental determinants of health literacy. The term *race*, albeit a scientifically unjustifiable concept (Williams 1997), that is used inconsistently throughout the literature (Williams 1994; Kaplan 2003), is often applied to denote immigrant groups such as so-called Hispanics/Latinos/Latinas (López 2010). If this term is accompanied by information that the person who was categorised by race is a migrant, we will use the term race (or the synonymous term 'ethnicity') as a personal determinant of health literacy. Thus, migration can be integrated in the model as a personal (i.e. race or ethnicity), situational (i.e. pre-, peri-, and post-migration status), or societal and environmental factor (i.e. culture) to determine health literacy.

We will follow the PRISMA-Equity (PRISMA-E) reporting guidelines for systematic reviews to acknowledge equity as an important determinant of health (Welch 2012; Welch 2015).

Description of the intervention

This review will assess different interventions with the purpose of improving individual health literacy in migrants or outcomes associated with at least one of the four health information processing steps from the integrated health literacy model developed by Sørensen 2012. These may include community-based health-related interventions, such as community education or schooling programs, and individual-based health-related interventions such as online provision of information, personal (face-to-face) provision of information, or others. Interventions can be delivered by any person involved in the health care or social work field and working closely with migrants and their descendents. Furthermore, the outcomes of these interventions should be measured using either an established assessment tool for health literacy as a construct, or an assessment tool that is capable of measuring the outcomes of the respective processing step that are targeted in the intervention. Health literacy could be assessed using remote (e.g. online, telephone) or face-to-face questionnaires or surveys. Interventions for improving health literacy that target health care providers, services or information materials rather than the consumer, will be included only if the effects of such interventions are directly measured in female and male migrants (How the intervention might work). We will focus on interventions targeting individual health literacy. Broader interventions that address the health literacy environment solely, such as health literacy toolkits for health systems (Dodson 2015), or approaches to create health literate health care organisations exist (Brach 2012), but are beyond the scope of this review.

How the intervention might work

Specific design features of interventions targeted for low-health-literacy populations (e.g. presenting essential information first, presenting information in simple language or formats, or substantiated by video or illustrated narratives) have been shown to be effective in terms of improving comprehension of information. Furthermore, multiple interventions such as intensive self- and disease-management or adherence interventions, have shown promise to mitigate the effects of limited health literacy with regard to reduced emergency department visits and hospitalisations, and reduced disease prevalence (Berkman 2011; Sheridan 2011). A recent meta-analysis indicated that on average health literacy interventions significantly improved participants' health literacy (22%) and treatment adherence (16%) among those who participated in a health literacy intervention compared to those who did not. However, particular methodological and measurement moderators greatly affected the effect sizes of health literacy interventions on participants' level of health literacy. For instance, subjective health literacy measures showed higher effect sizes over objective measures and health literacy improvements were higher when participants self-assessed their health literacy compared to assessment by a clinician or other members of the clinical team (Miller 2016). Therefore, conclusions have to be drawn carefully, since the effects may be highly variable within the included studies.

Apart from interventions that aim to improve health literacy in a general sense, we will also include interventions that target at least one of the four steps of health information processing. Pathways for these interventions may include empowering people by strengthening their skills in accessing, understanding, appraising or applying health information. For example, a web navigation training intervention (imparting knowledge) has been shown to improve health information search strategies of people living with HIV/AIDS, thereby focusing on the improved ability to search for and find online information (Kalichman 2006). Reproductive health knowledge was strengthened by a health education intervention that aimed to improve understanding of health information (Mbizvo 1997). The appraisal of such information was enhanced by matching content presentation to the control health locus for recipients (Williams-Piehota 2004). Individually tailored information on behavioural change increased cholesterol screening rates and physical activity (Kreuter 1996).

A successful interaction with health care providers is dependent on the communication skills of the patient on the one hand (e.g. language proficiency) and those of the health care professionals on the other hand (e.g. use of plain language and taking time for explanation). Therefore, another pathway for improving migrant's health literacy can include improving health care providers' communication skills, rather than educating the individual migrants themselves. Such interventions can indirectly improve health literacy skills and in turn health-related outcomes through a patient-provider communication that is respectful and tailored to the patient's health literacy needs. For instance, Tavakoly 2018 found that health provider communication skills training significantly improved patient communication skills, self-efficacy, adherence to medication, and hypertension outcomes.

Beauchamp 2017 developed a three-step approach that identified health literacy issues of health professionals or consumers; developed appropriate interventions; and implemented, evaluated and improved these interventions by using Plan-Do-Study-Act (PDSA) cycles. Successful interventions involved one of the following four pathways: improvement of clinician skills and resources for health literacy, the active engagement of community volunteers to disseminate health promotion messages, the direct impact on consumers' health literacy, and the redesign of existing health care services. Such studies indicate that an individual's health literacy can be improved through both direct and indirect means.

Why it is important to do this review

Research on migrants' health is highly relevant to gain a better understanding of migrants' specific health care needs, and how to respond best and most efficiently to these needs. Understanding the effectiveness of available interventions and pathways through which they have their effects is of great interest for decision-makers in health care systems, who face the challenge of rolling out interventions for improving health literacy across populations. Furthermore, it is important to identify effective approaches for improving access, understanding, appraisal and application of health information by migrants, since an appropriate response to health care needs entails the proper application of the health information found. However, people with limited health literacy skills face considerable barriers in accessing high quality health information, understanding, appraising, and applying the information for their own health care decisions and behaviours (Friis 2016; HLS-EU Consortium 2012; Schaeffer 2017). These and other challenges should be identified in the research on migrants' health literacy to ensure equitable and humane health care systems on the one hand, and empowered individuals on the other hand.

There is no prior Cochrane effectiveness review on migrants' health literacy. There is a published Cochrane effectiveness review on interventions for improving consumers' online health literacy (Car

2011), and a published Cochrane protocol on interventions improving health literacy in people with kidney disease (Campbell 2016). However, we do not expect overlap among the reviews because health literacy is defined differently in each, and the phenomena and populations under study differ greatly.

