Factors for Successful Implementation of a Preventive Counseling Program in Routine Prenatal Care in Germany – a Process Evaluation

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The studies reported on in this dissertation were conducted within the *GeMuKi* project (Gemeinsam gesund: Vorsorge plus für Mutter und Kind; Strengthening Health Promotion: Enhanced Check-up Visits for Mother and Child). The project was funded by a grant from the Innovation Fund of the German Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA), Module 3: Improving Communication with Patients and Promoting Health Literacy (Grant number: 01NVF17014).

Zusammenfassung

Hintergrund: Übergewicht und Adipositas sind ein wichtiges Public Health Problem und Risikofaktoren für Folgeerkrankungen sowohl bei Kindern als auch bei Erwachsenen. Es besteht ein dringender Bedarf an wirksamen präventiven Maßnahmen und an geeigneten Settings, in denen diese eine breite Öffentlichkeit erreichen. Forschungen zur perinatalen Programmierung zeigen, dass der Lebensstil der Mutter während der Schwangerschaft das Risiko für Schwangerschafts- und Geburtskomplikationen sowie das Risiko für Übergewicht und chronische Krankheiten bei Kindern langfristig beeinflusst. Studien belegen, dass eine Lebensstilberatung während der Schwangerschaft wirksam zur Verbesserung der Gesundheit von Müttern und Kindern beitragen kann. In Deutschland werden Lebensstilthemen jedoch nicht konsistent im Rahmen der regelmäßigen Schwangerenvorsorge besprochen.

Methoden: Die GeMuKi Intervention erweitert die gesetzlichen Vorsorgeuntersuchungen während der Schwangerschaft um präventive Lebensstilberatungen. Mit der Unterstützung einer digitalen Gesundheitsplattform führen Frauenärzt:innen und Hebammen in verschiedenen Regionen des süddeutschen Bundeslandes Baden-Württemberg eine Lebensstilberatung mit Elementen der Motivierenden Gesprächsführung durch.

Begleitend zur Wirksamkeitsevaluation, wird eine Prozessevaluation durchgeführt, um förderliche und hemmende Faktoren für die Implementierung zu identifizieren, und um zu untersuchen, inwieweit die Intervention wie geplant umgesetzt wird.

Die vorliegende kumulative Dissertation adressiert diese Ziele anhand von drei Studien (Studien I-III) sowie ergänzenden Daten, die den Implementierungsprozess in verschiedenen Phasen analysieren. Vor dem Hintergrund verschiedener theoretischer Konzepte, wird eine Kombination aus quantitativen und qualitativen Forschungsmethoden genutzt, um den Implementierungsprozess aus verschiedenen Perspektiven zu erfassen und zu verstehen. Unterschiedliche Fragebögen (n=401; n=46) und administrative Daten wurden mit Hilfe der deskriptiven Statistik ausgewertet, während semistrukturierte Interviews mit dem GeMuKi-Rekrutierungspersonal (n=6), multiprofessionellen Leistungserbringern (n=13) und schwangeren Frauen (n=12) sowie weiteres Textmaterial wie Beobachtungsprotokolle (n=29) und interne Projektdokumente (n=99) mit Hilfe der qualitativen Inhaltsanalyse analysiert wurden.

Ergebnisse: Die routinemäßigen gesetzlichen Vorsorgeuntersuchungen während der Schwangerschaft erwiesen sich als geeignetes Setting um Lebensstilthemen zu adressieren. Sowohl Schwangere als auch Leistungserbringer äußerten das Bedürfnis, Lebensstilthemen zu besprechen. Intrinsische Motivation und persönliches Interesse an den Themen Ernährung, Bewegung und Übergewicht/Adipositas förderten die Implementierung, da sie für eine aktive Teilnahme der Leistungserbringer entscheidend waren. Ein weiterer förderlicher Faktor war die flexible Aufgabenteilung zwischen Frauenärzt:innen und medizinischen Fachangestellten. Ein zentraler hinderlicher Faktor für die Implementierung war der Zeitmangel im Praxisalltag aufgrund vieler anderer Aufgaben im Zusammenhang mit der Routineversorgung. Nicht alle Komponenten der Intervention konnten wie vorgesehen umgesetzt werden. Während beispielsweise die Auswahl der Beratungsthemen und die Kombination aus gemeinsamer Zielsetzung, Feedback-Gesprächen und Push-Benachrichtigungen gut angenommen wurden, wurden andere Maßnahmen wie die Gesprächsmethode MI nicht einheitlich durch die Leistungserbringer umgesetzt. Die Evaluation deckte Informationslücken bezüglich der Gewichtszunahme in der Schwangerschaft auf und zeigte viel Verbesserungspotenzial in der interprofessionellen Zusammenarbeit zwischen Frauenärzt:innen und Hebammen.

Schlussfolgerung: Die Ergebnisse liefern wertvolle Hinweise darauf, wie die Vorsorgeuntersuchungen während der Schwangerschaft umgestaltet werden könnten, um die zukünftige Belastung durch chronische Krankheiten für Mütter und Kinder zu verringern. Für eine erfolgreiche Überführung in die Regelversorgung sollte über Anpassungen einzelner Interventionskomponenten sowie Strategien zur Verbesserung der interprofessionellen Zusammenarbeit diskutiert werden. Angesichts des zunehmenden Bedarfs an präventiven Maßnahmen zur Verringerung des Risikos lebensstilbedingter Krankheiten, sollten die Möglichkeiten und der gute Zugang, den die Routineuntersuchungen im ambulanten Setting bieten, nicht ungenutzt bleiben.

Summary

Background: Overweight and obesity are major health challenges and risk factors for subsequent diseases in both children and adults. There is an urgent need for effective preventive interventions and suitable settings in which they can be provided to a wide public. Research on perinatal programming indicates that maternal lifestyle during pregnancy influences the risks for pregnancy and birth complications, as well as the risks of obesity and chronic disease in children in the long term. There is evidence that lifestyle counseling interventions during pregnancy can be effective in improving maternal and infant health outcomes. In Germany, however, lifestyle topics are not consistently discussed during regular prenatal care.

Methods: The *GeMuKi* intervention enhances prenatal care by embedding lifestyle counseling in routine checkup visits during pregnancy in different regions of the southern German state Baden-Württemberg. Supported by a novel shared telehealth platform, gynecologists and midwives provide lifestyle counseling to pregnant women using motivational interviewing (MI) techniques. Alongside the effectiveness trial, a process evaluation is conducted to identify factors that facilitate or inhibit the implementation of the intervention and to investigate the extent to which the intervention is implemented as intended. The cumulative dissertation addresses these objectives by providing three studies (Studies I-III) as well as supplementary data that analyzed the implementation process at different stages. Guided by different theoretical frameworks, a combination of quantitative and qualitative research methods is used to comprehensively understand and cover the implementation process from different perspectives. Different Questionnaires (n=401; n=46) and administrative data were analyzed using descriptive statistics, while semi-structured interviews with the *GeMuKi* recruiting staff (n=6), multiprofessional healthcare providers (n=13) and pregnant women (n=12) as well as other text material like observation protocols (n=29) and internal project documents (n=99) were analyzed using qualitative content analysis.

Results: Check-up visits in routine prenatal care proved to be a suitable setting for focusing on lifestyle topics. Pregnant women as well as healthcare providers expressed a need to address lifestyle topics. Intrinsic motivation and personal interest in the topics of nutrition, exercise, and overweight/obesity acted as facilitators for the implementation as they were crucial for the active participation of healthcare providers. A flexible distribution of tasks between gynecologists and medical assistants also facilitated the implementation. Lack of time due to many other tasks related to routine care was a key barrier to the implementation. Not all intervention components were implemented as intended. For instance, while the selection of counseling topics and the combination of joint goal-setting, feedback discussions, and push notifications were well received, other measures such as the conversational approach MI were inconsistently implemented by healthcare providers. The evaluation revealed information gaps regarding gestational weight gain and demonstrated much room for improvement in the inter-professional cooperation between gynecologists and midwives.

Conclusion: The results provide valuable guidance as to how healthcare services in prenatal care might be reorganized, with the aim of reducing the future burden of chronic diseases for both mothers and children. For a successful translation into routine care, adaptations of specific intervention components as well as strategies to improve inter-professional cooperation should be discussed. In light of the increasing need for preventive action to reduce risks of lifestyle-related diseases, the opportunities and high accessibility offered by routine check-ups in community-based settings should not be missed.

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List of Abbreviations

BMI	Body Mass Index
GeMuKi	Gemeinsam gesund: Vorsorge plus für Mutter und Kind" (English: Strengthening Health Promotion: Enhanced Check-up Visits for Mother and Child)
GiL	Netzwerk Gesund ins Leben (Healthy Start—Young Family Network)
HCP	Healthcare provider
IOM	Institute of Medicine
KVBW	Kassenärztliche Vereinigung Baden-Württemberg (Association of Statutory Health Insurance Physicians of Baden-Württemberg)
MI	Motivational Interviewing
MRC	Medical Research Council
NAM	National Academy of Medicine
RE-AIM	Theoretical Framework Acronym for Reach, Effectiveness, Adoption, Implementation and Maintenance
SMART	A 'SMART' goal is Specific, Measurable, Achievable, Reasonable and Time-Bound
TICD	Tailored Implementation for Chronic Diseases
WHO	World Health Organization

1. Introduction

Overweight and obesity are major public health concerns and associated risk factors for subsequent diseases [1]. In Germany, every second adult and about 15% of children and adolescents are overweight [2,3]. These numbers illustrate an urgent need for effective preventive measures and suitable settings in which they can be provided to the population.

Since the foundation for overweight and obesity is established at an early age, the period of pregnancy represents a unique time for preventive actions. Maternal lifestyle has a considerable influence on a child's development, which broadly speaking relates to processes of perinatal programming [4]. Previous studies have demonstrated that excessive weight gain during pregnancy has long-term effects on a child's risk for obesity and chronic diseases later in life [4–8]. For instance, overweight and obesity in pregnant women increase the risk of pregnancy and birth complications such as gestational diabetes (GDM), caesarean section, preeclampsia, macrosomia and Large for Gestational Age (LGA) [9–19].

The guidelines of the National Academy of Medicine (NAM, formerly known as the Institute of Medicine, IOM), based on pre-pregnancy Body Mass Index (BMI), recommend a total weight gain of 11,5-16 kg for normal weight women (BMI=18,5-25 kg/m2), and a total weight gain of 7-11,5 kg for overweight women (BMI=25-29,9 kg/m2) [20]. The percentage of women who experience excessive weight gain during pregnancy based on the NAM guidelines varies between 47 to 68.5% across different studies and countries [5,9,13,21–24].

There are several behavioral risk factors for adverse pregnancy outcomes and lifelong non-communicable diseases that can be modified: unhealthy diet, a lack of physical activity, alcohol consumption, and smoking during pregnancy [25]. Numerous studies have shown that lifestyle interventions have been effective in limiting excessive gestational weight gain and improving maternal lifestyle [25–30].

Experts in the collaborative network i-WIP (International Weight Management in Pregnancy) have therefore called for the incorporation of lifestyle counseling in routine prenatal care structures [31]. Moreover, the World Health Organization's 'Global Strategy on Diet, Physical Activity and Health' emphasizes routine contacts with health services as a critical element for prevention [32]. Since medical practices in routine care are visited across all societal groups, even hard-to-reach groups can be addressed in this way [33].

Introduction

In Germany, lifestyle topics are not consistently discussed as part of routine prenatal care [34,35]. Since almost all pregnant women undergo routine prenatal care in Germany and receive particularly close monitoring throughout their pregnancies [35], routine prenatal check-ups appear to be a particularly suitable setting for preventive activities.

In recent years, there have been attempts by German researchers to embed standardized lifestyle interventions in routine care: The pilot trial FeLIPO ("Feasibility of a lifestyle intervention in pregnancy to optimize maternal weight development") enrolled 250 pregnant women and was effective in reducing the proportion of women with excessive gestational weight gain [36]. Based on these results, the GeliS trial ("Gesund leben in der Schwangerschaft"/Healthy living in pregnancy) was carried out as a cluster-randomized controlled trial in Bavaria including 2286 women. The GeliS trial could not observe any major effects from the intervention on gestational weight gain or pregnancy complications [37].

Both studies focused largely on analyzing effectiveness and did not comprehensively examine the implementation process of the interventions. Consequently, it is not known exactly which factors promoted or inhibited successful implementation and why the intervention was either effective or ineffective.

Considering these findings, a new form of care was designed and evaluated by including a process evaluation that closely monitored and evaluated the process of implementation alongside an effectiveness trial. The *GeMuKi* intervention (acronym for "Gemeinsam gesund: Vorsorge plus für Mutter und Kind"—Strengthening Health Promotion: Enhanced Check-up Visits for Mother and Child), tackled the abovementioned risk factors by providing a computer-assisted, multi-professional lifestyle counseling using Motivational Interviewing (MI) techniques. Recently operating in five regions in the German state of Baden-Württemberg, *GeMuKi* is a complex intervention embedded in the routine check-up visits during pregnancy. Health system-related aims include building inter-professional counseling networks involving gynecologists, midwives and medical assistants, and strengthening the communicative competences of the healthcare providers (HCPs) [38,39].

Besides the effectiveness of the *GeMuKi* intervention, which was analyzed in a cluster-randomized controlled trial (c-RCT) [38,40], a comprehensive process evaluation was conducted to investigate the underlying conditions, associated factors, and processes of the

intervention and its implementation [38,41]. Process evaluations have the potential to reveal why an intervention works or fails, how it could be optimized and which factors influence the implementation [42,43]. Furthermore and crucially, results of process evaluations can inform the modification of implementation strategies in the process and provide policy makers and practitioners with important guidance for the replication of the intervention in real world practice [42,43].

This cumulative dissertation analyzes the implementation process of the *GeMuKi* intervention in routine prenatal care. The aim is to investigate the extent to which the intervention is implemented as intended as well as to identify facilitating and inhibiting factors for the implementation under the conditions of routine care. These findings can be used to derive recommendations for an improvement in the provision of prenatal care. Moreover, based on the identified factors, specific implementation strategies can be modified in order to successfully implement the program in case of a nationwide rollout.

To address these objectives, the cumulative dissertation is based on the following structure. Chapter 2 describes the theoretical background of the dissertation. It starts by discussing insights of process evaluations and implementation science (2.1.), then goes on to describe the current status of routine prenatal care in Germany (2.2.) as well as the *GeMuKi* intervention and evaluation (2.3). In light of this background, Chapter 3 describes the specific aims and objectives of the dissertation. Chapter 4 describes the methods and data sources used to investigate implementation processes. In Chapter 5, results are presented by providing three peer-reviewed journal publications (**Study I-III**; 5.1., 5.2., 5.3.), together with the analysis of supplementary data in 5.4. This is followed by a summary and consolidation of the results (5.5.), including a synoptic presentation of the concrete implementation of individual components (5.5.1.) along with an overarching identification of key facilitators and barriers for the implementation (5.5.2.). Chapter 6 discusses the presented results (6.1.) and implications for research and practice (6.2.), as well as methodological strengths and limitations (6.3). The dissertation concludes with a summary of its findings in Chapter 7.

2. Background

This section describes the background of this dissertation's field of investigation. First, the theoretical background is presented by discussing the conduction of process evaluations and insights from implementation science. Next, the project's background is explained in order to clarify the context of this dissertation: the status quo of prenatal care in Germany is presented, followed by a description of the *GeMuKi* intervention and the corresponding evaluation.

2.1. Theoretical Background

Process Evaluation of Complex Interventions

Complex interventions are used in a wide variety of public health areas. They usually contain a number of interacting components, target different groups, require various behaviors by HCPs and patients, and contain a different number and variability of outcomes [44,45]. Complex interventions often need to allow a degree of flexibility, since they may work best if tailored to local circumstances and different settings [45]. The Medical Research Council (MRC) has developed and continually updated guidance on the evaluation of complex interventions [43–46]. It was last updated in 2021, mostly taking into account a need "for greater attention on understanding how and under what circumstances interventions bring about change" [43]. While previous guidance mostly focused on questions regarding the effectiveness of interventions, the updated guidance aims to support researchers in evaluating "whether and how the intervention will be acceptable, implementable, cost effective, scalable, and transferable" in real-world settings [43]. Hence, the execution of a comprehensive process evaluation is essential.

Based on different available frameworks Hulscher and Wensing (2020) [47] describe the aim of a process evaluations as the documentation of "[…] the implementation strategy as developed and planned, the strategy as delivered, the actual exposure of participants to the implementation activities as part of the strategy, the experience of the people exposed (participants), and the contextual factors that also might play a role" [47].

A core element of any process evaluation is an assessment of implementation fidelity, for example, whether the intervention was delivered as intended [42,47]. Process evaluations usually also provide information on dose, a term that refers to the quantity of intervention implemented [42]. Furthermore, process evaluations can deliver insights into mechanisms of

change, and clarify the role of contextual factors that affect the implementation and outcomes [42,43]. For this purpose, process evaluations provide information on the experiences of the participants, including their perspectives and attitudes, for example on the quality of the delivery [47]. A process evaluation has the potential to determine why an intervention unexpectedly fails or has unforeseen consequences, or, conversely, to explain why it works and identify ways in which it can be optimized [43]. Process evaluations are essential for optimizing implementation strategies as well as for generating scientific knowledge on the implementation of healthcare innovations [47]. The results of process evaluations are important for policy makers and practitioners who seek guidance for the replication of the intervention in real world practice [42,43].

Implementation Science

The design and conduct of the process evaluation employs knowledge gained from 'Implementation Science'. Implementation science is defined as the "scientific study of the methods to promote the uptake of research findings into routine healthcare in clinical, organizational, or policy context" [48]. Implementation Science is a growing and rapidly evolving field within health research, and there are various theories and practical frameworks that provide guidance for research projects [49]. Another popular term used together with 'Implementation Science' or 'Implementation Research' is 'Knowledge Translation'. All three terms describe actions that aim to reduce the knowledge-practice gap [50].

It is well known from implementation science that the effectiveness of an intervention depends largely on the quality of implementation [51,52]. Also speaking of "translation of research knowledge into practice", the underlying assumption is that evidence, for instance from a trial, can be generalized and applied to another setting or population [48]. Implementation science may take into account any aspects of implementation, such as the "factors affecting implementation, the processes of implementation, and the results of implementation, including how to introduce potential solutions into a health system or how to promote their large scale use and sustainability" [53]. The objective of implementation science is to describe and analyze processes in the implementation of concepts or programs. In this context, the perceptions, behaviors, and decision-making rationales of the actors involved are of special importance. Especially during the introduction of new programs or procedures, implementation science gains importance in order to identify inaccuracies, conceptual

weaknesses, flawed planning, or false expectations. If those factors are identified at the beginning, they can be modified during the course of the project [54]. Implementation science also aims to cover a broad spectrum of "research questions, implementation outcome variables, factors affecting implementation, and implementation strategies" [53]

Very different approaches have been used to describe and operationalize successful implementations, or to clarify how well new treatments, programs, or services are implemented. A conceptualization and theoretical foundation of implementation processes may enhance the understanding and efficiency of implementation processes [54].

A large number of theories and conceptual frameworks exist, often overlapping in some categories [48,55,56]. Theories or frameworks have the ability to guide implementation practice as they may identify facilitators and barriers that must be considered when undertaking an implementation effort. Furthermore, they are useful for evaluations, as they specify aspects that could be important for the evaluation [55]. According to a survey conducted by Birken et al. (2017), implementation scientists mostly use theories and frameworks to "identify implementation determinants, inform data collection, enhance conceptual clarity, and guide implementation planning" [56].

This is also how theoretical foundations are applied in the context of this cumulative dissertation. Three broader framework, also overlapping in some categories, informed the planning, conduct, and reporting of the research activities presented: 1) the 'RE-AIM-Framework' [57] informed the overall evaluation; 2) the 'Taxonomy of Implementation Outcomes' [58] was used to systematize data collection, measurements and reporting of the process evaluation; 3) while the 'Tailored Implementation for Chronic Diseases' (TICD) framework [59] was considered additionally during the process to inform the development of the interview guides. Below, each of the three frameworks is described in detail with respect to its use within the scope of this dissertation. Collaboratively, the frameworks were used to monitor implementation success and, accordingly, to identify factors that influenced it.

1) RE-AIM Framework

Among others, the RE-AIM (an acronym for Reach, Effectiveness, Adoption, Implementation and Maintenance) framework, developed by Glasgow and colleagues [57,60,61], specifies aspects to be addressed in evaluating an intervention and provides conceptual guidance to

researchers and practitioners [55,62]. Designed to be useful for all evaluation phases from planning to reporting, the RE-AIM framework is a popular framework in public health and is used most often for dissemination and implementation evaluation [63].

Glasgow and colleagues define the categories as follows: "**R**each = proportion of the target population that participated in the intervention; **E**ffectiveness = success rate if implemented as in guidelines; defined as positive outcomes minus negative outcomes; **A**doption = proportion of settings, practices and plans that will adopt this intervention; **I**mplementation = extent to which the intervention is implemented as intended in the real world; **M**aintenance = extent to which a program is sustained over time [57].

The RE-AIM framework was used to inform the overarching evaluation of the *GeMuKi* intervention, as it has been developed for evaluation of effectiveness and implementation. The published *GeMuKi* study protocol (see Appendix 1) contains a summary for each dimension of the RE-AIM framework and data sources used [38]. This dissertation addresses the dimensions **A**doption, **I**mplementation and **M**aintenance. For a more in-depth evaluation of the implementation process and to understand factors influencing it, the taxonomy of implementation outcomes and the TICD checklist are additionally considered.

2) Taxonomy of Implementation Outcomes

Based on implementation science, Proctor and colleagues developed a taxonomy of implementation outcomes to assist in organizing key variables and formulating research questions [58]. They define implementation outcomes "as the effects of deliberate and purposive actions to implement new treatments, practices, and services" [58]. Implementation outcomes thus serve three important functions: they can be used as indicators of implementation success, map the implementation process, and serve as an important intermediate outcome [52,58]. The taxonomy includes "eight conceptually distinct implementation outcomes—acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability" [58]. To increase their chances of success, implementation strategies can be tailored toward the improvement of individual implementation outcomes [58]. Definitions of the individual implementation outcomes are displayed in Table 1.

Table 1: Implementation Outcomes by Proctor et al. 2011

Implementation outcome	Definition by Proctor and colleagues (2011) [58]
Acceptability	"Perception among implementation stakeholders [e.g. administrator, payers, provider, and consumer] that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory."
Adoption	"Intention, initial decision, or action to try or employ an innovation or evidence-based practice. Adoption also may be referred to as 'uptake.'"
Appropriateness	"Perceived fit, relevance, or compatibility of the innovation or evidence based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem."
Cost	"The cost impact of an implementation effort" (incremental or implementation cost).
Feasibility	"The extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting."
Fidelity	"The degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers; typically measured by comparing the original evidence-based intervention and the disseminated/implemented intervention in terms of (1) adherence to the program protocol, (2) dose or amount of program delivered, and (3) quality of program delivery."
Penetration	"The integration of a practice within a service setting and its subsystems. […] Penetration also can be calculated in terms of the number of providers who deliver a given service or treatment, divided by the total number of providers trained in or expected to deliver the service."
Sustainability	"The extent to which a newly implemented treatment is maintained or institutionalized within a service setting's ongoing, stable operations."

Implementation outcomes can already provide information at an early implementation stage, for example about why HCP or patients accept or (partly) do not accept new interventions.

Based on these findings, implementation strategies and/or project components can be modified. Implementation outcomes are capable to address different levels of change and accordingly different levels of analysis. For example, 'acceptability' can be measured on an individual level in terms of HCP's and patient's satisfaction with aspects of an innovation [58]. While other outcomes, "[…]such as penetration may be more appropriate for aggregate analysis, at the level of the health care organization" [58].

All implementation outcomes are addressed in this dissertation, with the exception of 'costs', as results on health economic aspects are yet to be published. The addressed implementation outcomes informed research methods, guided the selection of data sources, and were used to closely monitor implementation success.

3) Tailored Implementation for Chronic Diseases (TICD) Framework

Additionally, the TICD framework [59] was considered to systematize the research interest and ensure that all important aspects were covered in the interview guides (**Study III**). The TICD framework provides a checklist for identifying determinants of practice. It is based on a systematic review and a comprehensive analysis of 12 frameworks, theory syntheses, and planning models, focused on barriers and enablers of change of professional practice or the organization of care. The checklist includes 57 concepts in nine domains: guideline factors, individual health professional factors, patient factors, professional interactions, incentives and resources, capacity for organizational change, and social political and legal factors [59]. Because the 'implementation outcomes' are rather defined widely, concepts of the TICD framework were used to develop and structure the questions for the interview-guides. These concepts mostly overlap with the implementation outcomes, while going into more detail and further specifying the research interest. An important element of the TICD framework is the detailed consideration of the domain 'patient factors'. Within this domain all of the following concepts were considered for the interview guides: patient needs, patient beliefs and knowledge, patient preferences, patient motivation and patient behavior [59].

2.2. Status Quo of Prenatal Care in Germany

In Germany, a standardized and comprehensive concept of prenatal care has been implemented for more than 50 years and includes most of the World Health Organization (WHO)'s standards for health promotion [35,64]. It is offered nationwide on the basis of the established maternity records ('Mutterpass') and regular adaptation of the legal requirements of the maternity guidelines [34,35]. The maternity guidelines, issued by the Joint Federal Committee (G-BA), regulate medical care during pregnancy and after delivery. They specify in particular the scope and timing of healthcare services, cooperation between gynecologists and midwives, and documentation of data in the maternity records [34]. Maternity records are kept in a small booklet that is given to women at the beginning of pregnancy. Since January 2022, it has been possible to use digital maternity records [65]. Since not all HCPs who are involved in the provision of care have the technical prerequisites yet, it will still require considerable time before the system of digital maternity records is fully implemented.

Among the general principles set forth in the maternity guidelines, one is that the primary goal of physician prenatal care is the early detection of high-risk pregnancies and high-risk births. It is also stated that in order to provide the necessary information about the value of medical care during pregnancy and after delivery in accordance with the findings of medical science, physicians, health insurance providers, and midwives should work together [34].

In Germany, both gynecologists and midwives provide prenatal care. Self-employed office-based gynecologists are the main HCPs, and provide prenatal care outside of the hospital [66]. Most of the prenatal care can in principle be provided individually by gynecologists or midwives, but it should ideally be utilized and carried out in a complementary approach [35]. After a gynecologist determines that a pregnancy is progressing normally, almost all preventive checkups can be performed and documented by midwives. Ultrasound screenings, for example, are an exception, as the pregnant woman must always visit a gynecologist's practice for these procedures [67]. According to the maternity guidelines, about ten screening appointments are scheduled throughout the pregnancy. In most cases, the gynecologist will perform these approximately every four weeks during pregnancy, and every fourteen days from the 32nd week of gestation [34].

100% of pregnant women in Germany attend at least one prenatal checkup, 98% of them being performed by their gynecologist [68]. Consequently, vulnerable groups can also be reached

through offers of regular preventive medical check-ups. By now, women with a migration background show similarly favorable utilization patterns of prenatal care by physicians to non-immigrant women [69]. Pregnant women with social burdens and from socioeconomically disadvantaged backgrounds also take advantage of preventive check-ups, although less frequently than the overall average [70]. The costs of prenatal care are covered by the statutory health insurance funds or private health insurances. Overall, pregnant women are monitored very closely throughout the entire course of their pregnancies [35]. Gynecologists have a unique role in healthcare delivery, as they are the primary HCPs for women of childbearing age. In most cases, they are acquainted with these women from adolescence and then for many years, seeing them annually for regular preventive check-ups [71].

As already stated, prenatal checkups focus on early identification of diseases and developmental problems in the fetus [34,35]. Up to now, lifestyle topics are not consistently discussed in the scope of routine preventive check-ups [34,35].

Lifestyle topics are mentioned only briefly in the maternity guidelines, which state: "nutritional recommendations must also be included in the medical counseling as a measure of health promotion. In particular, adequate iodine intake and the relationship between diet and caries risk should be emphasized" [34]. The guidelines also say that "in the case of gestational diabetes, options for risk reduction through increased physical activity and dietary adjustment should be included in the decision about subsequent treatment" [34]. The German maternity guidelines contain no further information or instructions in this regard [34]. Nevertheless, it is to be documented in the maternity records that counseling on nutrition (including iodine intake), alcohol, tobacco and drugs, as well as on travel and sports, has taken place. As a standard part of the check-ups, weight has to be checked and documented [72].

In contrast, the WHO guidelines explicitly recommend counseling on healthy eating and physical activity during pregnancy to prevent excessive gestational weight gain, and give detailed information on the benefits of exercise and dietary interventions [64]. They also point out that "Interventions should be woman-centered and delivered in a non-judgmental manner, and developed to ensure appropriate weight gain" [64].

Due to the risks of obesity and gestational diabetes during pregnancy, the German Diabetes Society (DDG) has called for counseling on nutrition and physical activity to be included in statutory preventive care [73]. A number of preventive service programs are covered by specific health insurers. However, it is very inconsistent in terms of which HCPs are involved in those programs and to which women of different health insurance companies they can offer and bill these programs.

Considering the frequency of regular preventive check-ups, the high levels of patient attendance, and the unique relationship between women and HCPs, the regular preventive check-ups seem to be a particularly suitable setting for lifestyle counseling.

2.3. The *GeMuKi* Intervention and Evaluation

GeMuKi was developed on the basis of existing evidence about lifestyle interventions during pregnancy. Its feasibility was tested in one district of Baden-Württemberg between 2012 and 2014 in the pilot project "9+12 Healthy together during pregnancy and in the first year of life" [74]. *GeMuKi* was implemented and evaluated by a consortium of different partners, and monitored by a scientific advisory board with regular meetings and exchanges to discuss its progress.

The project was funded by a grant from the Innovation Fund of the German Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) in the section “New forms of care”. New forms of care go beyond the previous standard care provided by the statutory health insurance system. Funding is provided for models that improve cross-sectoral care for insured parties by optimizing intra-sectoral interfaces or including approaches aimed at overcoming the separation of the sectors [75,76]. If the new form of care is evaluated positively, there is the possibility that the G-BA will advocate for a transition into routine care.

Intervention

The *GeMuKi* project implemented a computer-assisted, multi-professional intervention to address lifestyle related risk factors for overweight and obesity in expectant mothers and their infants [38]. *GeMuKi* aims to reduce the proportion of pregnant women with excessive gestational weight gain; to minimize complications in pregnancy and birth; and to strengthen health literacy in expectant mothers. Health system-related aims include building inter-professional counseling networks and strengthening the communicative competences of the

HCPs. During pregnancy, up to six additional preventive counseling sessions were embedded in routine check-ups.[1] Four sessions were carried out by trained gynecologists, and two by trained midwives (see Figure 1).

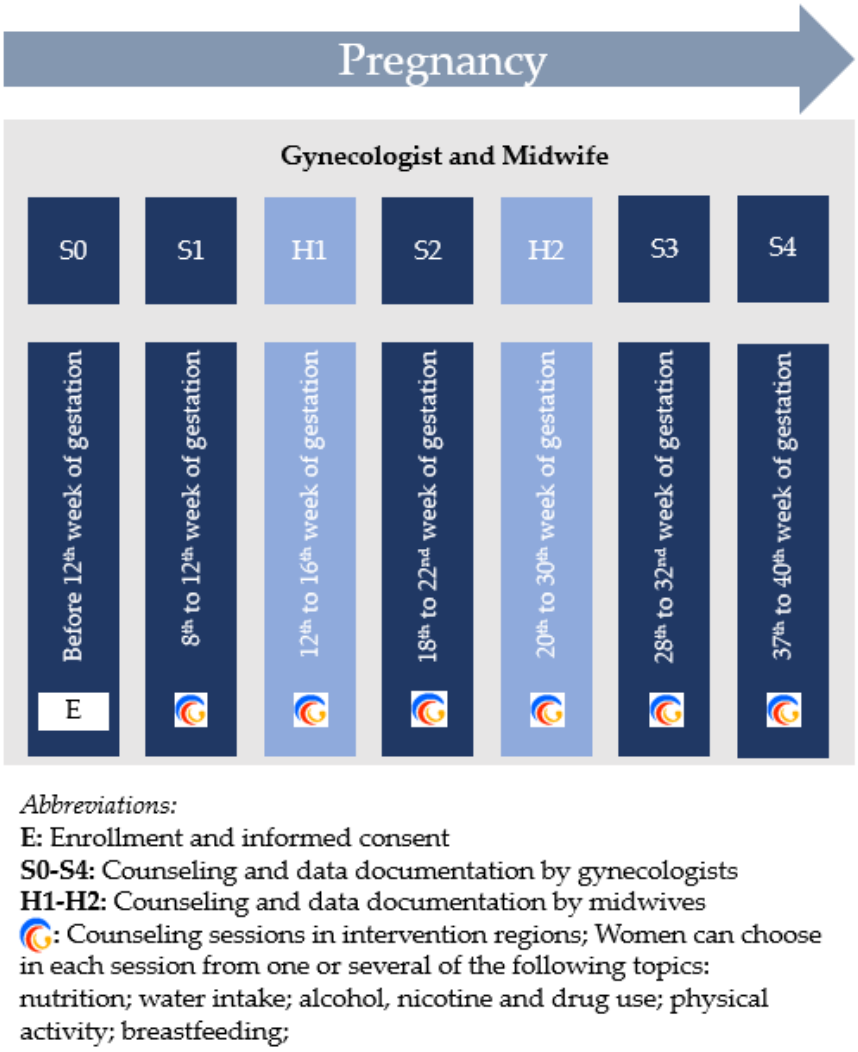

Figure 1: Study Design; Time Points and Topics of the Counseling Sessions[2]

The individual counseling sessions with elements of Motivational Interviewing (MI) were designed to promote health literacy and reduce lifestyle-related risks for the development of overweight and obesity. MI is a client-centered approach designed to evoke intrinsic motivation for behavioral change [77,78].

[1] According to the study protocol, the intervention was supposed to be continued by pediatricians during the first year of the child's life. For various reasons, such as difficult recruitment and low participation of gynecologists in many regions, very few children could be followed up in the intervention by pediatricians. This dissertation therefore focuses mainly on the period of pregnancy.

[2] Figure 1 was drawn and modified from the GeMuKi project proposal.

