Promoting Health Literacy in Pregnant Women using a Lifestyle Intervention

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Zusammenfassung

Die Schwangerschaft ist eine einzigartige Zeit, in der eine Frau sowohl für ihre eigene Gesundheit als auch für die ihres ungeborenen Kindes verantwortlich ist. Lebensstilentscheidungen in der Schwangerschaft wie körperliche Aktivität, Ernährung, Alkoholkonsum und Rauchen beeinflussen die Gesundheit der Frau, was wiederum die Gesundheit und Entwicklung des Kindes beeinflusst. Daher ist es für schwangere Frauen entscheidend, ein gesundes und gesundheitsförderliches Verhalten zu entwickeln und beizubehalten. Ein Ansatz der dabei helfen kann ist die Verbesserung der Gesundheitskompetenz. Eine höhere Gesundheitskompetenz wirkt sich positiv auf das Verstehen und Anwenden von Gesundheitsinformationen aus und kann somit Gesundheitsverhalten verbessern. In der aktuellen Forschung fehlt es jedoch an Untersuchungen zur Gesundheitskompetenz bei Schwangeren.
Die vorliegende Arbeit schließt diese Lücke anhand von vier Dissertationsprojekten (DP). Es wurde eine Lebensstilintervention entwickelt, um die Gesundheitskompetenz von schwangeren Frauen als Teil der Schwangerschaftsvorsorge zu fördern. Die Ergebnisse der DPs bieten Diskussionsansätze für die Integration von gesundheitskompetenzsensibler Beratung in die Schwangerschaftsvorsorge.
DP 1 zeigt den aktuellen Forschungsstand zur Gesundheitskompetenz in der Schwangerschaft anhand eines systematischen Reviews. Hierbei wird das Niveau der Gesundheitskompetenz und Interventionen zur Verbesserung dieser bei schwangeren Frauen dargestellt.
DP 2 beschreibt die Entwicklung einer Lebensstilintervention (GeMuKi) und wie die Gesundheitskompetenz im Rahmen dieser Intervention adressiert wird.
DP 3 befasst sich mit der Entwicklung und Evaluation eines wissensbasierten Fragebogens zur Erhebung des Wissensstands schwangerer Frauen in Bezug auf Lebensstilthemen. Dies ist Teil der objektiven Erhebung der Gesundheitskompetenz im Rahmen der Lebensstilintervention.
DP 4 evaluiert die Effektivität der Lebensstilintervention (sowohl objektiv als auch subjektiv gemessen) auf die Verbesserung der Gesundheitskompetenz schwangerer Frauen.
Die Ergebnisse von DP 1 deuten darauf hin, dass Forschung im Bereich der Gesundheitskompetenz bei Schwangeren kaum vorhanden ist und dieses Gebiet mehr Aufmerksamkeit erfordert. Es fehlt an Studien, die die Gesundheitskompetenz messen und solche, die sie durch Interventionen verbessern. Die in DP 2 entwickelte Intervention beinhaltet eine umfassende Lebensstilberatung und ist in die regulären Vorsorgeuntersuchungen in der Schwangerschaft integriert. Als Teil der Intervention werden Schwangere aktiv in die Lebensstilberatung einbezogen um die Gesundheitskompetenz positiv zu beeinflussen. In DP 3 wird anhand des entwickelten Fragebogens mit insgesamt 8 Items das Wissen der Schwangeren zu Lebensstilthemen erhoben. Die Ergebnisse weisen Lücken zu bestimmten Lebensstilthemen auf. Dies betrifft Themen wie Stillen und empfohlene Gewichtszunahme während der Schwangerschaft, welche in der Beratung besondere Aufmerksamkeit brauchen. In DP 4 zeigt die Evaluation der Lebensstilintervention im Bereich Gesundheitskompetenz, dass Rund 66% die Studienteilnehmerinnen eine adäquate Gesundheitskompetenz haben. Die Intervention konnte die subjektiv gemessene Gesundheitskompetenz nicht verbessern, während ein signifikanter, positiver Effekt in der Verbesserung der objektiv gemessenen Gesundheitskompetenz erzielt wurde.

Summary

Pregnancy is a unique time during which a woman is responsible for both her own health and that of her unborn child. Lifestyle choices during pregnancy such as physical activity, diet, alcohol consumption and smoking affect a woman's health, which in turn affects the health and development of the child. It is thus crucial for pregnant women to develop and maintain healthy behaviors that promote good health. One approach that can help is improving health literacy. Increased health literacy has a positive impact on understanding and applying health information and thus can improve health behaviors. However, current research is lacking in terms of investigations into health literacy in pregnant women.

This dissertation fills this gap using four dissertation projects (DPs). A lifestyle intervention was developed to promote health literacy in pregnant women as part of prenatal care. The results of the DPs offer discussion approaches for integrating health literacy-sensitive counseling into prenatal care.

DP 1 presents the current state of research on health literacy in pregnancy using a systematic review. Here, the level of health literacy and interventions to improve it in pregnant women are presented.

DP 2 describes the development of a lifestyle intervention (GeMuKi) and how health literacy is addressed within this intervention.

DP 3 addresses the development and evaluation of a knowledge-based questionnaire to assess pregnant women's knowledge on lifestyle topics. This forms part of the objective health literacy assessment in the lifestyle intervention.

DP 4 evaluates the effectiveness of the lifestyle intervention (measured both objectively and subjectively) on improving pregnant women's health literacy.

The results of DP 1 suggest that research in health literacy among pregnant women is scarce and requires more attention. There is a lack of studies that measure health literacy and efforts to improve it through interventions. The intervention developed in DP 2 includes a comprehensive lifestyle counseling and is integrated into the regular antenatal appointments. As part of the intervention, pregnant women are actively involved in the lifestyle counseling to positively influence health literacy. In DP 3, the developed questionnaire with a total of eight items is used to assess pregnant women's knowledge on lifestyle topics. The results show gaps on certain lifestyle topics. This concerns topics such as breastfeeding and recommended weight gain during pregnancy, which need special attention in counseling. In DP 4, the evaluation of the lifestyle intervention regarding health literacy shows that approximately 66% of the study participants had adequate health literacy. The intervention was not able to improve subjectively measured health literacy, while a significant, positive effect was achieved in improving objectively measured health literacy.

List of Abbreviations

AMA	American Medical Association
AXIS	Appraisal tool for Cross-Sectional Studies
BHLS	Brief Health Literacy Screener
BMI	Body-Mass-Index
CI	Confidence Interval
DP	Dissertation Project
GEE	generalized estimating equations
GeMuKi	Gemeinsam Gesund: Vorsorge plus für Mutter und Kind
GWG	Gestational Weight Gain
HbA1c	Hemoglobin A1c
HLS-EU-Q	European Health Literacy Survey Questionnaire
IOM	Institute of Medicine
MI	Motivational Interviewing
NAM	National Academy of Medicine
OR	Odds Ratio
RCT	Randomized-Controlled-Trial
RoB	risk-of-bias tool for randomized trials
SMART	Specific, Measurable, Achievable, Reasonable, Time-Bound
t(x)	point of time (x)
WHO	Word Health Organization
ß	regression coefficient
Δ	difference

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CHAPTER 1

Introduction

1. Introduction

Health literacy is a concept that has been discussed frequently in recent decades and has become central in both health research and health policy [1,2]. The term refers to a person's ability to access, understand, appraise, and apply health information in order to make decisions relating to healthcare, disease prevention and health promotion [3]. Despite the availability and accessibility of health information, considerable parts of the population still possess inadequate health literacy. This is the result of a multinational study revealing that 12% of the respondents possess inadequate and 47% limited health literacy, with major differences across countries [4]. This has major implications on healthcare, since limited health literacy is associated with insufficient self-management and worse health outcomes in chronic diseases [5]. Individuals with limited health literacy have more emergency department visits, more and longer hospital stays, worse outcomes in healthcare, and utilize preventive services less [6].

Research on this topic began with assessments of the health literacy levels of various patient groups, and eventually evolved into the development of interventions aimed at positively impacting health literacy. The patient groups on which this work focuses are usually elderly people, individuals with chronic diseases, children and adolescents. To date, pregnant women as a group have not received adequate attention with regard to their health literacy levels. This is striking, since pregnancy is an important time for women due the unique situation of them having to care for both themselves and for the fetus, the latter through a process called perinatal programming. During perinatal programming, external factors such that impact a woman's health (e.g. lifestyle choices) also influence the health and growth of the fetus. Since health literacy impacts health behavior, it is important to ensure that pregnant women possess adequate health literacy. There are few existing studies that assess the health literacy levels of pregnant women, and intervention studies aimed at improving health literacy are scarce [7]. Existing studies utilize subjective measures of health literacy, which limits the validity of their results. There is a lack of objective health literacy measures in these studies, particularly those that focus on lifestyle knowledge of pregnant women. Insights into lifestyle knowledge can be used as indicators of pregnant women's health behavior, which impacts the health of their unborn child.

One lifestyle intervention that does aim to improve understanding of lifestyle topics during pregnancy, and hence health literacy, is GeMuKi (acronym for 'Gemeinsam Gesund: Vorsorge plus für Mutter und Kind'—Strengthening health promotion: enhanced check-up visits for mother and child) [8]. In this intervention study, pregnant women received additional counseling on lifestyle topics during pregnancy from their gynecologist and, where applicable, their midwife. The counseling was aimed at improving health literacy in order to help women make healthy behavior choices.

The aim of this dissertation is to analyze whether a lifestyle intervention improves health literacy levels among pregnant women. Chapter 2 offers a theoretical background, which forms the basis of the research questions. Chapter 3 outlines the aims and objectives, while Chapter 4 describes the methods used in each dissertation project. Chapter 5 illustrates the state of the art with regard to research on health literacy among pregnant women in the form of a systematic review. Chapter 6 provides a study protocol on the GeMuKi study, as well as its influence and assessment of health literacy. Chapter 7 explains the development and evaluation of a questionnaire aimed at assessing lifestyle knowledge among pregnant women. Chapter 8 analyzes whether a lifestyle intervention (GeMuKi) improves health literacy levels among pregnant women. The methods and main findings are discussed in Chapter 9, while Chapter 10 provides a conclusion to this dissertation.

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CHAPTER 2

Theoretical Background

2. Theoretical Background

2.1. The Evolution of the Definition of Health Literacy

Initial discussions of health literacy focused on the individual's ability to understand medical information provided by health professionals in order to improve compliance. This led to the clinical understanding of 'functional health literacy', which focused on the significance of literacy with regards to healthcare [1, 2]. At the turn of the millennium, health literacy was detached from the clinical context by the World Health Organization (WHO) and moved to a public health approach, in people's everyday lives under the premise of prevention and health promotion. The concept subsequently expanded in complexity to encompass individual skills and resources for health-related actions and behaviors in a variety of contexts. As a result, some approaches now focus on the individual's skills, while others concentrate primarily on literacy, and others still incorporate broader cognitive, social, and psychological characteristics into their understanding of the term. At some times, health literacy is related exclusively to the understanding of health information; at others, it is expanded to include motivation and action implementation by individuals or institutions.

While health literacy has been discussed in recent decades and has become a central concept in both health research and health policy, there is still no ultimate consensus on how it is best defined. Broadly speaking, it concerns the ability of an individual to make health decisions in their day-to-day life [3]. However, even today, there is no common definition of the term; this is in line with Paasche-Orlow and colleagues, who concluded that clarifying health literacy and its relation to health is an iterative process [4]. Some of the most frequently used and more elaborate definitions applied in past works stem from the American Medical Association (AMA) [5], the National Academy of Medicine (NAM; formerly known as Institute of Medicine (IOM)) [6] and the WHO [7]. Although each institution's definition varies, one common aspect is that they all concern the individual's capacity to "obtain, process and understand health information and services necessary to make appropriate health decisions" [8]. The lack of one consistent definition and theoretical basis has led to the use of several different approaches when measuring health literacy, thus making it difficult to ensure that research data in this field is sound and comparable [9]. It was not until 2012 that Sørensen and colleagues published a critical synthesis of existing definitions in order to conceive their own definition:

"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." [8], p.3.

In accordance with this definition, Sørensen and colleagues developed a conceptual model, which encompasses relevant aspects and coherences from previous models (see Figure 1).

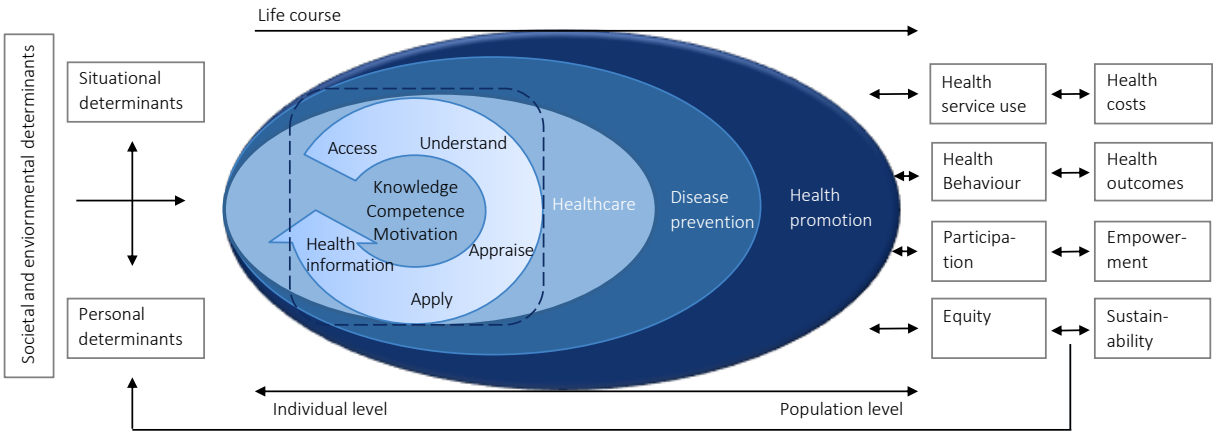

Figure 1 Conceptual model of health literacy by Sørensen et al. (2012) [8], p. 9

At the core of this model, indicated in the figure by the dashed box, lie the individual's knowledge, competence, and motivation with regard to accessing, understanding, appraising, and applying health information in the three domains (healthcare, disease prevention and health promotion).

The left-hand side of the conceptual model describes distal (societal and environmental) and proximal (personal and situational) factors that influence health literacy. Distal factors include societal and environmental factors such as demographic circumstances and language, while proximal factors focus on the personal level (e.g. socioeconomic status, age, income) and the situational level (e.g. social support, family influence).

On the right-hand side of the model, Sørensen and colleagues show correlative factors that are influenced by health literacy. Health literacy affects health behavior, which in turn affects health outcomes. This subsequently influences the use of health services, and thereby determines the costs that arise within the health system. Adequate health literacy further enhances participation in public health discussions. As such, being health literate

and participating in dialogue allows for empowerment, thus leading to equity and sustainability with regard to changes in public health.

2.2. The Operationalization of Health Literacy

The skills (accessing, understanding, appraising and applying health information) in the three domains (healthcare, disease prevention and health promotion) of the conceptual model form a matrix, shown in Table 1. Each of the four stages of processing health information crosses all three of the health domains.

Table 1 Health literacy matrix containing four skill dimensions within three health domains [8]

	Access	**Understand**	**Appraise**	**Apply**
Healthcare	Information on medical or clinical issues	Medical information and deriving meaning	Interpreting and evaluating medical information	Informed decisions on medical issues
Disease prevention	Information on risk factors for health	Information on risk factors and deriving meaning	Interpreting and evaluating information on risk factors for health	Informed decisions on risk factors for health
Health promotion	Information and keeping up to date on determinants of health in the social and physical environment	Information on determinants of health in the social and physical environment and deriving meaning	Interpreting and evaluating information on health determinants in the social and physical environment	Informed decisions on health determinants in the social and physical environment

The matrix (Table 1) published by Sørensen and colleagues, was used to develop a comprehensive, generic health literacy instrument, the European Health Literacy Survey Questionnaire (HLS-EU-Q). The HLS-EU-Q was originally a 47-item instrument based on the subdimensions of health literacy displayed in the matrix, designed for the reporting of self-assessed skills for dealing with health-related information. The HLS-EU-Q is a subjective measurement instrument that goes far beyond pure literal skills, as it takes a multidimensional approach to general health literacy. Respondents are asked about their subjectively perceived difficulty in coping with tasks and activities related to finding, understanding, appraising and applying health information in the three domains. Based on this 47-item questionnaire, a 16-item version (HLS-EU-16) was derived to allow more practical implementation for research purposes. The questionnaire categorizes health literacy into three levels: adequate, insufficient, and problematic [10]. In order to aid comprehension, this thesis simply uses the terms “inadequate” (covering both insufficient and problematic) and “adequate” to qualify degrees of health literacy. Subjective instruments of health literacy such as the HLS-EU-Q provide a fast means of assessing

opinions on health literacy that does not require high cognitive skills [11]. This is also the case with the Brief Health Literacy Screener (BHLS), for example, a three-item instrument that has been used in clinical settings to gain insights into an individual's health literacy levels [12]. Despite the easy application, one weakness of using this approach lies in the fact that an individual's opinion does not necessarily translate to their actual skill level [11].

To counteract this issue, it is advisable to utilize an objective measure that assesses literacy skills within a medical context or condition in parallel with the subjective assessment. Instruments that address individual aspects of literacy skills usually take the form of comprehension and pronunciation questionnaires regarding medical terms or information relevant to one's health [13]. The objective instruments used to date often focus on disease- or condition-specific knowledge, such as cancer literacy [14] or mental health literacy [15]. This indicates that objective measures alone are not comprehensive, as they do not cover the other aspects of health literacy. Nevertheless, objective measures are insightful as knowledge is an element of health literacy [16]. As such, objective measures in the form of knowledge assessment instruments are suitable for measuring health literacy with regard to a particular condition or circumstance.

2.3. Interventions Aimed at Promoting Health Literacy

Although health literacy has long been understood as an individual skill, there is growing recognition that health literacy does not depend solely on the skills and abilities of individuals [17]. Instead, it is a combination of the individual's skills and the demands of healthcare systems and organizations (Figure 2). Inadequate health literacy can thus be addressed at the individual level by increasing personal health literacy while at the same time making changes at the system level by making health-related tasks less complex (Figure 2).

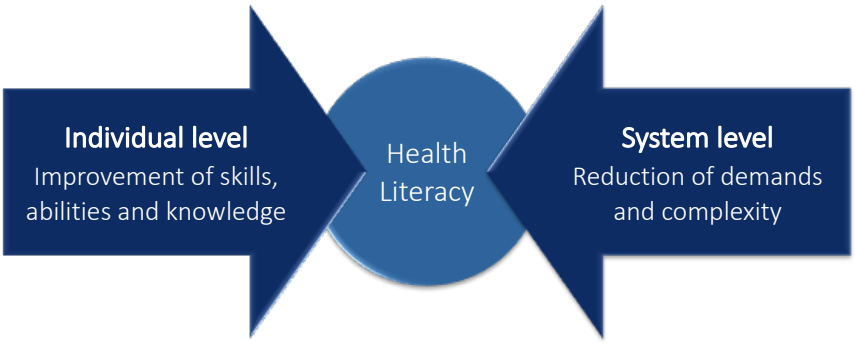

Figure 2 Health literacy framework based on Parker (2009) [18]

This multicausality implies that health systems can support health literacy, acting as health literacy supportive organizations. Brach and colleagues (2012) presented a number of attributes that an organization should possess at the system level in order to support individual health literacy [19]. If an organization is health literacy supportive, this makes it easier for the individual to navigate, understand and use the information and services provided to help them take care of their health [19]. Among other factors, being a health literacy supportive organization entails meeting the needs of individuals with different health literacy levels, providing easy access to health information and services, and providing comprehensible health information. Health systems, including healthcare providers, can be health literacy sensitive or supportive by offering health information in simple and plain language to facilitate navigation through the system.

Approaches for improving health literacy have advanced in recent decades. Interventions have been developed to target different age groups (e.g. adolescents, elderly people), individuals with particular diseases (e.g. chronic conditions) and individuals with different socioeconomic-statuses (e.g. limited education). The types of interventions developed mainly focus on education in the form of providing information on the condition at hand, counseling, decision aids, training sessions, and workshops [20, 21].

However, it is noticeable that most studies do not focus on health literacy as their primary outcome. Instead, interventions aim to improve health literacy so that other outcomes, such as utilization of health services [22], health outcomes [20, 22], or behavior [23, 24], change or improve. In their systematic review, Visscher et al. conclude that evidence from health literacy interventions is sparse, and point to heterogeneity in terms of study design, measurement tools and outcomes measured [25].

There was evidence in systematic reviews of a positive link between adequate health literacy and the improvement of primary outcomes, though results are not always consistent. The inconsistency in results is attributed to inconsistent definitions of health literacy, and thus diversity in measurement instruments. Nevertheless, interventions on health literacy and health behavior in adolescents, for example, reveal that adequate health literacy was related to general health-promoting behavior, including preventive behaviors regarding tobacco use, health responsibility, diet and physical activity [23]. A further positive link was found in the seeking of health information among adolescents [23].

There is also evidence that health literacy interventions can have a positive effect on health outcomes. A diabetes self-management intervention targeting the health literacy component 'applying health information in healthcare' improved glycemic control, knowledge and diabetes-related mental well-being [26]. A further educational intervention on diabetes showed that the intervention group had reduced HbA1c levels and improvements in knowledge and quality of life compared to the control group [26].

