Adoption of a Digital Intervention for Clinical Decision Making in Polypharmacy
-
Implementation Science Perspective on Pathways to Advance the Adoption

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CONTENTS

Abstract

Background

Applying implementation science (ImpSci) methodology in process evaluation studies represents an emerging approach that is grounded in the contextualization of evidence. The disruptive power of digital transformation is creating uncertainties that render the generation of evidence more difficult and pose significant challenges for researchers tasked with explaining its complex interrelationships. This unparalleled challenge has led to a rethinking of the conventional methods employed in health services research for process evaluation in this dissertation. Accordingly, the proposed approach proved beneficial for focusing on contextual influences in implementation pathways and mechanisms and for exploring uncertainties in the evidence regarding the implementation effectiveness of digital interventions for polypharmacy management in primary care practice.

Objectives

The principal objective of this cumulative dissertation was to explore implementation pathways in the adoption of a digital intervention for decision support in polypharmacy, applying the methodology of ImpSci at the intersection with a context-focused process evaluation. The secondary objective was to triangulate process evaluation data in a mixed-methods design to confirm mechanisms of impact in the implementation process.

Methods

This research involved a qualitative study, a psychometric evaluation study and a mixed-methods study:

- Qualitative study: The qualitative study focused on exploring the role of physicians' habitus in the adoption of the digital intervention, both in simple and complex implementation pathways.
- Psychometric evaluation study of the *Implementation Leadership Scale:* A translation and psychometric evaluation of the original *Implementation Leadership Scale (ILS)*, tested the validity and reliability of *ILS* for German-speaking use in a primary care setting, with a focus on the associations between *ILS* and organizational variables.
- Mixed-methods study: A mixed-methods study with a confirmatory approach to assess which possible implementation pathways and mechanisms lead to the adoption of the digital intervention.

Results

Empirical results

The findings indicated that the application of ImpSci methodology in process evaluation is necessary to generate insights on contextual evidence in implementation processes at different levels of abstraction. The analysis considers the following levels: 1. Contextual evidence on implementation pathways and the influence of physicians' habitus. 2. Latent

contextual factors in different forms of physicians' leadership behavior in implementation, which have a predictive influence at the organizational level; 3. Mediating contextual factors in the form of physicians' beliefs about the effectiveness of the digital intervention and their role in implementation mechanisms.

Methodological results

The qualitative study and the validation study demonstrated the utility of employing the determinants framework CFIR (Consolidated framework for implementation research) in conjunction with the MRC (Medical research council) framework for process evaluation of complex interventions, particularly in identifying a specific research focus for process evaluation. However, CFIR lacks guidance on which areas of the comprehensive framework to prioritize and which methods for empirical implementation research match. More specific middle-range theoretical approaches were necessary to create conceptual models for process evaluation dependent on our research questions. In contrast, the MRC Framework provides a list of potential methods for empirical research, thereby offering a complementary approach to the CFIR. Identified insights were integrated to inform the advanced mixed-methods study design. This third study incorporates theoretical and methodological approaches from technology acceptance research and realist evaluation. These approaches are then integrated to conceptualize a qualitative configurational model. Subsequently, the model is confirmed through the application of a mediation model utilizing structural equation modeling. Our approach represents an application of the ImpSci methodology to the empirical investigation of implementation pathways and mechanisms.

Conclusion

The doctoral projects critically evaluated the experiences of physicians from sensitization to adoption of a digital intervention for polypharmarcy management. They proposed potential solutions, key learnings and implications for prospective research. The current ImpSci methodology guidance for process evaluation is severely constrained, particularly in regard to defining criteria for generating evidence on the implementation effectiveness of evidence-based digital interventions. The development of a mixed-methods study design for studying implementation mechanisms with ImpSci methodology yielded extended methodological findings. While suitable for scenarios involving rapidly emerging technologies, decision-makers must consider the specific features of ImpSci methodology within process evaluation, like the high effort of its conduct. Futher research is needed for remaining questions, such as to determine how the contextualized evidence on implementation mechanisms can be generalized and best utilized in comparable contexts.

Zusammenfassung

Hintergrund

Die Methodologie der Implementierungswissenschaft in Studien der Prozessevaluation anzuwenden stellt einen sich entwickelnden Ansatz dar, der auf der Kontextualisierung von Evidenz basiert. Die disruptive Kraft der digitalen Transformation führt zu Unsicherheiten, welche die Generierung von Evidenz erschweren und große Herausforderungen für die Forschenden darstellen, die mit der Erforschung ihrer komplexen Zusammenhänge beauftragt sind. Diese Herausforderungen führten in dieser Dissertation zu einer Neubetrachtung der konventionellen Methoden der Versorgungsforschung für die Prozessevaluation. Der vorgeschlagene Ansatz erwies sich als vorteilhaft, um kontextuelle Einflüsse auf Implementierungspfade und -mechanismen zu untersuchen, und um bestehende Unsicherheiten in der Evidenz zur Implementierungswirksamkeit digitaler Interventionen für Polypharmazie-Management in der Praxis zu erforschen.

Zielsetzung

Das primäre Ziel der kumulativen Dissertation bestand darin, Implementierungspfade und - mechanismen in der Annahme einer digitalen Intervention für Polypharmazie-Management zu erforschen, wobei die Methodologie der Implementierungswissenschaft an der Schnittstelle zu einer kontextbezogenen Prozessevaluation angewendet wurde. Das sekundäre Ziel bestand darin, Daten der Prozessevaluation in einem Mixed-Methods-Design zu triangulieren, um Wirkmechanismen in der Implementierung zu bestätigen.

Methoden

Eine qualitative Studie, eine psychometrische Evaluierungsstudie und eine Mixed-Methods Studie:

- Qualitative Studie: Die qualitative Studie konzentrierte sich auf die Erforschung der Rolle des Habitus von Hausärzten während der Annahme der digitalen Intervention, sowohl in einfachen als auch komplexen Implementierungspfaden.
- Psychometrische Evaluation der *Implementation Leadership Scale (ILS)*: Übersetzung und psychometrische Tests der originalen *ILS* zur Validität und Reliabilität für den deutschsprachigen Gebrauch in der Primärversorgung, mit einem Schwerpunkt der Untersuchung von Assoziationen zwischen *ILS* und organisationalen Variablen.
- Mixed-Methods-Studie: Eine Mixed-Methods-Studie mit einem konfirmatorischen Ansatz zur Bewertung, welche möglichen Implementierungsmechanismen zur Annahme der digitalen Intervention führen.

Ergebnisse

Empirische Ergebnisse

Die Ergebnisse legen nahe, dass die Anwendung von ImpSci Methodologie in der Prozessevaluation notwendig ist, um Erkenntnisse über kontextbezogene Evidenz zu Implementierungspfaden und -mechanismen auf mehreren Abstraktionsebenen zu gewinnen. Die

Analysen beschrieben die folgenden Ebenen: 1. Kontextuelle Evidenz zu Implementierungspfaden und dem Einfluss des hausärztlichen Habitus; 2. Latente Kontextfaktoren in unterschiedlichen Formen von ärztlichen Führungsverhalten in der Implementierung, welche prädiktiv auf die Organisationsebene wirken; 3. Mediierende Kontextfaktoren in Form von hausärztlichen Überzeugungen zur Wirksamkeit der digitalen Intervention und ihre Wirkweise in Implementierungsmechanismen.

Methodische Ergebnisse

Die qualitative Studie sowie die Validierungsstudie legen nahe, dass der Framework für Implementierungsdeterminanten CFIR in Verbindung mit dem MRC (Medical Research Council)-Framework für die Prozessevaluation komplexer Interventionen vorrangig verwendet werden kann, insbesondere für die Identifizierung eines spezifischen Forschungsschwerpunkts in der Prozessevaluation. Allerdings mangelt es dem CFIR an einer Anleitung, welche Bereiche des umfassenden Frameworks zu priorisieren sind und welche Methoden sich für die empirische Forschung eignen. Um konzeptuelle Modelle für die Prozessevaluation in Abhängigkeit von den Forschungsfragen zu entwickeln, waren spezifischere theoretische Ansätze mittlerer Reichweite erforderlich. Demgegenüber stellt der MRC-Framework eine Liste potenzieller Methoden, wodurch er als ein ergänzender Ansatz zum CFIR passend ist. Die gewonnenen Erkenntnisse wurden in die Entwicklung des fortgeschrittenen Mixed-Methods Design einbezogen. Ein Realist-Evaluation-Ansatz wurde für die Konzeptualisierung eines qualitativ konfigurationalen Modells der Implementierungsmechanismen verwendet, sowie Annahmen zum kontextuellen Einfluss in einem Mediationsmodell bestätigt. Der vorgeschlagene Ansatz basiert auf Kernannahmen der ImpSci Methodologie angewandt in der empirischen Untersuchung von Implementierungspfaden und Wirkmechanismen in der Implementierung.

Schlussfolgerung

Die Promotionsprojekte widmeten sich kritisch der Evaluation ärztlicher Erfahrungen von der Sensibilisierung bis zur Annahme einer digitalen Intervention für das Polypharmaziemanagement. Aktuell verfügbare ImpSci-Methodenanleitungen für Prozessevaluationsstudien erwiesen sich als stark eingeschränkt bezüglich definierter Kriterien für die Generierung von Evidenz zur Implementierungswirksamkeit digitaler Interventionen. Potenzielle Lösungsansätze, wesentliche Erkenntnisse und Implikationen für die zukünftige Forschung wurden aufgezeigt. Weitere Untersuchungen sind erforderlich, beispielsweise um festzustellen, wie die kontextualisierte Evidenz zur Wirkweise von Implementierungsmechanismen verallgemeinert und in vergleichbaren Kontexten bestmöglich nutzbar ist.

LIST OF ABBREVIATIONS

AdAM	Application of a digitally assisted pharmacotherapy management system (original German acronym for the c-RCT project)
BI	Behavioral intention to use/adoption
CB	Contextualized innovation effectiveness beliefs
CDSS	Clinical decision support system
CFI	Comparative Fit Index
CFIR	Consolidated Framework for Implementation Research
CMOc	Context-Mechanism-Outcome configuration
COREQ	Consolidated criteria for reporting qualitative research
C-RCT	Cluster Randomized Controlled Trial
EBI	Evidence-based Intervention
EBM	Evidence-based Medicine
EBP	Evidence-based Practice
ILS	Implementation Leadership Scale
ImpSci	Implementation Science
IT	Information technology
MeSH	Medical Subject Headings
MM	Measurement model
MRC	Medical Research Council
ORIC	Organizational readiness for implementing change
RMSEA	Root Mean Squared Error of Approximation
SEM	Structural Equation Model
TAM	Technology acceptance model
TiDIER	Template for Intervention Description and Replication
TLI	Tucker-Lewis index
TPB	Theory of planned behavior
TRA	Theory of reasoned action

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1. Background

1.1 Formative and process evaluation of complex interventions in health services research

The conventional methods employed in health services research for the evaluation of complex interventions address two core areas: the optimization-oriented design of the intervention and the monitoring of the implementation processes of new interventions (formative and process evaluation) [1, 2]. These methods entail a systematic assessment of change processes and consider the interactions between the organization (meso-level), its members (micro-level), and the societal system (macro-level). The two core areas delineate the scope of research questions in health services research, assisting researchers in formulating precise research questions and operationalizing them for empirical research [3]. To enhance the quality of results in implementation, the methods for formative and process evaluation studies can also be informed by theory-driven approaches. This necessitates the selection of pertinent theories in conjunction with the research question, enabling researchers to describe, explain, and understand the presumed mechanisms of an intervention.

Formative or process evaluation studies in health services research must adhere to the methodology that has been established as the gold standard for evidence-based medicine (e.g. through the a systematic approach to clinical problem solving; integration of clinical expertise and patient values; conduct of randomized controlled trials, cluster-randomized trials or quasi-experimental designs) [4]. The principal objective of formative and process evaluation studies is to conduct empirical investigations with the aim of identifying the essential conditions for the implementation of effective healthcare interventions. This is done in order to provide support for effectiveness research and to enhance outcomes that directly benefit patients.

However, conventional formative or process evaluation studies in health services research are not designed for adapting evidence to specific contexts and, thus, may not ensure the tailoring of adequate implementation strategies. In scenarios involving rapidly emerging technologies, such as the digital transformation, the utility of conventional formative and process evaluation studies may be limited. One potential solution to this challenge is the promising methodology of implementation science, which provides context-specific, adaptable, and tailored information for healthcare decision-makers and stakeholders [5].

1. 2 Process evaluation in implementation science as emerging evaluation type

1.2.1 Applying implementation science methodology in process evaluation studies

Process evaluation studies in implementation science (ImpSci) represent an approach to the evaluation of implementation processes and strategies during the implementation phases of evidence-based practices (EBP's), interventions (EBI's), and policies. The objectives of ImpSci studies are the exploration, adoption, implementation and sustainment of these practices into routine healthcare and public health settings [6]. Process evaluation in ImpSci draws on a particular set of implementation theories and frameworks for the study of implementation determinants, strategies and outcomes associated with implementation. These can be used to inform empirical research in the field (see Fig. 1). As a result, the ImpSci methodology is particularly well suited to highly relevant areas of research that are characterized by substantial uncertainty due to the dynamic nature of the context in implementation processes and the need for continuously adapted evidence bases. The intricacies of implementation science have been explored and discussed in the journal *Implementation Science*, which was launched specifically to address implementation science issues. Since its inception in 2006, the field has grown in prominence, as evidenced by a number of applied examples of implementation science studies and the introduction of a dedicated *Implementation Science* MeSH term in 2019 by the National Library of Medicine.

The integration of implementation science approaches into health services research can facilitate a more profound comprehension of the processes underlying the successful implementation, realization and sustainable application of innovations in practice [1]. By employing implementation science methodology, it is possible to conduct an analysis of critical factors such as organizational readiness for change, implementation leadership, and contextual conditions that are pivotal in determining the success or failure of an implementation. The application of implementation theory within theory-driven process evaluations enables researchers to systematically identify potential contextual factors to implementation and develop strategies to overcome these barriers [7].

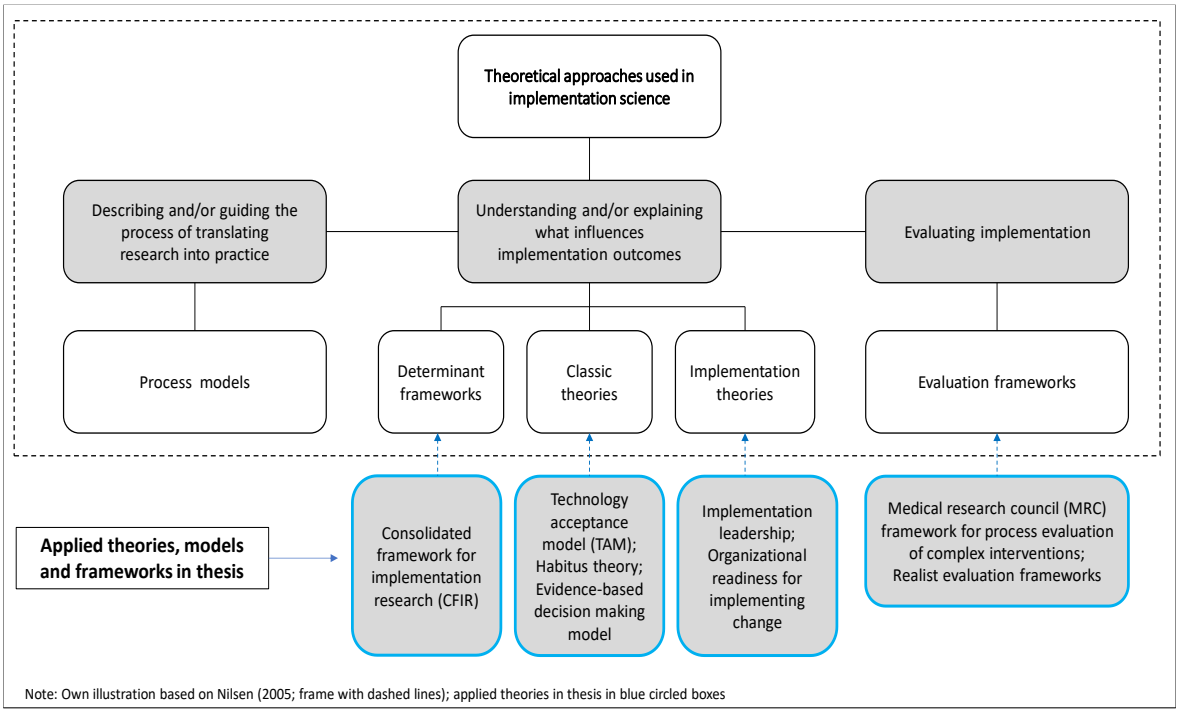

Figure 1: Theoretical approaches used in dissertation projects [7–12].

1.2.2 Understanding and explaining what influences implementation outcomes

In a nutshell, the dissertation employed theoretical approaches to elucidate the pathways and mechanisms through which the intervention impacted the outcome of adoption. In order to achieve this, theoretical approaches were employed iteratively and as sensitizing concepts in qualitative research part, and in a confirmatory and theory-testing sense in the mixed-methods and quantitative research part. In order to gain insight into the factors that shaped the implementation outcome of adoption, the meta-framework for implementation determinants, the Consolidated Framework for Implementation Research (CFIR), was employed to develop the survey instruments in a theory-driven manner [8]. In particular, the CFIR was employed with a particular focus on the domains of *intervention characteristics* and the *inner setting* - which is also employed in other studies as a synonym for measures pertaining to the context of interventions. The associated constructs are typically anchored at the meso level of organisational structure. These two domains are described in greater detail below (intervention characteristics and inner setting).

In order to gain a deeper comprehension of the *characteristics of the digital intervention*, the TiDIER checklist for intervention description was completed and a rapid literature search on digital decision support systems was conducted (see Appendix of Study 1) [13]. A concise description of the functions of the digital clinical decision support system (CDSS) can be provided as follows: it offers physicians patient-relevant drug-therapy information based on an overview of the patient's medication history, providing insights that extend

beyond the scope of information accessible through conventional care pathways. Informations include data on diagnoses, treatment, and medical products, based on claims data. The digital intervention enables physicians to conduct systematic reviews of medications for appropriateness, add medications, and modify them as necessary. Furthermore, instructions on medications will be subjected to systematic review, and any necessary additions or modifications will be made. Additionally, guidance will be provided on potential drug-drug interactions, drug-disease interactions, age-related potentially inappropriate medications (PIMs), duplicate medications, renal dose adjustments, allergies, as well as general inappropriateness, such as prescriptions associated with Dear Doctor letters ('Rote-Hand Briefe') [14].

The term 'adoption', which was used as an implementation outcome in this dissertation, was used to describe the intention, initial decision or action to try or employ an innovation or evidence-based practice [15]. It may also be referred to as 'uptake', and can be measured from the perspective of the provider or organisation. In this dissertation, adoption was measured from the perspective of the participating physicians at the micro level. Moreover, and with reference to the technical nature of the intervention, the Technology Acceptance Model (TAM) has also constituted a pivotal theoretical foundation upon which both the survey instruments and the data modelling were based [9]. In the context of developing the evaluation's study design and based on the initial literature review on determinants of behavioral change in physicians, which was to be achieved by the introduction of the digital intervention, the theory of habitus was also employed as a relevant explanatory concept and as an influencing factor for adoption. The third theoretical approach at the micro and behavioral level of physicians integrated in the dissertation was the general model of evidence-based decisions. This model is based on the assumption that physicians' decisions are informed by three key factors: their own experiences, patient preferences, and scientific evidence [4, 16].

In summary, the working hypotheses for the dissertation were developed on the basis of the assumption that the heterogeneous implementation effectiveness of digital interventions observed in numerous studies is associated with variations in physicians' adoption behavior. To gain a deeper understanding of these variations and elucidate their underlying causes, an examination of the contextual factors influencing the implementation process was conducted. The objective was to examine three further contextual factors. Firstly, the influence of physicians' habitus on their polypharmacy prescribing practices. Secondly, the influence of implementation leadership skills and organisational factors, such as the willingness of the organisation to implement changes. And thirdly, the way in which physicians' beliefs about the effectiness of the intervention serve as a mediator between organizational variables

and the adoption process. Further details on the theoretical approaches used are provided in the individual dissertation projects.

1.2.3 Differences between process evaluation in implementation science and health services research

Although process evaluation in conjunction with clinical trials adheres to the established methods of evidence-based medicine (EBM), there are specific methodological considerations pertaining to ImpSci that must be predetermined at the protocol stage. The primary distinctions between process evaluation in ImpSci and conventional formative and process evaluation in health services research are presented in a comparative table 1. In this regard, it is essential to determine which of the three hybrid study types is most appropriate for the intervention to be implemented. This decision should be consistent with the recommendations outlined in the seminal article published in 2012 by Curran et al. (updated in 2022), which emphasized the need to select the appropriate type of hybrid study based on the nature of the effectiveness data available for the intervention of interest [17, 18]. In essence, the more robust the existing evidence base for the effectiveness of the intervention under examination, the greater the scope for a process evaluation to focus on testing the effectiveness of implementation strategies (for example, by randomizing not only the clinical intervention but also the implementation strategies). Conversely, when evidence for the effectiveness of the intervention is limited, the focus of process evaluation in ImpSci is more on context assessment and the exploration of facilitators and barriers of implementation.

Table 1: Distinction between evaluation approaches

	Conventional formative and process evaluation	Process evaluation in implementation science
Definition of hybrid study type 1, 2, 3	x	✓
Implementation-specific outcome measures for evaluation	x	✓
Tailoring of implementation strategies	x	✓
Classifying different types of content and contextual modifications of EBI's in implementation	x	✓
Systematization of implementation knowledge across levels of social systems	x	✓
Optimization of intervention design	✓	x
Utilization of evidence-based medicine methodologies	✓	✓

1.2.4 Describing the rationale for conducting an implementation science-focused process evaluation

As outlined by Moore et al., an isolated examination of clinical outcomes leaves numerous significant queries unanswered, which also hold relevance for policymakers and stakeholders [19]. These questions can be addressed by the methodology of implementation science. As a preliminary overview in light of the extant literature on conducting process evaluation studies, this dissertation has considered the following conditions to be necessary for an ImpSci and context- focused process evaluation to be designated as a suitable form of analysis: 1. the level of uncertainty is high with respect to the available evidence regarding the (in-)effectiveness of the implementation of the evidence-based intervention in question; 2. the research question of the process evaluation must be of particular importance for understanding the mechanisms of impact of context in the implementation process of an evidence-based intervention; and 3. the area of interest is rapidly evolving and there is a need to contextually adapt evidence about the digital intervention and possible implementation strategies to the mechanisms emerging in the implementation process.

1.2.5 Core steps for conducting a process evaluation in implementation science

Process evaluation in ImpSci follows EBM methodology for key steps in the design of the study, as shown in Table 1. It can be conducted within feasibility testing phases, alongside effectiveness evaluations, or alongside post-evaluation scale-up. For ImpSci goals and objectives, the hybrid study approach is advantageous. It advances the field and enhances the generation of generalizable evidence on implementation strategies. In general, there is no consensus regarding a unified and general definition of process evaluation or comprehensive checklist that is universally accepted. However, a number of key functions and guiding principles exist that inform the conduct of process evaluations [19]. In the MRC framework for process evaluation, the key functions integrate the analysis of implementation issues, which are examined from a variety of perspectives, including the interaction between *context*, *implementation*, and the manner in which the implementation is delivered, as well as the relationship between implementation and *mechanisms of impact* [2, 20]. Figure 2 illustrates the process of conducting process evaluation studies within IS, including the key steps.

Once the preliminary decision regarding the most suitable hybrid study type has been made, the subsequent steps involve documenting the manner in which process evaluation is integrated into a clinical trial, protocol registration, as well as any additional considerations specific to process evaluation in ImpSci (first step). This is followed by the commencement of the actual conduction process (see Fig. 2). The second step is to describe the intervention in question, including its constituent components, in order to clarify the causal assumptions

and to present the theoretical approaches that inform its anticipated effectiveness (e.g., in a programme theory or in a logic model). The subsequent step is an investigation of the contextual factors that influence the implementation process of the intervention. This will entail an engagement with the existing literature to identify the current state of theoretical evidence in this field and to ascertain the potential contributions that the proposed process evaluation may offer. This step also requires a significant decision regarding the selection of an appropriate analytical approach, given the proliferation of literature on the relationship between implementation and context in recent years [21, 22]. However, there is currently no consensus on a unified perspective on this topic. The prevailing assumption is that implementation must be conducted in a context-sensitive manner to ensure success. The fourth step is to identify the key uncertainties regarding the existing knowledge on the relationships between implementation, impact mechanisms and contextual factors. This involves determining which research questions should be prioritized in light of these uncertainties, consulting the evaluation team and policy/practice stakeholders (step five), and avoiding the collection of superfluous data that cannot be meaningfully analyzed. The research team, engaging with program developers and implementers, performs steps one through five with the objective of comprehending the fundamental mechanisms of the interventions. The results of steps two through five must be taken into account when developing implementation strategies that align with local context barriers and are therefore most suitable to be prioritized and selected. In the seventh stage of the research process, the most suitable outcome measure and methods are selected to address the specific objectives of the study, for example, to analyse mechanisms of impact, causal inference approaches. The eighth and ninth steps pertain to the reporting of the results. Consequently, in the eighth step, the most appropriate reporting standards are selected based on the range of methods utilized in the fourth step. In the ninth step, the results are disseminated to relevant stakeholders, policymakers, and the scientific community, and published. The ultimate step is specific to process evaluation in IS and encompasses the refinement of the initial (theoretical) assumptions regarding the functioning of the implementation strategy given the empirical results of the implementation pathways for the context. In view of the inherent unpredictability of the issues that will emerge during

the process evaluation in IS, it is imperative that the planning and conduction of the evaluation be carried out in a flexible and iterative manner.

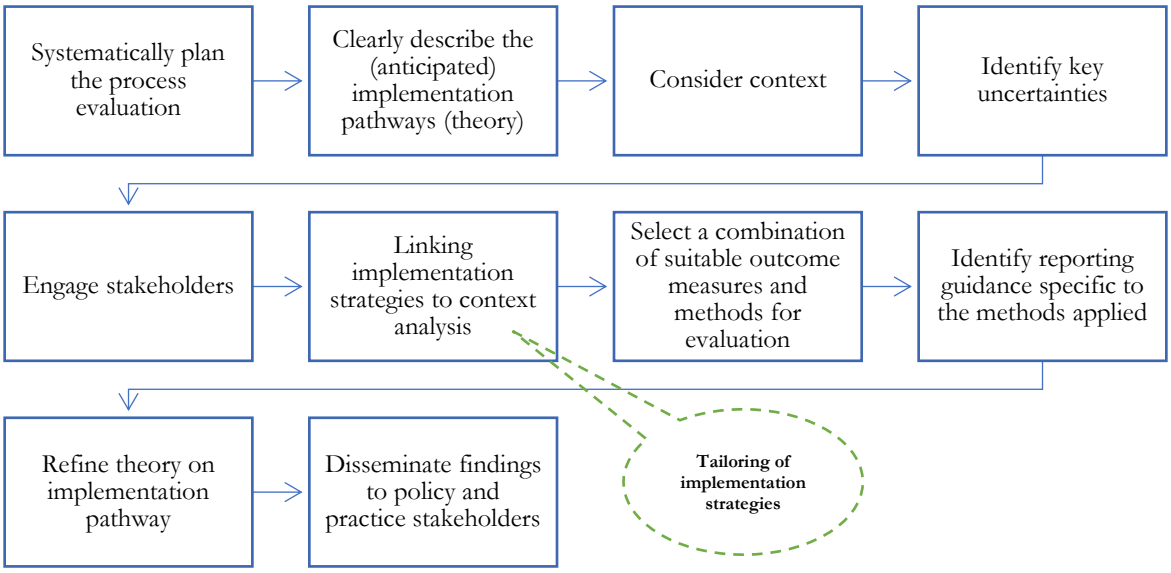

Figure 2: Core steps in conducting process evaluation in ImpSci (own illustration).

1.3 Tailoring of implementation strategies in process evaluation

A defining feature in ImpSci is the analysis of the continuous adaptation of evidence to contexts. In the field of ImpSci, there is a pervasive assumption that evidence, in the form of interventions, is adapted to specific contexts during the translation of evidence into practice [23]. In the process of translating evidence into practice, ImpSci's approach is to prioritize the most suitable implementation strategies. These strategies can be conceptualized as an additional intervention to be integrated into the implementation process, alongside an evidence-based intervention designed to directly influence clinical outcomes. Implementation strategies, in contrast, are designed to directly influence the implementation process in health care organizations or at the behavior change level of health care professionals. Moreover, it is suggested that determinants of implementation can provide valuable insights into the suitability of specific implementation strategies within a given context [24]. The integration of the task of tailoring implementation strategies in the conduct of process evaluations is contingent upon the focus of the overarching research question and the degree of emphasis that can be afforded to their examination. In general, there is an intersection between the goals of process evaluation and implementation science, which is reflected in the key functions or core topics that guide the analysis of "mechanisms of action", "context" and implementation. In addition, ImpSci places an emphasis on examining the effectiveness of implementation strategies within the analysis of context and the mechanisms of impact. In regard to the selection and tailoring of implementation strategies to match the context, two options

are proposed by ImpSci. A more theory-driven approach to the selection of implementation strategies, which takes into account existing ImpSci evidence in combination with an empirical context assessment. An alternative approach would be to adopt more participatory methods for the selection of implementation strategies, with stakeholders engaged in the entire process of tailoring the selected strategy to the context [25].

