Evaluation of a preventive counseling intervention delivered in routine healthcare

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The studies reported on in research projects 1 to 3 of this dissertation were conducted within the GeMuKi (Gemeinsam gesund: Vorsoge plus für Mutter und Kind; Strengthening health promotion: enhanced check-up visits for mother and child) project, which 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

Übergewicht und Adipositas sind ein dringliches Public Health Problem. Die mütterliche Gewichtszunahme während der Schwangerschaft ist eine bedeutende und potenziell modifizierbare Determinante des Übergewichts- und Adipositasrisikos sowie anderer gesundheitlicher Folgen für Mutter und Kind. Daher stellt die Gewichtszunahme in der Schwangerschaft einen erfolgversprechenden Ansatzpunkt für präventive Interventionen dar. Da die Inanspruchnahme von Vorsorgeuntersuchungen während der Schwangerschaft hoch ist, gilt die Implementierung von wirksamen präventiven Maßnahmen in die regulären Vorsorgeuntersuchungen als vielversprechende Strategie. Auf diese Weise können Interventionen die angestrebte Zielgruppe in hohem Maße erreichen und somit eine größtmögliche Wirkung in der Population Schwangerer entwickeln. Die vorliegende Arbeit adressiert die Evaluation einer präventiven Kurzintervention zum Gesundheitsverhalten in der Schwangerschaft, die in die reguläre Schwangerenvorsorge eingebettet ist, anhand von drei Forschungsprojekten. Auf der Grundlage der Ergebnisse dieser Dissertation kann der Wert der Intervention im Hinblick auf ihre Effektivität bestimmt sowie Perspektiven für eine Ausweitung in die Routineversorgung diskutiert werden. Die Dissertation umfasst die folgenden Ziele:

1) Das erste Ziel der Dissertation besteht darin, die Wirksamkeit einer Intervention, die im Rahmen der regulären Vorsorgeuntersuchungen erbracht wurde, hinsichtlich der Prävention übermäßiger Gewichtszunahme während der Schwangerschaft und gesundheitsrelevanter Outcomes von Mutter und Kind zu evaluieren.

2) Das zweite Ziel der Dissertation stellt die Untersuchung von Faktoren dar, die zusätzlich zur Wirksamkeit auch mit der Skalierbarkeit der Intervention zusammenhängen. Dazu gehört eine Bewertung der Reichweite (*Reach*) und der Annahme (*Adoption*) der Intervention.

Die Ergebnisse der Dissertation zeigen, dass die Intervention den Anteil an Frauen mit übermäßiger Gewichtszunahme reduzierte und die Höhe der Gewichtszunahme verringerte. Die Ergebnisse zur Reichweite der Intervention weisen jedoch darauf hin, dass sich die Studienteilnehmerinnen von der schwangeren Gesamtbevölkerung unterschieden, was die Verallgemeinerbarkeit der Wirksamkeitsergebnisse einschränkt und darauf schließen lässt, dass die Intervention die Zielgruppe nicht in ausreichendem Maße erreichte. Darüber hinaus war die Anzahl an Leistungserbringern, die an der Studie teilgenommen und die Intervention durchgeführt haben, gering. Es wurden mehrere Hürden für die Annahme der Intervention identifiziert. Daher sollten Strategien entwickelt werden, um die Intervention für eine Ausweitung in die Regelversorgung anzupassen, sodass eine breite Gruppe an Schwangeren adressiert werden kann. Wenn dies gelingt, stellt die Intervention eine vielversprechende

Strategie zur Vorbeugung von Übergewicht und Adipositas in der Bevölkerung und zur Förderung der Gesundheit von zwei Generationen dar.

Summary

Overweight and obesity are major public health concerns. Maternal weight gain during pregnancy is an important and potentially modifiable determinant for the risk of overweight and obesity and other health outcomes of mother and child. Therefore, it presents a favorable opportunity for preventive interventions. Incorporating effective interventions on gestational weight gain (GWG) into routine prenatal care is seen as a promising strategy to increase an intervention's impact in the population of pregnant women, as utilization of prenatal healthcare is high.

This thesis addresses the evaluation of a brief counseling intervention embedded in routine prenatal healthcare using three research projects. Based on the results of this thesis, the overall value of the intervention regarding its effectiveness can be determined and perspectives for scale-up can be discussed.

The thesis covers the following objectives:

1) The first objective of this thesis is to assess the effectiveness of a health intervention in the routine healthcare setting to prevent excessive gestational weight gain and improve maternal and infant health outcomes.

2) The second objective of this thesis is to investigate factors beyond effectiveness that are associated with the scalability of the intervention. These include an assessment of the intervention's reach and adoption.

The results of the dissertation indicate that the intervention effectively lowered the proportion of women with EGWG and reduced the absolute amount of GWG. However, findings on the reach of the intervention show that trial participants differed from the overall pregnant population which limits the generalizability of the effectiveness results and implies that the intervention did not address the target group to a sufficient extent. Moreover, numbers of healthcare providers who adopted the intervention were low and several barriers for the adoption of the intervention were identified. Therefore, further work must be undertaken to increase the intervention's suitability for scale-up for the intervention to become accessible to a wide population of pregnant women. If this is achieved, the intervention provides a promising strategy to prevent overweight and obesity in the population and to promote the health of two generations.

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List of abbreviations

EGWG – Excessive gestational weight gain

G-BA – Gemeinsamer Bundesausschuss

GDM – Gestational diabetes mellitus

GeliS – Gesund leben in der Schwangerschaft

GeMuKi – Gemeinsam gesund: Vorsorge plus für Mutter und Kind

GWG – Gestational weight gain

IOM – Institute of Medicine

MI – Motivational Interviewing

NAM – National Academy of Medicine

RCT – Randomized controlled trial

RE-AIM – Reach Effectiveness Adoption Implementation Maintenance Framework

WHO – World Health Organization

1 Introduction

Overweight and obesity are major public health concerns affecting nearly 60 % of adults and almost 30 % of children in Europe [1]. Too much body weight is associated with a number of chronic conditions leading to a high burden of disease for the society [2]. Measures to effectively prevent overweight and obesity are therefore urgently needed and are not yet widely implemented in an effective, broadly adopted and sustainable manner [3,4]. Research has shown that the risk of obesity in an individual's lifetime is already determined during the prenatal period by maternal health behaviors, a process called perinatal programming [5,6]. Maternal weight gain during pregnancy is an important and potentially modifiable predictor of a child's risk of obesity and chronic disease later in life and therefore a favorable opportunity for health interventions [7–12]. As utilization of prenatal healthcare by pregnant women in developed countries is high, routine prenatal care provides an ideal setting to reach the target group of pregnant women irrespective of socioeconomic background [13–17]. Previous studies have shown that interventions targeting gestational weight gain (GWG) significantly reduce weight gain and improve maternal and infant health outcomes [18–20]. However, little is known on the effectiveness of these interventions when embedded in routine prenatal care and administered by prenatal healthcare providers under real-world conditions.

There is consensus that preventive measures should only be incorporated into routine care if their success has been sufficiently proven [21,22]. In this context, Green and Glasgow claimed that "if we want more evidence-based practice, we need more practice-based evidence." [23]. Therefore, evaluating the impact of an intervention in the context in which it is implemented in practice is of great importance to assess the overall value of the intervention [24]. Additionally, effective interventions can only generate positive impact on population health, when expanded into broader policy and practice [25]. One barrier for bringing effective interventions into practice, that has been reported in the literature, is the lack of information relevant for policy-makers to decide about the intervention's suitability to be scaled-up [26]. The scalability of an intervention is determined by factors that comprise, but go beyond effectiveness and include, among others, the reach, adoption, acceptability, and fit of the intervention within the local context [27–30]. Assessing an intervention regarding these dimensions is therefore essential to increase the usability of research results in the decision process of scaling-up an intervention [26].

This thesis is based on data generated within the cluster-randomized controlled GeMuKi (Gemeinsam gesund: Vorsorge plus für Mutter und Kind; Strengthening health promotion: enhanced check-up visits for mother and child) trial, which was funded with the explicit perspective to scale up successful interventions and to include them into routine healthcare

[31]. Based on this objective, the evaluation of the intervention needs to take a broad focus and needs to involve dimensions related to the scalability of the intervention in order to be able to provide policy-makers with the relevant information. Hence, this dissertation aims to evaluate the impact of a health intervention in a real-world healthcare setting. The intervention was assessed regarding its effectiveness, reach, and adoption using qualitative and quantitative research methods.

The theoretical background of the dissertation is described in chapter 2. In chapter 3, the aims and objectives of the dissertation are outlined. Chapter 4 contains three peer-reviewed journal publications, providing the results of the dissertation. The findings of the dissertation are discussed in chapter 5. The dissertation closes with a summarizing conclusion, which is outlined in chapter 6.

2 Theoretical Background

In the following chapter, the theoretical background of the dissertation is outlined. The chapter starts with a description of the health problem. After that, an overview is given of the intervention setting and the health intervention. The chapter closes with a description of the domains covered by the evaluation of the health intervention.

2.1 Description of the health problem and relevance of the intervention

Despite extensive efforts, the prevalence of overweight and obesity in the World Health Organization (WHO) European Region is rapidly increasing [1]. The WHO describes obesity as a global epidemic illustrating the magnitude and urgency of the issue [32]. In Germany, more than 50 % of adults as well as 15 % of children are overweight [33,34]. Given the high burden of disease arising from overweight and obesity, maintaining a healthy body weight is crucial for the overall population [2]. However, as research on perinatal programming shows, it is even more important for women of childbearing age, as the risk of overweight and obesity during an individual's lifetime is already influenced during pregnancy by maternal health behaviors [5,6]. Hence, during pregnancy the course is set for the health of two generations [35,36].

Besides health behaviors such as diet and physical activity, GWG is known as an important factor in the context of perinatal programming [37]. Excessive gestational weight gain (EGWG) is hypothesized to modify maternal and fetal hormone levels which ultimately lead to changes in the offspring's energy regulation [38]. Infants of mothers who experienced EGWG are at higher risk for adverse outcomes such as stillbirth, macrosomia, preterm birth, low 5-minute-Apgar score, admission to the neonatal unit and childhood obesity [7,8,18,19,39–44]. In addition to negative health impacts on the infant, EGWG also negatively impacts the short- and long-term health of (pregnant) women. EGWG is a known risk factor for gestational diabetes mellitus (GDM) which increases the risk of developing diabetes mellitus type 2 later in a woman's life, hypertensive disorders, caesarean sections and long-term weight retention [45–50].

Based on existing evidence, the National Academy of Medicine (NAM, formerly known as Institute of Medicine (IOM)) developed recommendations for adequate GWG, which were published in 1990 and were updated in 2009 [35,51]. About 30 years after the first publication of the recommendations, numbers of pregnant women exceeding these GWG guidelines are still high. Depending on operationalization within studies and country of assessment, the prevalence of EGWG varies between 47% and 68.5% [7,44,47,52–55]. In Germany, 68.5 % of pregnant women gain more weight than recommended by the NAM [55].

In summary, EGWG is common among pregnant women and impacts maternal and child health negatively, placing it as a highly relevant opportunity for intergenerational obesity prevention and health promotion. Important determinants of EGWG include maternal health behaviors such as physical activity and diet, which are potentially modifiable [35,36]. Prevention programs therefore aim to improve these behaviors. Various intervention strategies have been applied by previous prevention programs including dietary counseling, keeping a food diary, weight monitoring, group education on lifestyle topics, and strategies relating to physical activity, such as structured light-intensity exercises and daily walking targets [56]. Combinations of these strategies are also common [56]. Results of these intervention strategies are promising. Meta-analyses found evidence that diet and physical activity-based interventions positively affect GWG [18–20].

Incorporating health interventions into routine prenatal care is a recently advocated strategy to improve access to interventions during pregnancy [57]. The results reported in the above-mentioned meta-analyses are based on randomized controlled trials (RCTs) conducted mostly in non-healthcare settings and/or with highly selected study populations. Although high in internal validity, findings drawn from such studies are of limited use when assessing the value of an intervention in a real-world scenario [58]. However, evidence on the impact of interventions targeting health behaviors that are embedded in real-world routine care settings and are conducted by prenatal healthcare providers is scarce.