Research on health literacy has the overarching aim of establishing common understanding of health literacy, informing development of appropriate assessment tools, and effective interventions to improve health literacy. Health literacy measurement is evolving and most international research is targeted to assess individuals' ability to function in the health care environment, mostly measuring functional health literacy (i.e. reading and writing abilities in the medical context) and neglecting procedural characteristics of the four health information processing steps in other than clinical settings (Guzys 2015; Haun 2014). Particularly, the theory-driven approach of applying the integrated model of health literacy as an umbrella framework to assess the effectiveness of interventions that address the four health information processing steps, has not yet been determined. This review can therefore contribute to a more profound understanding of health literacy as a multidimensional construct by identifying effective pathways and design features of interventions targeted for migrants that address the relevant health information processing steps sufficiently. As a result, evidence found in this review can aid the development of new interventions, which enable the improvement of health literacy equally and effectively across populations. Thus, we expect these findings to have relevant implications for different states and their health care systems, particularly in western, industrialised countries, that have experienced great waves of migration in recent years.

OBJECTIVES

- To assess the effectiveness of interventions for improving health literacy in migrants.
- To assess whether female or male migrants may respond differently to the identified interventions.

Such interventions must address health literacy either as a comprehensive construct or at least one of its four health information processing steps (access, understand, appraise, apply). However, we do not aim to equate general health literacy interventions that include a range of activities targeted to all of the four health information processing steps with interventions that aim to improve only one step (e.g. understand). We aim instead to create a comprehensive picture of the effect of health literacy interventions by applying the integrated model as an umbrella framework for a deductive analysis of the four steps of health information processing.

We will not restrict this review to specific settings or diseases because we aim to provide an overview of all available interventions for improving health literacy addressing migrant populations.

Extending this review with a qualitative evidence synthesis

The author team of this effectiveness review will conduct a qualitative evidence synthesis (QES) in parallel: *Gender differences in health literacy of migrants: a synthesis of qualitative evidence* (Aldin 2019). Since we expect that relatively few studies will explicitly aim to explore if female and male migrants respond differently to a selected health literacy intervention, or even contain data on female and male migrants that can be extracted separately, the QES will supplement the effectiveness review in terms of gender-specific aspects that can affect the health information processing steps. Additionally, it will attempt to identify factors associated with gender and migration that may play a role in the design, delivery and effectiveness of health literacy interventions for female and male migrants, as it may be able to identify other relevant determinants that cannot be explored by quantitative methods. The QES will be linked to the effectiveness review by using the conceptual framework of health literacy developed by Sørensen 2012. The synthesised evidence from the effectiveness review and the linked QES will ultimately validate the applicability of the integrated model by Sørensen 2012 in interventions for improving health literacy in migrants. On the basis of the joint results, we will develop a logic model that includes the identified factors that must to be taken into account in the development and delivery of health literacy interventions for female and male migrants. The author teams will continuously exchange on methodological issues and support each other within the review process.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs), cluster RCTs (trials in which groups of participants are randomised) (see Data collection and analysis), and quasi-RCTs (trials in which randomisation is attempted but subject to potential manipulation, such as allocating participants by day of the week, date or birth, or sequence of entry into trial). We anticipate that few, if any, RCTs will have been conducted in the context of health literacy and migration (e.g. if study populations include both migrants and non-migrants but not separately identified).

Types of participants

We will include migrants, referring to these people as immigrants, refugees, asylum seekers, wandering people and other individuals who migrated (first generation migrants). This corresponds with the definition by the International Organization for Migration (IOM), which states that migration is the "the movement of a person or a group of persons, either across an international border, or within a state. It is a population movement, encompassing any kind of movement of people, whatever its length, composition and causes; it includes migration of refugees, displaced persons, economic migrants, and persons moving for other purposes, including family reunification" (IOM 2018a). Thus, movement within a state will be considered as migration only if it is embedded within the movement of a population.

We will include adults aged 18 years or over. We will apply no gender or ethnicity restrictions. We will exclude trials if fewer than 80% of participants are adults, and if no subgroup data are available.

Studies that include only extractable data about individuals of established ethnic minority communities (e.g. Latino Americans in the USA), defined as descendants of migrants who have settled in the respective country at least one generation ago, will be excluded. If data for subgroups, who are explicitly designated as first generation migrants can be extracted, the study will be included. We will include studies in which at least 80% of participants are migrants according to our definition. If no clear distinction between ethnic minority group and the migrant status according to our definition can be made (e.g. whether it is not stated which migrant generation is targeted), the study will be excluded.

Types of interventions

Eligible studies for inclusion can entail, for instance, interventions that aim to:

- improve health literacy in different settings (e.g. group-based education programs for pregnant women on post-partum care in an immigrant community);
- improve health literacy in hard-to-reach groups (e.g. telephone interventions to improve patients' engagement in disease management);
- improve health professionals' communication skills in consulting patients with low literacy skills (e.g. teach-back training, if the effect was measured in migrants);
- improve access to health information (e.g. access to telemedicine in rural areas);
- improve knowledge or understanding of information about health, disease or treatment (e.g. mitigate effects of limited language proficiency through the provision of information in different languages);
- affect the appraisal of health information (e.g. by individually tailoring the information provided); and
- improve the use of health information (e.g. providing information to support antibiotic treatment adherence).

For the main analysis, we will include health literacy interventions that are explicitly named as such. Such interventions can address health literacy either as a general concept, or at least one of its four health information processing steps (access, understand, appraise and apply).