1.4 The digital transformation and the methodology of implementation science

1.4.1 Digital transformation – opportunities for clinical decision-making in polypharmacy

In its most general sense, digital transformation is defined as a fundamental change process [26]. In practical terms, this signifies the incorporation of digital technology into all facets of society, including the healthcare sector. It is crucial to acknowledge that this change process encompasses not only the technological transformations that emerge as a consequence of the integration of digital technology but also a disruption that gives rise to significant organizational, social, and behavioral adaptations that occur during the transition from analog to digital clinical routines. The phenomenon can be elucidated through the lens of innovation diffusion, or the requisite theoretical approaches deployed at the micro, meso, and macro levels contingent on the research topic [27–29]. To implement digitalization initiatives, significant structural changes are required. The legal prerequisites for this have been specified in Germany in the current 'Digital Act' (2022) [30] and the 'E-Health Act' (2015) [31]. However, despite remarkable progress in developing individual digital applications, the overall level of digitalization in the German healthcare system is still considered relatively low compared to other social subsystems and international standards [32]. The gap between evidence implementation and practice has remained fairly constant over the last decade [33, 34]. In addition to the structural prerequisites that are indispensable for implementation, it is imperative to ascertain the optimal methodology for the implementation of digital interventions. It is therefore recommended that particular consideration be given to the analysis of mechanisms of impact throughout the change processes of the digital transformation. The implementation of digital interventions for clinical decision-making represents a significant digitalization effort with the potential to enhance the quality of healthcare for patients with polypharmacy. This technology is especially beneficial in primary care and for general practitioners due to the growing number of patients with multiple chronic conditions, complex medication regimens, and increased risks of adverse side effects and drug interactions [35–37]. It has been demonstrated that a dearth of pertinent patient information, including medication history, laboratory values, allergies, and diagnoses, can result in significant errors and

adverse effects, particularly in patients with multiple chronic conditions and polypharmacy. Digital applications not only serve as knowledge databases but also have further developments in the area of digital clinical decision support systems (CDSS) based on patient-relevant data [38–41]. Furthermore, digital CDSS, which are based on patient-relevant data and currently use the best available evidence to create side effect and risk profiles, can also be useful for identifying patients and preventing patient harm, whose inappropriate medication could lead to lethality, increased mortality, and rehospitalization. In conclusion, digital CDSS present a promising opportunity to enhance the care of patients on polypharmacy and to streamline the work of primary care physicians and other healthcare professionals. Moreover, in light of the current critical public health developments, including the shortage of nursing staff and medical specialists, the increasing number of multi-morbid patients with polypharmacy, and the workload of physicians in health services, it is imperative to leverage the potential of the digital transformation for clinical decision-making in the healthcare sector [42, 43].

1.4.2 Is the methodology of implementation science suitable for research projects on the digital transformation of healthcare?

Compared to previous transformations in the history of medicine, such as the introduction of science into medical practice during the early 20th century, which is also referred to as the transitional era of evidence-based medicine, the digital transformation has an unparalleled impact on the entire social system of healthcare delivery [44]. The digitalization of previously analog processes is enabling a cultural shift toward greater service orientation in organizations and is also seen as a driving force that is forcing incumbent organizations to adapt the way they deliver services [45]. The changes affect the understanding of the roles and activities of all stakeholders in the health system, including patients, nurses and physicians, health insurance companies, and policymakers. They also necessitate adjustments to infrastructure, processes, and knowledge. Concurrently, the emergence of new digital clinical decision support systems has introduced new challenges and complexities in clinical practice of decision-making. In order to guarantee that physicians have the best possible and most accessible digital CDSS, it is essential that the technologies in question are fully functional, developed in a way that meets the needs of daily practice, and are user-oriented [46–49]. Implementing digital applications developed in this manner into healthcare practice can subsequently lead to reduced workload for employees, increased efficiency [50], improved quality of care [51], easier access to the healthcare system for patients [52], and support in clinical decision-making in the areas of diagnosis, prevention, therapy, and rehabilitation [53–55]. To enhance the implementation process of digital interventions, it is essential to consider the

key factors when implementing digital innovation (e.g., innovation characteristics, inner setting of healthcare organizations, characteristics of individual and process) to guarantee its safety, effectiveness, and alignment with clinician and patient needs [33]. Therefore, the application of implementation science methodology to evaluate the implementation processes of digital interventions as part of the digital transformation is particularly appropriate given that the methodology is inherently concerned with change processes. The field of implementation science offers a range of theoretical evidence, including assumptions that differentiate the various stages of implementation, specific implementation outcomes, and assumptions about the use of implementation strategies that facilitate the systematic evaluation of the research topic in question [56]. Furthermore, it provides specific study designs for the systematic evaluation of implementation strategies. The proposed approach in this dissertation is situated within ImpSci methodology and used a spectrum of appropriate methods for empirical analysis which has demonstrated that process evaluation can be understood not only in terms of evidence generation for the improvement of the digital intervention itself, but also in terms of the improvement of the implementation process through understanding the functioning of implementation pathways and mechanisms.

2. The PhD Project Objectives

The principal aim of this cumulative dissertation was to explore implementation pathways in the adoption of the digital intervention for polypharmacy management, by applying the methodology of implementation science at the intersection of the process evaluation. The objective of this application was to effectively address the emerging challenges posed during the implementation of the digital innovation. The secondary goal was the triangulation of qualitative, quantitative and theoretical evidence to confirm mechanisms of impact in the implementation in a real-world implementation project through mixed-methods empirical research. This cumulative dissertation comprises three distinct yet interrelated papers, collectively examining the application of ImpSci methodology in process evaluation. The initial paper is a qualitative study on the implementation process from physicians' perspectives. The second is a psychometric evaluation study of the implementation leadership scale. The third is a mixed-methods paper that employs a realist evaluation framework in conjunction with a belief-elicitation approach, resulting in the development of a mediation model using a confirmatory structural equation modeling approach. An overview of the objectives, projects and their connections is visually depicted in figure 3 (p. 16). In chapter 3 of the dissertation, visual abstracts and written summaries of the three studies are provided.

Publication 1: From sensitization to adoption? A qualitative study of the implementation of a digitally supported intervention for clinical decision making in polypharmacy

The qualitative study aimed to explore mechanisms of impact and the influence of the physicians' habitus on the adoption of the digital intervention (implementation outcome), exemplified by a qualitative data analysis of interviews and focus groups with physicians from the intervention and wait-list control group within the C-RCT project "Application for a Digitally Supported Pharmacotherapy Management System" (AdAM project—original German acronym for the project). As a result of synthesizing results of qualitative data analysis using two different qualitative methodological approaches, namely a content analysis and a documentary methods approach, a process model of implementation pathways was developed.

Publication 2: How is leadership behavior associated with organization-related variables? Translation and psychometric evaluation of the implementation leadership scale in German primary healthcare

The primary aim of the translation and psychometric evaluation study was to validate an implementation science measurement instrument, namely the Implementation Leadership Scale (ILS), for German-speaking use in a primary care setting, as well as the analysis of

associations between leadership behavior (ILS) and organizational variables using a sample of primary care physicians.

Publication 3: Complex implementation mechanisms in primary care: do physicians' beliefs about the effectiveness of innovation play a mediating role? Applying a realist inquiry and structural equation modeling approach in a formative evaluation study

In this mixed-methods study, we employed a sequential-exploratory design to investigate the mediating impact of contextualized variables in implementation mechanisms. The findings of our preceding research and the data gathered from both qualitative and quantitative sources were employed to construct two models of implementation mechanisms and to corroborate the results through triangulation. In particular, we examined the relationships between organizational and individual variables in a differentiated manner, with the aim of clarifying the links between these variables as sources of complexity in the implementation mechanisms.

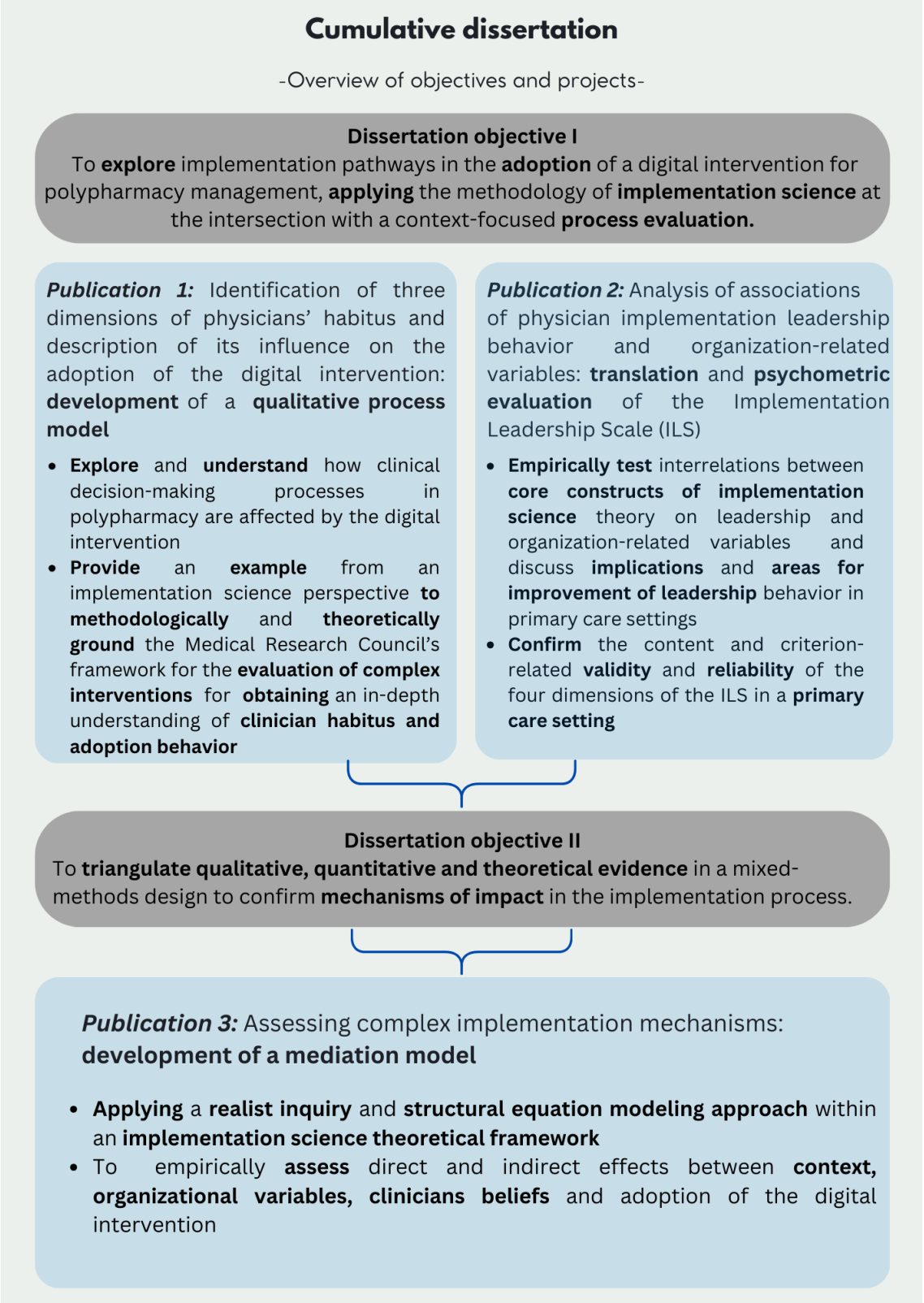

Figure 3: Overview of dissertation objectives (own illustration).

3. Synopsis of Study Results

3.1 Study 1: Clinician habitus in implementation pathways

Citation of the published article:

Söling, S., Köberlein-Neu, J., Müller, B. S., Dinh, T. S., Muth, C., Pfaff, H., & Karbach, U. (2020). From sensitization to adoption? A qualitative study of the implementation of a digitally supported intervention for clinical decision making in polypharmacy. Implementation Science, 15, 1-12. DOI: https://doi.org/10.1186/s13012-020-01043-6.

Journal Impact Factor (2020): 7.327

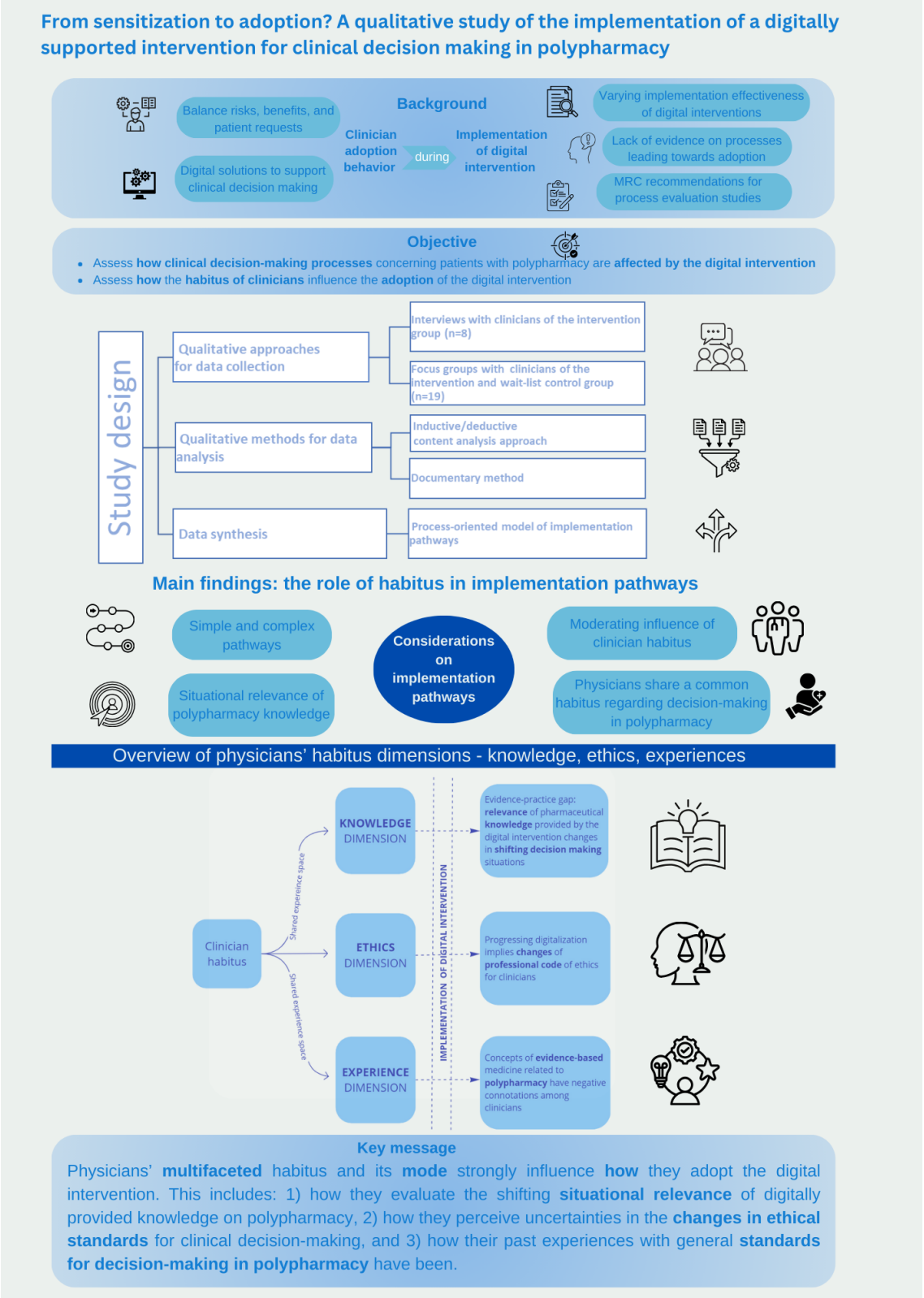

Figure 4: Visual abstract of qualitative study.

Written summary and main results

Background and objectives

The evidence base for the implementation effectiveness of digital interventions for polypharmacy management was characterised by a high degree of uncertainty. Accordingly, the qualitative study was devised with the objective of elucidating the underlying reasons for this phenomenon. Therefore, the mechanisms of impact in the implementation, identified as a key function in the Medical Research Council (MRC) framework for process evaluation of complex interventions, were examined at the intersection with ImpSci methodology, by examining mechanisms of impact in relation to the implementation outcome of the adoption of the digital intervention. The aim for empirical analysis was to explore the implementation of the digital intervention as perceived by physicians and to examine it in the light of physicians' habitual prescribing practices for polypharmacy with and without the digital intervention.

Methods

In the theory-driven development of the topic guides for the conduct of interviews and focus groups with physicians from the intervention and wait-list control group, topics were extracted from the widely used Consolidated Framework for Implementation Research (CFIR), with a focus on the constructs of the inner setting of organizations. The subsequent iterative data analysis, conducted following the initial inductive coding, revealed that the levels of abstraction associated with the constructs pertaining to the inner setting of CFIR were too elevated to permit the drawing of conclusions and the refinement of theory. As a result, the theoretical basis of the second interpretive methodological approach was employed in the data analysis, with the codes assigned to various aspects of the participants' lives (e.g., individual, social, historical), and the relationships between them examined. This theoretical approach was informed by habitus theory, which provided a mid-range theoretical foundation for understanding the mechanisms of impact in the behavior and social interactions of physicians in the implementation at the micro level.

Main results and key messages

This qualitative paper posits that the qualitative analytical approach of the documentary method is particularly suited to ImpSci methodology in exploring the mechanisms of impact, especially in the context of habitual clinical practices in the adoption process of digital interventions.

Physicians' habitual prescribing practices

Qualitative data from interviews and focus groups with 27 physicians in the intervention and wait-list control groups were subjected to analysis. The habitual prescribing practices were investigated, and three dimensions were identified that may moderate the adoption process, depending on the mode. The knowledge dimension demonstrates that supplementary data regarding polypharmacy, which the digital intervention makes accessible to inform clinical decisions, is evaluated in terms of its applicability to prescribing practices, contingent on the (ambiguous) decision-making situation (e.g., between treating chronic and acute patients). Furthermore, the ethical dimension of habitus pertains to the modifications in interprofessional interactions and (legal) uncertainties about the physicians' accountability in utilising the digital intervention. In addition, the experiential dimension has a negative connotation in analogous decision-making processes in the field of polypharmacy (e.g., guidelines that are not practically applicable). This dimension is also transferred into digital decision-making processes by physicians.

Simple and complex implementation pathways

A pathway from increased risk-awareness about polypharmacy and willingness to base clinical decision-making on scientific evidence to adoption of the digital intervention was observed when physicians experienced positive interactions with the intervention. However, during the adoption process, a number of unexpected behavioral outcomes and an increase in the complexity of decision-making among physicians were also observed, largely due to the overall information transparency provided the intervention and a lack of clarity about how the information is to be process in everyday practice. The utilization of the digital intervention may also yield ambiguous behavioral outcomes if physicians question its benefit during the adoption process. If physicians don't perceive learning effects and tend to trivialize risky prescribing practices, they maintained their habitual analog prescribing practices. This pathway ultimately results in a delayed adoption of the digital intervention.

Conclusion

The analysis provided insight into the factors influencing the implementation effectiveness of digital interventions. In particual, it elucidated the role of physicians habitual prescribing behavior in shaping the adoption processes. It is possible to alter habitual (analog) prescribing practices, if insights about the clinician habitus is taken into account when planning and evaluating implementation strategies to increase the uptake of digital interventions for polypharmacy management.

3.2 Study 2: Implementation Leadership Scale Validation Study

Citation of the published article:

Söling, S., Pfaff, H., Karbach, U., Ansmann, L., & Köberlein-Neu, J. (2022). How is leadership behavior associated with organization-related variables? Translation and psychometric evaluation of the implementation leadership scale in German primary healthcare. BMC Health Services Research, 22(1), 1065. DOI: https://doi.org/10.1186/s12913-022-08434-z.

Journal Impact Factor (2021): 2.9

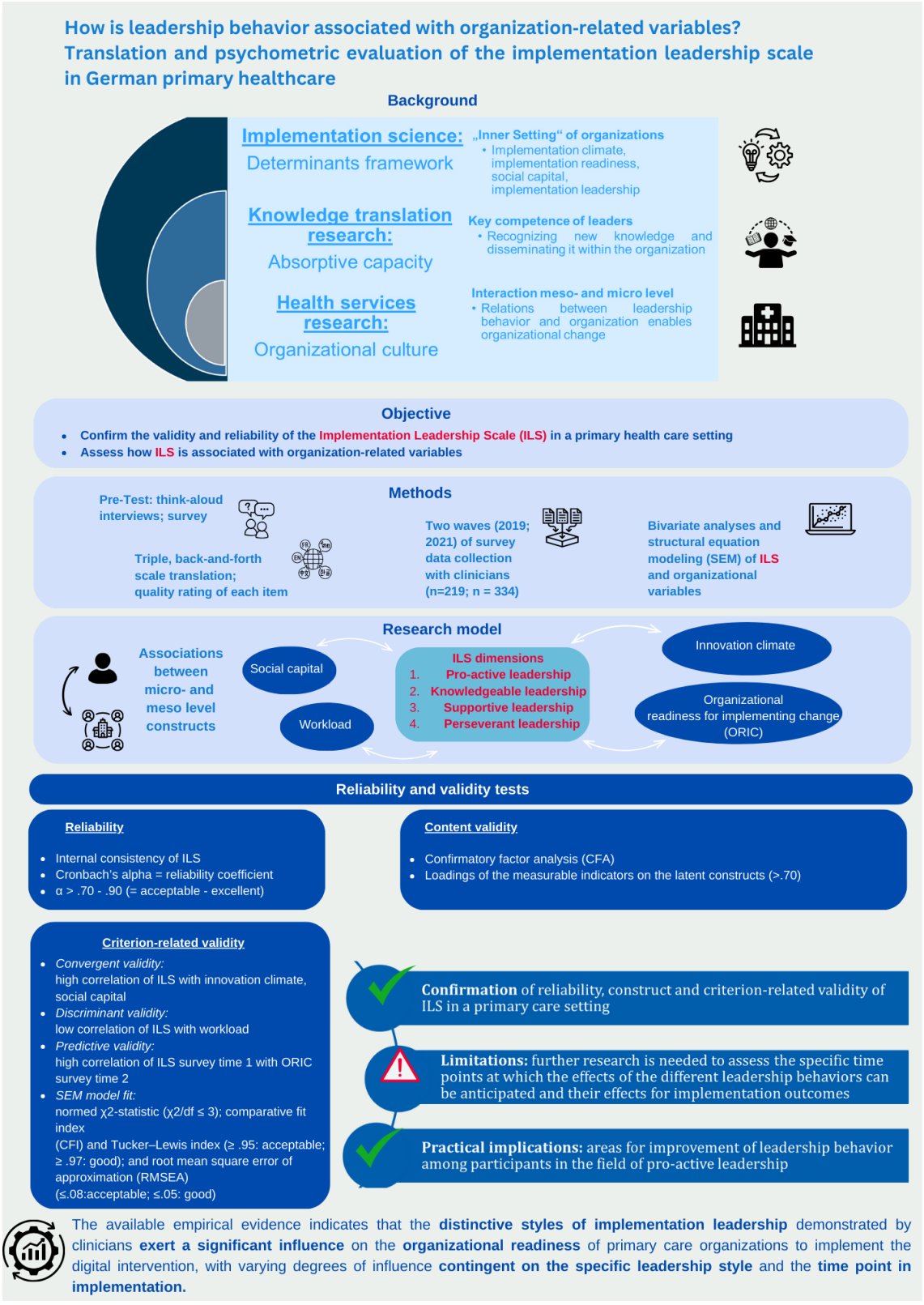

Figure 5: Visual abstract of ILS validation study (own illustration).

Written summary and main results

Background and objectives

The new concept of the implementation leadership scale (ILS) has its theoretical underpinnings situated within the broader field of implementation science, as exemplified by the Consolidated Framework for Implementation Research (CFIR). Moreover, the concept of leadership is a pervasive topic of discussion in a multitude of disciplines, with varying foci of attention. Implementation leadership comprises four distinct leadership types that can positively influence the implementation climate and, consequently, successful implementation. Further details are displayed in the visual abstract. In the psychometric evaluation study of the ILS the bivariate relationships between implementation leadership behavior and organizational variables were investigated.

Methods

In this study, data were drawn from the two survey waves of physicians in the intervention group who utilized the digital intervention. To improve the response rate, a tailored design approach was employed, comprising the dissemination of three reminders to physicians. Furthermore, the initial questionnaire was subjected to a pretesting phase, resulting in the refinement of its presentation. The data were linked pseudonymously and assessed for content-related and criterion-related validity and reliability using the scales of innovation climate, social capital, workload, and organizational readiness to implement change (ORIC). To test the predictive validity of the ILS, the data from the initial measurement point were linked with the data from the ORIC of the subsequent measurement point. The content validity of the scale was examined through a confirmatory factor analysis (CFA), which aimed to ascertain the extent to which the measurable indicators assigned to the latent subscales reached the defined thresholds and strained the corresponding constructs. Bivariate and path analyses were conducted using structural equation modeling to assess criterion-related validity.

Main results and key messages

The available empirical evidence indicates that physicians' implementation leadership behavior is a significant factor influencing organizational outcomes. The psychometric properties of the scale have been demonstrated to be suitable for use in primary care settings. The four-dimensional structure of ILS was verified due to the presence of good global and local fit indices (CFI = .968, RMSEA = .05). The results of the criterion-related data analysis indicated that leadership is a predictive factor for ORIC. Despite the necessity for specific knowledge to apply a new practice in knowledge translation processes and EBM implementation, the knowledgeable leadership type was only weakly or not at all associated with

organizational readiness for implementing change. Other leadership styles, such as supportive leadership, appear to exert a more pronounced influence on organizational team members readiness to implement change in primary care practices.

Conclusion

The ILS is a brief, psychometrically sound instrument that can be used to investigate the effects of distinct leadership behaviors during change processes in primary care organizations. Results indicated that implementation leadership is a significant resource in the implementation process of digital innovations. Further investigation is required to ascertain the manner, rationale, and temporality of the varying effects exerted by distinct forms of leadership behavior on the implementation process.

3.3 Study 3: Mixed-Methods Study on Complex implementation mechanisms

Citation of the published article:

Söling, S., Demirer, I., Köberlein-Neu, J., Hower, K. I., Müller, B. S., Pfaff, H., & Karbach, U. (2023). Complex implementation mechanisms in primary care: do physicians' beliefs about the effectiveness of innovation play a mediating role? Applying a realist inquiry and structural equation modeling approach in a formative evaluation study. *BMC Primary Care*, *24*(1), 131. doi: https://doi.org/10.1186/s12875-023-02081-x.