One form of intervention for promoting health literacy is lifestyle interventions, which have shown promising results with regard to medical outcomes. Such interventions can include a wide range and combination of components, such as the provision of information, materials, coaching and goal setting. A randomized-controlled-trial (RCT) demonstrated that a lifestyle intervention improves diabetes outcomes and was effective in reducing weight in the intervention group [26]. A systematic review concluded that, even though a lifestyle intervention was not effective in the reduction of risk factors for cardiovascular diseases, the participatory approach can be strategized for future intervention aimed at improving health literacy [26].

Even though there have been efforts to assess health literacy among different groups of people, there is one particularly important group has been neglected in health literacy research so far: pregnant women.

2.4. Health Literacy and Pregnancy

Pregnancy is an important time during which a woman is not only responsible for herself, but also for the health and development of a fetus. The amount of health information a woman needs to process during pregnancy makes it difficult to distinguish between

reliable and unreliable information. Even when they are able to find reliable information, women often find the amount of information available overwhelming.

Prior to this PhD thesis, there has been one systematic review that touches upon health literacy and reproductive health. The authors of said review mention that inadequate health literacy implicates unfavorable behavior during pregnancy and postpartum. Pregnant women with inadequate health literacy engage in prenatal care at a later gestational age, rather than at the beginning of the pregnancy. Similarly, they miss prenatal care appointments [27, 28]. With regards to vitamin supplements, inadequate health literacy is associated with not taking necessary supplements, such as folic acid [27]. Smoking was observed to be more common among pregnant women with inadequate health literacy. Adequate health literacy, on the other hand, is associated with a higher level of knowledge with regard smoking and its impact during pregnancy. As such, it is not surprising that this group of women have a greater need for information than women with adequate health literacy [27].

Although the systematic review provides clues as to how inadequate health literacy influences reproductive health, there are many gaps in the research field of health literacy among pregnant women. To date, it is still not clear what level of health literacy pregnant women possess, or what interventions – if any – exist to improve this.

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CHAPTER 3

Aims and Objectives

3. Aims and Objectives

This dissertation aims to fill the gaps in research into health literacy among pregnant women by providing an overview of the current state of this research, assessing the health literacy levels of pregnant women participating in a lifestyle intervention, and evaluating the effect of this lifestyle intervention on improving health literacy levels.

These aims will be addressed by the following objectives:

(1) The first dissertation project provides an overview of current research into health literacy during pregnancy. It is a systematic review that illustrates health literacy levels among pregnant women and the kind of interventions that are available to improve health literacy among pregnant women.

(2) The second dissertation project describes the development of a lifestyle intervention (GeMuKi) and how health literacy is addressed within said intervention.

(3) The third dissertation project is the development and evaluation of a knowledge-based questionnaire as part of the objective health literacy assessment in the lifestyle intervention. The questionnaire assesses how much knowledge pregnant women possess with regard to lifestyle topics during pregnancy, and how this links to socio-demographic factors. Descriptive statistics and regression analyses were conducted in order to evaluate the questionnaire.

(4) The fourth dissertation project evaluates the effect of the lifestyle intervention on the improvement of health literacy among pregnant women. Data on demographic variables, health literacy and knowledge were analyzed using generalized estimating equations (GEE).

CHAPTER 4

Methods

4. Methods

Since each of the Dissertation Projects (DP) follows a different objective, several methodological approaches were taken accordingly to address the specific aim and research question at hand.

4.1. Dissertation Projects

Dissertation Project 1

The first DP was a systematic review on the status quo of health literacy among pregnant women and the interventions that exist for improving health literacy. In this DP, a systematic search was conducted using scientific databases. Search terms and inclusion/ exclusion criteria were defined prior to the search. Two authors independently screened and evaluated all the abstracts found. All the relevant information from the included studies was extracted independently by the two authors and input into a predefined data extraction tool. Due to the diversity of the studies' characteristics and the way the results were presented, no meta-analysis was conducted [1]. In order to assess the methodological quality of the studies included in the review, standardized checklists were used for each different type of study design. For RCTs, the risk-of-bias tool for randomized trials (RoB 2.0) provided by the Cochrane group was used [2]. For cross-sectional studies, the Appraisal tool for Cross-Sectional Studies (AXIS) was applied [3]. The two authors conducted the quality assessment independently, and any conflicts were resolved through discussion.

Dissertation Project 2

To date, there is little research on the role of health literacy during pregnancy. Specifically, there is a lack of interventions aimed at improving health literacy among pregnant women and evaluations of their effectiveness. As such, the second DP resulted in a descriptive study protocol of the lifestyle intervention, which seeks to address this gap. It explores the relationship of health literacy within the GeMuKi Project [4].

Dissertation Project 3

In order to achieve an objective measurement of health literacy, a knowledge-based questionnaire was developed in DP 3 with the aim of assessing women's knowledge of lifestyle-related topics during pregnancy. The questionnaire was developed based on the

topics discussed as part of the counseling within the GeMuKi Project, and was pre-tested on pregnant women (n = 8) at the Women's Clinic at the University Hospital Cologne. The pregnant women were asked if they had any feedback on the questionnaire, which is in line with the principles of cognitive questionnaire pre-testing [5]. Changes were made accordingly. This cross-sectional study used baseline data collected between February 2019 and September 2021 from a sample of 1466 women participating in the GeMuKi Project. The data was analyzed using descriptive and inferential statistics such as frequency count, percentage, and multiple regressions in IBM® SPSS®. To answer the question whether sociodemographic factors and pregnancy variables have an influence on knowledge levels, regression analyses were conducted. For this purpose, the women's knowledge on lifestyle topics was selected as the dependent variable, and the individual knowledge questions and the sum score were used to build multiple logistic and linear regression models [4]. The linear regression model used listwise deletion. Age, nullipara, net income, migration background and educational level formed the independent variables [4]. A p-value of <0.05 was considered statistically significant.

Dissertation Project 4

The objective of DP 4 was to assess the impact of the lifestyle intervention on health literacy [6]. The data were collected in two ways: a paper-based questionnaire was utilized at baseline to collect demographic data and app-based questionnaires were used to collect data on health literacy and knowledge of pregnancy-related lifestyle topics.

The German version of the HLS-EU-16 was used at baseline to depict a broad picture of the health literacy levels among the pregnant women in our sample. The BHLS was used at baseline and the end of pregnancy to assess changes in health literacy levels after the intervention. As an objective measure of health literacy that focuses specifically on pregnancy-related lifestyle knowledge, the knowledge-based questionnaire described in DP 3 was used at both timepoints as well. Descriptive statistics were used to analyze participant characteristics. Demographic variables were used as independent variables in multiple regression analysis.

To consider the cluster structure of the study, multiple regression models using GEEs were conducted. This was used to answer the question of whether the GeMuKi intervention improved the health literacy of pregnant women. This difference (Δ) in the BHLS sum score between the two timepoints were used as a continuous dependent

variable, and group affiliation as an independent variable adjusted for age, nullipara, income, migration background and education level (covariates) [6]. To answer the question of whether the GeMuKi intervention improved pregnancy-specific health literacy, a second GEE model was tested using the same independent variables and covariates, and Δ of the knowledge questionnaire sum score between the two points in time as the dependent variable [6]. A p-value of <0.05 was considered statistically significant.

4.2. The GeMuKi Project

The GeMuKi Project to which this thesis refers to is a lifestyle intervention during pregnancy that makes use of brief counseling sessions during routine prenatal checkups (also called antenatal appointments) in the state of Baden-Wuerttemberg (Germany). The intervention group received a brief counseling session during regular pregnancy checkup visits, while the control group received regular care. The data on health literacy was collected between October 2017 and March 2022. The project was designed as a cluster-RCT using a hybrid effectiveness-implementation design [7]. It is a multiprofessional, computer-assisted lifestyle intervention carried out by gynecologists and midwives during pregnancy. It's primary outcome is the reduction of the proportion of women with excessive GWG, the secondary outcome it the improvement of health literacy and to positively affect lifestyle-related risk factors in women and their infants.

In order to ensure a particular focus on health literacy, the pregnant women were actively involved in the process of deciding which lifestyle topic to focus on during the counseling session. In order to strengthen the health literacy of the women participating in the study, the healthcare providers were given training before the initiation of the intervention. The healthcare providers were trained to communicate key messages on lifestyle topics (such as nutrition and physical activity) from the national recommendations by means of Motivational Interviewing (MI). At the end of each counseling session, the participant set up SMART (Specific, Measurable, Achievable, Reasonable, Time-Bound) goals with the aid of their healthcare provider in order to make a positive change to their behavior. These goals were designed to be accomplished by the patient's next appointment. The SMART goals were individualized and thus tailored to the specific health literacy levels of the women in question. In addition to this, the pregnant women downloaded an app as part of the intervention in order to fill in the questionnaires and to receive health information

on pregnancy and receive their SMART goals as push notifications. The app was designed to be user-friendly and accessible for women with different health literacy levels.

The healthcare providers received an analogue online counseling tool, which provided assistance such as supporting questions, built on the tenets of MI to ask during the counseling session for each lifestyle topic. The healthcare providers used this platform to document the SMART goals during each counseling session, after which they would be displayed in the women's app. The counseling tool gave the gynecologists and midwives access to each of their patients' chosen lifestyle topics and goals in order to ensure continuity in the counseling.

Health literacy was assessed using the HLS-EU-16 at t0 (baseline) to provide a detailed picture of the general health literacy levels of the pregnant women. The BHLS was used to assess changes in health literacy as a result of the GeMuKi intervention. The questionnaire was used at t0 and t1 (at the end of pregnancy). Both the HLS-EU-16 and BHLS are subjective measures, which is why a knowledge-based questionnaire was developed to assess objective estimates of pregnancy-related health literacy. The questionnaire was based on the topics from the national recommendations discussed during counseling. A detailed description of the project and its approaches to improve health literacy can be found in DP 2 [4].

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CHAPTER 5

Dissertation Project 1

Health Literacy in Pregnant Women: A Systematic Review

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Abstract

Health literacy plays a crucial role during pregnancy, as the mother's health behavior influences both her own health and that of her child. To the authors' best knowledge, no comprehensive overview on evidence of the health literacy of pregnant women and its impact on health outcomes during pregnancy exists. Therefore, this review aims to assess health literacy levels in pregnant women, whether health literacy is associated with outcomes during pregnancy and whether effective interventions exist to improve the health literacy of pregnant women. A systematic literature search was conducted in PubMed and EBSCO, resulting in 14 studies. The results show mixed levels of health literacy in pregnant women. Limited health literacy is associated with unhealthy behaviors during pregnancy. Mixed health literacy levels can be attributed to the recruitment site, the number of participants and the measurement tool used. Quality assessment reveals that the quality of the included studies is moderate to good. The review revealed that randomized controlled trials and interventions to improve health literacy in pregnant women are rare or do not exist. This is crucial in the light of the mixed health literacy levels found among pregnant women. Healthcare providers play a key role in this context, as pregnant women with limited health literacy rely on them as sources of health information.

Keywords: health literacy; pregnancy; lifestyle; health behavior; systematic review

Introduction

Health literacy is widely defined as "[…] 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" [1] (p. 3). Despite the availability and accessibility of health information, considerable parts of the population still engage in risky health behavior such as insufficient physical activity, unbalanced nutrition and smoking. These risk factors are associated with chronic diseases such as diabetes, which cause more than 75% of deaths worldwide [2]. Limited health literacy is an important driver in health disparity as it is associated with insufficient self-management and worse health outcomes in chronic diseases [3]. Individuals with limited health literacy have more emergency department visits, more and longer hospital stays, worse outcomes in healthcare, and lower utilization of preventive services than people who show an adequate level of health literacy [4]. A multinational study conducted in Europe for example revealed that 12% of the respondents possessed inadequate health literacy and 47% displayed limited health literacy, with major differences across countries [5].

Adequate access, understanding and application of health information is important, especially with regard to high-risk health behaviors and in vulnerable situations. One example of such a situation where health behavior becomes particularly important is pregnancy, since in this phase behaviors affect the health of both the woman and the fetus. During pregnancy, women are confronted with a variety of health information from different sources [6]. This information entails recommendations regarding health behavior. Despite the existence of evidence-based recommendations and information materials, pregnant women with limited health literacy are less likely to take folic acids during pregnancy or engage in prenatal care at a later gestational age, and have more hospital stays [7]. Moreover, these women are less likely to engage in breastfeeding for the first two months after birth [8]. At the same time, women with adequate health literacy levels have a better understanding of the dangers of smoking during pregnancy [9]. For women with limited health literacy, written information on antenatal services is more difficult to understand. As such, these women are less likely to make informed medical decisions [10]. Since maternal lifestyle during pregnancy influences child health in later years through epigenetic programming, it is essential to

develop approaches to improve health literacy among pregnant women in order to keep both mother and child healthy.

In recent years, research has mainly focused on the assessment of health literacy levels among the general population and particular at risk groups such as older people, immigrants and people with a low socio-economic status, or has only taken particular focus on gestational weight gain [11] and reproductive health [10]. Despite the growing recognition of the importance of health literacy, there has not yet been any comprehensive literature review on the association between health literacy levels among pregnant women and health outcomes during pregnancy. Additionally, it is unclear whether effective interventions exist that improve health literacy among pregnant women.

Therefore, a systematic review was conducted to assess (1) health literacy levels in pregnant women; (2) whether health literacy is associated with outcomes during pregnancy; (3) whether interventions exist to improve the health literacy of pregnant women.

Materials and Methods

Data sources

A bibliographic search was conducted in PubMed and EBSCO. In addition to this, a hand search was conducted using Google Scholar. The search terms were kept general in order to maximize search sensitivity. Table 1 displays the search strategies, as well as the inclusion and exclusion criteria. We included studies published in the last ten years (2009-2019, with an updated search in 2020), as we wanted to obtain recent literature and health literacy became an increasingly relevant field of research in the last decade. Studies had to be in English and had to measure health literacy among pregnant women using at least one validated quantitative tool. We only included studies that measured health literacy as a multidimensional concept, and excluded studies that exclusively assessed knowledge. The inclusion and exclusion criteria can be found in Table 1.

Two authors (F.N., F.K.) independently screened and evaluated all the abstracts. Where applicable, the articles were subsequently included for full-text review and data extraction.

Table 2 Inclusion and exclusion criteria and search strategies

Inclusion criteria	-	Pregnant women at any week of gestation
	-	English literature

	- Quantitative studies - All study designs - Health literacy as an outcome - General/overall health literacy - Health literacy measure with at least one validated tool - Assessment of one of the following: • Health literacy levels among pregnant women • The effects of health literacy on outcomes during pregnancy • Interventions that (in)directly affect (improve) health literacy
Exclusion criteria	- Preconception - Postnatal, after birth - Reproductive health - Languages other than English/German - PhD theses - Qualitative studies - Topic-specific health literacy
PubMed	(health literacy) AND pregnan* Sort by: Best Match Filters: published in the last 10 years (2009-2019 with updated search in 2020)
EBSCO	health literacy AND pregnan* Limiters - Publication Year: 2009-2019 (with updated search in 2020)

*= truncated search term.

Data extraction

Relevant information from the retrieved studies, including the general characteristics of the study and the quantitative results, was extracted based on a predefined data extraction tool. Two researchers (F.N., F.K.) independently extracted information related to the authors and the country of origin, the year of publication, the data collection setting, and factors that might have an impact on the health literacy level, such as the recruitment strategies, the underlying definition of health literacy, and the health literacy tool used.

Quantitative results were extracted as provided in the studies, e.g. as percentages of women with limited or adequate health literacy, average health literacy scores, results of tests for group differences, and the respective significance levels. Quantitative data were extracted independently by two reviewers (F.N., A.S.). Due to the diversity of the studies' characteristics and the way the results were presented, the data were not summarized quantitatively in a meta-analysis.

Quality assessment

The methodological quality of all the studies included in the review was assessed using standardized checklists. Since this review included different types of study designs, a number of different quality assessment tools were used. For randomized controlled trials (RCT), we used the RoB 2.0 risk assessment tool provided by the Cochrane group

[12]. This tool covers five domains of bias, focusing on trial design, conducting and reporting. Each domain entails three to seven aspects, for which the risk of bias is rated as 'Low', 'High' or 'Some concerns'. A study is rated as having an overall high risk of bias if any of these aspects is rated as having a 'High risk' of bias. For cross-sectional studies, we applied the Appraisal tool for Cross-Sectional Studies (AXIS) [13]. This tool has a set of 20 questions that cover every section of a cross-sectional study, from the introduction to discussions. Each question is answered using 'Yes/No' or 'Don't know/Comment'. The AXIS does not provide an overall assessment of a study. Two reviewers (F.N, F.K) rated the study quality independently, and any conflicts were resolved through discussion.

Results

Study selection

Figure 1 shows the flow chart used for study selection. 691 studies were identified in total. 112 duplicates were removed. The titles and abstracts of the 579 remaining studies were then screened. 532 of these studies did not match the inclusion criteria, which left 47 studies for full-text screening. Eventually, 14 remained to be included in this review after an updated search in August 2020. No additional studies were retrieved through hand search.

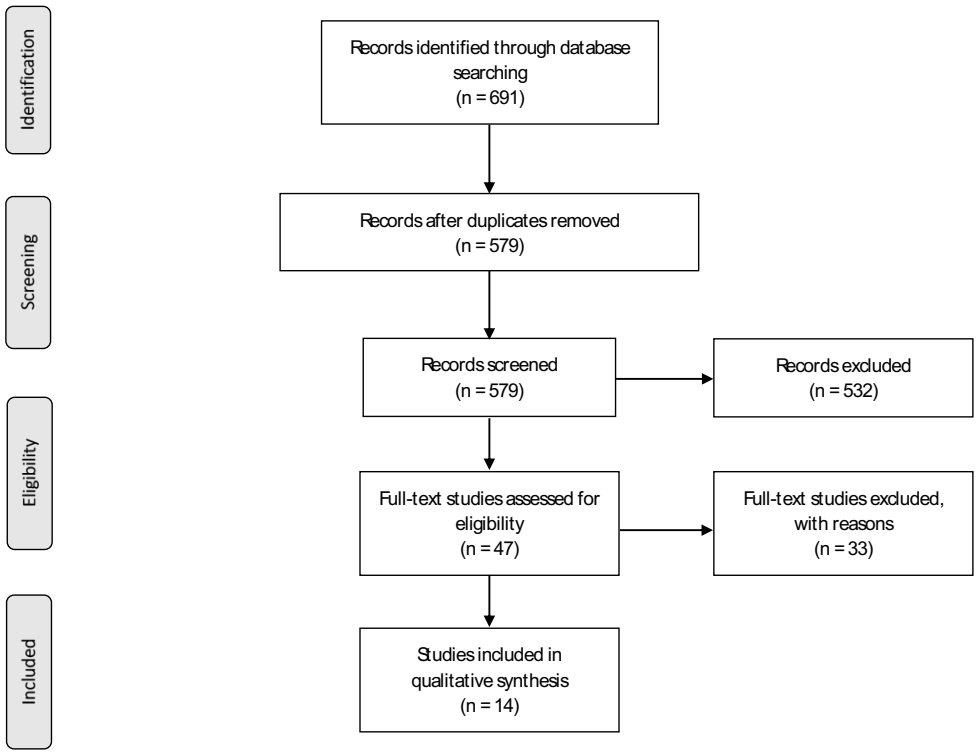

Figure 3 PRISMA flow chart.

Study characteristics

The included studies are summarized in Table 2. Thirteen of the 14 studies were cross-sectional in nature. One study used an experimental design, comparing a treatment group receiving an interactive patient education tool for prenatal screening and diagnosis to a control group that was receiving standard care counselling [14].

Most of the studies were conducted in Europe, Canada and the USA. The sample size of study participants ranged from n=34 to n=4999. Except for a minimum age of 18 years, the inclusion criteria for the study participants varied across the studies. The time of gestation at inclusion varied, with some studies only including women at the beginning of the pregnancy [15] and others including women at the end of pregnancy [21]. The studies did not in- or exclude women based on their ethnicity or educational attainment. Further details on these characteristics are provided in Supplementary S1 (online). Most of the studies required the women involved to be healthy [15, 17]; however, some also included women at risk of a condition [31, 32], depending on the main outcome of the study. Primary outcomes also varied across the studies.

Table 3 Study characteristics.