Therefore, to fill these gaps in current research, an intervention trial was conducted to evaluate the impact of a complex health intervention in a routine prenatal care setting in Germany. Routine prenatal care provides a promising setting to deliver the intervention to the target group. In the next chapter a description of the setting, in which the intervention was implemented, is given to improve the understanding of contextual factors influencing intervention impact. As the trial was conducted in Germany, the German prenatal healthcare setting is depicted.

2.2 Description of the setting

In Germany, routine prenatal healthcare is anchored in the maternity guidelines (*Mutterschaftsrichtline)* [59] which are continually adapted by the Joint Federal Committee (Gemeinsamer Bundesausschuss, G-BA), the highest decision-making organ of the self-governing German healthcare system [60]. Prenatal healthcare is therefore clearly structured and the scope of preventive, diagnostic and therapeutic measures that are covered by the statutory health insurance is explicitly defined. Prenatal healthcare in Germany is predominantly conducted in the outpatient healthcare setting by community-based gynecologists and midwives.

Utilization of prenatal care in Germany, as in other developed countries, is high. In Germany, 100 % of statutory insured pregnant women are in contact with a prenatal care provider at least once during pregnancy [16]. Vulnerable groups such as pregnant women from socioeconomically disadvantaged population groups, migrants or women with social burden take part in prenatal care, but utilization of prenatal health services by these groups is considerably lower compared to the overall population [17,61]. During pregnancy, pregnant women typically attend between 10-12 appointments with prenatal healthcare providers [62]. It follows that routine prenatal care provides the opportunity for interventions to be continuously and frequently delivered during prenatal appointments. At the first appointment, after the pregnancy is confirmed, every pregnant women is issued a maternity booklet which is used throughout pregnancy to document data related to pregnancy progress and occurrence of complication [59].

According to the maternity guidelines, the primary goal of routine prenatal care is to detect high-risk pregnancies and births at an early point [59]. Preventive counseling on health behavior related topics such as diet and physical activity is not part of the maternity guidelines and is thus not yet conducted on a regular basis. In 2016, the WHO published *Recommendations on Antenatal Care for a Positive Pregnancy Experience* which describe key elements of routine prenatal care [63]. In contrast to German guidelines, the WHO concept contains counseling on health behaviors and gestational weight gain as part of routine prenatal care [63]. Efforts to improve care during pregnancy and childbirth at the national level are reflected in the National Health Goal (Nationales Gesundheitsziel) *Health around childbirth* (*Gesundheit rund um die Geburt*) [64].

In Germany, community-based healthcare provider practices are run by self-employed physicians. Within their practice these physicians typically employ a team of medical assistants. In larger practices additional salaried physicians are employed [65]. Community-based practices in Germany do not engage in research activities on a regular basis and are usually not trained to conduct trials. Research practice networks are rare and only exist in certain fields of expertise (e.g., family medicine) [66,67]. Additionally, in contrast to hospitals, there are only few hierarchical structures in community-based practices. The decision to take on tasks outside of healthcare delivery, such as engagement in research programs, is therefore made by the practice owner on behalf of the practice team.

Taken together, the gap in current healthcare regarding counseling on health behaviors in connection with the favorable opportunity for intervention delivery offered by the prenatal healthcare setting build the rationale for the GeMuKi trial. The organizational structures and unique characteristics of community-based healthcare-provider practices described above pose special challenges for conducting the evaluation of the intervention. In the next chapters

an overview of the intervention is given which is followed by a description of the theoretical background of the evaluation.

2.3 Description of the health intervention

The GeMuKi intervention aimed to positively modify health behaviors of pregnant women and thus increase adherence to GWG guidelines and improve the health of mother and child. To reach this goal, multiple intervention components were utilized which were aimed at different levels (individual and system level). A detailed description of the intervention and implementation strategies used is also given in the study protocol of the GeMuKi trial which was coauthored by the author of this dissertation [68] as well as in an article of Lück et al. [69]. The study protocol can be viewed in the appendix of this thesis.

The core component of the intervention were brief individual counseling sessions on health behavior topics conducted by healthcare providers (gynecologists, midwives) during routine prenatal care appointments. The counseling sessions were intended to take about 10 minutes each. During pregnancy up to four counseling sessions at gynecologists' practices and up to two counseling sessions with midwives were scheduled. Intervention contents were based on national guidelines for a health promoting lifestyle issued by the German initiative *Healthy Start – Young Family Network (Netzwerk Gesund ins Leben)* [70] and comprised diet, physical activity, breastfeeding as well as substance abuse. Pregnant women could choose for themselves which of these topics they would like to discuss during each session. By doing so, it was intended that the counseling fits the individual needs of the pregnant woman in question. The intervention was delivered using components of 'Motivational Interviewing' (MI), which is a theory-based counseling method [71]. The effectiveness of MI-based interventions for various health behaviors has previously been shown in meta-analyses [72–74]. MI requires the counselor to ask open ended questions which are aimed at exploring and resolving ambivalence and increasing the individual's intrinsic motivation to change [71,75]. As part of every counseling session, healthcare providers and participants agreed on goals for health behavior change, which could be met until the next counseling session.

In order to adequately prepare healthcare providers for conducting the intervention, preparation workshops were held by the trial team prior to the start of the intervention phase. During these one-day events, the guidelines on health promoting behaviors during pregnancy as well as MI techniques were covered.

The conduct of the brief counseling sessions was supported by a digital data platform, which served several objectives. Within the digital data platform, data on weight development and complications during the course of pregnancy was entered by healthcare providers at prenatal care appointments and could be accessed by all healthcare providers involved in the care of a

patient. Additionally, this data was used for the purpose of evaluation. Further, within the data platform, information on intervention content and MI compliant sentence blocks was provided to support healthcare providers in conducting the intervention. Moreover, data on counseling topics covered as well as individual goals for health behavior change were entered by healthcare providers and issued to the smartphone of the patient. Besides, individual notes on patients could be entered and shared among all healthcare providers involved in the care of a patient. Participants in the GeMuKi trial were asked to download an app on their smartphone which enables them to receive reminders regarding the behavior change goals they have set during counseling sessions. Additionally, the app provided further information on a healthy lifestyle. Lastly, the app served as a further data collection tool for research purposes, as participants answered questionnaires via the app throughout the trial.

The implementation of the intervention and trial conduct was supported by study coordinators who served as a first point of contact for healthcare providers. To additionally support the implementation of the intervention, healthcare providers were financially reimbursed for additional tasks (i.e. informed consent procedure, conducting the counseling, collecting data) [68,69].

2.4 Evaluation of the health intervention

In the maternity guidelines, the Joint Federal Committee claims that measures should only be used if their “diagnostic and preventive value is sufficiently proven” [59]. This requirement poses implications for the design of the trial and evaluation concept which will be outlined in this section.

Interventions in the field of public health or healthcare are oftentimes characterized as complex interventions [76]. On the one hand, properties of the intervention itself contribute to its complexity [76]. An intervention itself can be complex for example because of a high number of intervention components which might interact with each other, a high number of intervention settings or a high level of expertise needed by those conducting the intervention [76]. Interactions of the intervention and the context in which it is implemented can act as another source of complexity [76]. The important role of such interactions is described in the work of Hawe et al. who refers to complex interventions as “events in systems” [77].

On the other hand, the concept of complex interventions highlights the context in which an intervention is implemented as another important factor that needs consideration when evaluating an intervention’s value [29,58,76]. This is also reflected in the seminal work of Flay et al. who concluded that under real-world conditions a “program will be *effective* only if an *efficacious* treatment/program is delivered/implemented in such a way as to be made *available*

to an appropriate target audience in a manner *acceptable* to them (i.e., that they will be receptive to, participate in, comply with, or adhere to)" [78].

The assessment of factors that are linked to effectiveness, as described in the statement above, is also relevant to decide about the next step of an intervention after its effectiveness has been proven. As interventions need to be expanded to have a high impact on the health of a population, availability of information on aspects related to the potential of an intervention to be scaled up (i.e., its scalability) is needed. The translation of research findings into practice is a critical aspect and much research is undertaken to improve this process [25,58,79]. As indicated above, the complexity of the intervention as well as the context play a major role in this process and as Glasgow and Emmons conclude, "much research fails to translate into practice because the programs and methods used fail to address contextual factors." [80].

Hence, evaluation concepts should aim to assess the intervention under conditions as close as possible to real-world conditions and should broaden the spectrum of dimensions covered to capture the overall impact of the intervention including its potential to be scaled up [81].

The RE-AIM (**R**each **E**ffectiveness **A**doption **I**mplementation **M**aintenance) framework picks up the issue illustrated by Flay et al. and describes five dimensions of outcomes important to comprehensively assess the impact of complex interventions in real-world settings [82]. The framework was initially developed to promote better balance of internal and external validity and thus improve generalizability of research findings [28]. The overarching goal of the framework is to increase translation of research findings into practice [28,82,83]. The framework can be flexibly used to guide planning, evaluation and report of research results [82,83]. Within RE-AIM, *Reach* refers to the absolute number and percentage of participants reached by the intervention and the representativeness of the participants for the target population. *Effectiveness* describes the impact of the intervention in terms of health outcomes, quality of life or economic outcomes. *Adoption* covers the absolute number, proportion and representativeness of settings and staff who agreed to implement the intervention. Within the RE-AIM framework *Implementation* is the fidelity of intervention providers to the intervention's protocol. *Maintenance* describes long-term effects at individual and setting levels as well as modifications made to sustain delivery of the intervention [28,81,83]. The framework is particularly useful for the assessment of complex interventions, as it recognizes the complexity of the intervention and setting and includes various dimensions and indicators of intervention impact [28].

In the context of the GeMuKi trial, the intervention was implemented in the routine healthcare setting which is composed of a variety of structures, actors and activities [65]. Prenatal healthcare providers delivered the intervention alongside routine day-to-day healthcare. Practice structures and work processes within each healthcare provider practice differed

widely, creating a heterogenous setting [84]. The intervention consisted of a number of components as described in chapter 2.3. Additionally, the level of expertise needed to deliver the intervention exceeds the level of knowledge of most prenatal healthcare providers which implied the need for additional training. Because of these factors the GeMuKi intervention can be regarded a complex intervention.

Pragmatic evaluation designs are considered to be most suitable to answer the question of whether an intervention works under real-world conditions [85]. Pragmatic trials seek to balance between scientific rigor (internal validity) and generalizability as well as applicability of results (external validity) [86]. Design features that differentiate pragmatic from explanatory trials are reported by Loudon et al. [87]. Accordingly, the evaluation design of the GeMuKi trial featured several pragmatic aspects: First of all, inclusion criteria were set broadly in order to reflect real-world conditions in routine healthcare. In addition, participants were recruited in the routine healthcare setting. Hence, no additional effort was involved in approaching participants. Likewise, the intervention was conducted by prenatal healthcare providers during routine prenatal care. Moreover, the delivery of the intervention was flexible such that healthcare providers could adapt the intervention to the needs of the individual patient and their own workflow. Another pragmatic aspect of the GeMuKi trial included the measurement of the outcomes. Outcome measures used in the evaluation were mostly equivalent to measures routinely collected during prenatal healthcare (e.g., maternal weight, pregnancy complications and anthropometric measures of the neonate retrieved from maternity and child medical record booklets) and follow-up visits were connected to routine care appointments. Further, no additional measures were taken to improve compliance and adherence to the trial protocol and the analysis utilized an intention-to-treat approach including all participants irrespective of adherence, dropout or change of group assignment.

In conclusion, the GeMuKi trial was designed to investigate the complex health intervention under conditions as close as possible to routine healthcare. To gain a comprehensive picture of the real-world value and scalability of the intervention, information on reach, adoption and effectiveness of the intervention was collected, analyzed and interpreted collectively within the scope of this dissertation.

3 Aim and objectives of the dissertation

This thesis aims to evaluate the impact and scalability of a complex health intervention in a real-world setting. This includes the assessment of the effectiveness, reach and adoption of the intervention. By this, the dissertation contributes to the knowledge on the value of a preventive intervention and provides information on its scalability.