For the secondary deductive analysis, we will include health literacy interventions that address at least one of the four health information processing steps, even if they are not explicitly named as such, so long as the addressed processing step can be assigned to health literacy as an umbrella concept. For example, if a study reports a 'health literacy intervention' as simply providing an information pamphlet on an available health service and reports a health literacy measure, we will include the study, but it will most likely not be suitable for the main analysis, since the effect cannot be assigned to health literacy as a general concept. This study will rather be included in the deductive analysis, as the intervention targets only the health information processing step 'access'. We will also include the study in the deductive analysis, if the pamphlet is targeted to individuals with limited language proficiency and the effect that is measured is the level of understanding that these individuals achieve regarding the information provided. In this case, the intervention will be assigned to the processing step of 'understand' in the deductive analysis.

We will exclude interventions that solely address the health literacy environment, i.e. interventions that focus on health care organisations or health systems without measuring the effect of these interventions on migrants' health literacy.

Types of comparisons

The types of comparisons will include the following:

- health literacy intervention versus no intervention (including usual care); and
- health literacy intervention versus another health literacy intervention.

Types of outcome measures

Outcome categories refer to empirically indicated associations of health literacy with the respective outcome category (Berkman 2011; HLS-EU Consortium 2012; Paasche-Orlow 2007; Paasche-Orlow 2005; Sheridan 2011). Applied health literacy assessment tools can be either performance-based or perception-based (self-assessment). We will prioritise validated (health literacy) assessment tools in preference to non-validated assessment tools. However, we will not exclude studies based on whether the assessment tool used has been validated or not.

If single trials report more than one outcome that maps to the same category we will list all reported outcomes. If an outcome is measured in more than one way in a single trial (e.g. pill count, prescription refill, self-report), we will report these outcomes narratively for each included study, but we will prioritise objective outcome measures (e.g. blood glucose level, pill count) in preference to subjective outcome measures (e.g. self-reported medication taking). All outcomes reported in the included studies will be assigned independently to the review's outcome categories. Any differences in categorisation will be resolved by the involvement of a third review author. We will conduct a meta-analysis if at least two studies measure the same outcome in the same way (see Data synthesis). If more than one outcome per category per trial is eligible for meta-analysis, we will prioritise objective measures in preference to subjective measures so to not double-count data for the same outcome category for the same population in one analysis.

Primary outcomes

Primary outcomes include:

- Health literacy.
- Adverse events associated with the intervention (e.g. anxiety, stigmatisation).

Secondary outcomes

Secondary outcomes include:

- Quality of life.
- Health outcome (e.g. severity of disease, subjective health status, depression).
- Health behaviour (e.g. use of preventive measures, smoking rate, medication adherence).
- Health-related knowledge (e.g. disease-specific knowledge).
- Health service use (e.g. use of emergency room services, hospitalisation rate).
- Individual skills (e.g. self-efficacy, self-awareness).
- Health care costs.

Main outcomes for 'Summary of findings' table:

- Health literacy;
- Adverse events associated with the intervention (e.g. anxiety, stigmatisation);
- Quality of life;
- Health outcome (e.g. severity of disease, subjective health status, depression);
- Health behaviour (e.g. use of preventive measures, exercising rate, medication adherence);
- Health service use (e.g. use of emergency room services, hospitalisation rate);
- Health-related knowledge (e.g. disease-specific knowledge); and
- Individual skills (e.g. self-efficacy, self-awareness).

Timing of outcome assessment

We will include all time points of outcome assessment in this review and categorise them into short-, medium-, and long-term time points, if applicable.

Search methods for identification of studies

Electronic searches

We will adapt search strategies as suggested in Chapter Six of the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2011). The search strategy will be developed by an information specialist in consultation with the review authors. The concept of health literacy has evolved continuously since its first mention in 1974. Thus, we will search for studies that measure health literacy as a comprehensive concept, or one of its processing steps, even if these are not explicitly mentioned as such in the respective study. We will include full-text articles and publications available as abstracts only if sufficient information is available on study design, characteristics of participants, and interventions provided.

We will search the following electronic databases:

- The Cochrane Central Register of Controlled Trials (CENTRAL, the*Cochrane Library*) (Appendix 1);
- MEDLINE (OvidSP) (Appendix 2);
- PsycINFO (OvidSP) (Appendix 3) and
- CINAHL (EBSCO) (Appendix 4).

The search strategy contains a study filter for RCTs and will be adapted to each database. No date, language or geographic restrictions will be applied for the search.

Searching other resources

We will search reference lists of included studies and relevant systematic reviews.

We will also search online trials registers for ongoing and recently completed studies:

- ClinicalTrials.gov;
- WHO International Clinical Trials Registry Platform (ICTRP); and
- EU Clinical Trials Register.

We will also search conference proceedings of the following conferences:

- International Conference for Migration and Development;
- First World Congress on Migration, Ethnicity, Race And Health (MERH);
- European Public Health Conference (EUPH); and
- The Migration Conference.

Data collection and analysis

Selection of studies

Two review authors will independently screen all titles and abstracts identified from searches to determine which meet the inclusion criteria. We will retrieve the full text of any papers identified as potentially relevant by at least one review author. Two review authors will independently screen full text articles for inclusion or exclusion, with discrepancies resolved by discussion, and if necessary, by consultation with a third review author to reach consensus (Higgins 2011). All potentially-relevant papers excluded from the review at this stage will be listed as excluded studies, with reasons provided in the 'Characteristics of excluded studies' table. We will document the process of study selection in a flow chart, as recommended by the PRISMA statement (Liberati 2009), showing total numbers of retrieved references and numbers of included and excluded studies. We will also provide citation details and any available information about ongoing studies, and collate and report details of duplicate publications, so that each study (rather than each report) is the unit of interest in this review.