1st author	Year	Country under study	Study design	Eligibility criteria	HL definition	Measure	n in analysis	Sampling & Recruitment
Delanoe *[15]*	2016	Canada	Cross-sectional, embedded in a questionnaire pilot test	≥ 18 years old; second trimester of pregnancy; no high-risk pregnancy (excluding down syndrome risk)	Nutbeam (2000) [16]	NVS; BHLS	45	Convenience sample from three clinical sites
Delanoe *[17]*	2016a	Canada	Cross-sectional	≥ 18 years old; ≥ 16 weeks pregnant; no high-risk pregnancy; decided about prenatal screening	Nutbeam (2008) [18]	STOFHLA; BHLS	346	Web-based survey
Duggan *[19]*	2014	Ireland	Cross-sectional	≥ 18 years old; English-speaking; no visual or aural impairments	Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs (1999) [20]	REALM	404	Convenience sample from a university hospital
Lupattelli *[21]*	2014	Australia, Austria, Canada, Croatia, Finland, France, Iceland, Italy, Netherlands, Norway, Poland, Russia, Serbia, Slovenia, Sweden, Switzerland, UK, USA, some South American countries	Cross-sectional	Any week of gestation	Nielsen-Bohlman, Panzer, Kindig (2004) [22]	BHLS	4999	Web-based survey Advertisement was placed on websites used frequently by pregnant women, inviting them to take part in the survey
Sahin *[23]*	2020	Turkey	Cross-sectional	≥ 18 years old; Turkish-speaking	Definition provided without source	HLS-EU-25	326	At a hospital
Sheinis *[24]*	2018	Canada	Cross-sectional	Low and high-risk obstetrics patients; English-speaking	Safeer and Keenan (2005) [25]	NVS	139	Convenience sample from a hospital
Sheinis *[26]*	2018a	Canada	Cross-sectional	Primipara; receiving prenatal care hospital of conduct and attending prenatal visit in a low risk obstetrics clinic; English-speaking	None provided	NVS	218	Convenience sample from a hospital

Shieh *[27]*	2009	USA	Cross-sectional	≥ 18 years old; English-speaking; publicly funded or no health insurance	Kutner, Greenberg, Jin, Paulsen (2006) [28]	STOFHLA	143	Convenience sample from a prenatal clinic in an urban community that predominately catered to low-income patients
Shieh *[29]*	2010	USA	Cross-sectional	≥ 18 years old; English-speaking; government subsidized health insurance or no health insurance	Rootman (2004) [30]	STOFHLA	143	Convenience sample from a prenatal clinic in an urban community that catered to low-income patients
Van Schendel *[31]*	2016	Netherlands	Cross-sectional, survey of HL embedded in pre/post design	≥ 18 years old; increased risk of trisomy; >10 weeks pregnant; no multiple pregnancies, no vanishing twin, no structural fetal anomalies, no maternal history of malignancy or chromosomal abnormality	None provided	BHLS	1091	Eight prenatal diagnosis centers
Van Schendel *[32]*	2017	Netherlands	Cross-sectional	See van Schendel, 2016	None provided	BHLS	682	See van Schendel, 2016
Wilson *[33]*	2012	Jamaica	Cross-sectional	≥ 18 years old; attending the clinic for prenatal care	Baker (2006) [34]	REALM	34	Convenience sample from two community health centers that predominately catered to low-income patients
Yee *[14]*	2014	USA	RCT	≥ 18 years old; 6th-26th weeks pregnant; not undergone any prenatal testing; English-speaking; no multiple gestations	None provided	REALM	150 (75/75)	During routine prenatal visits in a clinic
You *[35]*	2012	USA	Cross-sectional	≥ 18 years old; 18th-40th weeks pregnant; English-speaking; no visual or aural impairments	None provided	STOFHLA	110	Convenience sample from a university clinic

NVS = Newest Vital Sign; BHLS = Brief Health Literacy Screener; S-TOFHLA = Short Test of Functional Health Literacy in Adults; REALM = Rapid Estimate of Adult Literacy in Medicine; HLS-EU-25 = Health Literacy Survey Europe Questionnaire.

Three of the studies used a version of the Rapid Estimate of Adult Literacy in Medicine (REALM), four studies used the Short Test of Functional Health Literacy in Adults (S-TOFHLA), three the Newest Vital Sign (NVS), five the Set of Brief Health Literacy Screener (BHLS). Some studies utilized two instruments. One study used the 25-item version of the Health Literacy Survey Questionnaire (HLS-EU-Q) (Table 3). Since each of these tools uses different terms to define health literacy scores, this paper summarizes the definitions as 'Limited' (original: Limited, Inadequate, Insufficient, Low), 'Marginal' (original: Marginal, Medium), and 'Adequate' (original: Adequate, Sufficient, High).

Table 4 Tools used in the studies.

Tool	Description	Scoring
REALM **[36]**	This objective tool is an oral reading and recognition test with 66 medical terms. Every correctly pronounced word equals one point.	Total score: 66 0–44 is limited health literacy (6th grade or below); 45–60 is marginal health literacy (7th–8th grade); 61–66 is adequate health literacy (above 9th grade)
S-TOFHLA **[37]**	This objective tool measures both reading comprehension and numeracy. The reading part entails a fill-in-the-blank text that offers a choice of four words. The numeracy part uses hospital forms and labelled vials, and requires interpretation of such numbers.	Total score: 36 0–16 is limited health literacy; 17–22 is marginal health literacy; 23–36 is adequate health literacy
NVS **[38]**	This objective tool is based on an ice cream label. Patients have to answer a total of six questions related to the label: four requiring numeracy skills and two requiring reading skills.	Total score: 6 0-1 is the high likelihood of limited health literacy; 2-3 is the possibility of limited health literacy; 4-6 is adequate health literacy
BHLS **[39]**	This subjective screener consists of three questions concerning medical forms and information.	Total points: 12 0–5 is limited health literacy; 6–9 is marginal health literacy; 10–12 is adequate health literacy
HLS-EU-25 **[40]**	This subjective tool covers the process of accessing, understanding, appraising and applying health-related information within the fields of healthcare, disease prevention and health promotion.	Total score: 125, without qualitative categorization of HL

Objective one: Health literacy levels in pregnant women

The studies included in this review (Table 4) show mixed findings regarding health literacy levels among pregnant women. Two studies report that health literacy levels among pregnant women are limited based on the REALM [14, 33], which corresponds to 4th–6th grade reading level (Table 2). By contrast, about 85% of the participants in the

study conducted by Duggan et al. in 2014 demonstrated adequate levels of health literacy using the REALM [19].

Based on the utilization of the S-TOFHLA, the participants in three of the studies scored adequately [27, 29, 35]. Similarly, Delanoe et al. [17] found that health literacy levels in their population were adequate using both the S-TOFHLA as an objective tool and the BLHS as a subjective tool (Table 4). The study by You et al. also reveal adequate health literacy levels. However, the scoring in their study reach up to 100, indicating that this study likely used the TOFHLA and not the short version of it as stated in their study [35].

Lupattelli et al. [21] conducted a transnational study. The overall health literacy levels using BHLS were mixed: 54.5% scored high, 40.3% scored marginal and 5.2% scored low. Both studies from van Schendel et al. [31, 32] depict adequate health literacy in pregnant women using the BHLS. A further study from Delanoe et al. [15] demonstrated mixed results using both the BHLS (marginal health literacy) and NVS (adequate health literacy).

Sheinis et al. [26] split the health literacy results of their study population into two age groups, both of which revealed adequate health literacy.

Table 5 Studies that described health literacy levels in pregnant women.

1st author	Tool	Result/health literacy level	Remarks
Yee, 2014 [14]	REALM	43.3% with limited health literacy, 56.7% with adequate health literacy	One cut-off point, it is not apparent at which score
Duggan, 2014 [19]	REALM	15.3% with limited health literacy, 84.7% with adequate health literacy	One cut-off point at a score of > 60 = adequate health literacy
Wilson, 2012 [33]	REALM	85% with limited health literacy, 15% with adequate health literacy	Study offers differentiated scores, which were taken together for comparability*
Shieh, 2009 [27]	S-TOFHLA	14.7% with limited health literacy, 85.3% with adequate health literacy	Cut-offs (> 30 adequate health literacy) different to those suggested by the original tool
You, 2012 [35]	S-TOFHLA	9% with limited health literacy, 91% with adequate health literacy	Cut-offs (≥ 66 = adequate health literacy) different to those suggested by the original tool. It appears that the study uses the TOFHLA rather than S-TOFHLA, since scores go up to 100 instead of 36
Shieh, 2010 [29]	S-TOFHLA	Mean: 32.35 (5.14)	S-TOFHLA presented as mean score instead of health literacy distribution
Delanoe, 2016a [17]	S-TOFHLA	Median: 36	No further analysis with S-TOFHLA due to lack of variability. Cut-offs for BHLS different to those suggested by the original tool (> 10 = adequate health literacy); no health literacy distribution for either tool
	BHLS	Median: 10	

Lupattelli, 2014 [21]	BHLS	45.5% with limited health literacy, 54.5% with adequate health literacy	Study offers differentiated scores, which were taken together for comparability*
Van Schendel, 2017 [32]	BHLS	6.8% with limited health literacy, 93.2% with adequate health literacy	One cut-off point, it is not apparent at which score
Van Schendel, 2016 [31]	BHLS	8.5% with limited health literacy, 91.5% with adequate health literacy	One cut-off point, it is not apparent at which score
Delanoe, 2016 [15]	BHLS	Median: 8 / mean: 8.2 (1.6)	BHLS and NVS are each presented as one score instead of health literacy distribution
	NVS	Mean: 5.3 (1.6) / median: 6	
Sheinis, 2018a [26]	NVS	Mean: 4.5 (1.53) <35 years old; Mean: 4.7 (1.39) ≥ 35 years old	NVS presented as means and cut-off was set at age (35 years)

*Note: For purposes of comparability, attempts were made to make the results of each study consistent. However, this was not possible because some studies a) used different cut-off points than those suggested in the original tool or b) used different statistical methods, and the original data were not available.

Objective two: Effect of health literacy on outcomes during pregnancy

Health literacy is associated with a variety of outcomes, which can be categorized into 'Beliefs/attitudes', 'Knowledge' and 'Lifestyle' (Table 5).

Table 6 Studies that indicated an association between health literacy and other outcomes during pregnancy.

Study	*Outcome*	*Univariate analysis*	*p-value*	*Multivariate analysis*	*p-value*
	Beliefs/attitudes				
Duggan, 2014 [19]	Women with limited HL have more negative beliefs regarding medicines, even when controlling for age and education. *Note: Rather than being shown as a single score, negative beliefs aresplit into general harm and general overuse based on the Beliefs About Medicine questionnaire.*	Comparison of means (t-test) General harm Limited HL: M = 11.85 (SD = 2.81) Adequate HL: M = 9.75 (SD = 2.11) General overuse Limited HL: M = 12.48 (SD = 2.63) Adequate HL: M = 11.51 (SD = 2.73)	<.001 .01	Multiple linear regression DV: General harm IV: Limited HL with β = 1.73; 95% CI [1.11-2.34] DV: General overuse IV: Limited HL with β = 0.95; 95% CI [0.19-1.70]	<.001 .01
Van Schendel, 2017 [32]	Women with limited HL experience greater residual anxiety (using the State-Trait Anxiety Inventory (STAI) and Pregnancy Related Anxiety Questionnaire-Revised (PRAQ-R)) after receiving normal Non-Invasive Prenatal Testing (NIPT) results.			ANCOVA for women with normal NIPT results (covariate: STAI and PRAQ-R) DV: Post-test-result STAI score IV: HL Limited HL: M = 31.6 Adequate HL: M = 28.6 DV: Post-test-result PRAQ-R score IV: HL Limited HL: Data not shown Adequate HL: Data not shown	.047 <.001
Shieh, 2010 [29]	Limited HL was inversely correlated with the 'Powerful others' dimension from the Fetal Health Locus of Control (FHLOC) scale, indicating that women perceive healthcare provider as the party responsible for the child's health. No association was found between HL and the seeking of health information.	Correlation between HL and FHLOC: r = -0.28 Univariate linear regression DV: Seeking of health information IV: HL with β = -0.05	.003 .58		
Shieh, 2009 [27]	Pregnant women with limited HL used the Internet less frequently as a source of information. Women with limited HL tend to use interpersonal	Fisher's exact test Frequent Internet use Limited HL: 14.3% Adequate HL: 46.7%	.007		

	information such as healthcare providers and friends/family sources more frequently.				
Delanoe, 2016 [15]	Subjective HL, using the BHLS, was positively association with the intention to use a decision aid for prenatal screening (IDAPS). Objective HL was not significantly correlated with this.	Correlation between subjective HL and IDAPS: Rho = 0.32	.04		
Delanoe, 2016a [17]	HL does not influence the intention to use a decision aid for trisomy 21 screening.	Bivariate ordinal logistic regression DV: intention level IV: STOFHLA IV: BHLS	.27 .52	Ordinal logistic regression DV: intention IV: attitude, subjective norm, perceived control (model I) Adding moral, descriptive norm and anticipated regret leads to model II. Model I vs. model II: Δ deviance = 41.33 Adding the BHLS to modell II leads to model III and: Δ deviance = 0.63	<.001 .43
Van Schendel, 2016 [31]	Women with adequate HL were more likely to make an informed choice concerning prenatal testing.	Univariate logistic regression DV: Informed choice Covariate: Adequate HL with OR = 3.14, 95% CI [1.77-5.57]	<.001	Multiple logistic regression DV: Informed choice IV: Adequate HL with OR = 2.60, 95% CI [1.36-4.95]	.004
	Knowledge				
Sheinis, 2018a [26]	HL correlated positively and significantly with knowledge of age-related pregnancy risks.	Correlation between HL and knowledge of age-related risks: r = 0.146	.03	Multiple linear regression DV: Knowledge score IV: HL with β = 0.261	.027
Wilson, 2012 [33]	Incorrect responses regarding the benefits and risks of the vaccines were more common among women with lower REALM scores.	By category of response (F-test) REALM Score Tuberculosi vaccine benefits 42.7 Correct 41.6 Partially correct 31.4	.41		

		Incorrect 46.2 Tuberculosis vaccine risks 42.6 Correct 20.5 Partially correct Incorrect 45.6 Hepatitis B vaccine 42.5 benefits 30.6 Correct Partially correct 45.5 Incorrect 44.3 Hepatitis B vaccine risks 21.9 Correct Partially correct Incorrect	.01 .13 .01		
You, 2012 [35]	Women with adequate HL returned significantly better scores in a preeclampsia questionnaire. However, this association was not significant in the multivariate analysis.	Comparison of means (t-test) Preeclampsia questionnaire score Adequate HL: M = 44.6% Marginal/inadequate HL: M = 29.6%	.035		
Yee, 2014 [14]	Regardless of HL levels, women in both the education tool group and the standard care group demonstrated a similar improvement in knowledge scores.			Two-way ANOVA Test scores (% correct) Standard care Limited HL: 39.7 (SD = 13.7) Adequate HL: 49.9 (SD = 15.0) Educational tool Limited HL: 64.7 (SD = 13.7) Adequate HL: 73.8 (SD = 13.3)	.81 (Inter-action)
Sheinis, 2018 [24]	HL was not shown to be a predictor of knowledge of prenatal screening for trisomy 21.			Multiple linear regression DV: Knowledge of trisomy 21 IV: HL with $\beta = 0.46$	.52
	Lifestyle				
Lupattell, 2014 [21]	1) Women with inadequate HL tend to smoke during pregnancy.	1) No smoking (%)	1) <.05	3) Generalized estimating equations DV: Non-adherence	

	2) Women with inadequate HL have higher risk perception and negative beliefs regarding medication. 3) Non-adherence to prescribed medicines differed across HL groups.	Limited HL: 81.9, Marginal HL: 89.8, Adequate: 92.1 2) Correlation between HL and belief sum score: Rho = -0.160 3) Non-adherence (%) Limited HL: 25.0, Marginal HL: 22.5, Adequate: 19.2	2) <.01 3) <.001	IV: Limited HL with OR = 1.43, 95% CI [1.09-1.88] Covariates: region of residency, maternal age, educational level, employment status, immigrant status	
Sahin, 2020 [23]	There is a significant positive association between HL and aspects of health promoting lifestyle, and with a significant negative association between HL and intake of antidepressants and flu vaccines. Women with planned pregnancy and who used medication during their pregnancy have a high level of HL	Correlation between HL and: Spiritual growth: r = 0.16 Interpersonal relations: r = 0.16 Antidepressants: r = -1.13 Flu vaccines: r = -.15 Comparison of means (t-test) HL score by: Planning status of pregnancy Yes: M = 76.73 (SD = 29.86) No: M = 68.15 (SD = 29.77) Medication use during pregnancy Yes: M = 79.05 (SD = 28.20) No: M = 63.80 (SD = 31.23)	.02 .05 .04 .01 .01 <.01		

CI = Confidence interval; DV = Dependent variable; HL = Health literacy; IV = Independent variable; M = Mean; SD = Standard deviation; r = Pearson coefficient; Rho = Spearman coefficient; OR = Odds ratio.

Limited health literacy is associated with more negative beliefs regarding medicine [19] and a higher level of residual anxiety when receiving normal results for genetic tests [32]. This is due to the fact that women did not fully understand the normal test results they were given, which indicated that the fetus was less likely to suffer from a form of trisomy [32]. In contrast, adequate health literacy was associated with making an informed choice with regard to prenatal testing. In turn, informed choices were associated with lower levels of decisional conflict and anxiety [31]. Women with limited health literacy believed that the health provider was responsible for their infants' health [29] and made more use of interpersonal information sources such as information provided by health professionals, friends and family [27]. Delanoe et al. [17] concluded that health literacy does not influence the intention to use a decision aid for trisomy 21 screening. All pregnant women are influenced to the same degree by socio-cognitive factors when it comes to using a decision aid for screening. A different study by Delanoe et al. [15] showed that only subjective health literacy was associated with the intention to use a decision aid for prenatal screening. However, this result does not apply when considering objective health literacy. The NVS was not discriminative enough, leading to the conclusion that the women's own perception of health literacy influences their intention to use a decision aid.

Smoking behavior was addressed in one study, which found that women with limited health literacy smoke during pregnancy [21]. Moreover, limited health literacy was associated with higher risk perception and negative beliefs with regard to medication, and non-adherence to prescribed medicines [21]. One study concluded that health literacy is significantly and positively association with a health promoting lifestyle (spiritual growth and interpersonal relations) and negatively association with the intake of antidepressants and flu vaccines. Moreover, women with planned pregnancy and who used medication during their pregnancy have a high level of health literacy [23].

Women with limited health literacy gave more wrong answers in a questionnaire on the risks, benefits and safety of Tuberculosis and Hepatitis B vaccines [33], and an adequate health literacy level was associated with better scores in a preeclampsia questionnaire [35]. However, the latter association was not significant in the multivariable regression, which can be explained by the small number of participants who had limited health literacy [35]. Higher health literacy scores correlated positively and significantly with knowledge of age-related pregnancy risks in the study by Sheinis et al. [26]. However, in a different study by Sheinis et al. health literacy was not associated with knowledge of trisomy 21 [24].

Objective three: Interventions to improve health literacy among pregnant women

None of the studies included in the review were aimed at improving health literacy among pregnant women. One study conducted an RCT aimed at improving knowledge of prenatal genetic testing among pregnant women [14]. The women in the intervention group received an interactive educational tool, while the control group received standard care. The results showed that, regardless of health literacy levels, women in both groups had a similar improvement in knowledge scores (Table 5). This indicates that the intervention did not particularly improve health literacy, but still was health literacy-sensitive.

Quality assessment

All the studies included in this review met at least 13 out of the 20 possible AXIS points (range: 13-19). Two of the studies achieved 13 points, three achieved 14, one achieved 15, one achieved 16, five achieved 17, one achieved 18 and another achieved 19 points.

All the studies fulfilled the quality criteria reflected in the inclusion criteria of this review, such as specifying the target group and using a validated measurement tool. All the studies reported the use of a precision estimate (e.g. p-values), either directly in the Methods sections or indirectly in the results presented in the study. Additionally, all of the studies included in the review provided a discussion of their own limitations. However, some of the studies did not meet items of the quality assessment tool that have a significant impact on how a study is conducted. Eight of the studies included in the review did not provide grounds for their sample sizes. Only one study addressed and categorized non-responders. The response rate raised concerns with regard to non-response bias in five of the studies. Most studies (n = 8) applied convenience sampling. Twelve studies provided indications that there might be a lack in the representativeness of the sample.

The overall quality of the included RCT was rated as 'High risk', since the points "Risk of bias in measurement of the outcome" and "Risk of bias due to deviations from the intended interventions" were rated as having high risk of bias. An extended overview of the quality assessment can be found in Supplementary S2 (online).

Discussion

To the best of our knowledge, this review is the first to review systematically overall health literacy among pregnant women. We identified 14 studies on the health literacy of pregnant women, measured quantitatively with at least one validated tool.

These studies also report on the effect of health literacy on beliefs/attitudes, knowledge and lifestyle during pregnancy.

Regarding the first objective of this review, the studies show mixed results regarding the health literacy levels of pregnant women. The majority of the studies included in the review indicate that the women surveyed have an adequate health literacy level. However, the women in the studies included in this review were recruited mainly from western high-income countries and cities, or web-based panels to which they signed up willingly. This may lead to the assumption that these groups have adequate health literacy than the general population [17]. In contrast, research suggests that women in countries below poverty level are more likely to possess only limited health literacy [33].

Nevertheless, some studies display limited health literacy levels in the target group. This can be attributed to the use of different measurement tools. Even though all the tools used have been validated for measuring health literacy, they measure the concept differently: While the BHLS and HLS-EU measure health literacy subjectively, the NVS, S-TOFHLA and REALM are objective measures. Health literacy research indicates that when both objective and subjective tools are used to measure health literacy within the same population, conflicting results can occur, since associations with other variables emerge differently when using objective tools to when using subjective ones [15, 41-44]. Even within the objective measures, the tools use differing methods to assess health literacy. While the NVS measures numeracy and reading skills based on a nutrition label from an ice cream container, the S-TOFHLA also measures these skills using a fill-in-the-blanks text with a choice of words and the REALM measures health literacy by means of an oral reading and recognition test. Moreover, studies repeatedly point out that tools might not have been sensitive or discriminative enough [15, 29]. Additionally, the majority of the studies included in the review did not use the cut-off points to display different health literacy levels, as suggested in the manuals of the original tools. The studies mostly condensed the 'High', 'Medium' and 'Low' cut-offs for health literacy to just 'High' and 'Low'. Other studies [15, 17, 26, 29] offered an overall mean score, which impedes comparisons across studies.

