Recruitment in Health Services Research - A Study on Facilitating and Inhibiting Factors Regarding The Recruitment of Community-Based Healthcare Providers

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Abstract

Background

In healthcare intervention trials, the recruitment of patients is frequently conducted by community-based healthcare providers. The recruitment of healthcare providers is therefore a crucial prerequisite that can determine the success of a trial right from the start. However, the recruitment of healthcare providers often poses a major challenge, and little is known about its influencing factors.

Methods

The study was conducted alongside an intervention trial evaluating the effectiveness of a lifestyle intervention during pregnancy. Triangulation techniques were used to identify facilitators and barriers to the recruitment of healthcare providers. Qualitative text analysis of internal documents and semi-structured interviews with study coordinators were performed. These results were used to derive the facilitating and inhibiting factors for recruitment.

Results

Our findings identified intrinsic motivation and interest in the trial's aims and goals as the most important 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 results in active trial participation in the long run. The perceived availability of eligible patients emerged as another barrier. Some healthcare providers declined trial participation because they anticipated that they would not have any patients that would suit the intervention due to high social burden or low need on the part of the patients.

Conclusions

During the planning of a trial, more attention should be paid to the recruitment phase. Researchers should seek input from healthcare providers when planning their trial design and recruitment strategies, and conduct a thorough needs assessment to avoid barriers and create a sense of ownership. Financial compensation for the trial burden emerged as a basic requirement, but this is not sufficient for recruitment if used as the sole means of motivation. Adaptable recruiting and intervention strategies that suit different patient populations are important in helping healthcare providers feel adequately prepared for trial tasks. The recruitment skills of healthcare providers and the communication skills of trial staff should therefore be addressed explicitly before the start of the recruitment phase.

Trial registration

German Clinical Trials Register (DRKS00013173). Registered 3rd of January 2019

Introduction

In community-based healthcare intervention trials, the recruitment of patients is frequently conducted by healthcare providers. The recruitment of healthcare providers is therefore a crucial prerequisite that can determine the success of a trial right from the start.

However, the recruitment of healthcare providers often proves to be a major challenge. As a result, trials 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 (1). Suitable and effective recruitment strategies are therefore needed in order 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 (2, 3). Peer-to-peer recruitment, 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 (4–7). The role of other strategies, such as the use of (financial) compensation, remains unclear (8–11). 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 (12, 13, 2). These designs hold high risks of bias, as hypothetical participation decisions do not inevitably lead to actual trial participation (14). In addition to this, studies on recruitment processes frequently focus on the recruitment and retention of patients in trials (14–16). There is still a lack of information on how to master healthcare provider recruitment as a first step. Various initiatives launched by stakeholder groups and researchers in the field of trial methodology have called for methods to improve recruitment for research and develop strategies for better integration of trials into routine care (17, 18). In order to fill this gap in the existing research, this article describes findings on the process of recruiting healthcare providers during a community-based healthcare intervention trial. While the focus of the study lies on the recruitment of healthcare providers, the recruitment of patients by providers is also discussed briefly, as it could potentially have a considerable influence on the motivation and activity of healthcare providers during recruitment processes.

This study identified facilitators and barriers to the recruitment of 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 successful recruitment will be discussed for planning and conducting future trials in community-based settings.

Recruitment in the GeMuKi trial

The GeMuKi trial evaluates the effectiveness of incorporating a structured, low-threshold lifestyle counseling intervention into routine prenatal visits and infant check-ups. The trial is funded by the Innovation Fund of the German Federal Joint Committee (G-BA). It is designed as a hybrid effectiveness-implementation trial and carried out in four intervention and four control regions in the German state of Baden-Wuerttemberg (19). Pregnant women are eligible if they are ≥18 years old and insured by a cooperating health insurance provider. Participants in the four intervention regions receive the additional preventive counseling, while participants in the four control regions receive standard care. Trained gynecologists, midwives and pediatricians conduct brief counseling sessions using elements of motivational interviewing (MI) (20). Pregnant women (n=1860) are recruited by participating gynecologists before the 12^{th} week of gestation (19). 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. The recruitment of gynecologists is therefore crucial for the success of the trial. The GeMuKi trial's recruitment process is illustrated in Figure 1.