This aim is addressed through the following objectives:

1) The first objective of this dissertation is to assess the effectiveness of a health intervention in the routine healthcare setting to prevent EGWG and improve maternal and infant health outcomes.

2) The second objective of this dissertation is to investigate factors beyond effectiveness that are associated with the scalability of the intervention. These include an assessment of the intervention's reach and adoption.

This dissertation's objectives are addressed through three research projects. For this, the results of the three research projects are collectively reviewed and interpreted with regard to the overarching aim of the dissertation. Results on the effectiveness of the intervention are provided in research project 3. Further on, an assessment of the intervention's reach is performed in research project 3. Research projects 1 and 2 provide information on the adoption of the intervention. By integrating the results of the three research projects a comprehensive picture of the impact and scalability of a complex health intervention in a real-world setting is given.

4 Scientific publications of the cumulative dissertation

In the following section the results of the three research projects are presented in the form of publications in scientific peer-reviewed journals.

4.1 Research project 1

Published as:

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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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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[1] geteilte Erstautorenschaft.

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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

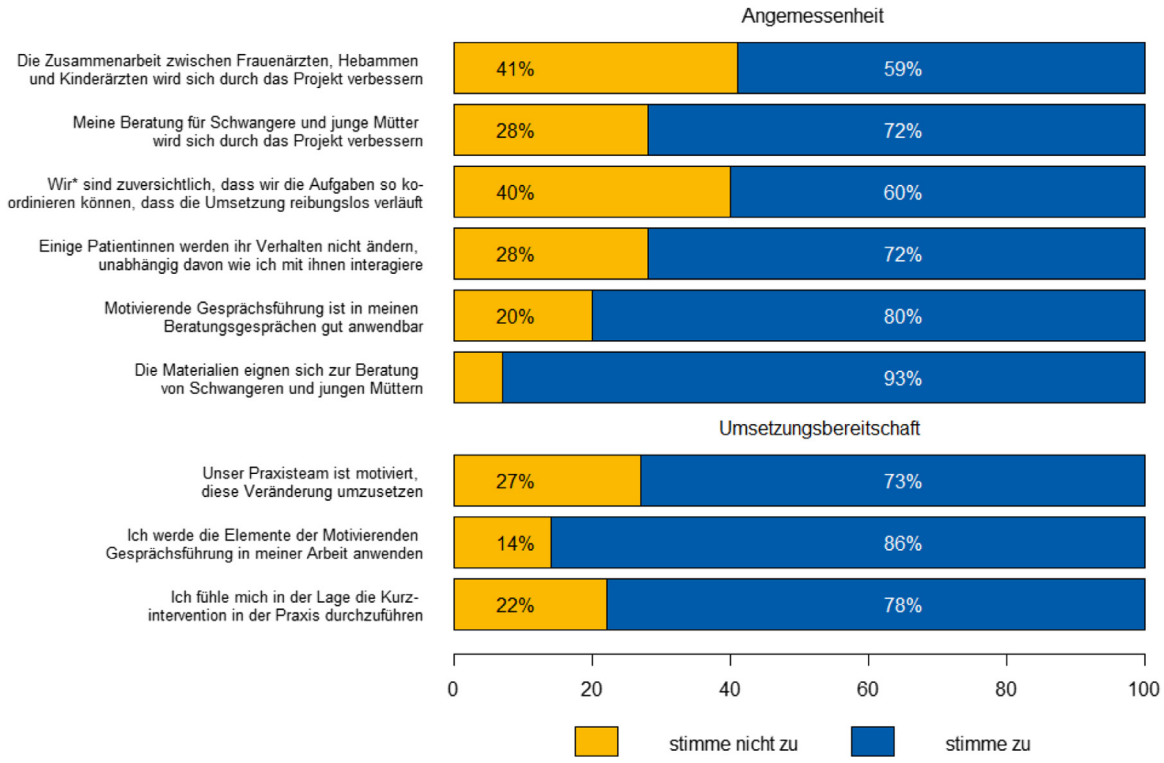

Abbildung 1. Ergebnisse der geschlossenen Fragen zu den Implementierungsoutcomes Angemessenheit und Umsetzungsbereitschaft.

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).

Förderung

Das Projekt GeMuKi wird aus Mitteln des Innovationsfonds des G-BA von 10/2017 – 9/2021 im Bereich „Neue Versorgungsformen“ gefördert (Förderkennzeichen: 01NVF17014) und unter Beteiligung folgender Konsortialpartner durchgeführt: Plattform Ernährung und Bewegung, Institut für Gesundheitsökonomie und Klinische Epidemiologie am Universitätsklinikum Köln, Fraunhofer Institut für Offene Kommunikationssysteme FOKUS, BARMER, Kassenärztliche Vereinigung Baden-Württemberg.

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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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4.2 Research project 2

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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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Article

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.

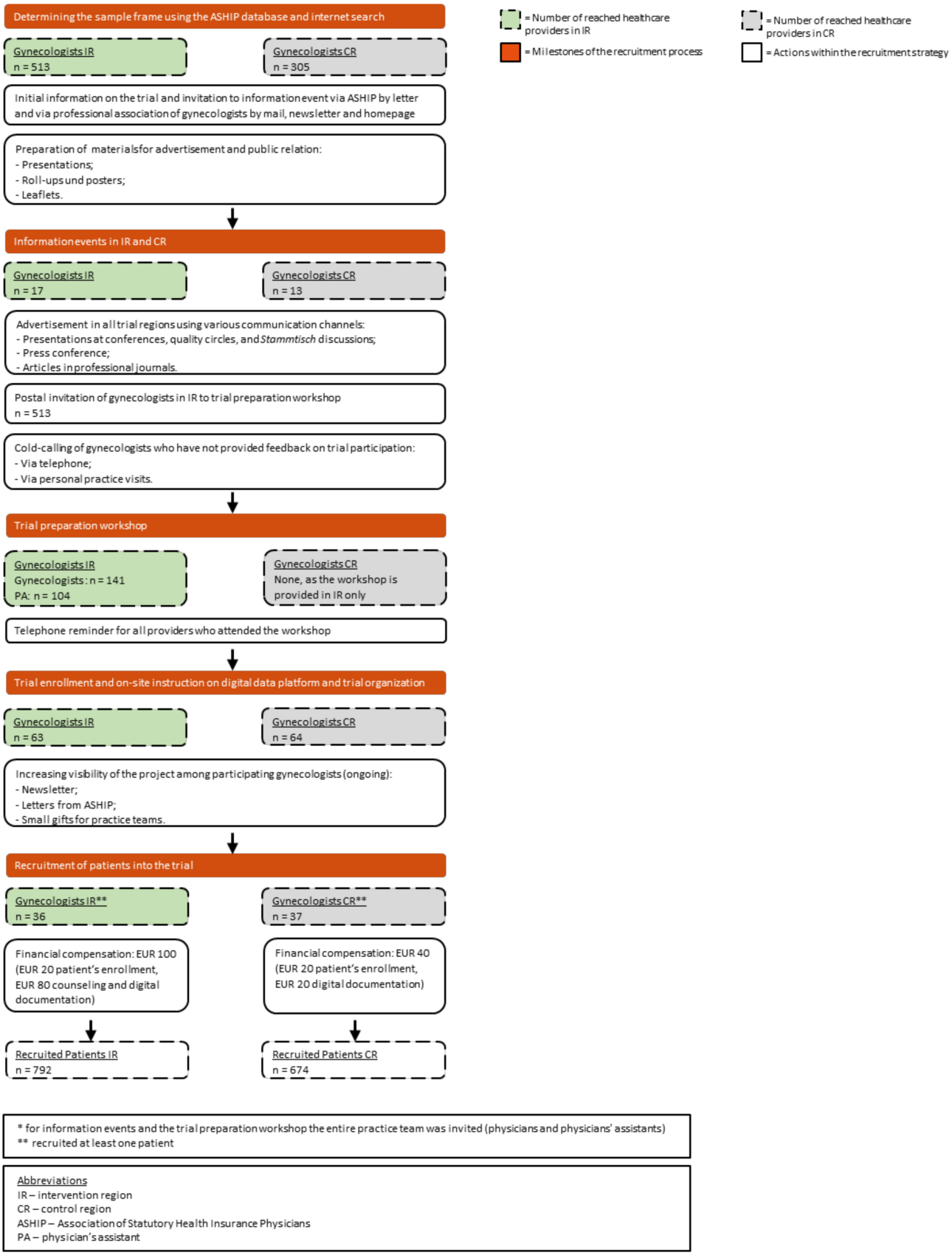

Figure 1. Flowchart for the recruitment process in the GeMuKi trial.

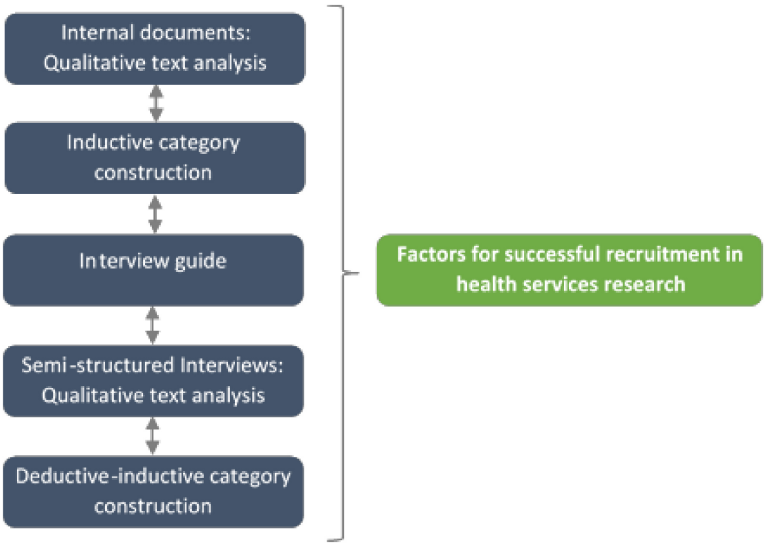

Figure 2. Iterative data collection and analytical approach.

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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4.3 Research project 3

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Effectiveness of a Brief Lifestyle Intervention in the Prenatal Care Setting to Prevent Excessive Gestational Weight Gain and Improve Maternal and Infant Health Outcomes

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Effectiveness of a Brief Lifestyle Intervention in the Prenatal Care Setting to Prevent Excessive Gestational Weight Gain and Improve Maternal and Infant Health Outcomes

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Abstract: Research on perinatal programming shows that excessive gestational weight gain (GWG) increases the risk of overweight and obesity later in a child's life and contributes to maternal weight retention and elevated risks of obstetrical complications. This study examined the effectiveness of a brief lifestyle intervention in the prenatal care setting, compared to routine prenatal care, in preventing excessive GWG as well as adverse maternal and infant health outcomes. The GeMuKi study was designed as a cluster RCT using a hybrid effectiveness implementation design and was conducted in the prenatal care setting in Germany. A total of1466 pregnant women were recruited. Pregnant women in intervention regions received up to six brief counseling sessions on lifestyle topics (e.g., physical activity, nutrition, drug use). Data on GWG and maternal and infant outcomes were entered into a digital data platform by the respective healthcare providers. The intervention resulted in a significant reduction in the proportion of women with excessive GWG (OR = 0.76, 95% CI (0.60 to 0.96), $p = 0.024$). Gestational weight gain in the intervention groupwas reduced by 1 kg (95% CI (−1.56 to −0.38), $p < 0.001$). No evidence of intervention effects on pregnancy,birth, or neonatal outcomes was found.