The topics of the counseling sessions included nutrition, water intake, physical activity, breastfeeding, alcohol, nicotine, and drug use (see Figure 1). In addition, the study protocol requires that recommendations for an appropriate weight gain during pregnancy should be communicated by the HCP at the outset. The contents were based on the national recommendations for a healthy lifestyle during pregnancy published by the 'Healthy Start—Young Family Network' (GiL) ("Netzwerk Gesund ins Leben") [79]. During each counseling session, the woman was asked to select one or more of the topics on which she was interested in talking. Each counseling session ended with the woman and the HCP agreeing on a jointly set SMART (Specific, Measurable, Achievable, Reasonable, Time-Bound) goal for lifestyle change. In the follow-up counseling session, they would discuss how and how far this goal had been achieved.

Another important element of the *GeMuKi* intervention was a novel shared telehealth platform that aided multi-professional HCPs during the counseling process (the *GeMuKi*-Assist counseling tool) and a corresponding app (the *GeMuKi*-Assist app) for the women participating in the intervention. HCPs documented counseling topics, jointly agreed goals, and gestational weight gain and other maternal and infant outcomes from the maternity records in the counseling tool. Within the counseling tool, HCPs were also supported by information on the counseling contents, and the display of an individual weight curve for every woman. Since the intervention was supposed to be carried out by different HCPs, the *GeMuKi*-Assist counseling tool allowed them to record notes about the patient for other consultants, thus establishing a counseling network.

The participating women had access to the *GeMuKi*-Assist app to view the jointly agreed goals. They received push notifications as a reminder. In addition, the *GeMuKi*-Assist app offered a collection of links to supplementary information for a healthy lifestyle during pregnancy and regional offers for support. Furthermore, the survey of the trial was conducted via the *GeMuKi*-Assist app.

A mandatory eight-hour training session prepared all HCPs who were interested in enrolling into the program for conducting the intervention. The training curriculum included the core messages on healthy lifestyles of the recommended actions of the GiL network, the basics of MI as a counseling method, and the central functions of the shared telehealth platform. The HCPs received continuing education points for their participation in the training. After

completing the training, HCPs were eligible to recruit women in their practice before the 12th week of gestation, and subsequently carry out the intervention. The intervention was rolled out in both rural and urban areas.

Another implementation strategy included the ongoing support of regional study coordinators via phone and during regular practice visits. They assisted HCPs with all possible implementation challenges, including technical issues for example. Furthermore, they took care of data management using a digital study monitor connected to the *GeMuKi*-Assist counseling tool and app.

All participating HCPs signed a contract with the Association of Statutory Health Insurance Physicians of Baden-Württemberg (KVBW), which represents the legal basis for all billing processes. HCPs in the intervention regions could bill 15 € per counseling session and 5 € per documentation. It follows that gynecologists could bill a total of 80 € and midwives could bill 40 € for lifestyle counseling during pregnancy. Additionally, HCPs could bill 20 € per patient as a recruitment bonus.

Further details on the *GeMuKi* intervention, the *GeMuKi* training, and the novel shared telehealth platform can be found elsewhere [39,80,81].

Evaluation

The *GeMuKi* program was carried out in five intervention regions in the southern German state of Baden-Württemberg between January 2019 and January 2022. A cluster-randomized controlled trial was conducted with five control regions, where participants received standard care. The evaluation of the *GeMuKi* program considered the effectiveness, the implementation process, and health economic aspects. The RE-AIM framework [61] guided the selection of data sources, as it has been developed for evaluation of effectiveness and implementation.

Survey data, as well as electronic health records and routine data, were used to assess the effectiveness of the intervention in the frame of a summative evaluation. A process evaluation was conducted alongside the trial to take an in-depth look at implementation in routine care. It was designed to examine the extent to which the intervention was implemented as planned and what factors helped to implement it, but also what barriers were encountered. The process evaluation systematically examines how the implementation of the *GeMuKi*-intervention in the settings proceeds and determines the factors that influence it. If *GeMuKi* did not prove

effective, it would be important to know whether the intervention was ineffective in a given setting (intervention failure), or if *GeMuKi* was a good intervention that was deployed incorrectly (implementation failure) [58,82]. In the sense of a formative evaluation, data generated throughout the intervention may be used to modify the intervention procedures or implementation process during the study [83,84]. Resources used to capture implementation processes at different stages included guided interviews with HCPs, participating women, and regional study coordinators; a survey completed by HCPs at the training; administrative data; minutes of various meetings; and a questionnaire completed by study coordinators. The process evaluation's findings provide a basis to inform the transition to standard care and can be used to develop guidance for a possible nationwide rollout of *GeMuKi*.

The final sample consisted of 1466 pregnant women. The *GeMuKi* intervention proved to be effective in reducing the proportion of women who experienced excessive weight gain during pregnancy (primary outcome), while there was no evidence that the intervention had effects on pregnancy, birth, or neonatal outcomes [40]. The results regarding the effects on lifestyle (e.g. nutrition, physical activity) during pregnancy or health economic aspects are yet to be published.

Further information on the design of the trial and the intervention can be found in the study protocol, which this author supported as a co-author [38]. The study protocol is attached to the Appendix of this dissertation (see Appendix 1).

3. Aims and Objectives of the Dissertation

The objective of this dissertation is the evaluation of the implementation process of the *GeMuKi* intervention in prenatal care. The process evaluation was conducted concurrently to the effectiveness trial to closely examine the implementation in routine care. It was conducted to investigate the extent to which the intervention was implemented as planned, as well as to identify which factors promoted or inhibited the implementation.

These aims lead to the following research questions:

1. Was the *GeMuKi* intervention implemented as planned?
2. What factors were facilitators in the implementation of the *GeMuKi* intervention?
3. What factors were barriers to the implementation of the *GeMuKi* intervention?

Three peer-reviewed journal publications (**Study I, Study II, and Study III**) as well as **supplementary data** are considered in order to answer these research questions. Guided by the theoretical frameworks, the supplementary data is added to complete information on penetration and implementation fidelity of the intervention.

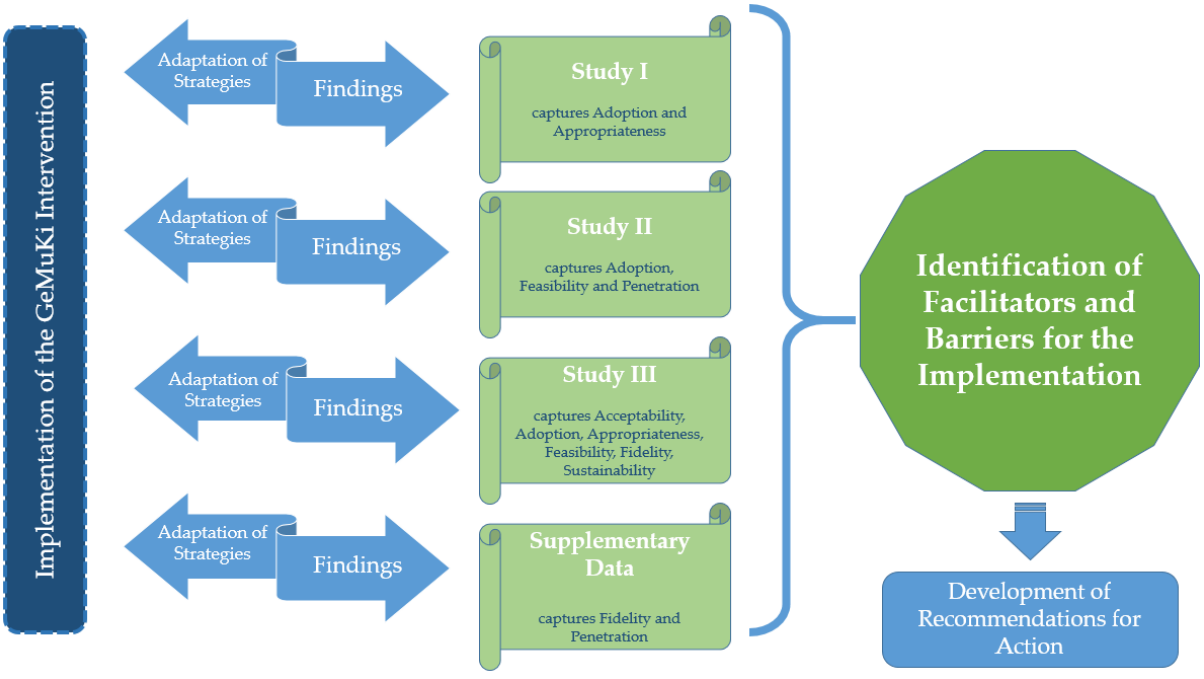

Figure 2: Context of the Cumulative Dissertation Studies

Study I aimed to capture implementation outcomes at an early stage to identify barriers to implementation, and adjust implementation strategies and intervention components

accordingly. It analyzed how HCPs rate appropriateness and adoption of the intervention after they received the mandatory preparation training.

Study II aimed to identify facilitators and barriers to the recruitment and active participation of community-based HCPs for the *GeMuKi* project. It thereby captured the implementation outcomes adoption, penetration and feasibility.

Study III aimed to capture and compare needs, demands, and experiences of pregnant women and corresponding HCPs with regard to the preventive lifestyle counseling provided in the *GeMuKi* intervention. It thereby addressed the implementation outcomes acceptability, adoption, appropriateness, feasibility, fidelity, and sustainability.

Supplementary data were evaluated to gain additional information on implementation fidelity, including adherence, dose (the quantity of intervention implemented), as well as on penetration in terms of the proportion of HCPs who delivered the intervention.

Figure 2 illustrates the joint consideration and interpretation of the three studies and the supplementary data in order to comprehensively evaluate the implementation process of the *GeMuKi* intervention. During the implementation process, findings of the single studies were used - where possible - to inform and adapt implementation strategies for an improvement in implementation outcomes. This was guided by the presented theoretical frameworks (see 2.1.), which were collaboratively used to monitor implementation success and, accordingly, to identify facilitators and barriers for the implementation. These findings are relevant for both policymakers and practitioners. They can be used to develop recommendations for action aimed at improving prenatal care, and to inform a nationwide rollout of intervention components.

4. Methods

The process evaluation was conducted alongside the implementation of the intervention in order to examine the implementation process in routine care conditions. The MRC guidance for process evaluations recommends a combination of methods appropriate to the research question: e.g. in providing descriptive quantitative information on fidelity, dose, and reach, and using qualitative methods to "capture emerging changes in implementation, experiences of the intervention and unanticipated or complex causal pathways" [42]. In accordance with this guidance the process evaluation used qualitative and quantitative methods in a convergent parallel mixed methods design [85]. Consistent with the usual practice in qualitative research, the research design, data collection, and data analysis informed each other in an iterative way [86]. This approach was formative in nature, meaning that findings collected at the beginning were used to modify the implementation plan during the process (see Figure 2).

This dissertation includes three studies (**Studies I-III**) that analyzed the implementation process at different stages. Table 2 provides an overview of the methods used in the three studies. Detailed information can be found in the in the peer-reviewed journals publications, the full texts of which are displayed in Chapter 5. As described in the theoretical background (see 2.1.), additional information is needed to gain a comprehensive insight into the implementation process. This includes information on implementation fidelity, including adherence, dose (the quantity of intervention implemented), as well as penetration in terms of the proportion of providers who delivered the intervention [58]. The three studies are therefore **supplemented** with the evaluation of administrative data, and a questionnaire completed by the regional study coordinators for every participating practice they supported during the implementation phase.

Administrative Data

Even though **Study II** provides initial data on the enrolled HCPs, administrative data is used to analyze the final number of HCPs who were enrolled in the program and the proportion of HCPs who actively supported the intervention. In addition, the HCPs' documentations of the counseling sessions are included: the number of counseling sessions conducted, the content of

the individual counseling sessions, and the women's assessment of the goal agreements were evaluated using descriptive statistics.

Questionnaires

Although information on implementation fidelity was gained from qualitative interviews (see **Study III**), it became evident that a broader assessment would be beneficial. For this purpose, a standardized questionnaire was developed (see Appendix 2) to assess the practices specific implementation procedures, their utilization behavior of the digital counseling tool, and their organizational readiness for change. To evaluate the latter, four items of the valid measure 'ORIC' (Organizational Readiness for Implementing Change), covering change commitment and change efficacy of the practices, were adapted and included [87]. The questionnaire included text entry fields in which the study coordinators could record documented goals, special characteristics and conspicuous features of the practices. The study coordinators documented their experiences and impressions six months after the inclusion of the first participant for each *GeMuKi* practice.

Table 2: Overview[3] of Methods used in the Studies of the Cumulative Dissertation

	Study I [88]	**Study II [89]**	**Study III [90]**
Title	*Prospects for the implementation of the Innovation Fund project GeMuKi – a cross sectional study on attitudes of healthcare providers regarding preventive lifestyle counseling in routine prenatal visits and infant check-ups. (Published 20 August 2021)*	*Recruitment in Health Services Research—A Study on Facilitators and Barriers for the Recruitment of Community-Based Healthcare Providers (Published 7 October 2021)*	*Preventive Counseling in Routine Prenatal Care—A Qualitative Study of Pregnant Women's Perspectives on a Lifestyle Intervention, Contrasted with the Experiences of Healthcare Providers (Published 18 May 2022)*
Research Questions	How do interventions for obesity prevention need to be designed and implemented so that 1) they are perceived by HCPs as appropriate, and 2) HCPs are willing to implement them in their daily practice?	What are facilitators and barriers to the recruitment of community-based HCPs using the *GeMuKi* trial as an example?	1) What needs, demands, and experiences do women have with regard to the preventive lifestyle counseling provided in the *GeMuKi* intervention? 2) How do their perspectives correspond to the experiences of HCPs?
Implementation Outcomes[4]	Adoption, Appropriateness	Adoption, Feasibility, Penetration	Acceptability, Adoption, Appropriateness, Feasibility, Fidelity, Sustainability
Methods	Data collection took place between January 2019 and June 2020 during 29 *GeMuKi* training sessions that HCPs completed in preparation for implementing the intervention. A convergent parallel mixed methods design was used: HCPs completed a questionnaire (n=401) that contained standardized questions as well as text entry fields. In addition, the project team prepared observation protocols for each training session (n=29). The questionnaire was analyzed using descriptive statistics. Text entry fields and protocols were evaluated using qualitative content analysis.	Data collection took place after recruitment was completed in July 2020. Internal project documents (n=99; all produced between October 2017-June 2020) were analyzed using an inductive approach by means of qualitative content analysis. This analysis informed the topics of an interview guide, for interviews with the *GeMuKi* recruiting staff (n=6). A qualitative content analysis of transcribed interviews (using an inductive–deductive category-based approach) was performed.	Data collection took place between July 2019 and March 2020, (for an additional study region in October-November 2020). 25 interviews were conducted: 12 with pregnant women and 13 with multi-professional HCPs using a semi structured interview-guide. Interviews were analyzed by qualitative content analysis using an inductive–deductive category-based approach.

[3] Contents were drawn from the three studies [88],[89],[90].

[4] As described by Proctor et al. [58].

5. Results

The following sections present the results of this dissertation. First, the three peer-reviewed scientific publications (**Study I, Study II, and Study III**) are displayed in sections 5.1, 5.2. and 5.3. To address the aims and objectives of the dissertation. The three publications are supplemented by further information on penetration, dose delivered, and implementation fidelity in section 5.4.

Section 5.5. summarizes the results by discussing whether components were implemented as planned (5.5.1.) and identifying facilitating and inhibiting factors for the implementation of the *GeMuKi* intervention (5.5.2.).

5.1. Scientific Publication of the Cumulative Dissertation: Study I

Study I

Published as: „Perspektiven für die Implementierung des Innovationsfondsprojekt GeMuKi: Eine Querschnittserhebung der Einstellungen von Leistungserbringern zu einer präventiven Lebensstilberatung in den Schwangerschafts- und Kindervorsorgeuntersuchungen“

[English title: Prospects for the Implementation of the Innovation Fund project GeMuKi – a cross sectional study on attitudes of health care providers regarding preventive lifestyle counseling in routine prenatal visits and infant check-ups]

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Versorgungsforschung / Health Services Research

Perspektiven für die Implementierung des Innovationsfondsprojekt GeMuKi: Eine Querschnittserhebung der Einstellungen von Leistungserbringern zu einer präventiven Lebensstilberatung in den Schwangerschafts- und Kindervorsorgeuntersuchungen

Prospects for the implementation of the Innovation Fund project GeMuKi – a cross sectional study on attitudes of health care providers regarding preventive lifestyle counselling in routine prenatal visits and infant check-ups

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ZUSAMMENFASSUNG

Einleitung: Übergewicht und Adipositas sind ein wichtiges Public Health Problem in Deutschland. Aufgrund der guten Erreichbarkeit von Patient*innen bietet das Setting der Arztpraxis ein hohes Potenzial für Prävention. Die bisher zurückhaltende Umsetzung von Präventions- und Gesundheitsförderungsmaßnahmen in Arztpraxen weist allerdings darauf hin, dass Hürden bei der Implementierung bestehen. Die vorliegende Studie beschäftigt sich daher damit, wie Interventionen zur Übergewichtsprävention gestaltet und implementiert werden sollten, damit sie als angemessen wahrgenommen werden und Leistungsbringer bereit sind, diese in ihrem Praxisalltag umzusetzen. Die Untersuchung wird exemplarisch anhand des Innovationsfondsprojektes „GeMuKi" durchgeführt. Ziel ist es, eine Präventionsmaßnahme im Rahmen der Schwangerschafts- und Kindervorsorgeuntersuchungen zu implementieren.
Methoden: Es wurde eine Mixed-Methods Studie durchgeführt. Die Datenerhebung fand im Rahmen der GeMuKi-Fortbildung statt, die die Leistungserbringer zur Vorbereitung auf die Durchführung der Intervention absolvieren. Frauenärzt*innen, Kinder- und Jugendärzt*innen, Hebammen und Medizinische Fachangestellte füllten hierzu einen Fragebogen aus. Die Fragen betrafen die Implementierungsoutcomes „Angemessenheit" und „Umsetzungsbereitschaft". Über Freitextfelder konnten Angaben zu Umsetzbarkeit, erwarteten Erfolgsfaktoren und Hürden gegeben werden. Zudem wurden Beobachtungsprotokolle zu jeder Fortbildung angefertigt. Geschlossene Fragen wurden deskriptiv statistisch ausgewertet. Offene Fragen und Protokolle wurden anhand der inhaltlich strukturierenden qualitativen Inhaltsanalyse ausgewertet.
Ergebnisse: Es liegen Daten von 401 Leistungserbringern vor. Fast drei Viertel (73%) der Leistungserbringer gibt an, motiviert zu sein, die Präventionsmaßnahme umzusetzen. Gleichzeitig werden Bedenken hinsichtlich der organisatorischen Umsetzbarkeit im Praxisalltag geäußert. Dennoch erwarten 72%, dass sich ihre Beratung durch das Projekt verbessern wird.
Schlussfolgerung: Die befragten Leistungserbringer stehen der Umsetzung einer präventiven Lebensstilberatung im Praxisalltag positiv gegenüber. Durch die Erhebung von Faktoren, die die Implementierung beeinflussen, können identifizierte Hürden adressiert werden.

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ABSTRACT

Introduction: Overweight and obesity are major public health concerns in Germany. As patients can easily be accessed via physicians' offices, this setting provides a high potential for prevention. However, the limited implementation of prevention and health promotion interventions in physicians' offices so far indicates that barriers to implementation exist. This study therefore addresses how obesity prevention interventions should be designed and implemented so that health care providers perceive them as appropriate and are willing to adopt them in their daily practice. The study is performed by taking the Innovation Fund project "GeMuKi" as an example.

Methods: A mixed-methods study was conducted. Data collection took place within the context of the GeMuKi training session that health care providers complete in preparation for implementing the intervention. Gynecologists, pediatricians, midwives, and medical assistants completed a questionnaire. The questions covered the implementation outcomes "appropriateness" and "adoption". Text entry fields were used to obtain information on feasibility as well as anticipated facilitating and hindering factors. In addition, observation protocols were prepared for each training session by the project team. The questionnaire was analyzed descriptively. Text entry fields and protocols were evaluated using qualitative content analysis.

Results: Four hundred and one (n = 401) training participants completed the questionnaire. Almost three quarters (73 %) of the health care providers indicate that they are motivated to implement the intervention. At the same time, concerns are expressed about organizational feasibility in everyday practice. Nevertheless, 72 % expect their care to improve as a result of the project.

Conclusion: The health care providers surveyed are positive about the implementation of the project in everyday practice. By documenting concerns about the implementation, the barriers identified can be addressed during the project course.

Einleitung

Übergewicht und Adipositas sind ein wichtiges Public Health Problem in Deutschland. Jeder zweite Erwachsene sowie ca. 15% der Kinder und Jugendlichen sind übergewichtig [1,2]. Diese Zahlen verdeutlichen eindrucksvoll den Bedarf an wirksamen Maßnahmen zur Prävention in der Bevölkerung. Zur Ergänzung und Erweiterung bereits bestehender Interventionsansätze könnten präventive Beratungen bei Ärzt*innen eine Möglichkeit darstellen, einen möglichst großen Personenkreis mit Präventionsmaßnahmen zu erreichen. Da Arztpraxen über alle sozialen Gruppen hinweg aufgesucht werden, können über diesen Weg entgegen dem häufig beobachteten Präventionsdilemma auch schwer erreichbare Gruppen angesprochen werden [3]. In diesem Zusammenhang stellen insbesondere die Vorsorgeuntersuchungen in der Schwangerschaft sowie im Kleinkindalter eine bisher wenig genutzte Möglichkeit für Präventionsbotschaften dar [4].

Studienergebnisse zur perinatalen Programmierung weisen darauf hin, dass das Risiko für Übergewicht und chronische Erkrankungen des Kindes bereits während der Schwangerschaft durch den mütterlichen Lebensstil beeinflusst werden kann [5–7]. Darüber hinaus gilt die Schwangerschaft als günstige Phase für Lebensstilveränderungen, da in vielen Fällen besondere Motivation zur Verhaltensänderung besteht [8]. Die Strukturen der Schwangerschaftsvorsorge und Kinderuntersuchungen bieten auch deshalb großes Potenzial für Präventionsmaßnahmen, da neben der bereits angesprochenen günstigen Erreichbarkeit aller sozialen Gruppen, die Häufigkeit der Vorsorgetermine in dieser Lebensphase eine hohe Interventionsfrequenz ermöglicht. Präventive Beratungen zum Lebensstil sind allerdings derzeit nicht Teil der Mutterschaftsrichtlinie und werden daher in der regulären Schwangerenvorsorge nicht standardmäßig durchgeführt [9]. In der kinderärztlichen Vorsorge werden Lebensstilthemen im Kontext der Prävention teilweise thematisiert [10].

Die bisher zurückhaltende Umsetzung von Präventions- und Gesundheitsförderungsmaßnahmen in Arztpraxen weist darauf hin, dass Hürden in der Implementierung bestehen. Nur wenn es gelingt, diese Hürden zu identifizieren und abzubauen, kann das große Potential, das ein Zugang über Arztpraxen für die Prävention von Übergewicht bietet, auch effektiv genutzt werden.

Die vorliegende Studie beschäftigt sich daher damit, wie Interventionen zur Übergewichtsprävention gestaltet und implementiert werden sollten, damit sie als angemessen wahrgenommen werden und Leistungserbringer bereit sind, diese in ihrem Praxisalltag umzusetzen. Die Untersuchung wird exemplarisch anhand des Innovationsfondsprojektes „GeMuKi – Gemeinsam gesund: Vorsorge plus für Mutter und Kind" durchgeführt.

Hintergrund GeMuKi

Die neue Versorgungsform GeMuKi ergänzt die bereits bestehenden Strukturen der gesetzlichen Vorsorgeuntersuchungen bei niedergelassenen Frauenärzt*innen, Kinder- und Jugendärzt*innen und Hebammen durch individuelle präventive Lebensstilberatungen in den Bereichen Ernährung, Bewegung, Genussmittelkonsum und Stillen [11]. Der primäre Zielparameter der GeMuKi-Studie ist die Gewichtszunahme in der Schwangerschaft, da bekannt ist, dass durch eine exzessive Gewichtszunahme während der Schwangerschaft das Risiko für späteres Übergewicht des Kindes ansteigt [5]. Aktuell nehmen in Deutschland 53% der Schwangeren übermäßig an Gewicht zu [12]. Neben patientenbezogenen Zielen besteht ein weiteres Projektziel in der Stärkung der interprofessionellen Zusammenarbeit zwischen den beteiligten Berufsgruppen, um einen optimal verzahnten Beratungsverlauf zu ermöglichen. Am Projekt teilnehmen können Frauenarztpraxen, Kinder- und Jugendarztpraxen sowie Hebammen in zehn Regionen Baden-Württembergs.

Die Wirksamkeit der GeMuKi-Intervention wird in einer Studie, die über vier Jahre angelegt ist, evaluiert [13]. Ein ausführliches Protokoll zur Studie wurde bereits von Alayli et al. [13] publiziert, eine detaillierte Beschreibung der Intervention findet sich bei Lück et al. [11].

Die Intervention sieht präventive Beratungen zu elf Zeitpunkten im Verlauf der Schwangerschaft und im ersten Lebensjahr des Kindes vor. Die Beratungsinhalte basieren auf den Präventionsbotschaften des Netzwerks „Gesund ins Leben" [14–16]. Die Beratungen werden in Form einer Kurzintervention mit Bausteinen der Methode „Motivational Interviewing" (MI; Motivierende Gesprächsführung) durchgeführt [17]. MI ist ein patientenzentrierter Beratungsansatz, bei dem durch das Erkunden und Auflösen

von Ambivalenzen intrinsische Motivation für eine Verhaltensänderung aufgebaut werden soll [17]. In verschiedenen Metaanalysen konnte die Effektivität von MI-basierten Interventionen für verschiedene Gesundheitsverhaltensweisen gezeigt werden [18–20].

Zur Vorbereitung auf die Durchführung der Intervention erhalten die beteiligten Leistungserbringer eine eintägige (achtstündige) Fortbildung. In diesen Veranstaltungen werden die Gesprächsmethode MI, die einheitlichen Präventionsbotschaften sowie organisatorische Projektabläufe vermittelt. Eine ausführliche Beschreibung des Fortbildungskonzepts geben Neumann et al. [21].

Hintergrund zur Untersuchung der Implementierung

Neben der Wirksamkeit wird der Prozess der Implementierung der GeMuKi-Intervention wissenschaftlich begleitet. Implementierung ist definiert als ein aktiver und zielgerichteter Prozess im Zuge dessen potentielle Hürden für die Umsetzung wissenschaftlicher Erkenntnisse in die Praxis identifiziert und diese durch Anreize und organisatorische Änderungen überwunden werden [22].

Aus der Implementierungsforschung ist bekannt, dass die Effektivität einer Intervention maßgeblich von der Implementierungsqualität abhängt [23,24].

Neben der Wirksamkeit der Intervention werden daher im Rahmen der Prozessevaluation auch Implementierungsoutcomes [25] erhoben. Anhand dieser gemeinsamen Erhebung kann untersucht werden, ob eine Intervention in einem bestimmten Setting effektiv implementiert ist und somit in der Praxis wirksam sein kann [23]. Proctor et al. definieren Implementierungsoutcomes als „Effekte absichtlicher und gezielter Handlungen, um neue Behandlungen, Maßnahmen und Dienstleistungen [im Versorgungsalltag] zu implementieren“ [25] (Übersetzung nach [23]). Implementierungsoutcomes erfüllen demnach drei wichtige Funktionen: Sie können als Indikatoren des Implementierungserfolgs genutzt werden, bilden den Implementierungsprozess ab und dienen als wichtiges Zwischenergebnis [25].

Bereits in der frühen Phase von Projekten können Faktoren identifiziert werden, die die Implementierung beeinflussen. In diesem Stadium des Projekts sind zwei der von Proctor et al. definierten Faktoren besonders relevant: die Angemessenheit der Intervention und die Umsetzungsbereitschaft der Leistungserbringer [25]. Das Implementierungsoutcome *Angemessenheit* beschreibt „die wahrgenommene Relevanz und Kompatibilität einer Innovation mit dem Praxissetting oder mit einer Situation oder einer Zielgruppe sowie das wahrgenommene Lösungspotential für bestehende Probleme“ [23]. Das Implementierungsoutcome *Umsetzungsbereitschaft* wird definiert als „die Absicht oder initiale Entscheidung eine Innovation (z.B. eine evidenzbasierte Intervention) zu erproben und anzuwenden, um diese im weiteren Verlauf durch konkrete Handlungen umzusetzen“ [23]. Diese Implementierungsoutcomes können demnach schon in einer frühen Projektphase Aufschluss darüber geben, warum Leistungserbringer eine neue Intervention annehmen oder (teilweise) nicht annehmen. Anhand dieser Erkenntnisse können dementsprechend Implementierungsstrategien und/oder Projektkomponenten angepasst werden.

Die Untersuchung dieser Faktoren in der vorliegenden Studie liefert Hinweise für die Implementierung von Präventionsvorhaben innerhalb der Vorsorgeuntersuchungen. Darüber hinaus zeigt die Untersuchung exemplarisch, wie frühzeitig Chancen und Hürden in der Implementierung von Interventionen identifiziert und adressiert werden können.

Material und Methoden

Als Teil der Prozessevaluation wird eine Untersuchung der wahrgenommenen Angemessenheit und Umsetzungsbereitschaft der Leistungserbringer gegenüber der GeMuKi-Intervention durchgeführt. Die Datenerhebung findet im Rahmen der Fortbildungsveranstaltungen statt, in denen die Leistungserbringer auf die Durchführung der Intervention vorbereitet werden. Alle Hebammen, Frauenärzt*innen, Kinder- und Jugendärzt*innen und zugehörige Medizinische Fachangestellte (MFAs) der niedergelassenen gynäkologischen und pädiatrischen Praxen in den Interventionsregionen werden eingeladen, an der Fortbildung teilzunehmen. Diese ist Voraussetzung, um in der Interventionsgruppe am Projekt teilnehmen zu können. Die Rekrutierung erfolgte über Einladungsbriefe der Kassenärztlichen Vereinigung und der jeweiligen Berufsverbände sowie über zusätzliche persönliche Praxisbesuche von regionalen Studienkoordinatorinnen.

Es wird ein Mixed-Methods-Ansatz verfolgt, bei dem quantitative und qualitative Datenerhebungs- und Datenanalyseverfahren angewandt werden. Die quantitative Erhebung über einen standardisierten Fragebogen wird parallel zu einer qualitativen Erhebung über Freitextfelder und Beobachtungsprotokolle durchgeführt. Damit folgen die Autorinnen des Artikels dem convergent parallel mixed methods design nach Creswell et al. [26], um durch Zusammenführung der Ergebnisse ein tiefergehendes Verständnis des Forschungsgegenstandes zu erhalten.

Fragebogenerhebung

Im Anschluss an die GeMuKi-Fortbildungen werden die teilnehmenden Leistungserbringer gebeten einen zweiseitigen Fragebogen (siehe Appendix A) auszufüllen. Die Fragen sind abgeleitet aus Fragebögen zu Implementierungsoutcomes [27–29] und ergänzt durch Fragen zur Evaluation von MI-Trainings [30] und Fortbildungsveranstaltungen. Im Bereich der Angemessenheit werden Erwartungshaltungen zur Relevanz, Kompatibilität und dem Lösungspotential der Intervention erfasst. Beispielsweise wird erfragt, ob Leistungserbringer die neu erlernte Gesprächsmethode im Versorgungsalltag für anwendbar halten. Im Bereich Umsetzungsbereitschaft wird die Intention zur Anwendung der gelernten Inhalte in der Praxis erfasst. Hier wird unter anderem erfragt, ob das Praxisteam motiviert ist, die neuen Aufgaben umzusetzen. Die Beantwortung erfolgt über fünffach abgestufte Zustimmungsskalen („stimme voll und ganz zu“ bis „stimme überhaupt nicht zu“). Zudem werden über Freitextfelder weitere Einschätzungen der teilnehmenden Leistungserbringer hinsichtlich der praktischen Umsetzbarkeit, Erfolgsfaktoren und Hürden gesammelt.

Beobachtungsprotokolle

Zusätzlich fertigen Mitglieder des Projektteams bei jeder Fortbildung Protokolle an, in denen Beobachtungen zur Gruppendynamik und Atmosphäre sowie Erwartungshaltungen und Meinungen, die die Leistungserbringer im Laufe der Veranstaltung äußern, festgehalten werden. Die Beobachtungen der Fortbildungen liefern weiterführende Hinweise zu Chancen und Hürden für die Implementierung, die die Leistungserbringer in den Fragebögen nicht benannt haben.

Datenanalyse

Geschlossene Fragen des Fragebogens werden deskriptiv statistisch ausgewertet. Es werden prozentuale Zustimmungswerte zu Aussagen in den einzelnen Items berechnet. Die fünfstufige Likert-Skala wird hierfür dichotomisiert („stimme zu“ und „stimme

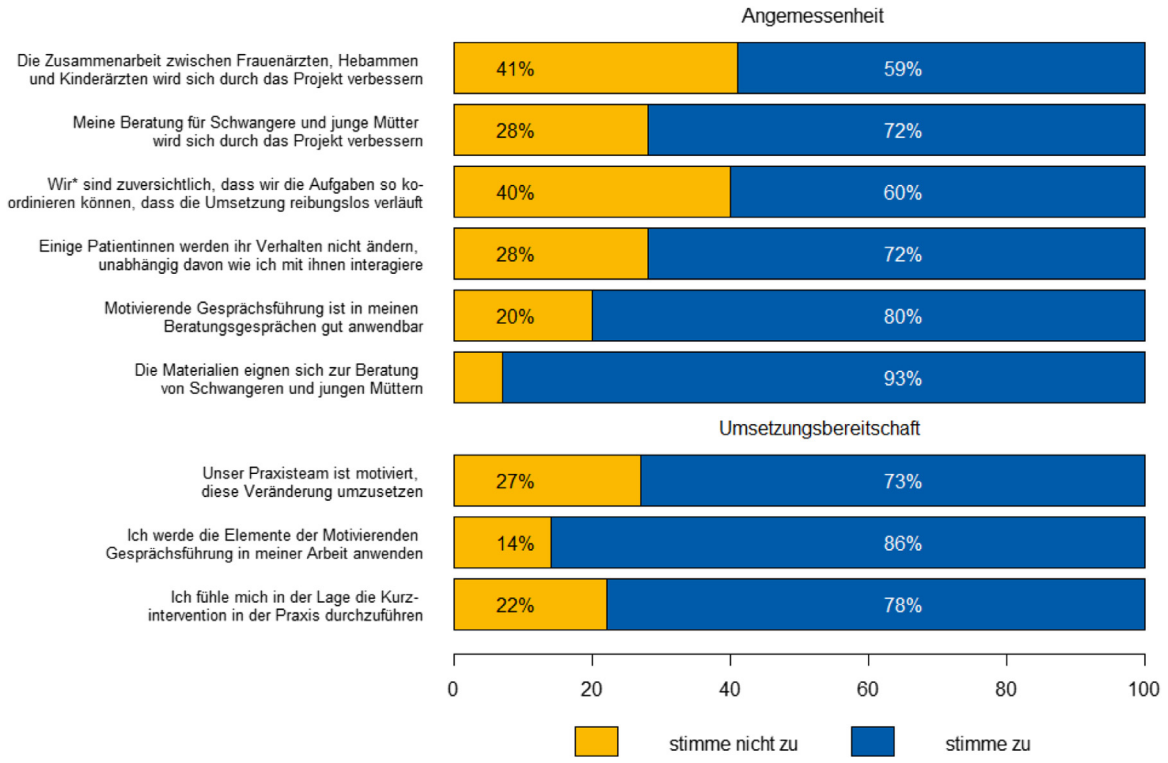

Abbildung 1. Ergebnisse der geschlossenen Fragen zu den Implementierungsoutcomes Angemessenheit und Umsetzungsbereitschaft.