Study coordinators in the regions carry out the entire recruitment process, from identifying contact details within the sample frame to enrollment and ongoing support afterwards. Eligible healthcare providers are identified based on the Association of Statutory Health Insurance Physicians (ASHIP) database and supplemented by Internet searches. The final sample frame consists of 818 gynecologists. Information events and presentations at physician's quality circles and *Stammtisch* discussions (regular, informal meetings outside of work) are held to promote the trial within the study regions. In addition to this, the study coordinators conduct cold calls and distribute mass information media such as flyers. Other tools used to publicize the trial include press articles and newsletters. All the gynecologists in the intervention regions (n = 513) are invited to participate in a trial preparation workshop, which is a prerequisite for the intervention group to participate in the trial and deliver the intervention. 141 gynecologists and 104 associated practice assistants attended the trial preparation workshop. Gynecologists in the control regions do not receive training, as they are solely required to collect data and do not conduct the intervention themselves. Data collection is conducted via a digital data platform. Of the gynecologists invited to participate, 63 (12% of those eligible) in the intervention group and 65 (21% of those eligible) in the control group were subsequently enrolled in the trial. In order to reach the sample size of 1860 participants, each gynecologist in the intervention group would have to recruit 13 patients, while gynecologists in the control group would have to recruit 17 patients each over the course of the trial. The participating gynecologists receive an incentive of €100 per patient in the intervention group and €40 per patient (data documentation only) in the control group. During the trial process, adjustments were made to the recruitment plan: Two additional trial regions (one intervention and one control) were added to enlarge the sample frame, and participant recruitment was extended from 12 months to 31 months in order to reach the target sample size. The total timeframe for the healthcare provider recruitment was 18 months. In conclusion, 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. During the trial, strategies to enhance the recruitment of participants by healthcare providers were implemented. These included offering physicians' offices the opportunity to outsource the informed consent procedure for patients to the trial staff, providing advice from peers on how to best recruit patients, offering rewards for high recruitment numbers, providing additional reimbursement to practice assistants for each patient recruited, and creating a paper-based trial data documentation option outside of the digital platform. In order to further simplify the patient recruitment process, the inclusion criterion that participants needed to be insured by specific health insurance providers was removed during the course of the trial so that patients insured with any statutory health insurance provider could participate.

Methods

A qualitative study was conducted using a sequential design. Figure 2 provides an overview of the iterative data collection and the analytical approach. In order to provide the most comprehensive insight into the research topic, triangulation techniques were used (21). All data collection and analyses were conducted by FK and LL both of whom hold a master's degree and are experienced qualitative researchers.

As a first step, an analysis of internal project documents was performed in order to establish an overview of the factors that influence the recruitment process. Based on this, semi-structured interviews with the study coordinators were conducted and analyzed. In the third step, all the results from the two analysis steps were merged and factors for successful recruitment in trials were discussed.

Data sources

All the data used in the study were collected after the recruitment of the healthcare providers had been completed. For the document analysis, all the available records (n= 137) were collected, such as documents from staff meetings, discussions with occupational associations and healthcare providers, and written trial correspondence (see Additional File 1 for overview of included documents). The records were prepared by various members of the trial team (data triangulation). All the collected documents were reviewed by FK and LL independently and included or excluded for further analysis depending on whether they contained information relevant to the recruitment process (22). Of the 137 documents collected, 99 were included in the final analysis. In the second step of the analysis, semi-structured interviews were conducted with the study coordinators, as their experience allows them to provide an in-depth description and assessment of the recruitment strategies. The researchers and study coordinators know each other from their cooperation in the host trial and have a friendly working atmosphere. The topics of the interview guides were based on the results of the document analysis (see Additional File 3). The interview guide included questions based on the experience of the study coordinators. The objective of the interviews was to gather information on the reasons why healthcare providers and patients decided to participate or decline to participate in the trial, and also to assess the various recruitment strategies and ideas for optimization (see Additional File 2). The interviews (n = 6) were performed by FK and LL via