Keywords: maternal health; overweight; obesity; intervention; pregnancy; gestational weight gain

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1. Introduction

Overweight and obesity are major public health concerns. The world health organization (WHO) has identified obesity as a global epidemic and called for urgent public health measures in response to it [1]. Despite this, over 50% of adults and more than 16% of children in Organization for Economic Co-operation and Development (OECD) countries are still overweight or obese [2]. Besides causing multiple health problems in the overall population, maintaining a healthy bodyweight is particularly important in women of childbearing age. In addition to prepregnancy body weight, gestational weight gain (GWG) also plays an important role in terms of maternal and infant health outcomes [3]. Gestational weight gain and infant health are linked through a process known as perinatal programming [4,5]. Excessive GWG is associated with a number of adverse outcomes for both mother and child, such as gestational diabetes mellitus, hypertensive disorders, caesarean sections, being large for gestational age (LGA),macrosomia, childhood obesity, and long-term weight retention in women [6–14].

In 1990 and 2009, the National Academy of Medicine (NAM, formerly known as IOM) published recommendations for adequate GWG [15]. However, based on the evidence available, the percentage of pregnant women who gain more than the recommended weight still varies between 47–68.5% across studies and countries [7,8,11,16–19]. In Germany, 68.5% of pregnant women experience excessive GWG [19]. These numbers illustrate the

need for effective preventive measures to reduce the proportion of women experiencing excessive GWG.

Important and potentially modifiable determinants of GWG include maternal health behaviors, such as diet and physical activity [15,20]. Prevention programs to reduce excessive GWG are therefore aimed at modifying these behaviors [21]. Intervention strategies applied in previous prevention programs include dietary counseling, keeping a food diary, weight monitoring, group education on lifestyle topics, and strategies relating to physical activity, such as structured light-intensity exercises and daily walking targets. It is also common to apply a combination of these strategies. Behavior change techniques such as goal setting, reminder messages, and conversational methods such as 'motivational interviewing' (MI) are also incorporated into intervention strategies [22].

Meta-analyses on the effect of diet and physical-activity-based interventions in reducing GWG indicate significant beneficial effects [23–25]. In a meta-analysis of 49 RCTs, diet and/or exercise interventions reduced the risk of excessive GWG by 20% [25]. Two other meta-analyses reported significant mean reductions in total GWG of 1.42 kg [24] and 0.7 kg [23].

However, it is still unclear as to what extent weight gain reductions can be considered clinically important. Evidence on the effects of lifestyle interventions in relation to maternal and neonatal outcomes is inconsistent. In their recent meta-review, Fair et al. reported "some evidence that [...] interventions may reduce the odds of gestational diabetes," while no effects on other maternal or neonatal outcomes were found [26]. In two other meta-analyses, positive intervention effects on gestational diabetes, macrosomia and LGA [27], and caesarean section rates [23,27] were reported. At the same time, other studies did not find that lifestyle interventions during pregnancy had any effect on any maternal or neonatal health outcomes [28,29].

The International Weight Management in Pregnancy Collaborative Group (i–WIP) has called for lifestyle counseling to be incorporated into routine prenatal consultations as a public health measure to "tackle the obesity epidemic in pregnancy" [30]. Prenatal care settings provide a unique opportunity for lifestyle interventions, as the utilization of prenatal healthcare services by pregnant women in developed countries is high [31–33]. Additionally, the results of a systematic review have demonstrated that interventions delivered by healthcare providers during routine prenatal care achieve superior results when compared to interventions that are conducted in other settings and/or by other health professionals (e.g., dieticians, physiotherapists). However, of the 32 studies reviewed, only a small number ($n = 7$) were delivered by healthcare providers in a prenatal care setting, and heterogeneity regarding study populations, calculation of GWG, intervention strategies and effect sizes across these studies was high [34]. Additionally, the review focused exclusively on pregnant women who were overweight or obese.

As adequate GWG reduces the risk of adverse outcomes, including long term weight retention across all body mass index (BMI) categories [9,23,35], further evidence is required on the effectiveness of lifestyle interventions in routine prenatal care settings that target the general pregnant population. In order to bridge these gaps in the current research, an intervention trial was conducted to assess the real-world effectiveness of incorporating a brief lifestyle intervention into routine prenatal care in terms of the impact on GWG and maternal and infant health outcomes.

2. Materials and Methods

2.1. Trial Design

The GeMuKi trial (acronym for 'Gemeinsam gesund: Vorsorge plus für Mutter und Kind'—Strengthening health promotion: enhanced check-up visits for mother and child) was designed as a cluster-randomized, controlled trial using a hybrid effectiveness-implementation design (type II) [36]. As such, data on the implementation process for the intervention was collected alongside effectiveness data. Results on the implementation process for the intervention into regular prenatal care will be published separately. A study

protocol entailing detailed information on the rationale,design, and methods of the trial has been published previously [37]. In brief, community-based gynecologists, midwives, and pediatricians in the intervention arm of the trial were recruited to conduct the GeMuKi lifestyle intervention during routine prenatal visits andchildren's check-ups. Healthcare providers in the control arm provided care as usual. To reduce the risk of contamination, the intervention was allocated at the regional level as opposed to on an individual level.

The trial was conducted in 10 urban and rural regions within the German state of Baden-Wuerttemberg. Two of these regions (one intervention region and one control region) were added at a later stage in order to enlarge the sample frame. The intervention and control regions were paired via propensity score matching,using the average income per capita, birth numbers of BARMER insured persons, and numbers of community-based gynecologists as the matching criteria. The data of BARMER insured persons were used because BARMER was the first insurer to agree to take part in the project. The two regions that were added at a later stage were selected for their comparability with the original regions in terms of these characteristics. The matched study region pairs were subsequently randomized into intervention and control regions.

2.2. Participants

The recruitment of pregnant women was conducted by community-based gynecological practices in the trial regions. Broad inclusion criteria were chosen in order to reflect conditions in real-world routine care. Pregnant women wereeligible to participate if they were <12 weeks of gestation, ≥18 years of age, had provided written informed consent, possessed proficient German language skills, were insured witha statutory health insurance provider, and were enrolled by one of the participating gynecological practices.

To reduce the risk of bias due to co-interventions, pregnant women who scored highly on the Edinburgh Postnatal Depression Scale (sum score > 9 and/or score = 3 on item 10) were excluded from this trial and were referred to another intervention, which took place simultaneously in the same regions and which targeted stress and anxiety during pregnancy [38].

2.3. Lifestyle Intervention Program

The GeMuKi lifestyle intervention program consisted of up to six brief counseling sessions (about ten minutes each) held alongside routine prenatal visits. In Germany, care for pregnant women is primarily provided in the outpatient setting by community-based gynecologists and/or midwives. Regular prenatal appointments provide an ideal setting for preventive measures, as the utilization of prenatal care is high [31,32,39] and they allow for continuous interventions (up to six counseling sessions in six months).

Prior to the start of the field phase, participating healthcare providers in the intervention regions received training on how to deliver the intervention. The lifestyle counseling was conducted using elements of MI. The counseling content was determined in accordance with evidence-based recommendations issued by the German initiative 'Healthy Start–Young Family Network' [40]. Lifestyle topics covered during the counseling included physical activity, diet, breastfeeding, and substance use. As part of every counseling session, healthcare providers and pregnant women agreed upon SMART (Specific, Measurable, Achievable, Reasonable, Time-bound) lifestyle goals which could be met by the next counseling session. Following the counseling session, theparticipating pregnant women received these goals via reminder messages within an app that was specifically designed for the trial. To aid the gynecologists and midwives during the counseling, information on each participant's previous counseling progress were provided within a web-based data platform, together with sample questions for MI. Information on counseling topics and progress was entered by all the healthcare providers involved, at every counseling session. Details on the GeMuKi lifestyle intervention and digital tools have been published previously [41,42].

2.4. Outcomes

The primary outcome of this study was identifying the proportion of women with excessive GWG according to the NAM guidelines of 2009 [15]. Once they had been recruited, the pregnant women filled out a short, paper-based questionnaire to facilitate the collection of their baseline demographic data and prepregnancy weightand height. Data collection in gynecologists', midwives', and pediatricians' practices was carried out via a web-based data platform. The healthcare providers used this data platform to enter information on weight development and complications during check-up visits.

For the primary outcome, GWG was calculated as the difference between the self-reported prepregnancy weight collected at baseline and the weight measured by the gynecologists or midwives during the last prenatal visit. The pregnant women were categorized into four prepregnancy BMI subgroups using WHO cut-off values [43]. Once this was done, each woman's weight gain was classified as either adequate or excessive, specific to her prepregnancy BMI and gestational age at the time of her last weight measurement, according to 2009 NAM guidelines. As gestational length varies between women, the duration of time over which weight can be gained is different for every participant. Accounting for gestational age at the time of the last weight measurement reduces the risk of misclassification of GWG, and therefore provides themost accurate metric for excessive GWG prevalence [15,44,45]. For this, NAM recommends the following rates of weekly weight gain for the second and third trimesters: 0.44–0.58 kg/week for underweight women; 0.35–0.50 kg/week for women of normal weight; 0.23–0.33 kg/week for overweight women, and 0.17–0.27 kg/week for obese women. For the first trimester, a weight gain of 0.5–2 kg is recommended for all BMI categories[15]. For twin pregnancies, weight gain rates as described by Fox et al. (2010) were applied accordingly, [46] as the 2009 NAM guidelines do not provide weekly weight gain ranges for women carrying twins. In addition to excessive GWG, differences in GWG (measured in kilograms) between the intervention and control groups were also evaluated.

The secondary outcomes discussed in this article cover pregnancy and obstetric and neonatal complications. The healthcare providers recorded information on complications during every check-up appointment using the digital data platform. The outcomes that were considered were: gestational diabetes, hypertensivedisorders, bleeding, caesarean sections, preterm birth, being small for gestational age (SGA), LGA, macrosomia, and abnormal 5 min Apgar scores. SGA and LGA were defined as infantbirth weight < 10th and >90th percentiles respectively, adjusted for sex and gestational age. Macrosomia was defined as a birthweight > 4000 g, and an abnormal 5 min Apgar score was classified as a score ≤ 6.

Data quality and plausibility was monitored continually throughout the data collection phase. Where data points seemed implausible, the healthcare providers or the pregnant women in question were contacted in order to obtain the correct information.

2.5. Sample Size

Sample size was calculated based on the assumption that the intervention would result in a 10% reduction in the proportion of pregnant women who exceeded the gestational weight gain recommendations. This assumption was based on results of previous intervention trials [25]. Further parameters for the sample size calculation included power = 0.80, $\alpha = 0.05$ and ICC of 0.05. This resulted in a net sample size of 620 pregnant women per group.

2.6. Statistical Analyses

The primary and secondary outcomes were compared between the two trial arms using generalized estimating equations (GEEs). This modeltype was chosen to account for clustering in the data due to the design of the trial. The primary outcome was analyzed by fitting a logistic model, as excessive GWG was coded as a binary variable. Furthermore, to assess differences in the effect of the treatment by prepregnancy BMI category, an interaction

model containing a BMI-by-treatment interaction term was run. For continuous outcome data, linear generalized estimating equation models were fitted. Secondary outcomes were analyzed accordingly. The GEE models were specified using an exchangeable working correlation structure and robust standard errors. The adjusted effect sizes and corresponding 95% CIs were calculated, adjusting for prepregnancy BMI category, age, parity, migration status and educational level. All the analyses were performed on an intention-to-treat (ITT) basis. Multiple imputation by chained equations was used to impute missing data, creating 100 imputed datasets. All the analyses were performed using the public domain statistical software R 4.1.2 (http://cran.r-project.org, accessed on 25 November 2021).

The robustness of the results was examined by performing sensitivity analyses. First, a complete case analysis was conducted including only those participants for whom complete data was available. In addition to this, the primary analysis was rerun using inverse probability of treatment weighting (IPTW) as an additional method to account for imbalances in baseline demographic characteristics among women in the intervention and control groups. Imbalances were assessed by calculating standardized mean differences (SMDs). Differences of >0.1 indicate a potential imbalance [47,48]. IPTW eliminates differences between the treatment and control groups by weighting the observations based on their propensity for being treated. Doubly robust estimates were obtained by incorporating the propensity score weights into the outcome regression models.

3. Results

3.1. Sample Description

A total of 1466 pregnant women were recruited for the trial. After recruitment, 45 women were lost to follow-up due to miscarriage. Another 12 women declined further participation, and 28 women were no longer contactable. The participant flow is depicted in Figure 1.