Journal Impact Factor (2023): 3.2

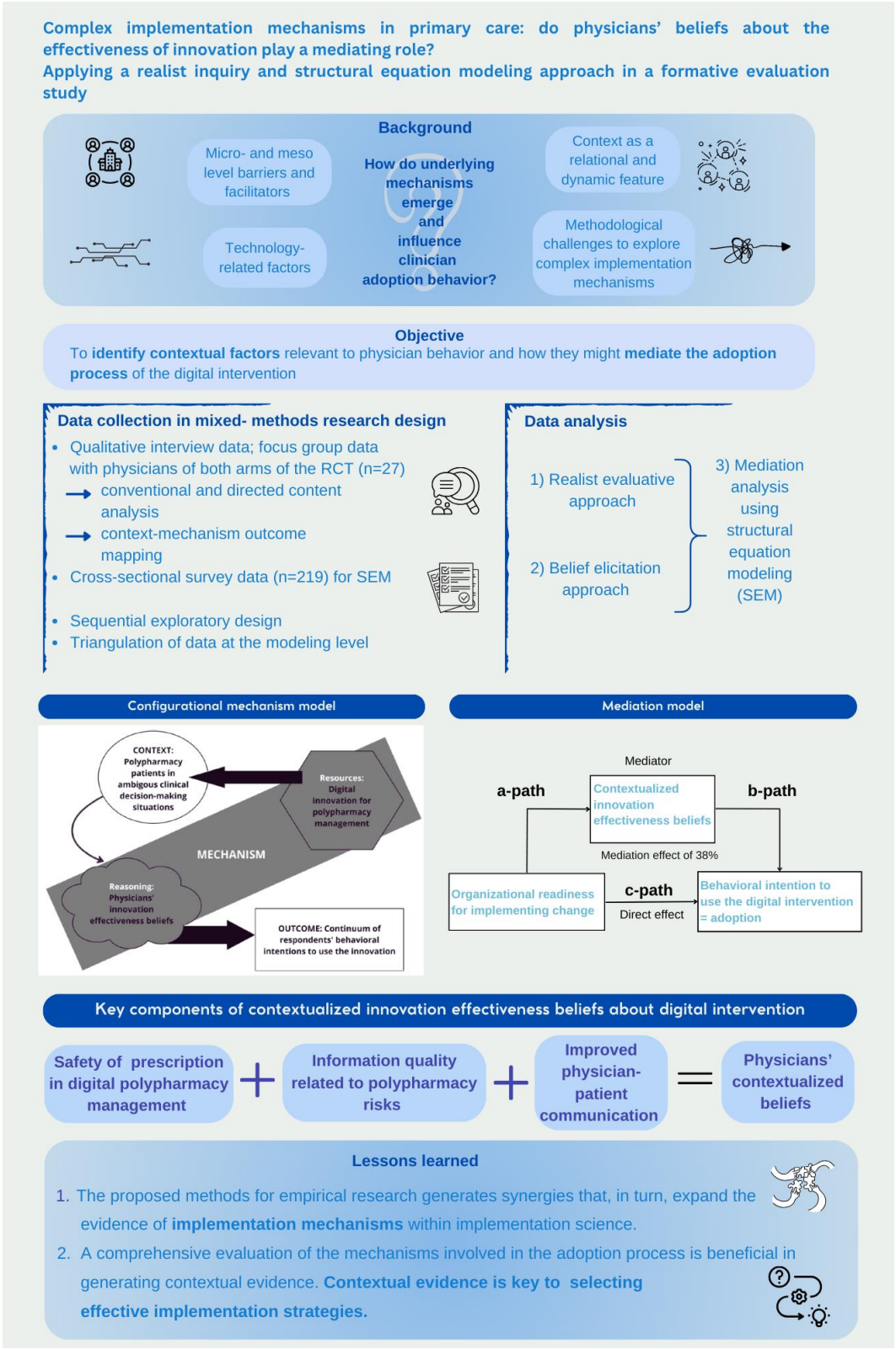

Figure 6: Visual abstract of mixed-methods study (own illustration).

Written summary and main results

Background and objectives

In the field of primary care research, there is a dearth of evidence examining the impact of contextual factors on the adoption of digital innovations for the management of polypharmacy. To enhance the adoption and delivery of care for polypharmacy patients, it is essential to gain a more detailed understanding of the complex underlying implementation processes. The principal objective of the study was to identify contextual factors influencing physician behavior and their potential role in mediating the adoption process.

Methods

A combination of methodological approaches was employed for the conceptualization and operationalization of the research models and for the triangulation of data in a sequential and exploratory design.

Theoretical framework

Context was defined as the relational and dynamic features that influences the mechanisms by which interventions operate and the different levels of a social system over time, thereby giving rise to complex effect relationships. Theoretical approaches to explain the influence of barriers and facilitators, which may be relevant for the adoption of the digital intervention at the various levels of the social system of a healthcare organization, were derived from the literature on technology acceptance, as well as assumptions about organizational determinants.

Methodological approaches

A realist evaluation approach was employed to describe a qualitative context-mechanism-outcome configuration. In the second step, a data-driven belief-elicitation approach was used to operationalize the insights derived from the qualitative data analysis and to generate tailored contextualized items for standardized quantitative surveys with physicians. In the third step, the theoretical and qualitative evidence was used to develop a quantitative mediation model that employed a confirmatory approach. Psychometric properties of the contextualized scale were tested in a measurement analysis.

Data collection

Qualitative and quantitative data from physicians who participated in the evaluation study of the AdAM project was used.

Main results

In this mixed-methods study, the qualitative data of 27 physicians from the intervention and wait-list control groups, and the quantitative data of 218 physicians from the intervention group, who participated in the AdAM study and implemented the digital intervention for polypharmacy management, were utilized.

Qualitative configurational model

A qualitative model was developed using a realist evaluation approach, which described the functioning of the intervention and the contextual components in relation to the implementation mechanism and outcome. The findings of the extensive qualitative data analyses, as presented in Publication 1, were used to provide a condensed description of the core topic of context, with a particular focus on the ambiguity that characterizes the decision-making situation of primary care physicians when clinical decisions have to be made for polypharmacy patients. In this description, the mechanism included both the resources provided by the digital intervention and the reasoning of physicians regarding the effectiveness of the innovation – in relation to the given context for clinical decision-making. Furthermore, the description of the presumed mechanism of impact in implementation was employed to delineate the assumptions for the quantitative model.

Quantitative mediation model

In the operationalization of the structural equation model, the contextual empirical insight derived from the qualitative analysis and modeling was integrated into the mediation model and subjected to testing of the underlying theoretical assumptions. The objective was to ascertain whether contextualized beliefs, defined as those related to salient topics relevant to the prescribing practices of physicians, serve as a mediating factor in the relationship between organizational readiness for change and the behavioral intention to utilize the intervention.

Implications for research

The mixed-methods study design enabled a comprehensive description of the various components of implementation mechanisms. The decisions regarding the modeling were based on a synthesis of data-driven and theoretically informed approaches. To gain further insight, a recently considered combination of two approaches was employed: a realist inquiry approach with a specific focus on certain components of mechanisms and structural equation modeling to test the qualitative results in a quantitative mediation model [57, 58]. The approach holds considerable promise for research into the mechanisms of implementation. Nevertheless, the employment of this approach necessitates a considerable investment of resources, given the considerable effort involved in the development of theory-driven survey

instruments, conceptual models, diverse data collection procedures, and the presence of methodological expertise for the triangulation of disparate approaches.

Implications for practice

The described and refined theory for an implementation mechanism includes the requirements and needs of the various stakeholders involved in the implementation of the digital intervention. These include, for example, software developers, organizations that control the implementation, scientists who evaluate the implementation process, as well as physicians and staff of the physician's office. In the context of scientific inquiry and practical application, the findings can serve as a foundation for the development of suitable implementation strategies.

Conclusion

The study design allowed for a comprehensive analysis of qualitative and quantitative components of implementation mechanisms and the generation of contextual evidence. The question of why numerous research publications documented inconsistent implementation effectiveness of digital interventions can be attributed, from the perspective of the present results, to the fact that contextual factors have not been sufficiently investigated and considered in the planning process. The context-related analysis indicates that there are specific crucial elements for medical practitioners that have a distinctive function in the implementation mechanisms. In particular, it is imperative that the digital intervention be demonstrably safe for patients, that clinical decisions be reinsured by the advice of the digital intervention, and that the information provided be of the highest quality. For doctors in practice, this signifies that the information must be pertinent to the specific clinical decision-making situation, readily comprehensible, and promptly accessible. Additionally, it is imperative to delineate responsibilities pertaining to its utilization, both interprofessionally and in alignment with the physicians' ethical code of conduct. In particular, in the area of prescriptions for patients on polypharmacy, the use of the digital intervention should facilitate enhanced doctor-patient communication by enabling the physician to more effectively convey to the patient the rationale behind the prescription or discontinuation of specific medications and medication combinations. These aspects should be given special consideration when selecting implementation strategies and planning the implementation of digital interventions.

4. Discussion

4.1 Summary of results of the doctoral projects

The principal aim of this cumulative dissertation was twofold: firstly, to explore implementation pathways by applying the methodology of implementation science at the intersection of process evaluation in the implementation of a digital intervention for clinical decision-making in polypharmacy; secondly, to triangulate qualitative, quantitative and theoretical evidence and confirm mechanisms of impact in the implementation process.

In order to achieve the principal aim, a qualitative paper was included in this dissertation which employed a theory-driven approach using an implementation science framework (CFIR) and integrating it in empirical research in combination with the MRC framework for the process evaluation of complex interventions. Implementation science theory on implementation determinants and outcomes informed the development of data collection instruments for qualitative interviews and focus groups with physicians in a primary care setting. The qualitative study evaluated and compared the spectrum of physicians' experiences and expectations pertaining to clinical decision-making facilitated by digital innovation in the intervention and wait-list control group. The study discussed the combination of two distinct qualitative methodological approaches, namely a content analysis approach and an interpretative qualitative approach for habitus reconstruction of physicians. This resulted in the synthesis of the results of the qualitative data analyses within a process-oriented model for the implementation pathways. During the synthesis process, both simple and complex pathways were identified, and the moderating influence of the multidimensional physicians' habitus was also highlighted. Furthermore, the psychometric evaluation study of the Implementation Leadership Scale examined a pivotal factor in fostering an implementation-conducive climate, particularly in regard to organizational factors. Moreover, this scale was employed for the inaugural time in a primary care setting. The findings indicate that the specific types of leadership behaviors are evaluated differently by physicians. However, certain types of leadership behaviour are particularly salient at the organisational level, in particular perseverant and supportive implementation leadership behavior. This indicates that there are potential avenues for fostering the leadership behaviors of primary care physicians in this domain, which can be achieved through the implementation of tailored implementation strategies, particularly in areas that are less developed, such as proactive implementation leadership behavior.

In order to achieve the secondary objective, a new methodological approach was developed to triangulate qualitative, quantitative and theoretical evidence within a mixed-methods study design. This was conducted in order to address the overarching research

question of which underlying mechanism can explain variations in clinician adoption behavior. The study served to reinforce some of the findings that had been previously explored and indicated the critical revision of the mechanisms of impact in the implementation process which represents a pivotal area within the MRC framework for the process evaluation of complex interventions. This endeavour has resulted in the formulation of a forward-thinking methodological approach that integrates a realist configurational model, a data-driven belief elicitation approach, and the development of a mediation model for the analysis of the underlying implementation mechanisms [59]. At the same time, the realist configurational model demonstrated the ability to elucidate the links between the components of a probable mechanism, including the digital intervention as a resource and physicians' reasoning about the effectiveness of the digital intervention [57]. In addition, the realist model revealed the coherence of the mechanism within the context in which physicians face ambiguous clinical decision-making scenarios for patients with polypharmacy, which may explain different outcomes in terms of implementation effectiveness and clinician adoption behavior, depending on the various scenarios. Similarly, the belief-elicitation approach was employed as a data-driven method, whereby salient components relevant to physicians' prescribing practices were identified and operationalized in a latent variable. To guarantee transparency in the reporting of the diverse techniques utilized, an overview flow chart was integrated, delineating the methodological stages involved in organizing and transforming data within the mixed-methods design. While the majority of research questions pertaining to implementation mechanisms could be addressed through the identified evidence, uncertainties persist in the event that additional unobserved contextual factors may exist.

4.2 Implications for applying implementation science in process evaluation studies

Certain aspects and features of applying ImpSci methodology in process evaluation studies require special consideration due to potential limitations in the conduction process. A process evaluation in general, which encompasses numerous sub-areas and typically involves the collection of a significant amount of primary data from stakeholders and healthcare providers, and additional secondary data, represents a considerable burden on research resources. The monitoring of (unintended) occurrences during the implementation processes of an intervention and their impact upon both the resulting clinical and implementation outcomes can be extensive, contingent upon the challenges encountered in implementation. The production of a process evaluation study that employs applied implementation science is a time-consuming endeavour. Each section of the study requires special attention and may necessitate refinement. Furthermore, process evaluation studies are conducted in

the course of real-world implementation projects. The publication of results is contingent on successful recruitment and/or randomization of participants into the project, an appropriate response rate, and data quality of the primary data collection. Further methodological challenges and considerations remain unresolved in practice and require additional guidance. A significant challenge is to identify and determine the areas of greatest uncertainty with regard to the mechanisms of impact that are assumed to be involved in the implementation. Furthermore, the integration of well-known frameworks from implementation research is often only a first orientation to advance theory-driven evaluation. Many frameworks are too broad and the level of abstraction is so high that other theoretical approaches need to be integrated in order to operationalize specific relationships at the organizational or individual level. There is little concrete guidance for these steps. A comprehensive examination of a framework's themes, such as those outlined in the CFIR, within the empirical study of a process evaluation can result in the generation of a multitude of data sources. However, the generation of systematic evidence on key areas in implementation science can only be achieved through the combination of an appropriate study design and methods for empirical research. In the absence of a targeted process evaluation in prioritized areas of implementation science, the results may appear incoherent and fail to provide an explanation of the underlying mechanisms that lead to the emergence of implementation and clinical outcomes.

4.3 Implications for research

4.3.1 Growing the evidence base for the analysis of implementation pathways

In the study protocol section of the formative evaluation study, which is part of the study protocol of the cluster-randomized controlled trial of the AdAM project – original German acronym for "Application for a Digitally Supported Pharmacotherapy Management System", the objective was defined as follows: to identify and evaluate factors that facilitate or hinder the implementation of the digital intervention from the perspective of physicians [14]. In alignment with this study objective, the sequential exploratory multistage mixed-methods approach was predetermined at the protocol stage, thereby establishing a foundation for the evaluation's study design [60]. Moreover, the initial literature search revealed that the most significant uncertainty in the evidence base of effectiveness research pertains to the varying degrees of implementation effectiveness of digital decision support systems [40, 53, 61–64]. Consequently, the specific research questions for the dissertation projects were to elucidate how to understand and explain these variations in implementation effectiveness. To this end, the focus was on expanding the evidence base on implementation pathways in the first qualitative study. One particularly noteworthy aspect of the analysis was the

identification of a variety of adoption pathways, including both simple, unexpected and complex pathways. Additionally, an advanced data analysis approach was employed that permitted the reconstruction of the physicians' professional habitus. In the synthesis of the data, both the results of the qualitative content analysis and the habitus reconstruction were presented in a process model, as well as the physicians' habitus, which was identified as a moderating factor [10]. In comparison with existing literature on the implementation of evidence-based clinical guidelines in other domains, the role of the medical habitus as an influencing factor has rarely been examined. The investigation of behavioral and individual professional factors as potential barriers to guideline implementation is currently underway in other studies that include the context as a domain [65]. Furthermore, a recent review examined the role of professional identity in the implementation of CDSS. This review revealed that professional identity, as manifested in the clinician habitus, may act as a potential barrier to the implementation of e-health and artificial intelligence systems for decision support. This conclusion is consistent with the results of the qualitative study of the doctoral project [66]. Moreover, a theoretical foundation has already been established for the concept of habitus from the perspective of implementation science [67]. But this foundation is based on a different theoretical approach than that used in this dissertation, which was part of a theoretical approach to sociology and integrated into the reconstructive method of the documentary method based on Bohnsack . This illustrates that the concept of habitus is addressed in implementation research, albeit from disparate perspectives [10]. However, there is no consensus on the definition of the concept, which may impede the discourse on the role of habitus in implementation.

In the second study, the focus shifted to a pivotal core concept in implementation science which is also aligned to the inner setting or context domain in CFIR: the Implementation Leadership Scale [11]. This scale was translated into German for the first time and subsequently evaluated in a primary care practice setting. In this study, the relationships between the micro and meso levels were also examined, as complexity is defined in the process evaluation of complex interventions as arising from the interplay between the different levels of a social system. The findings of this study align with those of other investigations that have identified a robust correlation between leadership conduct and organizational success and learning [68]. The extent to which leadership behavior differs in terms of implementation can be subjected to critical evaluation. Alternatively, it may be hypothesized that general leadership behavior in relation to implementation leadership behavior would manifest quite differently in observation. Further research is required in this field. Nevertheless, the results of the second doctoral project could be used to develop an evidence base for general practice,

particularly highlighting the necessity for primary care physicians to have access to implementation guidelines within their own organizations, in addition to guidelines on polypharmacy, as indicated by the weakest ratings in the area of proactive implementation leadership – these measures are designed to assess behaviors related to the management of activities during the implementation processbehavior among the physicians. The findings of both the first and second studies have broadened the focus of implementation paths, directing attention towards the investigation of the underlying implementation mechanisms. In particular, the range of methods for empirical research has been expanded with the aim of developing an approach to explaining causal implementation mechanisms and of broadening the theoretical assumptions about the mechanisms in question within a realist evaluation framework. As the research progressed and additional data were collected through qualitative and quantitative methods, and subsequently analyzed, a growing level of certainty emerged concerning the evidence presented.

The emergence and evolution of new knowledge on the implementation of digital interventions was mainly based on the primary data collections and analytic approaches included in the mixed-methods design. In the qualitative study, the randomized AdAM trial was employed as the basis for interviewing the physicians from both groups, while in the quantitative strand it has not been considered to collect baseline data of the intervention and control group, impeding comparability between groups over time. Moreover, there was no evidence on primary care practice staff perception on the implementation process of the digital intervention. It would be highly interesting to assess whether the intervention is more effective if tailored implementation strategies are employed for physicians, primary care practice staff or primary care organizations, at an early implementation stage. Nevertheless, ongoing research is investigating the implementation of comparable digital tools for clinical decision-making in polypharmacy. The findings of this research may help to resolve some of the aforementioned uncertainties.

4.3.2 The digital transformation and its impact on evidence generation

The precise impact of the digital transformation on the evidence pipeline in implementation science remains to be fully elucidated. First and foremost, it is imperative to acknowledge the ever-present challenge surrounding the boundaries of the central issues in the field of implementation science. Despite the updated version of the CFIR in 2022, which implies a shift in focus, for example by changing the central term "intervention" to "innovation," other voices in implementation science maintain a strong adherence to the notion that implementation research only commences when the evidence base of an intervention has

been validated [69–71]. However, this is not always the case in the field of implementing digital innovation. One might also posit that it is only through effective implementation that it can be demonstrated whether an evidence-based intervention is also an innovation, in that it is actually adopted by the population it is intended to reach. Moreover, it is essential to define the term (health service) "innovation" and to establish the criteria that ImpSci will utilize to classify an evidence-based innovation [72].

A further significant issue in the field of digital transformation in healthcare is the question of how previously analog services or processes are to be translated into a digital format. This gives rise to a number of questions. It is uncertain whether an evidence-based analog practice, such as conducting a medication review for patients taking multiple medications to improve drug therapy safety, will yield the same outcomes when performed digitally. This is because there is a paucity of evidence regarding the extent to which previously evidence-based analog practices and associated service delivery processes can be transferred directly into the digital domain. This depends on two intertwined factors.

1) The decision of whether or not to translate an analog evidence-based practice or process into a digital format depends on the initial effectiveness of said practice. In other words, one must consider whether an ineffective analog process of an evidence-based practice should undergo digitalization at all, or whether the first step should be to improve the effectiveness of the healthcare delivery process, and

2) More fundamentally, even if the analog process has been demonstrated to be effective, the decision ultimately depends on the recognition that the transition to a digital practice has consequences for an entire social system of health service delivery that extend far beyond the mere application of digital technology.

Consequently, some scholars have proposed a shift towards transdisciplinary, convergent transformation research to address questions arising changes in health service delivery due to the digital transformation [73]. Furthermore, implementation research can contribute to this transformation, offering a methodology that is specifically designed to assess and facilitate change processes. The extent to which the existing central assumptions of ImpSci will be expanded will also depend on the extent to which some of the assumptions that have previously only been formulated in theory and conceptually can also be tested empirically. In particular, the field of implementation mechanism research is still in its nascent stages within the ImpSci methodology. Some approaches have identified potential links to experimental medicine and a need for a more precise approach to implementation research [74, 75]. Overall, it is evident that research into mechanisms necessitates a more granular examination of

individual components within a mechanism, and that evidence must be gathered through multiple consecutive studies to generalize effects and contextual influences.

4.4 Strengths and limitations of this cumulative dissertation

An important strength of this dissertation is that it includes three publications on applying implementation science methodology within process evaluation and contributes to the refinement and adaptation of outdated parts of process evaluation methods in health services research in an emerging research fields. The qualitative study revealed the challenges and weaknesses of the available methods for process evaluation experienced by authors applying implementation science methodology related to a digital transformation topic. Potential solutions and implications were offered to others engaged in similar research activities. The empirical studies revealed a dearth of guidance on the application of implementation science methodology within process evaluation. In order to address this gap, the studies presented a variety of conceptual models as illustrative examples and different methods for empirical studies, with the aim of demonstrating how the ImpSci methodology and process evaluation could be integrated. Moreover, this cumulative dissertation employed implementation science methodology in a mixed-methods study utilizing process evaluation data in accordance with rigorous methodological standards. Consequently, the empirical findings from the qualitative study, the validation study, and the mixed-methods study may prove beneficial in informing and guiding future researchers and facilitating further advancements in the digital transformation of health services. Additionally, the results could inform the development of new methodological guidance.

The conducted process evaluation study can be classified as a hybrid type 1 study. Given the pilot nature of the digital intervention to be implemented, a primary objective was to conduct a comprehensive investigation of the contextual factors, with a view to identifying potential barriers and facilitators. The insights gleaned about pertinent implementation barriers and contextual elements salient in the implementation processes could be leveraged to inform the development of implementation strategies that could potentially address these barriers. A hybrid type 1 study is not designed to address questions of the effectiveness of implementation strategies. Rather, the selection of implementation strategies should be based on evidence regarding contextual factors and barriers. Therefore, a hybrid type 1 study provides an excellent evidence base for deriving and selecting appropriate implementation strategies. Nevertheless, from the standpoint of implementation science, additional research is necessary to address questions regarding the effectiveness of selected implementation strategies. This could include, for instance, the conduction of hybrid type 2 or type 3 studies. To

date, hybrid studies of the type 2 or type 3 have been conducted with some infrequency within the field of German health services research. The lack of conducting hybrid studies is partly due to the fact that implementation science is a relatively new scientific field in comparison to health services research. Furthermore, there may be a lack of awareness among health services scientists regarding the methodology and insights of implementation science. Moreover, hybrid studies require a greater expenditure of time and resources than conventional studies. This may also inform the decision-making process regarding the choice of methodology, particularly in the case of hybrid type 3 studies. In light of the aforementioned, the principal findings of the dissertation pertain to the domain of contextual factors from the perspective of physicians, as discerned through the examination of self-reported primary data. Notwithstanding the potential constraints associated with the utilisation of self-assessment measurement instruments, the data analyses yielded invaluable insights pertaining to the identification of key areas for advancement in the implementation of the intervention, as well as the assessment of its effectiveness perceived by physicians, who are the primary users of the digital intervention in practice and the principal agents in its implementation. In this regard, the self-reported data are of particular significance for the research question of this dissertation.

5. Conclusion

This cumulative dissertation offered substantial and critical insights regarding the methodology of implementation science in a context-focused process evaluation study and demonstrated how this methodology can be applied to a dynamic and evolving research topic. The application of ImpSci methodology to conduct a mixed-methods study has served to corroborate the primary empiricial and methodological findings. The dissertation projects addressed important methodological aspects for process evaluation studies related to a digital transformation topic and suggested potential solutions and implications for future research. A significant deficiency in the available guidance for implementation science methodology at the intersection of context-focused process evaluation studies was identified, prompting efforts to elucidate the utility of supplementary inquiries in identifying the focal point for a process evaluation and to promote the integration of middle-range theoretical approaches when examining the (de-) prescribing practices of physicians who implemented and utilized the digital intervention for polypharmacy management. ImpSci methodology in context-focused process evaluation studies is highly suitable for exploring digital transformation research topics. Nevertheless, the suitability of the methodology must be subjected to thorough evaluation, and all the distinctive characteristics associated with the methodology of implementation science at the interface with process evaluation must be identified, described, and integrated into the further development of the methods when new challenges emerge.

Context analysis provides a robust foundation for advancing the adoption of digital interventions. By elucidating the heterogeneous impacts of the implementation of digital interventions, evidenced by inconsistent results of implementation effectiveness, it offers a comprehensive understanding of the contextual nuances that might determine the implementation effectiveness of digital interventions as identified in the different simple, unexpected, and complex implementation pathways. In light of these findings, it can be concluded that context analysis should be an integral component of any implementation project, conducted at the earliest possible stage, specifically during the pilot phase. There is a possibility that physicians' adoption behavior might advance if implementation science can offer personalized implementation strategies to address the heterogeneous implementation effects. Further research is required to elucidate the outstanding questions and constraints.

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Appendices

Appendix 1: Scientific contributions of authors

Publication 1: Qualitative Study

From sensitization to adoption? A qualitative study of the implementation of a digitally supported intervention for clinical decision making in polypharmacy

Implementation Science [Impact factor at time of publication: 7.327]

CRediT authorship contribution statement

Sara Söling: conceptualization, theoretical framework, methodology, investigation, software, formal analysis, visualization, writing – original draft

Juliane Köberlein- Neu: writing – review & editing

Beate Sigrid Müller: writing – review & editing

Truc Sophia Dinh: writing – review & editing

Christiane Muth: conceptualization, writing – review & editing

Holger Pfaff: funding acquisition, writing – review & editing, supervision

Ute Karbach: funding acquisition, conceptualization, writing – review & editing

Publication 2: Validation study

How is leadership behavior associated with organization-related variables? Translation and psychometric evaluation of the implementation leadership scale in German primary healthcare

BMC Health Services Research [Impact Factor at time of publication: 2.908]

CRediT authorship contribution statement

Sara Söling: conceptualization, theoretical framework, formal analysis, methodology, investigation, visualization, writing – original draft

Holger Pfaff: funding acquisition, writing – review & editing, supervision

Ute Karbach: funding acquisition, writing – review & editing

Lena Ansmann: methodology, writing – review & editing

Juliane Köberlein-Neu: conceptualization, investigation, writing – review & editing

Publication 3: Mixed-methods study

Complex implementation mechanisms in primary care: do physicians' beliefs about the effectiveness of innovation play a mediating role? Applying a realist inquiry and structural equation modeling approach in a formative evaluation study.

BMC Primary Care [Impact Factor at time of publication: 3.2]

CRediT authorship contribution statement

Sara Söling: conceptualization, theoretical framework, formal analysis, methodology, investigation, visualization, writing- original draft

Ibrahim Demirer: methodology, writing – review & editing

Juliane Köberlein- Neu: conceptualization, writing – review & editing

Kira Isabel Hower: formal analysis

Beate Sigrid Müller: writing – review & editing

Holger Pfaff: funding acquisition, writing – review & editing, supervision

Ute Karbach: funding acquisition, writing – review & editing

Appendix 2: List of publications, research reports and presentations

Publications (*peer-reviewed)

*Brünn R, Basten J, Lemke D, Piotrowski A, **Söling S**, Surmann B, Greiner W, et al., for the AdAM study group. Digital Medication Management in Polypharmacy - Findings of a Cluster-Randomized, Controlled Trial With a Stepped-Wedge Design in Primary Care Practices (AdAM). *Dtsch Arztebl Int* 2024; 121: 243-50. doi: 10.3238/arztebl.m2024.0007.

***Söling S**, Demirer I, Köberlein-Neu J, Hower K I, Müller B S, Pfaff H, Karbach U, and AdAM Study Group (2023). Complex implementation mechanisms in primary care: do physicians' beliefs about the effectiveness of innovation play a mediating role? Applying a realist inquiry and structural equation modeling approach in a formative evaluation study. *BMC Primary Care*, 24(1), 131. doi: https://doi.org/10.1186/s12875-023-02081-x.

*Piotrowski A, Coenen J, Rupietta C, Basten J, Muth C, **Söling S**, Zimmer V, Karbach U, Muth C, Köberlein-Neu J, and the AdAM study group (2023). Factors facilitating the implementation of a clinical decision support system in primary care practices: a fuzzy set qualitative comparative analysis. *BMC Health Services Research*, 23(1), 1161.

***Söling S**, Pfaff H, Karbach U, Ansmann L, Köberlein-Neu J (2022). How is leadership behavior associated with organization-related variables? Translation and psychometric evaluation of the implementation leadership scale in German primary healthcare. *BMC Health Services Research*, 22(1), 1065. https://doi.org/10.1186/s12913-022-08434-z.

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Appendix 3: Original Publications

Appendix i: Study I (Qualitative interview and focus group discussions)

Söling et al. Implementation Science (2020) 15:82
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Implementation Science

RESEARCH Open Access

From sensitization to adoption? A qualitative study of the implementation of a digitally supported intervention for clinical decision making in polypharmacy

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Abstract

Objective: Formative evaluation of the implementation process for a digitally supported intervention in polypharmacy in Germany. Qualitative research was conducted within a cluster randomized controlled trial (C-RCT). It focused on understanding how the intervention influences behavior-related outcomes in the prescription and medication review process.

Methods/setting: Twenty-seven general practitioners (GPs) were included in the study in the two groups of the C-RCT, the intervention, and the wait list control group. Behavior-related outcomes were investigated using three-step data analysis (content analytic approach, documentary method, and design of a model of implementation pathways).