The definition and level of education in the samples of the included studies is heterogeneous. Therefore, specific subgroup-analysis based on education were not feasible. Studies depict that the majority of participants had some form of higher education, such as college or university degree. Yet still, health literacy levels are not consistently adequate throughout the studies. High educational attainment alone does not

translate to adequate health literacy levels [21] and is not sufficient to prepare pregnant women for events that occur during pregnancy, such as counselling for prenatal genetic testing [14]. Hence, health literacy sensitive interventions during pregnancy could be beneficial for all pregnant women, regardless of their educational and health literacy levels [14].

The studies included in this review depict associations between health literacy and outcomes within the categories of health beliefs and attitudes, knowledge and lifestyle (objective two). Women with limited health literacy had more negative beliefs regarding medication [19], whereas women with adequate health literacy made more informed choices with regard to prenatal testing [31]. Women with adequate health literacy scored better in knowledge-based questionnaires. The positive association between adequate health literacy and adequate knowledge is supported by other studies [45]. Concerning lifestyle, one study found a positive association between limited health literacy and probability of smoking. Health literacy research confirms this association, as well as other negative behaviors that go hand-in-hand with limited health literacy [46].

Although research in the field of health literacy has gained more attention in recent years, it was not possible to identify a study that was aimed at improving health literacy among pregnant women, and that therefore addressed our third research objective. Only one study conducted an RCT with an intervention in order to improve knowledge that resulted in health literacy sensitivity, meaning women benefitted equally regardless of their health literacy levels [14]. This is striking, since the majority of the studies stress the importance of health literacy-sensitive actions in improving health literacy among pregnant women. RCTs on health literacy actions should also consider facilitators and barriers for implementation such as the time required for cli-nicians to provide adequate consultation, improvement of health information regarding health literacy and the format of material provided (e.g. written or web-based). Enabling people to find, understand, appraise and apply health information is also highly relevant to ensure the provision of truly informed consent.

The studies included in the review reveal that the role of health professionals during pregnancy is crucial, since they provide women with prenatal counselling. It is therefore crucial for healthcare providers to ensure that women understand the health information they are given. Women with limited health literacy might benefit from additional explanation for genetic testing both prior to the test and after receiving normal test results [32]. This is, as women with an adequate level of health literacy are more likely

to make an informed choice with regard to whether or not to have NIPT [31]. Medicine adherence is also dependent on the healthcare providers' responsiveness to the women's ability to understand health information [21]. This is particularly the case for women with limited health literacy, who mainly rely on the information provided by healthcare providers because they do not use the Internet to find health information. Instead, they are more likely to rely on interpersonal communication and, primarily, on their healthcare providers, because they lack the skills required to find and understand health information from other sources [29]. This reliance is also likely to result in a 'powerful others'-oriented fetal health locus of control, meaning that women with limited health literacy believe their healthcare provider is responsible for the infants' health [29]. Research already suggests that interventions are needed to improve health literacy in patients from a systems perspective, meaning that health professionals need to improve their communication skills towards being more health literacy-sensitive [47, 48]. Visscher et al. identified three factors that increase the likelihood of health literacy interventions being effective: (1) The interventions' activities are tailored to the particular needs of people with limited health literacy, (2) they target interactive and/or critical health literacy skills (as opposed to being purely knowledge-based) and (3) they present information in an understandable way [49].

Limitations

The results of this review must be viewed in the light of several limitations. Firstly, the studies included in the review were mainly of moderate quality. This is critical to the validity of this review, as studies with a good level of evidence are lacking. This can be attributed to the nature of the study designs, namely cross-sectional studies. However, the majority of the studies that exist in the field have a cross-sectional design, which indicates the need for RCTs in the field of health literacy among pregnant women. This way, causal associations can be evaluated. Additionally, the majority of studies indicate that the sample might not be representative, which is attributable to the sample size or sampling method. Moreover, educational level was not categorized in a standardized manner, which hindered separate analyses based on this characteristic. Secondly, no interventions exist for improving health literacy among pregnant women. Due to the lack of such studies, it was not possible for us to achieve the third objective of this review. Thirdly, we did not include databases that cover midwifery in our search. This might have led to the omission of relevant literature. Fourthly and finally, the decision to limit eligible

literature to that published in English might also have led to the neglect of important studies.

Conclusions

The results of this review indicate that health literacy levels in pregnant women vary across different studies. Even though most studies were conducted in western countries, limited health literacy was present and might be due to the socio-economic status of the study participants. Some of the studies included in the review recruited women from clinics that predominantly catered to low-income patients, which might be attributable to the low socio-economic status of such women. However, data formats did not allow for analyses e.g. based on educational level. The association between health literacy and different health outcomes that are present in the studies of this review are well known for other populations as well. Health literacy research suggests that inadequate health literacy is associated with smoking, higher risk perception and negative beliefs about medication and non-adherence to prescribed medicines, which is also true for pregnant women. With the studies depicting low levels of health literacy, it is striking that no interventions exist to improve the health literacy during pregnancy. Not only because an adequate level of health literacy is important for the health of the women involved, but also because health literacy levels influence other health outcomes and behaviors during pregnancy, which will most likely affect the unborn child's health and development. Additionally, to ensure informed consent in medical decision-making conforms to legal and ethical requirements, the effects of health literacy on providing informed consent should be investigated. Overall, randomized-controlled intervention studies are needed to build evidence-based strategies to increase health literacy for better health among pregnant women.

Supplementary Materials: The following are available online at https://www.mdpi.com/article/10.3390/ijerph18073847/s1, Table S1: Ethnicity and Education and Table S2: Quality Assessment.

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CHAPTER 6

Dissertation Project 2

Health literacy among pregnant women in a lifestyle intervention trial: protocol for an explorative study on the role of health literacy in the perinatal health service setting

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Abstract

Introduction Pregnancy is a vulnerable period that affects long-term health of pregnant women and their unborn infants. Health literacy plays a crucial role in promoting healthy behaviour and thereby maintaining good health. This study explores the role of health literacy in the GeMuKi (acronym for 'Gemeinsam Gesund: Vorsorge plus für Mutter und Kind'—Strengthening health promotion: enhanced check-up visits for mother and child) Project. It will assess the ability of the GeMuKi lifestyle intervention to positively affect health literacy levels through active participation in preventive counselling. The study also explores associations between health literacy, health outcomes, health service use and effectiveness of the intervention.

Methods and analysis The GeMuKi trial has a hybrid effectiveness–implementation design and is carried out in routine prenatal health service settings in Germany. Women (n=1860) are recruited by their gynaecologist during routine check-up visits before 12 weeks of gestation. Trained healthcare providers carry out counselling using motivational interviewing techniques to positively affect health literacy and lifestyle-related risk factors. Healthcare providers (gynaecologists and midwives) and women jointly agree on Specific, Measurable, Achievable Reasonable, Time-Bound goals. Women will be invited to fill in questionnaires at two time points (at recruitment and 37th–40th week of gestation) using an app. Health literacy is measured using the German version of the Health Literacy Survey-16 and the Brief Health Literacy Screener. Lifestyle is measured with questions on physical activity, nutrition, alcohol and drug use. Health outcomes of both mother and child, including gestational weight gain (GWG) will be documented at each routine visit. Health service use will be assessed using social health insurance claims data. Data analyses will be conducted using IBM SPSS Statistics, version 26.0. These include descriptive statistics, tests and regression models. A mediation model will be conducted to answer the question whether health behaviour mediates the association between health literacy and GWG.

Ethics and dissemination The study was approved by the University Hospital of Cologne Research Ethics Committee (ID: 18-163) and the State Chamber of Physicians in Baden-Wuerttemberg (ID: B-F-2018-100). Study results will be disseminated through (poster) presentations at conferences, publications in peer-reviewed journals and press releases.

Trail registration German Clinical Trials Register (DRKS00013173). Registered pre-results, 3rd of January 2019, https://www.drks.de

Strengths and limitations of this study

- Health literacy will be measured subjectively as well as objectively.
- All questionnaires are self-administered, which might lead to overestimation.
- A comprehensive recruitment strategy, supported by all German statutory health insurance companies, will contribute to inclusion of pregnant women with different health literacy levels.
- Women not proficient in German language are not included, which might result in exclusion of migrants and illiterate women.
- As inclusion takes place before the 12th week of gestation, other vulnerable groups that are less likely to use early antenatal care might not be included (such as women under the age of 18 years, heavy drug or alcohol users).

Introduction

Health literacy describes a person's ability to access, understand, appraise and apply health information to make informed decisions regarding their health [1]. Inadequate health literacy is associated with a diversity of negative outcomes, such as more hospital visits and medication use, less utilisation of screening as well as negative health behaviours, such as drug and alcohol use and unhealthy nutrition [2,3]. Accordingly, adequate health literacy is important to achieve and maintain good health.

A population-based study in 2014 revealed that more than 50% of the German population has an inadequate health literacy level [4]. As a result, a group of experts from academia, practice and policy was formed to develop a 'National Action Plan Health Literacy' (NAP) to improve health literacy in Germany [5,6]. The action plan advocates for addressing health literacy both early in life and through measures at the healthcare system level, for example, by facilitating navigation, creating user-friendly information as well as comprehensible communication between health professionals and users [5]. The action plan points out that measures to strengthen health literacy should focus on various user groups in the healthcare system, particularly vulnerable groups, for example, people with limited socioeconomic resources and people with migration backgrounds.

Pregnancy is a vulnerable time in which women are confronted with a diversity of changes, not only physically, but also with regards to the responsibilities of being pregnant and becoming a parent. These changes make women and parents sensible to preventive health information [7]. However, the large quantity and diverse quality of the available information make it difficult for women to understand and decide which information is relevant to them [8]. Studies demonstrate that compared to women with adequate health literacy, women with inadequate level of health literacy more frequently smoke during pregnancy, do not exclusively breast feed their child the first months after birth and do not engage in prenatal care at the beginning of the pregnancy [9-13]. These lifestyle behaviours are likely to impact long-term health outcomes for both mother and child. Through a process referred to as perinatal programming, external factors such as maternal health behaviours influence the fetal development alongside genetic factors and thereby affect the risk of developing obesity and chronic diseases [14]. For example, a pregnant woman's nutrition and physical activity can result in excessive gestational weight gain (GWG). GWG is linked to increased pregnancy and birth complications, including the risk of obesity or chronic conditions, such as type 2 diabetes in the offspring [15]. Therefore, to reduce these risk factors, it seems important that pregnant women

find, understand and apply health information relevant to a healthy lifestyle and GWG during pregnancy.

Research suggests that health literacy-sensitive educational interventions promote desirable health outcomes such as self-care behaviour, particularly physical activity [16]. To date however, little is known about the role of health literacy during pregnancy. Health literacy interventions for pregnant women and studies examining the effectiveness of such are also lacking [17,18]. Interventions that exist do not measure health literacy directly, which leads to the lack of evidence in this area [17,18]. This study seeks to address this gap. It explores the relationship of health literacy with other variables within the GeMuKi (acronym for 'Gemeinsam Gesund: Vorsorge plus für Mutter und Kind'—Strengthening health promotion: enhanced check-up visits for mother and child) Project. The GeMuKi Project examines a novel lifestyle intervention during pregnancy. The intervention consists of a brief lifestyle intervention implemented during routine prenatal check-ups (also often referred to as antenatal appointments) in the German state of Baden-Wuerttemberg. The intervention aims to contribute to a healthy lifestyle and adequate GWG by strengthening health literacy of pregnant women. Building on the NAP, GeMuKi seeks to strengthen health literacy through (a) involving pregnant women actively in the counselling, (b) enabling participation when setting joint goals to improve health behaviour and (c) making health information understandable in counselling sessions.

For the present study, it is hypothesised that (a) health literacy levels are positively affected by the GeMuKi intervention through increased knowledge, more active participation, better adherence to lifestyle goals; and (b) health literacy has an impact on further variables, including health outcomes, health behaviour as well as health service use during pregnancy. The following research questions will be answered:

1. Can health literacy levels in pregnant women be improved by means of the GeMuKi lifestyle intervention during regular check-ups?
2. Do health outcomes, health behaviour and health service use differ between pregnant women with high and low health literacy levels participating in the GeMuKi lifestyle intervention trial?
3. Is the association between health literacy and weight development during pregnancy mediated by health behaviour?

Methods

Data on health literacy, health outcomes and health service use during pregnancy will be collected in the GeMuKi Project, which started in October 2017 and will end in March 2022. The project uses a hybrid effectiveness–implementation design (type II). Hybrid effectiveness–implementation designs allow for the blended assessment of clinical effectiveness and implementation to rapidly translate research results into practice. Type II indicates that clinical and implementation areas are tested simultaneously as opposed to other types [19]. The study consists of two arms: the intervention group receives a brief counselling (GeMuKi) in addition to regular care, while the control group receives regular care. The lifestyle intervention takes place within the 11 regular check-up visits during pregnancy and the infants' first year. The present study will focus on the period from the first check-up during pregnancy until birth. It will consider only check-ups conducted by gynaecologists and midwives. Since the study takes place in Germany, the setting needs explanation: in the German healthcare system, women usually visit a gynaecologist to confirm a pregnancy and from then onward visit their gynaecologist and if possible a midwife for check-up appointments. A detailed description of the general design of the GeMuKi Project can be found elsewhere [20]. Health literacy is a complex concept that has been insufficiently studied during the time of pregnancy. Therefore, a separate in-depth analysis of health literacy-related aspects is warranted. This paper particularly focuses on health literacy and addresses research questions that have not been described elsewhere, as they go beyond the evaluation of effectiveness and implementation of the GeMuKi Project.

Study sample

The study sample is recruited in participating gynaecologist practices. Gynaecologists determine the eligibility of pregnant women, using the following inclusion criteria: ≥18 years old, <12 weeks of gestation at recruitment and proficient German language skills. Women are not eligible when scoring high on the Edinburgh Postnatal Depression Scale, defined as a total score of greater than 9 (probability of a depression) or a score of 3 (answering 'yes, very often') on item number 10 'The thought of harming myself has occurred to me'. The exclusion is justified by the probability of depression and/or suicidal thoughts for which women need urgent and particular care. In the event of the explained scoring, the project team also suggests another project, which takes place simultaneously

with a focus on maternal depression. This procedure aims to reduce the risk of bias that could be introduced by co-interventions [20].

The sample is expected to include a wide range of health literacy levels, since inclusion criteria are widely defined and different statutory health insurance companies partake in the project with different characteristics of the insured people. The inclusion of different insurance companies that exist in Germany allows to include women with diverse socioeconomic status, migration background and health status (e.g., smoking behaviour, obesity and cardiovascular disease) [21]. Moreover, about 84% of all pregnant women come for the first check-up before the 13th week of pregnancy; 80% attend at least 10 preventive examinations during pregnancy [22].

A more detailed description of the study sample is provided by Alayli et al. [20]. They estimated 1860 participants to be needed in the study. For the health literacyrelated research questions described here, this sample size is considered sufficient. To counteract cumulating type 1 errors due to multiple testing, Bonferroni corrections will be made.

Health literacy strengthening intervention

GeMuKi is a multiprofessional computer-assisted lifestyle intervention [23]. During pregnancy, the intervention is carried out by gynaecologists and midwives. It aims at strengthening health literacy and positively affecting lifestyle-related risk factors in women and their infants.

Preventive counselling to strengthen health literacy

Health literacy will be strengthened during the counselling sessions by actively involving pregnant women in the decision-making process, which lifestyle topic to focus on in the counselling. This way, women reveal themselves in which areas they need further counselling and the healthcare provider does not provide information when it is not needed. Participation is one of the recommendations of the NAP to improve health literacy. The topics of the counselling are based on the national recommendations on a health-promoting lifestyle during pregnancy and after birth from the 'Healthy Start—Young Family Network' (Netzwerk Gesund ins Leben) [24]. The recommendations provide gynaecologists, midwives, paediatricians and other medical professionals with a basis for counselling a healthy lifestyle [24]. The first recommendations from 2012 were updated in 2018, adding recommendations for the time before pregnancy and around the conception phase [24].

To strengthen health literacy of the participants, healthcare providers receive a training, focusing on lifestyle during pregnancy, including nutrition and physical activity. Healthcare providers are trained to communicate key messages from the recommendations by means of Motivational Interviewing (MI). The counselling is practised in role-plays with all participants. As behaviour change is considered a health literacy skill, MI is used, which is built on the notion that people autonomously change their behaviour [25]. This should be considered by healthcare providers when carrying out the counselling: healthcare providers are supposed to actively listen and react with open-ended questions to trigger behaviour change. It is in line with the NAP, which recommends that health professionals should communicate sensitively to the health literacy levels of the individuals in order to positively affect their health literacy and thus health behaviour. At the end of each counselling appointment, the participant, along with the support of the healthcare provider, will set up SMART (Specific, Measurable, Achievable, Reasonable, Time-Bound) goals to positively change behaviour, which can be accomplished until the next appointment. The SMART goals are individualised and adapted to the capacities of women. This way, the counselling and the SMART goals are tailored to the health literacy levels of women.

Digital intervention component to strengthen health literacy

Digitalisation is used as recommended by the NAP to strengthen health literacy by providing pregnant women with the GeMuKi app. The app is used by the participants to (1) receive health information on pregnancy and (2) receive the SMART goals as push notifications. The app is designed in an easy-to-handle way, which is accessible for women with different health literacy levels. App usage on mobile phones is the most appropriate way to reach women, as research suggests that women with low level of health literacy rather use mobile phones than email communication or the internet [26]. For purposes of the evaluation study, the app is also used by pregnant women to fill in questionnaires.

Table 7 Variables and data sources

Variable	Data source	Measures
Participant characteristics	Paper-based questionnaire	Age, weight, height (also from the child's father)
Health literacy	Questionnaires, answered in the app	HLS-EU-16, BHLS, knowledge-based questions
Maternal health outcomes	Maternity record booklet data, entered into the counselling tool	Health data such as weight, gestational diabetes mellitus

(including GWG)		
Foetal and neonatal health outcomes	Child medical record booklet data, entered into the counselling tool	Health data such as large for gestational age
Maternal health behaviour	Questionnaires, answered in the app	PPAQ, FFQ, alcohol and smoking
Health services use	Health insurance claims data	Inpatient and outpatient treatment, medication use, aids and remedies, sick leave

BHLS, Brief Health Literacy Screener; FFQ, Food Frequency Questionnaire; GWG, gestational weight gain; HLS-EU-16, Health Literacy Survey-16 items; PPAQ, Pregnancy Physical Activity Questionnaire.

Healthcare providers enter results from the prenatal check-ups into the maternity and child medical record booklets. These data, along with GWG and the chosen lifestyle topic, are entered into the GeMuKi-Assist counselling tool. The tool is a component of the telehealth platform GeMuKi-Assist, which was particularly developed for the healthcare providers. The counselling tool also provides supporting questions on each counselling topic that healthcare providers can ask during the counselling, which are built on the tenets of MI. In this platform, healthcare providers document the SMART goals during each counselling, which later will be displayed in the women's app. Via the counselling tool, the gynaecologist and midwife of a particular woman have access to the chosen lifestyle topics, goals and medical record booklet data to ensure continuity of the counselling. Study coordinators are available in every study region to support healthcare providers with any question arising, including questions on the content of the counselling, the counselling procedure, data entry and technical support. In addition to that, handouts and folders are handed to all participating healthcare providers before patient recruitment starts.

Variables

Table 1 provides a summary of the variables that will be used in the data analysis. Data will be derived from various data sources collected in the GeMuKi Project: weight, data from the maternity record booklet and child medical record booklet are entered by healthcare providers in the GeMuKi-Assist counselling tool. The app entails questionnaires that women fill in at two time points during pregnancy (figure 1). Participating health insurance companies provide health insurance claims data.

Participant characteristics

Demographic information and anthropometric data (such as height and length) to characterise the sample will be derived from a paper-based questionnaire handed out at

baseline in the GeMuKi Project (before the 12th week of gestation; figure 1) of both the pregnant woman and the infant's father. These data will give information on the body mass index (BMI) of the parents, which later will be included in the analysis [20].

Health literacy

Health literacy is assessed using different instruments: the Health Literacy Survey (HLS-EU-16) will be used at baseline, to assess a detailed description of the general health literacy levels of pregnant women. When applied in the German general population, it has shown a high internal consistency (Cronbach's alpha of 0.90) [27]. Additionally, this instrument has been used in other studies in Germany, offering the possibility to compare results with our study population. Questions can be answered on a 5-point Likert scale ('very difficult'–'very easy'; 'I don't know'). Since the HLS-EU-16 also includes questions on illness, these questions may not be suitable for our study population as we cannot assume that all pregnant women have some kind of illness and pregnancy cannot be translated into illness. Therefore, we have supplemented the regular 16-item HLS-EU with two further questions, which particularly aim at pregnancy ('How easy would you say it is to find information on your pregnancy?' and 'How easy would you say it is to use information the doctor gives you to make decisions about your pregnancy?'). Since paper-based questionnaires provide the option to not tick an answer and skip questions, for all questions the additional response category 'I do not want to answer this question' is included in the app-based survey. To asses change in health literacy as a result of the GeMuKi intervention, the Brief Health Literacy Screener (BHLS) will be used at both time points (t0 and t1). The tool screens for inadequate health literacy using three questions, which can be answered on a 5-point Likert scale ('never'–'always' and additionally 'I do not want to answer this question'). Other studies demonstrated high internal consistency for this instrument with a Cronbach's alpha of 0.80 among hospital patients [28]. Modification of health literacy levels will be observed by assessing changes in the proportion of study participants with inadequate health literacy between the beginning and end of pregnancy.