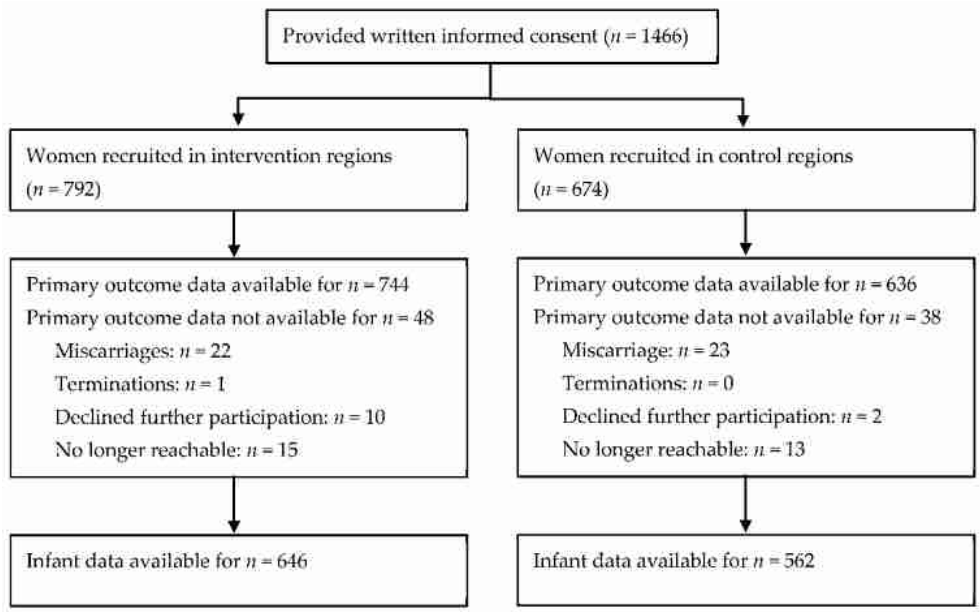

Figure 1. Participant flow.

The demographic characteristics for the sample at baseline are shown in Table 1. The SMDs of the following variables were close to or passed the threshold of 0.1 indicating potential baseline imbalances: prepregnancy BMI (SMD = 0.20), parity (SMD = 0.09), and migration status (SMD = 0.14). To account for these imbalances, all the models were adjusted for the imbalanced variables and only the adjusted results were reported.

Table 1. Baseline characteristics of study participants.

	Control Group (n = 674)	Intervention Group (n = 792)	Total (n = 1466)
Age, years	31.3 ± 4.4	31.3 ± 4.3	31.3 ± 4.3
Height, cm	167.0 ± 6.0	166.9 ± 6.1	167.0 ± 6.0
Prepregnancy weight, kg	67.1 ± 14.8	69.8 ± 16.3	68.6 ± 15.6
Prepregnancy BMI, kg/m^2	24.1 ± 5.2	25.0 ± 5.6	24.6 ± 5.4
Prepregnancy BMI category, n (%)			
BMI < 18.5 kg/m^2	33/674 (4.9%)	20/792 (2.5%)	53/1466 (3.6%)
BMI 18.5–24.9 kg/m^2	438/674 (65.0%)	477/792 (60.2%)	915/1466 (62.4%)
BMI 25.0–29.9 kg/m^2	132/674 (19.6%)	172/792 (21.7%)	304/1466 (20.7%)
BMI ≥ 30.0 kg/m^2	71/674 (10.5%)	123/792 (15.5%)	194/1466 (13.2%)
Parity, n (%) nulliparae	345/658 (52.4%)	366/764 (47.9%)	711/1422 (50.0%)
Living with partner	640/667 (96%)	760/780 (97.4%)	1400/1447 (96.8%)
Gestational age at study entry, weeks	9.9 ± 2.0	9.9 ± 1.9	9.9 ± 1.9
Smoker, n (%)	18/636 (2.8%)	30/738 (4.1%)	48/1374 (3.5%)
Education, n (%)			
Primary	2/645 (0.3%)	0/759 (0.0%)	2/1404 (0.1%)
Lower secondary	19/645 (2.9%)	20/759 (2.6%)	39/1404 (2.8%)
Upper secondary	259/645 (40.2%)	331/759 (43.6%)	590/1404 (42.0%)
University degree	365/645 (56.6%)	408/759 (53.8%)	773/1404 (55.1%)
Immigrant status, n (%) immigrants	132/671 (19.7%)	197/776 (25.4%)	329/1447 (22.7%)
First-generation	84/130 (64.6%)	128/194 (66.0%)	212/324 (65.4%)
Second-generation	46/130 (35.4%)	66/194 (34.0%)	112/324 (34.6%)

3.2. Gestational Weight Gain

The results for the primary outcome are shown in Table2. An estimated proportion of 52.8% of the women in the intervention group and 59.6% of the women in the control group experienced excessive GWG. The results of the adjusted regression analysis showed a significant treatment effect on the proportion of women whohad experienced excessive GWG (OR = 0.76, 95% CI (0.60 to 0.96), p = 0.024). The estimated prevalence of excessive GWG was highest in the overweight BMI category and lowest in the underweight BMI category. The subgroup analysis yielded a significant treatment effect in women of normal weight only (OR = 0.71, 95% CI (0.52 to 0.97), p = 0.031). There were trends for lower proportions of excessive GWG with the intervention in the overweight and obese BMI subgroups, and a higher proportion in the underweight subgroup, though these results did not reach statistical significance.

Table 2. GWG by treatment group.

			Treatment Effect		
	Control Group [a]	Intervention Group [a]	Adj. OR (95% CI) [b]	Adj. Mean Difference (95% CI) [c]	Adj. p-Value
Women exceeding GWG recommendations (total)	59.6%	52.8%	0.76 (0.60 to 0.96)		0.024
BMI < 18.5 kg/m^2	21.2%	25.8%	1.30 (0.41 to 4.08)		0.605
BMI 18.5–24.9 kg/m^2	57.5%	48.9%	0.71 (0.52 to 0.97)		0.031
BMI 25.0–29.9 kg/m^2	81.1%	78.2%	0.84 (0.45 to 1.54)		0.566
BMI ≥ 30.0 kg/m^2	68.8%	65.6%	0.87 (0.51 to 1.49)		0.658
Total gestational weight gain, kg	14.2	13.3		−0.97 (−1.56 to −0.38)	0.001
BMI < 18.5 kg/m^2	14.0	14.0		−0.06 (−0.77 to 0.65)	0.873
BMI 18.5–24.9 kg/m^2	15.5	14.6		−0.85 (−1.57 to −0.14)	0.019
BMI 25.0–29.9 kg/m^2	15.6	13.9		−1.69 (−2.65 to −0.74)	<0.001
BMI ≥ 30.0 kg/m^2	11.6	10.9		−0.65 (−2.59 to 1.30)	0.514

[a] Estimated shares/means. [b] Adjusted for prepregnancy BMI, parity, age, migration status, and educational level. [c] Adjusted for prepregnancy BMI, parity, age, migration status, educational level, and gestational age at last weight measurement.

The estimated mean GWG was 14.2 kg in the control group and 133 kg in the intervention group, resulting in a highly significant reduction of 1 kg (95% CI (−1.56 to −0.38), $p = 0.001$) due to the intervention. This effect depended on the prepregnancy BMI category for the women in question. Significant differences in total gestational weight gain between the intervention and control groups were shown in the subgroups for women of normal weight (β = −0.85, 95% CI (−1.57 to −0.14), $p = 0.019$) and overweight women (β = −1.69, 95% CI (2.65 to −0.74), $p < 0.001$), but not in underweight (β = −0.06, 95% CI (−0.77 to 0.65), $p = 0.873$) or obese women (β = −0.65, 95% CI (−2.59 to 1.30), $p = 0.514$). The biggest effect size occurred in the overweight BMI subgroup, with a highly significant mean reduction of 1.7 kg.

3.3. Pregnancy, Birth and Neonatal Outcomes

No significant differences were found between the groups for gestational diabetes, hypertension, preterm birth, or birth mode. A trend for a reduction in the rates of bleeding was found, although this result did not reach statistical significance (OR = 0.5, 95% CI (0.23 to 1.10), $p = 0.084$). Similarly, neonatal outcomes did not significantly differ between groups (see Table 3).

Table 3. Pregnancy, birth, and neonatal Outcomes.

			Treatment Effect		
	Control Group [a]	**Intervention Group [a]**	**Adj. OR (95% CI) [b]**	**Adj. Mean Difference (95% CI) [b]**	**Adj. *p*-Value**
Pregnancy and birth outcomes					
Gestational diabetes mellitus	11.3%	12.4%	1.12 (0.77 to 1.63)		0.537
Dietary treatment	4.0%	4.2%	1.05 (0.55 to 2.02)		0.876
Insulin treatment	2.2% (*n* = 15)	1.9% (*n* = 15)	[c]		[c]
Bleeding	5.1%	2.6%	0.5 (0.23 to 1.10)		0.084
Gestational hypertension	2.4% (*n* = 16)	1.7% (*n* = 13)	[c]		[c]
Preterm birth	7.5%	9.4%	1.28 (0.69 to 2.36)		0.428
Caesarean section	31.6%	35.2%	1.19 (0.86 to 1.64)		0.301
Instrumental delivery	6.9%	7.9%	1.16 (0.68 to 1.96)		0.592
Neonatal outcomes					
Birth weight, g	3329.7	3332.1		2.47 (−57 to 61.94)	0.935
Birth length, cm	51.5	51.4		−0.14 (−0.64 to 0.35)	0.572
LGA	5.9%	4.6%	0.76 (0.44 to 1.31)		0.320
SGA	8.5%	8.4%	1 (0.58 to 1.73)		0.993
Macrosomia (birthweight > 4000 g)	10.3%	8.2%	0.76 (0.51 to 1.13)		0.172
Abnormal 5 min Apgar-score (≤6)	2.1% (*n* = 12)	0.5% (*n* = 3)	[c]		[c]

[a] Estimated shares/means; in cases of small number of cases, no model-based estimations could be obtained and raw shares are displayed in italics. [b] Adjusted for prepregnancy BMI, parity, age, migration status, and educational level. [c] No statistical modeling due to small number of cases.

3.4. Sensitivity Analyses

The effect estimates for the primary outcome obtained from the complete case analysis were comparable to those calculated from the multiply imputed dataset by means of the ITT analysis. Likewise, the IPTW-weighted models and non-weighted models yielded similar results, confirming the validity of the primary analysis strategy (see Supplementary Materials).

4. Discussion

Lifestyle interventions delivered by healthcare providers during pregnancy offer the potential to prevent excessive GWG and, in consequence, may improve health outcomes for both mother and child. The results of this study show that a brief lifestyle intervention embedded in routine prenatal care and delivered by prenatal healthcare providers led to a significant reduction in the proportion of women who gained excessive weight according to

NAM guidelines. The odds of excessive GWG were reduced by 24% for the women in the intervention group. The subgroup analyses suggested that the treatment effects were only significant in women of normal prepregnancy BMI. Total GWG in the intervention group showed a significant reduction of 1 kg. The greatest reduction in total GWG was found in women in the overweight prepregnancy BMI subgroup, who had a significant reduction of 1.7 kg when compared to the women in the control group. However, the observed decrease in the proportion of women experiencing excessive GWG and a reduction in total GWG were not reflected in the form of evidence for improved pregnancy, birth, or neonatal outcomes.

The results of this trial only provided evidence for intervention effects on excessive GWG in women of normal weight. Women of normal weight represent the largest BMI group among pregnant women in Germany [19]. In conclusion, the intervention could benefit a large number of pregnant women. However, the study did not reveal significant effects regarding excessive GWG in overweight or obese women, the subgroup of women at the highest risk of excessive GWG [49], although a trend for slightly reduced odds was found in the intervention group: by 16% for overweight women and 13% for obese women. Considering the significant reduction in total GWG of 1.7 kg for the overweight women in this study, it can be hypothesized that the intervention was not intense enough for women in this BMI subgroup to achieve an effect on GWG that was large enough to be translated into increased adherence to NAM guidelines. Similarly, in the meta-analysis published by Thangaratinam et al., a significant reduction in GWG of 1.42 kg through interventions was reported in a sample of all BMI categories, without observing the effects on the proportion of women adhering to NAM guidelines [19]. However, every kilogram by which GWG can be reduced should be considered valuable, as GWG is associated with postpartum weight retention and, in the longer term, affects the BMI status of women during subsequent pregnancies [50,51].