Results: Content analysis showed that physicians were more intensely aware of polypharmacy-related risks, described positive learning effects of the digital technology on their prescribing behavior, and perceived a change in communication with patients and pharmacists. Conversely, they felt uncertain about their own responsibility when prescribing. Three main dimensions were discovered which influenced adoption behavior: (1) the physicians' interpretation of the relevance of pharmaceutical knowledge provided by the intervention in changing decision-making situations in polypharmacy; (2) their medical code of ethics for clinical decision making in the context of progressing digitalization; and (3) their concepts of evidence-based medicine on the basis of professional experiences with polypharmacy in primary care settings. In our sample, both simple and complex pathways from sensitization to adoption were observed. The resulting model on adoption behavior includes a paradigmatic description of different pathways and a visualization of different observed levels and applied methodological approaches. We assumed that the GP habitus can weaken or strengthen interventional effects towards intervention uptake. This formative evaluation strategy is beneficial for the identification of behavior-related implementation barriers and facilitators.

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Conclusion: Our analyses of the adoption behavior of a digitally supported intervention in polypharmacy revealed both simple and complex pathways from awareness to adoption, which may impact the implementation of the intervention and therefore, its effectiveness. Future consideration of adoption behavior in the planning and evaluation of digitally supported interventions may enhance uptake and support the interpretation of effects.

Trial registration: NCT03430336, 12 February 2018.

Keywords: Clinical computerized decision support systems, Polypharmacy, Digitalization, Evidence-based medicine, Implementation, Qualitative study

Contributions to the literature

- Digitally supported interventions have not yet been widely evaluated, and it is necessary to demonstrate effectiveness. However, great challenges are associated with obtaining insights into the complexity of adoption behavior, and little research is available in this area.
- This qualitative research synthesis study aims to methodologically and theoretically ground the Medical Research Council's framework for the evaluation of complex interventions for obtaining an in-depth understanding of adoption behavior.
- Our analyses have shown that changes in clinical decision making about polypharmacy may occur if physicians have positive interaction experiences with the intervention, as they perceive an increased risk-awareness and willingness to base clinical decision making on scientific evidence. In comparison, physicians without digital support use habitual strategies in their daily practice to compensate for uncertainties.

Background

A worldwide need exists for optimized and technically supported polypharmacy management in primary health care; such management systems should be based on profound evidence and prevent patient harm [1]. Even though polypharmacy is a controversial term in medical articles, it is typically associated with the use of five or more drugs and defined as a multifactorial problem of older and multimorbid patients [2]. Furthermore, it is associated with excessive and unindicated drug consumption that leads to high-risk prescription scenarios for polypharmacy patients [3]. To increase patient safety and decrease the number of potentially inappropriately prescribed medications or adverse drug events, new interventions such as technology-based management solutions have been developed, implemented, and reviewed [4, 5]. It has been demonstrated that interventions with clinical decision support systems that provide patient-specific alerts have a positive effect on prescription quality and can reduce medication errors in polypharmacy [6, 7]. In addition, there is evidence that decision aids shown on screen instead of paper-based information, as well as information provided automatically, lead to improved compliance with the recommended practice by physicians [8]. These technical solutions should enable general practitioners (GPs) to appropriately deal with high-risk prescription scenarios in polypharmacy, where they need to balance risks, benefits, and patient requests as well as avoid errors [9, 10]. Nevertheless, research regarding the implementation of health information technology is continuously reporting inconsistent effects concerning the effectiveness of technology-based interventions [7, 11].

In Germany, several health services policies have aimed to drive forward the digitalization of drug therapy safety systems and quality improvements, and many regulations are yet to be implemented in standard care [12]. In the context of the digital transformation of the German health care system, we aimed to understand primary care practitioners' perceptions of a digitally supported intervention for improving medication safety for patients with polypharmacy.

Therefore, in this qualitative study conducted within the scope of the C-RCT project "Application for a Digitally Supported Pharmacotherapy Management System" (AdAM project—original German acronym for the project), processes leading towards adoption were analyzed. Since little is currently known about the processes through which technology-based interventions produce change and through which specific pathways lead to desired outcomes via the implementation process, our implementation process evaluation focused on this area [13]. Our research topic is in line with the Medical Research Council (MRC) framework for the process evaluation of complex interventions (2015) [14]. This framework provides one of the most promising research models for process evaluation. It proposes that a key function of process evaluation is to investigate specific mechanisms through which participants' interactions with the intervention influence outcomes (mechanisms of impact). In accordance with the MRC framework, our study aimed to examine physicians' behavioral interactions with the intervention and related behavior change processes.

Our research questions were the following: (1) how are clinical decision-making processes concerning patients with polypharmacy affected by the digital intervention, and (2) how does the habitus of primary care practitioners influence the adoption of the digital intervention?

Methods

To theoretically substantiate our study, we needed to conceptualize behavior-related outcomes. Therefore, we used the definition of adoption as a phase when the decision to accept and undertake the change(s) is made [15]. "Adoption," "usage behaviour," or "uptake" of interventions are examples of many terms that have been used interchangeably in the field of implementation science [16]. Donaldson et al. showed that there are many theoretical approaches in implementation science that describe the same significant problem: the translation of evidence into practice [15].

The data used in this study stem from qualitative interviews and focus groups, which were collected alongside the C-RCT of the AdAM project. We investigated this topic using two different qualitative methodological approaches for data analysis: (1) We used a content-analytical approach to get an overview of the range of participants' opinions in our study. (2) To get deeper insights into the dynamics of the change processes triggered by the intervention, we used the documentary method (interpretive methodological approach) since it is well suited for examining practical behavior-related actions and interactions [17].

An interpretive methodological approach aims to interpret qualitative data in the context of participants' life and the interrelatedness of different aspects in life (for example individual, social, historical factors) [18]. A detailed and separate sequence analysis was conducted using a documentary methodological approach. Table 1 summarizes the methodological aspects of the study.

Data saturation was reached in an iterative process. Therefore an adequate sample size was defined as one which allows sufficiently answering the research questions and includes a range of opinions [19]. The transcription of qualitative data was done by a qualified transcription office, following specific transcription rules [20]. A smooth verbatim transcription style was used. Colloquial expressions, incorrect expressions, and incorrect sentence structures were retained. Transcripts were analyzed in anonymized form. Data was coded by two researchers independently. MAXQDA was used to support data coding. The COREQ checklist was used as a reporting guideline (see Additional file 1) [21].

Data analysis

During the iterative coding process in qualitative data analysis, it is important for (1) content analysis to find main categories under which descriptions and narrations can be subsumed and choose a level of abstraction for labeling categories (individual, social, and health care delivery level). We are speaking about the interventional influences on different levels, if descriptions or narrations of participants indicate that. The individual level is defined by us through codes related to cognitive or emotional experiences by the physicians. The health care delivery level relates to codes that include speeches about perceived changes in interdisciplinary or doctor-patient relationships caused by the intervention that might influence future health care delivery. The social level could be seen as linked to the social group of general practitioners and their perceptions of interventional influences that change their professional role (documentary method analysis).

The (2) documentary methodological approach is related to different theoretical approaches and associated with the fields of social phenomenology, ethnomethodology, and sociology of knowledge. That approach has provided specific theoretical assumptions about the evolution of collective orientations. These are important for understanding data analysis. According to Bohnsack, practical actions and interactions are guided by the habitus of social actors, who share common experience spaces and belong to similar milieus [17].

Habitus has also been defined as an organizing structure of attitudes and dispositions or "second nature," as the way social actors behave, act, and think; it is attained unconsciously through socialization and is internalized by the actors. As Bourdieu states, practices evolve in social contexts. They can be seen as relatively autonomous, so social actors instantly understand one another if they share a habitus that guides their practical actions [22]. We therefore assume that primary care practitioners share professional experiences that are connected to a particular habitus and guide the way they behave and interact with the intervention in the implementation process.

Table 1 Study design of formative evaluation

Qualitative approaches for data collection	Interviews, focus groups
Qualitative methodological approaches for data analyses	Content analysis, documentary method
Data synthesis	Process-oriented model of implementation pathways

Criteria for applying documentary method

The documentary method is a method of interpretation which is conducted by analyzing sequences of qualitative data (text) in a methodologically controlled way. Constitutive criteria for applying documentary method were complied with 1–3.

1) The selection process was passed through by screening of all interviews and focus groups. By consent, two sequences of a focus group (intervention group) were chosen on the basis of the relevance of content and specific text types included, for example narrations and descriptions [FG3, GP_AA-DD, p.5-6, p.22-24].
2) Interactive density of discussion during the sequences was high. By analyzing transcripts of focus group discussion, we can observe fundamental forms of sociality. The different forms of sociality are also analyzed using the methodological terminology of the documentary method. As a result, the analysis of interactive references to each other during the focus group discussion will be presented in the discourse organization [17].
3) The habitus reconstruction is a step in the process of data analysis with documentary method, in which it is examined how the same topic is dealt with in different ways by participants. Therefore, the different layers of knowledge are sequentially analyzed in the two steps of formulating interpretation (communicative or explicit meaning of talk) and reflective interpretation (conjunctive or implicit meaning of talk). Subsequent to the reconstruction of different layers of knowledge, the frames of orientation or habitus of actors can be described with the aim to understand what guides actors' practical actions.

Description of the intervention

The intervention evaluated in our study took place in general practices in the German state of North Rhine-Westphalia. It included multiple design components (a digitalized clinical decision support system for polypharmacy, patients' medication history and diagnostics, information about other medical specialists, training on system use, management, and technical support for the GPs, recommendations for prescribing in polypharmacy). Patient consent allows the BARMER health insurance company to transfer actual medication data to the decision support system (medication history of the last 36 months). The study's patient inclusion criteria were (1) prescription of five or more drugs continuously throughout the previous 6 months, (2) current insurance coverage by BARMER, and (3) adult without dementia. Signed up GPs were randomized into the wait list control group or intervention group. The external system provides, e.g., data about the patient's diagnoses, treatment, and hospital stays, and includes an alert system for drug-drug, drug-disease, and drug-age interactions. After 15 months in the wait list control group, GPs switch to the intervention group and receive access to the software. GPs in the control group provide usual care. GPs are compensated for participation in the trial with €80 per year for each patient treated with the aid of the digital application. Concerning reporting standards, the TIDieR-checklist was used (see Additional file 2) [23].

Participants

All contacted GPs were established doctors and provided primary outpatient care. GPs already included in the main trial received an invitation to participate in our qualitative study. The association of statutory health insurance physicians supported the recruitment process by providing the GPs with information about participating in the process evaluation study (via fax or flyer). To participate in the study, interested GPs in the intervention and wait list control group contacted our research department. We conducted interviews with the intervention group to enter the research field and get familiar with the so far made experiences of the physicians with the intervention. Focus groups were conducted with both groups of the RCT. We aimed to compare project-related expectations and experiences, depending on the participants' C-RCT group. Participants were chosen from the RCT to evaluate the physician- and behavior-related barriers and facilitators of the implementation, which might influence the intended results of the RCT. The intervention was planned to be implemented in about 1080 practices. At the time of data collection for our qualitative study, 491 physicians were participating in both groups. Inclusion criteria were that the doctors had registered for the AdAM project and had given consent to participate in an interview or focus group with audio recording. From 36 physicians who gave us feedback for participation, 27 participants of both RCT groups were selected. The following dropout reasons were documented and represent the total number of dropouts (n = 9): GPs did not consent to audiotaping (n = 6), were not interested in participation (n = 1), opted out of the project (n = 1), or did not use the digital application (n = 1). All interviews with GPs of the intervention group were telephone interviews and conducted by the first author of this article (SS). Focus groups took place close to the medical practices of participating physicians, in buildings of associated medical institutions in Dortmund and Muenster. The first author of this article moderated them without the presence of non-

participants. The researcher introduced herself before all interviews and focus groups and stated her professional and occupational background (health services researcher, qualified in public health and social sciences).

Topic guides

Topic guides were used to structure the interviews and focus groups with GPs. They were created using iterative processes, applying a quality-assuring qualitative method and informed by the Consolidated Framework for Implementation Research (CFIR) [24, 25]. CFIR was used deductively and for matching the inductively developed topics. It includes a collection of important categories and a comprehensive typology in implementation research. In a workshop with a team of five multidisciplinary health services, researchers generated 17 questions related to five topics. Different topic guides for interviews and focus groups with intervention and control groups were developed and structured by main subjects and related questions. The topic guides differed in particular with regard to experiences or expectations concerning the intervention, depending on the participants' C-RCT group and in relation to the narrative stimulus at the beginning of the focus group. Narrative stimulus in the intervention group invited participants to prioritize important experiences in the interaction with the intervention. In the control group, participants were invited to prioritize important expectations of upcoming changes related to the intervention. They were applied to gain a deeper understanding of the polypharmacy management-related health care processes that GPs employed in everyday practice. We considered the topic guides an essential narration stimulus for our research focus on the understanding of participants' perspectives. The following five topics were chosen for process evaluation and qualitative data collection: (1) participants' experiences or expectations towards the AdAM project; (2) GPs' current stage of health care and polypharmacy management [26]; (3) GPs' perceptions of interdisciplinary and doctor-patient cooperation in polypharmacy management; (4) GPs' perceptions of the usability of the digitally supported intervention [27]; (5) organizational culture in the GPs' practices [28–30].

Results

In total, 27 GPs were included in our study, 15 of which were in the intervention group and 12 in the wait list control group. Table 2 shows participant characteristics as well as the average length (with range) of interviews and focus groups. From May through September 2018, in the first year of the implementation, participants were included in the evaluation study. Meanwhile, the overall recruitment process for the inclusion of GPs in the AdAM project was ongoing.

Results of content analysis

Content analysis revealed four general outcomes in both C-RCT groups. They applied to different stages of behavior-related outcomes on the individual level and the health-care delivery level. The behavior-related outcomes mentioned in stage 1 are sensitization to risks related to polypharmacy (a.1) and perceived changes of interdisciplinary and doctor-patient cooperation (b.1). In stage 2, the behavior-related outcomes mentioned are learning effects through using the digital tool (a.2), and overall perceived changes in doctor-patient communication are observed (b.2).

Physicians' views of interventional changes in stage 1

An especially prominent topic mentioned by participants was an emphasis on ideas of sensitization to risks related to polypharmacy. As they saw it, through increased transparency it would be possible to reflect on prescription practices and interdisciplinary or doctor-patient relationships in standard care (a.1).

> You get a little more sensitive about the interactions, especially when it comes to specialist medication that you often don't have on your radar. […] If the patients don't tell us that they are getting the medication, then we don't know either. [FG4, GP_CC, p.14]

> I think it's good that polypharmacy is coming into focus. That doctors are sensitized to it, or that everyone is sensitized to it, and patients are also sensitized to it, and it is still a bit difficult to really get down get down from ten to five [drugs], I don't

Table 2 Characteristics of participating GPs

Intervention group			Wait list control group	
	Interviews	Focus groups (n = 2)	Focus groups (n = 2)	Total
Number of participants	8	7	12	27
Female % (n)	25% (2)	43% (3)	67% (8)	48% (13)
Male % (n)	75% (6)	57% (4)	33% (4)	52% (14)
Duration in minutes (min)/hours (h) average (range)	24 min (10–47)	1.21 h (1.15–1.27)	1.16 h (1.11–1.20)	

always see myself in a position to do that, but I think it is important to be more involved than in the past ten years. And the goal is really, yes, maybe less is more. [FG2, GP_DD. p.24]

Participants described a vision where better conversations, grounded on an overview of patients' medication history, would allow better care to be created. Achieving this would mean providing patients with evidence-based explanations on their medication, and for general practitioners to rethink interdisciplinary work with pharmacists, who are consistently identified as important experts (b.1).

So, they [patients] feel safer and also, I think, more confident about why they take something. Because you can explain what the tablets are really good for. [GP7, p.4]

I know it otherwise, as I said, also from the pharmacists, because I constantly or conveniently get information from them, like there is an incompatibility with azithromycin or something else. But where we have a comprehensive medication list from all kinds of doctors who have treated the patient, that has not yet existed. [FG3, GP_BB, p.8]

Physicians' views of interventional changes in stage 2

Participants expressed strong consensus on perceived learning effects triggered by the intervention: to use new, digitally enabled information on polypharmacy increases transferable knowledge into practice and changes dynamics in risky prescription scenarios. Especially the overall aim to facilitate better partnerships between actors in the communication processes related to polypharmacy prescriptions was mentioned (a.2).

I like to use it [digital tool] and see also a lot of sense in it, because I also learn again, refresh again, knowledge that is perhaps still present somewhere in the back of my mind, but to update this again, but I find this information very good.[…] It makes my work as a doctor much easier when prescribing, so I think that makes a lot of sense. [GP1, p.6]

I now find myself with my patients, well, coming to their routine visits, simply perceiving these risks more intensely and then changing it, yes, with the other patients as well, if I consider it initiated. And I found that, for example, quite good. [FG3, GP_DD, p.9]

Looking at the data together during routine visits was specifically intended to improve communication processes for individual patients. The information generated by the digital intervention was also used for initiating medication reviews with specialists (b.2).

I have patients where the medication just did not really fit and where I can exchange views with the specialists, who are also named [in the digital tool], where patients are being treated. [FG4, GP_CC, p.5]

It's good, especially for the patients, they all saw great sense in it and found it good. So, I did that mostly in the presence of the patients, so they immediately saw what kind of information there was about interactions. [GP1, p.2]

The findings by the two RCT groups were similar concerning the awareness of high-risk prescription scenarios of patients with polypharmacy and reflections on changes of professional responsibilities when using digital support for decision-making. The findings differed with regard to expectation of interventional effects. Participants in the control group expressed stronger expectations of the intervention and its effects. An additional data file shows more quotes related to interventional changes in different stages (see Additional file 3). The results of the content analysis will be used in the following to be able to interpret the connections between individual, social, and interprofessional factors in the implementation process and to understand the context in which the habitus works and can be interpreted (documentary method analysis).

Results of the documentary method analysis (formulating interpretation)

The presented core sequence analysis builds the reference point for comparisons between different text passages in our study. Different forms of sociality and the interactive references to each other during the focus group discussion are presented in the discourse organization (Table 3).

At first sight, the formulating interpretation reveals *what* GPs are discussing. It is structured by topics. The introductory subject and proposition contains the description of medication review as a professional task of pharmacists (subtopic 1). In the course of the discussion, the following additional subtopics were identified: (2) balancing the effort and usefulness of the digital intervention; (3) amount of information provided by the digital intervention; (4) deprescribing after hospital discharge; (5) evidence-based clinical decision making vs. "healing art"; (6) long-term medication and acute events.

Table 3 Core sequence analysis

Major topic: habitus of primary care physicians	
Formulating interpretation	**Reflecting interpretation (discourse organization)**
Subtopic 1: medication review as a professional task of pharmacists	Proposition: introduction of a new frame of orientation
Subtopic 2: balancing effort and usefulness of the digital intervention	Elaboration in the mode of a description with modifying extension
Subtopic 3: amount of information provided by the digital intervention	Background construction in the mode of exemplification with argumentative insertion
Subtopic 4: deprescribing after hospital discharge	Validated elaboration of exemplification in the mode of differentiation
Subtopic 5: evidence-based clinical decision-making vs "healing art"	Opposition in the mode of argumentation
Subtopic 6: long-term medication and acute events	Differentiation in the mode of exemplification

In the next step, the way *how* GPs are discussing these topics is considered. The core sequential analysis with a documentary method approach furthermore demands analyzing the dynamics of interactions between participants during the discussion. *How* the discussion is organized is reflected (discourse organization) and the primary care habitus (re-)constructed.

Results of the documentary method analysis (reflecting interpretation)

In the interplay of the sequence, the ambivalent attitudes of GPs towards evidence-based practices are manifested (subtopics 1–6). *How* the GPs discuss their usual deprescribing practice after hospital discharge documents implicitly a resistance towards integrating external evidence in their decision making (subtopics 4 and 5). Their practical actions are focused on reaching quick decisions on deprescribing based on their professional experience and without a need for external evidence.

In the transitional phase of the implementation of the new digital intervention, previous experiences with evidence-based guidelines are discussed. GPs perceive guidelines as contradictory and not applicable to medical practice in primary care (subtopic 5).

In this context, *how* primary care physicians can "heal" was discussed in comparison to medical specialists (e.g., surgeons), in a juxtaposition of physicians' different voices and introduced topics. Medical specialists were described as a positive counter-horizon in comparison to primary care physicians because they routinely applied informed consent standards in therapeutic interventions. GPs discussed whether this practice should be transferred to prescribing practices in primary care settings in order to promote safer prescribing in polypharmacy and to share responsibility with the patient. The discourse organization shows reciprocal increase and promotion, with the dramaturgical climax being reached with the "medical healing" topic (subtopic 5).

From this finding, the generic principle of the primary care habitus—the way GPs cope with the integration of external evidence-based information from the intervention—can be derived. Guidelines for polypharmacy and included external evidence-based information are negatively connotated, and integration into practice generates resistance as a short-term reaction. The benefit of the integration of external evidence was questioned in the context of what healing means in primary care settings. GPs reflected on the opportunity to "heal" patients in a primary care setting in comparison to medical specialists' settings not being enhanced by using the external evidence base of the digital intervention. Nevertheless, the interactions of the GPs show that they know about the severe effects of polypharmacy ("not only surgeons cut sharply," GP_DD, p.23) and about the possibility that using the digital tool might enhance the quality of polypharmacy prescriptions. GPs discussed the implementation of the digital intervention in an orientation framework that refers to concepts of evidence-based medicine, adjusted to their professional experiences in primary care settings. Physicians share this common experience space, which is an indicator of a relevant dimension that is part of the primary care habitus.

The evolution of the focus group discussion shows that additional shared experience spaces exist and that various dimensions are layered in primary care habitus. To the extent that physicians belong to different common experience spaces (dimensions) and these reciprocally overlap, the habitus is multidimensional. Another important dimension that is represented in the narrations of physicians is the reasoning about ethical orientation regarding specific values like responsibility, avoiding patient harm, and codes of ethics for healing in primary care. Furthermore, a shared experience space was discovered regarding changing decision-making situations in the context of polypharmacy (subtopic 6).

Since GPs cope with polypharmacy in everyday practice, mostly concerning patients with chronic diseases, external evidence-based information is not perceived as very relevant for decision-making. Nevertheless, the integration of external evidence-based information into practice can become more relevant for GPs in cases where the condition of a patient with polypharmacy becomes acute and the patient requires urgent care as well as in ambiguous decision-making situations. In summary, the following three dimensions are included in the multidimensional habitus and reconstructed in the shared experience spaces of physicians: (1) relevance of pharmaceutical knowledge in shifting decision-making situations in polypharmacy; (2) medical code of ethics

for clinical decision-making in the context of progressing digitalization; (3) concepts of evidence-based medicine based on professional experiences with polypharmacy in primary care settings.

Results of documentary method analysis (primary care physicians' habitus)

As we showed in the sequence analysis, three main dimensions of habitus were reconstructed (knowledge, ethics, professional experiences). We assume that the multidimensional habitus can lead to ambiguous behavioral outcomes regarding the acceptance of an intervention. The analyzed sequence contains descriptions and narrations leading to the conclusion that professional habitus may weaken or strengthen interventional effects. Because habitus is constituted during the professional socialization of physicians and is part of their professional identity, it is interpreted as a permanent characteristic of each physician that changes rather slowly—depending on physicians' experiences during the implementation process. We found that physicians who discuss positive learning experiences and tend to base clinical decision-making on scientific evidence also describe themselves as motivated to use the intervention. In these examples, habitus functions as a facilitator of the implementation and can strengthen interventional effects. On the other hand, when the habitus favors resistance against integrating external evidence and an insistence on well-known practices, habitus functions as a barrier to implementation. In these cases, habitus weakens the motivation to adopt the intervention, and interventional effects on long-term outcomes are delayed.

Results of the process-oriented model of implementation pathways

We aimed to synthesize results of content analysis and documentary method in the process-oriented model of implementation pathways and identify relevant and commonly shared topics among the two C-RCT groups related to

- Stages of behavior-related outcomes and
- The individual, social, and health care delivery level.

Due to our process-related research focus, we allocated the results of content analysis to the different levels and stages in the implementation process. This approach gives us an overview of the subjectively experienced effects of the intervention as perceived by the physicians. In the context of content analytical result, the moderating influence of physicians' habitus on adoption of the intervention is interpreted (Fig. 1). Scenarios of simple and complex pathways can be differentiated paradigmatically with increasing complexity (a–c):

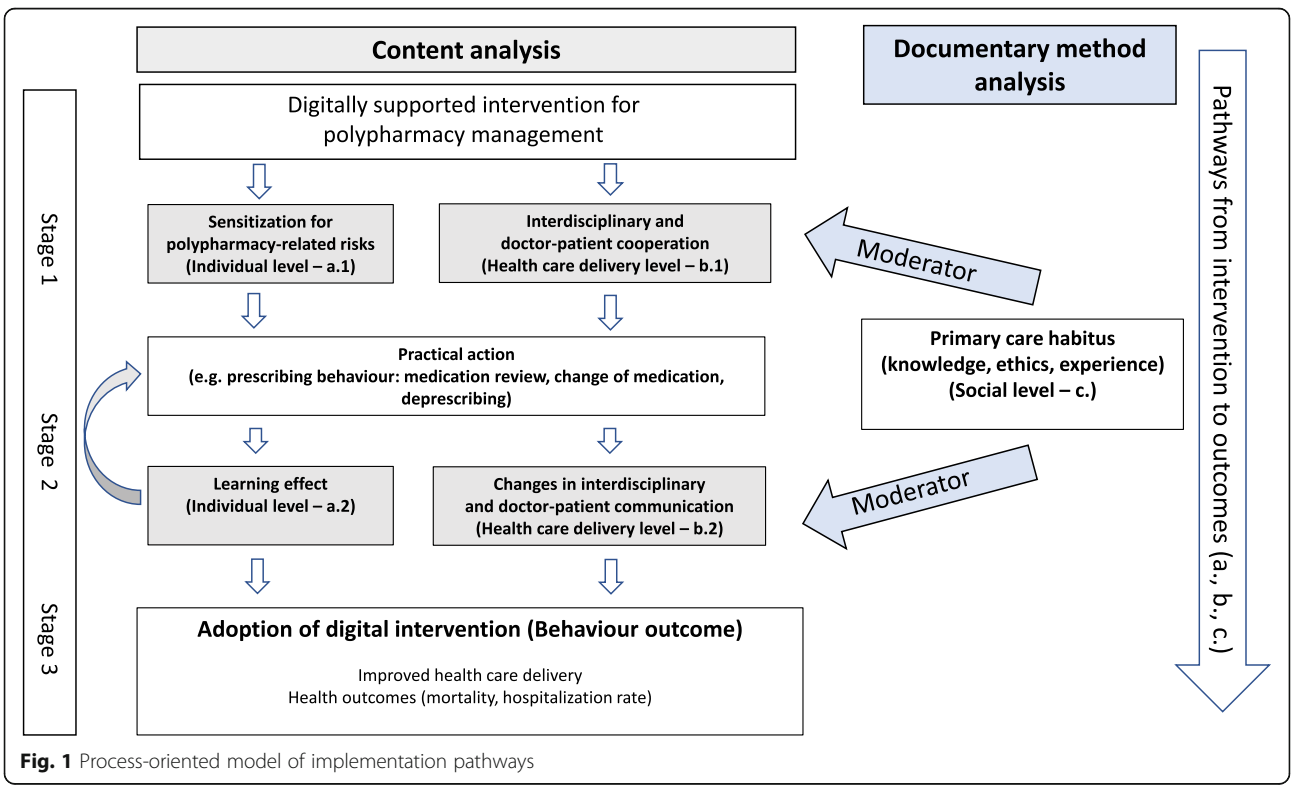

Fig. 1 Process-oriented model of implementation pathways

a. Simple pathway (positive behavioral outcomes): On the individual level, the digital intervention influences the participants' cognitive experience of becoming sensitized to the risks associated with polypharmacy (stage 1), which leads to the practical action of changing their usual prescribing behavior. Adherence to the recommendations of the digital decision support system and the use of the pharmacological knowledge base results in a learning effect (stage 2). In a feedback loop, prescribing behavior changes sustainably, and the adoption of the intervention (stage 3)—as a regular tool in medical practice—is perceived as beneficial. The description of this pathway is informed by outcomes of content analysis on the individual level (a.1 and a.2).
b. Complex pathways (unexpected behavioral outcomes): In the context of the digital transformation, physicians perceive a change in familiar forms of cooperation with pharmacists as experts in pharmacotherapy (health care delivery level). Physicians can digitally retrieve information and notes on pharmacotherapy. Additional information about other medical specialists involved in treatment is continuously available. As a result, overall transparency but also complexity in decision-making is increasing. Physicians seek orientation concerning mandatory ethical standards governing their professional responsibilities. The description of this pathway is informed by outcomes of content analysis on the health care delivery level (b.1 and b.2).
c. Complex pathways (ambiguous behavioral outcomes): Primary care habitus functions as a moderator. It influences how the intervention affects short-, intermediate-, and long-term outcomes. Physicians question the benefits of using the pharmacological knowledge base of the intervention for clinical decision-making. Sensitization to polypharmacy-related risks through the use of the digital intervention is hindered, and learning effects are not experienced (individual level). The impact of risky prescribing behavior on patients' well-being is trivialized by GPs, and information is not shared with patients (health-care delivery level). The usual prescribing practice is maintained (stage 2). The adoption of the intervention is delayed, depending on the level of the primary care habitus, until the benefits of its use are perceived (stage 3). The description of this pathway is informed by outcomes of content analysis and documentary method analysis (c.).