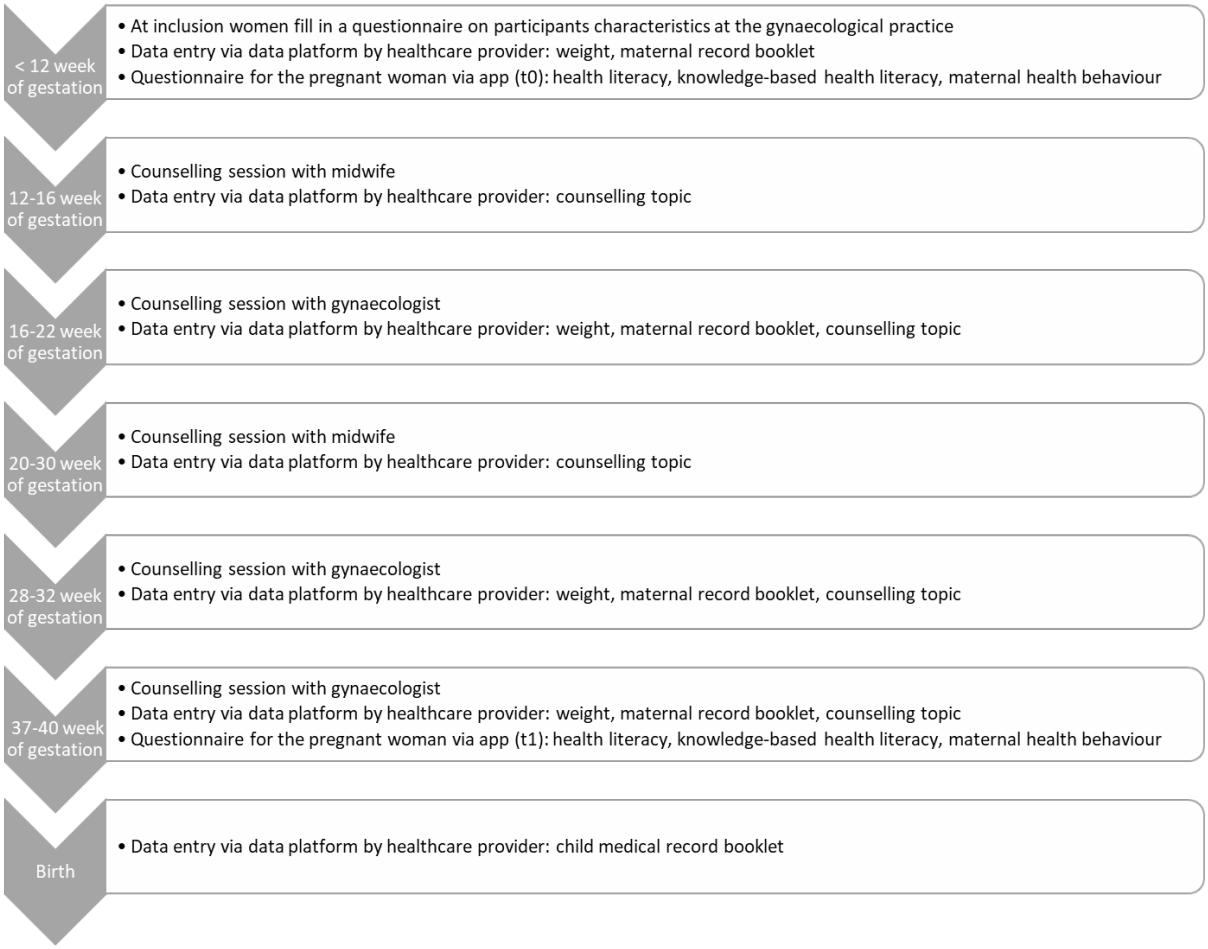

Figure 4 Overview of counselling sessions and time points of data collection.

Knowledge-based health literacy

In addition to the above described measures, which provide subjective estimates of health literacy, an objective measure of health literacy was developed, consisting of knowledge-based questions. Knowledge-based questionnaires can be used to assess health literacy because knowledge acts as a proxy for health literacy [29]. Each question was developed based on the topics of the national recommendations discussed during counselling. They cover the following topics: weight development, nutrition, alcohol and drug use, physical activity, water intake and breast feeding. The questionnaire was developed by researchers of the project with the support of nutritionists who work in the project. Answers can be given on a 'yes/ no/I don't know' scale. The questionnaire will be statistically analysed calculating frequencies of correct answers.

Maternal health outcomes

During every routine prenatal visit, practice assistants enter data from the maternity record booklet into the GeMuKi-Assist counselling tool. To evaluate maternal health outcomes, one composite measure will be used, derived from the following variables: pre-

eclampsia or pregnancy-induced hypertension, gestational diabetes mellitus, caesarean section and preterm delivery. This measure has been proposed in a Delphi study on the evaluation of lifestyle interventions during pregnancy [30].

Fetal and neonatal health outcomes

Health data of the child will be recorded at birth in the child medical record booklet. It entails among others the following variables: small for gestational age and large for gestational age.

Maternal health behaviour

Physical activity will be measured using the Pregnancy Physical Activity Questionnaire. This instrument assesses the duration, frequency and intensity of physical activity in pregnant women. It has been used internationally and exhibits Cronbach's alphas above the threshold of 0.70 [31,32]. Nutrition will be assessed using an adjusted version of the Food Frequency Questionnaire from the German Health Examination Survey for Adults [33]. This instrument evaluates the frequency of consumption of food groups. Alcohol and smoking is assessed using questions from the German Health Interview and Examination Survey for Children and Adolescents [34].

Table 8 Weight gain recommendations adjusted by BMI.

Weight	**BMI (kg/m²)**	**Recommended weight gain (range in kg)**
Underweight	<18.5	12.5-18
Normal weight	18.5-24.9	11.5-16
Overweight	25.0-29.9	7-11.5
Obese	≥ 30.0	5-9

BMI, body mass index.

Gestational weight gain

Maternal weight is documented in every pregnancy check-up visit using the maternity record booklet and entered into the telehealth platform GeMuKi-Assist. In this study, the recommended range of GWG is defined according to the Health and Medicine Division of the National Academies of Science, Engineering and Medicine [35]. The recommendations are based on prenatal BMI and are displayed in table 2.

Weight gain above the recommendation is classified as excessive weight gain. These recommendations were recently confirmed by 25 pooled cohort studies [36].

Health service use

Data on health service use will be based on health insurance claims and delivered by the participating health insurance companies. These data are pseudonymised and entail data on inpatient and outpatient treatment (diagnosis, duration of hospital stay and costs), medication use (pharmaceuticals, amount and costs), aids and remedies (duration of service and costs), and sick leave periods (duration of sick leave and sick pay) [37].

Data analysis

Plausibility checks of the data will be performed continuously during data collection and before data analysis. Multiple imputation methods will be used to deal with missing values. Descriptive statistics will be used to analyse participant characteristics, such as age and BMI at baseline. Correlations will be calculated to examine whether health literacy levels vary depending on BMI, health outcomes, socioeconomic status and migration background.

Differences in means will be calculated to answer whether the intervention improved health literacy levels in pregnant women. Health literacy change will be analysed comparing the proportion of women with inadequate health literacy at baseline and end of pregnancy. Regression analysis will be used to answer the question whether health literacy levels influence the effectiveness of GeMuKi as well as maternal and fetal health outcomes and health service use. A mediation analysis will be conducted to answer the question whether health behaviour (mediator) mediates the association between health literacy (independent variable) and GWG (dependent variable) (figure 2).

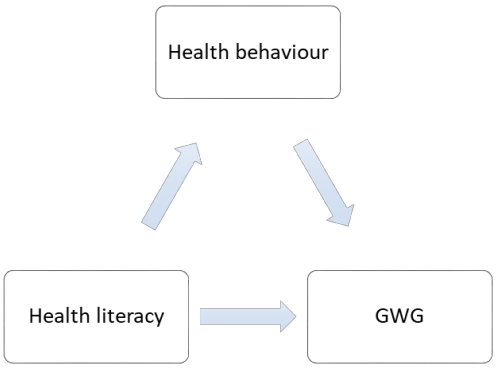

Figure 5 Mediation model. GWG, gestational weight gain.

Patient and public involvement

Within the frame of the GeMuKi Project, a process evaluation will be conducted, including interviews with participating pregnant women. The interviews aim to answer questions

on hindering and supporting factors of the intervention. The overall results of the GeMuKi Project will be made available to all participants at the end of the project period.

Ethics and Dissemination

The GeMuKi Project was approved by the University Hospital of Cologne Research Ethics Committee (ID: 18-163) and the State Chamber of Physicians in Baden-Wuerttemberg (ID: B-F-2018-100). Inference to study participants is not possible since the collected data are pseudonymised in accordance with the European Union General Data Protection Regulation. Written informed consent will be obtained from all study participants at baseline. Participants are reassured that they are free to withdraw from the study at any time during the study without consequences. Study results will be disseminated through (poster) presentation at conferences and publications in peer-reviewed journals. Additionally, press releases are made to inform the general public. A closing event is planned with stakeholders to discuss the potential implementation of GeMuKi into regular care.

Discussion

To date there is little research on health literacy in pregnant women and interventions to improve health literacy in this population according to two newly published systematic reviews [17,18]. Even though pregnant women are confronted with a lot of health information during pregnancy, it is difficult to differentiate between the quality of information and which one is important [8]. This is particularly important in light of informed decision-making, not only to make a decision for their own health but also for the infant [38]. For instance, adequate health literacy supports pregnant women in deciding to use complementary medicine products [39].

Studies on health literacy in pregnant women are scarce and if they exist, they do not evaluate the change of health literacy as a result of an intervention [17]. To our knowledge, this is the first study assessing the impact of an intervention that aims at improving health literacy in pregnant women and the influence of health literacy on various outcomes during pregnancy, such as GWG, lifestyle and health service use. It is hypothesised that health literacy is increased by a lifestyle intervention that is health literacy-sensitive.

Pregnancy offers an important phase, in which the health literacy level of pregnant women is not only relevant to their own health but also to that of the (unborn) child. This study is set up at the very beginning of the pregnancy to explore the impact of health

literacy on the health of both mother and child. The GeMuKi Project evaluates a low-threshold lifestyle intervention that is accessible for all pregnant women as it is provided in the regular check-ups during pregnancy. Previous research supports that low-threshold interventions are easily accessible for women with both high and low health literacy levels and lead to successful implementation of an intervention [40]. The intervention consists of brief counselling sessions conducted by means of MI, a technique with which healthcare providers can tailor the counselling to the health literacy levels of pregnant women. MI techniques also allow women to participate actively in the counselling sessions, strengthening the autonomy, which is a skill that positively affects health literacy [1]. Research suggests that MI is effective in promoting and positively changing health behaviour [41], which in turn results in better health outcomes according to the model of Sorensen et al. [1]. To be health literacy-sensitive, the intervention makes use of digitalisation. Each counselling session is concluded with a SMART goal, defined by both the healthcare provider and the woman and recorded in the counselling tool, which will then be displayed in the GeMuKi app of the pregnant woman. The app also provides further information on topics that pregnant women might be concerned with and are easily accessible. Using digitalisation to promote health literacy has been part of other studies and is proven to be effective [40]. Briefly worded, the GeMuKi Project focuses on the empowerment of participating women, which is a crucial health literacy skill [1] and is seen as an empowerment tool for mothers [42]. The empowerment is supported by active participation of the women in the counselling and goal setting, which will strengthen the autonomy, support behaviour change and thus result in better health outcomes.

An advantage of this study is that we will answer questions that arise with regards to health literacy in pregnant women. Studies to date have measured health literacy in pregnant women, however it was only one of many secondary outcome variables [17,18]. To better understand the association between health literacy of pregnant women and (health) outcomes in both mother and child, we analyse different data using questionnaires, data entry from the healthcare provider and health insurance data of participants. Additionally, health literacy is measured using different instruments. The HLS-EU-16 is tailored to the study participant's situation by adding questions regarding pregnancy. The BHLS is used at the beginning and end of the pregnancy to assess for changes in the health literacy levels. Knowledge-based health literacy questions were

developed to assess objectively whether women understand health information on lifestyle during pregnancy and answer these questions correctly.

However, some limitations have to be taken into consideration with regard to this study. Associations between health literacy and other variables are examined within the GeMuKi Project. Hence, we cannot conclude that the results can be generalised to other interventions. Additionally, the implementation of the counselling is not monitored, which is why it is not guaranteed that healthcare providers follow the principles of promoting health literacy and implement what was taught in the training. With regard to the training, it must be mentioned that health literacy is a secondary outcome of the GeMuKi Project, which is why health literacy did not take as much time as lifestyle topics during the training. Even with the inclusion of different health insurance companies, illiterate pregnant women might not be able to fill in the baseline questionnaire and will be excluded from the study, which rules out an important group that most likely requires health literacy strengthening. Even though the GeMuKi app was developed to be easily manageable, it cannot be guaranteed that this is sufficient for women who have low digital health literacy skills. This might impact the handling of the app. The app entails self-administered questionnaires, which are prone to overestimation, a further limitation we have to take into account. Results of this study can contribute to the better understanding of health literacy on various outcomes and health service use, particularly during pregnancy. Study findings can provide insights for researchers and policy-makers, who want to develop and fund health literacy-sensitive interventions starting during pregnancy.

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CHAPTER 7

Dissertation Project 3

Understanding Determinants of Pregnant Women's Knowledge of Lifestyle-Related Risk Factors: A Cross-Sectional Study

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Abstract

Research indicates that a woman's lifestyle during pregnancy influences her child's health and development. Therefore, women need to possess sufficient knowledge regarding the elements of a healthy lifestyle during pregnancy. To date, there has been little research on the assessment of lifestyle knowledge of pregnant women in the perinatal healthcare setting. This study describes the development and application of a knowledge-based questionnaire for pregnancy, to be used in a lifestyle intervention trial conducted in Germany. Within the trial, pregnant women receive counselling on lifestyle topics. These topics are based on the German initiative 'Healthy Start—Young Family Network' (GiL), which provides evidence-based recommendations regarding diet and lifestyle before and during pregnancy. These serve as a basis for health professionals who provide counselling on healthy lifestyle choices during the antenatal period. The questionnaire consists of eight items, each of which can be answered using 'Yes', 'No' or 'Don't know'. The pregnant women who completed the questionnaire at baseline around the twelfth week of gestation were recruited within the host trial from gynaecological practices in Germany. Demographic variables and the respondents' answers to the questionnaire were analysed using descriptive statistics and regression analyses. Descriptive statistics show that more than 85% of participants answered the majority of questions (n = 5) correctly. Questions on whether tap water is safe and the normal range for gestational weight gain (GWG) were answered correctly by about 62% and 74% of the women, respectively, and the question on whether it is beneficial to obtain information on breastfeeding at an early stage was answered correctly by about 29%. The results of the regression analyses indicate that age, gestational week, education and income are positive predictors for answering the questionnaire correctly. Nullipara and migration background are predictors for answering the questions incorrectly. This study indicates that there are gaps in women's knowledge regarding lifestyle during pregnancy. Particular focus on certain topics, such as breastfeeding and normal GWG ranges, is still required during counselling. Our analysis shows that migration background is a predictor of insufficient knowledge and incorrect answers to the questions. Women with such backgrounds require special attention during antenatal counselling in order to cater to their needs and the gaps in their knowledge.

Keywords: questionnaire; knowledge; pregnancy; lifestyle; gestational weight gain; nutrition; physical activity; substance use

Introduction

Research indicates that a mother's health behaviour during pregnancy influences her child's health and development. Through a process referred to as perinatal programming, external factors, such as a pregnant woman's lifestyle influence risks during pregnancy, birth complications and the child's susceptibility to health impairments, such as obesity and chronic diseases [1–3]. The way the pregnant woman's weight changes play a key role in this regard. Excessive weight gain increases the risk of birth complications and gestational diabetes [4–6], macrosomia [7], large for gestational age (LGA) [8] and obesity later in the child's life [9]. Beneficial behaviours include exercise and physical activity, as these are positively associated with pregnancy outcomes, such as the reduction in LGA and gestational diabetes mellitus (GDM) [10], lower likelihood of preterm birth [11] and normal mode of delivery [12]. Alcohol con-sumption during pregnancy is a further risk factor and bears an increased risk of a variety of negative health outcomes for the offspring. These include growth defects, tissue and nerve damage and behavioural impairments [13]. The same holds true for smoking, which is also associated with negative health effects for the foetus, such as preterm birth, obesity and intellectual impairments [14].

Existing within the German antenatal healthcare setting, the 'Healthy Start—Young Family Network' (GiL) is an alliance that provides evidence-based recommendations for counselling on healthy lifestyle choices during pregnancy to health professionals involved during the antenatal period (e.g., gynaecologists, midwives, paediatricians) [15]. The network was established by the German Federal Centre for Nutrition (BZfE) and consists of a multidisciplinary scientific task force in the antenatal field. The information it provides on healthy lifestyle choices is tailored to specific target groups: either the aforementioned health professionals or families and women in the antenatal phase. The recommendations provided by the GiL are based on extensive systematic reviews, which were first published in 2012 and later updated in 2018 [15]. Regarding weight gain, the GiL recommends a range of 10–16 kg for women of normal weight, while about 10 kg is considered sufficient for overweight and obese women [15]. They also suggest for pregnant women to be physically active for at least 30 min, five days a week [15]. Guidelines on energy intake are difficult to find. However, a well-balanced diet, fruit, vegetables and wholegrain product consumption are recommended [16–18]. According to the German recommendations, energy requirements during pregnancy only increase by 10% in the last trimester [15]. The consump-tion of alcohol is advised against at both

the national and the international level, as there is no available evidence regarding the amount of alcohol that can be consumed safely during pregnancy. Even if a pregnant woman does not smoke herself, passive smoking also bears risks, which is why pregnant women are additionally advised to avoid being in rooms where people are smoking [15–18]. Breastfeeding after birth is highly recommended wherever possible due to the benefits it offers both mother and child [19,20]. In order to enable them to follow a healthy lifestyle during pregnancy, it is necessary to ensure that women possess a full understanding of these health facts regarding the lifestyle factors that influence their child's development during pregnancy. Since these recommendations are supposed to be communicated by healthcare providers during antenatal appointments, pregnant women should possess sufficient knowledge on these topics. However, research indicates that this is not the case: international studies show that women lack knowledge when it comes to pregnancy-related risk factors that might be harmful to the health and development of their unborn children, such as alcohol use, (passive) smoking, nutrition [21] and obesity in the mother [22,23].

Few existing questionnaires assess lifestyle knowledge among pregnant women. While questionnaires do exist on the assessment of separate topics, such as nutrition [24,25], nutrition and physical activity [26], nutrition and supplement intake [27], pregnancy-related risk factors [28] and alcohol consumption [29], we were unable to find a comprehensive questionnaire that assessed knowledge levels regarding both lifestyle and breastfeeding during pregnancy. Only one recent study conducted in Germany had developed a questionnaire covering lifestyle and expanded it to include topics such as dental health [30]. With its 22 items and multiple-choice and multiple-select answers, this tool might be impractical for a clinical setting. As such, we have developed a short, knowledge-based questionnaire on lifestyle during pregnancy in the antenatal healthcare setting that could be used as a screening instrument and provided initial results on its usage. The aim of this study is to evaluate the level of knowledge concerning lifestyle behaviour among pregnant women and the association between socio-demographic and pregnancy variables and knowledge levels.

Materials and Methods

For this cross-sectional study, we developed a knowledge-based questionnaire to be filled in by pregnant women around their twelfth week of gestation, which is at baseline, in the perinatal health service setting. The questionnaire was developed as part

of the GeMuKi (acronym for 'Gemeinsam Gesund: Vorsorge plus für Mutter und Kind'—Strengthening health promotion: enhanced check-up visits for mother and child) project, the host trial, which provides counselling on lifestyle topics in addition to regular antenatal care. Details on the project and its design can be found elsewhere [31,32]. According to the definition of health literacy provided by Sorensen et al. (2012), knowledge is a contributing factor to health literacy [33]. As such, we developed a knowledge questionnaire based on the topics that are communicated during counselling by a healthcare provider, which again are based on the GiL's recommendations. The questionnaire was developed by the research team and was then discussed with subject matter experts from the study group. It was pretested on pregnant women (n = 8) at the Women's Clinic at the University Hospital Cologne. Women were asked prior to their antenatal appointment whether they were willing to fill in the questionnaire as part of a questionnaire pretest. In accordance with the principles of cognitive questionnaire pretesting [34], the women were asked whether they had any remarks on the questionnaire after they had filled it in, particularly with regards to comprehension and the phrasing of the questions. Changes were made accordingly, and the questionnaire was finalised.

Description of the Knowledge Questionnaire

The questionnaire development process resulted in eight questions in total, which can be answered on a 'Yes/No/Don't know' scale [31]. Table 1 provides an overview of the items that make up the questionnaire.

Table 9 Knowledge questionnaire.