As half of women in the GeMuKi sample were primipara, intervention effects on lifestyle changes leading to lower GWG may also be beneficial with regard to the prospect of subsequent pregnancies. Evidence on the sustainability of intervention effects on maternal lifestyle beyond the period of pregnancy is limited; however, initial results from previous studies suggest modest improvements [52–54]. The effects of the GeMuKi intervention on dietary and physical activity behaviors during pregnancy and the postpartum period are yet to be published.

This study did not show intervention effects on any of the pregnancy, birth, or neonatal outcomes, which is in line with previous research [23,28,29]. The i-WIP Collaborative Group conducted a meta-analysis of individual participant data that included 12,526 women. The authors found strong evidence for intervention effects on reduced odds of caesarean sections, but not for other pregnancy, birth, or neonatal complications. The authors reported a mean GWG reduction of 0.7 kg with diet and physical-activity-based interventions [23], which is comparable to the effect size found in the GeMuKi study. Evidence on the long-term effects of excessive GWG suggests that it results in a higher risk of overweight and obesity in a child's later life [8,55,56]. As such, the observed decrease in the proportion of women experiencing excessive GWG and reduction in total GWG are likely to have a positive impact on infant health in the long run, despite the lack of effects in terms of short-term outcomes. Moreover, as the power calculation in the GeMuKi trial was based on the primary outcome, the trial was most likely underpowered in terms of detecting differences in secondary outcomes. Therefore, more RCTs with an adequate sample size need to be conducted in order to determine the effects of lifestyle interventions on short- and long-term maternal and infant health outcomes beyond GWG.

The GeMuKi intervention utilized established structures of routine prenatal care for intervention delivery. Prenatal healthcare providers (eg., gynecologists and midwives) are particularly well-suited to carrying out the intervention, as they often have a long and trusting relationship with the women in question. However, previous studies reported a lack of knowledge, confidence, and counseling skills on the part of healthcare providers as

being barriers to discussing weight and lifestyle-related topics during routine care [57,58]. In the GeMuKi trial, healthcare providers received training on counseling techniques, weight, and lifestyle topics prior to implementation. In addition to this, it became clear that the healthcare providers participating in the GeMuKi trial were particularly interested in lifestyle topics, and were motivated to discuss these during their everyday prenatal care [59]. For lifestyle interventions to be implemented successfully into routine perinatal care on a large scale, strategies for reaching out to gynecologists and midwives across the country and encouraging them to participate in the lifestyle intervention are required. In addition to this, the importance of weight control during pregnancy and lifestyle topics should be incorporated into the education curricula for perinatal healthcare providers. Furthermore, future research should also focus on strategies for reaching underserved and disadvantaged women, as the effects could prove to be even larger in these populations. The participants in the GeMuKi sample were generally well-educated, and migrant women were underrepresented. More research is therefore required in order to identify successful approaches for these populations.

Strengths and Limitations

The results of this study are drawn from a large, randomized, controlled trial carried out in a routine prenatal care setting, and thus provide real-world evidence. Broad inclusion criteria were deployed in order to permit recruitment of a diverse sample that reflected the general population of women seeking routine prenatal care. Although routine prenatal care theoretically provides an ideal setting in which to reach pregnant women of all status groups, our sample generally consisted of well-educated, middle-class women. This is, to some extent, reflective of the region in which the trial was conducted, but may also be attributed in part to the requirements of the study, which precluded women with insufficient German language skills from participating, for example. As a result, migrant women were underrepresented in the study sample (22.7% in the GeMuKi sample when compared to 33% in the female German population of the same age group [60]). Moreover, it became clear that the intervention and control groups were imbalanced in terms of baseline characteristics such as prepregnancy BMI, parity, and migration status. In cluster RCTs in health services research, the allocation of the intervention is often conducted before the patients can be recruited, for organizational reasons. As both the recruitment and the delivery of the intervention were conducted by healthcare providers, blinding the providers to treatment allocation was not possible. As such, the imbalances in the baseline characteristics very likely reflect a recruitment bias induced by healthcare providers in selecting the patients they deemed the best fit for the intervention. To minimize bias, regression models were adjusted for confounding variables, and an additional IPTW regression approach was applied to support the validity of the primary analysis. Furthermore, the number of counseling sessions completed varied between participants and only a few participants completed the maximum number of six session. More details on the implementation process of the GeMuKi intervention will be published elsewhere.

Another important strength was the MI-based counseling approach, which provided the trial with an established, theory-based technique for facilitating behavioral change [61]. In addition to this, digital intervention components were used to aid the sustainability of the intervention and to simplify research-related processes (e.g., electronic data collection via an app). Digital components have also been shown to be promising intervention tools for vulnerable and hard-to-reach groups, which supports the transferability of the intervention into these populations [62–65]. Moreover, in the GeMuKi trial, the pregnant women were recruited in an early stage of pregnancy (before the 12th week of gestation) in order to maximize the length of the intervention period. Another of the study's strengths is the application of NAM weekly weight gain targets in order to determine excessive GWG, which was corrected for gestational age. This reduced the risk of excessive GWG misclassification arising from differences in gestational length. Moreover, this approach meant that the analysis was not restricted to full-term pregnancies only, as would have

been the case with the use of total GWG targets also provided by the NAM. Hence, a more stringent ITT approach was applied. Beyond the primary analysis, one limitation of the trial can be seen in the sample size. The results of the subgroup analysis may suffer from a lack of statistical power, as some of the subgroups (underweight women, obese women) only contained a few participants. Likewise, the study was not sufficiently powered to be able to detect differences in secondary outcomes. Another drawback is that the follow-up period was too short to capture changes in long-term health outcomes for mother and child. One-year follow-up results of the study will be prepared for future publications. Lastly, it should be noted that parts of the study were conducted during the COVID-19 pandemic (March 2020–January 2022). Contact restrictionsand lockdown measures may have influenced study outcomes independently of the intervention.

5. Conclusions

A brief lifestyle intervention delivered by prenatal healthcare providers embedded in routine prenatal care is effective in reducing the prevalence of excessive GWG and GWG, although no evidence for improved maternal and infant health outcomes was found. Excessive GWG places both mother and child at risk of overweight and obesity. As such, lifestyle interventions as part of routine prenatal care offer the potential to promote healthy weight development for multiple generations. Future studies should cover longer follow-up periods in order to evaluate the long-term effects of lifestyle interventions during pregnancy on maternal and infant health. In addition to this, more research should focus on how interventions should be adapted in order to reach underserved and disadvantaged populations. Furthermore, information is required on the processes for implementing lifestyle interventions in routine prenatal care settings, in order to successfully scale up interventions. The GeMuKi trial included a study on implementation processes; this will provide further insights into how healthcare providers and pregnant women have experienced the implementation of the intervention.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/ijerph19105863/s1, Table S1: Results of the sensitivity analyses.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki. Ethical approval to conduct the trial was obtained from the University Hospital of Cologne Research Ethics Committee (ID:18–163)on 22 June 2018, and the State Chamber of Physicians in Baden-Wuerttemberg (ID: BF-2018-100) on 28 November 2018. The trial is registered in the German Clinical Trials Register (DRKS00013173, Dateof 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: Informed consent was obtained from all subjects involved inthe 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 Discussion

The aim of this thesis was to evaluate the impact of a health intervention implemented in a real-world healthcare setting. The intervention was assessed regarding its effectiveness, reach and adoption. With the findings of this thesis, a detailed description of the value of the intervention is provided, to guide policy-makers in the decision to scale up the intervention. The dissertation covered the following objectives:

1) The first objective of this dissertation was to assess the effectiveness of a health intervention in the routine healthcare setting to prevent excessive gestational weight gain and improve maternal and infant health outcomes.

2) The second objective of this dissertation was to investigate factors beyond effectiveness that are associated with the scalability of the intervention. These included an assessment of the intervention's reach and adoption.

5.1 Key findings and discussion of the research projects

In research project 1 the adoption of the health intervention by healthcare providers in the healthcare setting was assessed. For this, the perspectives and attitudes of community-based healthcare providers who were eligible for the GeMuKi project were studied using a mixed-methods approach. The study was conducted before the intervention was implemented. Healthcare providers expressed a sense of urgency around health behavior related topics during pregnancy and were generally motivated to improve care for their patients. They reported being increasingly confronted with the issue of overweight and obesity during routine prenatal care and described a high need for information on the part of pregnant women. Within the study, factors regarding the fit of the intervention to the values and capacity of the setting were identified. In general, healthcare providers were positive about the applicability of the intervention materials and counseling technique. However, MI was sometimes approached with skepticism, as the counseling technique clearly differs from the counseling style healthcare providers were used to. Particularly, healthcare providers raised doubts about the benefit of the MI-based counseling for health behavior change. Moreover, concerns were expressed about the time frame of the counseling sessions. On the one hand, it was discussed whether the intervention duration of 10 minutes was sufficient to adequately address the intervention topics; on the other hand, the additional time required was mentioned as a primary barrier to adoption. In addition to the intervention-related factors mentioned above, the study identified several barriers for the adoption of the intervention that mostly relate to organizational capacity. As depicted above, time-related barriers were predominant, as the healthcare providers perceived that routine prenatal care appointments take up significantly more time due to the intervention. Related to this, 40% of healthcare providers expressed doubts that the

new tasks could be coordinated in routine practice in such a way that the implementation would run smoothly. Additionally, in some cases the need for a higher financial compensation was raised. Moreover, it became clear, that even though healthcare providers were motivated to address health behaviors during prenatal care, they lacked knowledge regarding these topics. More than half (53%) of perinatal healthcare providers were not aware of the existence of the national guidelines on nutrition and physical activity during pregnancy and in the first years of life. Therefore, training on health behavior related topics needs to be addressed for the intervention to be scaled up and adopted broadly. Thus, embedding content on health behaviors and weight development in the standard curriculum of perinatal healthcare providers' education as well as offering recurring training sessions on these topics should be pursued further.

In research project 2 the process of recruiting community-based healthcare providers was described and barriers and facilitators for the adoption of the intervention by healthcare providers were further investigated. The results of research project 2 give detailed insights into the rate of adoption of the intervention as well as reasons of healthcare providers for adopting the intervention. Of the 818 gynecologists who were eligible for participation (513 in intervention regions and 305 in control regions), 28 % (n = 142) participated in the trial preparation workshop (intervention regions only). A total of 12 % (n = 63) of gynecologists eligible in the intervention regions and 21 % (n = 65) of those eligible in the control regions enrolled in the trial. Furthermore, 57 % (n = 36 in intervention group; n = 37 in control group) of enrolled gynecologists (i.e., ca. 7 % of all healthcare providers eligible) in both intervention and control groups actively recruited pregnant women. In general, healthcare providers adopting the intervention appeared to be particularly interested in the topics of the trial and motivated to implement the intervention into their routine prenatal care regimen. It became clear that participating healthcare providers partly already addressed health behavior related topics to varying extend within routine care prior to the start of the intervention. However, it took 18 months to recruit the final sample of healthcare providers as opposed to 9 months as originally planned, reflecting problems with motivating healthcare providers to adopt the intervention. This is supported by reports of the recruiting trial personnel who highlighted building motivation in healthcare providers as the most difficult task during the recruitment phase.

During the implementation phase of the trial, a number of adjustments were made in order to tackle reported barriers to adoption. However, no gain in active participation of healthcare providers was created through these measures. In conclusion program planners should foster early engagement of healthcare providers in the planning phase to avoid barriers for adoption and to ensure that the intervention is designed in such a way as to achieve optimal fit with the stakeholders delivering it.