Discussion

This study provides fresh insights into a specific aspect of the implementation process: the complexity of adoption behavior. Our findings show that in implementation science, the combination of qualitative methodological approaches like content analysis and documentary method analysis (habitus reconstruction), and visualization of implementation pathways contributes to the understanding of varying adoption behaviors.

Allocating content analytic results to different stages of behavior-related outcomes adds value to the identification of different pathways. In an empirical analysis, we were furthermore able to observe that physicians' descriptions and narrations are related to experiences on the individual, health care-delivery, and social levels. Even though the habitus of physicians changes rather slowly and can weaken interventional effects promoting adoption, the analysis shows that physicians' positive interaction experiences with the intervention might influence the change in habitus in the long term. The differentiation and visualization of topics in a model of implementation pathways help understand the complexity of adoption behavior. Furthermore, specific implications and policy strategies can be derived, depending on the addressed level.

In contrast to Straßner et al. [31], we found that on the individual level, physicians consider pharmacological information an essential dimension in the prescribing process in polypharmacy. They expect the digital availability of pharmacological knowledge to simplify decision-making. Also, physicians value the fact that recommendations made by the digital intervention can be used to enhance communication about medication changes with the patient. Referring to the digital expert system makes them feel more secure when explaining any initiated medication changes.

Our findings are consistent with previous research by Bauchner, who found that the complexity of clinical decision-making by physicians is embedded in a broad context of social norms [32]. As shown by Vogd, while evidence-based medicine aims to simplify the relationship between medical science and practice, it can instead burden it with more complexity [33]. Our study supports these findings since physicians mention their need for clear external evidence on which to base their decision-making but perceive the provided information as very complex for quick decision-making in practice. Physicians compared previous experiences with evidence-based guidelines with this digital intervention in a way that questioned the benefits of using it. Unexpected in this context was the physicians' discussion of the orientation provided by ethical standards. They perceived the use of digital support to be associated with a change in professional and legal responsibilities.

Like Sinnige et al. [34], we found that physicians employ similar medication management strategies for polypharmacy, although there are variations in actual performance. Our findings also support the idea that physicians value decision support in polypharmacy, especially for geriatric and multimorbid patients. Unlike Sinnige et al., we did not find that physicians wanted the decision support option of meetings with pharmacists in which to discuss patients with complex problems. In our study, physicians perceived the digital intervention itself as a pharmacological expert system that processes patient data in a similar way as a pharmacist. It remains unclear if physicians experience the regular use of the digital intervention to replace the pharmacist, or whether an additional discussion is still needed.

Supporting the results of van de Velde et al. [8], our findings show that the adoption of the intervention critically depends on patient information being provided to physicians fast and automatically, rather than requiring a lengthy search. In Germany, a current (paper-based) medication plan has been mandatory for patients since 2016, and physicians expressed their expectation for this information to also be integrated automatically into the digital system.

Our findings have important implications for upscaling the intervention: Physicians perceive their behaviour to become more transparent through the digitalization of the prescribing process. Therefore, implemented evidence-based tools must be as transparent as possible concerning their database and underlying calculations. Increased transparency is a goal to encourage users to routinely use the intervention and accept the related workload during the implementation process.

Clinical decision-making processes in polypharmacy are influenced by the intervention on several levels that influence each other. It has been shown that there is an individual need for support in the field of polypharmacy, but the adoption of the intervention is strongly influenced by the social environment of the doctors. The professional role of GPs, which is reflected in the habitus of general practitioners and their socialization, is evidence of how strongly the social environment influences the doctors' practical actions in the prescription process and thus the adoption of the intervention. The intervention also influences and changes social relationships in the clinical decision-making process (doctor-patient, interprofessional cooperation), with doctors reporting reassurance in the prescription process while using the intervention, even though the changes in interprofessional cooperation caused by the intervention and their influence on the quality of prescriptions merit further study.

Physicians in the intervention group may change their prescribing behavior and prioritization of important aspects of clinical decision-making when prescribing polypharmacy - in terms of examining the needs of the individual patient, scientific evidence, and medical experience. Positive interaction experiences with the intervention are associated with physicians' perceptions of an increased risk-awareness and behavioral intention to base clinical decision-making on polypharmacy prescribing on scientific evidence. In comparison, we have found that clinical decision-making on polypharmacy without digital support is associated with great uncertainty. Physicians have developed habitual strategies to compensate for these uncertainties in practice but have expressed a need for new practical approaches to the management of polypharmacy.

Strengths and limitations

The findings of this study reflect the opinions of 27 primary care physicians and provide an in-depth understanding of the GPs' expectations and interactions with the digital intervention. A purposive sampling strategy was planned to be conducted, but we were unable to choose participants exclusively by theoretical characteristics. A pragmatic decision was made to apply a convenient sampling strategy with a purposive aim to collect data from GPs of both C-RCT groups. Data analysis used qualitative data collected in the first year of implementation, so only physicians who were enrolled during that period had the opportunity to participate in our study. It can be assumed that early adopters, who participated in this initial phase of the project, are more engaged and motivated to adopt the intervention. Despite their overall interest in the project, this sample still expressed relatively stable concerns about the adoption of the system. The implication is that although over time, higher numbers of physicians are going to use the intervention, this development will not reliably directly result in routine uptake of the digital intervention in practice.

Conclusion

German physicians experience positive effects and increasing polypharmacy-related risk awareness while applying the digital intervention. They expect the digital expert system to provide reassurance during prescribing processes and benefit their communication with patients concerning medication management. However, they have not yet routinely adopted the intervention.

Physicians are relatively open to change processes in polypharmacy management. In the short term, the intervention sensitizes physicians to polypharmacy-related risks. The intervention also affects interdisciplinary and doctor-patient communication. Therefore, adoption of the digital intervention, behavior changes, and transformation of physicians' habitus are anticipated in the

intermediate and long term. To ensure uptake, it is necessary to address the above-mentioned implications, such as by promoting (1) facilitated positive learning experiences, (2) simplified evidence-based information, and (3) a clarified professional code of ethics and responsibilities. Variations in actual performance and use of the digital intervention are moderated by the physicians' multidimensional habitus (knowledge, ethics, experience). The analysis of the moderating influence of physicians' habitus adds evidence in explaining variations in the effectiveness of digital interventions on health-related outcomes.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s13012-020-01043-6.

Additional file 1. COREQ (COnsolidated criteria for REporting Qualitative research) Checklist.

Additional file 2. The TIDieR (Template for Intervention Description and Replication) Checklist*.

Additional file 3. Stages of behavior-related outcomes of the digital intervention.

Abbreviations

TiDIER: Template for Intervention Description and Replication;
COREQ: Consolidated criteria for reporting qualitative research

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Authors' contributions

SS drafted the first version of the manuscript with input from JKN, HP, and UK. UK, HP, and SS designed the study. SS conducted interviews and focus groups and performed qualitative data analysis and interpretation. UK contributed to the analysis and data interpretation. CM, BSM, and TSN provided substantial conceptual input. All authors read and approved the final manuscript.

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Availability of data and materials

No datasets are available from this study due to participant consent restricting data use to the research team.

Ethics approval and consent to participate

Study design and realization were presented to the ethics committee of the Medical Association of North Rhine (application no. 2017184). No objections were raised to any part of the study. All interviewees and focus group participants gave written informed consent to participate and be audiotaped.

Consent for publication

All participants gave permission for their comments to be published in anonymized form.

Competing interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that their institutions and work in the research project AdAM are financially supported through grants by the German Federal Joint Committee.

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Publisher's Note

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	9
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	9
Occupation	3	What was their occupation at the time of the study?	9
Gender	4	Was the researcher male or female?	9
Experience and training	5	What experience or training did the researcher have?	9
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	9
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	9
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	9
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	5
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	8
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	8
Sample size	12	How many participants were in the study?	1
Non-participation	13	How many people refused to participate or dropped out? Reasons?	9
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	9
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	9
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	10
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	9
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	N/A
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	9
Field notes	20	Were field notes made during and/or after the inter view or focus group?	N/A
Duration	21	What was the duration of the inter views or focus group?	10
Data saturation	22	Was data saturation discussed?	5
Transcripts returned	23	Were transcripts returned to participants for comment and/or	N/A

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	5
Description of the coding tree	25	Did authors provide a description of the coding tree?	6;13
Derivation of themes	26	Were themes identified in advance or derived from the data?	6;9
Software	27	What software, if applicable, was used to manage the data?	5
Participant checking	28	Did participants provide feedback on the findings?	N/A
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	11-12
Data and findings consistent	30	Was there consistency between the data presented and the findings?	18-21
Clarity of major themes	31	Were major themes clearly presented in the findings?	18
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	17-18

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME	Application for a digitally supported Medication Management Support System (AdAM)	
1.	Provide the name or a phrase that describes the intervention.		
	WHY	By providing drug-therapy-relevant patient information to the general practitioners in the intervention group via a digitally supported application, the quality and safety of prescribing for patients with polypharmacy should be improved (e.g. decrease of potentially inappropriate medication, adverse drug events).	
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.		
	WHAT	The digitalized decision support system can be used by general practitioners in the intervention group via personal access.	https://clinicaltrials.gov/ct2/show/NCT03430336

		GPs in the wait-list control group provide usual care. The decision support system provides drug-therapy relevant information of patients with polypharmacy. Other features are: modification of medication, assessment of medication appropriateness; medication plan; guidance in medication process)	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	General practitioners can use the provided drug-therapy relevant information to modify medication and generate an up-to-date medication plan and hand it out to their patients.	https://www.kvwl.de/arzt/ivf/innov_fonds/adam_infoblatt.pdf https://www.kvwl.de/arzt/ivf/innov_fonds/adam_kurzinfo_versorgungsvertrag.pdf
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	After physicians register for participation in the study, the Association of Statutory Health Insurance Physicians (KVWL) provides telephone support and training to use the digital application for general practitioners and their medical assistants in the intervention group. Training includes an	

		one hour frontal teaching for the use of the digital application with additional information material. Via an online platform, training and information material can also be used by the GPs of the intervention group. Telephone support and training is provided on a voluntary basis.	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	The Health Insurance Company (BARMER) and the Association of Statutory Health Insurance Physicians (KVWL) are responsible for the delivery of the intervention to general practitioners and patients. Pharmacists or pharmaceutical technical assistants employed by KVWL provide training and support. Telephone support is provided by trained employees of KVWL via a telephone hotline.	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	The digital application is delivered via internet and personalized access	

		on the computer of general practitioners in the intervention group. Training and support are provided face-to-face (individually and in groups) or in general practices and via telephone.	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	The intervention is delivered to the registered general practices of the intervention group. Information is retrieved user-initiated.	Internet access
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Assessment of medication appropriateness should be conducted at least one time per year for each included patient. Depending on physicians' demand, the assessment can also be carried out more often.	01.01.2018 – 31.12.2020
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	N/A	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	_____
	HOW WELL		

11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	To measure physicians' adherence, medication appropriateness is monitored throughout the study.	Evaluators from the participating universities in the project AdAM (see https://clinicaltrials.gov/ct2/show/NCT03430336
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not yet applicable	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Additional File 3 Stages of behavior-related outcomes of the digital intervention

Stage 1	Interviews (intervention group)	Focus groups (intervention group)	Focus groups (wait list control group)
Sensitization for risks related to polypharmacy (individual level)	"Yes, the necessity of the interaction check in polypharmacy, especially for our geriatric patients. That is, just when psychiatric medications are added, which have unknown indications, that one ultimately no longer has in mind what interacts with each other in what way. And that simply gives one the security then to carry out this analysis. The thing is, we have more and more chronically ill, old patients with a lot of drugs, that this also ... and that is increasing. And that is why I believe it is increasingly necessary to have this feeling of security that everything is going well concerning polypharmacy." [GP1, p.3] "It suddenly comes to unclear laboratory values which you cannot explain, and then it is, of course, interesting to know, are there possibly other drugs. Or are there other doctors involved that you don't know about." [GP 8, p.5]	"As I said, you get a little more sensitive about the interactions, especially when it comes to specialist medication that you often don't have on your radar. Well, I always try to include them in the medication plan and then write behind it, neurologist, gynecologist, or something else, but we don't get any reports from the gynecologists, yes. If the patients don't tell us that they are getting the medication, then we don't know that either. Also, with the neurological patients, with some of them, I was surprised by what they take on the side." [FG4, GP_CC, p.14] "And the advantage of this system, or this program in general, is that I have reviewed the patients who are now enrolled […] that I looked again on the medication plan and see, does he still take everything that I have there now, or does he already take more." [FG4, GP_AA, p.10]	"Well, I'd like an overview of the actual medications taken by each patient. From other colleagues, or even what he might get in the pharmacy. Then I would like professional assistance with the assessment of interactions, side effects, contraindications, and which of the drugs are suitable for old people at all, and which tend not to be." [FG1, GP_CC, p.3] "I think it's good that polypharmacy is coming into focus. That doctors are sensitized to it, or that everyone, everyone is sensitized to it, and patients are also sensitized to it, and it is still a bit difficult to really get down from ten to five [drugs], I don't always see myself in a position to do that, but I think it is important to be more involved than in the past ten years. And the goal is really, yes, maybe less is more." [FG2, GP_DD. p.24]
Interdisciplinary and doctor-patient cooperation (health care delivery)	"So now you get, practically all the time, calls from pharmacists who think something is not working with one or the other, but they don't see the clinical presentation. Now, if you have a Parkinson's patient and want to calm him down somehow because he's nervous all night, then maybe that reduces the effect of his Parkinson's medication, but then from the pharmaceutical perspective alone, that's not seen. The medical assistant sits there, a red light goes on, and they tell the patient, watch out, this reduces the effect of the Parkinson medication; then a relative comes by and says, you wrote down something that possibly reduces the effect of the Parkinson medication, we cannot take that. What impression does that make? If then ... that's what it is, if there are a lot of people interfering, that's bullshit. Somebody has to say how it works and then it's okay." [GP6, p.8]	"I didn't have that experience, of course, but... well, that's new to me. I know it otherwise, as I said, also from the pharmacists, because I constantly or conveniently get information from them, like there is an incompatibility with azithromycin or something else. But where we have a comprehensive medication list from all kinds of doctors who have treated the patient, that has not yet existed." [FG3, GP_BB, p.8] „Where is the sense and purpose [using the digital tool]? What is the whole thing supposed to do ... what is important information? Where do I perhaps not need to look like that? Do I only perceive it, the specialist medication or should I integrate it into the system? [FG3, GP_AA, p.13]	"I think if you participate in such projects, you also have the chance to work better with patients, nursing services, with colleagues or sometimes with hospitals. So that you call back and say, is that really the case? Can't you change one or the other or don't always add the next one? Another specialist and another specialist, the urologist and the cardiologist and the hospital, then again and then the nursing service with a proposal. Well, I think it has an important control function. So, not in a negative sense, but in a very positive sense." [FG1, GP_EE, p.4]

	"So, they [patients] feel safer and also, I think, more confident about why they take something. Because you can explain what the tablets are really good for." [GP7, p.4]		
Stage 2	Interviews (intervention group)	Focus groups (intervention group)	Focus groups (wait-list control group)
Learning effect (individual level)	"I like to use it [digital tool] and see also a lot of sense in it, because I also learn again, refresh again, knowledge that is perhaps still present somewhere in the back of my mind, but to update this again, but I find this information very good. When it comes to dosage, for example in the case of kidney failure, oh yes, aha, right, of course ... you could think about it or just recommend something to implement, so I think that's very good. It makes my work as a doctor much easier when prescribing, so I think that makes a lot of sense." [GP1, p.6] "It's okay to pay more attention, but I... on the basis of this, yes, the recommendation I can ... I will still not change the therapy because this is also from the cardiologist and this is the treatment for heart failure, yes, even if the side effects or the interactions are known." [GP2, p.3]	"It's always one of those little training sessions you do. Other patients also benefit from it because I suddenly see that, oh, these medications don't go together so well after all." [FG4, GP_AA, p.33] "I now find myself with my patients, well, coming to their routine visits, simply perceiving these risks more intensely and then changing it, yes, with the other patients as well, if I consider it initiated. And I found that, for example, quite good." [FG3, GP_DD, p.9]	"And at the moment, when a project like AdAM is running, we can, of course, say, okay, we've had it reviewed externally again. Someone looks at it again, and of course, we are a bit more on the safe side from a legal point of view. Of course, our responsibility is still to give or not to give medication at all, but we can at least say what the medication is like, what the consequences are and that interactions have been checked externally." [FG2, GP_DD, p.6]
Changes in interdisciplinary and doctor-patient communication (health care delivery)	"You could see right away [using the digital tool], okay, he got two different ones within one quarter, that was a bit strange. Then I talked to a neurologist on the phone, where several drugs were administered that change the QT time. For things like that it was good. Nothing happened, but, well, something could have happened." [GP5, p.8] "It's good, especially for the patients, they all saw great sense in it and found it good. So, I did that mostly in the presence of the patients, so they immediately saw what kind of information there was about interactions." [GP1, p.2]	"I have patients where the medication just did not really fit and where I can exchange views with the specialists, who are also named [in the digital tool], where patients are being treated. Well, I think that's quite good. [FG4, GP_CC, p.5] "Such prescription chains are created, and I believe that these chains cannot be broken by specialists because they think too narrowly. And we as general practitioners, we have to try to break them up again with such instruments [digital tool]." [FG3, GP_AA, p.10]	"Yes, and of course, that is also where you would get a bit of support with software that recognizes things in a structured way, as long as you have to rely on your knowledge, on what you try to achieve through extensive further training and the like. The pharmacist is, of course, a very important interface, especially since pharmacists already have better software products at their disposal than we have in our practices, in terms of interactions, for example." [FG2, GP_EE, p.5]

[GP= General practitioner, FG= Focus Group, AA-EE = synonyms for GPs in FGs]

Appendix ii: Study II (Implementation Leadership Scale Validation Study)

BMC Health Services Research

RESEARCH

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How is leadership behavior associated with organization-related variables? Translation and psychometric evaluation of the implementation leadership scale in German primary healthcare

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Abstract

Background: The Implementation Leadership Scale (ILS) was developed to assess leadership behavior with regard to being proactive, knowledgeable, supportive, or perseverant in implementing evidence-based practices (EBPs). As part of a study on the implementation of a digitally supported polypharmacy management application in primary care, the original ILS was translated and validated for use in the German language.

Rationale: This study aimed to translate the original ILS into German and evaluate its psychometric properties.

Methods: The validation sample consisted of 198 primary care physicians in a cluster-randomized controlled trial in which the intervention group implemented a digitally supported clinical decision support system for polypharmacy management. The ILS was assessed using a 12-item scale. The study included a process evaluation with two evaluation waves between 2019 and 2021. The ILS was used within this process evaluation study to assess the leadership support with regard to the implementation of the polypharmacy management. The ILS was translated in a multi-step process, including pre-testing of the instrument and triple, back-and-forth translation of the instrument. We tested the reliability (Cronbach's alpha) and validity (construct and criterion-related validity) of the scale.

Results: The four-dimensional structure of the instrument was confirmed (comparative fit index = .97; root mean square error of approximation = .06). Convergent validity was demonstrated by correlations with organizational innovation climate, social capital, and workload, which was consistent with the proposed hypothesis. Criterion-related validity of the ILS was demonstrated by predicting the organizational readiness for change scores using structural equation modeling. The reliability of the scale was good ($\alpha = .875$).

Conclusion: The German version of the ILS created in this study is a reliable and valid measure. The original four-dimensional structure of the ILS was confirmed in a primary care setting. Further psychometric testing is needed to establish the validity and reliability of the ILS and to transfer it to other health care settings. It is a useful tool for

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identifying the areas for implementation leadership development. Further research is needed on how, why, and when distinct types of leadership behaviors have different effects on healthcare organizations in implementation processes.

Keywords: Digital technology, Leadership, Change management, Organizational culture, Innovation climate, Social Capital, Medication therapy management

Background

Implementing change in healthcare organizations can be challenging. In recent decades, however, there has been a paradigm shift from a simplified and static understanding of implementation processes to a more complex and dynamic one. Hunter (2020) argued that successful implementation comprises the dynamic interplay of facilitating conditions, innovation, recipients, and context [1]. In this complex interplay of significant factors, implementation-supportive leadership behavior is important for a successful change process in healthcare organizations.

In addition to the theoretical assumptions, empirical evidence supports the significance of the role of leaders in the implementation process [2, 3]. Particularly, the full-range leadership model (FRLM), which includes a typology of leadership behaviors such as transformational, transactional, non-transactional laissez faire leadership, has often been used as a conceptual basis in research for investigating correlations between leadership and organizational performance [4–6]. Leadership influences multiple factors in the organizational context – such as culture, communication, networks, and resources – and is the key enabler in creating a climate conducive to the implementation of EBPs [7].

In implementation research, these relevant implementation factors can be mapped to a proven framework for investigating change processes – the consolidated framework for implementation research (CFIR). In the field of health services studies, the conceptual approach of CFIR has often been used to guide and facilitate, plan, and evaluate the implementation of evidence-based practices (EBPs) [8, 9]. From a meta-theoretical perspective on implementation research, this framework provides a compilation of constructs that have been associated with effective implementation [2]. Determinants are grouped within five main domains relevant for implementation research: the intervention, inner setting, outer setting, individuals involved, and process by which implementation is accomplished. The domain "inner setting" contains relevant constructs to capture the internal dynamics of the organization in a focused manner. One important element of the "inner setting" is leadership, which is also linked to the construct of "implementation climate" and "implementation readiness". Leadership in particular and the theories associated with it play an important role in explaining the translation of theory into practice and have evolved and have been integrated into implementation research [10, 11].

In addition to a theoretical conceptualization of leadership in implementation research, there is a body of theoretical literature in health services research: the knowledge translation and exchange literature [12–15]. In this research area, change processes are examined primarily with regard to the exchange of knowledge during change. In the dynamic and interactive change process, the ability to transfer knowledge is defined as a core competency of the leader [13, 16]. Because the nature of knowledge transfer processes is associated with diverse boundaries, the leader needs to be able to recognize and use new knowledge (absorptive capacity). The degree of leaders' absorptive capacity in knowledge transfer promotes or inhibits organizational learning and facilitates or prevents the successful implementation of change processes at the organizational level [17, 18].

Implementation leadership: a new concept

Implementation leadership (IL) is a recently emerged concept developed on the basis of literature on organizational climate and cultural change [19, 20]. It has been operationalized in using different theoretical leadership models [21, 22]. The Implementation Leadership Scale (ILS), which is the focus of this paper, is based on the full-range leadership model, which includes aspects of the transformational leadership theory, as in the theoretical development of the scale indicated by Aarons et al. (2014) [23]. Other conceptual approaches related to IL include the behavioral leadership model and the Ottawa model of implementation leadership [24] or the hierarchical framework of leadership behaviors [25]. The models and related items differ particularly in their description of the leadership behaviors being measured.

The ILS measures leadership types in the context of EBP implementation. It has been used in many countries such as Greece, Norway, and China and in various settings (e.g., nursing or mental health care settings), and its validity was confirmed [26–28]. It focuses on leader behaviors related to organizational culture and climate-embedding mechanisms that promote strategic climates for EBP implementation. In addition, leadership behaviors that focus on a strategic imperative related to

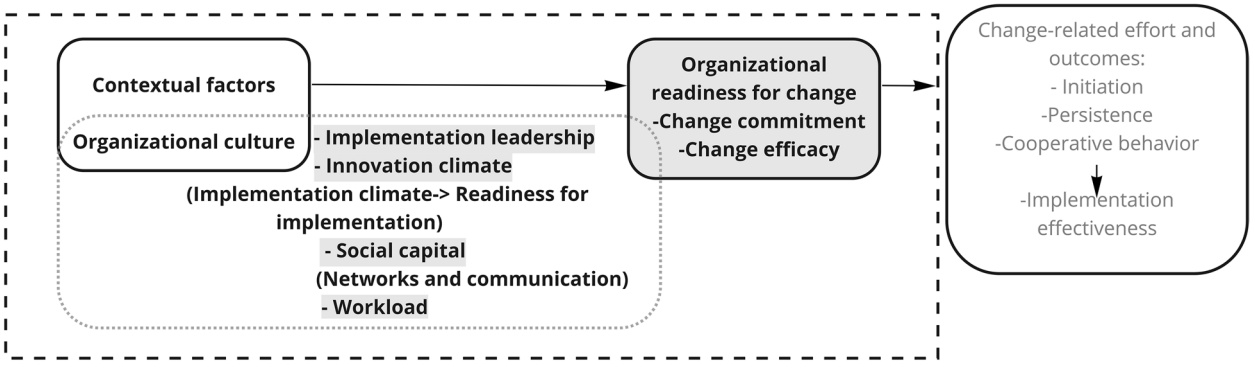

Fig. 1 Conceptual Model. Notes: The subject matter of the present study = all measures colored in gray; determinants and outcomes of organizational readiness approach = all constructs in frames with solid lines; inner setting domain of CFIR (related constructs) = frame with dotted lines

an implementation outcome such as adopting or applying an EBP may influence team members' attitudes and behaviors regarding the imperative [23]. The four types of leadership behavior in ILS represent specific leadership behaviors – in contrast to general leadership behavior – that leaders may perform to facilitate EBP implementation, for example, removing obstacles to EBP implementation (proactive leadership); communicating benefits of EBP (knowledgeable leadership); recognizing, appreciating, and supporting employee efforts in learning and using EBPs (supportive leadership); and persisting through challenges in implementing EBP (perseverant leadership).

However, to our knowledge, no specific measurement tool is available for the primary care setting in Germany. As the purpose of the study was to identify a process evaluation measure that focused on our primary research question on evaluating barriers and facilitators in the implementation process, we sought a brief and specific measure related to the leadership behavior of primary care physicians (PCPs) – as a facilitating factor. To this end, we investigated the original ILS (leader version), which we translated, and evaluated its application in the German primary care context.

Conceptual model

Assumptions about the interrelationships among the constructs investigated in our study are mainly based on the CFIR and an organizational theory approach. As described by Weiner (2009) or Damschroder (2009), receptive organizational context factors or internal factors of organizations are determinants in the implementation process [29] (see Fig. 1).

Furthermore, two constructs related to the organizational level were investigated in our study. The items in these scales are formulated generically and do not directly address implementation activities (innovation climate, social capital). One scale is also described in the CFIR in a broader sense as a facilitating factor for implementation processes. It is assigned to the construct on "networks and communication processes" (social capital). In the context of the above classification and description of ILS and CFIR, the social capital scale represents a specific aspect of the networking and communication processes in an organization (CFIR). We hypothesize that social capital facilitates the implementation processes and may be positively associated with leadership [30]. In addition, we hypothesize that support for implementation through quality management implementation practices (measured by ILS) will foster a positive climate for innovation implementation (innovation climate) [19]. In a further step, we included variable workload in our model. It is not directly mentioned in the literature on which our theoretical–conceptual framework is based, but it is reasonable to assume that the workload of leaders increases. However, in our study, we assumed that there cannot be a positive relationship between the two factors. The variable used refers to workload related to general practice activities in primary care, which remained stable in our study (measured by the number of patient appointments during implementation). It therefore does not serve as a direct indicator of implementation activities.

The last construct that is examined in our study – implementation readiness – is operationalized through direct indicators of organizational commitment to the decision of implementing an innovation. These include leadership commitment at the micro level (measured by ILS) and organizational readiness at the meso level (measured by organizational readiness for implementing change [ORIC]). ORIC is conceptualized following Weiner (2009) and measures the extent to which members in an organization are psychologically and

behaviorally prepared to implement organizational change [29, 31]. With reference to our study setting, we assume that the direction of the effect relationship runs from the micro (ILS) to the meso level (ORIC; predictive validity) [32]. Nevertheless, in some situations, leadership behavior may be independent of ORIC. Even if leaders initiate many implementation activities, ORIC may not necessarily be accomplished, for example, if appropriate resources are also not provided at the organizational level. In addition to resource allocation, temporal elements may also have a significant impact on the implementation process. Depending on the phase of the intervention (initiation phase versus implementation phase), the concentration of decision-making autonomy (centralization) by individual actors (e.g., leaders) was found to be negatively or positively associated with innovation [33, 34]. Consequently, the quality of micro- and meso-level relations over time will be decisive to the effectiveness of implementation.