Topic	Question
GWG	Is it generally recommended for women of normal weight to gain 20 kg during pregnancy?
Portion size	Do pregnant women have to eat larger portions right from the start of their pregnancy to make sure that the baby gets enough food?
Alcohol	Can even small amounts of alcohol harm the unborn baby at any point during pregnancy?
Smoking	Does it harm the unborn child if people smoke around the pregnant woman (passive smoking)?
Physical activity	Does it harm the unborn child if women exercise during pregnancy?
Breastfeeding	Does breastfeeding work better the earlier a pregnant woman receives information about breastfeeding?
Water	Is tap water just as good for a pregnant woman as bottled mineral water?
Whole grains	Are wholegrain products usually the better choice if you want to eat pasta, bread or rice while pregnant?

Sample

The study uses the sample and baseline data from the GeMuKi lifestyle counselling trial conducted in routine antenatal care settings in the state of Baden-Württemberg, Germany [32]. Gynaecologists participating in said trial asked eligible women if they were interested in taking part in the project. These women were handed a paper-based questionnaire at enrolment as a means of obtaining demographic data. After enrolment, they were asked to fill in the knowledge-based questionnaire using an app developed by the Fraunhofer Institute for Open Communica-tion Systems (FOKUS), Berlin, Germany, for the purpose of the trial. Data collection took place from February 2019 to September 2021. They were analysed in November 2021 and entail a sample of 1466 women. The inclusion criteria for the host trial were as follows: on statutory health insurance (in Germany, health insurance is required by law and approximately 86% of the population are enrolled in the statutory insurance [35]), a patient at a participating gynaecological practice, signed informed consent, aged ≥ 18, proficient in German and not yet at the end of the twelfth week of gestation. Additionally, women with mental health issues were excluded, as they would be receiving specialised care.

Statistical Analysis

The questionnaire was statistically analysed using descriptive and inferential statistics such as frequency count, percentage and multiple regressions. In order to calculate the frequency with which questions were answered correctly, each correctly answered question was coded 1; incorrectly answered questions were coded 0. A sum score was built to display the overall score of the questionnaire by adding together the number of correct answers for every single question. The sum score thus ranged from 0 to 8. In order to allow for the application of regression models, the answer 'Don't know' was coded as a missing value. In order to answer the question on the association between sociodemographic and pregnancy variables and knowledge levels, regression analyses were conducted. The women's knowledge regarding lifestyle choices during pregnancy was subsequently selected as a dependent variable, and the individual questions and the sum score were used to build multiple logistic and linear regression models. The linear regression model used listwise deletion. Age, nullipara, net income, migration background and educational level were used as independent variables. Age was used as a continuous variable. Nullipara and migration background were used as dichotomous variables (Yes/No). For migration background, an indicator was calculated using the following

items: a person who was not born in Germany, whose parents were not born in Germany, who has moved to Germany at a later point in life or whose mother tongue is not German. Net income was categorised into percentiles and used as an ordinal variable. Educational level was categorised using the International Standard Classification of Education (ISCED) [36] and likewise used as an ordinal variable. For the purpose of this study, we adapted the following categorisation according to ISCED: primary, lower secondary, upper secondary, post-secondary-non-tertiary and university degree. The sample size was calculated for the initial trial using a different primary outcome than this study [32]. Marital status was excluded from the regression analysis since this variable was collected very vaguely by categorising it into single, married and divorced. A *p*-value of <0.05 indicated statistical significance. Tables with results of the regression analysis entail the total number of included cases. All the analyses were conducted using IBM® SPSS® Statistics for Windows, Version 28.0.

Results

Table 2 provides an overview of the demographic characteristics of the participants.

The mean age of the women who participated in the study was 33; half of the study population did not have any children at the time of participation (50.0%). The household net income was EUR 4295 per month. More than half of the participants had a university degree (55.1%) and were married (67.8%). Women with migration backgrounds represented 22.7% of the total sample.

Table 3 displays the results of the knowledge-based questions. The results indicate that most of the questions (n = 5) were answered correctly by the majority of women (more than 85% of participants). Questions on water intake and GWG were answered correctly by about 62% and 74% of the women, respectively, and the question on breastfeeding was answered correctly by about 29%.

Table 10 Sample characteristics.

Characteristics	
Age	32.8 years (SD 4.37)
Nullipara	50.0% (n = 711/1422)
Migrant	22.7% (n = 329/1447)
Income	Mean: EUR 4295 Percentile 25 = EUR 3250 50 = EUR 4250

	75 = EUR 5200
Education level	
Primary	0.1% (n = 2/1404)
Lower secondary	2.8% (n = 39/1404)
Upper secondary	9.9% (n = 139/1404)
Post-secondary-non-tertiary	32.1% (n = 451/1404)
University degree	55.1% (n = 773/1404)
Marital status	
Single	30.1% (n = 425/1412)
Married	67.8% (n = 958/1412)
Divorced	2.1% (n = 29/1412)

Note: percentages are provided for categorical variables and means for continuous variables. EUR = Euro.

Table 11 Evaluation of questionnaire.

Topic	Correct Answer	Incorrect Answer	Do Not Know	Missing
GWG	1083 (73.9)	76 (5.2)	208 (14.2)	99 (6.8)
Portion size	1366 (93.2)	5 (0.3)	6 (0.4)	89 (6.1)
Alcohol	1257 (85.7)	109 (7.4)	12 (0.8)	88 (6.0)
Smoking	1320 (90)	8 (0.5)	46 (3.1)	92 (6.3)
Physical activity	1327 (90.5)	13 (0.9)	36 (2.5)	90 (6.1)
Breastfeeding	426 (29.1)	541 (36.9)	408 (27.8)	91 (6.2)
Water	909 (62)	247 (16.8)	215 (14.7)	95 (6.5)
Whole grains	1279 (87.2)	41 (2.8)	54 (3.7)	92 (6.3)

Note: results are displayed as n (%).

None of the women scored one or zero points (Table 4). The majority of the women scored six or seven points (27.4% and 39.6%, respectively), and 16.8% percent scored eight points in the sum score.

Table 12 Sum score of knowledge-based questionnaire (missing n = 88 (6%)).

Score	N	%
2	3	0.3
3	11	1.1
4	40	3.2
5	146	11.7
6	345	27.4
7	485	39.6
8	211	16.8

Variables Affecting Knowledge of Lifestyle-Related Risk Factors

Table 5 shows the linear regression model with the knowledge sum score as a dependent variable. Age, gestational week, education and income were positive predictors for the sum score, indicating that women with increased age, higher education levels, income and later gestational weeks possess significantly more knowledge regarding lifestyle factors during pregnancy. Nullipara and migration, on the other hand,

were negative predictors. Note: while the residuals were normally distributed (histogram and p–p plot not shown), homoscedasticity was not evident (significant Breusch–Pagan test). Bootstrapping was performed to account for this uncertainty and confirmed the significance of the predictors of the regression model.

Table 13 Linear regression model (dependent variable = sum score, n = 1191).

Independent Variables	R^2	B	SE	*p*	95% CI
Model fit	0.116				
Age		0.016	0.008	0.040 *	0.001–0.031
Gestation week		0.037	0.015	0.017 *	0.007–0.067
Nullipara		−0.248	0.064	0.000 ***	−0.373–−0.122
Education level		0.142	0.027	0.000 ***	0.090–0.194
Migrantion background		−0.377	0.073	0.000 ***	−0.520–−0.235
Income		0.065	0.013	0.000 ***	0.040–0.090

* $p < 0.05$; *** $p < 0.001$.

The logistic regression (Table 6) with the single questions indicates that there was a significant positive association between age and nullipara and the ability to answer the question on GWG correctly (OR = 1.067, 95% CI [1.000–1.139] and OR = 2.549, 95% CI [1.452–4.474], respectively). However, there was a significant negative association between nullipara and the question of whether or not it is safe to use tap water (OR = 0.375, 95% CI [0.262–0.537]). This differs for income, indicating that increased income was a predictor for the ability to answer the questions on tap water (OR = 1.080, 95% CI [1.009–1.155]), wholegrain products (OR = 1.254, 95% CI [1.118–1.406]), alcohol consumption (OR = 1.104, 95% CI [1.011–1.205]) and GWG (OR = 1.114, 95% CI [1.013–1.226]) correctly.

There was a significant negative association between migration background and the ability to answer the questions on alcohol consumption (OR = 0.454, 95% CI [0.288–0.714]), smoking (OR = 0.187, 95% CI [0.041–0.854]) physical activity (OR = 0.260, 95% CI [0.074–0.911]) and tap water (OR = 0.375, 95% CI [0.262–0.537]) correctly, indicating that women with migration backgrounds tended to answer these questions incorrectly. At the same time, migration was a positive predictor for answering the question on breastfeeding correctly (OR = 1.602, 95% CI [1.136–2.257]).

Table 14 Logistic regression with single questions.

Independent Variables			Age			Gestation Week			Nullipara			Education			Migration Background			Income		
Dependent Variable	**$R^2_{Nagel-kerke}$**	**$p_{Hosmer-Lemeshow}$**	**OR**	**95% CI**	***p***	**OR**	**95% CI**	***p***	**OR**	**95% CI**	***p***	**OR**	**95% CI**	***p***	**OR**	**95% CI**	***p***	**OR**	**95% CI**	***p***
GWG (n = 1010)	0.073	0.958	1.067	1.000–1.139	0.050	1.058	0.931–1.203	0.384	2.549	1.452–4.474	0.001	1.079	0.875–1.331	0.478	1.052	0.575–1.923	0.870	1.114	1.013–1.226	0.027
Portion size (n = 1188)	0.157	0.439	1.105	0.853–1.432	0.449	1.032	0.600–1.775	0.910	0.000	0.000.	0.992	1.167	0.473–2.882	0.737	0.841	0.085–8.270	0.882	1.143	0.812–1.608	0.444
Alcohol (n = 1183)	0.037	0.799	0.968	0.916–1.022	0.240	1.008	0.901–1.128	0.890	0.748	0.471–1.188	0.219	1.028	0.851–1.242	0.775	0.454	0.288–0.714	0.000	1.106	1.017–1.204	0.019
Smoking (n = 1152)	0.116	0.915	1.143	0.920–1.422	0.228	1.252	0.861–1.820	0.240	1.516	0.288–7.992	0.624	0.640	0.311–1.315	0.225	0.187	0.041–0.854	0.030	1.207	0.904–1.610	0.202
Physical activity (n = 1161)	0.063	0.909	0.982	0.839–1.149	0.818	0.914	0.655–1.276	0.597	0.511	0.130–2.000	0.335	0.911	0.516–1.608	0.747	0.260	0.074–0.911	0.035	1.167	0.933–1.460	0.176
Breastfeeding (n = 850)	0.022	0.235	1.024	0.987–1.063	0.200	1.017	0.946–1.094	0.641	1.165	0.862–1.573	0.320	1.119	0.990–1.265	0.072	1.602	1.136–2.257	0.007	0.982	0.925–1.043	0.562
Water (n = 1012)	0.125	0.568	1.004	0.963–1.046	0.868	1.158	1.063–1.262	0.000	0.465	0.327–0.663	0.000	1.346	1.168–1.550	0.000	0.375	0.262–0.537	0.000	1.080	1.009–1.155	0.026
Whole Grains (n = 1142)	0.081	0.921	1.027	0.943–1.119	0.541	1.006	0.839–1.207	0.947	0.783	0.376–1.628	0.512	1.020	0.760–1.370	0.895	0.523	0.253–1.079	0.079	1.254	1.118–1.406	0.000

There was a significant positive association between gestational week and education and the question on tap water consumption, indicating that women with later gestational weeks (OR = 1.158, 95% CI [1.063–1.262]) and higher education levels (OR = 1.346, 95% CI [1.168–1.550]) tended to answer this question correctly.

Discussion

The questionnaire described above assesses lifestyle knowledge among pregnant women in the German perinatal healthcare setting. The questionnaire particularly focuses on lifestyle during pregnancy, including GWG, nutrition, alcohol consumption, smoking, physical activity, water consumption and breastfeeding. Assessing lifestyle knowledge during pregnancy is essential, as research suggests that pregnant women lack knowledge when it comes to pregnancy-related information.

More than 83.8% of all the women surveyed produced a total score of six or more in the questionnaire. This is not surprising in light of the high level of education amongst our study population. However, it is surprising that the majority of the participants have a university degree, considering that people insured by all statutory health insurance funds took part in the study, including people with a wide range of socioeconomic statuses, and that the sample size is large enough to offer diversity. The highly educated population might also be a result of selection bias, as educated women possibly want to receive counselling on lifestyle topics because they are more interested as opposed to women with lower educational levels. Fewer women answered the question on the effectiveness of obtaining information on breastfeeding early during pregnancy correctly (36.6%) or did not know that this is beneficial (27.8%). This is a crucial result suggesting that pregnant women might not be aware that breastfeeding can come with difficulties. Preparing women for breastfeeding early by means of counselling might contribute to better-informed future mothers who have more realistic expectations about breastfeeding and seek help earlier. In Germany, the 'Becoming Breastfeeding Friendly' research project has developed recommendations to promote an environment that supports breastfeeding [37]. The effectiveness of such strategies is yet to be investigated. This is particularly important, as research suggests that engaging with the topic of breastfeeding early on during pregnancy supports the initiation and continuation of this approach [38].

As in the study by Oechsle et al. [30], the majority of our study population answered the questions on alcohol consumption and smoking correctly (85.7% and 90%,

respectively). Moreover, the majority answered the questions on physical activity, portion size and wholegrain products correctly (90.5%, 93.2% and 87.2%, respectively). This could be attributed to the informative counselling that women may receive during their pregnancy and the fact that more than half of our study population possessed above-average educational levels (university degree). A study comparing all of Germany's 16 federal states indicated that the state of Baden-Württemberg, from which the women in this study were retrieved, is ranked fourth in terms of education [39]. Nevertheless, knowledge gaps and different predictors for the correct and wrong answering of the question were identified.

Even though the majority of our study population answered the question on GWG correctly, a proportion of women do not know the normal range for weight gain during pregnancy. This finding suggests that a lack of knowledge on healthy weight gain may contribute to high rates of GWG above the normal range. It has implications for lifestyle counselling, which should address knowledge in addition to other influencing factors, such as social norms regarding the acceptability of weight gain during pregnancy that have been identified previously [40,41].

Particular focus must also be placed on the initial BMI of the women before or at the beginning of the pregnancy in order to ensure that they receive appropriate counselling on GWG [15]. The question on GWG was more likely to be answered by women who had no children at the time of participation. This might be because first-time mothers are more aware of and receptive to health information, as they want to be well-prepared for their first child. It is also possible that counselling on GWG has improved over time to the benefit of new mothers.

A migration background was a predictor for the questions on alcohol, smoking, physical activity and water consumption. In all cases, women with migration backgrounds were significantly more likely to answer these questions incorrectly. Women with a migration background might not know that alcohol consumption is harmful to their unborn child; however, research suggests that pregnant women with migration backgrounds are less likely to consume alcohol [42]. This might be explained by health beliefs and practices from their home countries, which they continue to follow even after migration [43,44]. An Israeli study of 3815 pregnant women on the awareness of alcohol consumption recommendations during pregnancy showed that no Muslim women reported alcohol consumption during pregnancy [45]. An analysis of this subgroup was not possible since we did not collect data on religious beliefs. The countries from which

the parents of our sample migrated vary, covering Europe and beyond, from Turkey, Russia, Romania, Poland, Kazakhstan, to Italy, which is too widespread to make conclusions on health behaviour or possible religions and beliefs. With regards to the results and existing literature, a distinction has to be made between knowing a fact and behaving accordingly. Similarly, research on smoking indicates that in practice, a migration background in pregnant women is associated with less exposure to smoking [46]. Increased smoking behaviour only comes with higher acculturation, as indicated by a German study of pregnant women with Turkish backgrounds [47]. A migration background is a predictor for answering the breastfeeding question correctly. Studies indicate that immigration is associated with increased breastfeeding initiation [48,49]. This might be explained by cultural beliefs and traditions from the person's country of origin and also by the possibility of immigrants living in communities that have closer ties to their homelands and traditions/cultures there that support breastfeeding [48].

According to our results, a substantial portion of pregnant women does not think that it is safe to drink tap water or do not know whether this is the case. In the context of Germany, however, it is possible to drink tap water and prepare milk or meals for children using tap water. The results of this study indicate that a migration background and nullipara are negative predictors for answering this question correctly, which might be due to tap water safety in the participants' countries of origin. Participants with later gestation weeks and higher levels of education and income answered this item correctly. Research on the consumption of tap water in pregnant women in different countries is lacking, and further investigation is thus required.

One limitation of this study is the low complexity of the questionnaire, which might have not been discriminating enough. The questionnaire was developed so that all the women who participated in the study could answer the questionnaire, regardless of their educational levels. Therefore, we cannot preclude the possibility that the questions and answering scale might have been leading. Additionally, the results of this study indicate that the majority of women have a university degree. Moreover, the sample might not be representative. The inclusion of participants insured by all the statutory health insurance funds allowed for the inclusion of clientele with different socio-economic backgrounds. However, it appears that even with the inclusion of all statutory health insurance funds, our sample might not be representative, as it is outstandingly well-educated. This may be attributable to the gynaecologists who recruited the patients, who may have excluded potentially eligible pregnant women due to their socio-economic status or language

barriers. In addition to that, women who are more interested in lifestyle topics and counselling might be higher educated and more likely to participate in the GeMuKi project [50]. Additionally, it is possible that women in the study regions simply are outstandingly well-educated, as the ranking within Germany showed.

Conclusions

This study indicates that women's knowledge of lifestyle-related factors during pregnancy differs with regard to particular topics and socio-economic factors. Particular focus on certain topics, such as the benefits of early familiarisation with breastfeeding, the safety of tap water in Germany and the normal ranges of GWG with regards to the initial BMI of the woman, is required during antenatal counselling. Our analysis has shown that a migration background is a predictor for answering the questions on alcohol and smoking incorrectly. However, it is likely that pregnant women with a migration background still exhibit correct behaviour due to cultural beliefs retained from their homelands, such as not drinking alcohol as a general habit. Nevertheless, this group of women requires special attention during antenatal counselling in order to cover their needs and knowledge gaps.

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Institutional Review Board Statement: Ethical approval was obtained from the University Hospital of Cologne Research Ethics Committee (ID: 18–163) and the State Chamber of Physicians in Baden-Wuerttemberg (ID: B-F-2018-100). The study data will only be processed in a pseudonymised form in accordance with the EU General Data Protection Regulation (GDPR).

Informed Consent Statement: Written informed consent will be obtained from all the study participants at baseline.

Data Availability Statement: The datasets used and/or analysed during this study are available from the corresponding author on reasonable request.

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CHAPTER 8

Dissertation Project 4

Health Literacy among Pregnant Women in a Lifestyle Intervention Trial

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Abstract

Health literacy plays a crucial role during pregnancy, influencing the mother's health behavior which in turn affects the unborn child's health. To date, there are only few studies that report on health literacy among pregnant women or even interventions to promote health literacy. GeMuKi (acronym for "Gemeinsam Gesund: Vorsorge plus für Mutter und Kind"—Strengthening health promotion: enhanced check-up visits for mother and child) is a cluster-randomized controlled trial, aimed at improving health literacy in pregnant women by means of a lifestyle intervention in the form of brief counseling. The women in the intervention group receive counseling on lifestyle topics, such as nutrition and physical activity, during their regular prenatal check-ups. The counseling is tailored to the needs of pregnant women. Demographic data is collected at baseline using a paper-based questionnaire. Data on health literacy is collected using the Health Literacy Survey Europe with 16 items (HLS-EU-16) at baseline and the Brief Health Literacy Screener (BHLS) questionnaire at two points during the pregnancy by means of an app, which was developed specifically for the purpose of the project. The results of the study indicate that around 61.9% of the women participating in the GeMuKi study have an adequate level of health literacy at baseline. The regression analyses (general estimating equations) showed no significant effect of the GeMuKi intervention on general health literacy as measured by the BHLS (ß = 0.086, 95% CI [−0.016–0.187]). However, the intervention was significantly positively associated with pregnancy specific knowledge on lifestyle (ß = 0.089, 95% CI [0.024–0.154]). The results of this study indicate that GeMuKi was effective in improving specific pregnancy related knowledge, but did not improve general health literacy.

Keywords: health literacy; pregnancy; lifestyle intervention; health behavior

Introduction

Finding, understanding, appraising and applying health information—behaviors associated with having adequate health literacy—are a necessity for improving and maintaining one's health. This becomes particularly important during pregnancy, as pregnant women have great impact on their own health and that of their unborn child. During this period, women need to possess adequate health literacy to support a healthy lifestyle during this new and challenging time period.

Pregnant women can influence the health of their unborn child through a process referred to as perinatal programming, particularly by adapting their lifestyle. More precisely, unhealthy behavior, which leads for example to excessive weight gain during pregnancy, also influences the health and growth of the unborn child. Evidence suggests that a woman's excessive weight gain during pregnancy results in higher odds of the unborn infant developing overweightness, obesity or a chronic condition later in life [1–4]. In light of this association, it is desirable that pregnant women adhere to healthy lifestyles. Since health literacy levels are closely related to health behaviors [5,6], it is important that pregnant women are supported regarding their health literacy. Studies indicate for example, that pregnant women with inadequate health literacy are more likely to make unhealthy lifestyle choices, have more hospital stays and engage less in prenatal care [5,7,8].

There is little evidence regarding the health literacy levels of pregnant women in Germany. Studies from a recent international systematic review reported mixed findings, with some studies indicating that health literacy among pregnant women was adequate, while others indicated it was inadequate [9]. Nonetheless, researchers are in agreement that adequate health literacy during pregnancy facilitates a healthy lifestyle [6], informed decision making, and knowledge concerning prenatal tests [10,11].