Tabelle 1
Leistungserbringer nach Berufsgruppen.

Berufsgruppe	N (%)
Frauenärzt*innen	142 (30.1)
Kinder- und Jugendärzt*innen	60 (12.7)
Hebammen	109 (23.1)
MFAs	160 (34.0)
Gesamt	471 (100)

nicht zu“)[1]. Die offenen Fragen des Fragebogens und die Beobachtungsprotokolle werden anhand der inhaltlich strukturierenden qualitativen Inhaltsanalyse [31] von zwei Wissenschaftlerinnen ausgewertet. Alle Analysen werden in MAXQDA 18 der VERBI GmbH durchgeführt. Dabei wird eine Kombination aus deduktiver und induktiver Kategorienbildung angewendet. Es wird die Technik des konsensuellen Codierens angewendet, bei dem das Material von zwei Personen unabhängig codiert und anschließend in einem iterativen Prozess konsentiert wird [31].

Ergebnisse

Es wurden 29 Fortbildungsveranstaltungen im Zeitraum von Januar 2019 bis Juni 2020 durchgeführt, an denen insgesamt 471 Leistungserbringer verschiedener Berufsgruppen teilnahmen (Tabelle 1). Damit konnten 28% der in den Regionen ansässigen Frauenärzt*innen sowie jeweils 14% der in den Regionen ansässigen Hebammen und Kinder- und Jugendärzt*innen erreicht werden. Zu der Grundgesamtheit der MFAs in den Regionen lagen keine Daten vor[2].

Fragebogenerhebung

85% der teilnehmenden Leistungserbringer (N = 401) haben den Fragebogen ausgefüllt. Gut der Hälfte der Leistungserbringer (53%) waren die Handlungsempfehlungen des Netzwerks „Gesund ins Leben“ zu Ernährung und Lebensstil in der Schwangerschaft, im Säuglings- und im Kleinkindalter vor der Fortbildung nicht bekannt.

Die Ergebnisse zum Aspekt der Angemessenheit (Abb. 1) zeigen, dass 80% der befragten Leistungserbringer die in der Fortbildung vermittelten Bausteine der Methode MI in ihren Beratungsgesprächen für gut anwendbar halten. Darüber hinaus halten 93% die Interventions-Materialien zur Beratung von Schwangeren und jungen Familien für geeignet. Damit einhergehend erwarten 72%, dass sich ihre Beratung für Schwangere und junge Eltern durch das Projekt verbessern wird. Ebenso viele Leistungserbringer (72%) sind allerdings auch der Meinung, dass einige Patientinnen ihren Lebensstil nicht ändern werden, unabhängig davon, wie mit ihnen kommuniziert wird. Der Aspekt einer verbesserten Zusammenarbeit der Berufsgruppen durch das Projekt wird von 41% kritisch gesehen.

Hinsichtlich des Implementierungsoutcomes Umsetzungsbereitschaft (Abb. 1) geben 73% der Leistungserbringer an, dass sie motiviert sind, die Präventionsmaßnahme umzusetzen. Ein ähnlich hoher Anteil (78%) fühlt sich in der Lage, die Kurzintervention im Praxisalltag durchzuführen. 86% der teilnehmenden Leistungserbringer äußern die Absicht, die gelernte Beratungsmethode in ihrer Arbeit anzuwenden. Gleichzeitig äußern 40% Zweifel daran, dass

[1] Dichotomisierung wie folgt: „Stimme voll und ganz zu“, „Stimme zu“ -> „Stimme zu“; „Stimme überhaupt nicht zu“, Stimme eher nicht zu“, „Teils / teils“ -> „Stimme nicht zu“.

[2] Die Grundgesamtheit der in den Regionen ansässigen Leistungserbringer wurde ermittelt auf Basis von Daten der Kassenärztlichen Vereinigung Baden-Württemberg und der jeweiligen Berufsverbände. Die Daten wurden durch Recherchen der regionalen Studienkoordinatorinnen geprüft und aktualisiert.

sich die neuen Aufgaben im Praxisalltag so koordinieren lassen, dass die Umsetzung reibungslos verläuft.

Im Freitextbereich des Fragebogens haben 301 Leistungserbringer Einträge vorgenommen. Als primäre Hürde für die Umsetzung wird der organisatorische und zeitliche Mehraufwand im Praxisalltag genannt (N = 92). Hierunter fällt die Einschätzung der Leistungserbringer, dass die regulären Beratungsgespräche durch die Intervention deutlich mehr Zeit in Anspruch nehmen werden. Im Zusammenhang damit wird der Wunsch nach einer höheren Vergütung genannt (N = 13). Als Voraussetzung für eine erfolgreiche Umsetzung wird die Rekrutierung von genügend Kolleg*innen in den Regionen herausgestellt (N = 65). Zudem wünschen sich Leistungserbringer insgesamt mehr Informationen zum Lebensstil in der Schwangerschaft und im ersten Lebensjahr (N = 16). Wiederkehrende Fortbildungen zu den erlernten Inhalten werden ebenfalls nachgefragt (N = 6).

Beobachtungsprotokolle

Die Analyse der Beobachtungsprotokolle (N = 29) zeigt, dass bei den Fortbildungen insgesamt eine positive Grundstimmung gegenüber der GeMuKi-Lebenstilintervention herrscht. In Gesprächen bewerten teilnehmende Leistungserbringer die Inhalte der Fortbildung als relevant und äußern sich motiviert, die Intervention im Praxisalltag auszuprobieren. Daher unterzeichnen viele Leistungserbringer direkt im Anschluss an die Fortbildung den Vertrag zum Projekt. Die Umsetzungsbereitschaft zeigt sich zudem darin, dass die Leistungserbringer bei ihren Kolleg*innen in der Region für das Projekt werben möchten.

Die teilnehmenden Leistungserbringer halten vor allem das Thema Ernährung in ihrer Beratung für relevant. Bei den Fortbildungen werden insbesondere Fragen zur vegetarischen und veganen Ernährung (in der Schwangerschaft wie auch im Kindesalter) gestellt. Es wird von einem hohen Informationsbedarf der Schwangeren und jungen Eltern berichtet. Demgegenüber wird kritisch diskutiert, ob es möglich sei, in einer Kurzintervention von circa zehn Minuten überhaupt Zugang zu einer Patientin zu finden und ob in der Kürze der Zeit ausreichend auf Inhalte eingegangen werden kann.

In diesem Zusammenhang stößt die Anwendung der Gesprächsmethode MI vereinzelt auf Skepsis, da einige Leistungserbringer befürchten, dass die Informationsweitergabe zu kurz kommt und sich diese Gesprächsmethode zu sehr von ihren etablierten Beratungsabläufen unterscheidet. Sie befürchten zudem, nicht adäquat auf Fragen der Patient*innen reagieren zu können. Demgegenüber sehen einige Leistungserbringer insbesondere in der Gesprächsmethode eine Chance, einen Zugang zu „aufgeregten“ Patient*innen zu gewinnen, um gemeinsam über Lösungen nachzudenken. Die Gesprächsmethode wird mehrfach als relevant bewertet, da so individuelle Lösungen gefunden werden können und den Patient*innen keine standardisierte Beratung „übergestülpt“ wird. Darüber hinaus besteht der Wunsch nach mehr Übung, um die Gesprächsmethode korrekt umsetzen zu können.

Bezüglich der angestrebten Versorgungskette (Frauenärzt*in – Hebamme – Kinder- und Jugendärzt*in) werden Schwierigkeiten in der Umsetzung gesehen. Das Studienprotokoll sieht vor, dass ausschließlich Frauenärzt*innen Teilnehmerinnen einschreiben. Da in einigen Regionen nur wenige Frauenärzt*innen aktiv am Projekt beteiligt sind, sehen die Kinder- und Jugendärzt*innen eine Teilnahme als nicht sinnvoll an, da so nur sehr wenige GeMuKi-Kinder in ihren Praxen betreut werden können. Zudem kommt mehrfach die Frage auf, ob die Vorsorge in der Frauenarztpraxis der richtige Ort für präventive Beratungen ist, oder ob diese bei anderen Leistungserbringern in der Versorgungskette einfacher umgesetzt werden können.

Wie bereits in den Freitextantworten der Fragebogenerhebung äußern Leistungserbringer Bedenken bezüglich des zusätzlichen Zeitaufwandes für Beratung und Dokumentation. Als weitere Hürden werden parallellaufende Selektivverträge sowie Umstrukturierungen in der Vorsorge thematisiert.

Diskussion

Die Angemessenheit und Umsetzungsbereitschaft der neuen Versorgungsform GeMuKi unter Leistungserbringern zu erfassen ist relevant, um vorhandene Chancen und Hürden bei der Implementierung frühzeitig zu identifizieren. Sollten sich hierbei Problemfelder zeigen, können Anpassungen vorgenommen werden, um die Einführung in die Versorgungspraxis zu erleichtern.

Die Ergebnisse der vorliegenden Studie sind für zukünftige Forschungsvorhaben in der ambulanten Versorgung bedeutsam:

Die Ergebnisse der Mixed-Methods Untersuchung zeigen, dass die Leistungserbringer der Umsetzung des Projekts im Praxisalltag insgesamt positiv gegenüberstehen. Erfolgsfaktoren werden vor allem in der verbesserten Versorgung der Schwangeren und jungen Eltern gesehen. Dies deckt sich mit Ergebnissen hinsichtlich der Umsetzungsbereitschaft aus anderen Studien, die zeigen, dass Leistungserbringer MI-basiert Interventionen positiv gegenüberstehen und Vorteile vor allem in der verbesserten Kommunikation mit den eigenen Patient*innen sehen [32]. Zudem wurde deutlich, dass die Leistungserbringer tiefergehendes Interesse an einer Verankerung von Präventionsbotschaften in der Regelversorgung haben. Auch in anderen Untersuchungen wurde auf eine hohe Umsetzungsbereitschaft der Ärzt*innen hinsichtlich der Durchführung von Lebensstilberatungen hingewiesen [33,34]. In diesem Zusammenhang ist hervorzuheben, dass vor der Fortbildung die Mehrzahl der Leistungserbringer die Handlungsempfehlungen des Netzwerks „Gesund ins Leben“ [14–16] nicht kannte. Dem Aspekt der Aus- und Fortbildung sollte demnach verstärkt Beachtung geschenkt werden [35].

Der zusätzliche zeitliche und organisatorische Aufwand wird als größte Hürde empfunden. Der zeitlich straffe Versorgungsalltag lässt wenig Raum für zusätzliche Aufgaben. Dies deckt sich mit der Literatur zur Implementierung von Lebensstilberatungen auf MI Basis, die zeitliche Barrieren als größte Hürde für die Implementierung identifiziert [32].

Aufgrund der geäußerten Bedenken der Leistungserbringer entwickelt das Projektteam im Verlauf der Feldphase verschiedene Strategien, um den Mehraufwand in der Versorgungspraxis weiter zu minimieren. So unterstützen regionale Studienkoordinatorinnen die Leistungserbringer zusätzlich bei administrativen Projektaufgaben wie der Patientinnenaufklärung und Datendokumentation und bieten telefonischen sowie persönlichen Support an. Durch diese persönliche Betreuung und individuelle Unterstützung soll die Implementierung in den Praxisalltag vor allem in der Anfangsphase gefördert werden. Darüber hinaus wird die Dauer der Fortbildung reduziert, um die zeitlichen Kosten bei der Implementierung der Intervention für die Leistungserbringer zu minimieren. Die zeitliche Reduktion betrifft dabei den projektorganisatorischen Teil (bspw. Dateneingabe in eine digitale Datenplattform) der Fortbildung. Diese Inhalte können in einem separaten Termin der Studienkoordinatorinnen in den Studienpraxen vor Ort effizienter an das Praxisteam vermittelt werden. Es ist zu beachten, dass Aufgaben, wie zum Beispiel das Einholen der Einwilligungserklärung für die Studie, ausschließlich im Rahmen der Evaluation anfallen und bei Implementierung in die Regelversorgung keine Rolle mehr spielen.

Aufgrund der kritischen Rückmeldungen hinsichtlich der Verbesserung der Zusammenarbeit zwischen den Berufsgruppen wurden Strategien entwickelt, um die Umsetzung dieses

Projektziels verstärkt zu adressieren. Derzeit besteht zwischen den Berufsgruppen kaum Austausch innerhalb ihrer Landkreise. Daher wurden Vernetzungslisten mit allen teilnehmenden Leistungserbringern ausgegeben. Die Listen wurden durch das Projektteam erstellt und beinhalten eine Auflistung aller Leistungserbringer, die im Projekt eingeschrieben sind. Weiterhin wurde eine Veranstaltung zum gegenseitigen Kennenlernen und Erfahrungsaustausch angeboten. Die Leistungserbringer gaben positives Feedback zu den getroffenen Maßnahmen.

Stärken und Schwächen

Eine Stärke der vorliegenden Studie liegt in der sehr hohen Rücklaufquote (85%).

Es ist daher davon auszugehen, dass die Ergebnisse die Einstellungen der teilnehmenden Leistungserbringer zur Implementierung der GeMuKi-Intervention gut abbilden. Allerdings kann aufgrund der Bereitschaft sich fortzubilden angenommen werden, dass die teilnehmenden Leistungserbringer besonders motiviert sind, präventive Beratung in der Regelversorgung umzusetzen. Demnach stellen die Ergebnisse dieser Studie nicht die Einstellungen aller in der ambulanten Versorgung beteiligten Akteure dar. Eine weitere Stärke liegt im Mixed-Methods-Design der Untersuchung. Die Kombination von quantitativen und qualitativen Forschungsmethoden ermöglicht es, die Fragestellung aus verschiedenen Blickwinkeln zu untersuchen und so ein genaueres Bild zu generieren. Darüber hinaus ist die vorliegende Studie als Teil der Prozessevaluation in die GeMuKi-Studie eingebettet. Die Ergebnisse dieses Artikels sind somit ein Baustein, der im Rahmen weiterer Untersuchungen dazu beiträgt, den Prozess der Implementierung einer komplexen Intervention abzubilden. Eine Limitation stellt das eingesetzte Messinstrument dar. Der in der vorliegenden Studie eingesetzte Fragebogen enthält Items aus verschiedenen Fragebögen zu Implementierungsoutcomes. Der Fragebogen war zudem sehr kurz, Um eine hohe Akzeptanz bei den Befragten zu erzielen, wurde der Fragebogen sehr kurz gehalten. Somit konnten die Konstrukte im Rahmen der Fragebogenerhebung nur mit einem begrenzten Detailgrad erhoben werden.

Schlussfolgerung

Über die Vorsorgeuntersuchungen besteht ein breiter Zugang zu Patient*innen für präventive Botschaften. Unter den Leistungserbringern besteht Interesse an präventiven Beratungen, da Übergewicht und Adipositas im Praxisalltag zunehmend eine Rolle spielen. Wenn Lebensstilthemen in die Vorsorge eingebettet werden sollen, müssen dazu erfolgreiche Strategien entwickelt und erforscht werden. Die Erfassung der Implementierungsoutcomes kann dazu beitragen, Barrieren für die Implementierung zu einem frühen Zeitpunkt zu erkennen und Implementierungsstrategien und Interventionskomponenten dementsprechend anzupassen. Die Erhebung gibt Hinweise darauf, wie Interventionen implementiert werden müssen, damit Leistungserbringer diese gerne und gut umsetzen können.

Nur wenn die identifizierten Hürden überwunden werden können, wird es möglich sein diesem gesundheitsrelevanten Thema in der Vorsorge verstärkt Beachtung zu schenken.

Ethikvotum und Registrierung

Für die GeMuKi-Studie liegt ein positives Ethikvotum der Ethikkommission der Medizinischen Fakultät der Universität zu Köln (ID:18–163) sowie der Ethikkommission der Landesärztekammer Baden-Württemberg (ID: B-F-2018-100) vor. Die Studie wurde am 03.01.2019 beim Deutschen Register Klinischer Studien registriert (DRKS00013173).

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Interessenkonflikt

Die Autorinnen erklären, dass kein Interessenkonflikt besteht.

Autorenschaft

FK und LL haben die Untersuchung konzipiert, die Datenerhebung und -auswertung durchgeführt und das Manuskript geschrieben. AA, FK, FN, LL und SS bilden das Evaluationsteam der GeMuKi Gesamtstudie. AA und SS haben das Evaluationsdesign für die Gesamtstudie konzipiert. DS hat im Rahmen ihrer Bachelorarbeit die Fragebögen digitalisiert und aufbereitet. AMB ist die Projektleitung des Gesamtprojektes (GeMuKi-Konsortialführung).

Appendix A. Zusätzliche Daten

Zusätzliche Daten verbunden mit diesem Artikel finden sich in der Online-Version unter: doi:10.1016/j.zefq.2021.06.005.

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5.2. Scientific Publication of the Cumulative Dissertation: Study II

Study II

Published as: "Recruitment in Health Services Research — A Study on Facilitators and Barriers for the Recruitment of Community-Based Healthcare Providers"

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Recruitment in Health Services Research—A Study on Facilitators and Barriers for the Recruitment of Community-Based Healthcare Providers

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Abstract: In health services research, the recruitment of patients is oftentimes conducted by community-based healthcare providers. Therefore, the recruitment of these healthcare providers is a crucial prerequisite for successful patient recruitment. However, recruiting community-based healthcare providers poses a major challenge and little is known about its influencing factors. This qualitative study is conducted alongside a health services research intervention trial. The aim of the study is to investigate facilitators and barriers for the recruitment of community-based healthcare providers. A qualitative text analysis of documents and semi-structured interviews with recruiting staff is performed. An inductive–deductive category-based approach is used. Our findings identify intrinsic motivation and interest in the trial's aims and goals as important facilitating factors in healthcare provider recruitment. Beyond that, extrinsic motivation generated through financial incentives or collegial obligation emerged as a conflicting strategy. While extrinsic motivation might aid in the initial enrollment of healthcare providers, it rarely resulted in active trial participation in the long run. Therefore, extrinsic motivational factors should be handled with care when recruiting healthcare providers for health services research intervention trials.

Keywords: recruitment; community-based healthcare providers; health services research

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1. Introduction

Ambulatory care is one major research field in health services research. Community-based practices are an especially important setting for research studies. In trials in the outpatient setting, the recruitment of patients is frequently conducted by community-based healthcare providers such as general practitioners or specialists. The recruitment of these healthcare providers is, therefore, a crucial prerequisite that can determine the success of a trial in health services research right from the start. The recruitment of patients via community-based healthcare providers provides the advantage of a comparatively easy access to the targeted patient group for researchers. However, unlike hospital-based healthcare providers, community-based healthcare providers operate independently, are not bound by instructions from a clinic director and are often not familiar with conducting and recruiting for research studies [1,2]. Thus, the recruitment of healthcare providers often proves to be a major challenge. As a result, trials frequently fail to reach the required sample size. Furthermore, recruitment problems can lead to delays in the schedule, increased trial costs and less conclusive results due to the decrease in statistical power [3]. Suitable and effective recruitment strategies are, therefore, needed to reach and attract healthcare providers for participation in trials. Various potential barriers to healthcare

provider recruitment are reported in the literature. These comprise anticipated time barriers (particularly related to increased paperwork and enrollment procedures), data privacy concerns, concerns with regard to recruiting one's own patients and the perception that the healthcare providers would have little involvement in the design of the trial [4,5]. Peer-to-peer recruitment, the use of existing networks, involvement in trial design, relevance of the research topic, perceived benefit for patients and low additional effort are, thus, discussed as beneficial for the recruitment of healthcare providers [6–9]. The role of other strategies, such as the use of (financial) compensation, remains unclear [10–13]. Existing studies on the recruitment of healthcare providers are subject to several limitations. This is because their results are drawn from surveys regarding healthcare providers' general attitudes towards research or hypothetical participation in trials [4,14,15]. These designs hold high risks of bias, as hypothetical participation decisions do not inevitably lead to actual trial participation [16]. In addition to this, studies on recruitment processes frequently focus on the recruitment and retention of patients in trials [16–18]. There is still a lack of information on how to master healthcare provider recruitment as a first step towards patient recruitment in health services research trials. The current state of research in the field of recruitment is summarized by Bower et al. (2009): "Recruiting for science is not underpinned by a science for recruitment" [19]. Various initiatives launched by stakeholder groups and researchers in the field of trial methodology have also called for methods to improve recruitment for research and develop strategies for a better integration of trials into routine care [20,21]. To fill this gap in the existing research, this article describes findings on the process of recruiting community-based healthcare providers during a health services research intervention trial.

This study identifies facilitators and barriers to the recruitment of community-based healthcare providers using the GeMuKi trial (acronym for "Gemeinsam gesund: Vorsorge plus für Mutter und Kind"—Strengthening health promotion: enhanced check-up visits for mother and child) as an example. Based on experiences gained in the GeMuKi trial, factors for the successful recruitment of healthcare providers for planning and conducting future trials in community-based settings are discussed.

2. Materials and Methods

2.1. Setting

The GeMuKi trial was designed as a hybrid-effectiveness-implementation trial (type II) and, therefore, collected data on effectiveness and implementation simultaneously [22]. It aimed at incorporating a structured, low-threshold lifestyle counseling intervention into routine prenatal visits and infant check-ups. The trial was funded by the Innovation Fund of the German Federal Joint Committee (G-BA). Details on the GeMuKi trial can be found elsewhere [23]. In short, trained gynecologists, midwives and pediatricians in the intervention group conducted brief counseling sessions using elements of motivational interviewing (MI). Data collection was conducted via a digital data platform [24]. For organizational reasons, assignment to intervention and control group was conducted on regional level rather than individual level, resulting in five intervention and five control regions. Pregnant women (n = 1860) were recruited by participating gynecologists in the study regions before the 12th week of gestation [23]. Since care for pregnant women in Germany is primarily provided in the outpatient setting by community-based gynecologists, gynecologist practices provide an ideal location in which to reach pregnant women for research purposes. The recruitment of gynecologists who, after being enrolled themselves, then recruited pregnant women was, therefore, crucial for the success of the trial. In Germany, community-based physicians are self-employed [25] and can, therefore, independently decide which additional programs they offer to their patients and whether or not to participate in health services research studies.

Study coordinators, who were based in the study regions, carried out the entire recruitment process of community-based health care providers in the GeMuKi trial. This included identifying contact details within the sample frame of community-based health-

care providers, enrollment of healthcare providers into the trial and ongoing close support afterwards. During this process, the study coordinators established personal contact to all healthcare providers within the sample frame to discuss trial participation. All study coordinators held a degree in the fields of nutrition or sports science.

The GeMuKi trial's recruitment process is illustrated in Figure 1. Eligible healthcare providers were identified based on the Association of Statutory Health Insurance Physicians (ASHIP) database, supplemented by internet searches. The final sample frame consisted of 818 gynecologists (513 in intervention regions und 305 in control regions). At the beginning, all healthcare providers were invited to information events. In total, 30 gynecologists attended (17 in intervention regions and 13 in control regions). After a constructive exchange at these events, advertising campaigns were launched to promote the trial within the study regions. For example, presentations at physician's quality circles and *Stammtisch* discussions (regular, informal meetings outside of work) were held and, in addition to this, the study coordinators distributed mass information media such as flyers. Other tools used to publicize the trial included press articles and newsletters. All gynecologists in the intervention regions (n = 513) were invited to participate in a trial preparation workshop, which was a prerequisite for the intervention group to participate in the trial and deliver the intervention. For those who did not provide feedback on trial participation, the study coordinators conducted cold calls via phone and personal practice visits. A total of 141 gynecologists and 104 associated physicians' assistants attended the trial preparation workshop. Gynecologists in the control regions did not receive training, as they were solely required to collect data and did not conduct the intervention themselves. After the workshops, the study coordinators sent reminders to all participants. In intervention and control regions, they visited the practices to provide on-site instruction on the digital data platform and trial organization. In conclusion, 63 (12% of those eligible) gynecologists in the intervention group and 65 (21% of those eligible) in the control group were, subsequently, enrolled in the trial. Finally, 36 gynecologists in the intervention group (57% of those enrolled) and 37 in the control group (57% of enrolled) actively recruited patients for the trial. The participating gynecologists received an incentive of EUR 100 per patient in the intervention group and EUR 40 per patient in the control group. By the end of recruitment, 792 patients had been recruited in the intervention regions and 674 patients in the control regions.

During the trial process, adjustments were performed to the recruitment plan: two additional trial regions (one intervention and one control) were added to enlarge the sample frame. The total timeframe for the healthcare provider recruitment was 18 months.

2.2. Study Design

This qualitative study was conducted alongside the GeMuKi trial using a sequential design. Figure 2 provides an overview of the iterative data collection and the analytical approach. The report and conduct of the study was based on the 'Consolidated criteria for Reporting Qualitative research' (COREQ) (Figure S1) [26]. All data collection and analyses were conducted by the two first authors, both of whom held a master's degree in the field of health sciences and sociology, respectively, and were experienced qualitative researchers.As a first step, a documentary analysis of internal project documents was performed to establish an overview of the factors that influence the recruitment process. Internal project documents are documents prepared as part of project implementation for use by members of the project team (e.g., meeting minutes, records of phone calls, etc.). Based on this, semi-structured interviews with the study coordinators, who were part of the project team and in charge of recruiting community-based healthcare providers, were conducted and analyzed. In the third step, all factors for successful recruitment of healthcare providers were discussed.

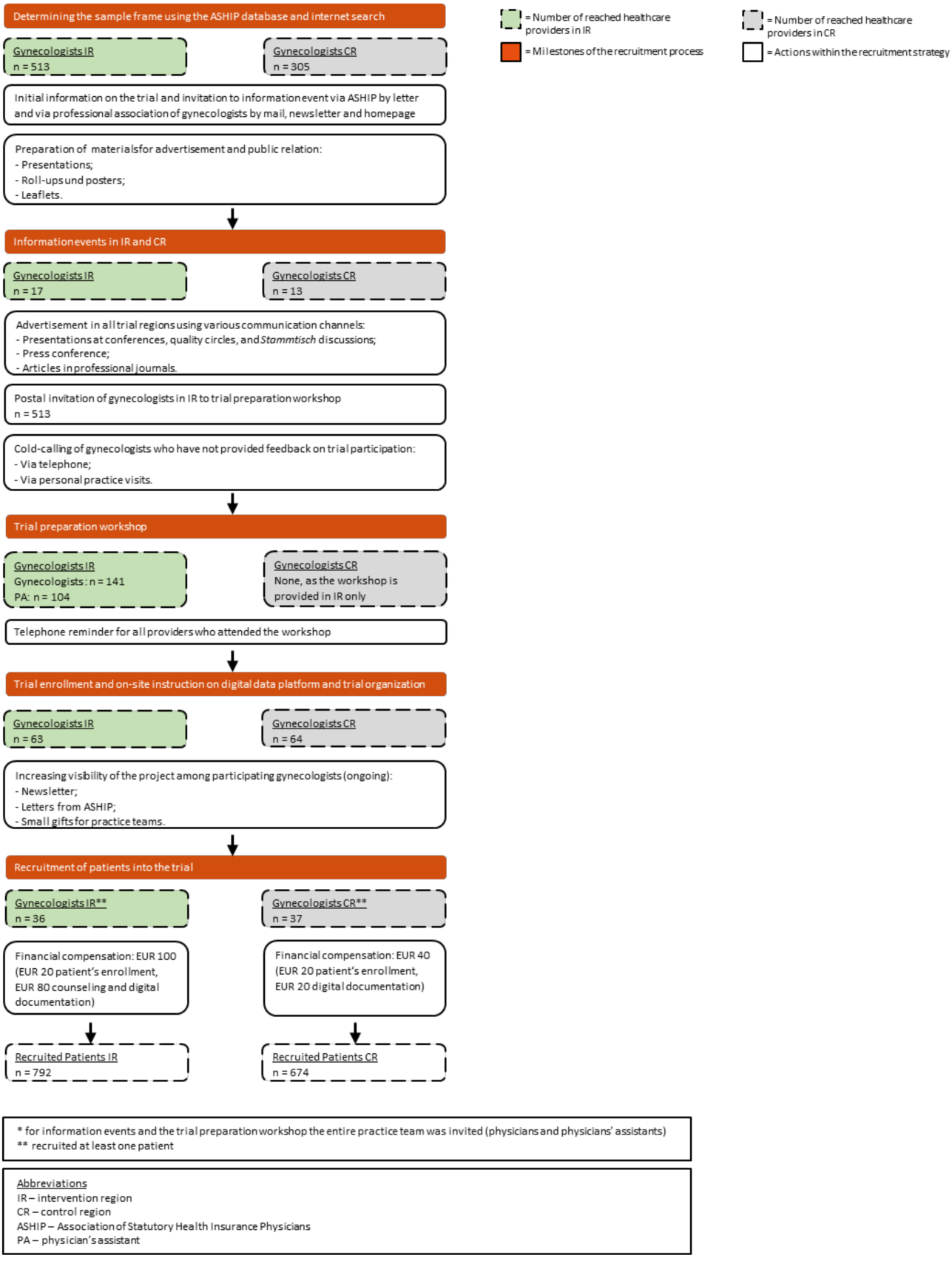

Figure 1. Flowchart for the recruitment process in the GeMuKi trial.

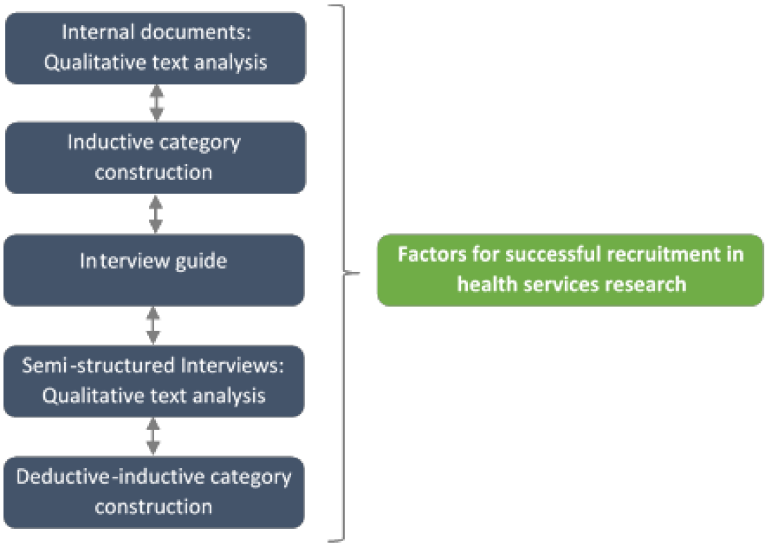

Figure 2. Iterative data collection and analytical approach.

2.3. Data Sources

All data used in the study were collected after the recruitment of healthcare providers was completed (data collection started on 30 June 2020). For the documentary analysis, all available records (n = 137) were collected, such as documents from trial staff meetings, discussions with occupational associations and healthcare providers, and written project correspondence (see Table S1 for an overview of included documents). The collected documents were reviewed and included or excluded for further analysis depending on whether they contained information relevant to the recruitment process [27]. Of the 137 documents collected, 99 were included in the final analysis. In the second step, semi-structured interviews were conducted with the study coordinators. The researchers and study coordinators knew each other from their cooperation in the host trial and had a friendly working atmosphere. The topics of the interview guides were based on the results of the documentary analysis. The interview guide (see Table S2) included questions based on the experience of the study coordinators. The objective of the interviews was to assess the various recruitment strategies and to gather information on the reasons why healthcare providers decided to participate or decline to participate in the trial. The interviews (n = 6) were performed via telephone due to COVID-19 contact restrictions. All study coordinators who worked in the GeMuKi trial were invited and agreed to participate in the interviews. Since interviews were conducted with all involved study coordinators, assessment of data saturation was not possible. Before the interview, the researchers outlined the aims and goals of the study to the interviewees. Field notes were taken by the researchers to record researcher's impressions as well as features of the interaction. The average interview duration was 39 min (min = 20 min, max = 65 min). All the interviewees gave their written consent for digital recording of the interviews, further data processing and publication of results in the form of anonymized quotes. The interviews were recorded and analyzed anonymously.

2.4. Data Analysis

First, all data sources (internal documents and interviews) were analyzed separately and integrated at the data interpretation stage. The internal documents selected as relevant to the research topic were evaluated by means of qualitative text analysis. The authors used thematic analysis as described by Kuckartz (2014), which is a category-based method for the systematic analysis of qualitative data [28]. The researchers opted for an inductive approach; consequently, the construction of the categories was based solely on the collected data [28]. The results of the documentary analysis were used to inform the development

of the interview guide. The data from the semi-structured interviews were transcribed and analyzed using thematic analysis in the MAXQDA 18 software (VERBI Software, Berlin, Germany). At this analysis step, a combination of deductive and inductive category constructions was deployed [29]. The deductive categories reflected the results of the previous documentary analysis. Consensual coding, a technique in which the material is independently coded by two researchers and then consensualized in an iterative process, was used [28]. The complex category system was visualized and was collaboratively discussed among the research team to sort, interpret and prioritize the results.