The research questions arising from the conceptual model and setting of our study are as follows: 1) can the validity and reliability of the ILS be confirmed in primary care organizations? and 2) how is the ILS empirically related to social capital, innovation climate, ORIC, and workload in our sample of primary care organizations (construct validity, criterion-related validity)?

Methods

Study design and data collection

In this secondary analysis, data from two surveys were used to examine the psychometric parameters of the German version of the ILS. The data were collected as part of the formative evaluation accompanying the effectiveness study in the project "Application of a digitally supported pharmacotherapy management system" (AdAM project), which was conducted in PCP practices from 2017 to 2021 [35]. The design of the effectiveness study influenced the data collection of this study. Because the effectiveness study was a stepped-wedge, cluster-randomized controlled trial (cRCT) with open cohorts and the second survey exclusively addressed adopters, data of only a subset of the participating physicians in both surveys are available for longitudinal analyses.

Data for the ILS were collected in the first survey as part of an eight-page questionnaire, which included information on physicians' attitudes regarding uptake of the intervention and other implementation factors. In addition to the ILS, it included a technology acceptance scale, demographic questions (e.g., gender, age, professional experience, and practice structure), and some questions that had been used in previous health services research studies. The results of these additional measurement tools were not used for validation, except for four measures: organizational innovation climate, social capital, workload, and ORIC. The second survey covered ORIC, process normalization, perceived implementation success, and practice resources. As data were documented pseudonymously, we were able to link both surveys at the participant level. All physicians with fully completed surveys on ILS, innovation climate, social capital, and workload measures at the first time point were included in the construct and criterion validity analyses. Only data sets from fully completed surveys on ILS and ORIC were included in the path analysis for testing predictive validity (data from the ILS at the first time point and from the ORIC at the second time point).

Participating physicians received the questionnaire by mail from the Association of Statutory Health Insurance Physicians of the Region Westphalia/Lippe. The inclusion criteria of this validation study were identical to the inclusion criteria of the formative evaluation study of the AdAM project. The data from the first survey were collected between November 2019 and January 2020. Data from the second survey were collected between September 2020 and December 2020. To increase the response rate, we used the tailored design approach by Dillman (1978), which means that physicians were reminded three times by e-mail to respond to the questionnaire [36]. The first questionnaire was pre-tested with PCPs in two stages: in think-aloud interviews ($n = 4$) to assess the comprehensibility of the questions and in a secondary sample survey by post ($n = 10$) to test whether the skip pattern had the desired effect and whether the entire range of the scales was used and not just one direction. On the basis of the results, minor modifications were made to the overall structure and presentation quality of the final questionnaire.

Setting and sample characteristics

The setting examined in the study was that of outpatient care by PCPs, where a digitally supported and evidence-based clinical decision support system for polypharmacy management was implemented in the AdAM project. PCPs implemented evidenced-based practices—such as digitally supported clinical decision making and medication reviews—for patients in the intervention group at least once a year. The digital software application provides the possibility to update information (e.g., on new diagnoses and prescriptions not yet settled with the patient's health insurance provider) and to add specific details that are not included in the data submitted to health insurance funds (e.g., height, weight, laboratory test results on renal function, over-the-counter drugs, and medication doses). PCPs then examined patients' medication regimens, supported by alerts from the

application in case of inappropriate prescriptions (e.g., drug–drug and drug–disease interactions, inappropriate dosages, or potentially inappropriate drugs because of the patient's age).

The final sample size of the first and second surveys was 219 respondents (68.3% response rate) and 334 respondents (44.5% response rate), respectively. The final measurement model included 198 physicians (see Fig. 2) with complete data in the intervention group from 2018 to 2019 in the AdAM project. The path analysis model included 183 physicians at the first time point and 135 physicians at the second time point (see Table 3). For the second survey, it should be noted that the group was partly different from the first survey – owing to the study design of the effectiveness study (stepped-wedge cRCT with an open cohort). At the second measurement point, there were more participants in the intervention group who could be approached for the survey. But the lower response rate may be related to the fact that the second survey targeted more physicians who had just started using the software and could not yet provide ratings. Nearly all respondents of the first and second surveys were practice owners (92 and 94%, respectively) and were predominantly men (65 and 63%, respectively) and 50–60 years old (46 and 49%, respectively); the participants had an average of 17 years (survey 1) and 18 years (survey 2) of experience working as a PCP. The study population represents the potentially includable population of PCPs in the region where the intervention was implemented in terms of the distribution of sex and age. The distribution in terms of position within the practice (professional title) supports our intention to validate the leader version of the ILS, as almost all physicians were practice owners and therefore had a leadership role. Consequently, we considered this measurement tool as suitable to be validated with our sample.

Translation of the implementation leadership scale

The translation process was guided by the recommendations of the World Health Organization for translating measures [37]. These recommendations call for a forward translation and then a back translation, supplemented by discussions on the translation process in which the terminology is discussed with regard to cultural differences in the meaning of the terms. Items were translated by bilingual translators from an independent translation agency. Every item of the scale was translated forward and back by three different bilingual translators. After the translation, three members of the research team rated the forward and back translations with regard to the comprehensibility of the translations for the German context. Each item was assessed and assigned a value of either 0 (no accordance), .5 (accordance, but not for all words), or 1 (accordance), which were summed up, and the final version was discussed. The translation of the scale was checked for comprehensibility in cognitive interviews with PCPs ($n = 4$) during the pre-test of the entire questionnaire. The respondents did not report any difficulties in understanding the individual items or technical terms relating to the ILS.

Measures

Data aggregation

The instruments used have been developed to assess innovation climate, social capital, and organizational

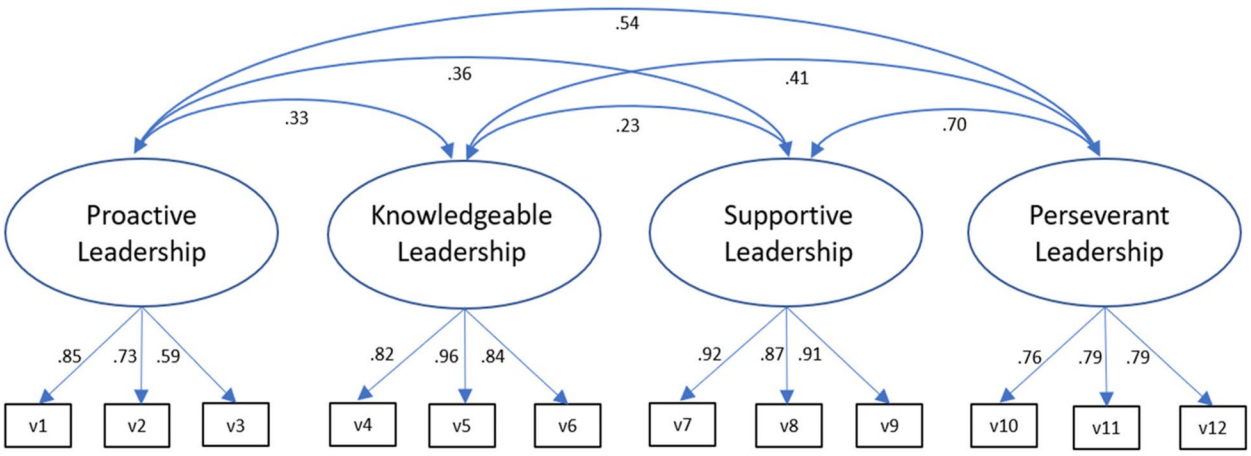

Fig. 2 Factor loadings for the implementation leadership scale. Note: $n = 198$; all factor loadings are standardized and statistically significant, $p < .001$; $\chi^2(48) = 84.59$, $p < .001$; comparative fit index = .974; Tucker-Lewis index = .965; root mean square error of approximation = .062; standardized root mean quare residual = .051

readiness at the organizational level of analysis. Physicians answered the organization-related aspects of our questionnaire as key persons of the participating practice. As recommended, measurement based on individuals' assessments of collective capabilities is preferable when collective outcomes depend on skillful teamwork [38]. All organization-related instruments (organizational innovation climate, social capital, ORIC) and individual-related instruments (ILS, workload) had an adequate item structure (items were written from the perspective of the collective for organization-related instruments and from the perspective of the individual for individual-related instruments). For the above measurement tools, we did not aggregate data at the organizational level because almost all physicians in our sample were solo practice owners and did not work in group practices.

Implementation leadership scale

In the original English version, the four subscales are described following Aarons (2014): "proactive leadership" (items 1 to 3), "knowledgeable leadership" (items 4 to 6), "supportive leadership" (items 7 to 9), and "perseverant leadership" (items 10 to 12) [23]. The scores for each subscale were created by computing mean scores for each set of items related to a given leadership type, with higher scores indicating stronger leadership activities. To adapt the scale to a specific research context, items can be made specific by adding the name of the EBP. In our survey, the EBP was specified as the use of project software (including digitally supported evidence-based medication management). Physicians were asked to answer the Leader version of the ILS survey on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree; $\alpha = .875$). The English items are presented in the Results section ($\alpha = .875$; see Table 1).

Organizational innovation climate

The "organizational innovation climate" scale consists of seven items and has been used in previous studies in health services research [39]. It measures the extent to which the organization's current perceived climate promotes innovative ideas and behavior among employees. The items assess the extent to which the ideas, suggestions for improvement, and efforts of the employees regarding the introduction of an innovation are taken into account in the organization (PCP practice). Respondents had to choose one answer on a four-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree; $\alpha = .804$).

Social capital

The "social capital" scale consists of six items and has been recently validated as an employee version [30]. It has been characterized by different dimensions related to mutual understanding, warm circle, trust, "we-feeling"

Table 1 Characteristics of the implementation leadership scale, subscales, and item statistics

Item #	Mean (*SD*)	Factor loading (Std.)	Acceptance (Completion rate in %)	Corrected item-total correlation	Item difficulty
Factor 1: Proactive leadership subscale	2.23 (.96)				
1) I developed a plan to facilitate EBP implementation.	2.23 (1.17)	.845**	98.16	.596	44.6
2) I removed obstacles to implementation of EBP.	2.39 (1.16)	.731**	97.24	.534	47.8
3) I established clear department standards for implementation.	2.30 (1.15)	.592**	98.62	.576	46.0
Factor 2: Knowledgeable leadership subscale	3.54 (.92)				
4) I know about EBP.	3.62 (1.00)	.820**	98.16	.541	72.4
5) I am able to answer staff questions about EBP.	3.41 (1.02)	.959**	98.62	.554	68.2
6) I know what I am talking about when it comes to EBP.	3.44 (1.05)	.839**	98.16	.599	68.8
Factor 3: Supportive leadership subscale	3.34 (1.22)				
7) I recognize and appreciate employee efforts.	3.15 (1.38)	.916**	97.24	.739	63.3
8) I support employee efforts to learn more about EBP.	3.31 (1.28)	.871**	98.62	.763	66.2
9) I support employee efforts to use EBP.	3.42 (1.39)	.905**	96.78	.730	68.4
Factor 4: Perseverant leadership subscale	3.08 (.97)				
10) I persevere through the ups and downs of implementing EBP.	2.74 (1.21)	.758**	98.16	.719	54.8
11) I carry on through challenges of implementing EBP.	3.23 (1.16)	.790**	99.08	.691	64.6
12) I react to critical issues regarding implementation of EBP.	3.17 (1.06)	.790**	96.78	.728	63.4
ILS Total	3.07 (.74)				

Notes: $n = 198$, *SD* = standard deviation, ** $p < .001$; items were rated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree)

(i.e., a sense of being part of a team), mutual help, and shared values. The scale captures the enablement of a person to "coordinate their activities in an implicit and efficient way and to develop a healthy social climate." The participants answered the items on a 4-point Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree; α = .899).

Organizational readiness for implementing change

The "organizational readiness for implementing change" scale with its two subscales "change commitment" and "change efficacy," proposed by Shea et al. (2014) [31], were recently translated and evaluated for the German context [40]. As recommended in the validation study of the German translation, we used a 9-item version of the scale instead of a 10-item version of the original scale. During the adaptation to the German context, the comprehensibility of item 10 remained low owing to inadequate translation of one term that has a strong cultural connotation and no equivalent phrase in German. Therefore, the item was omitted from the German version. The subscales capture the respondents' perceived readiness for implementing change at an organizational level using five items (items 1 to 5 = change commitment; α = .967) and four items (items 6 to 9 = change efficacy; α = .956), respectively, each to be answered on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree).

Workload

The item "workload" measured self-assessed perceptions of PCP workload over the past 2 weeks on a scale from 0 (not at all stressed) to 10 (very stressed; mean = 5.61, standard deviation = 0.20, confidence interval = 5.2–6.0). The item refers to the workload associated with general physician activities in primary care (e.g., diagnostic and therapeutic activities).

Statistical analyses

To assess the psychometric quality of the ILS in primary care organizations, a two-step procedure was conducted [41]. In the first step, a confirmatory factor analysis (CFA) was used to examine whether the construct of implementation leadership in its four dimensions (namely "proactive leadership" [items 1 to 3], "knowledgeable leadership" [items 4 to 6], "supportive leadership" [items 7 to 9], and "perseverant leadership" [items 10 to 12]) can be confirmed by assessing global and local fit Indices. To test the prerequisites for factor analysis, the Kaiser–Meyer–Olkin (KMO) test for sampling adequacy and Bartlett's test for sphericity were performed [41]. A factor analysis such as CFA is recommended to confirm content validity [29]. In the second step, bivariate analyses and structural equation modeling (SEM) were conducted to confirm criterion-related validity types such as convergent, discriminant, and predictive validity. Descriptive statistics were calculated for scale items (means, standard deviation, acceptance, inter-item correlations, corrected item-total correlations, item difficulty) and bivariate analyses (correlations; see Table 2). The maximum likelihood (ML) estimation procedure in Stata 15 software was used to test CFA and SEM, and Satorra–Bentler (SB) model fit measures were used to adjust more robust estimators for our study sample. No missing values were imputed for the final measurement model.

Content validity

The first step was the performance of a CFA with four factors for the entire data set. Factorial validity was verified by factor loadings of the 12 items of the ILS, where loadings ≤.71 were interpreted as excellent, ≤.63 as very good, ≤.55 as good, ≤.45 as fair, and ≤ .32 as poor [31]. The following thresholds were used to determine a good model fit: average variance extracted (AVE) ≥ .5, factor reliability ≥.6, reliability (Cronbach's α) ≥ .7.

Criterion-related validity

It was not feasible in the present study to test convergent validity with a similar validated instrument. Therefore, we analyzed the relationships between the ILS and theoretically related measures in the "inner setting" domain (CFIR). Bivariate analyses of the ILS were examined through organizational innovation climate, social capital

Table 2 Pearson product-moment correlations of Implementation Leadership Scale scores with organizational innovation climate and social capital scores (convergent validity) and workload scores (discriminant validity)

		Pro-active leadership	Knowledgeable leadership	Supportive leadership	Perseverant leadership	ILS total
Convergent validity	Organizational innovation climate	**.311****	**.262****	**.300****	**.479****	**.435****
	Social capital	−.060	.082	**.230****	.104	**.156***
Discriminant validity	Workload	.005	−.040	.051	.020	.065

Note: $n = 198$, *$p < .05$, **$p < .001$

scores (convergent validity), and the workload measure (discriminant validity; see Table 2).

We conducted a path analysis using the ILS and its subscales and the ORIC and its subscales and testing the predictive validity of ILS. Predictive validity was defined as "the ability of a test to measure an event or outcome in the future" [42]. In the path analysis, the higher-order constructs and subconstructs were modeled as latent variables and linked to their associated measurable indicator variables. A series of global goodness-of-fit indices were used to assess the extent to which the observed data were explained by the proposed models: normed χ^2-statistic ($\chi^2/df \leq 3$), comparative fit index (CFI), and Tucker–Lewis index (TLI $\geq .95$: acceptable; TLI $\geq .97$: good), and root mean square error of approximation (RMSEA $\leq .08$: acceptable; RMSEA $\leq .05$: good).

Results

Content validity

Responses to the twelve items of the ILS ranged from 1 (strongly disagree) to 5 (strongly agree), with means ranging from 2.23 (item 1) to 3.62 (item 4) and standard deviations ranging between 0.75 and 1.39 (see Table 1). Most participants assigned a rating in the middle of the scale, with a slight tendency to agree. Internal consistency yielded a four-factor solution with a good Cronbach's $\alpha = .875$ (for factor 1: $\alpha = .774$, for factor 2: $\alpha = .911$, for factor 3: $\alpha = .918$, for factor 4: $\alpha = .842$), and inter-item correlation values ranged from .150 to .785 (for factor 1: $r = .439$ to $-.635$, for factor 2: $r = .693$ to .819, for factor 3: $r = .762$ to .816, for factor 4: $r = .598$ to .692). Overall corrected item-total correlations ranged from .534 to .763. Taking all items into account, more than 97% of the measures were answered. Item difficulty ranged from 44.6 (item 1) to 72.4 (item 4). Prerequisites for the factor analysis were met, as the comprehensibility of the translated scale was checked in cognitive interviews; KMO measure was .832, and Bartlett's test of sphericity yielded a χ^2 value 1447.20 ($p < .001$). This indicates that a factor analysis of the data was appropriate [30]. CFA for the hypothesized four-factor structure of the model demonstrated a good fit, as suggested by multiple goodness-of-fit indicators ($n = 198$; $\chi^2(48) = 84.59$, $p < .001$; CFI = .974; TLI = .965; RMSEA = .062; SRMR = .051). Factor reliability exceeded critical values (factor reliability = .77, .90, .92, and .82, respectively; AVE = .53, .76, .80, and .60, respectively).

CFA was used to reproduce the second-order CFA proposed by Aarons for the original ILS with our sample [23]. Because this analysis could not be performed with our sample, we accounted for the theoretically assumed relationships between the subscales by calculating the covariances and achieved a reasonable model fit ($n = 198$; $p < .001$; $\chi^2(48) = 84.59$, $p < .001$; CFI = .974; TLI = .965; RMSEA = .062; SRMR = .051). Figure 2 provides an overview of the standardized factor loadings and covariances between subscales for the four-factor model. Factor loadings ranged from .59 to .96, and all factor loadings were statistically significant ($p < .001$).

Criterion-related validity

The results of the convergent validity analyses are summarized in Table 2. ILS total score and subscale scores were significantly correlated ($p \leq .001$) with organizational innovation climate, with the correlations ranging from .26 to .48. Supportive leadership was the only ILS subscale that was significantly correlated with social capital scores ($p \leq .01$; $r = .23$). All other ILS subscales individually had no significant correlations, whereas ILS total score was significantly correlated with social capital scores ($p \leq .05$; $r = .15$). ILS total score and subscale scores showed no correlation with workload scores.

Path analysis (SEM) to test predictive validity showed that the ILS total and subscale scores are significantly associated with ORIC total and subscale scores. In the bivariate path models, the influence of knowledgeable leadership on organizational change efficacy is the only one that was not significant, whereas perseverant leadership showed the strongest associations with ORIC (see Table 3).

Discussion

Implementation leadership behavior, as part of the organizational culture and contextual factors that determine implementation outcomes, is important to consider for the successful implementation of EBPs in healthcare organizations. The study of the interrelationships of inherent constructs of this implementation-related research subject requires validated scales in the context of ORIC. The main result of this validation study is that implementation leadership behavior is also empirically a relevant influencing factor determining at the organization-related level. The verified psychometric properties prove that the scale can be used in primary care settings. In addition, as suggested in other studies, we examined the influence of the ILS on multiple organizational factors [23]. To the best of our knowledge, our study is the first to validate and apply the scale to a primary health care context.

Our findings confirmed the four-dimensional structure of ILS, and they are consistent with similar ILS validation studies [26–28]; however, the second-order model could not be estimated in the first measurement model. To account for the theoretically assumed relationships between ILS subscales, we allowed for covariances between subscales. Furthermore, the global fit indices as

Table 3 Bivariate and full model of Implementation Leadership Scale (ILS) scores, subscale scores and organizational readiness for implementing change (ORIC) scores and subscale scores

	Change commitment (ORIC subscale; time 2)					Change efficacy (ORIC subscale; time 2)				
	Standardized Path coefficient (S.E.)	SRMR	RMSEA	CFI	TLI	Standardized Path coefficient (S.E.)	SRMR	RMSEA	CFI	TLI
Pro-active leadership (time 1)	403** (.08)	.047	.091	.975	.963	398** (.08)	.059	.074	.981	.969
Knowledgeable leadership (time 1)	191* (.08)	.049	.105	.973	.960	161 (.08)	.033	.011	1.00	.999
Supportive leadership (time 1)	347** (.08)	.048	.128	.959	.939	486** (.07)	.023	.062	1.00	1.00
Perseverant leadership (time 1)	518** (.07)	.021	.084	.980	.971	506** (.07)	.029	.058	.989	.983
ILS total (time 1)	545** (.08)	.065	.058	.966	.960	629** (.07)	.065	.050	.972	.967

Note: $n = 135$; ILS total = second order model; ILS total (time 1) - > ORIC total (time 2) = .593** (.06), standardized root mean quare residual = .065, root mean square error of approximation =.055, comparative fit index = .968, Tucker-Lewis index = .960, *p <.05, **p <.001

well as the local fit indices underlined the four-dimensional structure. On the basis of the good results of the measurement model, we retested the original second-order ILS model using SEM in the presence of the ORIC scale. On the basis of these calculations, the second-order ILS could be verified and adopted owing to good global and local fit indices (CFI = .968, RMSEA = .05).

Descriptive findings indicate medium agreement values for the ILS's single items and aggregated mean values with a slight tendency toward agreement; this was especially true regarding the knowledgeable leadership dimension. A possible explanation is that the practice owners, as drivers of implementation, are the first actors in the organization to come into contact with the intervention and have also received training in the use of the software. This then leads to a higher rating of their self-assessed knowledge of the intervention and knowledgeable leadership item. Other forms of leadership behavior may not have received as much training or education among PCPs in private practice, and they may not perceive themselves to be in a managerial role in their practice. Such self-perception is indicated by proactive leadership behavior scores, which measure behavior related to managing activities during the implementation process and were below the middle agreement category for both single items and on average.

The analysis of convergent validity provides insights into the relationship of the ILS with other constructs theoretically related to the conceptualization of the inner setting in CFIR. All IL subscale scores showed moderate correlation with organizational innovation climate as an organizational context factor. Although organizational climate has been used in other studies to validate the ILS for discriminant validity, our study showed significant correlations between the constructs [18]. This finding may be related to the fact that the constructs used in other validation studies have been conceptualized differently in comparison with our study, and related items focus on other aspects of organizational climate. In addition, a different conceptual background was chosen for the selection of the constructs in our study by integrating the inner setting description of CFIR. However, a study by Hower et al. (2019) examining the relationship between leadership behavior and innovation climate, as part of the organizational climate construct, confirms our content interpretation and also chose a construct of innovation climate similar to that used in our study [39]. Although the ILS total score and social capital scores also showed a significant correlation, it was only small, as all other ILS subscales showed no correlations with the social capital scores. The significant correlation of the supportive leadership subscale scores with the social capital scale scores was slightly higher than that of the ILS total score and plausible in terms of content because both scales measure aspects of social support within the organization. To select constructs unrelated to the ILS to demonstrate discriminant validity, we used the single item of PCP workload. Although physicians' perceived workload may have been higher owing to additional tasks related to the implementation, our data indicated that PCPs' perceived workload did not affect leadership behavior, and no significant correlations were found.

Criterion-related data analysis showed the predictive validity of leadership for ORIC. The criterion-related analytical approach used in our study was rigorous regarding the temporal element, as the ILS

measurement data were collected prior to the data collection of the ORIC. The PCPs' leadership behavior showed medium to high associations with organizational change commitment and change efficacy. This is consistent with other empirical findings suggesting that leading persons, as change agents, affect team members' willingness to change through their own change behavior [43]. The strongest predictive relationship has been shown between perseverant leadership behavior and commitment to organizational change. One possible explanation is that implementation processes are almost always accompanied by barriers that can only be overcome through perseverant leadership behavior. This behavior in turn has a strong positive influence on organizational commitment and may act as a facilitator in the implementation process. A comparison between the two surveys showed that leadership behavior did not influence the ORIC as strongly over time although the mean values of ORIC remained stable between time points. Over time, other factors may have also influenced the ORIC, for example, seasonal events such as flu outbreaks or the waves of the COVID-19 pandemic, unmet expectations for the project itself, or changes in leadership behavior during implementation.

In the context of the influence of knowledgeable leadership behavior, it is interesting to observe this variable in relation to organizational measurement tools. In the descriptive evaluations, this leadership behavior was rated the highest, whereas the path coefficients of organizational change commitment and organizational change efficacy were only very weakly or not at all associated with the knowledgeable leadership type. One possible explanation for this phenomenon is that the knowledge dimension does not play a relevant role in the social interactions of the organization related to change processes; it may have a considerably greater significance for an individual leader. Another would be that the knowledge dimension may have had a prominent importance in relation to the phase shortly after the decision of adopting the innovation. However, the findings indicate that the knowledge dimension has little to no significance in convincing the PCPs' team members to adopt the intervention. Social skills reflected in supportive leadership behaviors appear to have a stronger impact on organizational team members as personal appreciation for their work is expressed. This seems to be a common paradox in knowledge translation processes and EBP implementation: On the one hand, participants need specific knowledge to apply a new practice. On the other hand, the social processes of the organizational context play an equally important role in acquiring the knowledge in the first place and successfully adopting it into practice. The individual decision to adopt the innovation, in line with leadership behavior, may have had a positive influence on ORIC at the beginning of the intervention [33, 34]. Further research is needed to investigate whether, for example, centralization of decision making by PCPs in the initiation phase may have a positive effect on ORIC and why the influence changes during the implementation process (time 2).

Strengths and limitations

The results presented must be interpreted in light of the methodological limitations. The high path coefficient between ILS and ORIC may indicate that the constructs conceptually overlap although the two instruments assess at different levels of analyses (micro and meso levels, respectively). Additional assessment has shown that the indicators of all subscales of ILS and ORIC are positively correlated with their associated constructs and explain over 50% of the variance in the indicators (AVE). Only two of the IL subscales (proactive leadership and perseverant leadership behavior) and their indicators share variance with ORIC. Discriminant validity is slightly violated in these relationships. For calculating discriminant validity, we used a strict criterion in these analyses; discriminant validity was assumed only if all AVE values are greater than all squared correlations of latent variables with any other latent constructs. With regard to the discriminant validity of the individual subtypes of ILS, good results were obtained in accordance with the threshold values. Recently presented methodological approaches recommend further analyses to investigate discriminant validity [44]. In addition, some of the bivariate path models used to calculate predictive validity showed RMSEA values above the threshold values. We assume that this is owing to the small number of degrees of freedom in these models [45]. The RMSEA values in the full model and in the overview with the other indices have shown good model fit. Furthermore, another limitation of our study that needs to be discussed is the use of self-assessment instruments. These instruments may bias the results, as self-assessment of one's own abilities and behaviors lead to both underestimation and overestimation. There are several methodological approaches to address problems in self-assessment of leader behavior in general (e.g., by examining convergence [i.e., correlation] between leader and observer ratings) or specifically for physicians' self-assessment abilities [46–49]. From a research practice perspective, it is also important to clarify who the appropriate observers are for the behavior being measured and whether access to them is possible. Incentives to participate in our primary formative evaluation study were offered only to participating physicians, as

the intervention primarily involved a physician activity: prescribing medications. We did not include a separate research question about the perspective of practice staff regarding the intervention although our primary data had indicated that physicians involved their staff and delegated tasks related to the use of the software. Therefore, we did not have the possibility to compare the self-assessment with another (external) assessment in our secondary analysis. Despite the limitations that may occur when using self-assessment measurement instruments, data analyses provided us with important information about areas for improvement in the implementation of the intervention and how they are rated by physicians as the main users of the intervention in practice and the main actors in its implementation. In this sense, their self-assessment is of particular importance for our research question [50]. Furthermore, our findings may be specific for primary care settings and should be tested in other settings in Germany to extend the evidence base of a valid and reliable ILS.

Implications for research and practice

Researchers or organizations may apply the present findings to identify areas for improvement in implementation leadership in their healthcare organizations. Particularly in primary care, further research is needed to examine the effectiveness of implementation strategies focusing on leadership development for PCPs. In addition, the study results suggest that it may also be necessary to investigate how and why the distinct types of leadership behaviors have different effects related to the time point in the implementation process. Some evaluation studies have already considered the temporal element [51]. The organizational approach underlying ILS and management theory (especially with regard to the concept of absorptive capacity), as illustrated, views leadership in the change process as a concept oriented toward strategic capabilities [17, 23]. In contrast to the theory, our empirical results suggest that leadership behavior cannot be interpreted exclusively as a strategic capability. Professional self-concepts may also influence self-assessment of leadership behavior, for instance, the salient low ratings of the proactive leadership behavior type or the high ratings of the knowledgeable leadership type [13]. These findings highlight the need to examine the various occupational group-specific patterns of leadership behavior types in healthcare organizations. As the empirical analyses have shown, the distinct types of leadership behaviors have different effects on the investigated organization-related factors. Assuming that the behavior types are also associated with certain skills, it would also be relevant to clarify which skills are particularly important during the implementation process in practice.