Research Project 3 evaluated the counseling intervention in terms of its effects on GWG and maternal and infant health outcomes. In addition to this, the reach of the intervention was investigated. In total, 1466 pregnant women (n = 792 in the intervention group and n = 674 in the control group) were recruited for the trial. In the intervention group an estimated proportion of 52.8 % gained excessive weight during pregnancy whereas the estimated proportion of women with EGWG in the control group was 59.6 %. The results on the effectiveness of the intervention on EGWG provided evidence of significantly reduced odds of EGWG in the intervention group (OR = 0.76, 95% CI (0.60 to 0.96), p = 0.024). Subgroup analyses for different BMI categories indicated significant results in women of normal weight (OR = 0.71, 95% CI (0.52 to 0.97), p = 0.031). Moreover, the intervention resulted in significantly reduced mean GWG by 1 kg (95% CI (−1.56 to −0.38), p = 0.001). Estimated mean GWG was 13.3 kg in the intervention group and 14.2 kg in the control group. This effect was present in the subgroups of normal weight women (β = −0.85, 95% CI (−1.57 to −0.14), p = 0. 019) and overweight women (β = −1.69, 95% CI (2.65 to−0.74), p < 0.001) with the highest effect size in overweight women. The results for the secondary endpoints of pregnancy, birth and neonatal outcomes did not show any effects of the intervention on the outcomes studied. This is likely due to limited power to detect differences in these outcomes as the sample size calculation was based on the primary outcome. It has been shown in previous studies that EGWG is associated with longer-term health consequences such as postpartum weight retention in women [46,50,88] and overweight in the offspring's later life [7,8,39]. Hence, although the decrease in the proportion of women experiencing EGWG and reduction in mean GWG was not reflected in improvements of short-term secondary outcomes, the observed positive effects on weight development should be considered valuable.

The assessment of the reach of the intervention revealed that the study sample consisted of predominantly well-educated women. Moreover, migrant women were considerably underrepresented. Hence, the reach of the intervention was limited to rather privileged women. The rate of women who dropped out during the trial was extremely low (ca. 6 % in intervention and control group) leaving little likelihood for attrition bias and indicating high applicability of the intervention on the part of participating pregnant women.

In summary, the brief counseling intervention embedded in routine prenatal care and conducted by prenatal healthcare providers was effective in reducing the prevalence of EGWG and in lowering the absolute amount of GWG. The effect sizes found in the GeMuKi trial are comparable to those previously reported in meta-analyses of diet and physical activity based interventions during pregnancy [18,19]. Despite the positive results on maternal weight development in the GeMuKi trial the effects on pregnant women's weight were not reflected in improvements in pregnancy, birth and neonatal outcomes. Additionally, as the reach of the

intervention was limited to a privileged participant clientele the findings on the effectiveness of the intervention must be critically discussed regarding their generalizability. In the GeMuKi trial, recruitment of pregnant women was performed by community-based healthcare providers. For example, if the intervention was not adopted by healthcare provider practices in socially deprived areas, then consequently groups of disadvantaged women could not be reached by the intervention. Rates of adoption of the intervention were reported in research project 2 and show that only 7 % of gynecologists eligible for the trial (i.e., 57 % of those enrolled) actively participated. Moreover, it became clear that those healthcare providers who actively participated were the most motivated ones, indicating self-selection bias. Consequently, it remains unknown which impact the intervention would have when scaled-up to a nationwide implementation and thus be delivered by a more heterogeneous group of intervention providers to a more diverse population of pregnant women.

Moreover, recruitment skills of healthcare providers were shown to be an important bottleneck in research project 2 that can induce additional selection bias on the part of trial participants and limit the reach of the intervention. This has been observed in other studies within the healthcare setting as well [89]. Preparing healthcare providers for the task of recruitment in addition to training on how to conduct the intervention can be advisable to improve the reach of a trial and thus generalizability of results. Limitations in reach and adoption of the GeMuKi intervention can, however, at least partly be attributed to trial related demands which would not occur when implementing the intervention within routine care. Examples for this are the additional workload related to the enrollment procedure, obtaining informed consent from pregnant women as well as filling in questionnaires for trial participants. Yet, based on results from this trial it was not always possible to clearly differentiate between trial-related barriers and intervention-related barriers. Consequently, even though the GeMuKi trial was designed in such a way as to take a pragmatic approach to assess the impact of the intervention in a setting as close as possible to real-world health care, some features of the trial limited the external validity of research results.

Between 2013 and 2017 another intervention trial was undertaken with the aim to determine the effectiveness of a counseling intervention embedded in prenatal care in Germany [90,91]. The GeliS (acronym for *Gesund leben in der Schwangerschaft; Healthy living in pregnancy*) trial utilized a more explanatory evaluation design in contrast to the pragmatic approach taken in the GeMuKi trial. The evaluation design of the GeliS trial was characterized by the formulation of several exclusion criteria (e.g., exclusion of underweight and severely obese women, twin pregnancies), a less flexible intervention approach (standardized counseling that included the same content for all women) and a complete case analysis method (rather than intention-to-treat analysis). Therefore, the focus of the trial was laid more on internal validity

with compromises made regarding the external validity of trial results. The results of the trial indicated no significant effects of the intervention on GWG [90]. Furthermore, the evaluation design of the trial was primarily focused on intervention effectiveness which was accompanied by a single quantitative indicator of intervention fidelity. Information on contextual factors is not available. A more comprehensive assessment of the intervention's impact in the setting in which it was implemented would have added context to the non-significant findings on the effectiveness of the intervention and would have created valuable information for decision-makers and future research projects.

The results of this thesis show that a counseling intervention embedded in routine prenatal care can be effective in improving adherence to GWG guidelines. However, even though the GeMuKi trial was designed with clearly pragmatic attitudes to improve external validity, the findings of the research projects 1-3 indicate that the trial results cannot be generalized to the general population of pregnant women without restrictions. Additionally, the adoption of the intervention in the prenatal healthcare setting was found to be limited and several barriers for adoption have been identified. Therefore, as a next step to scale up the intervention, adaptations should be made to the intervention in order to improve adoption in the routine care setting and enhance the intervention's fit with a less privileged patient clientele. Several approaches for this have been identified in the research projects of this thesis. The results of this thesis are thus highly relevant for decision-makers deciding about the next steps of the intervention. For this, the findings on reach, effectiveness and adoption should also be considered alongside the results on the implementation of the intervention, which are published elsewhere [92].

5.2 Strengths and limitations

This dissertation has several strengths and limitations which are outlined in the following section.

The results of this dissertation are based on a large pragmatic cluster-randomized controlled trial within which data on multiple domains of the intervention's impact was collected. This variety of data made it possible to evaluate the intervention beyond its effectiveness and to draw conclusions about its applicability and potential for widespread adoption in practice. Furthermore, the dissertation utilized a mixed-methods approach which permitted to gain an in-depth understanding of factors determining adoption of the intervention and made it possible to include different perspectives.

However, one limitation associated with the assessment of barriers for adoption in research projects 1 and 2 lies within the sample of healthcare providers of whom data was available. In research project 1, the sample consisted of healthcare providers who already self-selected into

participating in the trial preparation workshop. It can be assumed that these healthcare providers are generally more interested and motivated to implement the intervention than healthcare providers who chose not to take part in the workshop. Thus, the perspectives and attitudes of workshop participants and the general population of healthcare providers are likely to differ. The same applies to the assessment of barriers for adoption, which was part of research project 2, as it was not possible to get access to healthcare providers who did not opt-in to participate in the trial in order to assess reasons for non-adoption. Likewise, the same problems apply on the level of trial participants (pregnant women) as assessed in research project 3. Only characteristics of pregnant women who enrolled in the trial could be considered in the evaluation of the intervention's reach. Information on pregnant women who denied participation and reasons for denial would have given further insight into the reach domain. To collect this data, the research team initially developed a questionnaire to be distributed to women who were approached but decided not to participate in the trial. However, the response rate for this non-responder questionnaire was extremely low, so no conclusions could be drawn from this approach. As population wide data on key characteristics, such as education and migration background, is publicly available, differences between the study sample and the general population could still be described sufficiently. The GeMuKi trial was designed so that study-related tasks would interfere as little as possible with everyday healthcare. Yet, it was not always possible to differentiate between barriers for reach and adoption that related to the intervention and barriers that arose from aspects related to the trial itself. One example that can be mentioned in this context is the digital data documentation. On the one hand, this served the purpose of providing all healthcare providers involved in the care of a pregnant women with relevant information on the course of counseling and pregnancy and, on the other hand, supplied data for the evaluation of the intervention.

Another limitation present in research projects 1-3 is the limited intervention period which prevents to draw conclusions on long-term health effects and sustainability of intervention adoption in the setting. Yet, the intervention period covered a duration of 2.5 years which, for a publicly funded trial, can be considered a long timeframe.

Further strengths and limitations arising from the specific methods applied in research projects 1-3 are outlined in the discussion sections of the respective peer-reviewed scientific publications [84,93,94].

6 Conclusion and implications for practice and research

Evidence on the effectiveness of counseling interventions embedded in routine prenatal care on maternal and infant health as well as relevant information on the scalability of these interventions is scarce. In Germany, a call for increasing health-promoting and preventive measures during the perinatal phase was made in the form of a National Health Goal in 2017 [64]. One year earlier the WHO released recommendations on the scope of prenatal healthcare which are aimed at improving the quality of routine care for pregnant women and newborns [63]. These examples demonstrate the relevance of health-promoting and preventive interventions for improving the health of pregnant women and newborns in the perinatal period. The GeMuKi project has picked up the plea for improvement of prenatal healthcare services by developing a MI-based counseling intervention delivered during routine prenatal care which aimed at optimizing health behaviors during pregnancy and thus prevent EGWG and improve maternal and infant health outcomes. Yet, if found to be effective, for the intervention to benefit a broad population of pregnant women, it must be expanded into broader practice.

This thesis sought to evaluate the effectiveness of a counseling intervention to prevent EGWG and improve maternal and infant outcomes as well as report on factors relevant for the scale-up of the intervention. The results of the dissertation indicate that the intervention effectively lowered the proportion of women with EGWG and reduced the absolute amount of GWG. No intervention effects on pregnancy, birth or neonatal outcomes were found. Findings on the reach of the intervention show that trial participants differed from the overall pregnant population which limits the generalizability of the findings on the effectiveness of the intervention and implies that the intervention did not address the target population to a sufficient extent. Moreover, the number of healthcare providers who adopted the intervention was rather low and those who adopted the intervention were particularly interested in the intervention's topics indicating self-selection bias on the part of intervention providers. Several barriers for the adoption of the intervention have been identified. Nevertheless, healthcare providers expressed a sense of urgency around the intervention's topics and aims which can be seen as a strong success factor for adoption. In conclusion, adaptation of the intervention is necessary to address the issues identified in this thesis and thus improve the potential of the intervention to be scaled up.

One measure to improve the adoption of the intervention is to further highlight the relevance of the intervention topics and to achieve strong advocacy and broad acceptance among healthcare providers. For this, close collaboration with the target group of healthcare providers, professional associations and other networks can be beneficial [95]. In addition, content on health behaviors and weight development during pregnancy should be incorporated into the

standard education curriculum of perinatal healthcare providers. This can serve a dual purpose as on the one hand, the relevance of the topics is emphasized, and on the other hand, healthcare providers acquire the knowledge needed to provide health behavior and weight related counseling to pregnant women. In connection with this, healthcare providers should be provided with strategies to address underprivileged groups and those most in need of counseling. The counseling intervention was designed to be flexibly adaptable to varying needs of different groups. However, in research project 2, it became clear that healthcare providers lack strategies to approach women with high intervention needs. This was also reflected in the description of the study sample in research project 3. Therefore, training to increase healthcare providers' confidence and sensitive counseling skills provides one strategy to increase the intervention's reach.

Additionally, as limited organizational capacity was identified as a key barrier to adoption, adaptations to reduce the intervention's burden should be developed. One possible approach would be to foster coordination and delegation of intervention tasks among physicians and physician's assistants and to reduce time requirements for documentation by better integrating documentation options into routinely used practice software. However, adaptations of the intervention, such as the above-mentioned, should be carefully documented and monitored throughout the scale-up process to ensure the effectiveness of the intervention is retained [26,95,96].