3. Results

The results for identified factors that promoted the recruitment of community-based healthcare providers were presented first, followed by factors that inhibited successful recruitment. Table 1 displays the final and comprehensive system of thematic categories. The results section summarizes the aspects that were most relevant for planning and conducting further health services research. The interviews were conducted and analyzed in German. Two researchers translated the quotes independently.

3.1. Facilitators for the Recruitment of Community-Based Healthcare Providers

All the interviewees described the intrinsic motivation of healthcare providers as the most important factor for active participation in the trial. For example, study coordinators provided the following assessments:

> *"For them, the focus is on perinatal programming, so they also know what responsibility the physician has [. . .] during pregnancy to address this [. . .] Yes, they have understood the importance of these topics and it is important for them, and that is the main motivation to participate in GeMuKi." (study coordinator 1_paragraph 16)*

> *"I think that it plays an important role that there is an intrinsic motivation to participate in something like this, that an interest in this topic is given, because/ and that one also, yes, simply has the motivation to do more about this in day-to-day life." (study coordinator 5_paragraph 10)*

Intrinsic motivation, thus, included an interest in the trial topics and a perception of them as important and relevant to regular care. It indicates the physicians' need to improve the care provided to their own patients and to contribute to the development of their profession. Additionally, intrinsic motivation involves a general openness and curiosity with regard to new learnings and being up to date. The respondents also addressed extrinsic motivational factors that led to participation in the trial. These included: financial compensation, continuing medical education credits, regional peer group dynamics, and professional–political mandates. However, the respondents claimed that these factors played only a secondary role in the decision on active participation. Although some statements indicated that the financial compensation should have been higher, there is an agreement that the financial aspect was not a decisive reason for whether a healthcare provider participated.

> *"No one would have taken part for the sake of money, in order to pimp their salary a bit. I do not see that at all." (study coordinator 6_paragraph 8)*

Table 1. Category system for thematic analysis.

Facilitators for the recruitment of community-based healthcare providers	Motivation for participation of healthcare providers	Intrinsic motivation	Relevance of the trial topic
			Professional development; improving care; support research
			Openness to learn something new/be up to date
			Improving professional cooperation
		Extrinsic motivation	Collegial obligation (generated by peer-to-peer recruitment)
			Committed to professional politics; professional–political mandates
			Financial Compensation
			Continuing education credits for informational event and training
	General set up of routine healthcare practice	Lifestyle topics were already part of regular care before entering the trial	
		Awareness that there is pent-up demand in medical care	
	Promising contact channels	Presentations at quality circles and Stammtisch events	
		Letters sent by the Association of Statutory Health Insurance Physicians (ASHIP)	
		Cold calls	
		Repeated personal visits combined with small presents for practice staff	
	Practice organization/distribution of tasks within the practice team	Coordination and communication within the practice teams	
		Participation of the physician's assistant in trial tasks and close exchange with the gynecologist	
	Other facilitators	Individual characteristics of the healthcare providers	
		Efficient and charming communication and adapting communication to individual situation in the practice	
		Particularly high need among patients (practices in deprived areas)	
		Low trial burden	

Table 1. *Cont.*

Barriers for the recruitment of community-based healthcare providers	General set-up of routine healthcare practice	Lack of time and excessive workload in day-to-day routine	
		Lifestyle topics were NOT part of regular care before entering the trial	
		Information management on the part of the physicians' assistants	
		Practice organization	Healthcare providers are reluctant to upset well-established practice structures
			Physicians' assistants often work part-time. Trial tasks must, therefore, be carried out by several people
			Change of staff in the practice
			Rejection of the entire practice team
	Trial-related processes (inclusion and implementation)	Financial compensation is perceived as too low by some healthcare providers	
		Incentive for patients is perceived unattractive	
		Structure and content of the trail preparation workshop should be improved	
		Inclusion criteria sometimes not feasible in day-to-day practice	
		Digital data documentation: some practices only work paper-based	
	Professional policy	Target group in trial regions not included in planning (only professional associations)	
		Lack of support from the professional association	
	Organizational aspects within the team of study coordinators	Using the most appropriate communication and marketing strategies was difficult at the beginning	
		Uncertainty about frequency of repetitive cold calls and reminders	
	Participant clientele	Healthcare providers do not perceive any need for intervention among their well-educated patient clientele	
		Healthcare providers perceive that their socially vulnerable patient clientele has too many other burdens and cannot be reached by the intervention	
	Participant rejection	Healthcare providers have difficulties to "sell" the trial	
		Administrative effort too high and benefits too low	
		Characteristics of patients: both groups with high and low intervention needs	
		Data privacy concerns	
		No interest	
		Lack of trust between patient and healthcare provider	
		Recruitment at an unsuitable time point: uncertainty in early pregnancy leads to rejection	

Table 1. *Cont.*

	Other barriers	Individual characteristics of healthcare providers
		Healthcare provider does not have any experience in recruiting patients
		Adjustments to trial workflows were delayed by long bureaucratic processes
		Skepticism regarding trials in general
Explanations for inactive practices	No active participation at all	Enrollment out of obligation; no honest interest
		Participation for receiving a free workshop and continuing education credits
	Active participation discontinued during the trial	Frustration as colleagues in the region do not participate
		Perceived complexity of the trial leads to problems and, ultimately, to healthcare providers quitting
		Repeated rejection by patients to participate in the trial
Unrelated discussion points and other matters	Suggestions for improvements	
	Expertise and knowledge exchange	

Some of the reported facilitating factors for recruitment related to the general set-up of a routine healthcare practice. For example, recruitment was reported to be easier if healthcare providers were already addressing the lifestyle topics as part of their regular care prior to entering the trial. All the interviewees cited convincing healthcare providers to participate in the trial within a short time frame as their most difficult task during the recruitment process. For example, they mentioned the importance of highlighting different information in the intervention and control groups and adapting their communication strategy accordingly. The amount of information relayed was, thus, scaled down to a minimum for busy practices, while more detailed explanations on the trial were provided when there was more time. Overall, the study coordinators emphasized the importance of efficient and charming communication when it came to recruitment:

> *"When I was out and about a few times for cold calls, at the beginning you're still a bit shy and at some point you know what you have to say to somehow get the people. So I think there is a lot of intuition and also empathy, on whom you encounter there and whether it then just falls on deaf or on open ears." (study coordinator 5_paragraph 44)*

Interviewees agreed that, in terms of promoting the trial among gynecologists at the very beginning, visits to quality circles and *Stammtisch* events were beneficial for recruitment.

3.2. Barriers to the Recruitment of Community-Based Healthcare Providers

The major inhibiting factor was a lack of time. This factor resulted from the general set-up of a routine healthcare practice. In many cases, the study coordinators reported that there was no time for additional tasks that went beyond standard care during a busy everyday care routine. In addition to this, many practices were working at the limit of their capacity, so additional time spent on individual patients due to trial tasks resulted in other patients not being cared for. The study coordinators, therefore, saw the additional workload caused by the trial as the most critical barrier to recruitment. During the recruitment activities, study coordinators reported on problems arising of trial-related processes and the additional workload for gynecologists—enrollment, documentation and counselling—which was described as not being manageable. In this context, the interviewees also experienced the financial compensation for trial effort to be too low to provide an inducement. Another factor reported in this category was the digital implementation of trial components (digital data platform), which in some cases led to a rejection of participation.

Additionally, the study coordinators described barriers to recruitment that arose from the relationship with the healthcare providers' professional association: the interviewees expressed their impression, that the actual target group, community-based gynecologists, did not feel sufficiently involved in the planning of the trial. Community-based healthcare providers in the study regions were not involved during the planning phase, though members of the German Professional Association of Gynecologists (Berufsverband der Frauenärzte) were present at trial meetings.

The interviewees problematized organizational aspects within the team of study coordinators. Interviewees reported that it was often not possible to obtain clear approvals or rejections for trial participation from healthcare providers, even after repeated contact attempts. In these cases, there was a lack of clarity as to how many contact attempts should be performed before a practice could be classified as not recruitable.

> *"So I couldn't tell the physician assistant anything more about it, she had already heard from me several times, HAD already presented everything to the physician [. . .], but there was no final feedback. Then [it] was just: Okay, do I remove them from the list? Better not do it? That was always the decision. I think many of the study coordinators then immediately deleted the practice." (study coordinator 1_paragraph 51)*

Another main difficulty in the recruitment work was seen in information management on the part of the physicians' assistants. This included passing the information to the right

person at the practice. In most cases, the initial telephone contact was conducted with physicians' assistants. Often, the physician's assistant acted as a gatekeeper. As a result of this, it was not possible to speak directly with the physician or practice owner. Frequently, the extent to which the information was passed on by the physician's assistant was unclear.

> *"[. . .] then you just have some physician's assistant on the line. Well, they don't tell you their NAME on the phone, they simply say "Practice such-and-such" and until you somehow get through to the one who is responsible [. . .] That really sucks (laughs lightly) [. . .]? If you then called them, they didn't know about anything and until/ I was (. . .) VERY, VERY rarely put through to the physician at recruitment and [. . .]/ I don't even suggest that anymore. There's no point." (study coordinator 4_paragraph 10)*

3.3. Inactive Practices

Inactive practices are practices that enrolled in the trial but did not recruit patients. In the GeMuKi trial, this applied to 43% of all the enrolled practices (see Figure 1).

The interviewees reported a lack of intrinsic motivation and, in contrast, predominantly extrinsic motivational factors for initial trial enrollment, such as collegial obligations or continuing education credits for practices that were inactive from the very beginning:

> *"With the practices that (laughs lightly) only participate out of somehow a sense of duty, because they are regional leaders or something, because they have the feeling "Yes, okay, I have to enroll in a trial", yes, or, yes, "I'm doing this here because it HAS to be somehow for the research", but who don't have such a real passion behind it, with them it's going slowly." (study coordinator 6_ paragraph 34)*

Study coordinators mentioned that the reasons for practices becoming inactive during the trial were repeated rejection from patients and the perceived complexity of the trial, which led to implementation problems. According to the interviewees, rejection by patients was in some cases caused by health care provider's lack of requisite arguments and techniques to convince eligible patients to participate in the trial. Furthermore, they reported that participating active healthcare providers felt abandoned in their region and become inactive due to frustration regarding the lack of engagement on the part of their colleagues.

4. Discussion

The aim of this article was to identify facilitators and barriers for the recruitment of community-based healthcare providers and to assess the recruitment strategies deployed in the GeMuKi trial.

Intrinsic motivation among healthcare providers clearly emerged as the most important prerequisite for actively participating in the trial. The importance of promoting intrinsic motivation has, likewise, been highlighted in previous studies on the recruitment of healthcare providers into trials [10,30,31]. When it comes to fostering intrinsic motivation, a strong emphasis should, thus, be placed on the added value of the trial [32]. Moreover, conducting an in-depth needs assessment within the target group of healthcare providers before conceptualizing a trial can be helpful in determining the fields of interest and perceived needs for the optimization of care [6]. This means that developing trial themes "bottom-up" can be used as a measure to increase the intrinsic motivation for trial participation among community-based healthcare providers [1,31,33].

In contrast, extrinsic motivating factors, such as financial incentives and collegial obligations, were shown to be overrated. The results of our study on financial compensation were inconsistent. While some healthcare providers called for higher financial compensation, study coordinators reported that financial compensation was not a motivator for active participation. In connection with this, no evidence of positive effects of peer-to-peer recruitment on recruitment rates was found in this study. This result was in contrast to previous research findings, highlighting the importance of peer-to-peer recruitment [9,13,34]. While in our study, this strategy did lead to trial enrollment in some cases, it rarely resulted

in active trial participation in the long run. The high number of inactive practices tied up many resources, as multiple attempts were performed by the study coordinators to motivate these healthcare providers to recruit patients for the trial. It follows, that providers who lack intrinsic motivation should be ruled out at an early stage.

In conclusion, extrinsic motivating factors emerged as a conflicting strategy when recruiting community-based healthcare-providers for an intervention trial. This result was unexpected, as extrinsic motivators such as peer-to-peer recruitment have been identified as beneficial in the literature. As the role of financial incentives remains unclear, more research is needed to assess the impact of this strategy on recruitment. The resulting issue of inactive practices that was found in this study might be unique to trials which place a high burden on participating healthcare providers. This is oftentimes the case in health services research when the intervention is carried out by healthcare providers themselves. In combination with a lack of intrinsic motivation, extrinsic motivating factors may create just enough engagement to enroll in the trial, but not enough to actively participate. However, published research investigating recruitment processes were mostly conducted within the frame of low-burden interventions. In this context the effects of extrinsic motivating factors can be completely different, leading to more beneficial effects of these strategies. When recruiting community-based healthcare providers for high-burden intervention trials, extrinsic motivating factors should be handled with care to avoid inactive practices in the enrolled sample.

Despite the results on the use of financial incentives for the active participation of health-care providers, financial incentives could still be regarded as a valuable tool in the process of recruiting physicians' assistants for the trial. The physician's assistant is generally the primary contact person for study personnel in the recruitment process; therefore, their cooperation and commitment is crucial. Information management on the part of the physicians' assistants was identified as a barrier in this study and has also been reported previously by others [34–36]. The effectiveness of financial incentives to manage gatekeeping behavior should, therefore, be further researched.

In addition to this, the barriers reported by healthcare providers should not be overestimated. Reported barriers may often be excuses for not participating or not recruiting patients into the trial [35–37]. Multiple adjustments after the start of the recruitment phase of the GeMuKi trial to address and overcome reported barriers cost many resources and, in the end, did not result in active participation on the part of healthcare providers. Hence, there seemed to be greater value in enhancing healthcare provider input during the planning phase of the trial and the recruitment strategy. By doing this, researchers could avoid barriers, create a sense of ownership and thereby build healthcare provider buy-in right from the start of the trial [1,6,30,32,38].

The findings of the study also emphasized the role of trial-related processes in healthcare providers' recruitment decisions. Trial protocols that require a substantial change in the general setup of healthcare practice and/or involve complex tasks pose too great a hurdle for most healthcare providers, leaving only the most motivated for recruitment into the trial. When developing a trial, trialists should, therefore, aim for the smallest possible additional burden and level of change to current practice with which it is still possible to achieve the trial's goals [13,32].

In the context of recruitment organization, the communication skills of the recruiting trial personnel were found to play a big role in recruitment. Effective and goal-oriented communication in recruitment was especially important during busy practice hours in community-based practice settings. As such, trial information must be adapted to different situations and actors, considering age, gender and professional status. Shortly after the start of recruitment, recruiting staff should reconsider which strategies have worked best and readjust as necessary. Effective communication between study sites and trial teams has been found to facilitate recruitment in other studies [6,30]. McDonald et al. proposed utilizing a business model approach and marketing techniques to foster trial recruitment [32]. This includes methods such as building brand values and adopting a formal marketing plan. To

implement this approach, trial teams should prioritize these tasks and obtain expertise in the field of marketing and communication.

Considering the issue of inactive practices (i.e., practices that were enrolled but did not actively participate by recruiting patients), a lack of recruitment skills of healthcare providers emerged as one key factor. In our study, healthcare providers did not recruit patients because they did not know how to introduce the trial and participation to their patients. Patient recruitment has previously been described as a 'sales pitch' [35,39], which poses a major challenge to healthcare providers. Furthermore, research shows that healthcare providers do not feel comfortable communicating the aims and design of the trial, do not want their patients to feel pressured to participate, and do not feel comfortable dealing with rejection [35,39,40]. Offering recruitment skills training in trial preparation workshops can overcome these barriers. The effectiveness of this strategy should, hence, be investigated further. Another strategy to counteract patient rejection, which can lead to frustration and the cease of patient recruitment on the side of the healthcare provider, is the use of comparatively high incentives for patients at the beginning of the trial. Options such as offering additional medical services are also conceivable as a viable incentive.

Community-based healthcare providers in Germany still only undertake trials rarely and lack research routines. To establish research structures in this setting, developing a network of research practices could be beneficial. The use of existing network structures for the recruitment of community-based physicians into trials has proven to be successful in other studies. In their quality of primary care trial, Wetzel et al. found general practitioner recruitment rates of 66% when recruiting from an established network, compared to 23% when these structures were not present [37]. It should be noted that recruiting from existing networks may induce sample effects and, therefore, lead to limitations in the generalizability of trial results [10,13,37]. However, the same argument also applies to a sample of healthcare providers who proactively engage in trials. These physicians are presumably more motivated to change current practice and do not represent the average physician in the field. Today, research practice networks are still rare in Germany and, if present, are limited to certain fields of expertise (e.g., family medicine). In the long term, aspects of conducting research and trial recruitment within routine care ought to be incorporated into the curriculum of community-based healthcare providers.

During the planning phase of the recruitment strategy in the GeMuKi trial, it became clear that advice on how to successfully recruit community-based healthcare providers was difficult to find. There was no doubt that parameters such as the trial design, the setting and the broader environment influenced the applicability and effectiveness of recruitment strategies. There are hardly any studies with a comparable research focus (prevention), in comparable settings (community-based physicians) and with a comparable trial burden on healthcare providers (recruiting patients, implementing, and performing an intervention, and documenting trial data). To better inform future health services research trials in recruitment planning, research should focus more on how the effectiveness of different recruitment strategies is influenced by these parameters.

Strengths and Limitations

The presented findings were drawn from a large pragmatic controlled healthcare intervention trial and, therefore, represent recruitment issues under real-world conditions, which was an important strength of the study.

Another strength of this study was the combination of different methods and data sources. With this approach, it was possible to gain a comprehensive understanding and, thus, map the complexity of the recruitment process in the most accurate way.

One limitation was that information on recruitment was available only from healthcare providers who were accessible after the invitation to participate in the trial. Therefore, the barriers experienced by healthcare providers with whom it was not possible to establish contact after the initial invitation to the trial remain unknown. Moreover, the results of this study were based on the appraisals of six study coordinators and were, therefore,

subjective in nature. It was not possible for the research team to gain direct access to healthcare providers to assess factors that influenced recruitment. As the recruiting trial staff was in contact with community-based healthcare providers on a daily basis, their experiences and perceptions were a valuable information source. The study described in this article was designed as a Study within a Trial (SWAT) [16]. As such, it was not possible to compare the effect of isolated recruitment strategies, as doing so would affect the scientific integrity of the host trial.

5. Conclusions

During the planning of a trial, more attention should be paid to the recruitment phase. Researchers should seek input from healthcare providers during the planning of the trial design and the recruitment strategy. It is advisable to conduct a thorough needs assessment to avoid barriers, address intrinsic motivation, and create a sense of ownership. Financial compensation for the trial burden emerged as a basic requirement, though this was not sufficient as a sole means of recruitment. Additionally, extrinsic motivational factors generally come with a risk of inactive participation. Moreover, clear, and goal-oriented communication skills on the part of trial staff were shown to positively influence recruitment. Sufficient preparation on how to introduce the trial to their patients is important for healthcare providers to feel adequately prepared for recruitment tasks. The recruitment skills of healthcare providers and the communication skills of the trial staff should, therefore, be addressed explicitly prior to the start of the recruitment phase.

Supplementary Materials: The following are available online at https://www.mdpi.com/article/10.3390/ijerph181910521/s1, Figure S1: COREQ Checklist, Table S1: Data base for the documentary analysis, Table S2: Topics of the interview guide.

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

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

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5.3. Scientific Publication of the Cumulative Dissertation: Study III

Study III

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Article

Preventive Counseling in Routine Prenatal Care—A Qualitative Study of Pregnant Women's Perspectives on a Lifestyle Intervention, Contrasted with the Experiences of Healthcare Providers

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Abstract: Maternal lifestyle during pregnancy and excessive gestational weight gain can influence maternal and infant short and long-term health. As part of the GeMuKi intervention, gynecologists and midwives provide lifestyle counseling to pregnant women during routine check-up visits. This study aims to understand the needs and experiences of participating pregnant women and to what extent their perspectives correspond to the experiences of healthcare providers. Semi-structured interviews were conducted with 12 pregnant women and 13 multi-professional healthcare providers, and were analyzed using qualitative content analysis. All interviewees rated routine check-up visits as a good setting in which to focus on lifestyle topics. Women in their first pregnancies had a great need to talk about lifestyle topics. None of the participants were aware of the link between gestational weight gain and maternal and infant health. The healthcare providers interviewed attributed varying relevance regarding the issue of weight gain and, accordingly, provided inconsistent counseling. The pregnant women expressed dissatisfaction regarding the multi-professional collaboration. The results demonstrate a need for strategies to improve multi-professional collaboration. In addition, health care providers should be trained to use sensitive techniques to inform pregnant women about the link between gestational weight gain and maternal and infant health.

Keywords: patient experience; prevention; qualitative research; pregnancy; gestational weight gain; maternal health; lifestyle intervention

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1. Introduction

Overweight and obesity are major public health challenges and risk factors for subsequent diseases in both children and adults [1,2]. The foundations for overweight and obesity are established early in life. There is growing evidence that excessive gestational weight gain and the maternal lifestyle during pregnancy can influence the child's risk of obesity and chronic disease in the long term [3–5]. Furthermore, excessive gestational weight gain is a risk factor for pregnancy and birth complications, such as preeclampsia, macrosomia, cesarean section, gestational diabetes mellitus (GDM), and Large for Gestational Age (LGA) [3,4,6–12].

Due to this, pregnancy is described as a unique "window of opportunity" for preventive interventions aimed at improving maternal and child health [13]. Modifiable behavioral risk factors for adverse pregnancy outcomes and lifelong non-communicable diseases include a lack of physical activity, unhealthy diet, alcohol consumption, and smoking during pregnancy [14]. Even though adopting a healthy lifestyle before pregnancy is beneficial for the health of the mother and child [15,16], the period of pregnancy is discussed as a "teachable moment" and may, therefore, be a favorable time for interventions. This is because pregnant women may be particularly motivated toward ensuring that they are in

good health, and the importance of risk factor modification and healthy lifestyles can be reinforced effectively [17,18]. There is evidence that lifestyle interventions can be effective in improving maternal lifestyle and limiting excessive gestational weight gain [14,19–23].

The percentage of women experiencing excessive weight gain during pregnancy based on National Academy of Medicine (NAM; formerly known as the Institute of Medicine, IOM) guidelines [24] ranges from 47 to 68.5% across various studies and countries [3,7,10,25–28]. These figures highlight the urgent need for preventive intervention. The International Weight Management in Pregnancy (i–WIP) Collaborative Network published a "statement on tackling obesity in pregnancy", in which it called for the incorporation of lifestyle counseling into routine prenatal care [29].

In Germany, lifestyle topics are not discussed consistently in the context of prenatal care [30,31]. Prenatal care in Germany is provided by office-based gynecologists and midwives, and focuses mainly on the early identification of diseases and developmental problems in the fetus [30,31]. While prenatal care can, in principle, be provided by midwives and gynecologists individually, it should preferably be administered in a complementary manner [31]. Almost all pregnant women in Germany utilize prenatal screening appointments, which are paid for by the Statutory Health Insurance. As a result, they are monitored closely throughout the entire course of their pregnancies [31]. In addition to this, gynecologists are often the main healthcare providers (HCPs) for women of childbearing age and accompany these women for many years during regular preventive check-ups [32]. As such, routine prenatal care provides an ideal setting for lifestyle intervention. The GeMuKi intervention (acronym for "Gemeinsam gesund: Vorsorge plus für Mutter und Kind"—Strengthening health promotion: enhanced check-up visits for mother and child), carried out in Germany, uses this setting to address lifestyle topics and to involve multiple HCPs who consistently complement each other [33,34].

In order for lifestyle interventions to be effective and sustainable, they must be adapted to the needs of pregnant women. At the same time, HCPs who implement these in routine care need to find the interventions acceptable and feasible [35]. A qualitative study conducted in the U.S. showed that most women had a positive attitude toward counseling during pregnancy, while HCPs discussed barriers to counseling, including, among others, a lack of time, lack of patient interest, or inadequate training [36]. A German study revealed information gaps among pregnant women in the fields of healthy eating and weight gain, as well as the need for information and motivation regarding suitable forms of exercise during pregnancy [37]. As demonstrated by an integrative review, evidence regarding women's overall experience with regard to prenatal care is currently limited and further research is needed to enable HCPs to modify their care to more adequately fit women's needs [38].

In light of this, this study aims to answer the following research questions: What needs, demands, and experiences do women have with regard to the preventive lifestyle counseling provided in the GeMuKi intervention? How do their perspectives correspond to the experiences of HCPs? The results can be used to develop strategies for adapting and improving prenatal care service structures.

2. Materials and Methods

2.1. Backrgound of This Study: The GeMuKi Intervention

This qualitative study was conducted as part of the process evaluation of the GeMuKi trial. The GeMuKi trial implemented a computer-assisted multi-professional intervention in order to address the lifestyle-related risk factors for overweight and obesity in expecting mothers and their infants. The intervention was carried out in five intervention regions of the southern German state of Baden-Wuerttemberg between January 2019 and January 2022 [33,34].

Embedded into regular check-up visits during pregnancy, six additional preventive counseling sessions were provided: four by trained gynecologists and two by trained midwives. All HCPs who delivered the intervention received eight hours of training in advance

on lifestyle topics and on motivational interviewing (MI) techniques. MI is a client-centered approach designed to evoke intrinsic motivation for behavioral change [39,40]. The counseling topics were based on the national recommendations for a healthy lifestyle during pregnancy issued by the 'Healthy Start—Young Family Network' ("Netzwerk Gesund ins Leben") [41]. During each counseling session, the women were asked to choose from the following topics: nutrition, water intake, physical activity, breastfeeding, alcohol, nicotine, and drug use. At the end of each session, the women and HCPs agreed on jointly set SMART (Specific, Measurable, Achievable, Reasonable, Time-Bound) goals for lifestyle changes. The achievement of these goals was then discussed in the next counseling session. The GeMuKi intervention included a novel shared telehealth platform that aids multi-professional HCPs during the counseling process (the GeMuKi-Assist counseling tool) and a corresponding app (the GeMuKi-Assist app) for the women participating in the intervention. One of the features used allowed HCPs to enter each women's jointly agreed SMART goals into the GeMuKi-Assist counseling tool. After each counseling session, the participants received a reminder (push notification) of their lifestyle goals in their GeMuKi-Assist app. Further details on the GeMuKi trial and the GeMuKi intervention can be found elsewhere [33,34,42]. The GeMuKi trial was designed as a hybrid effectiveness–implementation trial, meaning that data on effectiveness and implementation were collected simultaneously [43]. The results on the effectiveness of the intervention, which was evaluated using a cluster randomized controlled design, are yet to be published.

2.2. Study Design

The report and conduct of this study are based on the 'COnsolidated criteria for REporting Qualitative research' (COREQ) (Figure S1) [44].

Qualitative interviews were conducted alongside the GeMuKi trial as part of the process evaluation during the first year of implementation. In order to answer the research question, an in-depth perspective from both the participating pregnant women and the HCPs was required. The use of qualitative methods appeared to be most appropriate, since this allowed an intensive description of the needs and perceptions of the interviewees.

Ethical approval was obtained from the University Hospital of Cologne Research Ethics committee on 22 June 2018 (ID: 18-163) and from the State Chamber of Physicians in Baden-Wuerttemberg on 28 November 2018 (ID: B-F-2018-100).

The interviews were conducted using semi-structured interview guides, which can be found in the Supplementary Materials (Table S1). To systematize the research interest, the development of the interview guides was informed by theoretical frameworks for the factors that influence implementation. The frameworks included were the 'Implementation outcomes' developed by Proctor et al. 2011 [45] and the 'Tailored Implementation for Chronic Diseases (TICD) checklist' [46], which is based on a synthesis of frameworks and taxonomies for determinants of professional practice. The interview guides contain open-ended questions regarding the procedure and the topics of the counseling sessions, as well as the participants' satisfaction with the intervention and the needs of the pregnant women and HCPs. Depending on the flow of the conversation, the open-ended questions allowed individuals to bring up topics not covered by the interview guides.

At the end of the interviews, once the closing question had been answered, the pregnant women were asked to answer some questions related to sociodemographic factors and their pregnancy, while HCPs were asked about their professional experience and working environments. The interview guides were tested and discussed with women of childbearing age, experts from professional associations of gynecologists and midwives, and the project's scientific advisory board.

2.3. Recruitment and Sample

The sample for this study was drawn from women and HCPs who were enrolled in the GeMuKi-trial. HCPs and pregnant women were invited to participate if they had undergone at least two counseling sessions. This applied to 23 gynecologists and their

medical assistants from 17 gynecologic practices, 7 midwives, and 59 pregnant women. Pregnant women, gynecologists, and medical assistants were invited by postal mail to participate in the interviews. Letters of invitation were sent out to the women in June 2019, while invitations to the gynecological practices were sent out in October 2019 (in one of the five regions, the recruitment of interviewees was carried out one year later, as the implementation of the intervention in this region started one year later. This involved only one pregnant woman and two medical assistants). Midwives were recruited exclusively via telephone calls in October 2019 due to their limited postal accessibility.

Only two pregnant women and one medical assistant accepted the invitation, while two gynecologists and one medical assistant declined. No response was received from the remaining invitees. Because of this, all of the remaining participants already invited were contacted successively again by phone to ask if they were interested in an interview. While all contacted pregnant women were willing to be interviewed, 18 of the eligible gynecologists and 4 of the eligible midwives either rejected participation due to a lack of time or could not been reached. An appointment was scheduled with all of those who were interested. Once the interview was over, all of the interviewees received a gift (voucher) worth 15–20 euros as a thank you for their participation. After 12 interviews had been conducted with pregnant women, data saturation was discussed by the research team as no new themes emerged in the interviews. This was not possible in the same way for the HCP interviews, as no more HCPs could be recruited for an interview. The final sample consisted of 25 interviewees, of whom 12 were pregnant women and 13 were multi-professional HCPs (five gynecologists, five medical assistants, and three midwives). The sample characteristics are displayed in Tables 1 and 2. The participating women were about 33 years old on average, had an average body mass index (BMI) of 25.6, and half of them were first-time mothers. All of the interviews were conducted in the last trimester of pregnancy. The interviewed HCPs were mostly female, and their level of professional experience varied greatly between 4 and 42 years. They all had between 8 and 12 months of experience in implementing the GeMuKi intervention.

Table 1. Sample description of pregnant women; mean values (minimum; maximum).

	Participants (*n* = 12)
Interview duration (minutes)	21:16 (15:00; 26:44)
Age (years)	32.5 (30; 37)
Week of pregnancy	32 (28; 36)
BMI before pregnancy	25.64 (21.64; 33.06)
Parity	No children: 50.0% (*n* = 6) One child: 33.3% (*n* = 4) Two or more children: 16.7% (*n* = 2)

Table 2. Sample description of HCPs; mean values (minimum; maximum).

	Gynecologists (n = 5)	Assistants (n = 5)	Midwives (n = 3)
Interview duration (minutes)	40:00 (25:00; 60:00)	17:12 (7:00; 25:00)	28:20 (25:00; 30:00)
Gender	Male: 1/5 Female: 4/5	Male: 0/5 Female: 5/5	Male: 0/3 Female: 3/3
Professional experience (years)	8 (4; 16)	20,67 (5; 32)	22,67 (9; 42)
Office size	9 (3; 16)	9,8 (5; 20)	-
Employment relationship	-	-	Employed: 0/3 Self-employed: 3/3

2.4. Data Collection

The data collection for this study took place between July 2019 and March 2020 (in one of the five regions, the interviews were carried out in October and November 2020, as the implementation of the intervention in this region started one year later. This involved only the interviews with one pregnant woman and two medical assistants. These interviews were conducted during the COVID-19 pandemic. As the GeMuKi-intervention and the interviews for this study could be carried out in the same way as before the pandemic, there were no substantial differences). The first author (L.L.; female), who is a sociologist by training and an experienced qualitative researcher conducted 25 qualitative interviews. The interviewer was part of the evaluation team and had not met the interviewees before. The interviewees were informed in advance that the interviews would discuss their personal perspectives on and experiences of prevention and lifestyle counseling in prenatal care. They knew that their insights were needed to understand if the intervention fit their expectations and to improve the implementation process of the intervention in case of a national rollout. The interviews with the gynecologists were conducted in person in their offices. The interviews with the pregnant women, midwives, and medical assistants were conducted via telephone. All of the interviews were recorded digitally, anonymized, and transcribed verbatim according to the rules published by Dresing/Pehl (2011) [47]. The interviews with the pregnant women took an average of 21 min. The interviews with the medical assistants lasted a similar amount of time (17 min), whereas the interviews with the midwives and gynecologists took longer (Tables 1 and 2). A second researcher (F.K. or F.N.) was present during the interview and documented the atmosphere and specifics during the interview in a postscript. They also made sure that all of the aspects of the interview guide were covered.

2.5. Data Analysis

The transcribed interviews were analyzed by two researchers using 'thematic qualitative text analysis' as described by Kuckartz (2014), a particular form of qualitative content analysis [48,49]. An inductive–deductive category-based approach was used [48]. L.L. developed the category system. Initially, only deductive categories derived from the interview guides were applied. In an iterative process, two researchers coded the data and derived inductive categories from the text material. In a final pass, two researchers coded the interviews independently using the elaborate category system. Conflicts in coding were discussed among L.L., F.N., and F.K. until a consensualized version for all analyses was completed. All of the coding and analyzing processes were carried out with the aid of the MAXQDA 18 software (VERBI Software, Berlin, Germany) [50]. The interviews were conducted and analyzed in German. In order to make the results available to an international audience, two researchers translated the quotes independently into English. The names of the interviewees were pseudonymized. The thematic qualitative text analysis

focused on categories relevant to the research questions, which could be grouped into five main themes (see Figure 1).

Figure 1. Main themes of the Qualitative Content Analysis.

3. Results

The results from the interviews are presented here for the five main themes (see Figure 1), each of which is discussed below from the perspectives of both the pregnant women and the HCPs. After both perspectives are presented in detail, they are each contrasted in a summary figure at the end of every section (see Figures 2–6).

3.1. Perspectives on Motivation, Acceptance, and Satisfaction Regarding Lifestyle Counseling in Prenatal Care

3.1.1. Pregnant Women's Perspective

The women were interested in the intervention, mainly because they expected to receive more extensive counseling for themselves and their babies. Several of the women stated that they believed obesity to be a socially important issue, and that they would like to help to improve care for pregnant women and infants. The first-time mothers were especially interested in receiving more detailed counseling sessions. They often felt uncertain about various issues and were pleased to be given the opportunity to receive extended counseling sessions with HCPs. Some of the women who had already given birth also reported that they were often overstrained, especially during the first pregnancy.