telephone, due to Covid-19 contact restrictions. All study coordinators who worked in the GeMuKi trial at the time of the study were invited and agreed to participate in the interviews. 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 environment and interaction. The average interview duration was 39 minutes (min = 20 minutes, max = 65 minutes). All the interviewees gave their written consent for digital recording of the interviews and further data processing. The interviews were recorded and analyzed anonymously. Finally, the flowchart for recruitment in the GeMuKi trial was used as an additional source of data for framing and discussing the findings.

Data analysis

First, all the data sources were analyzed separately and integrated at the data interpretation stage as part of the data triangulation procedure (methods triangulation). The internal documents were evaluated by means of qualitative text analysis. The authors used thematic analysis, which is a category-based method for the systematic analysis of qualitative data (23). The documents selected as relevant to the research topic were analyzed by two researchers (FK and LL). The researchers opted for an inductive approach; consequently, the construction of the categories was based solely on empirical data (23). The results of the document analysis were used to inform the development of the interview guide. The data from the semi-structured interviews were transcribed and analyzed by two researchers (FK and LL) using thematic analysis in the MAXQDA 18 software (VERBI GmbH). As part of the triangulation process (investigator triangulation), consensual coding, a technique in which the material is independently coded by two researchers and then consensualized in an iterative process, was used (23). A combination of deductive and inductive category construction was deployed (24). The deductive categories reflected the results of the previous document analysis. The results of the analyses were validated in digital conferences between the researchers (FK and LL) and the project leader and project coordinator of the GeMuKi trial (AMB and IL).

Results

As part of the triangulation procedure, the results of all the analysis steps and data sources were merged and interpreted collectively. The results for identified factors that promote or inhibit the recruitment of healthcare providers will be presented first, followed by a brief overview of the results for the recruitment of patients by healthcare providers. The interviewees' suggestions for improvements to the recruitment process will be presented last. Additional File 3 details the final system of thematic categories.

Facilitators for the recruitment of healthcare providers

All the interviewees described the **intrinsic motivation**[1] of healthcare providers as the most important factor for active participation in the trial. For example, one study coordinator provided the following assessment:

"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)[2]

Intrinsic motivation thus includes 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. In particular, 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 or not 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)

Some of the reported facilitating factors for recruitment relate to the **general set-up of routine healthcare practice**. For example, recruitment was reported to be easier if healthcare providers were already addressing the trial topic 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.

Barriers to the recruitment of healthcare providers

The major inhibiting factor was a lack of time**.** This factor results from the **general set-up of 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 are working at the limit of their capacity, so additional time spent on individual patients due to trial tasks results in other patients not being cared for. The study coordinators therefore see the additional workload caused by the trial as the most critical barrier to recruitment. During the course of the recruitment activities, the gynecologists complained to the study coordinators about **trial-related processes** and additional workload – enrollment, documentation and counselling – which was perceived as not being manageable. In this context, the interviewees also mentioned that some healthcare providers considered the financial **compensation** for trial effort to be too low. Another factor reported in this category was the digital implementation of trial components (digital data collection platform), which in some cases led to a rejection of participation.

Additionally, the study coordinators describe barriers to recruitment that either arise from the relationship with the healthcare providers' **professional association** or are related to **professional policy**. The factors mentioned here related to the relationship between community-based gynecologists and their professional association: The interviewees reported 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. Furthermore, according to some study coordinators, the professional association should have invested more in the motivation of its members.