Data extraction and management

Two review authors will extract data independently from included studies. Any discrepancies will be resolved by discussion until consensus is reached, or through consultation with a third review author where necessary. We will develop and pilot a data extraction form using the Cochrane Consumers and Communication Review Group Data Extraction Template (available at: http://cccrg.cochrane.org/author-resources). The data extraction form will be pilot tested with the first five included studies, and refined as necessary.
Data to be extracted will include:

- General information: author, title, source, publication date, country, language, duplicate publications
- Quality assessment (risk of bias): allocation concealment, blinding (participants, personnel, outcome assessors), incomplete outcome data, selective
- outcome reporting, other sources of bias (e.g. methods of measurements)
- Study characteristics: trial design, aim of the intervention, setting and dates, source of participants, inclusion/exclusion criteria, random sequence generation, selective recruitment of cluster participants, subgroup analysis, treatment
- cross-overs, compliance with assigned intervention, length of follow-up, details of control group characteristics e.g. recruitment and selection strategy, types of comparisons (e.g. waiting list control).
- Participant characteristics: age, gender, ethnicity, number of participants recruited/allocated/evaluated, participants lost to follow-up, type of intervention
- Outcomes: primary outcomes: health literacy and adverse events; secondary outcome categories: quality of life, health outcome, health behaviour, health-related knowledge, health service use, individual skills, health care costs
- Data extraction by outcome: use of validated assessment tool, timing of outcome assessment
- Funding: details of the funding source, declaration of interests for the primary investigators

All extracted data will be entered into RevMan 5 (Review Manager 2014) by one review author, and will be checked for accuracy against the data extraction sheets by a second review author working independently. We will contact authors of individual studies to ask for additional information if required.

Assessment of risk of bias in included studies

We will assess and report on the methodological risk of bias of included studies in accordance with the Cochrane *Handbook* (Higgins 2011), and Cochrane Consumers and Communication guidelines (Ryan 2013), which recommend the explicit reporting of the following individual elements for RCTs: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data, selective outcome reporting; and other sources of bias such as health literacy measurement (e.g. social desirability in self-assessment tools). We will consider blinding separately for different outcomes where appropriate (for example, blinding may have the potential to differently affect subjective versus objective outcome measures). We will judge each item as being at high, low or unclear risk of bias as set out in the criteria provided by Higgins 2011, and provide a quote from the study report and a justification for our judgement for each item in the risk of bias table.
Studies will be deemed to be at the highest risk of bias if they are scored as at high or unclear risk of bias for either the sequence generation or allocation concealment domains, based on growing empirical evidence that these factors are particularly important potential sources of bias (Higgins 2011). We will assess and report quasi-RCTs as being at a high risk of bias on the random sequence generation item of the risk of bias tool. For cluster-RCTs we will also assess and report the risk of bias associated with an additional domain: selective recruitment of cluster participants.
In all cases, two review authors will independently assess the risk of bias of included studies, with any disagreements resolved by discussion to reach consensus. We will contact study authors for additional information about the included studies, or for clarification of the study methods as required. We will incorporate the results of the risk of bias assessment into the review through standard tables, and systematic narrative description and commentary about each of the elements, leading to an overall assessment the risk of bias of included studies and a judgment about the internal validity of the review's results.

Measures of treatment effect

For dichotomous outcomes, we will analyse data based on the number of events (e.g. mortality, hospitalisation rates) and the number of people assessed in the intervention and comparison groups. We will use these to calculate the risk ratio (RR) and 95% confidence interval (CI). Where continuous scales of measurement are used (e.g. health literacy measurement, length of hospital stay) we will analyse data based on the mean, standard deviation (SD) and number of people assessed for both the intervention and comparison groups to calculate mean difference (MD) and 95% CI. If the MD is reported without individual group data, we will use this to report the study results. If more than one study measures the same outcome using different tools, we will calculate the standardised mean difference (SMD) and 95% CI using the inverse variance method in RevMan 5.

Unit of analysis issues

We will check for unit-of-analysis errors if cluster-RCTs are included. If errors are found, and sufficient information is available, we will re-analyse the data using the appropriate unit of analysis, by taking account of the intra-cluster correlation (ICC). We will obtain estimates of the ICC by contacting authors of included studies, or impute them using estimates from external sources. If it not possible to obtain sufficient information to re-analyse the data, we will report effect estimates and annotate as unit-of-analysis error.

Dealing with missing data

We will attempt to contact study authors to obtain missing data (participant, outcome, or summary data). For participant data, where possible we will conduct analysis on an intention-to-treat basis, otherwise data will be analysed as reported. We will report on losses to follow-up and assess this as a source of potential bias. For missing outcome or summary data we will impute missing data where possible and report any assumptions in the review. We will investigate, through sensitivity analyses, the effects of any imputed data on pooled effect estimates.

Assessment of heterogeneity

Where studies are considered to be similar enough to allow pooling of data using meta-analysis (based on consideration of migration status, health literacy interventions or gender), we will assess the degree of heterogeneity by visual inspection of forest plots and by examining the Chi² test for heterogeneity. We will report our reasons for deciding that studies were similar enough to pool statistically. Heterogeneity will be quantified using the I^2 statistic. An I^2 value of 50% or more will be considered to represent substantial heterogeneity, but this value will be interpreted in light of the size and direction of effects and the strength of the evidence for heterogeneity, based on the P value from the Chi² test (Higgins 2011). Where heterogeneity is present in pooled effect estimates we will explore possible reasons for variability by conducting subgroup analysis.

Where we detect substantial clinical, methodological or statistical heterogeneity across included studies we will not report pooled results from meta-analysis but will instead use a narrative approach to data synthesis. In this event, we will clearly report our reasons for deciding that studies were too dissimilar to meta-analyse. We will also attempt to explore possible clinical or methodological reasons for this variation by grouping studies that are similar in terms of migrant populations, host countries, intervention features, methodological features, or other factors to explore differences in intervention effects.

Assessment of reporting biases

We will assess reporting bias qualitatively based on the characteristics of the included studies (e.g. if only small studies that indicate positive findings are identified for inclusion), and if information obtained from contacting experts and authors of studies suggests there are relevant unpublished studies.

If we identify sufficient studies (at least 10) for inclusion in the review, we will construct a funnel plot to investigate small study effects, which may indicate the presence of publication bias. We will formally test for funnel plot asymmetry, with the choice of test made based on advice from the Cochrane *Handbook* (Higgins 2011), and bearing in mind there may be several reasons for funnel plot asymmetry when interpreting the results.