> *"because when you don't have a clue at all and you're at the beginning and..: Hm, yes, what am I allowed to do now, what should I do, what can I NOT do, what would be better for me? At the beginning, you are a bit overwhelmed when you get your first [baby]"* (Christine, paragraph 67)

The women who had already had children felt that their first pregnancies had already provided them with all of the information they needed. They stated several times that they felt less need to talk. In addition to this, due to their already busy childcare schedules, they had less time to implement the recommendations on lifestyle changes.

The pregnant women were of the opinion that the opportunity for lifestyle counseling should be available as part of routine care, but women should be able to decide for themselves whether and with whom they would like to address the topics, depending on their needs.

Pregnancy is rated as a good time for lifestyle counseling because it is a time when women report taking greater care of themselves. During check-up visits, almost all of the women wanted to discuss what they were allowed to do and what they should avoid. For example, they expected instructions on what foods or sports they should avoid during pregnancy.

The women were mainly satisfied with their participation in the intervention, as it gave them more time to spend with HCPs.

> *"I am very pleased. In particular, the additional counseling from the gynecologist was of the main reasons why I participated in this intervention"* (Kerstin, paragraph 86)

Nevertheless, some of the women reported that they already knew everything the HCPs had told them during their counseling sessions. Some of the interviewees pointed out that the counseling should always be adapted to each woman's individual needs, and that maintaining a healthy lifestyle was already important to them before they became pregnant.

Some of the participants found it difficult to assess whether they had changed any aspects of their lifestyle as a result of the counseling sessions. Nevertheless, they noted that a recommendation from a physician had more impact than when an attempted change was driven by self-commitment alone. For example, one participant identified her unhealthy lifestyle patterns, and now wants to pay more attention to them. She felt that a face-to-face conversation strengthened her focus more than simply reading up on recommendations would. Several of the women reported that jointly agreed goals helped them and provided motivation. They also considered it beneficial to discuss the progress of reaching their goals with their gynecologists.

> *"I have to say I really like that because that gives you a little bit of an extra motivation, because every time when checking the app after visiting the doctor, there is a summary of what we talked about and what we agreed upon. That is an additional reminder and then you simply want to accomplish that [goal]."* (Kerstin, paragraph 26)

The pregnant women wanted their counseling goals to realistically fit their daily lives and be easy to implement. Only one of the participants reported that the sessions failed to motivate her at all, and that she already knew everything she was told prior to participating in the intervention.

In summary, minor changes, such as participants eating more fruit or getting up to exercise more, were attributed to counseling. Additionally, some of the women were repeatedly encouraged to exercise by their HCP, even though they had concerns at first.

3.1.2. Healthcare Providers' Perspective

All of the HCPs interviewed said that their patients generally responded positively to the offer of the intervention. In particular, they reported that the women who were going through their first pregnancies tended to be anxious, and were, therefore, grateful for receiving additional support. Furthermore, some of the women had weight problems during previous pregnancies, and therefore appreciated the counseling sessions.

The HCPs came away with the impression that most of the women were already very well informed prior to the intervention. They often needed reassurance that they were doing things right. When asked, some of the women would also always say that they were doing just fine and did not need the lifestyle advice.

All of the HCPs who were interviewed considered taking the time to provide additional counseling on lifestyle issues to be very worthwhile. They emphasized their intrinsic interest in participating, and noted that they had already dealt with the topics before. Some of the medical assistants stated that they had realized that additional counseling would be beneficial as a result of their own pregnancies. In addition to this, all of the HCPs agreed that there was a need for intervention with regard to overweightness and obesity issues.

Some of the HCPs felt that the counseling had helped the participants. In some cases, awareness was raised regarding the need for change. Sometimes, the help was nothing more than small tips for everyday routines that the patients had not come up with on their own. The HCPs also reported that the joint goal-setting process motivated their patients to give things a try. Some of the HCPs came away with the impression that the women preferred to have their hands held and be given a guideline.

According to one gynecologist, pregnant women are confronted by so many major changes in their life circumstances during pregnancy that they are not able to fundamentally change their diet and exercise if they have not already been eating/exercising adequately. Likewise, this gynecologist believed that women who were already overweight would fail to change their dietary habits, and said that the counseling intervention would thus be unable to help them.

> *"I think that during pregnancy, women are confronted with so many things, so many changes in life, that it is DIFFICULT for them to put everything into action, to have adequate physical activity, a healthy diet, when they didn't even manage to do that before. And that's what I've said right from the start: Those who do that ANYWAY, do not need the program, whereas those who weren't doing it before pregnancy, definitely won't manage it during pregnancy"* (gynecologist 5, paragraph 66)

In addition to this, some of the HCPs believed that there were always some women who thought that they already knew everything. This particularly applied to women in their second or third pregnancy. Likewise, there were certain women who were described as resistant to counseling and who did not value additional counseling. Some of the HCPs noted that these were often overweight women who were unwilling to talk about their lifestyle.

One gynecologist had the impression that the counseling was particularly well received by women who were well-educated and physically active, and thus did not really need it. In contrast, another gynecologist explained that he sometimes had to phrase the information somewhat differently depending on the patient's socioeconomic status, though he would not necessarily say that the better-off knew a lot more. In his opinion, the counseling sessions always needed to be tailored to the patients' needs and background. In spite of this, some of the HCPs observed an information leak for women with little formal education.

There was consensus that an established relationship of trust between the woman and the HCP, e.g., due to treatment and consultation during previous pregnancies, improved the readiness of the women to accept the counseling.

3.1.3. Summary and Comparison of Perspectives

A summary of the findings and comparison of the perspectives on the motivation, acceptance and satisfaction regarding the lifestyle counselling in prenatal care is given in Figure 2.

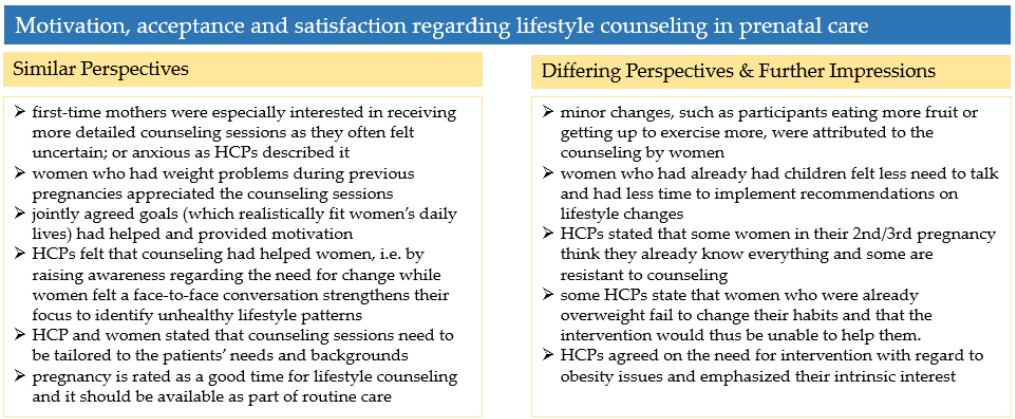

Figure 2. Summary of the results in Section 3.1.

3.2. Perspectives on Lifestyle during Pregnancy and Topic-Specific Needs for Counseling

3.2.1. Pregnant Women's Perspective

All of the women reported that they took more care of themselves during pregnancy. Nearly all of the participants used various pregnancy apps, online searches, and books to obtain information on lifestyle topics. The unborn child motivated them to adopt a healthy lifestyle.

> *"[. . .]and I think, for the good of the child, I think every mom would like to contribute something[. . .]"* (Elli, paragraph 97)

> *"Hm, how can I put it best? It's about doing my bit to ensure the development of our children"* (Frida, paragraph 63)

Nutrition during pregnancy was considered a very important topic, and advice on it was desired by almost all of the participants. Some of the women expected to be educated on foods that were "forbidden" foods during pregnancy, and to receive a list of rules from HCPs.

> *"Yes, so that she [the gynecologist] simply explains, what I can eat, and what's good for me and what's not."* (Christine, paragraph 87)

Some of the participants exercised regularly, but their fitness declined during the course of their pregnancy. The participants were unsure of what activities they were still allowed to do.

During the counseling sessions, nutrition was the most frequently chosen discussion topic. One participant reported that she had more in-depth counseling sessions on nutrition due to her gestational diabetes. Another participant needed specific advice because she wanted to maintain her vegetarian diet. In addition to nutrition, the integration of physical activity into the women's day-to-day routines was also discussed, as well as sufficient water intake. Smoking and alcohol were not discussed in depth because they were of no concern to any of the women who were interviewed.

One interviewee stated that she knew enough about the topics herself and therefore did not want to waste time receiving counseling on lifestyle issues. She believed that people thought enough about healthy lifestyle choices without the need for further advice. She had gained more weight than she wanted, and considered this to be due to a lack of physical activity.

The women reported that they would also like something to take home after the counseling session, such as an information brochure on the lifestyle topics they had discussed. The participants reported that their minds were often very busy during the counseling sessions, and that it would be great to be able to remind themselves of the conversation using written information the next day.

The predefined topics corresponded to the participants' expectations. Most of the women felt that, in addition to these topics, they could also address any other issue as necessary. One participant said she would also be open to home visits for counseling sessions on breastfeeding.

3.2.2. Healthcare Providers' Perspective

The HCPs believed there was a tremendous need for lifestyle counseling, since they provide care to many overweight women. One gynecologist said that the needs of pregnant women varied greatly depending on their initial weight and level of education. One gynecologist said that many women had no idea what healthy food was, and that they stopped exercising the moment they discovered they were pregnant.

> *"because they simply have no idea at all what is healthy food and what is not. They put themselves to bed: I'm not moving (laughs slightly), that could harm the child (laughs slightly). That's really blatant"* (Gynecologist 3, paragraph 8)

One medical assistant came away with the impression that the women were mostly asking for confirmation on whether they were eating enough and whether their diets were healthy enough.

> *"I would say that nutrition [is the most important topic for women]. Many are uncertain about this. Am I now eating sufficiently, am I now eating HEALTHY enough? So I always have this feeling, yes."* (Medical Assistant 3, paragraph 44)

The HCPs confirmed that nutrition was the most popular counseling topic, followed by physical activity. They also stated that nutrition was usually particularly important to women during their first pregnancy. One gynecologist said that the participants often had problems with gaining weight or drinking water. Some physicians stated that alcohol and nicotine-related issues were a problem. Smokers often do not manage to quit completely, while alcohol consumption is very taboo and often kept secret. The gynecologists stated

that many problems, such as substance abuse disorders, cannot be addressed in regular preventive care, and said that some women also needed psychological support.

One gynecologist reported that it was difficult for the participants to decide which lifestyle topic they wanted to discuss while still in the early phase of pregnancy. During this phase, worries and fears regarding the progress of the pregnancy are still highly prominent. In addition to this, the early stages of pregnancy involve a large number of medical tests and require the women in question to handle a multitude of information.

> *"the pregnant woman COMES to the determination of the pregnancy, then one determines the pregnancy and then she is OVERCOME first with completely many information. Right? And there are really MANY, MANY, MANY things, so she must first come to terms with the fact that she is pregnant at all, is happy or not happy, is afraid whether the pregnancy will go well or not—you don't know at the beginning of the pregnancy. Then (clears throat) is the explanation, okay, now maternity care starts. What does prenatal care mean, what do all the examinations that are done in prenatal care mean?"* (Gynecologist 4, paragraph 12)

As a result, they cannot remember everything. Due to this, some of their patients expressed disappointment that they did not receive any written information after the counseling sessions. They also noted that pregnant women needed to adjust to their new life circumstances, and did not consider lifestyle issues a priority for this reason.

3.2.3. Summary and Comparison of Perspectives

In Figure 3, the results on lifestyle during pregnancy and topic-specific needs for counselling are summarized and the perspectives on this main theme are compared.

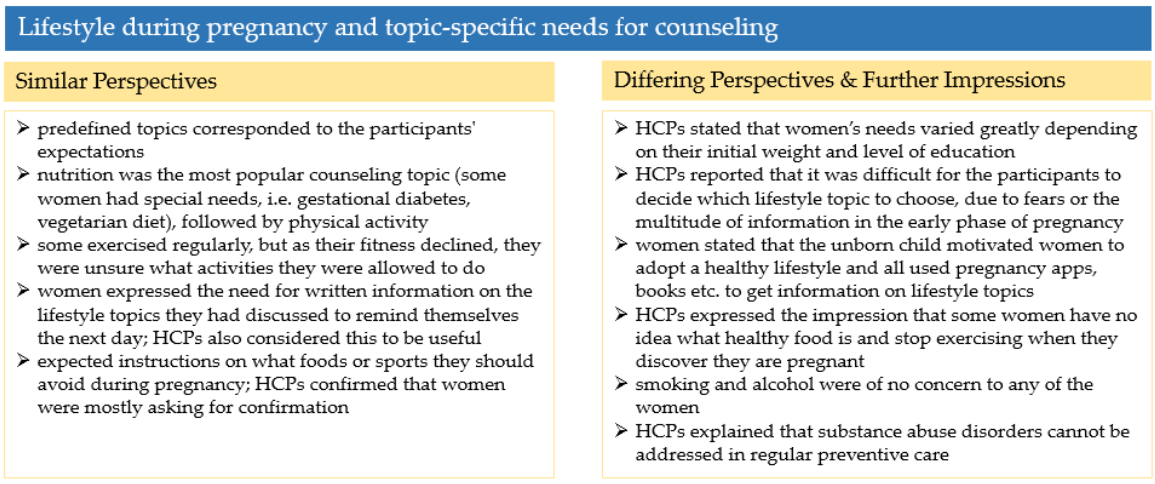

Figure 3. Summary of the results in Section 3.2.

3.3. Perspectives on Gestational Weight Gain and Needs for Counseling

3.3.1. Pregnant Women's Perspective

For the women who participated in the study, weight gain was seen as a normal part of being pregnant. The participants gave the impression that they were not particularly concerned about weight gain, and did not think they could do anything about it anyway. None of the participants associated weight gain with consequences for their own health or that of their child.

> *"I make sure that it's not so MUCH [weight], but I/Now if it's 15, 20 kilos, then that's just how it is [...] So it's just pregnancy (laughs lightly), so then you gain weight, right?"* (Christine, paragraph 54)

> *"Actually, it [weight gain] does not matter so much now. What is certain is that you gain weight. I am not exactly the skinniest of the participants. But I'm not worrying about it right now."* (Elli, paragraph 26)

> *"Well, I mean, you can't really influence it [weight gain] much, or you shouldn't really influence it much, by saying: Oh dear, I'm putting on far too much weight, I want to cut back. So I wouldn't do that, also with regard to the health of the child, that the child would then, I don't know, suffer any disadvantages in its development."* (Frida, paragraph 28)

Some of the interviewees seemed to be of the impression that they did not need to be counseled regarding weight gain, even if they had already gained a lot of weight or started their pregnancy at a high initial weight. One of the participants explicitly stated that she had gained very little weight, and, therefore, did not need to talk about weight. Some of the women reported that their weight was not discussed with a gynecologist or midwife at all. Others reported that sometimes, after weighing, they had been told that their weight gain was within limits, but that there was no further conversation on the topic afterwards.

Only one of the interviewees reported that her gynecologist had discussed and analyzed her weight gain with her. At the beginning of the pregnancy, she was afraid of gaining the same amount of weight as she had during her previous pregnancy. As a result, she was appreciative of the helpful advice on nutrition during the consultation.

One participant explained that she had gained a lot of weight, but said that she did not need to talk about it because she knew herself what had caused the gain. Her gynecologist advised her to write down her daily meals in spite of this, and she now reports that she is in better control of her weight.

In summary, it seems that none of the women were aware of weight gain recommendations or the risks associated with excessive weight gain.

3.3.2. Healthcare Providers' Perspective

The HCPs possessed differing views on the relevance of gestational weight gain. There were both midwives and gynecologists in the study who believed that it was not their job to talk about weight, and stated that they had many other important priorities.

> *"So I think as long as she feels good and does not have any side effects, so if blood pressure is okay, it's not important for me whether she gains 16 or 18 or 20 kg."* (Gynecologist 1, paragraph 56)

Some midwives even said that they did not want to address weight gain because it felt uncomfortable.

> *"You just have to be a little bit careful, and when I don't see the women during the course of the pregnancy, and only at these counseling sessions, I'm just a little bit more cautious about bringing up the subject of weight if it would be extreme in any way."* (Midwife 3, paragraph 24)

Moreover, some of the HCPs reported that they had had difficulty communicating recommendations regarding gestational weight gain to overweight women. One gynecologist believed that to do so would be in conflict with the MI technique, as consultants should not give instructions when using MI. In contrast, one medical assistant said that MI techniques were helpful because they provided a means of approaching the topic of weight gently and sensitively.

On the other hand, there were also gynecologists who said that they always addressed weight, and see regular weighing during check-ups in particular as an opportunity to repeatedly raise awareness. Their impression was that women were more sensitized to the issue of their weight when it was discussed frequently. In their opinion, a combination of regular weighing and information dissemination had the potential to change lifestyles. They, therefore, believed that pregnancy and the close accompanying monitoring can be particularly beneficial in this regard.

> *"So, of course, all you need is information, and also of course this/We weigh them every four weeks. They'll never have that again in their lives, right? So then they're like: (changes voice pitch) Oh, my God, I don't want to be asked about it again at the gynecologist."* (Gynecologist 3, paragraph 56)

Another gynecologist said that his patients know how strict he is with regard to weight gain. Even outside of pregnancy, he discusses options with obese women or refers them to colleagues.

> *"and then pregnancy starts, and I say "Yes, you know, weight development, how high it SHOULD be" and then you can see how it develops and that's good [. . .] So it seems to help if you keep pointing it out."* (Gynecologist 2, paragraph 26)

Another of the gynecologists said that, although she tries to address weight frequently, women have a very different focus and want to know if their child is healthy. Often, her patients are more concerned when they are perceived to not be gaining very much weight.

> *"The focus is on the child. After that, whether they've gained a lot of weight or not is only a minor concern. That's something that doesn't really interest them deeply. Funnily enough, it's more the NOT gaining weight. The significant weight gain shocks them rather less (laughs)."* (Gynecologist 4, paragraph 26)

One of the gynecologists noted that, for obese women, body weight is without a doubt an issue before pregnancy and that it should ideally have been talked about beforehand. In contrast, another of the gynecologists explained that she would only discuss lifestyle issues in the context of prenatal care, because, in such scenarios, they also have a direct impact on the health of the child. Outside of pregnancy, she sees no obligation to address the issue, and considers it the responsibility of a general practitioner.

One of the gynecologists was convinced that pregnant women are concerned about their weight because they are constantly being asked about their appearance. Nevertheless, most of her patients were unaware of the recommendation. Practically all of the HCPs observed that the women were not familiar with the recommendations for adequate weight gain during pregnancy.

3.3.3. Summary and Comparison of Perspectives

Figure 4 summarizes the findings on gestational weight gain and needs for counselling and compares the perspectives of pregnant women and HCPs.

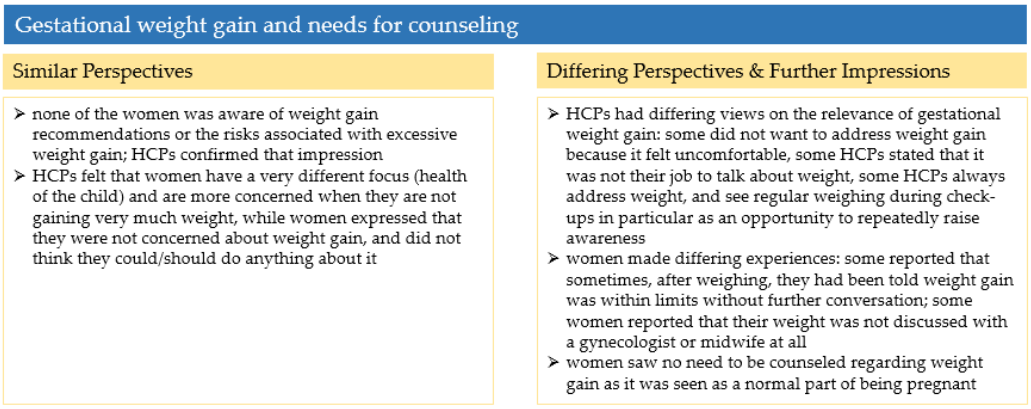

Figure 4. Summary of the results in Section 3.3.

3.4. Perspectives on the Appropriateness and Feasibility of Embedding Counseling Sessions into Routine Prenatal Check-Up Visits

3.4.1. Pregnant Women's Perspective

In all cases, the women appreciated the fact that the counseling sessions were carried out as part of their routine prenatal care.

> *"Yes, I think so. Because where else can you go/I think it makes sense when you're at the gynecologist's that you also talk about such topics."* (Elli, paragraph 58)

The majority of the participants were opposed to additional appointments outside of their regular check-up visits. The pregnant woman also said they would also only consult other healthcare experts outside of their routine prenatal care setting if problems arose. For

example, one participant said she could see herself contacting a lactation consultant if her breastfeeding was not going well.

The women provided highly differing descriptions of their counseling sessions. Some women felt that a lot of time was given to them. Others complained that there was little time for a conversation, and that things were rather hectic. One woman said that she stopped asking questions because everyone in the practice was so stressed. Some women reported that, despite being enrolled in the trial, they had not yet received counseling, nor had their lifestyle issues been addressed. However, the women also found it difficult to distinguish their standard care from the intervention.

Most of the interviewed women received lifestyle counseling at their gynecological practices. In half of the sample, there was no involvement at all from medical assistants in the intervention components. In some cases, they assisted with documentation or with preparing topics for the counseling sessions. For example, some medical assistants attempted to identify the topic the patients wanted to discuss. Two women reported that they had received counseling from medical assistants. Only one of the women who were interviewed received counseling from a trained midwife. The other participants reported that they only saw their midwives at a later stage of their pregnancy.

About half of the women who received counseling sessions chose the counseling topic themselves. The topics for the other half of the sample were predetermined by the respective HCP. From the interviews with the women, it appears that the HCPs often asked questions regarding their behaviors, then offered recommendations in response.

> *"For example, when it comes to eating behavior, she first asks me what I like to eat or what I eat in general, i.e., whether I eat healthily or not, or when it comes to drinking, what I drink all day, how much I drink and (clears throat) I answer all the questions. Then, if she has any other information that doesn't match my questions, then she informs me about it."* (Doris, paragraph 12)

3.4.2. Healthcare Providers' Perspective

All of the HCPs considered prenatal care to be an appropriate setting for preventive counseling. The gynecologists stressed that a gynecological practice is a good setting for preventive counseling because they usually already have a long-standing relationship with their patients and see them regularly. Emphasis was also placed on the fact that prenatal check-up visits at a gynecological practice present a reliable opportunity to speak to women about their health, since all women attend these services. Medical assistants can usually schedule appointments in order to tie the consultations to regular check-up visits.

The gynecologists did not take patient accessibility via midwives as a given, as many women are not in contact with midwives during their pregnancy; in fact, some have no contact with midwives at all. The gynecologists also pointed out that a medical practice provides a safe space where these conversations can take place uninterrupted. The gynecologists usually incorporated their consultations into the regular check-up visits. Some took 5–10 min for the consultation, and others between 15 and 20 min.

On the other hand, all of the gynecologists reported a lack of time due to many other issues relating to regular screening during check-up visits. One gynecologist stressed that gynecologists are mainly responsible for curative matters, and that preventive medicine is not something they generally deal with.

> *"Preventive medicine in general just basically isn't something we do, we are basically there for curative issues. But then that's a contradiction in itself, because there is no curative activity for us to carry out in maternity care. So we definitely need to talk about the extent to which such a practice procedure really offers room for it. But, yes, on the other hand, this is again contrary to the relationship work that one does as a caring doctor."* (Gynecologist 4, paragraph 64)

One gynecologist explained that she needed to educate the women on numerous topics, and suggested that midwives should be made more aware of prevention topics. However,

she also pointed out that midwives all have different levels of training. Despite this, the gynecologists stated that breastfeeding was a topic traditionally discussed in midwifery.

Several of the HCPs did not apply the conversational MI technique, deciding instead to stick to their usual conversational approach. One physician stated that he did not consider the technique applicable at all. One of the gynecologists considered MI inappropriate for topics such as breastfeeding.

All of the midwives stressed that they had always provided lifestyle counseling and saw themselves as suitable counselors, since they also assisted families after the birth. Nutrition and breastfeeding have always been topics on which midwives have provided detailed counseling.

Contrary to the study protocol, all of the midwives reported that they always made additional appointments for lifestyle counseling as part of the intervention, as they did not normally see their patients until shortly before birth. The midwives visited the women in their homes and spent about 20 min on counseling. They felt that going to the woman's home specifically for this purpose gave the consultation special relevance. The midwives also highlighted a number of other advantages to providing counseling in the home environment—there were no interruptions, they were able to take more time for the conversation, and they also gained an insight into the women's lifestyles in their homes. Nevertheless, they noted that the visits were time-consuming and not very profitable. In terms of scheduling, they said that the facts that they do not have practice offices and that it is difficult to coordinate on-site home visits were problematic. One of the midwives said that they would like a predefined guideline on how to incorporate the counseling sessions into her workflow. On the other hand, another of the midwives expressed concern that gynecologists' offices are too overburdened, and said that midwives can be more flexible and provide longer counseling sessions on an individual basis.

One gynecologist pointed out that the quality of counseling varied greatly among all colleagues. In addition, he emphasized that, in the gynecological practice, they can only cover the tip of the iceberg and highlight topics. He refers obese women to nutritional counseling and draws their attention to the services offered by health insurance companies.

Another of the gynecologists expressed concern that dedicated and well-educated women would follow the recommendation to see a nutritionist when they were actually the group that least needed to do so.

> *"So I think that it [the gynecological practice] is the right place, because they will definitely be there. [...] So if we now say that they should all go to a nutrition consultation, then I'll tell you: All the working women won't go, they're happy when they've managed to get the appointment here, ok? All those who more or less let everything slide anyway, i.e., the unmotivated ones, they will NOT go either. Then the women you have in the nutritional counseling are the ones who actually don't really need it, because they're already quite good anyway."* (Gynecologist 3, paragraph 124)

Some of the HCPs stressed that the program was unable to reach the women who needed to be addressed most urgently. All of the HCPs agreed that there was an urgent need to find a way of conducting good counseling sessions with non-German-speaking women. In addition to this, they said that all of the information materials needed be translated as standard.

Another of the gynecologists reported that most of her patients had a huge need for counseling on childbirth, and many fears and concerns that needed to be discussed. She said that sometimes there was more focus on this than on lifestyle issues. This gynecologist suggested using the counseling time to discuss all of the patient's fears first, otherwise, the women would not be able to concentrate on lifestyle issues.

One of the gynecologists said that she would like to see general changes in the health care system, and that it was not cost-effective for her to conduct in-depth consultations with her patients. She claimed that HCPs needed more time and adequate compensation. Likewise, the midwives said that they would like to be reimbursed for the consultation in a manner similar to a postpartum visit. In addition to this, it was agreed that regular training

should be provided. Some of the gynecologists also suggested that medical assistants should be more closely involved in the consultation process. The medical assistants echoed this preference.

> *"I have an additional qualification as a nutrition consultant and [. . .] I find it especially interesting in pregnancy and that was my motivation for me. [. . .] I would like to do more personally, but I'm kind of not allowed to. So I think that's a bit of a shame"* (Medical Assistant 1, paragraph 54; 92)

3.4.3. Summary and Comparison of Perspectives

A summary of the findings and comparison of the perspectives on the appropriateness and feasibility of embedding counselling sessions in routine prenatal check-up visits is given in Figure 5.

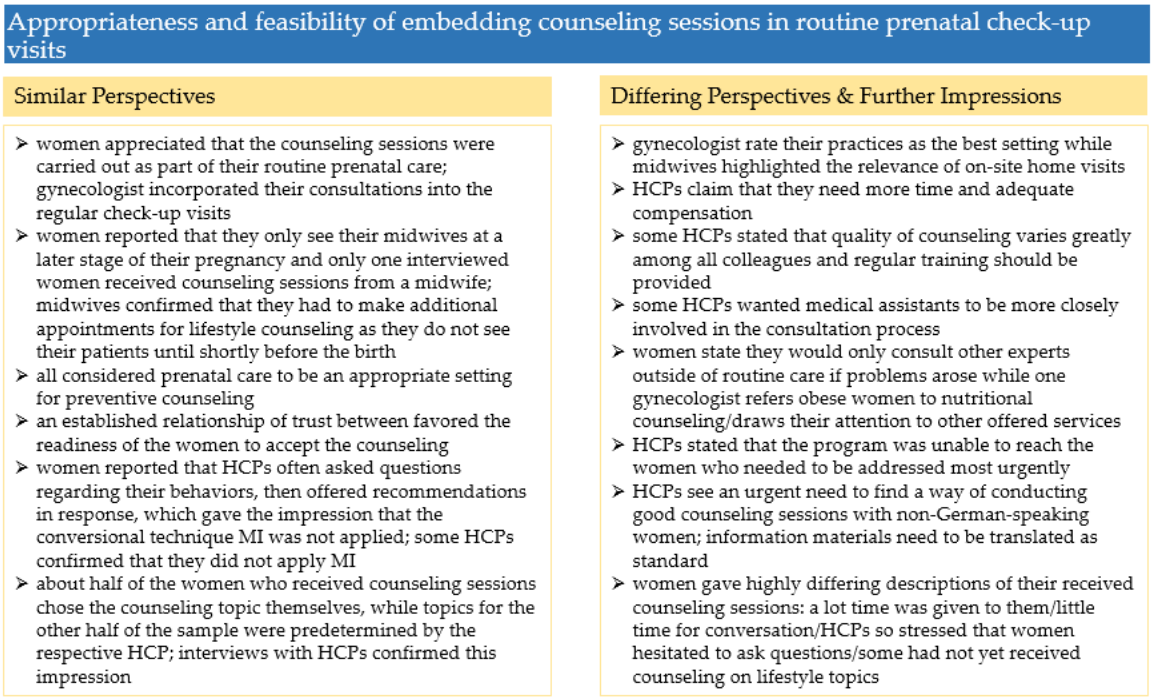

Figure 5. Summary of the results in Section 3.4.

3.5. Perspectives on Inter-Professional Cooperation and Receiving Counseling from Different Healthcare Providers

3.5.1. Pregnant Women's Perspective

Several of the women liked the idea of receiving lifestyle counseling from multiple HCPs. They felt that the more often they heard the key messages, the better. In addition to this, they believed that it would be a good idea for all of the professions involved to consult on lifestyle topics, as they hoped that this would give them a more comprehensive picture and the opportunity to explore different perspectives. In contrast, one of the women, who had already given birth to several children, said that she would have liked to choose who her counseling session was with, and did not want to have to discuss the topics with everyone.

> *"I am not sure whether I would be annoyed by this, when visiting all three providers, [. . .] I would say (sighs) one time would be enough. So I think it would be good if you could choose, so everyone offers it and you can decide who you trust the most. But hearing it from everyone, I think that is too much."* (Helga, paragraph 36)

Some of the women said that they only saw their midwives shortly before/after giving birth, or only for a birth preparation class. As a result, they had no counseling sessions with

their midwives. In some cases, the women already knew their midwives from previous pregnancies, and said that there was no need to see them early.

The women described a relationship of trust with their HCP as being particularly crucial for counseling. Which HCPs were trusted varied greatly from one woman to the next. Some participants reported that they already had a relationship of trust that had been established during a previous pregnancy. One of the participants felt that the gynecologist was the best person to provide the counseling, but said that she would still like the midwife to be more involved. One participant specifically said that she would prefer to confer with her gynecologist because, unlike the midwife, the gynecologist was someone who would continue to provide her with medical assistance for many years to come.

Some of the participants experienced a close relationship of trust with their midwives, and said that they would particularly like to receive advice from their midwives on breastfeeding. One participant said she would like to discuss all of the topics with her midwife, because she sees the midwife both during and after birth. Another of the women also placed considerable trust in her midwife, as she felt it was safe to assume that the midwife would have a particular interest in ensuring that the birth was free of complications. One of the participants reported that her midwife was available to her at all times and always responded promptly. In contrast, she hardly felt comfortable asking any questions at all at her gynecological practice.

The pregnant women expressed uncertainty regarding the relationship between gynecologists and midwives. Some of the women explicitly requested that the HCPs not contradict each other in counseling. The women were under the impression that midwives and gynecologists do not exchange information with one another and do not have access to the same data. In addition to this, the women assumed that HCPs do not maintain any contact with each other. Some of the participants were highly dissatisfied with the lack of collaboration, saying that there seemed to be a lack of mutual acceptance and respect.

The participants felt torn between their gynecologists their and midwives. They felt that some gynecologists seemed to believe that a midwife was not needed, while the midwife had offered to take over the preventive care.

> *"My midwife offered to do the usual prenatal care, just like the doctor would do it. That would be my choice, whether seeing the doctor or seeing her. They are both from this village, and she made the remark that my gynecologist is not convinced about letting the midwife do that and said I don't need a midwife anyway, and that's why I am thinking there is no cooperation between them."* (Frida, paragraph 46)

> *"Yes, I would say it [cooperation] is quite bad. I have a midwife who I am visiting for every second prenatal care appointment, because I want to give birth in a birthing center. And it seems like my gynecologist does not accept that. Every time I visit her she keeps saying to me that I should make the next appointment for in about two weeks, and I am not familiar with the legal situation of what is my right, and every time I see my midwife she keeps saying that my gynecologist did too much, and she wasn't allowed to do that, because it was agreed that my midwife would do that. That is a difficult situation for me."* (Brigitte, paragraph 49–50)

In addition to this, the midwives and the gynecologists offered differing advice on a number of topics. One participant reported a discrepancy between the information she had received from her gynecologist and that from her midwife. For example, the midwife might have recommended something, then the gynecologist would state that the proposed action would not be of any help, and, as a result, the participant would not know what to do. At the same time, some of the women described midwives as peculiar, and said that they were thus hesitant to follow their advice. In this context, the women described their physicians as the authority.

> *"Midwives are usually kind of a bit, let's call it 'special.' Every one of them has her direction where she's heading and she is super convinced of that, but I am not sure if they*

are able to judge objectively. Every one of them has her own, let's call it 'style.' So I would maybe rather lean towards the doctors." (Frida, paragraph 56)

One participant said that she was more likely to listen to or act on something a doctor might say than a midwife. The women were not generally referred to other health care experts. Unless there was any particular need, they might not think of visiting other experts. Two of the participants were diagnosed with gestational diabetes, and were, therefore, referred to a diabetologist.