The interviewees problematized particular **organizational aspects** within the team of study coordinators. Interviewees reported that it was often not possible to get 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 made 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 includes getting the information to the right person at the practice. In most cases, the initial telephone contact was made 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)

The interviewees also reported that characteristics of the respective **patient clientele** influenced the recruitment of healthcare providers. The responses revealed a contradictory picture: On the one hand, some interviewees reported that healthcare providers refused to participate because they did not see a need for the intervention among their own patients. On the other hand, participation was also rejected if a high need was seen. The physicians in the latter group assumed that there were too many other burdening factors in the patient's life situation, as a result of which the lifestyle intervention was not seen as useful.

"And the other one said he had mostly junkies […] and he said "They have such a social burden; I don't know at all where to start with counseling." (study coordinator 4_paragraph 50)

Patient recruitment

The interviewees also discussed factors that led to the active recruitment of participants by healthcare providers. Since the focus of the article is on the recruitment of healthcare providers, results that relate to the recruitment of patients will only be presented in brief. Nevertheless, this information is important, as it has a considerable influence on the motivation and activity of healthcare providers during recruitment processes.

Facilitators for the recruitment of patients

The interviewees outlined aspects of **practice organization** that could have a beneficial impact on the recruitment of patients. Well-organized and efficient working practices in general and the involvement of the physicians' assistants in the trial tasks were mentioned. In this context, most study coordinators believed that a division of the trial tasks among physicians and physicians' assistants and a close exchange of information between these two stakeholders facilitated the recruitment of participants. Overall, all the interviewees reported that stakeholders recruit more actively the less effort the trial requires from them. They also assume that recruiting patients is easier if the study only implements minor changes to existing routines. One interviewee provided the following statement on this topic:

"In my opinion, what helped most was that we took the [digital] documentation off their hands, [...] because these [paper-based data documentation] are processes that work in practice, which are tested, like writing by hand and faxing things. [...] Yes, that was actually the main incitement." (study coordinator 6_paragraph 38).

The option of including all patients with statutory health insurance and the paper-based data documentation option were described by the study coordinators as promoting patient recruitment. Other strategies for enhancing patient recruitment (see Recruitment in the GeMuKi trial) were rated as having little or no effect.

Barriers to the recruitment of patients

The study coordinators also named factors that impeded the recruitment of participants by healthcare providers. The major factor was **rejection by potential patients**. The reasons given for this included concerns regarding data privacy, a lack of interest in the trial topics, and the assumption of low benefits in return for high effort. The study coordinators reported that some healthcare providers lacked the requisite arguments and techniques to convince eligible patients to participate in the trial. Repeated refusals by patients have a negative impact on the motivation of the stakeholders, and lead to frustration and inactivity in the long term.

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 the free 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 complexity of the trial, which led to implementation problems. Furthermore, they reported that participating active healthcare providers feel abandoned in their region and become inactive due to frustration regarding the lack of engagement on the part of their colleagues.

Study coordinators' suggestions for improvements

The interviewees were asked for suggestions and ideas for successful recruitment. Some study coordinators suggested higher financial compensation for the trial efforts. However, all the interviewees pointed out that high compensation alone would not be sufficient to achieve successful recruitment rates.

Based on their experience in **recruitment organization**, some study coordinators recommended fostering marketing and communication skills within the trial team. This would provide them with the means to design recruitment materials (e.g. flyers and fact sheets) communicate directly with the physicians' practices in as efficient and successful a way as possible. This recommendation was based on the perception that undecided actors could still be recruited using good communication skills:

"Perhaps I would consider whether I a) bring people on board who simply have recruiting experience or whether I first train them, learn communication techniques, because I believe […] that you can really still

get people with words and with arguments. I mean, of course, those who really have ZERO interest or zero time, you bite on granite. But those who are still a bit undecided and actually already have an interest in the topic, but don't really (know what they are doing?), I think you can get through that". (study coordinator 5_paragraph 79)

Additionally, the interviewees viewed engaging staff members with recruitment experience related to the intended target group as a desirable approach.