In order to achieve adequate health literacy, interventions with a particular focus on strengthening health literacy are needed. Previous research indicates that health literacy sensitive interventions, by enhancing knowledge on the matter at hand, can be effective in improving health literacy, and are also beneficial in the promotion of a healthy lifestyle [12], regardless of the educational level. To date, there exist only a small number of interventions that focus specifically on the improvement of health literacy in pregnant women [13]. The GeMuKi (acronym for "Gemeinsam Gesund: Vorsorge plus für Mutter und Kind"—Strengthening health promotion: enhanced check-up visits for mother and child) intervention consists of brief lifestyle counseling sessions with a focus on

pregnancy related topics. The counseling sessions are implemented into routine prenatal check-ups [14]. The intervention is aimed at strengthening health literacy among pregnant women. The purpose of this study is to assess the status quo with regard to health literacy levels of pregnant women enrolled in the GeMuKi trial, and to evaluate whether the GeMuKi intervention improved health literacy levels [15].

Materials and Methods

Study Design

Health literacy was assessed within the GeMuKi trial, a lifestyle intervention implemented between October 2017 and March 2022. The cluster-randomized controlled trial took place in ten regions in the state of Baden-Wuerttemberg, Germany. Five of the regions provided the intervention while the other five provided regular care. The intervention, which took the form of brief counseling sessions, took place over the course of up to six check-ups during pregnancy. It was provided by gynecologists and midwives, in case the women opted for midwifery care. The primary outcome was the prevention of excessive gestational weight gain during pregnancy. The secondary outcomes were the improvement of maternal and infant health outcomes, and improved health literacy. This paper focuses particularly on health literacy; the publication of results of the primary outcome and other secondary outcomes are in progress. A detailed description of the general design of the GeMuKi Project can be found elsewhere [14,15].

The GeMuKi Intervention

The GeMuKi intervention consists of brief lifestyle counseling sessions implemented as part of routine check-ups during pregnancy. Participants in the intervention group received additional counseling as part of their antenatal care, while the control group received care as usual. Participants of both groups filled in one paper-based questionnaire at baseline, and further questionnaires using an app developed for the purpose of the study.

Health Literacy Strengthening Components

The GeMuKi intervention aims to strengthen the health literacy of pregnant women by actively involving them in brief lifestyle counseling. The women decided for themselves which lifestyle topic they would like to receive counseling on, thus promoting participation that is key to improving health literacy [16]. The topics were recommended by the 'Healthy Start—Young Family Network' (Netzwerk Gesund ins Leben), which is a

national network that aims to promote a healthy lifestyle during pregnancy. Its recommendations are based on systematic reviews [17]. Prior to the start of the intervention, the healthcare providers received training on communicating the key messages from the recommendations using motivation interviewing (MI) techniques [18]. Since the primary outcome of the study was gestational weight gain, this was the main focus of the training content. MI is based on the notion that individuals will change their behavior autonomously, which is considered a health literacy skill [19]. During the counseling sessions, healthcare providers listened to the information needs of the women and communicated using open-ended questions in order to trigger behavior change. This is in line with the 'German Action Plan Health Literacy', which states that healthcare providers should communicate sensitively according to the health literacy status of the patient in order to respond appropriately and strengthen the patient's health literacy [16]. At the end of the counseling session, the healthcare provider and the patient jointly came up with SMART (Specific, Measurable, Achievable, Reasonable, Time-Bound) lifestyle goals to be accomplished by the next counseling session. This ensured that the SMART goals were individual and tailored to the particular health literacy levels of the women in question.

In addition to the counseling, the intervention also made use of digital components to promote health literacy as recommended by the action plan [16]. The GeMuKi-App provided the women participating in the intervention with a collection of hyperlinks related to health information on pregnancy. The app is easy to use, making it accessible for women with different health literacy and education levels. The participants also filled in questionnaires on health literacy using the app. The healthcare providers were provided with a digital interface, the GeMuKi-Assist counseling tool. The tool included supporting questions on each lifestyle topic for the healthcare providers to refer back to during counseling. In order to ensure that they were aligned with the health literacy levels of the respective women, these supporting questions were based on the principles of MI, i.e., they were open-ended questions that would trigger communication on the part of the woman in question. The healthcare providers entered the jointly agreed SMART goals into GeMuKi-Assist, after which they were displayed in the woman's app in the form of push notifications.

Sample and Recruitment

Gynecologists participating in the GeMuKi trial recruited eligible pregnant women based on predefined inclusion and exclusion criteria. The women were deemed eligible if they were ≥18 years old, <12 weeks of gestation, carried statutory health insurance and possessed proficient language skills in German. The sample size was calculated based on the primary outcome of the GeMuKi study, for which a sample size of 1860 participants was required [14].

Ethical Approval

GeMuKi was approved by the ethics committee of the University Hospital of Cologne (ID: 18-163) and the State Chamber of Physicians in Baden-Wuerttemberg (ID: B-F-2018-100). Inference to study participants is not possible since the collected data is pseudonymized in accordance with the EU General Data Protection Regulation (GDPR). Written informed consent was obtained prior to participation in the study. The participants were reassured that they were free to withdraw from the study at any time without consequences.

Data Collection

The data for the analysis in this paper were derived from two sources. The women filled in a paper-based questionnaire at baseline (before the 12th week of gestation) in order to provide demographic variables. Data regarding health literacy and knowledge of pregnancy related lifestyle topics were collected using questionnaires via the app.

Health Literacy Assessment

Health literacy was assessed using two questionnaires. The German version of the HLS-EU-16 was utilized at baseline (t0) to provide a detailed picture of the health literacy level distribution of the pregnant women in our sample compared to the general population.

The HLS-EU-16 is based on the health literacy definition of Sørensen et al. (2012), which is based on a broad conceptualization of health literacy, including functional and critical health literacy.

The participants were asked to answer questions on a 5-point Likert scale ('Very difficult'–'Very easy'; 'I don't know'). Since paper-based questionnaires also allow individuals to skip questions, we added the option 'I do not want to answer this question' to the app-based survey.

In order to observe changes in health literacy levels after the intervention, we utilized a modified version of the Brief Health Literacy Screener (BHLS). This likewise allowed participants to answer questions on a 5-point Likert scale ranging from 'Never' to 'Always'. We also added 'I do not want answer this question' as an option. This questionnaire was used both at baseline (t0) and at the end of the pregnancy (t1).

Since the HLS-EU-16 and BHLS are both subjective health literacy measures which gauge general health literacy skills, we developed a knowledge-based questionnaire to provide objective estimates of pregnancy related health literacy [20,21]. The questionnaire was developed based on the topics from the national recommendations discussed during counseling. They cover: weight development during pregnancy, portion size, nutrition, alcohol consumption, smoking, physical activity, water intake and breast feeding. The questionnaire was applied at two time points, namely t0 and t1. The answering scale was 'Yes/No/I don't know'. A detailed description of this questionnaire can be found in the Supplementary Table S3 (online) while the baseline results can be found elsewhere [20].

Data Analysis

Plausibility checks for the data were performed throughout data collection and prior to analysis. Descriptive statistics were used to analyze participant characteristics. Age, parity (nullipara), net income, migration background and educational level were used as independent variables in multiple regression analysis. Age was defined as a continuous variable. Nullipara and migration background were defined as dichotomous variables (Yes/No). Net income was calculated as a continuous variable. Education level was used as an ordinal variable. Percentages are provided for categorical variables and means for continuous variables.

The HLS-EU-16 was analyzed based on official recommendations [22]: First, the individual items of the HLS-EU-16 were binarized by collapsing the two outer answer categories ("Very easy"/"Fairly easy" = 1; "Fairly difficult"/"Very difficult" = 0). Once this had been done, a sum score was calculated using the 16 binarized items. Respondents with more than two missing answers were excluded from the sum score calculation. The sum score was categorized into three health literacy levels: Adequate (score 13–16), Problematic (score 9–12) and Inadequate (score 1–8). This allowed for a display of the status quo with regard to health literacy level among pregnant women in accordance with prior population-based surveys in Germany and international studies [23–25].

The BHLS is a three-item questionnaire designed to assess health literacy status by asking about confidence using health-related forms [26]. Answers can be given on a 5-point Likert scale ranging from 'Never' to 'Always'. Scores can range from 5 to 15 points. Means are provided as a classification of health literacy.

To answer the question of whether the GeMuKi intervention improved the general health literacy of pregnant women, multiple regression models using general estimation equations (GEE) were used to account for the cluster structure of the study. This GEE included the deviation (Δ) of the BHLS sum score between the two time points (BHLS sum score at t1—BHLS sum score at t0) as a continuous dependent variable and group (intervention group = 1, control group = 0) as an independent variable adjusted for age, nullipara, income, migration background and education level (covariates). To answer the question of whether the GeMuKi intervention improved specific pregnancy related and knowledge-based health literacy, a second GEE model was tested using the same independent variables and covariates and the deviation of the knowledge questionnaire sum score between the two time points (knowledge sum score at t1—knowledge sum score at t0) as the dependent variable. The sum score was calculated by adding the number of correct answers for every single question [20]. Since health literacy was a secondary outcome of the cluster randomized controlled trial, no imputations were conducted. A *p*-value of <0.05 indicated statistical significance.

All the analyses were conducted using IBM® SPSS® Statistics for Windows, Version 28.0 (Chicago, IL, USA).

Results

The mean age of the study participants was 31; half of the study population did not have any children at the time of participation (50%). The mean household net income was EUR 4293 per month. More than half of the pregnant women had a university degree (55.1%) and 22.7% came from a migration background (Table 1).

Table 15 Demographic variables of study participants.

	Total n (%)	**Intervention group n (%)**	**Control group n (%)**
Age in years, mean (SD)	31.3 (4.3)	31.3 (4.2)	31.2 (4.4)
Nullipara	711/1422 (50.0)	366 (47.9)	345 (52.4)
Migrant	329/1447 (22.7)	197 (25.4)	132 (19.7)
Income in euros, mean (SD)	4293 (1663)	4304 (1706)	4281 (1613)
Education level			

Primary	2/1404 (0.1)	0.0 (0)	2 (0.3)
Lower secondary	39/1404 (2.8)	20 (2.6)	19 (2.9)
Upper secondary	590/1404 (42.0)	331 (43.6)	564 (40.2)
University degree	773/1404 (55.1)	408 (53.8)	365 (56.6)

Health literacy levels in the GeMuKi study population were adequate, with 66.5% (n = 908) of the sample possessing adequate health literacy. Around one third of the women who participated in the study possessed inadequate (5.3%; n = 73) or problematic (28.1%; n = 384) health literacy (Figure 1). Descriptive analysis of the BHLS revealed that participants had a mean score of 13.56 (n = 1373) at t0, and 13.54 at t1 (n = 1175).

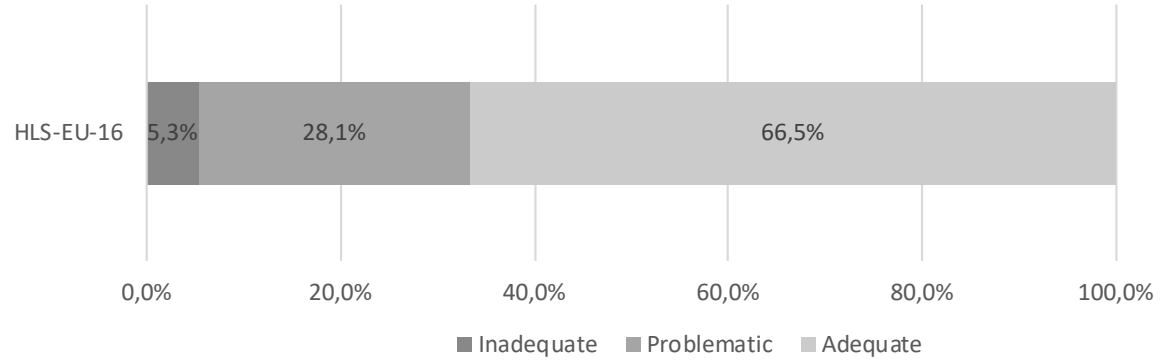

Figure 6 Results of the HLS-EU-16 (n = 1365).

Multivariable regression analysis using the BHLS as the dependent variable did not show any intervention effects on the improvement of health literacy (ß = .086, 95% CI [-.016 – .187]) (Table 3). No significant association was observed for the covariates age (ß = .000, 95% CI [-.035 – .036]), migration (ß = -.127, 95% CI [-.366 – .112]), income (ß = 5.676, 95% CI [-2.583 – 3.718]), education (ß = -.034, 95% CI [-.089 – .021]) or parity (ß = .061, 95% CI [-.072 – .194]).

Table 16 Multiple regression analysis using GEE (dependent variable: ΔBHLS, n = 1010).

Independent variable	ß*	SE*	*p*-value*	95% CI*
Group	.086	.051	.099	-.016 – .187
Age	.000	.018	.979	-.035 – .036
Migrant	-.127	.121	.299	-.366 – .112
Income	5.676	1.607	.724	-2.583 – 3.718
Education	-.034	.028	.224	-.089 – .021
Nullipara	.061	.067	.372	-.072 – .194

Note: ß = regression coefficient; SE = standard error; * all values are adjusted.

Table 3 displays the GEE using Δ knowledge as the dependent variable. It was possible to observe a significant positive effect of the intervention on knowledge in the

intervention group (ß = 0.089, 95% CI [0.024–0.154]). The only other significant association was seen with parity indicating that knowledge gain was predicted by giving birth for the first time (ß = 0.160, 95% CI [0.059–0.261]).

Table 17 Multiple regression analysis using GEE (dependent variable: Δ knowledge, n = 1016).

Independent variable	ß*	SE*	*p*-value*	95% CI*
Group	.089	.033	.007	.024 – .154
Age	-.003	.006	.697	-.016 – .010
Migrant	-.011	.050	.835	-.110 – .089
Income	-1.922	2.187	.380	-6.210 – 2.367
Education	.008	.031	.805	-.054 – .070
Nullipara	.160	.051	.002	.059 – .261

Note: ß = regression coefficient; SE = standard error; * all values are adjusted.

Discussion

This study is the first to our knowledge that provides data on the status quo for health literacy among pregnant women in Germany and assesses whether a lifestyle intervention during pregnancy improved general or pregnancy related health literacy levels.

The first point to note is that the analysis of the HLS-EU-16 indicates that about 33% of the pregnant women had inadequate or problematic health literacy, and more than two thirds of the pregnant women had sufficient health literacy right at the initiation of the GeMuKi trial. This is above average when compared to national and international studies on health literacy. A repeated representative study using the HLS-EU-16 in Germany from 2021 demonstrated that 59% of the population have problematic or inadequate health literacy [24], which is a decline of about five percentage points to 54% compared to 2016 [23]. The same holds true for data on the female population from the 2021 study, in which around 57% of the study participants possessed inadequate health literacy.

The comparatively high baseline health literacy levels among the trial participants were not surprising considering that the study population was highly educated, which is strongly associated with health literacy [19], in comparison to the general population. Several explanations as to why our population was highly educated may apply in this case. The region in which the study took place ranks highly in national comparisons of educational achievements, making it likely that more educated women would participate in the study. It is possible that some women with migration backgrounds were not

recruited by healthcare providers for the study due to insufficient language skills, which rules out one important vulnerable group. The inclusion criteria for participation in the study were set broadly; however, the choice of which women to include in the study was left to the gynecologists, which might have led to selection bias. This might also provide an explanation as to why we had so few women with a migration background in the study sample compared to the general population. Such women might have been excluded due to language barriers or because healthcare providers did not perceive them as eligible.

Multiple regression analysis using GEE did not show significant results regarding the question of whether this lifestyle intervention improved general health literacy. There are several explanations for why the intervention was not effective. Firstly, this again may be a result of the highly educated nature of the study population and the high initial levels of health literacy in both the intervention and control groups. Secondly, since it only contains three items, the BHLS does not offer a broad picture of health literacy. This could have been avoided by applying the HLS-EU-16 with 16 items at t1 as well as t0. For future studies we therefore highly recommend using a more detailed health literacy instrument. Thirdly, the intervention was not geared to general health literacy, which is measured using HLS-EU-16 and the BHLS. Therefore, the utilized instruments may have not been suitable. To depict pregnancy specific health literacy, we have developed a knowledge-based questionnaire. Fourthly, regarding the training the healthcare providers received, it can be argued that they might not have been educated well enough in the use of MI techniques which were supposed to be health literacy sensitive. It should be added that the content of the training mainly focused on the primary outcome of the intervention, which was gestational weight gain, rather than health literacy. The implementation of the counseling was not monitored, so we cannot assume that all the steps were conducted as taught in the training sessions. Lastly, we might have not met the needs of women with inadequate health literacy in our population. This can indicate that the intervention was not appropriate for that proportion of women.

According to the results of the GEE, the intervention was effective in improving the knowledge of pregnancy related lifestyles of women in the intervention group. The assessment of knowledge change in our study may have been successful as we developed a pregnancy specific health literacy instrument. The contents of the questionnaire were based on topics that the women received counseling on. This again speaks for the utilization of appropriate instruments for future studies, or that interventions are built based on the theoretical construct of the questionnaire, such as the HLS-EU-16.

The fact that the counseling helped pregnant women gain knowledge on pregnancy specific lifestyle topics can be seen as an argument in its favor. Scholars in the German healthcare setting support the provision of health information in the antenatal setting through gynecologists to improve pregnancy related lifestyle knowledge, since it has the potential to reach women of different socio-demographic status [27]. Counseling becomes particularly important regarding significant results for women that are going to be first-time mothers, as they are new to the experience of being pregnant and potentially need counseling on lifestyle during pregnancy.

Studies indicate that educational interventions to improve knowledge on pregnancy specific topics are effective; however, the transition from knowledge to behavior still requires research [28,29]. Small scaled interventions, on the other hand, already show promising results in improving knowledge of physical activity and nutrition, and hence improving behavior [30]. Similarly, interventions (also in the form of counseling) to reduce the risk of gestational weight gain were proven effective [31,32].

Conclusions

This study indicates that most women participating in a lifestyle intervention trial in Germany possessed adequate health literacy in our study population. Nevertheless, pregnant women with inadequate health literacy, who still make up about one third of the study population, should not be neglected, due to the effects that limited health literacy can have on the woman's health and that of their unborn child. The intervention was not able to improve general health literacy; this may be due to several determinants. The women included in our study possess both high levels of education and adequate health literacy. The needs of women with inadequate health literacy might not have been met, which might stem from the training that the healthcare providers received which did not consider different health literacy-based subgroups of women. The main focus of the training was on the primary outcome of the study, the prevention of excessive gestational weight gain. Nevertheless, the study had a significant positive effect on knowledge levels, which provides strong support for providing additional lifestyle counseling during pregnancy, especially for first-time mothers.

Future interventions might benefit from a comprehensive approach to measuring health literacy throughout the study period, rather than using short screeners. Additionally, approved communication methods for increasing health literacy need to be an inherent part of counseling.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/ijerph19105808/s1, Table S3: Knowledge questionnaire.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The datasets used and/or analyzed during this study are available from the corresponding author on reasonable request.

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CHAPTER 9

Discussion

9. Discussion

The aim of this PhD thesis was to identify the effects of a lifestyle intervention on the health literacy of pregnant women. Initially, investigations were conducted as to the current state of research on health literacy among pregnant women and potential interventions for improving health literacy. Once this was complete, a description of the lifestyle intervention to which this thesis refers, which is aimed at improving health literacy in pregnant women, was published. The study assessed the knowledge of pregnant women with regard to lifestyle topics, together with their health literacy levels and the impact of said lifestyle intervention on health literacy. In order to fill these gaps in the research, the four DPs followed different objectives, as outlined in Chapter 3. The DPs covered the following topics:

DP 1: A systematic review of health literacy levels among pregnant women and interventions aimed at improving health literacy of pregnant women.

DP 2: Study protocol of the lifestyle intervention (GeMuKi) and how health literacy is addressed within the intervention.

DP 3: Development and evaluation of a knowledge-based questionnaire as an objective, pregnancy-specific measure of health literacy. The questionnaire assessed the level of knowledge pregnant women possess with regard to lifestyle topics during pregnancy and the links between said knowledge and socio-demographic factors.

DP 4: Evaluation of the effect of the lifestyle intervention (GeMuKi) on health literacy among pregnant women. Statistical analyses were conducted using demographic variables, health literacy and knowledge questionnaires.

9.1. Key Findings of the Dissertation Projects

DP 1: The systematic literature search resulted in 691 studies, 14 of which were included in the review. The study characteristics showed that 13 of the 14 studies followed a cross-sectional design, one used an experimental design. Primary outcomes varied across the studies; this resulted in different inclusion criteria, such as healthy women [1] and women

with certain conditions [2]. The studies used a variety of health literacy instruments, with different cut-off points and terms for defining health literacy scores, making comparison of results across studies difficult.

The included studies showed mixed findings regarding health literacy levels among pregnant women, ranging from study participants having limited health literacy [3,4] to adequate health literacy [5]. Even when measured using both subjective and objective health literacy measures, the participants in one study showed adequate health literacy levels [6]. According to the evaluation of one transnational study, 54.5% of the participants scored highly, 40.3% scored marginally and 5.2% had a low health literacy score [7]. This indicates that almost half of the study population did not have adequate health literacy levels. It is thus not possible to make final statements on the health literacy status of pregnant women.