3.5.2. Healthcare Providers' Perspective

All of the HCPs said that there was a need to engage more with their colleagues regarding counseling on lifestyle topics. All of the HCPs also reported that the intervention had not led to any changes with regard to collaboration.

One of the gynecologists has always worked hand-in-hand with midwives in her practice; three midwives rent offices in her practice and the collaboration works very well. The gynecologist carries out the preventive care first, then the women usually go to see the midwife afterwards. The gynecologist in question strongly supports this approach. In her opinion, gynecologists and midwives have different areas of expertise, and, therefore, complement each other well. Nonetheless, she expressed concern that this is not the way things are done in most practices. She believed that legislation has hindered collaboration between midwives and gynecologists, and said that this was bad for all of the parties involved.

"It has also been hindered by the legislation. [. . .] This is not good for the pregnant women, for pregnancy counseling, for the midwife, and not for the doctors either, right? Nobody knows what that was all about. But (...) midwives can do different things to me. And I can do different things to the midwife. And of course I do my regular prenatal care, that's obvious, that's also obligatory, that's how it should be, that's what the women want. But they come HERE because they read on the Internet that I work with midwives, right? And then that's exactly how it is: they have their own consultation hours, and then the patients can just go there additionally." (Gynecologist 3, paragraph 156)

The other participating gynecologists reported that they had no contact with midwives. One gynecologist expressed regret at this, as she believes that messages are received better when they come from different HCPs. She would be open to gynecologists and midwives sharing prenatal care in a better way. For example, gynecologists could focus on more of the technically related matters and midwives could conduct more of the preventive work.

"in this room, the pregnant women are perhaps more receptive [. . .], because they are more focused on getting this information, and if one were to speak the same language and the pregnant women knew, okay, my midwife says this, and my doctor says the same thing, so in that imaginary scenario, okay, it's my job as a doctor to somehow record the technical points and perhaps then consult with the midwife. Maybe I would advise her to pay a little more attention with one patient, or discuss what could be done with another one, but then I would leave the intervention itself to the midwife." (Gynecologist 4, paragraph 72)

The remaining gynecologists expressed little interest in working with midwives. One gynecologist explained this by saying that they did not have time to network. Another of the doctors had had bad experiences in the past, and said that midwives had made questionable recommendations he did not agree with. Nevertheless, he recognized that midwives perform an important job and can offer women a closer level of care than a gynecological practice is often able to. Due to the shortage of midwives, the gynecologist in question said that he already advises all newly pregnant women to seek midwifery care as soon as possible.

One of the gynecologists said that he was not interested in networking and discussion because, firstly, he had no further use for other people's information, and secondly, he did not want to interfere with anyone else.

The medical assistants reported that discussion and collaboration in a large practice is difficult because it is not clear which midwife is in charge of which pregnant woman.

One of the midwives described the nature of the communication between physicians and midwives as old-fashioned: the midwife approaches the physician, but not vice versa.

> *"We midwives have been thinking about this for a long time, but it's hard to get the doctors to do it. So we go to them, but they don't come to us (laughs slightly) [. . .]. I think that's just an old-fashioned attitude to collaboration in general, which is certainly almost historically conditioned."* (Midwife 2, paragraph 122–124)

One midwife suggested that the lack of discussion was due to tight schedules and the overburdening of both physicians and midwives. In addition to this, competitive thinking could also play a major role. One midwife observed that women were more likely to follow advice from gynecologists than that from midwives.

The midwives in particular indicated that they would like to see an improvement in their collaboration with gynecologists. They all considered joint training to be beneficial, and emphasized the importance of understanding the respective skill sets of each professional group and the way in which each one consults. They saw knowing one another's faces as important in facilitating the exchange of patient information and further referrals. In addition to this, they advocated for a more holistic approach to counseling during pregnancy.

3.5.3. Summary and Comparison of Perspectives

The results and perspectives on inter-professional cooperation and receiving counseling from different healthcare providers are summarized and compared in Figure 6.

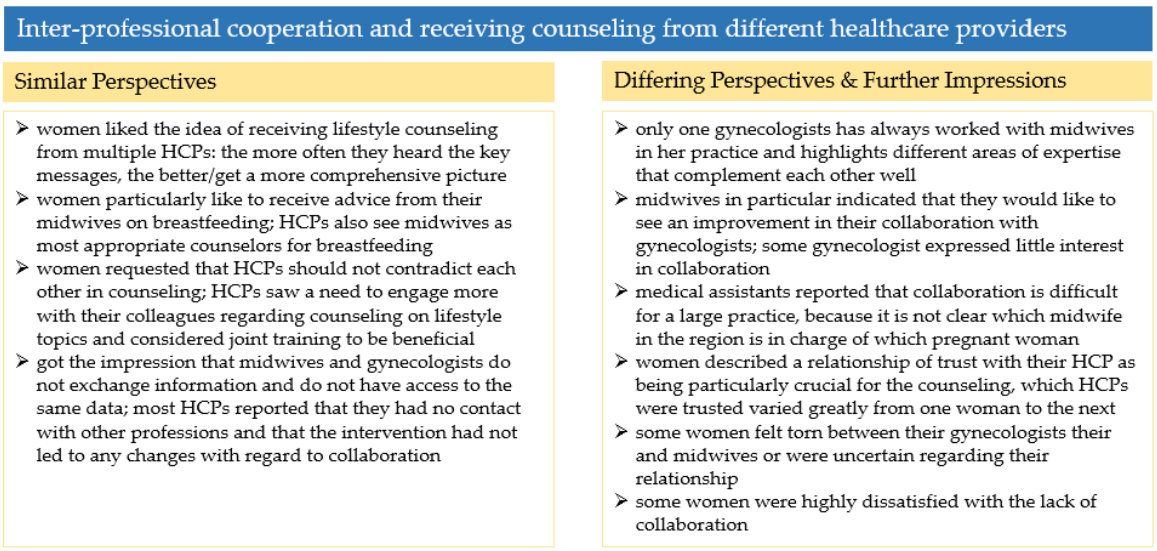

Figure 6. Summary of the results in Section 3.5.

4. Discussion

The results of this study are valuable for tailoring preventive measures in prenatal care according to the needs and expectations of pregnant women and their HCPs. The findings illustrate the similarities and differences in the expectations and experiences of women and HCPs with regard to the preventive counseling in pregnancy provided in the GeMuKi intervention. This demonstrates the importance of including both patients' and HCPs' perspectives when planning and designing implementation.

The pregnant women expressed a need to talk about lifestyle issues, mainly in terms of nutrition and physical activity. The first-time mothers in particular felt a great need for counseling and welcomed the extra time with HCPs. This was reflected by the HCPs in

their daily practice as well. Furthermore, the HCPs pointed out a tremendous need for lifestyle counseling, since they provided care to many overweight women.

All of the pregnant women who participated in the study stated that they wanted to strive for a healthy lifestyle in order to benefit themselves and their child. This behavior was not questioned and could represent a form of social desirability. Atkinson et al. (2016) found that women whose pregnancies were not characterized by a sense of vulnerability or anxiety made lifestyle decisions based upon a "combination of automatic judgements, physical sensations, and perceptions of what is normal or 'good' for pregnancy" [18]. Furthermore, Rockliffe et al. (2021) found that women wanted to adopt to the role of the 'good mother' by making healthy lifestyle changes, but, at the same time, a lack of understanding with regard to health consequences and low risk perception represented barriers to change [51].

The interviews emphasized that perspectives on gestational weight gain varied widely. Pregnant women assumed that they could not influence gestational weight gain and did not link it to the health of the child. Although the HCPs described the women as well informed, the HCPs believed that the women were not aware of recommendations for weight gain during pregnancy. Despite this, HCPs differed in how and whether they addressed weight gain, if they did so at all, and what relevance they attached to it. Moreover, some HCPs reported difficulties in communicating gestational weight gain recommendations to overweight women.

This is in line with findings that stated that pregnant women were not aware of the risks associated with gestational weight gain [37,52,53]. Pregnant women often base their behavior regarding diet and physical activity on their social and community environment and their peers' beliefs [54,55]. While risks, such as smoking during pregnancy, are discussed in these contexts, the risks relating to weight gain are often not known and are not talked about [55]. This further highlights the importance of sharing information on gestational weight gain through HCPs. There is evidence that women who have received information from their gynecologists have a higher level of knowledge with regard to lifestyle-related factors during pregnancy [56]. Liu et al. (2016) showed that weight gain recommendations made by HCPs are an important predictor of actual weight gain [57]. Furthermore, Deputy et al. (2018) found that both inadequate and excessive weight gains were more likely in women who had received no recommendation at all [58]. Research has also indicated that pregnant women assume that weight gain is not a relevant issue if it is never addressed by HCPs [59]. Additionally, findings illustrate a need for accurate advice from HCPs regarding gestational weight gain recommendations [60]. Research is needed on appropriate resources and materials to support HCPs in giving consistent weight gain advice [36].

All of the interviewees agreed that regular check-up visits in prenatal care were a good setting for lifestyle counseling. While the HCPs reported a lack of time due to many other issues related to regular screening, the women appreciated the fact that they did not have to attend additional appointments for lifestyle counseling outside of their normal check-up visits. Embedding additional counseling into routine care was not always feasible for midwives, while it was easy to organize in gynecological practices. While this was not a concern of the interviewed women, some HCPs pointed out that the intervention was unable to reach the women who needed to be addressed most urgently. More research is needed regarding methods to improve outreach to these women and to refer them to experts.

All of the interviewees agreed that joint goal setting and reminders may help pregnant women in making lifestyle changes. Aside from incorporating joint goal setting, the best approach for counseling on lifestyle-related topics remains unclear. The MI technique was not always used and some of the women tended to expect concrete instructions, rather than an open conversation. In contrast, the HCPs stressed that MI techniques had been particularly helpful in enabling them to address difficult and sensitive topics, such as weight. This is in line with other findings, which demonstrated that implementing MI

techniques can facilitate openness and create trust, but pose challenges to medical practices due to a lack of time in their daily routine [61,62].

However, it is important to consider that HCPs should be trained in sensitive communication. There is a risk that HCPs who are not trained and not aware of obesity and lifestyle issues may provide discriminatory advice. HCPs, therefore, require additional training to ensure that they do not stigmatize their patients and inadvertently harm the relationship or health outcomes [63,64]. Continuing education on lifestyle counseling could also benefit patients in other stages of life, such as those undergoing hormonal changes during menopause or cancer and cardiovascular disease [32].

The pregnant women described a relationship of trust with their HCP as particularly crucial for counseling. They were dissatisfied with the collaboration between gynecologists and midwives. Conflicts between the professional groups were sometimes acted out at the patients' expense, resulting in insecurity. The midwives in particular expressed a desire for improved cooperation, while the gynecologists mostly believed that discussion was only needed if complications occurred. Many women do not receive care from a midwife until the last few weeks before birth. Some of the interviewed gynecologists proposed a better division and coordination of consultations so that each profession could focus on their respective field of expertise. Interdisciplinary stakeholders in health care relating to childbirth in Germany have also called for improved collaboration, for example, through joint education and training, and resolution of legal ambiguities [65]. Different authors point to the importance of commitment, interpersonal skills, effective communication, respect, and trust among HCPs for successful collaboration [66–68]. More research is needed to examine the deep-rooted reasons for the difficulties in collaboration between gynecologists and midwives in Germany. Van der Lee et al. (2016) described a combination of exploring contemporary inter-professional practice with a historical perspective on inter-professional collaboration as beneficial to understand problems, and to provide guidance for improving collaboration [69]. From this, implications for policy and practice could be derived and could enable practitioners to implement actions for improving collaboration.

Strengths and Limitations

One strength of the study was the open and explorative character of the interviews. At the beginning, the women were asked to tell the interviewer about their last counseling session with their gynecologist and/or midwife. This led to an open flow of conversation in which the women were able to decide for themselves what to focus on. Another strength was the study's ability to incorporate inter-professional perspectives, as it allowed gynecologists, midwives, and medical assistants to share their experiences. The fact that different researchers were involved in the iterative analysis process represents another advantage, as it meant that the results were discussed in depth at various stages and according to the text material.

As shown in an evaluation of the recruitment procedures during the GeMuKi trial, intrinsic motivation was one of the major factors that led to HCPs participating in the GeMuKi trial [70]. The HCPs who consented to be interviewed were most likely motivated. It was, therefore, reasonable to assume that they did not represent typical HCPs in terms of implementing the intervention. A larger sample of different healthcare providers would have been beneficial. Unfortunately, it was not possible to recruit more healthcare providers for an interview. The interviews did not provide the information required for a comprehensive evaluation of the use of MI techniques. This would have required recurring observations of the counseling sessions, which was unfortunately not possible in practice.

5. Conclusions

Pregnant women and HCPs rated regular check-up visits during pregnancy as a good setting in which to focus on lifestyle topics. In particular, both pregnant women and HCPs reported that the combination of joint goal setting, reminders via push notifications, and feedback sessions helped women to make minor lifestyle changes. Nevertheless, it became

apparent that there was a lack of information among pregnant women with regard to the recommendations for adequate gestational weight gain, and that the counseling approaches adopted by HCPs varied greatly. A discussion should be held regarding using sensitive techniques to inform all pregnant women of the risks and consequences of excessive weight gain. In addition to this, strategies should be sought to improve inter-professional collaboration between all of the HCPs involved in regular prenatal care. The results of this study will help to improve health care in pregnancy by taking into account the perspectives of both pregnant women and their HCPs.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/ijerph19106122/s1, Figure S1: COREQ Checklist; Table S1: Interview guides. Table S2: Topics of the interview guide*: Interviews with healthcare providers.

Author Contributions: L.L. designed the study, collected and analyzed the data, and wrote the manuscript. F.K. and F.N. assisted in the recruitment of the interviewees and supported the iterative process of data coding. A.A., F.K., F.N., L.L. and S.S. were members of the research team for the host trial. A.A. and S.S. designed the evaluation of the host trial. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki. Ethical approval was received from the University Hospital of Cologne Research Ethics committee on 22 June 2018 (ID: 18-163), and from the State Chamber of Physicians in Baden-Wuerttemberg on 28 November 2018 (ID: B-F-2018-100). The trial was registered in the German Clinical Trials Register (DRKS00013173; date of registration: 3 January 2019). The study data were processed exclusively in a pseudonymized form in accordance with the EU General Data Protection Regulation (GDPR).

Informed Consent Statement: Written informed consent for the interviews and to publish the study was obtained from all the participants.

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

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5.4. Supplementary Data

As mentioned above, the three studies are **supplemented** with the evaluation of administrative data, and a questionnaire completed by the regional study coordinators. The incorporation of the supplementary data was needed to comprehensively cover the implementation outcomes described in the theoretical background. This analysis provides information on the implementation outcomes 'implementation fidelity', including dose and adherence, as well as additional information on the implementation outcome 'penetration'.

Administrative Data

In total, 63 of the 513 gynecologists contacted were enrolled in the intervention. Of these, 36 gynecologists actively (meaning at least one woman was enrolled by them) provided counseling to participants. Out of 771 midwives contacted, 36 midwives were enrolled in the intervention, while seven midwives actively provided counseling.

Over a period of 31 months, a total of 792 women were recruited and enrolled in the intervention, including 48 women who dropped out during the process. Figure 3 shows that according to the documentation of the HCPs, 729 women received a counseling session at the first check-up.

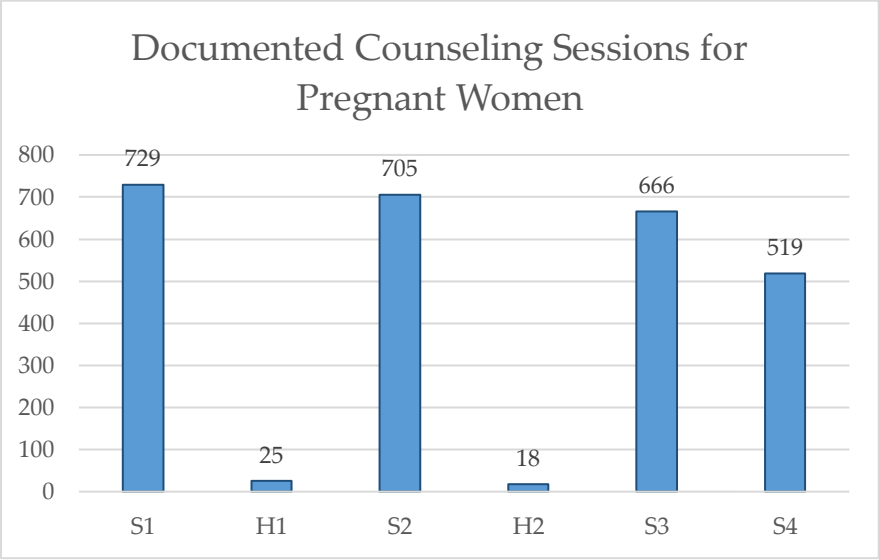

Figure 3: Number of Completed Counseling Sessions

The delivery of further counseling sessions on S2 and S3 decreased only slightly. At the last scheduled counseling date, there were somewhat fewer counseling sessions documented,

which could be due to preterm births, for example. Counseling was still documented for approximately 70 % of the enrolled women. As also shown in Figure 3, the vast majority of participating women received counseling in gynecological practices. In contrast, hardly any counseling sessions with midwives were documented. In total, only 18 (0.01%) participants received two *GeMuKi* counseling sessions with a midwife during pregnancy.

Furthermore, the documentation of the HCPs shows that the most frequently addressed topic during pregnancy was nutrition. At the beginning of pregnancy, the next most common topic was physical activity, while towards the end of pregnancy, breastfeeding was the most common topic discussed during counseling sessions.

At each counseling session, the HCPs asked the women to assess their success in achieving the goal set in the previous counseling session. The HCPs documented the women's answers within the digital counseling tool '*GeMuKi*-Assist'. Based on this, it was found that 90% of participants stated that they had done very well or well with the goals that had been previously agreed upon (see Figure 4).

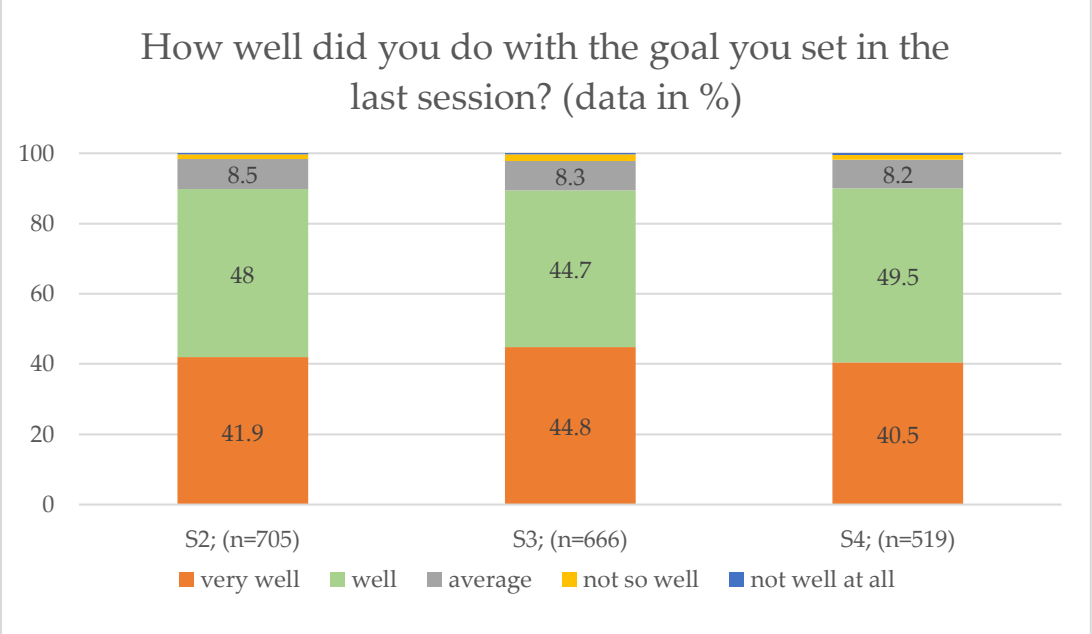

Figure 4: Women's Assessment of Success in Achieving the Goals

Questionnaires on Implementation Fidelity and Organizational Readiness for Change

Questionnaires were available for 46 practices and midwives. Due to personnel changes in the project team, some questionnaires couldn't be entirely completed. Some of the practices also

stopped participating during the course of the project. Initial results of the research questionnaire items concerning the implementation of the digital counseling tool have already been published [81].

The descriptive analysis regarding the type of documentation shows that of the 24 practices on which information is available, eight HCPs documented the data independently in the *GeMuKi*-Assist counseling tool as intended. Another five actors initially documented the data on paper and later transferred it to the counseling tool. About half of the actors (n=11) documented the data exclusively on paper, so that the responsible study coordinator added the documentation in *GeMuKi*-Assist afterwards. For the vast majority of HCPs (n = 29), the study coordinator indicated that no support was needed from the project team when using the digital counseling tool. At this point, not one of the HCPs recorded any notes in the counseling tool for other HCPs/networking. From the responses in text entry fields, it is apparent that in some cases the use of *GeMuKi*-Assist functioned smoothly from the outset, or was well accepted after a start-up phase in which documentation was still done on paper. However, some entries indicated a general rejection of digital technologies by HCPs, which is why in these cases the documentation was done on paper. Furthermore, in some cases there were technical problems (use of the website via iPad, storage of data), so that practices switched to paper documentation in due course [81].

As part of the questionnaire, the study coordinators were also asked to enter examples of the goal agreements for the respective practice. This was necessary because in order to ensure data confidentiality, the goals could not be provided via the data supply for the evaluation. The examples of goal-agreements revealed that the quality varied greatly and that the goals were often not formulated in a SMART approach.

Examples of formulated goals by HCPs:

- *"Minimize smoking, drink mostly water (aim for 2-2.5L)"*
- *"I want to breastfeed my second child. I will drink enough during breastfeeding. I will breastfeed regularly for the first 48 hours, 8-12 minutes. I will latch my baby properly onto the whole nipple. I will prepare my nipple care with little lanolin and breast milk."*
- *"5x fruits and vegetables, 3 main meals, 2 snacks, daily walking, 1x/week swimming"*
- *"Eats enough fruits and vegetables, does not want to gain weight during pregnancy, drink more (already doing better)"*

Based on the last examples, it became clear that some HCPs entered a description of the status quo or a summary of the counseling session, rather than a record of agreed-upon goals.

In the last section of the questionnaire, the study coordinators assessed the practices' organizational readiness for change.

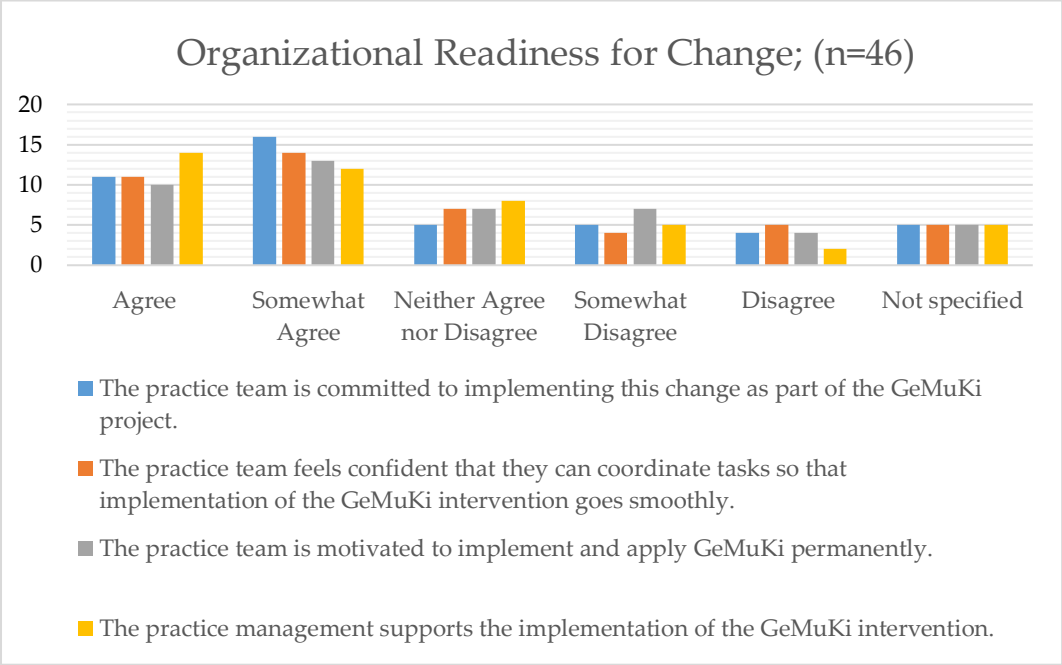

Figure 5: Results on Organizational Readiness for Change; (n=46)

Figure 5 displays the aggregated scores, which illustrate that the study coordinators have the impression that at least half of the practices are committed and motivated to implement the *GeMuKi* intervention. Data is missing for five out of 46 practices. Since questionnaires were only completed for practices that were actively involved in recruiting and caring for women, it is surprising that pessimistic ratings were still given for approximately one-third of the assessed sites.

5.5. Summary and Consolidation of Findings

The three studies presented as well as the findings of the supplementary data examine different aspects that affect the implementation of the preventive program at different stages. Guided primarily by the taxonomy of implementation outcomes, the implementation process was mapped and several implementation determinants were identified, that acted as facilitators or barriers for the implementation. For the final evaluation, the different data

sources are summarized and interpreted collaboratively. This section provides an overarching summary, while further details can be found in the studies presented (see chapter 5.1-5.4.).

The following section first summarizes the implementation of individual components of the *GeMuKi* intervention. This is followed by a presentation of the identified key barriers and facilitators for the implementation.

5.5.1. Implementation of Intervention Components

Overall, both HCPs and pregnant women rated the **embedding of counseling sessions into routine prenatal check-ups** very positively. Although HCPs stated a lack of time and an increasing burden in their daily practice, all of them considered the preventive check-ups to be a good and important setting for preventive counseling. Gynecologists emphasized the accessibility of women and the often long-standing relationships of trust. Since very few midwives were involved in the project, conclusions about the implementation of the intervention in their daily work are limited. During the interviews, the midwives emphasized their special relationship of trust, counseling in a confidential environment mostly in the woman's home, and their close involvement with lifestyle issues in their daily practice, as very good prerequisites to carry out the intervention. Nevertheless, it became apparent that the scheduling of counseling during pregnancy did not fit the midwives' work routine.

During the Covid-19 pandemic, preventive check-ups also proved to be a good setting, as they continued to be conducted and, consequently, so did *GeMuKi* counseling sessions.

Achieving sufficient **penetration** in the study regions was a challenge. A total of 12% of 513 available gynecologists were reached in the intervention group. About half of them actively provided counseling to pregnant women. Although 109 midwives attended the preparatory training –14 percent out of all available midwives in the regions – only seven midwives actively provided counseling in the end. Intrinsic motivation and personal interest in the topics of nutrition, exercise and overweight/obesity were crucial for the active participation and recruitment of women in the *GeMuKi* project. During the recruitment process, it became apparent that gynecologists who refused to participate were often not interested in the topics and/or did not feel comfortable with providing counseling on lifestyle topics.

Although during the training some HCPs stated that the **compensation for the counseling sessions** was insufficient, the results of the recruitment study (**study II**) indicate that

compensation was not a decisive factor for active participation. Moreover, some HCPs interviewed stated that while they would get along well with the compensation as part of the *GeMuKi* intervention, they regretted that the healthcare system often does not compensate HCPs for the time spent on proper talks or counseling sessions with patients.

Healthcare practices varied widely in how they **distributed the tasks** associated with the intervention. For example, gynecologists did everything independently, medical assistants assisted with documentation and/or recruitment, or medical assistants provided counseling and gynecologists merely performed recruitment.

According to the HCP's documentation, around 90 % of enrolled women received counseling at the first two check-ups, while the **dose delivered** decreased slightly for the last two check-ups. HCPs as well as pregnant women described a need for counseling, while women in their first pregnancy were especially grateful for additional counseling time. The HCPs report that women who have poor knowledge of German cannot be given proper counseling. In addition, HCPs reported that they often do not reach women who especially would need counseling. This would particularly affect vulnerable groups and women who are severely overweight.

The predefined topics and c**ontents of the counseling sessions** met the expectations and demands of the participants. In the counseling sessions, the most popular chosen topic was nutrition. Both women and HCPs gave the impression that pregnant women are unaware of the recommendations for **weight gain during pregnancy** and they do not feel they can affect it. Although weight gain was to be discussed as part of the *GeMuKi* intervention, implementation did not always occur. It became clear that HCPs assigned different levels of relevance to weight gain and, accordingly, addressed it inconsistently.

The **MI counseling approach** was also implemented inconsistently and was hardly used. Various reasons for this were discussed in the interviews: the approach differs greatly from the familiar counseling procedures, repetitive training would have been necessary, and some HCPs felt that it was not feasible for every woman, and too time consuming.

About half of the women interviewed reported choosing the topic of the counseling session themselves. The results also showed that in early pregnancy many uncertainties exist, so that in some cases it is difficult for women to decide on a lifestyle topic or to concentrate on lifestyle

counseling. Some women expected to be educated about "forbidden" foods during pregnancy, and to receive a list of rules from health professionals.

Even if the quality of the wording of the agreed goals varied greatly and was not always in the spirit of a **SMART goal**, the agreed goals were rated very positively by women and HCPs. The reminders through push notifications in the ***GeMuKi*-Assist app,** as well as feedback discussions with the HCPs, were evaluated as an encouragement to implement small lifestyle changes.

The use of the **digital counseling tool *GeMuKi*-Assist** varied greatly among the HCPs. The interviews showed that HCPs who actively used the counseling tool were able to operate it easily and intuitively. The rejection of the digital counseling tool was mostly explained by the fact that practices did not use digital tools in their day-to-day work, or did not want to use additional systems besides their current practice software. For these, the documentation on paper had to be created in the course of the project. This paper-based documentation was subsequently faxed to the study coordinators, who then were responsible for the digitalization of the data.

The findings reveal a large potential for improvement regarding **inter-professional cooperation** of gynecologist and midwives. A lack of mutual acceptance and differing recommendations and information led to insecurity among the pregnant women.

5.5.2. Facilitators and Barriers for the Implementation

Guided by the different theoretical frameworks, various facilitating and inhibiting factors were identified. Based on the presented results, a list of the key influencing factors is given below. These factors may be used to develop further recommendations for action aimed at improving the provision of care.

The following factors acted as facilitators in the implementation of the *GeMuKi* intervention:

1) The positive atmosphere at the mandatory training and the majority of HCPs assessing the training materials as suitable for counseling pregnant women promoted the implementation.
2) The HCPs' intrinsic motivation to fight lifestyle related chronic diseases as well as their pre-existing experience in lifestyle counseling facilitated their participation and accordingly the implementation of the intervention.
3) Pregnant women, and especially first-time mothers, have a particular need to receive more counseling time with HCPs.
4) The counseling content corresponds with the pregnant women's demands, and the HCP rate materials and contents as relevant for their professional practice.
5) The scheduling of the counseling sessions alongside routine preventive check-ups at gynecological practices had a positive effect on the implementation and acceptance of the intervention.
6) Close supervision and monitoring during routine check-ups in pregnancy enables continuous counseling.
7) The combination of joint goal setting, corresponding reminder (push-notifications on women's smartphones), and feedback discussions supported the realization of lifestyle changes as part of the intervention.
8) An existing relationship of trust between women and HCPs (e.g., from a previous pregnancy or many years of care) was beneficial for conducting lifestyle counseling sessions.
9) An adequate compensation supports HCPs to allow time for individual lifestyle counseling.
10) The non-standardized concept, which allows for a flexible distribution of work between gynecologists and medical assistants, had a beneficial effect on the implementation of the intervention.
11) The rooms and equipment in the medical practices are well suited for undisturbed counseling. Furthermore, there is a wide range of additional information material available as well as the possibility for making referrals to other experts in the healthcare system.
12) The involvement of the regional study coordinators facilitated implementation, as they were accessible at all times to deal with any problems, and contacted the HCPs on a regular basis to offer support.

The following factors acted as barriers in the implementation of the *GeMuKi* intervention:

1) HCPs report a lack of time in their daily practice and, as a result, they often have to prioritize issues other than lifestyle topics.
2) Lack of midwife participation impeded the intended implementation of the intervention.
3) The scheduled times for a midwife counseling session were inconvenient because most women did not plan to see their midwife until shortly before the birth.
4) Observed conflicts between professional groups (e.g., regarding shared care or mutual acceptance) create insecurity among pregnant women and families, and were therefore a barrier to implementation.
5) Different recommendations from different HCPs create uncertainty among pregnant women and families, and were therefore a barrier to implementation.
6) Information gaps among pregnant women regarding recommended weight gain and associated consequences for mother and child were a barrier to lifestyle changes as part of the intervention.
7) Lack of take-home information material to remind patients of the topics discussed in the counseling session was a barrier.
8) The fact that the MI counseling approach was very different from the usual conversational style of HCPs was a barrier in the implementation.
9) HCPs experienced difficulties in addressing sensitive topics, and expressed concerns about jeopardizing the relationship of trust with the patient. In some cases a lack of sensitive communication skills became a barrier to implementation.
10) HCPs reported that they couldn't reach some women who had a particular need to receive the intervention. For example, language barriers inhibited the implementation. Presumably, the intervention's design did not help to target certain women, which also hindered the Implementation.
11) The current level of digitalization in the practices, or the fact that many practices do not use digital tools in their daily work, was a barrier to implementation.
12) The recruitment and administrative aspects within the trial partially inhibited the implementation of the intervention. This was partly due to the lack of research routines in office-based healthcare settings in Germany, and partly to the refusal of some women to participate, which demotivated some HCPs.

6. Discussion

This chapter discusses and contextualizes the key findings presented above. It then goes on to draw practical implications for research and professional practice, as well as methodological strengths and limitations.