Data synthesis

We will decide to meta-analyse data based on whether the interventions in the included trials are similar enough in terms of participants, settings, intervention, comparison and outcome measures to ensure meaningful conclusions from a statistically pooled result. Due to the anticipated variability in different migrant populations, health literacy and outcome measurements, and health literacy interventions of included studies, we will use a random-effects model for meta-analysis.

If we are unable to pool data statistically using meta-analysis, we will provide clear reasons for this decision, and will group data based on the category that best explores the heterogeneity of studies and makes most sense to the reader (i.e. by interventions, migrant populations or outcomes). We will present data in tables and narratively summarise the results for each category.

Subgroup analysis and investigation of heterogeneity

If possible, we will conduct subgroup analyses for gender, ethnicity, and health literacy assessment (if named as such) (Objectives). Since health literacy can be defined and measured in different ways we will conduct a subgroup analysis for the different measurement tools applied in the included studies. Health literacy assessment tools may include performance-based assessment tools such as the Rapid Estimate of Adult Literacy in Medicine (REALM) (Davis 1991), that measure reading and writing abilities in the medical context. Perception-based assessment tools such as the Health Literacy Questionnaire (HLQ) (Osborne 2013), or the European Health Literacy Questionnaire (HLS-EU-Q) (Sørensen 2013), measure self-reported health literacy, including, for instance, the assessment of self-perceived difficulties in processing health information with regard to health promotion, disease prevention, and disease management (Sørensen 2013).

Sensitivity analysis

If meta-analysis is possible, we will conduct a sensitivity analysis for high risk and low risk of bias studies (see Assessment of risk of bias in included studies).

'Summary of findings' table

We will prepare a 'Summary of findings' table to present the results of meta-analysis and/or narrative synthesis for the major comparisons of the review, for each key outcome including potential harms, as (see Types of outcome measures). We will provide a source and rationale for each assumed risk cited in the table(s), and will use the GRADE criteria to rank the quality of the evidence based on the methods described in chapter 11 of the Cochrane *Handbook (*Schünemann 2011), using GRADEpro GDT software. If meta-analysis is not possible, we will present results as a narrative in a 'Summary of findings' table.

Involvement of consumers

This review is part of an overarching project which aims to examine gender-specific health literacy in migrants by applying a mixed methods approach. The project is funded by the Federal Ministry of Education and Research in Germany.

The involvement of consumers is important to get a deeper understanding of the performance and effectiveness of the interventions in this review, particularly how they reach consumers. We will involve consumers by conducting additional qualitative research to support our review, and particularly the interpretation of our findings. We will conduct gender-separate focus group discussions with female and male migrants, in which we will present and discuss our findings in order to reflect on our analysis. The protocol and review will receive feedback from at least one consumer referee in addition to a health professional as part of Cochrane Consumers and Communication's standard editorial process.

In a final symposium of this project, we want to present our primary and secondary research findings to experts in the political and health care context, and discuss the impact and implications of our primary and secondary findings for health care decision-making at the political level particularly in Germany. We expect our findings to contribute to relevant political decisions for the health care of migrants in Germany, and also provide implications for other health care systems as well.

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* *Indicates the major publication for the study*

A P P E N D I C E S

Appendix 1. CENTRAL search strategy

#1 MESH DESCRIPTOR TRANSIENTS AND MIGRANTS EXPLODE ALL TREES
#2 migrant*
#3 migration* NEAR3 (background* or human*)
#4 MESH DESCRIPTOR EMIGRANTS AND IMMIGRANTS EXPLODE ALL TREES
#5 MESH DESCRIPTOR UNDOCUMENTED IMMIGRANTS EXPLODE ALL TREES
#6 MESH DESCRIPTOR EMIGRATION AND IMMIGRATION EXPLODE ALL TREES
#7 (immigrant* or immgrat*)
#8 (emigrant* or emigrat*)
#9 (minorit* NEAR3 (population* or group*))
#10 ethnic* NEAR3 (population* or group* or patient* or background* or specific* or minorit* or identit*)
#11 ethnic* NEAR3 (population* or group* or patient* or background* or specific* or minorit* or identit*)
#11 displaced and (people or person*)
#12 MESH DESCRIPTOR VULNERABLE POPULATIONS EXPLODE ALL TREES
#13 MESH DESCRIPTOR REFUGEES EXPLODE ALL TREES
#14 foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn
#15 cultur* NEAR5 (differences* or cross* or background*)
#16 cultur* NEAR5 (differences* or cross* or background*)
#16 (border* and crossing)
#17 (culturall* NEAR3 (diverse* or patient* or parent* or communit* or background* or student* or woman or women or famil*))
#18 linguisticall* NEAR3 (diverse* or patient* or parent* or communit* or background* or student* or woman or women or famil*)
#19 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18
#20 MESH DESCRIPTOR ACCESS TO INFORMATION EXPLODE ALL TREES
#21 (access or gain access or obtain or seek out or find or indentify) NEAR5 (information* or health*)
#22 MESH DESCRIPTOR COMPREHENSION EXPLODE ALL TREES
#23 understand or comprehend or comprehension
#24 appraise or evaluate or process or interpret or assess
#25 assessment of information
#26 apply or decide
#27 use* NEAR3 (information* or health)
#28 MESH DESCRIPTOR DECISION MAKING EXPLODE ALL TREES
#29 (make or making or made or take) NEAR4 decision*
#30 acting or act or action
#31 judge*
#32 #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31
#33 MESH DESCRIPTOR CONSUMER HEALTH INFORMATION EXPLODE ALL TREES
#34 MESH DESCRIPTOR INFORMATION LITERACY EXPLODE ALL TREES
#35 MESH DESCRIPTOR HEALTH LITERACY EXPLODE ALL TREES
#36 information* NEAR3 health*
#37 health* NEAR3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)
#38 #33 OR #34 OR #35 OR #36 OR #37
#39 MESH DESCRIPTOR HEALTH EDUCATION EXPLODE ALL TREES
#40 MESH DESCRIPTOR EDUCATIONAL STATUS EXPLODE ALL TREES
#41 health* NEAR3 education*
#42 MESH DESCRIPTOR HEALTH SERVICES ACCESSIBILITY EXPLODE ALL TREES
#43 #39 OR #40 OR #41 OR #42
#44 #32 and #38 or #43