There are also several implications for research that can be drawn from this dissertation. Firstly, future research projects should be encouraged to use comprehensive and pragmatic evaluation designs in order to generate real-world evidence and relevant information needed for scale-up decisions [23,58,85,86,95]. Furthermore, aspects related to the scalability of an intervention should be considered from an early stage of an intervention's development for example in pilot studies [97,98]. During scale-up, the process and the intervention's effectiveness should be further monitored [26,95,96]. For this, methods that minimally interfere with the intervention setting and place minimal additional burden on intervention providers should be developed as some crucial aspects of the GeMuKi trial itself (for example paperwork due to informed consent procedure) have been found to negatively impact the reach and adoption of the intervention. Ongoing evaluation of the intervention's effectiveness during scale-up is also important for another reason: reach and adoption of the GeMuKi intervention during the trial was limited to the most motivated healthcare providers as well as rather privileged pregnant women. Thus, the effectiveness of the intervention in a more heterogeneous sample of healthcare providers and pregnant women remains unclear.

In conclusion, as a next step, researchers and stakeholders should work collaboratively towards adapting the intervention as suggested above in order to increase the intervention's

suitability for scale-up [99]. During the scale-up process, further monitoring of the intervention should be performed to ensure the intervention keeps its intended effects [26,95,96]. If this is achieved, the intervention provides a promising strategy to prevent overweight and obesity in the population and to promote the health of two generations.

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Appendix

Appendix 1: Study Protocol of the GeMuKi trial.

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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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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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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.

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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

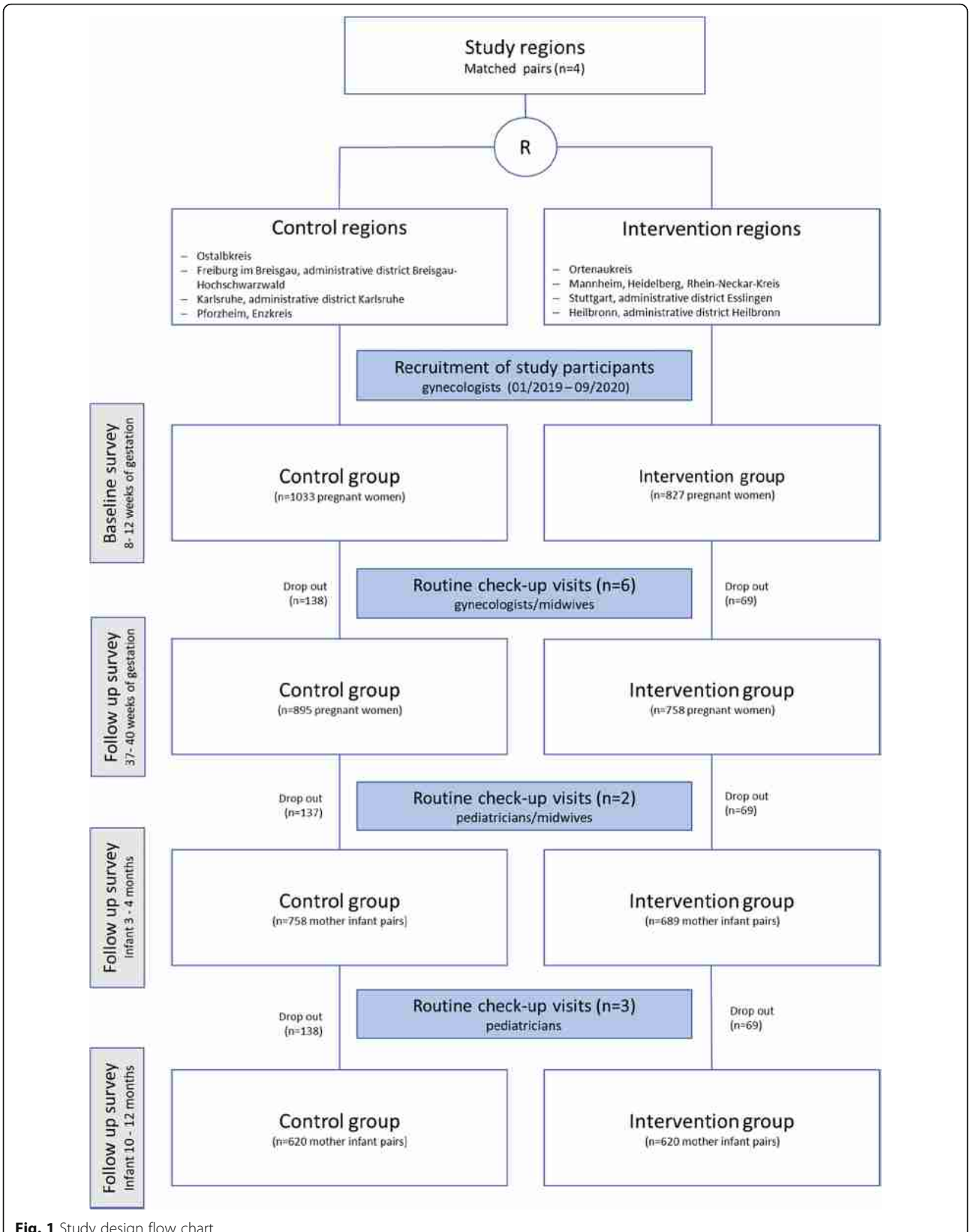

Fig. 1 Study design flow chart

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

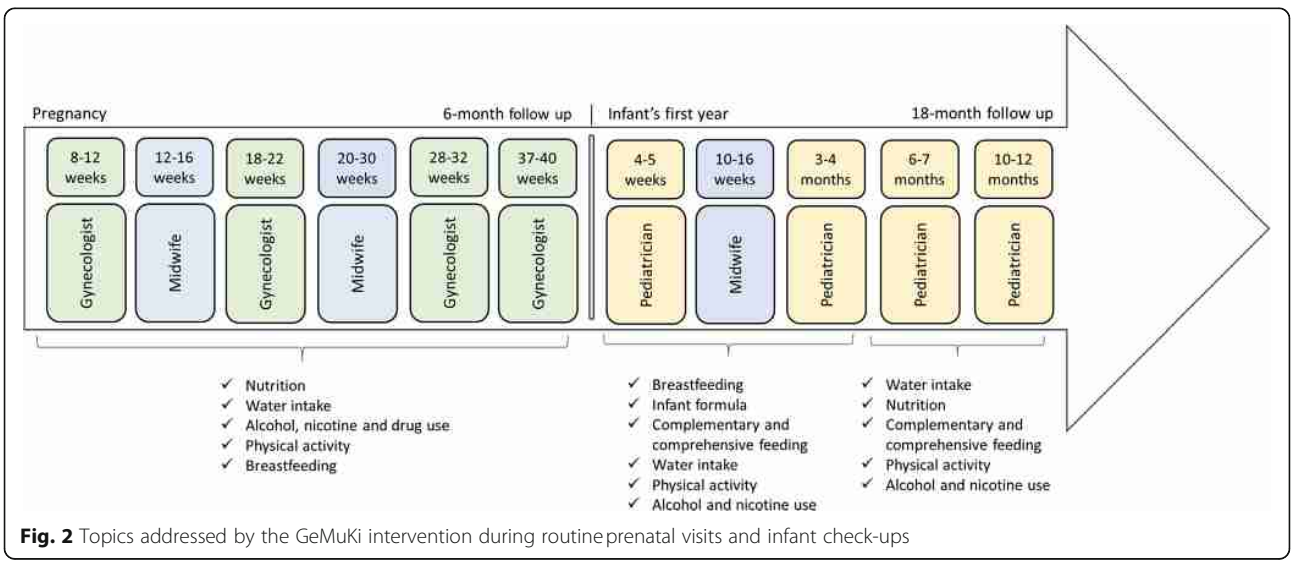

Fig. 2 Topics addressed by the GeMuKi intervention during routine prenatal visits and infant check-ups

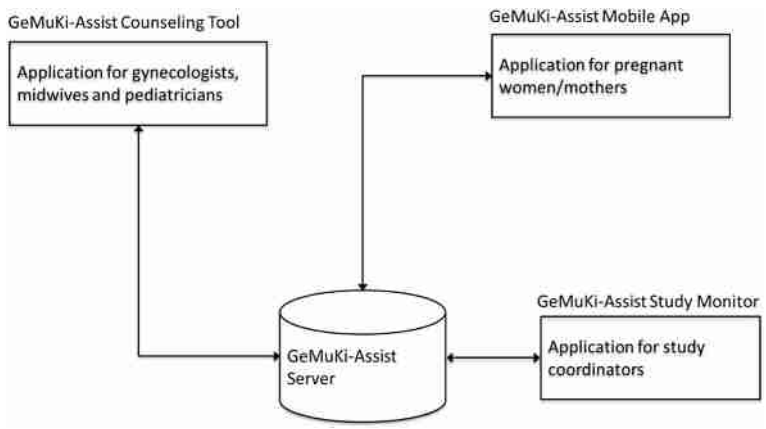

Fig. 3 Overview GeMuKi-Assist Telehealth platform

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

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)
   [Impact Factor at time of publication: 1.6]

   Author's contributions

   Franziska Krebs and Laura Lorenz developed the study idea. Franziska Krebs and Laura Lorenz designed the specific methods of the study. Specifically, Franziska Krebs designed the quantitative survey instruments and Laura Lorenz designed the qualitative survey instruments. Franziska Krebs and Laura Lorenz 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. Franziska Krebs and Laura Lorenz 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 host 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

Franziska Krebs and Laura Lorenz developed the study idea. Franziska Krebs and Laura Lorenz designed the specific methods of the study. A document analysis was conducted, incorporating 137 internal project documents. In detail, 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.
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 as part of the document analysis. Both Franziska Krebs and Laura Lorenz 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. Franziska Krebs conducted three semi-structured interviews. Laura Lorenz was present during the interviews, wrote a postscript, and ensured that all topics were discussed during the interview. Laura Lorenz conducted the remaining three semi-structured interviews. Franziska Krebs 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, Franziska Krebs analyzed three interviews and constructed inductive categories. Laura Lorenz 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. Franziska Krebs and Laura Lorenz 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 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 host study. All authors critically read and revised the manuscript and agreed to the published version of the manuscript.

3) **Effectiveness of a brief lifestyle intervention in the prenatal care setting to prevent excessive gestational weight gain and improve maternal and infant health outcomes**

Krebs, Franziska; Lorenz, Laura; 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

Stephanie Stock and Adrienne Alayli developed the study idea. Franziska Krebs designed the specific methods of the study. Franziska Krebs analyzed the data. Franziska Krebs conducted the interpretation and discussion of the results. Franziska Krebs wrote the manuscript and revised the text in cooperation with Laura Lorenz, Farah Nawabi, Adrienne Alayli and Stephanie Stock. All authors critically read and revised the manuscript and agreed to the published version of the manuscript.

Curriculum Vitae

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

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Erklärung

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Übersicht der Publikationen:

1) 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 (ZEFQ)* (165), S. 51–57. DOI: 10.1016/j.zefq.2021.06.005. (Impact Factor: 1.6)
2) Krebs, Franziska; Lorenz, Laura; Nawabi, Farah; Lück, Isabel; Bau, Anne-Madeleine; Alayli, Adrienne; Stock, Stephanie (2021): Recruitment in Health Services Research—A Study on Facilitators and Barriers for the Recruitment of Community-Based Healthcare Providers. In*: International Journal of Environmental Research and Public Health (IJERPH)* 18 (19), S. 10521. DOI: 10.3390/ijerph181910521 (Impact Factor: 3.4)
3) Krebs, Franziska; Lorenz, Laura; Nawabi, Farah; Alayli, Adrienne; Stock, Stephanie (2022): Effectiveness of a Brief Lifestyle Intervention in the Prenatal Care Setting to Prevent Excessive Gestational Weight Gain and Improve Maternal and Infant Health

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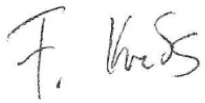

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