Conclusion

The ILS is a brief instrument that can be used in health services research to investigate the effects of leadership behaviors during change processes in healthcare organizations and to evaluate interventions to promote supportive implementation activities by key personnel; however, its sensitivity to temporal elements has not been fully demonstrated. In particular, the confirmed associations of the ILS or its subscales with social capital, innovation climate, and ORIC point to the relevance of implementation leadership behavior as a significant resource in the implementation process of innovations in healthcare organizations.

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Authors' contributions

Sara Söling: Conceptualization, formal analysis, methodology, investigation, writing – original draft; Holger Pfaff: funding acquisition, writing – review

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Availability of data and materials
The datasets generated and analyzed in the current study is not publicly available due to participant consent restricting data use to the research team. With permission of the AdAM consortium partners, represented by the Head of Project Management (BARMER, Wuppertal, Germany) (Petra.Kellermann-Muehlhoff@barmer.de), the data can be made available upon reasonable request.

Declarations

Ethics approval and consent to participate
The study design and evaluation protocol were approved by the ethics committee of the Medical Association of North Rhine (application no. 2017184). No objections were raised to any part of the study. This study processed anonymized data. Participants gave informed consent to participate in the study. All methods were performed in accordance with relevant guidelines and regulations.

Consent for publication
Not applicable.

Competing interests
Prof. Holger Pfaff is a member of the editorial board of BMC Health Services Research. All other authors declare that they have no competing interests.

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Publisher's Note

Appendix iii: Study III (Mixed-Methods Study)

BMC Primary Care

RESEARCH

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Complex implementation mechanisms in primary care: do physicians' beliefs about the effectiveness of innovation play a mediating role? Applying a realist inquiry and structural equation modeling approach in a formative evaluation study

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Abstract

Background The adoption of digital health technologies can improve the quality of care for polypharmacy patients, if the underlying complex implementation mechanisms are better understood. Context effects play a critical role in relation to implementation mechanisms. In primary care research, evidence on the effects of context in the adoption of digital innovation for polypharmacy management is lacking.

Study aim This study aims to identify contextual factors relevant to physician behavior and how they might mediate the adoption process.

Methods The physicians who participated in this formative evaluation study ($n=218$) were part of the intervention group in a cluster-randomized controlled trial (AdAM). The intervention group implemented a digital innovation for clinical decision making in polypharmacy. A three-step methodological approach was used: (1) a realist inquiry approach, which involves the description of a context-mechanism-outcome configuration for the primary care setting; (2) a belief elicitation approach, which involves qualitative content analysis and the development of a quantitative latent contextualized scale; and (3) a mediation analysis using structural equation modeling (SEM) based on quantitative survey data from physicians to assess the mediating role of the contextualized scale ($n=179$).

Results The key dimensions of a (1) context-mechanism-outcome model were mapped and refined. A (2) latent construct of the physicians' innovation beliefs related to the effectiveness of polypharmacy management practices was identified. Innovation beliefs play a (3) mediating role between the organizational readiness to implement change ($p<0.01$) and the desired behavioral intent of physicians to adopt digital innovation ($p<0.01$; $R^2=0.645$). Our contextualized model estimated significant mediation, with a relative size of 38% for the mediation effect. Overall, the model demonstrated good fit indices (CFI = 0.985, RMSEA = 0.034).

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Conclusion Physician adoption is directly affected by the readiness of primary care organizations for the implementation of change. In addition, the mediation analysis revealed that this relationship is indirectly influenced by primary care physicians' beliefs regarding the effectiveness of digital innovation. Both individual physician beliefs and practice organizational capacity could be equally prioritized in developing implementation strategies. The methodological approach used is suitable for the evaluation of complex implementation mechanisms. It has been proven to be an advantageous approach for formative evaluation.

Trial registration NCT03430336. First registration: 12/02/2018. ClinicalTrials.gov.

Keywords Digital technology, Polypharmacy, Primary health care, Clinical reasoning, Diffusion of innovation, Behavior and behavior mechanisms, Realist, Evaluation methodology

Background

The implementation of digital health technologies is expected to improve the quality of care and simplify clinical actions [1]. As an additional outcome, there is evidence that the implementation of digital systems, such as clinical decision support systems, can have a positive impact on patient safety [2–4]. Despite the potential to improve patient outcomes, research on implementation often demonstrates inconsistent effectiveness. This may be related to proximal outcomes of the actual complex implementation behavior during the change processes [5, 6]. The effectiveness of implementing and adopting digital innovations varies considerably across healthcare organizations [7]. Therefore, the underlying mechanisms are of great interest.

Research has already been conducted on a number of technology-related factors, including the interoperability of new technologies with existing practice systems [8], the availability of information on screen versus on paper [6], the compatibility of health IT and clinical work processes [9], and the level of physician involvement in the development of new technologies [5]. However, there is still limited evidence to date on the relationship between the context in which a digital innovation is implemented and its effectiveness [2, 6].

As part of the digital transformation of the German healthcare system, we sought to understand the complex implementation mechanisms that lead to the adoption of a digital innovation for polypharmacy management. Therefore, this formative evaluation study within the cluster-randomized controlled trial (cRCT) project "Application of a Digitally Assisted Pharmacotherapy Management System" (AdAM project—original German acronym for the project), was designed to analyze individual and organizational contextual factors related to implementation mechanisms [10]. A qualitatively described configurational model of context, mechanism, and outcome was developed for our study setting, and the intersection with structural equation modeling (SEM) was explored [11, 12]. In keeping with the realist approach, our study aimed to better understand the effects of contextual features on the implementation behavior of primary care physicians.

Our research questions were the following:

> What are the possible implementation mechanisms by which digital innovation for polypharmacy management results in intended outcomes?
> How and in what context does the digital innovation work for primary care physicians?

Theoretical framework

Although it is important to identify influential technology-related factors to analyze the complex implementation mechanisms of a digital innovation, these factors were not sufficient as explanatory variables for our theoretical framework. In our study design, we define complexity in terms of both the different levels of the social system in which an innovation is implemented and the influences of the context itself. In particular, the interaction of these factors in implementation mechanisms can be considered complex and the results unpredictable.

Therefore, disaggregating the different levels of the social system of primary care organizations was an important prerequisite to make the study of the complexity of implementation mechanisms more manageable for data analysis. In a subsequent step, the disaggregation enabled us to analyze how the inhibiting or facilitating contextual factors at the different levels influence adoption [13]. In particular, at the meso-organizational and micro-behavioral levels, the empirically studied and known implementation factors may have influenced the social system responses of primary care practices [14, 15].

Barriers and facilitators to adoption

Empirically studied implementation barriers and facilitators found in the initial literature search were categorized as follows:

1) Meso level: Research on organizational determinants that affect adoption include numerous topics, such as organizational culture; organizational readiness for change; networks and communication (collaboration and teamwork); resources (financial, education, and training); and leadership [16–20].
2) Micro level: The technology acceptance model (TAM) has been widely used as a research model since the 1980s to study the behavior-related micro-level determinants of adoption during the IT implementation process [21]. TAM is based on an adapted version of the social-cognitive theories of reasoned action (TRA) and planned behavior (TPB). The technology acceptance model measures dimensions of technology-related behavioral aspects, such as ease of use and usefulness, that influence the stakeholders' intentions to use [22]. In particular, the construct of behavioral intentions to use innovation—as the most proximal antecedent to actual information technology (IT) use—intersects with the outcome adoption of the implementation. Intention has been used synonymously in numerous studies to measure adoption [23] and has been demonstrated to be a valid proxy measure for the behavior of physicians [24]. On average, intention can account for 28% of the variance in behavior [25]. The behavioral factors described above, namely intention to use an innovation or adoption of an innovation, are particularly important for the formative evaluation of implementation processes. Contextual behavior-related factors may explain observed variation in implementation effectiveness or influence how clinicians cope with implementation challenges and how they interact with innovation in the health IT adoption process [26, 27].

Context in implementation research: a new approach

In addition to the empirically observed organizational and behavioral determinants, we examined the current state of research on context in implementation research [10, 28, 29]. Implementation research has shown that certain clinical practices are complex in nature (for example, the prescription of multiple drugs). Moreover, the adoption of new and complex practices may be influenced by facilitating or inhibiting contextual features.

Context is defined as "the relational and dynamic features that shape the mechanisms through which the intervention operates; context is assumed to be dynamic and emerge over time at several different levels of the social system" [10, 28]. From an implementation research perspective, empirical research should not only focus on the targeted clinical practice, but also on the contextual features of the implementation. The success of an innovation is inseparably linked to the context in which it is implemented [21].

Advanced empirical research is needed to understand the unresolved causal relationships between the contextual characteristics of implementation and the adoption of new and complex practices [16]. Although implementation science has developed several conceptual models to address contextual complexity [28, 29], these models lack specific methods for conducting empirical research. These findings emphasize the importance of developing new methods of analysis to determine the impact of contextual features on the complex responses of adaptive primary care social systems for three reasons: (1) to explain the emergence of generative mechanisms in implementation, (2) to explain the differences in implementation outcomes, and (3) to be able to develop targeted implementation strategies based on the discovered underlying mechanisms [11].

For this purpose, already confirmed general concepts from implementation and complexity research, health services research, and technology acceptance research can be integrated to generate empirically testable research models [17, 22, 29]. However, research models must also incorporate data-driven concepts adapted to the specific study context to gain new insights and to capture the complexity of context in implementation. In relation to our study objective, we sought to address the above challenges and to apply a novel methodological approach to an example of implementing digital innovation to manage polypharmacy in primary care (see Additional File 1).

Methods

Thus, the paradigm of context in (1) realist approaches is situated scientifically and analytically between positivist and constructivist approaches. The goal is to discover semi-predictable patterns related to contexts, underlying generative mechanisms, and outcomes (CMO), and to develop middle-range theories related to the object of study [10]. We used the formula revised by Dalkin et al. (2015), according to which a mechanism includes both resources and reasons. In addition, we assume a strong connection between context and reasoning (mechanism [resources] + context → mechanism [reasoning] = outcome) [11]. The revised formula suggests an alternative operationalization of context in realist approaches in which "intervention resources are introduced in a context, in a way that enhances a change in reasoning. This alters the behaviour of participants, which leads to outcomes." In this process, we used both the findings from an initial literature review and the results of a qualitative data analysis. The choice of the description of a context-mechanism-outcome configuration for the study setting was the result of an abductive

synthesis process. In addition, the conclusions drawn from that description were used to operationalize the structural equation model.

We then used the (2) belief elicitation approach to develop a contextualized latent scale. This data-driven approach allows the contextualization of behavior-related assumptions for a particular setting, population, or new behavior of interest [19, 22]. In technology acceptance research, the belief elicitation approach is recommended to identify health-related variables from the participants' perspective instead of arbitrarily including variables [22].

Regarding our research questions, we assumed that the (3) structural relations between meso and micro levels in participating primary care organizations should be differentiated in the structural equation model. Two objectives were pursued for empirical investigation: (a) to explain the influence of an organization-related variable on the implementation mechanism and the outcome of implementation (adoption) and (b) to examine the mediating effect of physicians' contextualized innovation beliefs. Relevant constructs were operationalized for different levels of the organization to enable the mediation model to explain the complex implementation pathways. Testable hypotheses were generated based on the different methodological and analytical steps applied.

Data collection and research design

We collected qualitative data (from May to September 2018) and quantitative data (from November 2019 to January 2020) from primary care physicians who participated in the formative evaluation study of the AdAM project. This formative evaluation study was conducted alongside the stepped-wedge, cRCT in AdAM. In the cRCT study protocol, we described the study design of our formative evaluation study, in which we aimed to examine physician-side barriers and facilitators to the implementation process using a mixed methods approach (see Additional File 2) [30].

Interviews with physicians from the intervention group were conducted to determine their experiences with digital innovation (see Additional File 3). Focus groups were conducted with both arms of the RCT. The objective was to compare project-related expectations and experiences according to the participants' cRCT group. All interviews and focus groups were conducted or moderated by the first author of this article (SS). Data were independently coded by two researchers from the University of Cologne's research team. MAXQDA was used to support data coding.

Data from the cross-sectional survey of physicians were used for structural equation modeling. The sample for the survey included all the physicians in the intervention group, who had enrolled at least one patient in the study. To increase the response rate, we used the tailored design approach by Dillman, which means that the physicians were reminded three times to respond to a questionnaire administered by post [31].

We used a sequential and exploratory design. Qualitative data analysis was conducted in an exploratory manner in the first phase of the study to identify categories related to the range of physician expectations and experiences, which were then used in the second phase of the study to develop a quantitative measurement instrument and build a model. In addition, we triangulated the data at the modeling level as the qualitatively developed model was transformed into a quantitative model. The results of the first phase of the study were confirmed in the second phase of the study in an attempt to reduce bias in the interpretation of the results. A meta-inference was generated by merging the inferences from the CMO and the mediation model to provide the final description of the mechanism [32, 33].

Description of the innovation

The digital innovation was implemented in 688 recruited general practices in North Rhine-Westphalia. It was expected to improve prescription quality and safety for adult patients with polypharmacy compared to patients receiving standard care. The innovation included several design components (e.g., a digitalized clinical decision support system for polypharmacy, patient medication history and diagnosis, information about other specialists, training on system use and management, technical support for physicians, and recommendations for prescribing in polypharmacy).

Data analysis

Qualitative data analysis was conducted for two purposes: (1) summarizing content-deductive mapping of the data material with the aim of describing the categories of context, resources, reasoning, and outcome (CMO) and (2) application of the belief elicitation approach through deductive-inductive qualitative content analysis to develop the latent measurement tool of contextual innovation beliefs for the structural equation model (SEM). A content analysis approach was adopted, which incorporated elements of conventional and directed content analysis [34]: conventional because interview data were used to describe the range of physicians' responses to innovation, and directed because the guides for interviews and focus groups were thematically structured and theory-driven, based on the results of the literature review. The content analysis was conducted in a deductive-inductive fashion: it was deductively oriented to the categories of CMO and the interview guides and inductively derived categories from the data material.

The quantitative items were operationalized based on categories identified by the content analysis and inserted into the structural equation model as latent variables with their measurable indicators ($n = 179$). The validity and reliability of the final construct were tested through factor analysis in the structural equation measurement model. We decided to apply SEM because it is particularly useful for mediation analysis and testing relationships between latent constructs, which otherwise remain unobserved or cannot be directly assessed [35, 36]. Structural equation modeling facilitates the analysis of latent constructs through the observed indicators representing the constructs of interest and provides multivariate evidence of causal mechanisms.

A two-stage approach to quantitative data analysis was implemented. In this approach, the measurement model and the structural model were analyzed separately [37]. The measurement model specifies the relationships between latent constructs and observed measures, whereas the structural model specifies the relationships among latent constructs and includes multivariate regression models [35]. The models were analyzed using STATA 15.1, and graphical path models were created. A covariance matrix was utilized as an input, and maximum likelihood with bootstrapped estimators was generated (200 replications). No missing values were inputted. The quality of the measurement model was tested by confirmatory factor analysis (CFA). Convergent validity was established by examining the significance of individual item loadings.

We evaluated model fit using the comparative fit index (CFI) and the Tucker–Lewis index (TLI). The values of CFI and TLI range from 0 to 1, with values from ≥ 0.90 to ≥ 0.95 representing acceptable to good fit [36]. In addition, we examined the root mean square error of approximation (RMSEA) and the associated confidence interval and p value. We considered RMSEA values < 0.08 and an upper bound of the confidence interval < 0.1 to be acceptable [38]. Furthermore, we assessed discriminant validity by comparing the average variance extracted for each construct to the squared correlation between two latent variables at one time point. Estimations of composite reliability and average variance extracted, as well as investigations of internal reliability (Cronbach's alpha), were the last steps of the measurement model analysis.

Hypothesis development: structural equation model

Because structural equation modeling focuses on testing of models of hypothesized theoretical relationships, we synthesized the results of our literature review to select theory-based latent constructs with the findings related to the qualitative configurational model (see Fig. 1) and integrated the data-driven construct developed to build the structural equation model (see Fig. 2).

We chose the construct of organizational readiness for change as an organizational variable at the meso level [17, 18, 39]. Organizational readiness models provide a perspective on the extent to which members of an organization are psychologically and behaviorally prepared to implement organizational change. Technology acceptance models (TAMs) were selected as a micro

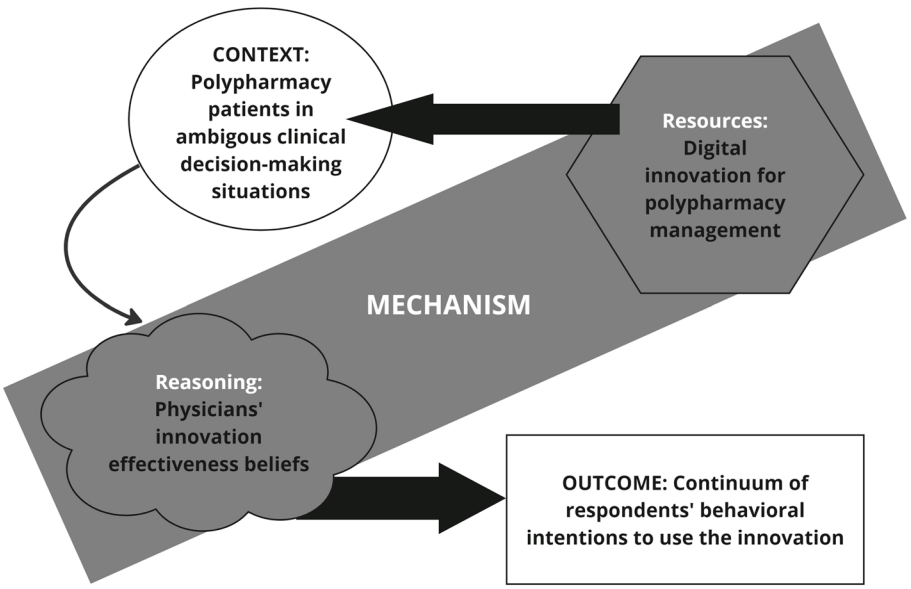

Fig. 1 Context-mechanism-outcome model for physician delivery of digital innovation

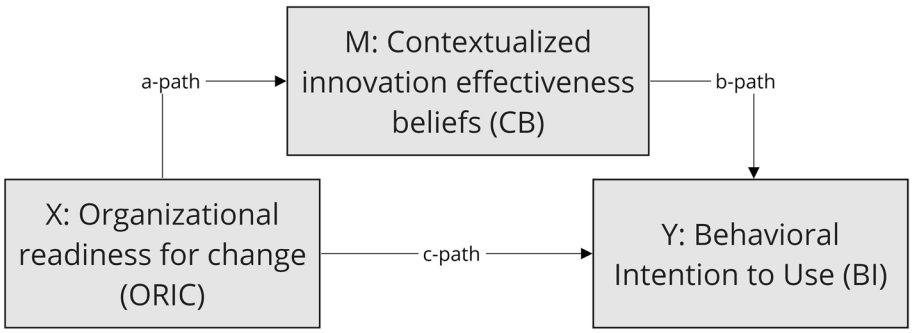

Fig. 2 Mediation model

Note: X = independent variable, M = mediator, and Y = outcome. The indirect effect is estimated as the product of the a- and b-paths (i.e., a*b). The c-path represents the direct effect of X on Y (i.e., the effect of X on Y that is not transmitted through the mediator, M)

level theoretical approach. TAMs focus on attitudes and behavioral intentions to use health IT [22]. With the use of a TAM, we included the intentions/adoption construct in the research, but none of the other constructs that measure other technology-related aspects. Regarding health IT adoption, alternative models suggest that organizational readiness to change can influence the individual level and, thus, the actual usage and adoption [17].

At the meso level, we hypothesized that organizational readiness for change is an important prerequisite to enable physicians to evaluate the effectiveness of innovation (mechanism [reasoning]; meso- and micro-level relations; a-path). This assumption was based on what our previous qualitative analyses demonstrated. For example, the process of patient registration and the groundwork for transferring additional patient data into digital innovation depend on the readiness of the primary care employees. They have to adapt to these changes brought about by the implementation of innovation. Both these tasks are related to organizational readiness and are important prerequisites for activating the part of the mechanism that corresponds to physician reasoning. The primary role of the physician is to make appropriate clinical decisions regarding the prescription of medications for patients with polypharmacy. Contextualized beliefs regarding the effectiveness of innovation consist of several components. These components are important from the pragmatic perspective of physicians in the management of polypharmacy patients in ambiguous clinical decision situations (context → mechanism [reasoning]). We hypothesized that physicians would only perceive the innovation as being effective if it addressed components relevant to the care of polypharmacy patients on a practical level.

Moreover, physicians' strong contextual beliefs increase a positive effect on the intention to use the innovation (b-path). Finally, we assessed whether the hypothesized direct relationship between the organization's readiness to implement innovation and the physician's intention to adopt (c-path) is mediated by the physicians' belief in the effectiveness of innovation.

Our empirical research questions for the mediation analysis are as follows: Do physicians' contextualized beliefs regarding the effectiveness of innovation (micro level) mediate the relationship between primary care organizations' readiness for change (meso level) and physicians' adoption behavior (micro level) during the change process of implementing digital innovation for polypharmacy management? How strong are the direct and indirect effects?

Based on the previous discussion, the following hypotheses are proposed:

H1: Organizational readiness for change has a positive direct effect on behavioral intention to use digital innovation (c-path).
H2: Organizational readiness for change has a positive direct effect on physicians' contextualized innovation effectiveness beliefs (a-path).
H3: Physicians' contextualized innovation effectiveness beliefs have a positive direct effect on behavioral intention to use digital innovation (b-path).
H4: Physicians' contextualized innovation effectiveness beliefs mediate the relations between organizational readiness for change and behavioral intention to use digital innovation.
H5: Physician and structural characteristics have direct and indirect effects on contextualized innovation beliefs and intention to use digital innovation.

Measurement instrument

The data collected in our survey were used to develop the SEM model. The questionnaire was pre-tested in two stages: in think-aloud interviews ($n = 4$) to assess the

comprehensibility of the questions and in a postal sample ($n=10$) to determine whether the filter guidance worked and whether the range of the scales was used. The findings were used to modify the questionnaire into the final version and improve its quality.

Accordingly, the survey included measurement items for each of the models' latent constructs: ORIC (organizational readiness for implementing change) [39], CBs (contextualized innovation effectiveness beliefs), and BI (behavioral intention to use/adoption) [40]. Each of the constructs was measured using multi-item scales.

Physicians answered the organization-related aspects of our questionnaire as key persons of the participating practice. Measurement based on individuals' assessments of collective capabilities is preferable when collective outcomes depend on skillful teamwork [41]. The organization-related instrument ORIC and individual-related instruments CBs and BI had an adequate item structure (items were written from the perspective of the collective for the organization-related instrument and from the perspective of the individual for individual-related instruments). For all measurement instruments, data were not aggregated at the cluster level because nearly all physicians in our sample were solo practice owners and did not work in group practices (cluster level).

Measurements: organizational readiness for implementing change (ORIC) (X)

The nine items used to measure ORIC are adapted from Shea et al. and the validated German version [39, 42]. The scale measures the extent to which members in an organization are psychologically and behaviorally prepared to implement organizational change (e.g., with items such as "People who work here are committed to implementing contents of the AdAM project" or "Challenges may arise in the implementation of the contents of the AdAM project. The people who work here are confident that they can overcome them") [42].

Measurements: contextualized innovation effectiveness beliefs (mediator)

Following the realist research approach, the items of the CB construct were developed to measure different components of beliefs regarding the effectiveness of innovation. The empirically observed influence of the context on the reasoning process from the qualitative analyses was included in the scale. The construct includes six items related to three components of physicians' contextualized beliefs related to polypharmacy management practices: (1) *safety of the prescription*: the perceived increase in awareness of prescription risks of polypharmacy and the transfer of newly gained knowledge about multimedication to other patients in the medical practice; (2) *information quality:* the perceived increase in information quality related to polypharmacy risk and adverse effect analyses; and (3) *communication:* the perceived improvement in doctor–patient communication (Cronbach's $\alpha=0.86$) (see Additional File 4).

Measurements: behavioral intention to use (BI) (Y)

Three items are used to measure the behavioral intention to use technology for routinely performed and future work tasks ("I routinely use digital innovation for my work with polypharmacy patients," "I would like to continue to use digital innovation for my work," "I have performed many of the routine tasks for my polypharmacy patients with the help of digital innovation"). In particular, we used a BI scale, which was validated, translated into German, and checked for reliability [40]. As described in the introduction, following other studies that measured behavioral intentions or adoption, we used the construct as an implementation outcome [23]. For all measures, the physicians could respond to items on a five-point Likert scale.

Measurements: covariates

Physician characteristics and structural factors were included as covariates. Physician characteristics included age, gender, and work experience in ambulatory care in full years. Age was categorized into three groups (<50 years, >50 years, and >60 years). Gender was dichotomized into male and female (because no answer was provided in the "diverse" category). Structural factors included the position within the primary care organization (i.e., practice owner or employee) and the regional location of the primary care organization (located in a rural or urban area).

Results

Qualitative data

The initial qualitative data collection of the evaluation study was conducted with 27 physicians, of whom 15 were in the intervention group and 12 were in the waitlist control group. A brief summary of the qualitative findings is provided as an overview; details of the qualitative data collection and the COREQ checklist used have been published elsewhere [43, 44].

Different behavior-related outcomes were identified: sensitization to risks related to polypharmacy; perceived changes of interdisciplinary and doctor–patient cooperation and communication; and learning effects through using the digital tool. The findings from the two RCT arms were similar in terms of physicians' awareness of high-risk prescription scenarios with polypharmacy and reflections on changes in professional responsibilities when using digital support for decision making.

Qualitative findings were synthesized to describe three different scenarios of simple and complex pathways, which have been differentiated paradigmatically with increasing complexity. The main findings of the qualitative study were captured in the qualitative model, and three relevant themes (prescription safety, information quality, and communication) were selected to operationalize the construct of contextual beliefs, which we predicted would have a significant impact on the main mechanism in the mediation model.

Descriptive statistics

Three hundred nineteen physicians who fulfilled the inclusion criteria were contacted. The final sample for our SEM research model included 179 physicians with complete data in all variables of interest, out of a total of 218 physicians (response rate of 68%) (see Table 1). The vast majority of participating physicians in the study were men (65%) between 50 and 60 years of age. The participants had an average working experience of 17 years (see Table 1). The study population represents the potentially includable population of primary care physicians in the region where the intervention was implemented in terms of the distribution of gender and age. The patient enrollment ratio averaged 59.97, indicating that physicians used the application for polypharmacy management for an average of 60% of the proposed patients.

Table 1 Descriptive statistics

Physician survey respondents (*n* = 218)	
	Mean or proportion of sample
Sociodemographic variables	
Gender	
Female	35%
Male	65%
Age	
< 50 (y)	29%
50–60 (y)	46%
> 60 (y)	25%
Physician work experience (y)	17.03 (SD: 9.11)
Structural variables	
Practice type	
Practice owner	92%
Employee physician	8%
Practice location (region)	
< 10.000 (i)	23%
> 10.000 (i)	19%
> 20.000 (i)	34%
> 100.000 (i)	24%

y years, *SD* standard deviation, *i* = inhabitants

Psychometric properties of the measurement analysis

To test for unidimensionality, exploratory factor analyses of the individual construct items and their Cronbach alpha reliabilities were first examined. The results of these analyses revealed that all scale items associated with a given construct or subconstruct loaded highly (> 0.70) on a single factor. One item from the behavioral intention to use construct violated this threshold slightly (0.56), and it also demonstrated loadings on a subconstruct of the contextualized beliefs, although these were weak (0.27). As a result, the final items were analyzed in the measurement model (MM) using CFA. Validation of the MM was performed by examining discriminant and convergent validity and reliability. The results indicated that the values for factor loadings and average variance extracted (AVE) were above recommended thresholds (> 0.5), with the value of the context-specific construct lying slightly below the cutoff. The composite reliability of each factor was above the threshold of 0.7, as were the internal reliability values (Cronbach's alpha > 0.7). Discriminant validity was assessed by calculating squared correlations of latent variables with any other latent constructs. Discriminant validity was assumed only if all AVE values were greater than square correlations of latent variables. Recommended cutoff values for fit indices supporting MM used in SEM are presented in Additional File 5.

Structural equation modeling: hypothesis testing

The results presented in Table 2 correspond to the SEM in Fig. 3 and meet the requirements for mediation analysis. Organizational readiness for change is significantly associated with behavioral intention to use innovation (c-path) and physicians' contextualized beliefs (a-path), and contextualized innovation effectiveness beliefs are significantly associated with behavioral intentions (b-path). The table compares the main statistical measures with and without the addition of covariates. After including the covariates, the effect measures changed slightly, with the largest difference in the b-path. In total, 65% of variance in BI is explained by CBs and ORIC ($R^2 = 0.645$).