#45 health litera*
#46 medical literacy
#47 ((health and literacy)):TI
#48 ((functional and health and literacy)):TI,AB,KY
#49 low-litera*
#50 litera*
#51 illitera*
#52 MESH DESCRIPTOR READING EXPLODE ALL TREES
#53 MESH DESCRIPTOR COMPREHENSION EXPLODE ALL TREES
#54 MESH DESCRIPTOR HEALTH PROMOTION EXPLODE ALL TREES
#55 MESH DESCRIPTOR HEALTH EDUCATION EXPLODE ALL TREES
#56 MESH DESCRIPTOR PATIENT EDUCATION AS TOPIC EXPLODE ALL TREES
#57 MESH DESCRIPTOR COMMUNICATION BARRIERS EXPLODE ALL TREES
#58 MESH DESCRIPTOR COMMUNICATION EXPLODE ALL TREES
#59 MESH DESCRIPTOR ATTITUDE TO HEALTH EXPLODE ALL TREES
#60 MESH DESCRIPTOR COMPREHENSION EXPLODE ALL TREES
#61 MESH DESCRIPTOR EDUCATIONAL STATUS EXPLODE ALL TREES
#62 #60 AND #61
#63 family and literacy
#64 drug labeling
#65 MESH DESCRIPTOR DRUG PRESCRIPTIONS EXPLODE ALL TREES
#66 comprehension
#67 (cancer or diabetes or genetics) and (literacy or comprehension)
#68 adult and (educational status or (educational and status) or literacy)
#69 (limited and (educational status or (educational and status) or literacy))
#70 (patient* and (educational status or (educational and status) or literacy))
#71 (patient* and (comprehension or understanding))
#72 #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53
#73 #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71
#74 #72 AND #73
#75 #19 and #44
#76 #19 and #74
#77 #19 and #44 or #74
#77 #75 or #76

Appendix 2. MEDLINE search strategy

searches
1 “TRANSIENTS AND MIGRANTS”/
2 migrant*.tw,kf,ot.
3 (migration* adj3 (background* or human*)).tw,kf,ot.
4 exp “EMIGRANTS AND IMMIGRANTS”/
5 UNDOCUMENTED IMMIGRANTS/
6 “EMIGRATION AND IMMIGRATION”/
7 (immigrant* or immgrat*).tw,kf,ot.
8 (emigrant* or emigrat*).tw,kf,ot.
9 (minorit* adj3 (population* or group*)).tw,kf,ot.
10 (ethnic* adj3 (population* or group* or patient* or background* or specific* or minorit* or identit*)).tw,kf,ot.
11 (displaced and (people or person$1)).tw.
12 VULNERABLE POPULATIONS/
13 REFUGEES/

14 (foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn).tw,kf,ot.
15 (cultur* adj5 (differences* or cross* or background*)).tw,kf,ot.
16 (border* and crossing).tw.
17 ((culturall* or linguisticall*) adj3 (diverse* or patient* or parent* or communit* or background* or student* or wom?n or famil*)).tw,kf,ot.
18 or/1-17
19 ACCESS TO INFORMATION/
20 ((access or gain access or obtain or seek out or find or identify) adj5 (information* or health*)).tw.
21 COMPREHENSION/
22 (understand or comprehend or comprehension).tw.
23 (appraise or evaluate or process or interpret or assess).tw.
24 assessment of information.tw.
25 (apply or decide).tw.
26 (use* adj3 (information* or health)).tw.
27 (capacit* adj4 health).tw.
28 accept*.tw,kf,ot.
29 DECISION MAKING/
30 ((make or making or made or take) adj4 decision*).tw.
31 (“behavior change” or “behaviour change”).tw,kf,ot.
32 (acting or act or action).tw.
33 judge*.tw.
34 or/19-33
35 exp CONSUMER HEALTH INFORMATION/ or INFORMATION LITERACY/
36 HEALTH LITERACY/
37 (information* adj3 health*).tw.
38 (health* adj3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)).tw.
39 or/35-38
40 HEALTH EDUCATION/ or EDUCATIONAL STATUS/
41 (health* adj3 education*).tw.
42 HEALTH SERVICES ACCESSIBILITY/sn [Statistics & Numerical Data]
43 or/40-42
44 34 and (39 or 43)
45 health litera$2.af.
46 medical literacy.af.
47 (health and literacy).ti.
48 (functional and health and literacy).tw.
49 low-litera$2.ti.
50 litera$2.ti.
51 illitera$2.ti.
52 READING/
53 COMPREHENSION/
54 *HEALTH PROMOTION/
55 *HEALTH EDUCATION/
56 *PATIENT EDUCATION/
57 *COMMUNICATION BARRIERS/
58 *COMMUNICATION/
59 *HEALTH KNOWLEDGE,ATTITUDES,PRACTICE/
60 *ATTITUDE TO HEALTH/
61 *COMPREHENSION/ and *EDUCATIONAL STATUS/
62 (family and literacy).ti.
63 (drug labeling.af. or DRUG PRESCRIPTIONS/) and comprehension.af.
64 ((cancer or diabetes or genetics) and (literacy or comprehension)).ti.