Most suggestions for improvement related to the **trial design**. Various interviewees emphasized the importance of carrying out a carefully conducted needs assessment among the target group prior to finalizing the trial concept. For this purpose, the study coordinators recommended that the status quo and possible shortcomings in current care should be discussed with community-based healthcare providers beyond the professional associations. Moreover, the study coordinators stressed that all the relevant stakeholders needed to be taken into consideration, both in the trial design and in advertising and communications. The interviewees mentioned that, as important key players, physicians' assistants should have been more central in recruitment efforts.

Furthermore, some interviewees suggested that the inclusion criteria for trial participants should be determined not only using scientific considerations, but also based on practicability in everyday care. In order to prevent frustration among the healthcare providers due to rejection from patients, the provision of an attractive incentive for patients right at the start of the trial is recommended.

Some of the suggestions for improvement related to the trial preparation workshop, which is a prerequisite for participation in the trial. Study coordinators recommended preparing information as concisely as possible in order to ensure that the relevant topics could be covered within an appropriate time frame. Another suggestion was to consider online formats for trial preparation.

In terms of the content, one study coordinator called for the inclusion of patient recruitment strategies in the curriculum:

"Because this is a scientific trial, after all, but we also wanted to sell that somehow, that the physicians do that. [...] all these recruitment strategies, these recruitment tips, [...] but somehow also explaining [to the physicians]: How do you recruit for a trial in the first place? Because they have 0.0 experience on that, yes." (study coordinator 1_paragraph 75)

This aspect was also discussed in the context of the fact that physicians seem to be reluctant to "persuade" their patients to participate in a trial and/or cease recruitment if multiple patients decline.

Footnote:

[1] Categories of the thematic analysis are presented in bold letters within the text.

[2] The interviews were conducted and analyzed in German. Two researchers translated the quotes independently.

Discussion

The aim of this article is to identify facilitating and inhibiting factors regarding the recruitment of community-based gynecologists and to assess the recruitment strategies deployed in the GeMuKi trial. In order to provide the most comprehensive view of the recruitment process possible, a triangulation strategy was applied.

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 (8, 25, 26). When it comes to fostering intrinsic motivation, a strong emphasis should thus be placed on the added value of the trial (27). Moreover, conducting an in-depth needs assessment within the target group of healthcare providers before conceptualizing a trial can be helpful in determining fields of interest and perceived needs for optimization of care (4). This means that developing trial themes “bottom-up” can be used as a measure to increase the intrinsic motivation for trial participation among healthcare providers (28, 29, 26).

In contrast, **extrinsic motivating factors**, such as financial incentives and collegial obligations, were shown in this study to be overrated. The results of our study on financial compensation were inconsistent. While healthcare providers called for higher financial compensation, study coordinators reported that financial compensation was not a motivator for active participation. Where incentives are used, it is advisable to provide them at the very beginning of the trial and to consider all the healthcare providers involved (e.g. physicians’ assistants). This is especially important in dealing with gatekeeping during the initial recruiting process. **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 (30–32). In order to counteract **rejection by participants**, the incentive for participants should likewise be set high at the beginning of the trial. Options such as offering additional medical services are also conceivable as a viable incentive.

This study found no evidence of the positive effect of peer-to-peer recruitment on recruitment rates as highlighted by others (32, 7, 11). While 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** ties up many resources, as multiple attempts were made by the trial team 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 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 (33–35). Multiple adjustments after the start of the recruitment phase of the GeMuKi-trial to address and overcome

reported barriers have cost many resources and, in the end, have not resulted in active participation on the part of healthcare providers. There therefore seems to be greater value in enhancing healthcare provider input during the planning phase of the trial and the recruitment strategy. By doing this, researchers can avoid barriers, create a sense of ownership and thereby build healthcare provider buy-in right from the start of the trial (28, 36, 27, 4, 25).