6.1. Discussion and Contextualization of the Key Findings

Although examining the effectiveness of an intervention is obviously of great importance from an evidence-based medicine perspective, this cumulative dissertation highlights the equal importance of closely analyzing implementation processes. While the *GeMuKi* intervention proved effective in significantly reducing the proportion of women with excessive weight gain during pregnancy [40], this process evaluation complements these results with highly important indications for a nationwide rollout. Indeed, even if the intervention is effective, it would not be appropriate to recommend an unmodified rollout for all components. The results of the process evaluation are indispensable for a transfer to routine care as well as for the contextualization of the effectiveness evaluation results. In addition, the inclusion of different perspectives demonstrates general opportunities and potential for improving preventive checkups during pregnancy.

While there are a large number of guidelines and frameworks for researching implementation processes, procedures and measurements must be dynamically adapted to the intervention, the setting, and the actors throughout the process. The theoretical frameworks used within this dissertation were essential for systematizing the research interest and selecting adequate methods and sufficient data sources. Particularly, on the basis of the taxonomy of implementation outcomes, it was possible to monitor implementation success throughout the entire process evaluation. This allowed an identification of factors that influenced the implementation outcomes and correspondingly, implementation strategies could be tailored to implementation success.

Community-based practices are self-managed and operate as autonomous entities. Since there is no supervising hierarchical level, such as the hospital management of different hospital departments, standardized implementation is a particular challenge. In the course of implementing the *GeMuKi* intervention, it has proven beneficial to react flexibly to different models of work-flows in the practices.

For instance, an early investigation done during the training of HCPs (**Study I**) helped to consider the needs of the HCPs and the specifics of their settings, and to adapt implementation strategies accordingly. For example, after HCPs expressed skepticism regarding an improvement in collaboration within the scope of the intervention, networking lists with contact details were created and distributed to all participating HCPs in the regions.

The recruitment study (**Study II**) demonstrated that the HCPs most likely to participate in *GeMuKi* were those who considered lifestyle topics to be particularly relevant to their professional practice, and were thus intrinsically motivated. This raises the question of whether less interested HCPs could provide equally effective counseling in the event of a rollout, and reveals a need to identify the best ways to engage them in the topics.

However, close monitoring of administrative data also showed that there were some insurmountable hurdles and strategies that did not work. For example, low midwife participation meant that the establishment of counseling networks was unsuccessful.

Research methods also had to adapt to the circumstances. Although the study protocol specified that focus group discussions would be conducted with HCPs as part of the process evaluation, this was not feasible due to the uneven and low participation of HCPs in the regions. As a result, guided interviews were conducted with HCPs as well as with the participating pregnant women. In this way, **Study III** was able to gather and discuss the needs and experiences of those involved after the implementation process had already progressed further. In turn, these included perspectives could provide important guidance for the implementation of the components and the maintenance of the intervention.

Taken together, the results give a comprehensive picture of the implementation process of a preventive counseling intervention in prenatal care in Germany. As summarized, overall the *GeMuKi* intervention led to satisfaction among HCPs and pregnant women, and fit with their needs and demands. According to them, preventive checkups are a good setting for lifestyle counseling, although the available time slots are often tight. Some HCPs said that involving medical assistants in the counseling process might relieve their workload. This concept is already being implemented in some places in German community-based practices. Examples include "relieving medical care assistants" (abbreviation: EVA: „Entlastende

Versorgungsassistentinnen“) or the "prevention assistant" (abbreviation: PA; „Präventionsassistent/in“) in pediatricians’ offices [91,92].

The HCPs have a broader interest in embedding preventive topics in routine care. Other studies also indicated that community-based physicians may be strongly engaged in the implementation of lifestyle counseling [93,94].

During the interviews it was also discussed whether women should receive counseling from designated experts, such as nutritionists. Pregnant women emphasized that they were reluctant to attend additional appointments outside of preventive checkups unless there was a problem. If applicable, physical proximity – such that found in medical care centers – could lower hurdles to uncomplicated referral.

Not all intervention components could be implemented as intended. For instance, while the selection of counseling topics and the combination of joint goal setting, feedback discussions, and push notifications were well-received, other measures such as the conversational approach MI were inconsistently implemented. This is in line with other studies that show that time constraints in the daily work of a medical practice are the biggest barrier to the implementation of lifestyle counseling based on MI [95–97].

Interviewed HCPs pointed out that compensation in the German healthcare system is not designed for the narrative medicine and that physicians often provide counseling time for no additional compensation. According to the WHO’s ‘Global Strategy on Diet, Physical Activity and Health’ governments should improve financial structures within existing clinical services “[…] to encourage and enable health professionals to dedicate more time to prevention” [32].

Providing financial structures for preventive services may also work as an incentives to engage in continuing education about communication techniques. Given the frequent need to discuss sensitive topics in preventive care, strengthening the communication skills of HCPs appears to be of great importance.

As discussed in **Study III,** the use of sensitive communication techniques is especially important when talking about weight. It must be ensured that HCP do not provide discriminatory advice or stigmatize their patients, which could harm other health outcomes as well as provider-patient relationships [98,99].

With respect to communication about weight, the intervention faces a dilemma. On the one hand, in line with MI, women themselves should determine priorities during counseling and HCPs should avoid giving unsolicited advice. On the other hand, there is a lack of knowledge on recommendations for gestational weight gain and the associated risks.

There is evidence that HCP's recommendations regarding gestational weight gain is an essential predictor for actual weight gain, so accurate advice is needed [100–103]. Strategies must be developed to convey factual information on recommendations for gestational weight gain to pregnant women using sensitive communication techniques.

The evaluation revealed that there is much room for improvement regarding inter-professional cooperation between gynecologists and midwives. Despite numerous efforts, the intended counseling network of gynecologists and midwives could not be realized. Very few midwives agreed to participate in the project. In addition, most women reported that they would not make appointments with their midwife until shortly before the birth, which is why the intended counseling sessions with midwives during the course of pregnancy were not practical. The problem is amplified by conflicts between the professional groups in terms of responsibilities and mutual acceptance, as well a shortage of midwives in the regions studied.

The professional associations of gynecologists and midwives have different views regarding shared prenatal care [104,105]. An ambiguous legal situation results in unclear responsibilities, which complicates cooperation and communication between the two professional groups. One positive exception was the report of a gynecological practice sharing space with some midwives (who were not enrolled in the *GeMuKi*-intervention) and cooperating very well in preventive care.

A large number of midwives work part-time, and there has been a sharp rise in demand. This may also be due to societal changes, as many young mothers live far away from their own families and mothers, and midwives often become the primary contact when women have questions related to their pregnancies [106]. Given the shortage of midwives, the question arises whether it is feasible to deploy midwives early in pregnancy. On the other hand, midwives assume an important role in health promotion and prevention. A new EU regulation on midwifery care, which has been implemented in Germany since 2020, aims to make the qualifications of European midwives comparable. Bauer and Luksch emphasize that health

promotion and prevention are perceived as genuine midwifery activities [107]. Midwives are particularly important in providing care for vulnerable families, although due to the shortage of midwives and women having to find a midwife without public help, vulnerable families are at a disadvantage when it comes to seeking midwifery care [107]. To improve access to midwifery care, Bauer and Luksch suggest, among others, midwifery services centers that could act as referring agencies [107].

On the one hand, the academization of midwifery is welcomed because it recognizes the relevance of the profession and enables cooperation on an equal footing. On the other hand, critics fear that it may lead to an even less clear distribution of competencies and an increase in the shortage of midwives [108]. Physician, midwife and parent representatives met at the German Congress "WIR - von Anfang an" in October 2019 to collaborate on solutions to pressing problems in obstetrics. Their demands include one-to-one care, adequate compensation, joint education and training of physicians and midwives to promote interdisciplinary working, and reorganization of liability insurance for all obstetrical practitioners [109,110].

The requirements of health care are becoming more and more complex due to the increasing aging of patients, changed disease patterns as well as the changing needs of patients and the use of medical technology [111]. These increased demands on the health care system require a structured approach to inter-professional cooperation in order to ensure holistic care to the satisfaction of patients and HCPs [111].

Experts point out the importance of inter-professionalism as an overarching educational principle that sets out essential prerequisites for implementing appropriate medical care for the increasing number of multimorbid, chronically ill, patients who will need care in the future [112,113]. In addition to joint training, as in other contexts, inter-professional quality circles could also help to exchange information, define responsibilities, and develop understanding for the other professional group's work situation and possibilities [114]. Beyond that, inter-professional cooperation must be organized and provided differently according to local conditions and infrastructure in rural or urban regions [115]. In regional contexts, the use of digital structures can be helpful and offers many opportunities for networking and exchanging information between all parties involved in the healthcare process [115].

The launch of the *GeMuKi* intervention began a year before the outbreak of the Covid-19 pandemic. At that time, many practices were not using digital tools in their everyday work yet. For them, alternatives had to be created to enable project participation. As a result of the Covid-19 pandemic, digital elements within the healthcare system have evolved rapidly [116]. It can be assumed that digital transformation is now at a different stage in many practices. This trend could lead to more flexible preventive care in the future, tailored to patient preferences. Additional telemedicine counseling could be an advantage for women who require increased support, and for women who have little free time due to busy work schedules and childcare [116].

6.2. Implications for Research and Practice

The results presented here provide important indications for future research efforts. Since recruitment is always a crucial prerequisite for successful health services research, **Study II** gives important insights into recruitment procedures and strategies in outpatient care. All key actors in the practices must be taken into account, and they must be well trained in approaching and recruiting patients to trials. A solution that could help overcome the lack of research routines in community-based HCPs in Germany might be to establish a network of research practices, which has proven to be successful in other studies [117].

The use of digital tools offers numerous opportunities not only for health interventions, but also for research processes. Although the levels of digitalization of practices were very diverse, the survey via the *GeMuKi* Assist app was beneficial in terms of patient satisfaction and response rate. Furthermore, the regional study coordinators used a digital study monitor, in which missing data could be identified at a glance. This allowed them to contact HCPs and patients in a timely manner and ask them to enter the data, which also led to a high response rate. This type of tool is valuable for simplifying data management and monitoring complex research projects [81]. Another rewarding possibility is the collection of metadata, which, while respecting privacy policies, could provide information on how often and when patients access health apps and how much time they spend on it.

Further research should be conducted on how to talk about weight in a sensitive, supportive, and nondiscriminatory manner in the healthcare setting. Studies should also explore how

HCPs can be efficiently and sustainably trained in sensitive communication techniques that are appropriate to their professional practice.

There is also a need for robust research that explores potential benefits of inter-professional cooperation in health care to align care processes in a patient-centered way [111].

As demonstrated in many places, the findings provide multiple indications and recommendations for both policymakers and practitioners:

HCPs should be sensitized for lifestyle issues and perinatal programming. Intrinsic motivation and personal interest in the topics of nutrition, exercise and overweight/obesity were decisive for active participation in the *GeMuKi* project. Therefore, the question arises whether the relevance of preventive topics could already be emphasized in professional training and university studies and/or strengthened by recurring continuing education.

Preventive check-ups should be used more intensively to focus on lifestyle topics. The involvement of medical assistants in preventive counseling could relieve physicians' workload in practices with high time and appointment pressure. Accordingly, thought should be given to providing medical assistants with an enhanced level of training on lifestyle topics, and to engaging them in preventive counseling.

Professional associations and policy makers should urgently develop strategies to improve collaboration between physicians and midwives. Since there was a lot of insecurity and confusion among the pregnant women who took part in these studies, it is essential that consistent information should be provided, and mutual acceptance between different professional groups should be improved. In addition, strategies for successfully implementing inter-professional collaboration should be explored.

Women often lack information about adequate gestational weight gain and associated risks. In order to close this gap, it seems useful to provide factual and sensitive information at the beginning of pregnancy about the recommendations for weight gain as well as the risks associated with excessive weight gain. In this context, the communication skills of HCPs must also be strengthened.

Due to language barriers, many women cannot be reached. Strategies need to be sought to make preventive counseling services also available to non-German speaking patients. Among other things, important materials and flyers should be translated into different languages.

In order to digitally support preventive counseling through a counseling tool, the digitization of the HCPs involved should be promoted and further advanced. Furthermore, feasible functions should be integrated into existing systems.

Considering the incorporation of lifestyle counseling within the maternity guidelines would be beneficial for public health and also in line with the existing WHO guidelines. The WHO guidelines explicitly recommend lifestyle counseling in a woman-centered and non-judgmental manner, to ensure appropriate weight gain [64]. Funding agencies, policymakers, and statutory health insurers have the opportunity to decide in a next step whether preventive counseling will be incorporated into maternity guidelines and thus made available to all women in routine care.

6.3. Methodological Strengths and Limitations

The evaluation of the *GeMuKi*-intervention covered all implementation processes under routine care conditions, which is important for identifying facilitators and barriers in a real-world setting. It was guided by the RE-AIM framework [57] as well as by further important concepts of implementation science, such as the taxonomy of implementation outcomes devised by Proctor et al. [58]. These guides informed the design of measurements and the incorporation of various different data sources. As recommended in the updated MRC guidance on process evaluations, the findings are "close to the care reality of those who actually deliver an intervention and do not just speculate about it" [43]. The implementation outcome 'costs' could not be addressed within this research, because results are yet to be published.

One strength of this evaluation is its mixed-methods design. The combination of quantitative and qualitative research methods makes it possible to examine the question from different perspectives, and thus to generate a more accurate picture: "The mixed methods approach offers a flexibility and depth of insight that is not possible to achieve by using either qualitative or quantitative methods alone" [118]. During interviews with explorative elements and an open flow of conversation, HCPs and pregnant women were able to set their own emphases in the conversation and bring in new, and perhaps unexpected, topics and experiences. Including patients' perspectives in research on implementation processes is a particular strength of the study [48]. On the other hand, while the incorporation of inter-professional perspectives was a strength, one limitation is the lack of participation of midwives in the trial.

During the implementation process, the different data sources were taken into account with a view to adapting implementation components, implementation strategies, and research measurements in a dynamic approach. Iterative research processes and regular meetings with the *GeMuKi* consortium, stakeholders, and the scientific advisory board supported the adaptation of implementation strategies and measurements and led to a more targeted exploration. However, it was not possible to implement all suggested changes, since the time of implementation was limited to a period of two and a half years. The qualitative researchers were also involved in planning and recruiting for the intervention, and it must be assumed that they did not conduct the interviews and analysis in a completely unbiased manner.

One challenge for the scientific evaluation was the need to perform a balancing act between predefined standardized procedures, on the one hand, and the consideration of the perspectives of HCPs, patients and stakeholders involved on the other. Existing standardized instruments for measuring implementation outcomes [119] have not been used either because they were not suitable in the contexts or would have placed a further burden on the participants as part of the trial. The recruitment study revealed that some HCPs and pregnant women refused to participate in the trial because of the high administrative and documentary burdens and questionnaires that formed part of the effectiveness evaluation.

A strength was the use of different data sources to assess implementation fidelity, in particular the development of the additional questionnaire for the study coordinators was beneficial. During the interviews, information is collected retrospectively and can therefore be biased. Furthermore, self-assessments often encounter the problem of social desirability, which leads to more project activities being reported than actually took place [54].

One limitation was that the HCPs were extraordinarily motivated to conduct counseling sessions and dealt with lifestyle topics before they enrolled in the trial. Accordingly, the results of this study do not represent the attitudes of all the actors involved in outpatient care. It would also have been beneficial to interview HCPs who opted not to participate in the intervention. On those topics, only secondhand information was available from the protocols of professional group meetings and from study coordinators' experiences in recruiting.

The present research was conducted alongside the *GeMuKi* trial as part of the process evaluation. The results of this dissertation are thus a building block that will contribute to the

process of implementing the complex intervention. The implementation fidelity of some components could not be comprehensively assessed. This would have required, for example, observations or audio recordings of counseling sessions, which were not possible in the medical practices. It could be helpful to conduct a stepwise implementation scale-up with close investigation of these components.

Further methodological strengths and limitations are discussed in the integrated studies (see **Studies I-III**).

7. Conclusion

This cumulative dissertation illustrates the importance of taking a close look at the implementation process of a complex intervention in different stages. The results give a comprehensive understanding of the implementation in their settings, and identify important facilitators and barriers for implementation. This is important for revealing potential for improvement and developing recommendations for a nationwide roll-out. In particular, the combination of quantitative and qualitative empirical methods, as well as considering the perspectives of all the participating HCPs and patients, leads to a profound understanding of implementation processes in the setting.

The process evaluation showed that preventive check-ups during pregnancy are perceived as a good setting for focusing on lifestyle topics. Scheduling additional counseling time as well as the counseling topics corresponded with the women's needs. A combination of joint goal setting and feedback discussion helped the women to adopt lifestyle changes. The HCPs see a great need for conversations on lifestyle and felt that the appropriate compensation enabled them to embed the counseling sessions reasonably in the regular preventive check-ups. Some components could not be implemented according to plan: for example, the MI conversational approach was inconsistently implemented. Furthermore, there were hardly any counseling teams of midwives and gynecologists, as very few midwives were involved in the project.

Although a lack of time in daily practice was in some cases a barrier to implementation, the intrinsic motivation of HCPs was a major facilitator for implementing the intervention. An important finding for the improvement of care is that the relevance of lifestyle counseling in preventive care is assessed differently by HCPs. In this context, it seems worthwhile to repeatedly raise awareness among HCPs about lifestyle issues and the opportunities offered by counseling in the context of routine check-ups.

A major barrier for the implementation was a lack of inter-professional cooperation, which led to insecurity among pregnant women. Policymakers, professional associations, and practitioners are called upon to develop and implement effective strategies for improving collaboration and clarify responsibilities. Findings also revealed a need to strengthen the communication skills of HCPs, especially when it comes to addressing sensitive topics.

Conclusion

As digital transformation continues in medical practices, digital counseling tools also present multiple new opportunities to improve counseling and dialogue with patients.

In light of the increasing need for preventive action to reduce risks of lifestyle-related diseases, the opportunities and high accessibility offered by routine check-ups in the community-based settings should not be missed

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Doctoral student's declaration of contribution

1) **Perspektiven für die Implementierung des Innovationsfondsprojekt GeMuKi: Eine Querschnittserhebung der Einstellungen von Leistungserbringern zu einer präventiven Lebensstilberatung in den Schwangerschafts- und Kindervorsorgeuntersuchungen**

Lorenz, Laura*/ Krebs, Franziska*; Nawabi, Farah; Senyel, Deniz; Alayli, Adrienne; Bau, Anne-Madeleine; Stock, Stephanie

*Authors contributed equally to this paper and share first authorship.

Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen (ZEFQ)
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Author's contributions

Laura Lorenz and Franziska Krebs developed the study idea. Laura Lorenz and Franziska Krebs designed the specific methods of the study. Specifically, Laura Lorenz designed the qualitative survey instruments and Franziska Krebs designed the quantitative survey instruments. Laura Lorenz and Franziska Krebs conducted the data collection of the study. Deniz Senyel digitalized the quantitative data. Franziska Krebs conducted quantitative analyses of the questionnaire survey. Laura Lorenz conducted the qualitative analyses of the free text fields and protocols. Franziska Krebs supported the iterative coding process of the Qualitative Content Analysis. Laura Lorenz and Franziska Krebs jointly integrated, discussed, and interpreted the results of the quantitative and qualitative analyses. Laura Lorenz described the introduction and the background of the study and researched and discussed the relevant literature. The text was revised in close cooperation with Franziska Krebs. Franziska Krebs described the quantitative methods; Laura Lorenz described the qualitative methods. Franziska Krebs described the results of the quantitative data; Laura Lorenz described the results of the qualitative data. Franziska Krebs described the discussion of the results and researched and discussed the relevant literature. The text was revised in close cooperation with Laura Lorenz. The manuscript was revised in cooperation with Farah Nawabi, Adrienne Alayli and Stephanie Stock. Stephanie Stock and Adrienne Alayli developed the design of the overall study. Anne-Madeleine Bau is the project head of the overall project (consortium leadership). All authors critically read and revised the manuscript and agreed to the published version of the manuscript.

2) **Recruitment in Health Services Research — A Study on Facilitators and Barriers for the Recruitment of Community-Based Healthcare Providers**
Krebs, Franziska*/Lorenz, Laura*; Nawabi, Farah; Lück, Isabel; Bau, Anne-Madeleine; Alayli, Adrienne; Stock, Stephanie

*Authors contributed equally to this paper and share first authorship.

International Journal of Environmental Research and Public Health (IJERPH) [Impact Factor at time of publication: 3.4]

Author's contributions

Laura Lorenz and Franziska Krebs developed the study idea. Laura Lorenz and Franziska Krebs designed the specific methods of the study. A document analysis was conducted, incorporating 137 internal project documents. In detail, Laura Lorenz analyzed minutes of the research team's meetings with study coordinators, written feedback from enrolled service providers, recruitment materials, and minutes of study coordinator work meetings. Franziska Krebs analyzed minutes of consortium partner meetings and telephone conferences, minutes of provider training sessions, minutes of recruitment events, and minutes of working meetings on the recruitment process as part of the document analysis.
Both Laura Lorenz and Franziska Krebs separately developed an inductive category system on the respective data material, which was then consented in an iterative process. Based on the results of the document analysis, the first authors collaboratively developed an interview guide. A total of six interviews were then conducted. Laura Lorenz conducted three semi-structured interviews. Franziska Krebs was present during the interviews, wrote a postscript, and ensured that all topics were discussed during the interview. Franziska Krebs conducted the remaining three semi-structured interviews. Laura Lorenz was present during the interviews, wrote a postscript, and ensured that all topics were discussed during the interview. The interviews were analyzed using Qualitative Content Analysis. Specifically, Laura Lorenz analyzed three interviews and constructed inductive categories. Franziska Krebs analyzed the remaining three interviews and constructed inductive categories. In an iterative process, the category system was agreed upon and then applied to the data material by both first authors independently of each other. Laura Lorenz and Franziska Krebs collaboratively interpreted and discussed the results. Franziska Krebs wrote the introduction and the background section of the manuscript and researched and discussed the relevant literature. The text was revised in close cooperation with Laura Lorenz. Franziska Krebs described the study setting and design (2.1. and 2.2.). Laura Lorenz described the data sources and data analysis (2.3. and 2.4.). Franziska Krebs visualized the recruitment process as a result of the document analysis in a flowchart. Laura Lorenz visualized the final category system of the Qualitative Content Analysis.

The results section was based on the category system, with Franziska Krebs describing the facilitating factors and Laura Lorenz describing the hindering factors.
Laura Lorenz described the discussion of the results and researched and discussed the relevant literature. The text was revised in close cooperation with Franziska Krebs. The manuscript was revised in cooperation with Farah Nawabi, Isabel Lück, Anne-Madeleine Bau, Adrienne Alayli, and Stephanie Stock. Stephanie Stock and Adrienne Alayli developed the design of the overall study. All authors critically read and revised the manuscript and agreed to the published version of the manuscript.

3) **Preventive counseling in routine prenatal care. A qualitative study of pregnant women's perspectives on a lifestyle intervention, contrasted with the experiences of healthcare providers**
Lorenz, Laura; Krebs, Franziska; Nawabi, Farah; Alayli, Adrienne; Stock, Stephanie

International Journal of Environmental Research and Public Health (IJERPH) [Impact Factor at time of publication: 3.4]

Author's contributions

Laura Lorenz developed the study idea. Laura Lorenz designed the specific methods of the study. Laura Lorenz analyzed and prepared the data and was supported by Franziska Krebs and Farah Nawabi in the iterative coding process of the Qualitative Content Analysis. Laura Lorenz conducted the interpretation and discussion of the results. Laura Lorenz wrote the manuscript. Stephanie Stock and Adrienne Alayli developed the design of the overall study. All authors critically read and revised the manuscript and agreed to the published version of the manuscript.

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With all my heart I thank Moritz, for always having my back, cheering me up, motivating me when needed, and above all, for being by my side.

Appendix

Appendix 1: GeMuKi Study Protocol

Appendix 2: Questionnaire: Study coordinators' assessment of each site

Appendix 1: *GeMuKi* Study Protocol

Published as: "Evaluation of a computer-assisted multi-professional intervention to address lifestyle-related risk factors for overweight and obesity in expecting mothers and their infants: protocol for an effectiveness-implementation hybrid study"

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STUDY PROTOCOL Open Access

Evaluation of a computer-assisted multi-professional intervention to address lifestyle-related risk factors for overweight and obesity in expecting mothers and their infants: protocol for an effectiveness-implementation hybrid study

Adrienne Alayli[1,2*], Franziska Krebs[1], Laura Lorenz[1], Farah Nawabi[1], Anne-Madeleine Bau[3], Isabel Lück[3], Andrea Moreira[3], Judith Kuchenbecker[3], Elena Tschiltschke[3], Michael John[4], Stefan Klose[4], Benny Häusler[4], Christian Giertz[4], Ulrike Korsten-Reck[5] and Stephanie Stock[1]

Abstract

Background: The first 1000 days after conception are a critical period to encourage lifestyle changes to reduce the risk of childhood obesity and early programming of chronic diseases. A healthy lifestyle during pregnancy is also crucial to avoid high post-partum weight retention. Currently, lifestyle changes are not consistently discussed during routine health services in Germany. The objective of this study is to evaluate a novel computer-assisted lifestyle intervention embedded in prenatal visits and infant check-ups. The intervention seeks to reduce lifestyle-related risk factors for overweight and obesity among expecting mothers and their infants.

Methods: The study is designed as a hybrid effectiveness-implementation trial to simultaneously collect data on the effectiveness and implementation of the lifestyle intervention. The trial will take place in eight regions of the German state Baden-Wuerttemberg. Region were matched using propensity score matching. Expecting mothers ($n = 1860$) will be recruited before 12 weeks of gestation through gynecological practices and followed for 18 months. During 11 routine prenatal visits and infant check-ups gynecologists, midwives and pediatricians provide lifestyle counseling using Motivational Interviewing techniques. The primary outcome measure is the proportion of expecting mothers with gestational weight gain within the recommended range. To understand the process of implementation (focus group) interviews will be conducted with providers and participants of the lifestyle intervention. Additionally, an analysis of administrative data and documents will be carried out. An economic analysis will provide insights into cost and consequences compared to routine health services.

(Continued on next page)

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(Continued from previous page)
Discussion: Findings of this study will add to the evidence on lifestyle interventions to reduce risk for overweight and obesity commenced during pregnancy. Insights gained will contribute to the prevention of early programming of chronic disease. Study results regarding implementation fidelity, adoption, reach and cost-effectiveness of the lifestyle intervention will inform decisions about scale up and public funding.

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

Keywords: Pregnancy, Overweight and obesity prevention, Lifestyle, Gestational weight gain, Multi-professional collaboration, Effectiveness, Implementation, Cost, Diet, Physical activity, Substance use.

Introduction

Overweight and obesity are increasing worldwide [1]. More than one in two adults and nearly one in six children are overweight or obese in OECD countries [2]. In Germany 35.9% of the adult population are overweight and 18.1% are obese [3]. Among children and adolescents 15.4% are overweight and 5.9% are obese [4].

The high prevalence of overweight and obesity represents a key risk factor for non-communicable diseases, including cardiovascular diseases, diabetes, musculoskeletal disorders and some cancers [1]. As childhood overweight and obesity tend to persist into adulthood [5], early interventions are essential.

There is growing evidence that lifestyle factors in the first 1000 days after conception are important predictors of childhood overweight and obesity. Maternal gestational weight gain (GWG), smoking and diet have been identified as predictors during pregnancy [6–10]. Rapid infant weight gain, nicotine exposure and infant feeding practices have been identified as essential factors after birth [6, 10–13].

Human epidemiology and animal model studies suggest that exposure to these factors affects developmental processes, which program susceptibility to obesity and other chronic conditions manifesting later in life [14, 15]. Pregnancy and early infancy therefore represent a critical period for targeted prevention efforts.

Lifestyle changes initiated during pregnancy also produce benefits for expecting mothers. Evidence suggests that adequate GWG can avoid high post-partum weight retention and thus reduce the risk of overweight and obesity following pregnancy [16, 17].

Several preventive interventions addressing maternal lifestyle during pregnancy have been evaluated. Two meta-analyses show that diet and exercise interventions during pregnancy can effectively reduce excessive gestational weight gain [18, 19]. There is also evidence that professional-led educational interventions can increase uptake of breastfeeding [20]. A Cochrane review indicates that counseling interventions during pregnancy can effectively increase smoking cessation rates [21]. High post-pregnancy relapse rates call for strategies to promote continued abstinence post-partum, however [21, 22].

Lifestyle intervention trials initiated during pregnancy that continue during infancy are scarce [23–25]. They are heterogeneous, have methodological limitations and have produced mixed results [23, 24]. Few intervention studies provide evidence for beneficial effects on growth status of infants or children of obese women only [24].

Interventions targeting multiple lifestyle related risk factors hold promise for more effective childhood obesity prevention [10, 26]. So far, intervention studies targeting feeding, diet and physical activity behaviors in combination with prenatal nicotine exposure are lacking [23].

The GeMuKi project (acronym for “Gemeinsam Gesund: Vorsorge plus für Mutter und Kind” - Strengthening health promotion: enhanced check-up visits for mother and child) aims to incorporate a brief multifactorial lifestyle intervention into routine prenatal visits and infant check-ups. In Germany, these check-ups currently focus on early identification of diseases and developmental problems only. Existing guidelines for pre- and postnatal care mention that providers have a role in discussing modifiable lifestyle factors, but they do not specify content or format of lifestyle counseling [27].

Recent findings of the GeliS trial (acronym for "Gesund leben in der Schwangerschaft") conducted in the German state of Bavaria suggest that incorporating lifestyle counseling into routine prenatal health services is feasible and leads to high compliance rates [28]. The lifestyle intervention itself achieved only slight improvements in prenatal intake of food items, exclusive breastfeeding behavior and maternal post-partum weight development [29, 30]. By continuing lifestyle counseling after birth and utilizing theoretically underpinned Motivational Interviewing (MI) techniques, the GeMuKi intervention addresses some limitations of the GeliS intervention. In addition, the GeMuKi intervention includes a novel shared telehealth platform to support multi-professional providers in the counseling process with a corresponding App for intervention participants.

The objective of this study is to examine effectiveness of the GeMuKi intervention and explore its potential for widespread implementation. It will answer the following research questions:

- Does the GeMuKi intervention effectively improve lifestyle-related risk factors for overweight and obesity in expecting mothers and their infants compared to routine practice?
- How does implementation of the GeMuKi intervention take place in practice? What factors facilitate or hinder successful implementation during routine prenatal visits and infant check-ups?
- What costs, health service use and consequences are associated with the GeMuKi intervention from a public payer perspective? How do these compare to routine health practice?

Methods/design

Study design

A hybrid effectiveness-implementation trial (Type II) is being used to simultaneously collect data on the effectiveness and implementation of the GeMuKi lifestyle intervention [31, 32]. This design was selected because there is strong evidence that interventions during pregnancy can effectively improve lifestyle-related risk factors, research indicates that lifestyle counseling during routine check-up visits is feasible in Germany and evidence on implementation of lifestyle interventions during pregnancy is scarce. The GeMuKi intervention comprises various components previously identified to enhance lifestyle counseling during pregnancy. To our knowledge, effectiveness of these components has not been evaluated in combination, yet.

The trial has two arms (see Fig. 1). In the intervention arm gynecologists, midwives and pediatricians carry out the GeMuKi lifestyle intervention during routine prenatal visits and infant check-ups. In the control arm they provide care as usual. The study takes place in both urban and rural areas within the German state Baden-Wuerttemberg. To reduce discrepancies between study regions intervention and control regions were matched into pairs using propensity score matching. Matching was conducted immediately after the project kick off in October 2017 to provide enough time for enrollment of multi-professional providers and for conducting implementation training in the intervention regions before commencing recruitment of study participants. Matching was based on average income per capita, the number of births among persons insured by BARMER (i.e. the statutory health insurer agreeing first to participate in the GeMuKi project) and the number of gynecologists in the study regions. This resulted in four matched study region pairs, which were randomized into intervention and control regions.

Data regarding effectiveness and implementation will be collected at multiple time points over an 18-month study period (see Table 2).

Recruitment procedure

Recruitment of multi-professional providers commenced in April 2018 and continues until December 2019. For this purpose, informational meetings are being conducted in the study regions. Regional opinion leaders are attending these meetings to raise awareness of the GeMuKi project and promote participation from a user-perspective. Additionally, the project is advertised through professional organizations, journals, conference presentations and through contacting providers directly over the phone and during personal visits.

Recruitment of study participants commenced in January 2019 and continues until September 2020. It takes place during routine prenatal visits conducted in participating gynecologist practices before 12 weeks of gestation. Gynecologists determine eligibility of pregnant women using pre-defined in- and exclusion criteria. They provide eligible women with a project brochure and additional information about the study. For each study participant, who enrolls in the study, gynecologists receive an expense allowance of 20€.

In- and exclusion criteria

Pregnant women are eligible to participate, if they provide informed consent, are ≥18 years old, are < 12 weeks of gestation at recruitment, are proficient in German language and are enrolled in one of the participating gynecologist practices. To participate in the study, pregnant women also require a health insurance plan from BARMER or from one of the following statutory health insurers, who became project partners upon commencement of the GeMuKi project: AOK Baden-Württemberg, Techniker Krankenkasse and through GWQ Service Plus: Audi BKK, BAHN-BKK, Bertelsmann BKK, BIG direkt gesund, BKK Deutsche Bank AG, BKK Schwarzwald-Baar-Heuberg, BKK Voralb HELLER *Index* LEUZE, Daimler BKK, Die Schwenninger Krankenkasse, energie-BKK, Heimat Krankenkasse, Salus BKK, SBK Siemens-Betriebskrankenkasse, SECURVITA Krankenkasse.

Pregnant women who screen positive for depression (i.e. defined as a sum score of > 9 or a score = 3 on item 10 of the Edinburgh Postnatal Depression Scale) are excluded from the study. They are referred to information about the 'Mind: Pregnancy' trial, which takes place simultaneously in the same study regions [33]. It evaluates an intervention to reduce psychological stress during pregnancy. This procedure aims to reduce risk of bias that could be introduced by co-interventions.