65 (adult and (educational status or (educational and status) or literacy)).af.
66 (limited and (educational status or (educational and status) or literacy)).af.
67 (patient$1 and (educational status or (educational and status) or literacy)).af.
68 (patient$1 and (comprehension or understanding)).ti.
69 or/45-53
70 or/54-68
71 69 and 70
72 18 and 44
73 18 and 71
74 18 and (44 or 71)
75 randomized controlled trial.pt.
76 controlled clinical trial.pt.
77 randomi?ed.ab.
78 placebo.ab.
79 drug therapy.fs.
80 randomly.ab.
81 trial.ab.
82 groups.ab.
83 or/75-82
84 exp ANIMALS/ not HUMANS/
85 83 not 84
86 74 and 85
87 from 86 keep 1-136

Key: tw: text word, kf: keyword heading word, ot: original title, ti: title, pt: publication type, ab: abstract, fs: floating subheading, hw: subject heading word, nm: name of substance word, sh: MeSH subject heading

Appendix 3. PSYCHINFO search strategy

Query
S74 S72 AND S73
S73 TX control OR TX random OR TX double-blind
S72 S18 and (S44 or S71)
S71 S69 and S70
S70 S54 or S55 or S56 or S57 or S58 or S59 or S60 or S61 or S62 or S63 or S64 or S65 or S66 or S67 or S68
S69 S45 or S46 or S47 or S48 or S49 or S50 or S51 or S52 or S53
S68 TI (patient* and (comprehension or understanding))
S67 SU (patient* and (educational status or (educational and status) or literacy))
S66 SU (limited and (educational status or (educational and status) or literacy))
S65 SU (adult and (educational status or (educational and status) or literacy))
S64 TI (cancer or diabetes or genetics) and (literacy or comprehension)
S63 SU (drug labeling or prescriptions, drugs) and comprehension
S62 TX family and literacy
S61 MA COMPREHENSION AND MA EDUCATIONAL STATUS
S60 MA “HEALTH PERSONNEL ATTITUDES”
S59 DE “HEALTH ATTITUDES”
S58 DE “HEALTH KNOWLEDGE” OR DE “HEALTH BEHAVIOR”
S57 DE COMMUNICATION
S56 DE COMMUNICATION BARRIERS
S55 DE HEALTH EDUCATION
S54 DE HEALTH PROMOTION
S53 DE COMPREHENSION
S52 DE READING

S51 TX illitera*
S50 TX literac*
S49 TX low-litera*
S48 TX functional and health and literacy
S47 TX health and literacy
S46 TX medical literacy
S45 TX health litera*
S44 S34 and (S39 or S43)
S43 S40 or S41 or S42
S42 MA HEALTH SERVICES ACCESSIBILITY
S41 TX health* N3 education*
S40 DE HEALTH EDUCATION OR (DE EDUCATION AND DE STATUS)
S39 S35 or S36 or S37 or S38
S38 TX health* N3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)
S37 TX information* N3 health*
S36 DE HEALTH LITERACY
S35 MA CONSUMER HEALTH INFORMATION OR DE INFORMATION LITERACY
S34 S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33
S33 TX judge*
S32 TX acting or act or action
S31 TX "behavior change" or "behaviour change"
S30 TX ((make or making or made or take) N4 decision*)
S29 DE DECISION MAKING
S28 TX accept*
S27 TX capacit* N4 health
S26 TX use* N3 (information* or health)
S25 TX apply or decide
S24 TX assessment of information
S23 TX appraise or evaluate or process or interpret or assess
S22 TX (understand or comprehend or comprehension)
S21 DE COMPREHENSION
S20 TX (access or gain access or obtain or seek out or find or indentify) N5 (information* or health*)
S19 MA "ACCESS TO INFORMATION"
S18 S1 or S2 or S3 Or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17
S17 TX (culturall* or linguisticall*) N3 (diverse* or patient* or parent* or communit* or background* or student* or woman or women or famil*)
S16 TX border* and crossing
S15 TX cultur* N3 (differences* or cross* or background*)
S14 TX (foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn)
S13 DE REFUGEES
S12 MA VULNERABLE POPULATIONS
S11 TX (displaced and (people or person*))
S10 TX ethnic* N2 (population* or group* or patient* or background* or specific* or minorit* or identit*)
S9 TX minorit* N2 (population* or group*)
S8 TX emigrant* OR TX emigrat*
S7 TX immigrant* OR TX immgrat*
S6 DE IMMIGRATION
S5 DE HUMAN MIGRATION
S4 MA "EMIGRANTS AND IMMIGRANTS"
S3 TX migration* N3 (background* or human*)
S2 TX migrant*
S1 MA "TRANSIENTS AND MIGRANTS"

Key: TX: all text, TI: title, DE: subject (exact), SU: subjects, MA: MeSH subject heading

Appendix 4. CINAHL search strategy

Query
S83 S80 AND S81
S82 S81
S81 S18 and (S44 or S70)
S80 S71 OR S72 OR S73 OR S74 OR S75 OR S76 OR S77 OR S78 OR S79
S79 TX ((singl* n1 blind*) or (singl* n1 mask*)) o(doubl* n1 blind*) or (doubl* n1 mask*) or (tripl* n1 blind*) or (tripl* n1 mask*) or (trebl* n1 blind*) or (trebl* n1 mask*)
S78 TX randomi?ed
S77 (MH “Random Assignment”)
S76 TX random* allocat*
S75 (MH “Randomized Controlled Trials”)
S74 TX placebo*
S73 (MH “Placebos”)
S72 (MH “Quantitative Studies”)
S71 TX allocat* random*
S70 S68 AND S69
S69 S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64 OR S65 OR S66 OR S67
S68 S45 or S46 or S47 or S48 or S49 or S50 or S51 or S52 or S53
S67 TI (patient* and (educational status or (educational and status) or literacy))
S66 MW (patient* and (educational status or (educational and status) or literacy))
S65 TI (limited and (educational status or (educational and status) or literacy))
S64 MJ (adult and (educational status or (educational and status) or literacy))
S63 TI (cancer or diabetes or genetics) and (literacy or comprehension)
S62 TX ((drug labeling or prescriptions, drug) and comprehension)
S61 TI family and literacy
S60 (MM “Educational Status”) AND TX comprehension
S59 (MM “Attitude to Health”)
S58 (MM “Health Knowledge”)
S57 (MM “Communication”)
S56 (MM “Communication Barriers”)
S55 (MM “Health Education”)
S54 (MM “Health Promotion”)
S53 TX comprehension
S52 MH READING
S51 TI illitera*
S50 TI litera*
S49 TI low-litera*
S48 TX functional and health and literacy
S47 TI health and literacy
S46 TX medical literacy
S45 TX health litera*
S44 S34 and (S39 or S43)
S43 S40 or S41 or S42
S42 (MH “Health Services Accessibility”)
S41 TX health* N3 education*
S40 (MH “Health Education”) OR (MH “Educational Status”)
S39 S35 or S36 or S37 or S38