Overall, the results demonstrate that the hypotheses (H1–H4) and the path model can be validated as a result of good global and local fit indices (CFI = 0.985, RMSEA = 0.034). From the results, it can be inferred that the proportion of the total effect for the outcome behavioral intention or adoption mediated by physicians' contextualized beliefs is 0.38%, and the ratio of the indirect effect to the direct effect is 0.62, or approximately $\frac{3}{5}$ of the direct effect (H1). Physician and structural characteristics had no effect despite the regional variable (H5).

Table 2 Standardized estimates of structural equation modeling

Path (a – c)	Direct effect	Indirect effect	Total effect
Path a:			
Organizational Readiness (ORIC) – > Contextualized beliefs (CB)	**0.560**** [CI: 0.25 – 0.69]	N/A	**0.560**** [CI: 0.25 – 0.69]
Std. Error	0.112		0.112
Path a (with covariates):			
Organizational Readiness (ORIC) – > Contextualized beliefs (CB)	**0.548**** [CI: 0.24 – 0.64]	N/A	**0.548**** [CI: 0.24 – 0.64]
Std. Error	0.103		0.103
Path b:			
Contextualized beliefs (CB) – > Behavioral Intention (BI)	**0.510**** [CI: 0.23 – 0.90]	N/A	**0.510**** [CI: 0.23 – 0.90]
Std. Error	0.169		0.169
Path b (with covariates):			
Contextualized beliefs (CB) – > Behavioral Intention (BI)	**0.478**** [CI: 0.25 – 0.92]	N/A	**0.478**** [CI: 0.25 – 0.92]
Std. Error	0.170		0.170
Path c:			
Organizational Readiness (ORIC) – > Behavioral Intention (BI)	**0.388**** [CI: 0.14 – 0.58]	**0.286**** [CI: 0.10 – 0.43]	**0.674**** [CI: 0.48 – 0.78]
Std. Error	0.114	0.082	0.077
Path c (with covariates):			
Organizational Readiness (ORIC) – > Behavioral Intention (BI)	**0.419**** [CI: 0.18 – 0.65]	**0.262**** [CI: 0.10 – 0.41]	**0.681**** [CI: 0.49 – 0.87]
Std. Error	0.118	0.079	0.097
Covariates			
Age < 50[a]	-0.075	-0.031	-0.106
Age > 50[a]	0.006	0.047	0.054
Gender	-0.054	0.017	-0.036
Length of PCP experience (Years)	0.004	0.027	0.031
Structural: Practice owner[b]	-0.040	-0.007	-0.048
Structural: Urban areac (GP practice)	0.068	0.068	**0.137***

Model Fit Statistics: CFI = 0.985; TLI = 0.981; RMSEA = 0.034.; SRMR = 0.055 (with covariates)

Total effects is the sum of direct and indirect effects; Indirect effects are the product of the regression coefficient leading to the outcome. For example, for CB, ORIC predicts CB and CB predicts BI. The indirect effect equals the product of the two regression coefficients from path a * path b

Effects of covariates relate to M and Y

** Statistically Significant ($p < 0.01$)

* Statistically Significant ($p < 0.05$)

[a] Compared to Age > 60

[b] Compared to employed primary care physicans (PCP)

[c] Compared to rural area

Discussion

Our overarching research objective was to examine complex implementation mechanisms that may explain variations in behavior-related outcomes, such as the adoption of innovation. To this end, we examined the relations between the three meso- and micro-level factors, organizational readiness for change, contextualized innovation effectiveness beliefs, and adoption. The findings indicate that an organizationally triggered mechanism lead to the adoption of innovation. The study further demonstrates how contextualized innovation beliefs function within the mechanism, which contributes to a broader understanding of the mechanism.

The empirical findings of this study contribute to the literature on realist evaluation research, organizational change, and the study of implementation mechanisms [45, 46]. The notion that physicians' beliefs about the expected effective impact of digital innovation is critical to their intentions to adopt innovations is supported by the mediation effect highlighted in this study. Physicians' perceptions of the effectiveness of digital innovation can actually enhance the impact of organizational readiness for change on innovation adoption. The inference from the indirect effect further supports that implementation strategies of primary care organizations that are not currently using digital innovations for polypharmacy management would benefit from addressing physicians' beliefs about the effectiveness of the innovation [46].

Regarding the last hypothesis, the control factors had no direct or indirect effects and only the regional

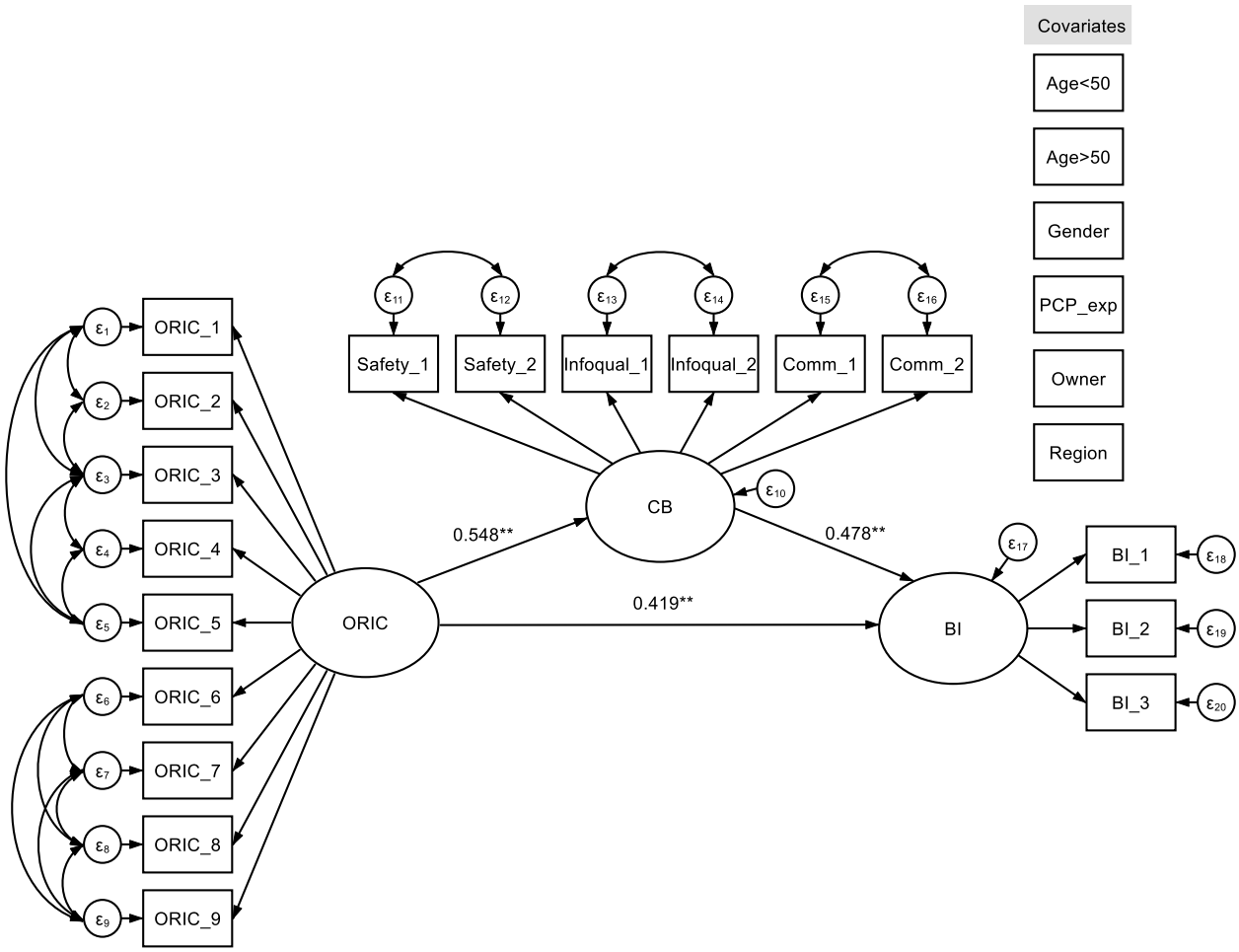

Fig. 3 Structural equation model. Note: See Table 2 for all effect measures; see Additional File 5 for all factor loadings of the measurable indicators on the latent constructs. Error terms omitted for visualization purposes. ORIC = organizational readiness for implementing change; CB = contextualized innovation effectiveness beliefs; BI = behavioral intention/adoption; PCP exp = primary care physicians' working experience (years)

variable exhibited minor effects. The results indicate that the implementation of digital innovation in urban or rural physician practices is significant. We can derive one possible explanation for this from our qualitative data collection; compared to physicians from rural areas, physicians from urban areas report that they are less knowledgeable about the medical histories and medications of some of their patients, because they see some patients only briefly. Therefore, it is more likely that they will expect additional benefit from using a digital innovation that provides patient-relevant information.

In this paper, we presented a novel approach to SEM mediation analysis that integrates qualitative findings from a context-mechanism-outcome configuration (realist inquiry) and a data-driven latent construct. In addition, the synergistic effects of the two analytic approaches of realist evaluation and SEM were explored. To the best of our knowledge and compared to previous studies in the field of polypharmacy management research [47–49], this study is the first to address the underlying mechanisms in the change process of implementing digital innovation for polypharmacy management in primary care. We achieved a broader understanding of the processes and relations between the micro and meso levels and the effects on physician adoption behavior.

The current state of research on polypharmacy indicates that there is an urgent worldwide need to simplify the complex clinical practice of polypharmacy management, because an increasing number of elderly and multimorbid patients will be affected by polypharmacy, and the workload of primary care physicians who care for these patients with complex medication regimens will increase [1, 47]. Hence, digital solutions that meet the physicians' needs and are regarded by them as effective tools for patient care are being sought.

Practical implications

At the time of data collection, the physicians were using digital innovation for approximately 60% of the patients who could potentially derive benefit from it. This indicates that the application was not yet fully implemented. This observation may have practical implications for developing implementation strategies for respondents who have not used digital innovation actively, have only used it infrequently, or have not even begun implementing it. Insights into the specific beliefs about the effectiveness of the innovation allow inferences to refine the initial qualitative model of the configuration of context, mechanism, and outcome (see Fig. 1) based on the empirical findings. A middle-range theory of the main complex implementation mechanism in our study setting may be described as follows:

The employees of primary health care organizations should be encouraged to develop a high readiness for change and to be prepared to perform new tasks. Innovation developers must understand which topics are relevant from the physicians' perspective, so that the physicians will perceive innovation as effective and adopt it (mechanism [reasoning] → outcome). Physicians need digital innovation that sensitizes them to the risks of polypharmacy, creates a learning effect, and provides valuable and helpful information for practice (mechanism [resources]). Beyond that, digital innovation must serve to reassure and support clinicians in ambiguous decision and communication situations with polypharmacy patients, when (de-) prescribing medications (context → mechanism [reasoning]). Organizations or researchers can use these findings to adapt primary care digital innovation and implementation strategies to improve digital health technology adoption (context → mechanism [reasoning + resources] → outcome) for polypharmacy management [50].

Strengths and limitations

The sample consisted of primary care physicians who implemented digital innovation for polypharmacy management. Only physicians who had participated in the study between 2018 and 2020 and were part of the intervention group during that period were included in the data analyses. It is likely that physicians recruited for the study at a later date had different initial conditions, because technical problems had been resolved and better communication strategies had been developed. Non-participation in the survey could be ascribed to physicians not using digital innovation regularly at the time of data collection and, therefore, being unable to provide responses.

The inferences drawn from the two strands of qualitative and quantitative data analysis were merged to create a comprehensive understanding of the digital innovation implementation process. The application of the modified methodological approach in this study enabled us to integrate the interdisciplinary evidence on the topic of contextual influences on change processes through realist evaluation. We then explored the intersection with a quantitative analysis method that uses a theory-based confirmatory approach to examine statistical relationships (SEM) [12].

The methodological synergy effects are particularly reflected in the development of the contextual measurement instrument, in which the findings of the qualitative content analysis and CMO were integrated. Furthermore, the directions of the effects and relationships of the micro and meso levels and the corresponding measurement instruments were determined on this basis and confirmed in the mediation model. As explained in the previous section, our analyses indicate reasonable reliability as well as the convergent and discriminant validity of the measurement instruments used in this study. In addition, the requirements for mediation analysis were met. Therefore, we argue that our study provides a robust methodological basis to confirm semi-predictable patterns between contexts, underlying generative mechanisms, and outcomes in primary care settings. Future studies should plan their study design accordingly to conduct more advanced, strictly quantitative mediation analyses. In the present study design, the focus was on the triangulation of the different models in the two study phases. To minimize bias, we sequentially analyzed qualitative and quantitative data and confirmed the assumptions made in the first study phase with the findings of the second phase [33]. In addition, we emphasized the methodological approach of realist inquiry and interpreted the theory-building assumptions in this framework.

Conclusion

Implementation research indicates inconsistent implementation effectiveness, possibly related to the proximal outcomes of the actual implementation behavior during the change processes. This study explored the underlying mechanisms. Empirical confirmation of contextual mechanisms expands the theories regarding the functioning of mechanisms triggered by the implementation of digital health technology. In addition, this study confirms that organizational readiness for change has a direct effect on physician adoption behavior. However, this relationship is indirectly affected by individual beliefs regarding the effectiveness of the innovation.

The adoption behavior of primary care physicians correlates strongly with the degree of meso-level readiness to implement change, as well as with the extent to which physicians view the digital innovation as beneficial to

their work. Innovation beliefs are related to three subdimensions that pertain to the extent to which the use of digital innovations is perceived as effective: (1) to improve patient safety, (2) to improve clinical decision-making during the course of risk and interaction analysis, and (3) to improve communication regarding the management of polypharmacy for patients in the context of ambiguous decision situations.

To the best of our knowledge, this is the first study to provide new insights into in-depth local needs assessment. The adoption of digital innovations for polypharmacy management in primary care organizations can be improved by tailoring implementation strategies accordingly. Our findings contribute to the understanding of the underlying mechanisms and complex adaptive processes of social systems that operate in a primary care setting. Therefore, our approach provides methodological insights into realist evaluation and contributes to current research that seeks to illustrate the complex contextual pathways and their effect on implementation outcomes [10, 11].

Abbreviations

AdAM	Application of a digitally assisted pharmacotherapy management system (original German acronym for the c-RCT project)
AVE	Average variance extracted
BI	Behavioral intention to use/adoption
CB	Contextualized innovation effectiveness beliefs
CFI	Comparative fit index
CFIR	Consolidated framework of implementation research
CMOc	Context – mechanism – outcome configuration
c-RCT	Cluster-randomized controlled trial
IT	Information technology
MM	Measurement model
ORIC	Organizational readiness for implementing change
RMSEA	Root mean square error of approximation
SEM	Structural equation model
TAM	Technology acceptance model
TLI	Tucker – Lewis index
TPB	Theory of planned behavior
TRA	Theory of reasoned action

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12875-023-02081-x.

Additional file 1. Flow diagram of the study.

Additional file 2. Study protocol section of the formative evaluation study.

Additional file 3. Interview guide.

Additional file 4. Contextualized innovation effectiveness beliefs scale (CB).

Additional file 5. Construct reliability of measuring instruments.

Additional file 6. AdAM Study Group.

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AdAM Study Group
See Supplementary Information (Additional File 6) for the complete list of AdAM Study Group members.

Authors' contributions
SS drafted the manuscript and developed interview guides and questionnaires, supported by UK's knowledge. KIH contributed to the formal analysis. JKN provided conceptual input. BSM critically commented on the manuscript. SS performed the qualitative and quantitative data collection and analyses, developed structural equation models and interpreted data with methodical input from ID. UK and HP revised the first version of the manuscript and contributed to the initial planning and discussion. All authors read and approved the final manuscript.

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Availability of data and materials
The datasets generated and analyzed during the current study are not publicly available due to participant consent restricting data use to the research team but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
Study design and evaluation protocol were approved by the North Rhine Medical Association's ethics committee (application no. 2017184). No objections were raised to any part of the study. This study processed anonymized data. Participants gave informed consent to participate in the study. All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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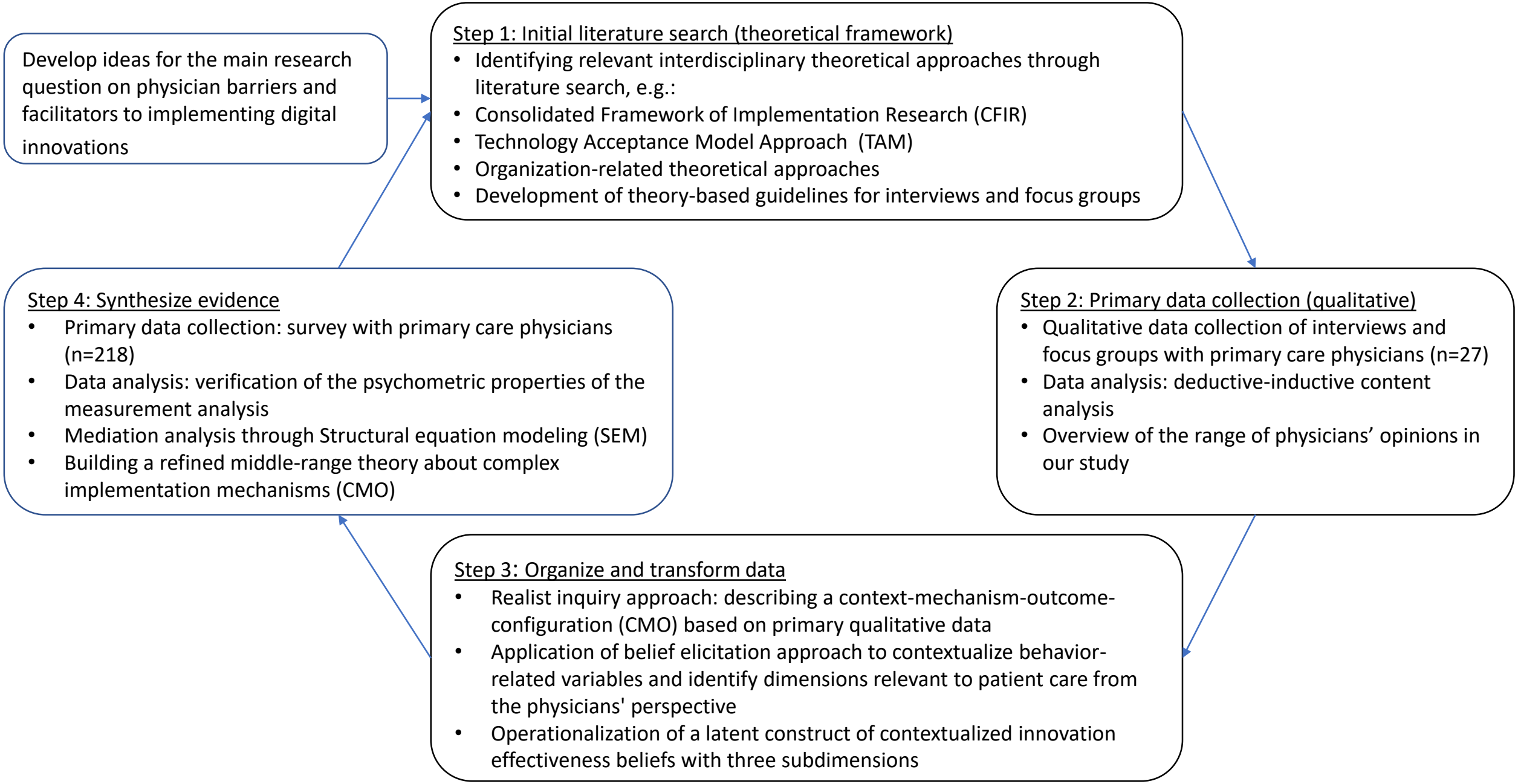
Publisher's Note

Additional File 1. Flow diagram of the study



Additional File 2

Study protocol section of the formative evaluation study. Analysis of barriers and facilitators: Qualitative Interviews, Focus Groups and Survey with Physicians, in:

Müller BS, Klaaßen-Mielke R, Gonzalez-Gonzalez AI, Grandt D, Hammerschmidt R, Köberlein-Neu J, Kellermann-Mühlhoff P, Trampisch HJ, Beckmann T, Düvel L, Surmann B, Flaig B, Ihle P, Söling S, Grandt S, Dinh TS, Piotrowski A, Meyer I, Karbach U, Harder S, Perera R, Glasziou P, Pfaff H, Greiner W, Gerlach FM, Timmesfeld N, Muth C. (2021). Effectiveness of the application of an electronic medication management support system in patients with polypharmacy in general practice: a study protocol of cluster-randomised controlled trial (AdAM). BMJ open, 11(9), e048191.

The aim of this sub-study is to identify factors facilitating or hindering the successful implementation of the intervention from a general practitioner's point of view and evaluate which factors facilitate or hinder the effective performance of systematic medication-checks and optimization. Hereby is expected to get insights how the intervention can be optimized and adapted for general practitioners' high-level acceptance and effectiveness of optimized medication-checks by area-wide implementation. Therefore, a multistage mixed-methods-Approach will be conducted (combination of qualitative and quantitative outcomes) (1).

Level 1: To analyze general practitioners subjectively perceived barriers and resources regarding implementation, guided expert-interviews will be conducted (n= 5-10) (face-to-face-interviews or telephone-interviews) (2,3) to explore the field. Therefore, a convenient sample strategy will be applied. Furthermore, formative evaluation will take part during the trial with two additional time points of qualitative data collection related to relevant emerging topics concerning successful implementation.
Level 2: Results of qualitative data collection will be used for understanding practical orientation patterns of general practitioners (how do they actually use AdAM in real life settings) and their conjunctive experiential space (4). Focus groups with general practitioners of intervention and control group (total, n= 4) will be conducted concerning their experiences and expectations of the project.
Level 3: Results of qualitative data collection will be used to prepare a quantitative general practitioners survey, in which all participating physicians of the intervention group will be asked about barriers and facilitators of the implementation. The survey aims representative detection of general practitioners factors, which facilitate or hinder implementation and identify specific attributes of 'early adapters' and 'late adapters' (5). Quantitative data will be evaluated descriptive and by applying appropriate multiple regression models.
The quality of the qualitative research data collection and analysis in interviews and focus groups is assured by audio recording as well as by transcription according to established standards and by independent coding and subsequent interpretation by a group of researchers. Data analysis will comprise qualitative content analysis according to Kuckartz (6). Quality assurance concerning the survey conduct is assured by standards of survey development, pretesting, Dillman's Total Design (7) method for increasing response rates and data preparation with the Teleform® software.

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Additional File 3. Interview Guide.

Themes	Key question	Follow-up question
Polypharmacy care situation	Ath the beginning of the interview, I would like you to ask you to tell me how good patient care can be provided to multimorbid patients with polypharmacy.	a) Please describe a situation with a patient in which the patient's multimedication care was well managed. b) Please explain what you think were the reasons you were able to provide good care.
	Please describe what poor quality patient care looks like for multimorbid patients with polypharmacy.	a) Please describe a situation with a patient in which the patient's multimedication care was less well managed. b) Please explain what you think were the reasons you were not able to provide good care. c) What are some other barriers to good patient care?
	How do you document multimedication in your practice or what is documented?	a) Please describe how the documentation of a patient's multimedication is done in your practice and who is involved (e.g., practice staff) and how the documentation is done (e.g., by computer, by hand).
AdAM	We are particularly interested in the implementation of AdAM in your practice. Please tell us about the extent to which you have been able to integrate AdAM into your daily work with the resources available in your practice.	a) How do you think AdAM can improve the care situation? b) What motivated you to participate in AdAM and what were your expectations for the project? c) To what extent did your practice's technical equipment influence your decision to participate? d) To what extent did the per-patient payment affect participation?
	Please share what topics you have discussed with your recent AdAM patients.	a) How did you explain AdAM to your patients and how did they accept it? b) How do you discuss prescribing new medications or discontinuing medications with your patients in AdAM and how do they respond?
	We are interested in how AdAM has changed the framework of care for multimorbid patients in your practice. Please describe to what extent AdAM has contributed to the change in the care situation.	a) To what extent do you use pharmaceutical information provided by AdAM to make decisions about prescribing or discontinuing medications? b) To what extent do you use the ability to share information about your patient's co-treatment with physician colleagues that AdAM provides to you when making decisions about prescriptions or discontinuing medications? c) How do you handle recommendations and alerts from AdAM? d) In your opinion, to what extent should AdAM be changed to improve patient care?
At the end of the interview, I would like to ask you if there is anything on this topic in general that is important from your point of view.		

Additional File 4

Contextualized innovation effectiveness beliefs scale (CB)

Item no.		Dimension
1	I think using the [name of digital innovation] has made me more aware of the risks of polypharmacy.	
2	I think that by using [name of digital innovation], I will be able to transfer my newly acquired knowledge about polypharmacy to other patients in this primary care organization.	*Prescription Safety*
	What information about your polypharmacy patients provided by [digital innovation name] has been most helpful to you in patient care?	*Information Quality*
3	a. Risk analysis information	
4	b. Side effect analysis information	
5	Using [name of digital innovation] in our primary care organization improves communication with my polypharmacy patients.	*Communication*
6	By using [name of digital innovation] in our primary care organization, I can better explain to my polypharmacy patients why their medications should be discontinued or switched.	

Note: For all measures, physicians were able to respond to items on a five-point Likert scale.

Additional File 5. Construct reliability of measuring instruments

Constructs	Mean (SD)	AVE	CR	Items	Factor Loading
Organizational Readiness for Implementing Change (ORIC)	3.17 (1.03)	0.759	0.967		
				ORIC1	.790
				ORIC2	.828
				ORIC3	.854
				ORIC4	.874
				ORIC5	.870
				ORIC6	.814
				ORIC7	.807
				ORIC8	.830
				ORIC9	.885
Contextualized innovation effectiveness beliefs (CB)	3.36 (.94)	0.490	0.842		
				CB1	.545
				CB2	.648
				CB3	.624
				CB4	.614
				CB5	.708
				CB6	.757
Behavioral Intention (BI)/ Adoption	2.43 (.91)	0.620	0.832		
				BI1	.808
				BI2	.809
				BI3	.741

For all measures physicians could respond items on a five-point Likert scale from 1 (strongly disagree) to 5 (strongly agree).

Appendix 4: Declaration of an oath (dt. Eidesstattliche Erklärung)

Hiermit an Eides statt, dass ich die vorgelegte Dissertationsschrift selbstständig und ohne die Benutzung anderer als der angegebenen Hilfsmittel angefertigt habe. Alle Stellen - einschließlich Tabellen, Karten und Abbildungen -, die wörtlich oder sinngemäß anderen Werken im Wortlaut oder dem Sinn nach entnommen sind, in jedem Einzelfall als Entlehnung kenntlich gemacht habe. Ich versichere an Eides statt, dass diese Dissertationsschrift noch keiner anderen Fakultät oder Universität zur Prüfung vorgelegt hat; dass sie – abgesehen von unten angegebenen Teilpublikationen – noch nicht veröffentlicht worden ist sowi, dass ich eine solche Veröffentlichung vor Abschluss der Promotion nicht ohne Genehmigung der/des Vorsitzenden des IPHS-Promotionsausschusses vornehmen werde. Die Bestimmungen dieser Ordnung sind mir bekannt. Hinsichtlich der Erstellung der Manuskripte habe ich Unterstützung von den in den Originalarbeiten als Koautoren/innen genannten Personen erhalten (siehe CRediT authorship contribution statement). Die von mir vorgelegte Dissertation ist von Prof. Dr. Holger Pfaff betreut worden.

Darüber hinaus erkläre ich hiermit, dass ich die Ordnung zur Sicherung guter wissenschaftlicher Praxis und zum Umgang mit wissenschaftlichem Fehlverhalten der Universität zu Köln gelesen und sie bei der Durchführung der Dissertation beachtet habe und verpflichte mich hiermit, die dort genannten Vorgaben bei allen wissenschaftlichen Tätigkeiten zu beachten und umzusetzen.

Übersicht der Publikationen

1. Söling S, Köberlein-Neu J, Müller B S, Dinh T S, Muth C, Pfaff H, Karbach U (2020). From sensitization to adoption? A qualitative study of the implementation of a digitally supported intervention for clinical decision making in polypharmacy. Implementation Science, 15, 1-12. doi: 10.1186/s13012-020- 01043-6.
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Ich versichere, dass ich alle Angaben wahrheitsgemäß nach bestem Wissen und Gewissen gemacht habe und verpflichte mich, jedmögliche, die obigen Angaben betreffenden Veränderungen, dem IPHS-Promotionsausschuss unverzüglich mitzuteilen.

11.02.2025	Sara Söling
…….	…….
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