Multi-professional computer-assisted lifestyle intervention

The development of the GeMuKi intervention has been informed by experiences from the project 9 + 12 [34] and the GeliS study [28–30]. It aims to positively influence

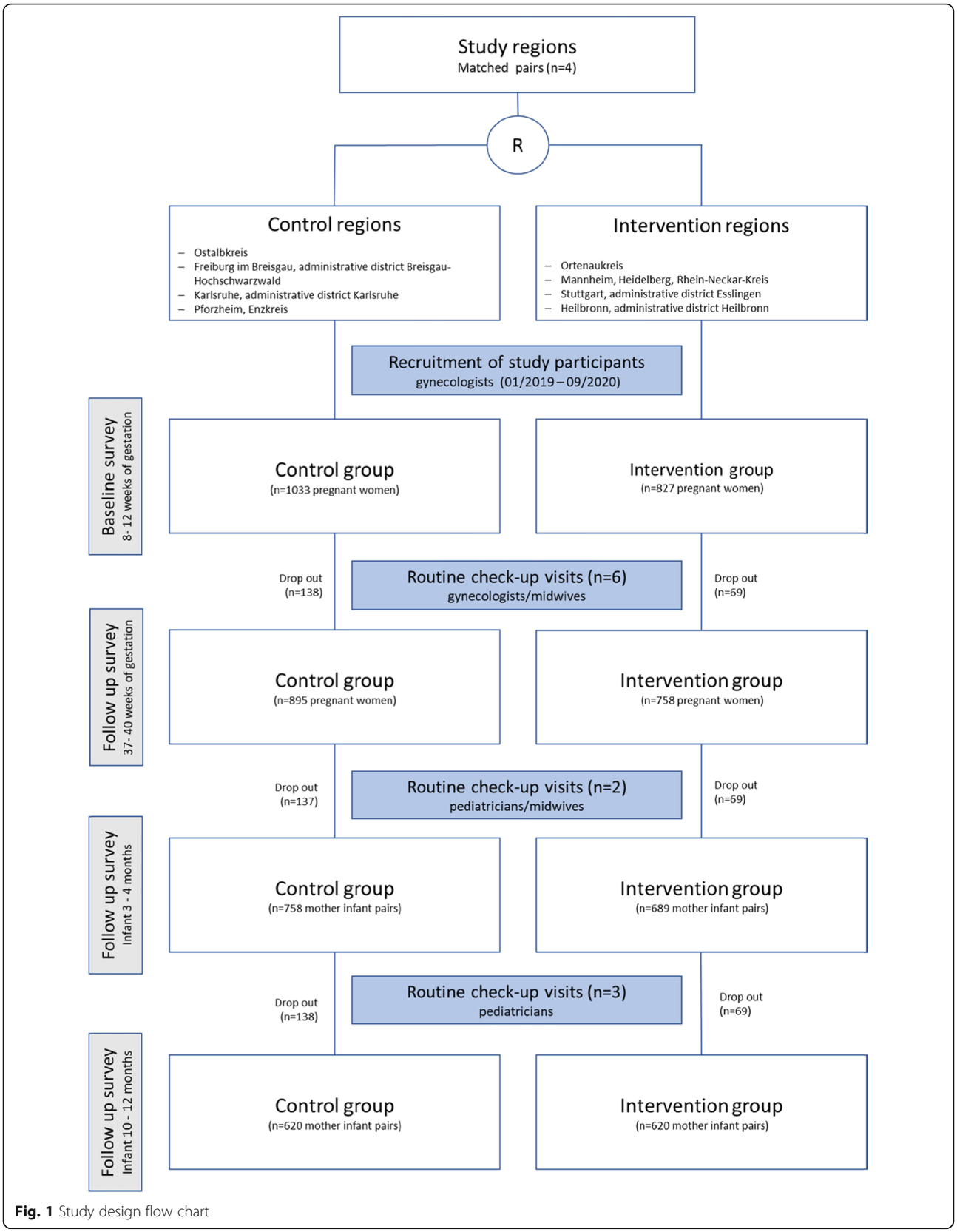

Fig. 1 Study design flow chart

lifestyle-related risk factors of expecting mothers and their infants. The GeMuKi intervention is designed as a series of brief (approximately 10 min) counseling sessions performed by gynecologists, midwives and pediatricians during 11 prenatal and infant check-ups (see Fig. 2). The counseling sessions cover topics relevant during pregnancy and the infant's first year relating to diet, physical activity, breastfeeding, and substance use. Figure 2 provides an overview of the topics addressed over the course of the GeMuKi lifestyle intervention. The topics are based on recently updated national recommendations developed by a multidisciplinary scientific task force [35, 36].

Traditionally, behavioral interventions aiming at lifestyle changes rely on providing information and advice. This has proven to be less successful compared to approaches using elements of Motivational Interviewing (MI) to improve communication by health professionals [37, 38].

The GeMuKi intervention takes into consideration that communication of providers should be sensitive to expecting mothers' health literacy in order to have a positive impact on behavior change. Therefore, multi-professional providers carrying out the GeMuKi intervention receive communication skills training. In addition to the content of the lifestyle intervention itself, the training covers MI techniques. MI is a client-centered counseling approach designed to enhance motivation for behavioral change by helping clients explore and resolve ambivalence [39].

A key element of MI used in the GeMuKi intervention is agenda mapping. Multi-professional providers employ agenda mapping to focus on a specific topic for lifestyle change (see Fig. 2). For this purpose, they use key message cards with pictograms developed by the Platform Nutrition and Physical Activity (peb) and experienced MI trainers.

After a participant has chosen a topic for lifestyle change, the provider continues the conversation using open-ended questions and then reacts to the participant's answers using reflective listening techniques. Guided by the provider, participants set SMART (Specific Measurable Achievable Reasonable Time Bound) goals for lifestyle change, which can be accomplished until the next check-up visit.

Another objective of the GeMuKi intervention is to increase the level of cooperation between gynecologists, pediatricians and midwives. To achieve this, a novel telehealth platform was developed, which assists providers in the counseling process and enables them to communicate with each other.

Telehealth platform GeMuKi-Assist

The telehealth platform GeMuKi-Assist has the objective to facilitate cooperation between providers and enhance continuity of lifestyle counseling. It consists of the GeMuKi-Assist Counseling Tool, GeMuKi-Assist App, GeMuKi-Assist Study Monitor and the GeMuKi-Assist Server (see Fig. 3).

Providers and trained practice staff in both intervention and control regions use the GeMuKi-Assist Counseling Tool to enter data routinely documented in the maternity and child medical record booklets. In the intervention regions these data are used to create a GWG curve showing the development of GWG for each individual study participant in relation to the recommended range. The infants' weight progression is displayed by means of percentile curves (see Additional file 1). Providers in the intervention regions also have access to key messages and guiding questions (i.e. standardized content) to support them in carrying out the GeMuKi intervention according to protocol and in alignment with MI

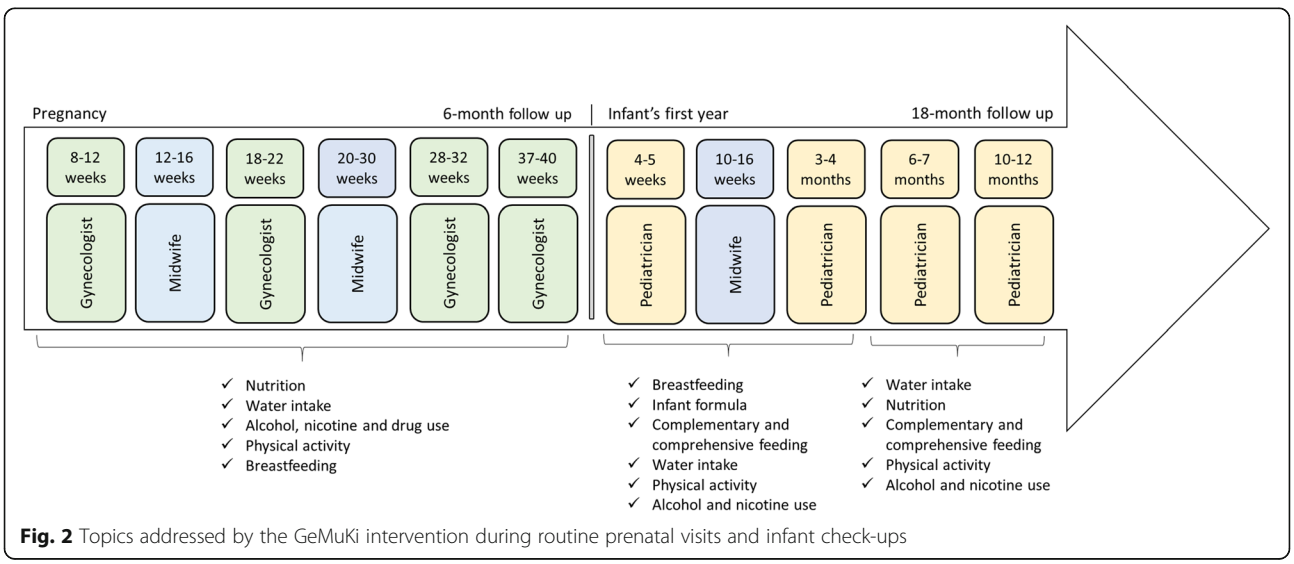

Fig. 2 Topics addressed by the GeMuKi intervention during routine prenatal visits and infant check-ups

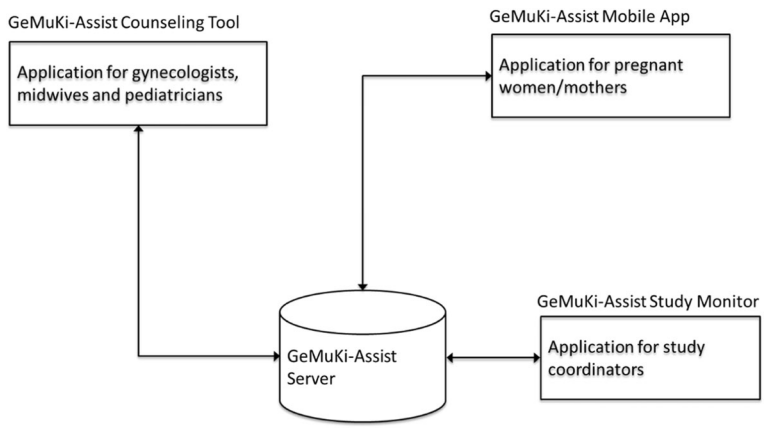

Fig. 3 Overview GeMuKi-Assist Telehealth platform

techniques. They can also document goals for lifestyle change participants want to accomplish until the next check-up visit and have an option to enter notes regarding individual participants. To ensure continuity of the counseling, this information can be accessed by multi-professional providers involved in the counseling process. Individual goals for lifestyle change entered into the counseling tool are automatically send to the GeMuKi-Assist App as a reminder for study participants.

The GeMuKi-Assist App aims to support intervention group participants in performing lifestyle changes. It provides an overview of individual goals formulated during lifestyle counseling and sends automatic reminders for encouragement (push notifications). The App includes links to reliable sources of information (e.g. institutions providing health education) as well as services and supports available in the region (e.g. psychotherapists and dieticians). An option to conduct automated google keyword searches (e.g. lactation consultant and smoking cessation classes) is also included (see Additional file 1). In addition to these features, which are only available for participants in the intervention group, all participants can use the App for creating personal notes and completion of the electronic surveys in the study.

The GeMuKi-Assist Study Monitor supports the research process alongside the GeMuKi intervention. It is used to create user profiles for providers and study participants and for assigning study participants to corresponding multi-professional providers. Study coordinators also use the tool to monitor the data collection process. Automatic alerts from the GeMuKi-Assist server inform them for instance about incomplete data from study participant surveys and data entries in the counseling tool (see Additional file 1).

The GeMuKi-Assist Server handles and saves the data derived from the mobile App, the counseling tool and the study monitor in one central database. Access is controlled for different user groups, who must authorize themselves before accessing the data.

Implementation strategy

To encourage uptake of the GeMuKi-intervention and implementation as planned an implementation strategy is being used consisting of the three elements: (1) a one-day training for gynecologists, midwives, pediatricians and practice assistants; (2) support by regional study coordinators in participating practices and (3) funding of novel tasks associated with the lifestyle intervention.

The one-day training is conducted before initiating the GeMuKi lifestyle intervention. It covers the basics of MI and the previously mentioned updated national recommendations for a health-promoting lifestyle during pregnancy and the infant's first year. The training material includes a PowerPoint presentation, key message cards as well as brochures and stickers for the maternity and child medical record booklets. The presentation provides information on the purpose of the lifestyle intervention and key messages for a health-promoting lifestyle. It also summarizes the most relevant aspects of the evaluation study conducted alongside the intervention. In addition, the fundamentals of MI are introduced and the implementation of the GeMuKi intervention using selected MI elements explained. Knowledge of theoretical concepts are applied practically through role-play exercises and reinforced by videos with MI examples. The training also covers how to use the GeMuKi-Assist Counseling Tool. The training is carried out by experienced MI trainers from the Healthy Start-Young Family Network (Gesund ins Leben-Netzwerk Junge Familie). The training materials were developed based on the content of the curriculum of the Healthy Start-Young Family Network [40] and additional literature [41–43].

Regional study coordinators provide ongoing support to participating providers over the phone and during

regular practice visits. They conduct a hands-on introduction to GeMuKi-Assist in the participating providers' practices in both intervention and control regions and answer questions to help solve technical issues with GeMuKi-Assist and other local implementation challenges. They also provide information and advice to encourage protocol compliance (e.g. regarding weighing during pregnancy and flawless documentation). Furthermore, they perform data management. In case of missing data or data error, they contact the respective providers.

All providers participating in the study receive funding for implementing the GeMuKi intervention. They sign a contract with the participating health insurers and the Association of Statutory Health Insurance Physicians of Baden-Württemberg (KVBW). This contract forms the legal basis for the billing process. Providers in the intervention regions can bill 15 € per lifestyle counseling session. Providers in both the intervention and control regions can bill 5 € per documentation in GeMuKi Assist. Gynecologists and pediatricians in the intervention regions can receive up to 80 € and midwives up to 60 € per study participant when they carry out all counseling sessions in the study period (see Fig. 2).

Data sources

Data will be collected at various points in time using multiple methods. Data sources include an electronic survey completed by study participants in the GeMuKi-Assist App at four points in time, data entered into the GeMuKi-Assist counseling tool during routine prenatal visits and infant check-ups, (focus group) interviews with multi-professional providers and intervention participants, statutory health insurance claims data and documents. At baseline, study participants also complete a short paper survey including demographic questions.

The selection of data sources was guided by the RE-AIM framework, which has been developed for evaluation of effectiveness and implementation of interventions in real-world settings [44, 45]. Table 1 provides a summary of constructs that will be measured for each dimension of the RE-AIM framework and data sources used.

Measures to assess effectiveness of the lifestyle intervention

Outcomes used to assess are described below. Table 2 provides a summary of the points of measurement and data collection methods.

Maternal weight

During every prenatal visit maternal weight is routinely measured and documented in the maternity record booklet (see Table 2). GWG is calculated as the difference between self-reported pre-pregnancy weight documented during the first prenatal visit and weight at the last prenatal visit.

Excessive GWG is defined according to recommendations of the Health and Medicine Division of the National Academies of Science, Engineering and Medicine (previously known as Institute of Medicine, IOM). These recommendations differ depending on pre-pregnancy Body Mass Index (BMI). For underweight women (BMI < 18.5) the recommended weight gain ranges from 12.5 to 18 kg, for normal weight women (BMI = 18.5–24.9) from 11.5 and 16 kg, for overweight women (BMI = 25–29.9) from 7 to 11.5 kg and for obese women (BMI ≥ 30) from 5 to 9 kg [46]. Weight gain above the recommended range is classified as excessive GWG. This definition of excessive GWG is similar to the definition used in German guidelines, which currently recommend a maximum weight gain of 16 kg for normal weight women and a maximum of 10 kg for overweight and obese women [36]. To assess postnatal weight-retention, maternal weight data will also be collected 1 year after birth.

Maternal lifestyle behaviors

Physical activity behavior during pregnancy will be measured using the Pregnancy Physical Activity Questionnaire (PPAQ) [47]. Maternal smoking behavior and alcohol consumption will be measured using questions from the German Health Interview and Examination Survey for Children and Adolescents (KIGGS) [48]. Dietary behavior will be assessed with a modified version of the Food Frequency Questionnaire used in the German Health Examination Survey for Adults (DEGS), which measures frequency and portion size of the main food groups consumed over the past 4 weeks [49].

Maternal knowledge

To assess the ability of the lifestyle intervention to increase maternal knowledge of health promoting lifestyle aspects addressed during brief counseling, the research team developed specific knowledge questions. These questions are based on key messages included in the previously mentioned national recommendations for a health-promoting lifestyle during pregnancy and the infant's first year [35, 36]. Data on study participants' health literacy will be collected as part of a separate study component, which will be reported elsewhere.

Infant weight development and body composition

Infant weight and length will be routinely assessed during infant check-ups. Infant BMI will be calculated and compared with age-specific reference values. The German Kromeyer-Hauschild reference system [50] will be used, because national reference data are more suitable for diagnosis of childhood overweight and obesity [4,

Table 1 Data sources and measured constructs aligned with RE-AIM dimensions

Dimension	Definition	Measured construct	Data source
Reach	The absolute number, proportion, and representativeness of individuals who are willing to participate in an initiative, intervention, or program.	Number and characteristics of participants and non-participants, reasons for non-participation	Administrative data in GeMuKi-Assist, focus groups with multi-professional providers, paper survey
Effectiveness	The impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes.	Proportion of participants with excessive weight gain, infant body composition and weight development	Administrative data in GeMuKi-Assist
		Maternal lifestyle, knowledge, infant feeding, infant diet and physical activity	Electronic survey
Adoption	The absolute number, proportion, and representativeness of settings and intervention agents (people who deliver the program) who are willing to initiate a program.	Proportion and characteristics of participating multi-professional practices, reasons for non-participation and drop-out of practices	Administrative data in GeMuKi-Assist, documents and publicly available statistics
Implementation	*Setting level:* the intervention agents' fidelity to the various elements of an intervention's protocol, including consistency of delivery as intended and the time and cost of the intervention.	Implementation of brief lifestyle advice intervention (how and by whom?)	Focus groups with multi-professional providers,
		Intervention costs: human resources and time, health service use, implementation costs and training	Administrative data in GeMuKi-Assist, interviews with study participants, social health insurance claims data, documents
		Utilization of the GeMuKi Assist Counseling Tool, local adaptations of the intervention	Focus groups with multi-professional providers, interviews with study participants, administrative data in GeMuKi-Assist
	Individual level: the clients' use of the intervention strategies.	Utilization of GeMuKi-Assist App, goal setting, links etc. Attainment of lifestyle change goals	Interviews with study participants, administrative data in GeMuKi-Assist
Maintenance	*Setting level:* the extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies.	Providers becoming experienced in delivering lifestyle advice, lifestyle advice becoming a routine component of practice processes	Focus groups with multi-professional providers, administrative data in GeMuKi-Assist
	Individual level: the long-term effects of a program on outcomes after 6+ months after the most recent intervention contact.	Maintenance of lifestyle changes and weight, drop out of study participants	Administrative data in GeMuKi-Assist, electronic survey

51]. To allow for comparisons with international research, the research team will also compare infant weight and length measures with WHO Growth Standards [52].

Infant feeding, diet and physical activity

Breastfeeding will be routinely documented in the GeMuKi-Assist counseling tool during infant check-ups. At the age of 10 to 12 months study participants will complete a modified version of the food frequency questionnaire used in the German Health Interview and Examination Survey for Children and Adolescents (KIGGS) [53]. It measures frequency and portion sizes of main food groups infants consumed over the past 4 weeks. Additionally, parental feeding practices will be examined with single items from the Comprehensive Feeding Practices Questionnaire (CFPQ) [54]. Study participants will also complete several questions on their infants' physical activity behavior developed by the research team.

Evaluation of the implementation process

To gain insights into the implementation process, the study team will examine which components of the lifestyle intervention are implemented as planned and which components are being modified. For this purpose, focus groups and interviews with multi-professional providers and study participants will be carried out. Additionally, data entered into the GeMuKi-Assist Counseling Tool will be analyzed. Among other variables, the research team will analyze counseling contents, characteristics of participating providers, characteristics of expecting women and infants reached by the intervention and the total number of lifestyle counseling sessions provided. Finally, documents will be analyzed, such as minutes taken during implementation training.

Qualitative interviews and focus groups will provide insights into factors facilitating and hindering implementation from the perspective of providers and participants in the lifestyle counseling. These qualitative data will also shed light on contextual factors influencing the

Table 2 Outcome measures at baseline and follow up

	Pregnancy				Infant's first year					
	8–12 weeks	18–22 weeks	28–32 weeks	37–40 weeks	At birth	3–10 days	4–5 weeks	3–4 months	6–7 months	10–12 months
Maternal weight [a]	x	x	x	x						x
Maternal physical activity	x			x				x		
Maternal smoking	x			x				x		x
Maternal alcohol use	x			x				x		x
Maternal diet	x			x				x		
Maternal knowledge	x			x				x		x
Breastfeeding [a]							x	x	x	x
Infant weight and length [a]					x	x	x	x	x	x
Infant nutrition										x
Infant physical activity								x		x

Notes: a = data are routinely collected and transferred into GeMuKi-Assist during check-up visits, all other measures are collected by an electronic self-report survey. Please note that this table only includes check-up visits, in which providers assess the specified outcomes

implementation process and outcomes for expecting mothers or their infants. To examine dynamic changes over time the research team will conduct interviews and focus groups both at the beginning and the end of the implementation process.

The evaluation of the implementation process will be informed by the Tailored Implementation for Chronic Diseases (TICD) checklist. This checklist is based on a synthesis of frameworks and taxonomies of determinants of professional practice [55]. It identifies determinants that influence professional practice in seven domains: guideline factors, individual health professional factors, patient factors, professional interactions, incentives and resources, capacity for organizational change, social political and legal factors. The checklist will guide the choice of measures used to understand factors influencing adoption, implementation and maintenance of the GeMuKi intervention by multi-professional providers.

Economic evaluation

A cost-consequence analysis will be performed, because the GeMuKi intervention seeks to modify multiple outcomes in expecting mothers, their infants and at the system level. Cost-consequence analyses compare costs and consequences of alternatives in a disaggregated manner [56]. This provides greater transparency to decision makers, who want to weigh multiple aspects against each other [57, 58].

The analysis will be conducted from a health insurance perspective. Cost components considered in the analysis include intervention costs, health service use and implementation costs. Intervention and implementation costs will be calculated based on documentation of personnel time and other resources used. Service use will be calculated using social health insurance claims data. These data include in- and outpatient treatment, medication use, aids and remedies, use of preventive services and sick leave periods. Outcomes considered in the analysis will include the above described lifestyle-related risk factors for overweight and obesity in expecting mothers and their infants. Additionally, outcomes at the system-level will be considered, such as changes in collaboration practices between multi-professional providers. These will be derived from qualitative data analyses conducted to gain understanding of implementation processes.

Sample size calculation

GWG was used as primary outcome for the sample size calculation, because healthy GWG is discussed with all expectant mothers participating in the lifestyle intervention. The brief lifestyle intervention is assumed to reduce the proportion of study participants with excessive gestational weight gain by 10%. Similar interventions have achieved a reduction in the proportion of excessive weight gain of around 20% [18, 59]. The target was set lower in this study, because the lifestyle intervention is implemented in a routine health service setting with less stringent inclusion criteria. To detect a 10% reduction in excessive gestational weight gain with a power of 80%, an alpha of 0.05 and an ICC of 0.05 a sample of $n = 1240$ pregnant women is required. This number was increased to $n = 1860$ to account for a drop-out rate of 25% in the intervention group and a 40% drop-out rate in the control group (see Fig. 1).

Data analyses

The data entry fields in the GeMuKi-Assist Counseling Tool and electronic surveys collected through the GeMuKi-Assist App are predefined to allow for plausible data only. Additional plausibility checks will be performed before commencing data analysis. Analyses of these quantitative data using descriptive statistics,

statistical tests and regression models will be conducted in SPSS and R. Analyses for all primary and secondary outcomes will follow an intention-to-treat principle, which compares the intervention arm to the control arm, without regard to intervention completion or compliance. Mixed effects models will be used to account for the clustered structure of the data. Multiple imputation methods will be used to deal with missing values. Exploratory analyses will be performed to explore intervention outcomes for subgroups of study participants, e.g. according to SES and migration background.

All focus groups and interviews will be audio-recorded and transcribed verbatim. Qualitative analysis of focus groups, interviews and documents will be carried out in MAXQDA using a framework analysis approach [60]. Two multidisciplinary researchers will conduct coding independently and discuss discrepancies. The principle of triangulation will be applied continuously to test validity through comparing information from different data sources.

To provide a better understanding of the overall process of implementation and gain insights into possible interactions between implementation and effectiveness of the GeMuKi intervention the research team will conduct integrated data analyses combining qualitative and quantitative data sources.

Discussion

This study will evaluate a brief counseling intervention to reduce lifestyle-related risk factors of overweight and obesity among expectant mothers and their infants. The GeMuKi intervention is innovative, as it combines several components that have been identified to enhance lifestyle counseling during pregnancy.

First, the lifestyle counseling is integrated into routine prenatal visits and infant check-ups. This puts a smaller burden on participants than add-on approaches [61] and provides a low threshold approach to reach expecting mothers and their infants. According to most recent estimates almost 90% of expecting mothers in Germany regularly attend prenatal visits [62] and over 95% of infants attend infant check-ups during the first year of life [63].

Second, lifestyle counseling is tailored to individual intervention participants. A tailored approach that recognizes individual differences in motivation, knowledge, needs and circumstances is recommended, because one-size fits all approaches have shown to be less effective in preventing overweight and obesity [61, 64]. The GeMuKi intervention consists of a series of brief counseling sessions using MI techniques. MI is a person-centered counseling approach, which encourages active involvement of intervention participants in the behavior change process. As evidenced by systematic reviews, MI has effectively promoted different health behaviors [65, 66] and has been associated with lifestyle changes in the long-term [67].

Third, providers implementing the GeMuKi intervention, will receive training in applying MI techniques. This will address needs expressed by professionals providing pre- and postnatal care to improve communication skills to discuss the sensitive topic of obesity and gestational weight gain [68–71].

Fourth, lifestyle counseling in the GeMuKi intervention will be supported by the novel telehealth platform GeMuKi-Assist. It includes a counseling tool for documentation and collaboration between multi-professional providers, an App for study participants with supporting information to encourage attainment of lifestyle change goals and a study monitor to support the evaluation study. An increasing body of evidence suggests that when used as an adjunct to face-to-face counseling methods computer and communication technology can be an effective tool to achieve lifestyle behavior changes, also among women with lower socio-economic status [72, 73].

Finally, the GeMuKi lifestyle counseling will be provided continuously over an 18-month period. This is in line with previous research findings, demonstrating that longer duration of lifestyle interventions result in more effects [74, 75].

The GeMuKi intervention will be evaluated in eight regions of the German state Baden-Wuerttemberg. To support implementation as planned, a comprehensive implementation strategy has been developed. It includes a training curriculum and funding scheme, which can be scaled up, in case the intervention proves to be effective. This evaluation study is designed to provide insights for policy makers at the German Federal Joint Committee (G-BA), who will decide about roll-out and public funding of the intervention on a federal scale.

Strengths of the study

The effectiveness-implementation hybrid design will concurrently provide insights into effectiveness of the GeMuKi intervention and the process of implementation. It combines design features from a pragmatic clinical trial with concepts from implementation research in order to facilitate a more rapid translation of research evidence into practice [31]. Guided by the RE-AIM framework, various data sources will be used to add further context to findings on effectiveness of the GeMuKi intervention. The study will provide information about factors that influence adoption of the intervention by multi-professional providers, reach of the target group, implementation fidelity and costs. Both from the perspective of providers as well as intervention participants the study will identify ways to optimize the intervention

to enhance effectiveness, client satisfaction and ease of implementation.

The 18-month follow up is a second strength of this study. Expecting mothers will be included in the study before 12 weeks of gestation and will participate in the GeMuKi intervention until 1 year after birth. The study findings will add to the limited evidence from intervention studies aimed at reducing risk of childhood overweight and obesity, which are commenced during pregnancy and continued after birth [23–25]. They will increase our understanding of effective early intervention strategies to prevent early programming of chronic disease.

Challenges and limitations

Execution of this study protocol involves several challenges. Embedding the GeMuKi intervention into routine care may pose a challenge for providers, who already have limited time during busy patient schedules [61]. To support providers in conducting the lifestyle counseling efficiently and as planned, the GeMuKi-Assist Counseling Tool includes various supports for providers, such as example questions to discuss with women.

Detecting expected effects of the GeMuKi intervention will require a large sample size. To address this challenge, multiple recruitment strategies will be used. To encourage intervention uptake by multi-professional providers the research team will involve regional opinion leaders among professional groups. Additionally, a relatively high drop-out rate was assumed in the power calculation.

An intervention provided in health service settings can only have a limited impact on individual lifestyle behaviors. Important other determinants in the social, physical and economic environment are not directly addressed by the GeMuKi intervention. Study participants can only be referred to additional supports and resources available in the community. Hence, the GeMuKi intervention can only be one element in an integrated, system wide approach required for successful obesity prevention.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12889-020-8200-4.

Additional file 1. GeMuKi-Assist Telehealth Platform – additional information and illustrations.

Abbreviations

BMI: Body Mass Index; GeMuKi: Gemeinsam Gesund Vorsorge Plus für Mutter und Kind (Strengthening health promotion: enhanced check-up visits for mother and child); GWG: Gestational weight gain; MI: Motivational Interviewing; OECD: Organisation for Economic Co-operation and Development

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Author's contributions

The GeMuKi project is carried out by a consortium, which is coordinated by AMB. SS, AA, FK, LL, FN are members of the research team and contributed to the design of the study. AA and SS developed the study protocol. AMB, IL, AM, JK, ET developed the enhanced lifestyle intervention. IL, JK, AM and ET coordinated the study in the study regions in Baden-Wuerttemberg. MJ, SK, BH and CG were responsible for the development of the GeMuKi-Assist Telehealth Platform. AA wrote the manuscript. All authors provided comments and approved the final manuscript.

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Availability of data and materials

Not applicable.

Ethics approval and consent to participate

Ethical approval to conduct this study was obtained from the University Hospital of Cologne Research Ethics committee (ID:18–163) and the State Chamber of Physicians in Baden-Wuerttemberg (ID: B-F-2018-100). Study data will only be processed in a pseudonymized form in accordance with the EU General Data Protection Regulation (GDPR). Written informed consent will be obtained from all study participants at baseline.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

Appendix 2: Questionnaire

Questionnaire on Study coordinators' assessment of each site[5]

[5] Questionnaires were used and completed in German. English translation was done for the use in this dissertation only.

Monitoring-Sheet for Practice Visits (GeMuKi-Intervention)

Date of enrollment of first GeMuKi participant:

Date:

Practice-ID:

Organization:	
Number of gynecologists	
Number of medical assistants	
Who performs the counseling?	Medical assistant ☐ Gynecologist ☐ I don't know ☐
How much additional time does the counseling require?	
How much additional time does the documentation require?	
How is the data documentation in GeMuKi-Assist organized in the practice?	☐ First on paper and then by the practice itself in GeMuKi-Assist. ☐ Directly by the practice in GeMuKi-Assist. ☐ First on paper and then documentation by study coordinators in GeMuKi-Assist. ☐ Other: _____ ☐ I don't know.
What is the weighing procedure?	With shoes ☐ Without shoes ☐ I don't know ☐

What are the general conditions of the counseling? (In other words, how is the counseling process organized in the practice? What needs to be improved so that there is enough time for each woman to have undisturbed counseling?)

Answer:

(If there are multiple GeMuKi counselors in group practices: Please note if the use of the note fields and goal agreements differ greatly within the practice and note an example for each counselor)

Utilization/Documentation/Networking via GeMuKi-Assist

	always	often	sometimes	rarely	never
The practice team needs support when working with GeMuKi Assist.	☐	☐	☐	☐	☐
The practice team seamlessly documents the medical data.	☐	☐	☐	☐	☐
I have to check with the practice because data is missing.	☐	☐	☐	☐	☐
I have to check with the practice because data was entered incorrectly	☐	☐	☐	☐	☐
The practice team documents the counseling in a reasonable and correct manner.	☐	☐	☐	☐	☐
The practice team documents the goal agreements.	☐	☐	☐	☐	☐
Please write down examples of goal agreements (preferably with different contents):					
The note field entry-feature is used.	☐	☐	☐	☐	☐
Please write down examples of a note field entries (preferably with different content and depth of detail):					
The practice team uses the note field entries to network with other professional GeMuKi counselors.	☐	☐	☐	☐	☐

Are there any other comments or observations about the utilization of GeMuKi-Assist?

Are there any other comments or issues regarding the practice in the GeMuKi project?

Which quality do the entries have for networking/information to other professional actors in the counseling network (reasonable, comprehensible?)? Do they respond to information from other professionals?

Final Assessment:

With how many patient contacts did the practice enter additional notes?

_____ of _____ contact

Assessment of the practice's commitment[1]					
	Agree	Somewhat Agree	Neither Agree nor Disagree	Somewhat Disagree	Disagree
The practice team is committed to implementing this change as part of the GeMuKi project.	☐	☐	☐	☐	☐
The practice team feels confident that they can coordinate tasks so that implementation of the GeMuKi intervention goes smoothly.	☐	☐	☐	☐	☐
The practice team is motivated to implement and apply GeMuKi permanently.	☐	☐	☐	☐	☐
The practice management supports the implementation of the GeMuKi intervention.	☐	☐	☐	☐	☐

Other notes:

[1] Items were adapted from a valid measure called 'Organizational Readiness for Implementing Change' (ORIC): Shea CM, Jacobs SR, Esserman DA, Bruce K, Weiner BJ. Organizational readiness for implementing change: a psychometric assessment of a new measure. Implement Sci. 2014;9:7. doi:10.1186/1748-5908-9-7.

Curriculum Vitae

Mein Lebenslauf wird aus Gründen des Datenschutzes in der elektronischen Fassung meiner Arbeit nicht veröffentlicht.

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Übersicht der Publikationen:

Lorenz, Laura*; Krebs, Franziska*; Nawabi, Farah; Senyel, Deniz; Alayli, Adrienne; Bau, Anne-Madeleine; Stock, Stephanie (2021): Perspektiven für die Implementierung des Innovationsfondsprojekt GeMuKi: Eine Querschnittserhebung der Einstellungen von Leistungserbringern zu einer präventiven Lebensstilberatung in den Schwangerschafts- und Kindervorsorgeuntersuchungen. In: Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen (165), S. 51–57. DOI: 10.1016/j.zefq.2021.06.005. (*=geteilte Erstautorenschaft)

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Köln, 16.12.2022 L. Lorenz

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Ort, Datum Unterschrift