S38 TX health* N3 (literac* or servic* or decision* or concept* or competenc* or system* or knowledg* or status or level* or needs or insurance or status or behaviour*)
S37 TX information* N3 health*
S36 (MH "Health Literacy")
S35 (MH "Consumer Health Information") OR (MH "Information Literacy")
S34 S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33
S33 TX judge*
S32 TX acting or act or action
S31 TX "behavior change" or "behaviour change"
S30 TX ((make or making or made or take) N4 decision*)
S29 (MH "Decision Making, Family") OR (MH "Decision Making, Patient")
S28 TX accept*
S27 TX capacit* N4 health
S26 TX use* N3 (information* or health)
S25 TX apply or decide
S24 TX assessment of information
S23 TX appraise or evaluate or process or interpret or assess
S22 TX understand or comprehend
S21 TX comprehension
S20 TX (access or gain access or obtain or seek out or find or identify) N5 (information* or health*)
S19 (MH "Access to Information")
S18 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17
S17 TX (culturall* or linguisticall*) N3 (diverse* or patient* or parent* or communit* or background* or student* or woman or women or famil*)
S16 TX border* and crossing
S15 TX cultur* N5 (differences* or cross* or background*)
S14 TX (foreigner* or asylum* or refugee* or undocumented or non-native or nonnative or foreign-born or foreignborn)
S13 (MH "Refugees")
S12 (MH "Population") AND (MH "Vulnerability")
S11 TX (displaced and (people or person*))
S10 TX ethnic* N3 (population* or group* or patient* or background* or specific* or minorit* or identit*)
S9 TX minorit* N3 (population* or group*)
S8 TX emigrant* OR TX emigrat*
S7 TX immigrant* OR TX immgrat*
S6 (MH "Emigration and Immigration")
S5 MH "Immigrants, Illegal"
S4 MH "EMIGRANTS AND IMMIGRANTS"
S3 TX migration* N3 (background* or human*)
S2 TX migrant*
S1 MH "TRANSIENTS AND MIGRANTS"
key: TX: all text, TI: title, MH: CINAHL exact subject heading, MM: CINAHL exact major subject headings, MJ: CINAHL word in major subject heading, MW: CINAHL heading word

CONTRIBUTIONS OF AUTHORS

Annika Baumeister developed and wrote the protocol.

Angela Aldin assisted in developing the protocol, proofread and commented on the draft.

Digo Chakraverty proofread and commented on the draft.

Ina Monsef developed the search strategies.

Tina Jakob proofread and commented on the draft.

Ümran Sema Seven provided expertise on migration research.

Görkem Anapa provided expertise on migration research.

Elke Kalbe proofread and commented on the draft.

Nicole Skoetz proofread and commented on the draft.

Christiane Woopen proofread and commented on the draft.

DECLARATIONS OF INTEREST

Annika Baumeister: Award of the grant by Federal Ministry of Education and Research for the University Hospital of Cologne to perform this systematic review does not lead to a conflict of interest.

Angela Aldin: Award of the grant by Federal Ministry of Education and Research for the University Hospital of Cologne to perform this systematic review does not lead to a conflict of interest.

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This protocol was developed in parallel, and in continuous exchange between Annika Baumeister (first author of this review) and Angela Aldin (first author of the linked Cochrane qualitative evidence synthesis).

Appendix 3: Declaration of an Oath (dt. Eidesstattliche Versicherung)

Hiermit versichere ich an Eides statt, dass ich die vorliegende Dissertationsschrift selbstständig und ohne die Benutzung anderer als der angegebenen Hilfsmittel angefertigt habe. Alle Stellen - einschließlich Tabellen, Karten und Abbildungen -, die wörtlich oder sinngemäß aus veröffentlichten und nicht veröffentlichten anderen Werken im Wortlaut oder dem Sinn nach entnommen sind, sind in jedem Einzelfall als Entlehnung kenntlich gemacht. Ich versichere an Eides statt, dass diese Dissertationsschrift noch keiner anderen Fakultät oder Universität zur Prüfung vorgelegen hat; dass sie - abgesehen von unten angegebenen Teilpublikationen - noch nicht veröffentlicht worden ist sowie, dass ich eine solche Veröffentlichung vor Abschluss der Promotion nicht ohne Genehmigung der / des Vorsitzenden des IPHS Promotionsausschusses vornehmen werde. Die Bestimmungen dieser Ordnung sind mir bekannt. Die von mir vorgelegte Dissertation ist von Prof. Dr. Christiane Woopen betreut worden.

Darüber hinaus erkläre ich hiermit, dass ich die Ordnung zur Sicherung guter wissenschaftlicher Praxis und zum Umgang mit wissenschaftlichem Fehlverhalten der Universität zu Köln gelesen und sie bei der Durchführung der Dissertation beachtet habe und verpflichte mich hiermit, die dort genannten Vorgaben bei allen wissenschaftlichen Tätigkeiten zu beachten und umzusetzen.

Übersicht der Publikationen:

Baumeister, A., Chakraverty, D., Aldin, A., Seven, Ü.S., Skoetz, N., Kalbe, E., & Woopen, C. (2021). “The system has to be health literate, too” - Perspectives among healthcare professionals on health literacy in transcultural treatment settings. *BMC Health Services Research*, 21, 716. https://doi.org/10.1186/s12913-021-06614-x

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