Even though studies on improving health literacy during pregnancy are scarce, potential negative impacts of inadequate health literacy during pregnancy were identified. As such, inadequate health literacy on the behavioral level is associated with pregnancy-related anxiety after receiving normal prenatal genetic test results [8], pregnant women seeing their healthcare provider as the person responsible for the child's health [9], and less utilization of the internet as a source of health information [10]. Similarly, with regards to knowledge, women with inadequate health literacy give incorrect responses regarding the risks and benefits of vaccines [4]. Concerning lifestyle, women with inadequate health literacy smoke during pregnancy [7], have higher risk perception and negative beliefs regarding medication, and do not adhere to prescribed medicine [7]. In contrast, adequate health literacy was associated with making informed choices with regard to prenatal testing [2] and the intention to use a decision aid for prenatal screening [11]. Additionally, adequate health literacy was associated with better scores in a preeclampsia questionnaire [1] and correlated positively and significantly with knowledge of age-related pregnancy risks [12].

The included studies of the review did not aim at improving or strengthening health literacy. Only one study aimed at improving knowledge of prenatal genetic testing among pregnant women by providing the intervention group with an interactive educational tool [3]. The results of the RCT indicate that regardless of the group affiliation, women had

similar improvements in knowledge scores. That is to say, the intervention did not particularly improve health literacy, but was still health literacy sensitive [13].
The quality of the studies included in the review was low to medium in both the cross-sectional studies and the RCT. A detailed description of the quality assessment can be found in the online supplementary materials by Nawabi et al., 2021 [13].

The quantity and the versatility of the disadvantages of inadequate health literacy during pregnancy implies that this is a period in which healthcare provider (particularly gynecologists, for the Germany antenatal setting) should intervene. The findings of the review indicate that pregnant women need healthcare providers who firstly, are responsive to the women's health literacy levels and secondly, are able to further elaborate on the given health information. The healthcare providers role is particularly crucial since women with inadequate health literacy rely heavily on interpersonal communication with their healthcare provider. However, understanding health information is not only the responsibility of healthcare providers. Here, digital- and e-health literacy plays a crucial role, in which individuals need to have the skills to properly find and judge information that the internet offers [14]. Again, this is a task for individuals to acquire the necessary skills, but also for the system level to make digital health information accessible and understandable.

DP 2: Building on two newly published systematic reviews (DP 1 and [15]), there is limited research on health literacy in pregnant women and interventions to improve such. The studies that exist do not evaluate changes in health literacy as a result of an intervention [13]. As such, the lifestyle intervention mentioned in this PhD thesis is aimed at improving health literacy among pregnant women. It is hypothesized that the use of a lifestyle intervention that is health literacy-sensitive increases health literacy.

The intervention is offered at the beginning of the pregnancy, as pregnant women in Germany take part in the regular prenatal screenings. This low-threshold approach also offers a chance to include women with different socio-economic backgrounds and health literacy levels. The results of the study can provide insights for national and international researchers and policymakers that aim to develop and fund health literacy-sensitive interventions during pregnancy [16].

DP 3: According to the health literacy definition provided by Sørensen and colleagues, knowledge is a contributing factor to health literacy [17]. Moreover, knowledge questionnaires measure health literacy objectively. As such, a knowledge questionnaire was developed within the lifestyle intervention, based on the lifestyle topics that are communicated by healthcare providers during counseling, which in turn are based on national recommendations. This resulted in eight questions that can be answered on a 'Yes/No/Don't know' scale. The questionnaire can be found in the online supplementary materials of Nawabi et al. 2022 [18].

The results indicate that five of the questions were answered correctly by the majority of women (more than 85% of participants). Linear regression models using the knowledge sum score as the dependent variable showed that women with increased age, higher education levels, higher income and in later stages of the gestation possess significantly more knowledge regarding lifestyle factors during pregnancy [18]. Logistic regression using the single questions indicated that there was a significant positive association between age and nullipara and the ability to answer the question on GWG correctly (OR = 1.067, 95% CI [1.000–1.139] and OR = 2.549, 95% CI [1.452–4.474], respectively) [18]. This result is not surprising considering that first-time mothers are receptive to health information [19], which may have supported in the correct answering of the question. Increased income was a predictor for the ability to answer the questions on tap water (OR = 1.080, 95% CI [1.009–1.155]), wholegrain products (OR = 1.254, 95% CI [1.118–1.406]), alcohol consumption (OR = 1.104, 95% CI [1.011–1.205]) and GWG (OR = 1.114, 95% CI [1.013–1.226]) correctly [18]. Research with other population groups have already suggested that higher income is positively associated with better quality of diets [20]. The results of our questionnaire point to the same evidence or at least that pregnant women with higher income have adequate knowledge on these topics and answered these questions correctly. Women with a migration background answered the questions on alcohol consumption (OR = 0.454, 95% CI [0.288–0.714]) and smoking (OR = 0.187, 95% CI [0.041–0.854]) incorrectly [18]. This, however, is contrary to other research findings, which indicate that women with migration backgrounds are less likely to consume alcohol [21, 22], which might stem from health beliefs from the countries of origin that are followed to even after migration [23, 24]. In accordance to this, a migration background in pregnant women is associated with less exposure to smoking [25]. Increased smoking only comes with higher acculturation of pregnant women with a migration background

[26]. Migration was a negative predictor for the consumption of tap water (OR = 0.375, 95% CI [0.262–0.537]), meaning that women with a migration background do not know it is safe to drink tap water in Germany. Since research in this field is lacking, we can only assume that consuming tap water in the countries of origin of these women is not recommended and not safe. Cultural differences speak again for the need of tailored counseling. At the same time, migration was a positive predictor for answering the question on breastfeeding correctly (OR = 1.602, 95% CI [1.136–2.257]), which is a conformation of current research that indicate that immigration is associated with increased breastfeeding initiation [48,49]. Here again, personal cultural believes, traditions and communities in which women with migration background live in, might be supportive of breastfeeding [48].

DP 4: Of the total GeMuKi sample, 66.5% (n = 908) possessed adequate health literacy using the HLS-EU-16. Inadequate health literacy was seen in 5.3% (n = 73) of women and problematic in 28.1% (n = 384). Analysis of the BHLS showed that women had a mean score of 13.56 (n = 1373) at t0 and 13.54 at t1 (n = 1175), out of a maximum achievable score of 15.

A multivariable regression analysis using the BHLS as the dependent variable did not show any effects on the improvement of health literacy due to the intervention (ß = 0.086, 95% [0.016–0.187]) [14]. There are several possible reasons for this. As discussed previously with the knowledge questionnaire, the study population is highly educated and, as descriptive analysis of both the HLS-EU and BHLS indicates, all the participants in both the intervention and control groups possessed high initial levels of health literacy. Another cause may lie in the implementation of the counseling and the training that the healthcare providers received. It is possible that the MI counseling techniques were not implemented as taught during training, since the counseling was not supervised. Such supervision would have not been viable, as it would have discouraged healthcare providers from taking part in the intervention. As the main content of the training was GWG because this was the primary outcome of the study, it is possible that health literacy, as a secondary outcome, did not receive enough attention during the training sessions. Lastly, it is possible that the needs of participants with inadequate health literacy were not meet. This may be an indication that the intervention was not appropriate for that proportion of women.

Even though the intervention was not effective in improving health literacy, it was effective in improving knowledge regarding pregnancy-related lifestyle choices among women in the intervention group (ß = 0.089, 95% CI [0.024–0.154]). This may have been detected due to the use of the tailored and topic-specific health literacy instrument: a knowledge-based questionnaire. The contents of the questionnaire were based on topics on which the women had received counseling. This again speaks for the utilization of appropriate instruments for future studies [14]. In regard to this, even though the intervention components included recommendations on how to improve health literacy, it is important to note that the intervention was not particularly focusing on improving general health literacy, since the primary outcome was GWG and not health literacy. This is a crucial point that needs to be considered when discussing the results, as an intervention on the basis of a theoretical model, such as the Sørensen model and corresponding utilization of the HLS-EU-16 might have yielded in improving general health literacy. However, the intervention's impact on knowledge represents an argument in favor of the provision of lifestyle counseling during pregnancy.

9.2. Methodological Strengths and Limitations

Even though this PhD thesis sheds light on health literacy research in pregnant women, the results must be considered alongside its strengths and limitations. The use of different methodological approaches within the DPs is a strength, as it provides a holistic picture of the research field. Firstly, a broad approach was taken in the form of a systematic review to reflect on the state of research in the field in DP 1. Secondly, a questionnaire was developed based on evidence-based national recommendations on lifestyle topics during pregnancy. This questionnaire was developed and pretested with the target population, the pregnant women, as described in DP 2 and DP 3. It is the first short instrument to assess lifestyle-related knowledge among pregnant women in Germany. Thirdly, quantitative approaches were taken to analyze the developed questionnaire (DP 3) and the data on health literacy and knowledge in order to determine the effectiveness of a lifestyle intervention (DP 4).

Nevertheless, the use of separate DPs also comes with limitations that need to be taken into account. The studies included in DP 1 are of moderate quality, which is critical to the validity of the review. In line with this, it is important to note that the included studies had a cross-sectional design, indicating a lack of RCTs and thus a good level of evidence.

The objective of the review was to display interventions for improving health literacy among pregnant women. Since there is a lack of such studies, it was not possible to fully achieve this objective.

With regard to the intervention (concerning DPs 2, 3 and 4), one limitation is that health literacy was not the main focus of the training received by the healthcare providers. Since the primary outcome of the intervention was the reduction of excessive GWG, this was also the main content focused on during the training sessions. Health literacy is a secondary outcome of GeMuKi, which is why less time was dedicated to it during the training sessions than to lifestyle topics. The implementation of the counseling was not monitored; as such, there is no guarantee that the healthcare providers followed the principles of promoting health literacy and implemented what they had been taught during the training sessions. This can be regarded as a further limitation.

From a methodological perspective, a reason why there could not be shown a significant effect of the intervention is the usage of measurement instruments. The BHLS, a three-item instrument, was used at both t0 and t1 to detect changes in health literacy. The initial idea for the usage of this short screener was to reduce the burden for participants to fill in a long questionnaire. Regarding the results, the usage of the HLS-EU-16 might have been the better choice to detect improvements, since it is a more detailed instrument with 16 items. Then again, it has to be considered that even with the usage of the HLS-EU-16 at both time points, this instrument is not pregnancy-specific, which the intervention was. This is not a criticism of the questionnaire itself, but rather displays the lack of instruments for pregnant women and thus the according topics. It is thus not certain whether the HLS-EU, as a general health literacy instrument, would have yielded different results. To counteract this, two additional, pregnancy specific questions have been developed and utilized in the study (see DP 2). The evaluation still has to be awaited.

Perhaps the greatest limitation is the fact that the study sample may not be representative. Even with the inclusion of all the statutory health insurance funds, the study sample was outstandingly well-educated, with the majority of women having a university degree. This may be attributable to the gynecologists who recruited the patients, as they may have excluded potentially eligible pregnant women due to their socio-economic status or language barriers. As such, we cannot not conclude that the results can be generalized to other interventions.

A more detailed description of the strengths and limitations can be found in the respective scientific publications (DP 1-4).

9.3. Relation to Current State of Research

Even though efforts have been taken to assess health literacy among different groups of people, there is one particularly important group that has been neglected in health literacy research thus far: pregnant women. The different objectives and thus wide range of results of the DPs offer a variety of discussion points.

DP 1 reveals gaps in assessing and improving health literacy in pregnant women [13]. There are only a few existing studies that assess the health literacy levels of pregnant women, some of which indicate adequate health literacy while others show health literacy among this population to be limited. However, this may be a result of the different health literacy measures in use [13], which in turn is a problem in health literacy research. The studies included in the review indicate that interventions can improve knowledge (e.g. of age-related pregnancy risks, genetic testing, breastfeeding) and positively affect pregnancy-related outcomes concerning selection of foods, informed decisions and anxiety [13,15]. The systematic review also reveals that there is a lack of interventions for improving health literacy among pregnant women; this is confirmed by a further systematic review [15]. This is a crucial and striking result in view of the effects limited health literacy can have during pregnancy and on pregnancy-related health outcomes.

To counteract this issue, GeMuKi was developed as a health literacy sensitive intervention (DP 2-4), which contributes to the current state of research. Using the knowledge-based questionnaire at baseline, results suggest that pregnant women have a good understanding of lifestyle-related topics during pregnancy. Similar results could be seen using the health literacy questionnaires, which resulted in adequate health literacy levels among study participants at baseline, both in the intervention- and control group. This is contrary to health literacy assessments with the HLS-EU-16 conducted in Germany, which indicate that 59% of the population have limited health literacy [21]. Similarly, 57 % of the German female population from a study conducted in 2021, have inadequate health literacy [14]. In contrast, out study population display high knowledge and health literacy scores, which are not surprising considering the highly educated nature of the sample, which is strongly associated with health literacy [17]. The non-representative sample is,

as mentioned in the strengths and limitations section, a limiting factor of the study, which does not allow for generalizability of the results.

Nevertheless, some questions on lifestyle knowledge were not answered correctly by a high proportion of the women. One example of this was the question as to whether it is effective to obtain information on breastfeeding at an early stage of one's pregnancy, which was only answered correctly by 36.6% of participants. This is a crucial result, as early information on breastfeeding can help mothers-to-be to have more realistic expectations regarding breastfeeding and seek help immediately. To support breastfeeding, the 'Becoming Breastfeeding Friendly' research project was initiated in Germany that has developed recommendations on how to promote breastfeeding [22]. This is in line with current research, suggesting that engaging with the breastfeeding topic early on during pregnancy supports initiation and continuation of this approach [23]. The project has not been evaluated yet.

The study sample did however answer the questions on alcohol consumption and smoking correctly, which is in line with current research in Germany [24]. The reasons for this result can be twofold: firstly, participating women may have profited from the counseling that they receive during their pregnancy and secondly, more than half of the study participants possessed above-average educational levels (university degree).

9.4. Implications for Research and Practice

The results of the systematic review indicate that limited health literacy in pregnant women is associated with a variety of negative behaviors that affect not only the health of the women in question, but also that of their unborn children. It is thus necessary to work towards improving health literacy by means of interventions. However, there are limited interventions for improving health literacy among pregnant women and definitely fewer RCTs, which are crucial in building evidence-based strategies for increasing health literacy in order to improve health among pregnant women. For future research, interventions that use RCTs are needed.

Even though the initial results of the knowledge-based questionnaire indicate that women have sufficient overall knowledge on lifestyle topics during pregnancy, the replies to a few of the questions were insufficient. This applies to knowledge regarding for instance the range of GWG. The lack of knowledge on the recommended range of GWG implies that

counseling is needed in order to improve knowledge, together with other influencing factors such as social norms regarding the acceptability of weight gain during pregnancy. When consulting on this topic, the patient's initial BMI before or at the beginning of the pregnancy must be considered, since the initial BMI impacts the recommended ranges of GWG [25]. This only confirms that tailored education and support during pregnancy is essential. The analysis of the knowledge-based questionnaire shows that a migration background is a predictor for answering the questions on alcohol and smoking incorrectly. As such, particular attention during counseling needs to be paid to certain vulnerable groups, such as women with migration backgrounds. With respect to reaching women of different socio-demographic status in Germany, researchers support the provision of health information in perinatal check-ups by gynecologists to improve pregnancy-related lifestyle knowledge [24]. The lack of knowledge on profound topics and the positive impact of the intervention both indicate the necessity of lifestyle counseling during pregnancy.

The intervention mentioned in this thesis was not built based on a theoretical framework. It did use national recommendations by policy makers and researchers designed to improve health literacy; however, the health literacy measurements did not yield significant results. This might be attributable to the initial high health literacy among the pregnant women and the high level of education they possessed. It is also possible that the measurement instruments did not measure changes because they are built upon health literacy frameworks, which the intervention was not. It is therefore advisable for future researchers and policy makers to develop interventions based on health literacy frameworks and work with suitably comprehensive measurement instruments.

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CHAPTER 10

Conclusion

10. Conclusion

The results of this PhD thesis reveal gaps in the research on health literacy among pregnant women. This applies primarily to the assessment of health literacy among pregnant women and interventions for improving it. It is well-known that the association present in the studies in DP 1 between health literacy and different health outcomes is also applies to other populations. Health literacy is particularly important during pregnancy, since it influences health outcomes and behaviors that, in turn, will most likely affect the health and development of the unborn child. As such, RCTs are needed in order to build evidence-based strategies for improving health literacy in order to ensure better health among pregnant women.

In order to fill this research gap, a lifestyle intervention was developed (DP 2). The intervention was provided in the health service setting and could thus only have a limited impact on the individuals' health literacy. Such interventions are unable to address further determinants in the social, physical and economic environments. As such, it is crucial to offer further resources to support health literacy in society as a whole.

The evaluation of objective health literacy using the knowledge questionnaire in a lifestyle intervention (DP 3) revealed that pregnant women have a good understanding of lifestyle topics during pregnancy. Despite this, however, they lacked knowledge in particular topics, which confirms findings of DP 1. Women participating in the lifestyle intervention lack for example knowledge regarding recommended GWG ranges, which is crucial as excessive GWG is a major cause of adverse health effects in both the woman and her unborn child. It is therefore essential to consult on this topic during antenatal care, taking the woman's initial BMI into account. Furthermore, migration was a predictor for answering questions wrong. This indicates that this group of women requires special attention during perinatal counseling to cover the needs and gaps in their knowledge. This can be achieved for example by providing information material and counseling offered in different languages.

Most of the participants in the lifestyle intervention possessed adequate health literacy (DP 4). Nevertheless, about one third possessed inadequate health literacy, a fact that the intervention was not able to improve due to several factors discussed in the previous chapter. These results are insightful for the development of future interventions. It is

recommended that health literacy interventions be developed based on a theoretical concept and using suitable measurement instruments. Furthermore, participating healthcare providers need training with a particular focus on different health-literacy-based subgroups of women so that they can act accordingly. Approved communication methods for increasing health literacy need to be an integral part of counseling. The study was effective in improving knowledge on lifestyle topics, which is a strong argument for providing additional lifestyle counseling during pregnancy, particularly for first-time mothers.

DOCTORAL STUDENT'S DECLARATION OF CONTRIBUTION

Doctoral student's declaration of contribution

[1] Health literacy among pregnant women in a lifestyle intervention trial: protocol for an explorative study on the role of health literacy in the perinatal health service setting

Farah Nawabi, Adrienne Alayli, Franziska Krebs, Laura Lorenz, Arim Shukri, Anne-Madeleine Bau, Stephanie Stock

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Author's contributions

Farah Nawabi, Adrienne Alayli, and Stephanie Stock developed the study protocol. Franziska Krebs, Laura Lorenz, and Arim Shukri are members of the research team , contributed to the study design and provided continuous feedback. Anne-Madeleine Bau is the project lead for the GeMuKi project and has also provided feedback. Farah Nawabi wrote the mansucript. All authors critically read and revised the manuscript and approved the final version of the manuscript for publication.

[2] Health Literacy in Pregnant Women: A Systematic Review

Farah Nawabi, Franziska Krebs, Vera Vennedey, Arim Shukri, Laura Lorenz, Stephanie Stock

International Journal of Environmental Research and Public Health [Impact Factor at time of publication 3.390]

Author's contributions

Farah Nawabi developed the concept, Stephanie Stock assisted. Farah Nawabi and Vera Vennedey developed the method. Farah Nawabi, Franziska Krebs and Arim Shukri did the data analysis (checking the suitability of the studies and statistical analysis). Farah Nawabi wrote the manuscript. All authors critically read and revised the manuscript and approved the final version of the manuscript for publication.

[3] Understanding Determinants of Pregnant Women's Knowledge of Lifestyle-Related Risk Factors: A Cross-Sectional Study

Farah Nawabi, Franziska Krebs, Laura Lorenz, Arim Shukri, Adrienne Alayli, Stephanie Stock

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Conceptualisation, F.N.; formal analysis, F.N. and A.S.; writing—original draft preparation, F.N.; writing—review and editing, A.A., F.K., L.L. and S.S.; supervision, S.S. All authors have read and agreed to the published version of the manuscript.

Farah Nawabi developed the concept. Farah Nawabi and Arim Shukri performed the data analysis. Farah Nawabi wrote the manuscript. Adrienne Alayli, Franziska Krebs, Laura Lorenz, and Stephanie Stock revised and edited the manuscript. All authors critically read and revised the manuscript and approved the final version of the manuscript for publication.

[4] Health Literacy among Pregnant Women in a Lifestyle Intervention Trial

Farah Nawabi, Franziska Krebs, Laura Lorenz, Arim Shukri, Adrienne Alayli, Stephanie Stock

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Übersicht der Publikationen:

[1] Farah Nawabi, Franziska Krebs, Vera Vennedey, Arim Shukri, Laura Lorenz, Stephanie Stock (2021). *Health Literacy in Pregnant Women: A Systematic Review.* Int. J. Environ. Res. Public Health 2021, 18, 3847. doi.org/10.3390/ ijerph18073847 (Impact Factor: 3.390)

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[3] Farah Nawabi, Franziska Krebs, Laura Lorenz, Arim Shukri, Adrienne Alayli, Stephanie Stock (2022). *Understanding Determinants of Pregnant Women's Knowledge of Lifestyle-Related Risk Factors: A Cross-Sectional Study.* Int. J. Environ. Res. Public Health 2022, 19(2), 658; doi.org/10.3390/ijerph19020658 (Impact Factor: 3.390)

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