The findings of the study also emphasize 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 (11, 27).

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 is especially important during busy practice hours in community-based practice settings. As such, trial information must be adapted to different situations and actors, taking into account 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 (25, 4). McDonald et al. proposed utilizing a business model approach and marketing techniques to foster trial recruitment (27). This includes methods such as building brand values and adopting a formal marketing plan. In order to implement this approach, trial teams should prioritize these tasks and obtain expertise in the field of marketing.

In addition to this, a lack of recruitment skills is one of the key barriers to patient recruitment. 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'(33, 37) 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 (38, 33, 37). Offering recruitment skills training in trial preparation workshops can overcome these barriers.

The results of the study on the influence of **patient clientele** show that the perceived availability of suitable patients poses another barrier to recruiting healthcare providers. Some healthcare providers declined to participate in the GeMuKi trial because they anticipated that the intervention would not suit their patients due to their high social burden or low need. In addition to this, enrolled healthcare providers tend to arbitrarily choose which of their eligible patients to recruit for the trial, despite broad trial inclusion criteria set by researchers (39). As found in previous studies, anticipated barriers due to language skills, education levels and psycho-social issues play a role in the physician's decision on whether to offer trial participation to an eligible patient, as do anticipations regarding their patients' motivation, compliance

and reliability (38, 40, 41). It is therefore particularly important to provide healthcare providers with adaptable recruiting and intervention strategies that suit different patient populations. This strategy will increase both recruitment rates and the external validity of the trial.

Community-based healthcare providers in Germany still only undertake trials rarely, and lack research routines. In order 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 (35). It should be noted that recruiting from existing networks may induce sample effects, and therefore lead to limitations in the generalizability of trial results (11, 8, 35). 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.

During the planning phase of the recruitment strategy in the GeMuKi trial, it became clear that advice on how to recruit healthcare providers successfully and subsequently persuade them to recruit patients to the trial is difficult to find. There is no doubt that parameters such as the trial design, the setting and the broader environment influence 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). In order to better inform future 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 are drawn from a large pragmatic controlled healthcare intervention trial, and therefore represent recruitment issues under real-world conditions, which is an important strength of the study.

Another strength of this study is its triangulatory approach. The combination of different methods and data sources applied by two independent investigators allow for a comprehensive understanding, and thus map the complexity of the recruitment process in the most accurate way.

One limitation is that information on recruitment was available only from healthcare providers who were accessible after the invitation to participate in the trial. However, 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 are based on the appraisals of six study coordinators, and are therefore subjective in nature. It was not possible for the research team to gain direct access to healthcare providers in order to assess factors that influenced recruitment. As the recruiting trial staff is in contact with healthcare providers on a daily basis, their experiences and perceptions are a valuable

information source. The study described in this article is designed as Study within a Trial (SWAT) (42). 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.

Conclusion

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 in order 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 is 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. Adaptable recruiting and intervention strategies that suit different patient populations are important skills in helping healthcare providers to feel adequately prepared for the trial 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.

List Of Abbreviations

ASHIP: Association of Statutory Health Insurance Physicians; CR: Control region; GBA: Gemeinsamer Bundesausschuss (German Federal Joint Committee); GeMuKi: Gemeinsam gesund: Vorsorge plus für Mutter und Kind (Strengthening health promotion: enhanced check-up visits for mother and child); IR: Intervention region, MI: Motivational Interviewing; PA: Physician's Assistant

Declarations

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Author's contributions

FK and LL designed the study, collected and analyzed the data and wrote the manuscript. AMB and IL validated the results. AA, FK, FN, LL, SS were members of the research team of the host trial. AA and SS

designed the host trial. AMB is the head of the GeMuKi consortium, and IL oversaw the implementation of the trial in the study regions. All the authors provided comments and approved the final manuscript.

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Ethics approval and consent to participate

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

Consent for publication

Not applicable

Availability of data and materials

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

Conflicting interests

The authors declare that they have no competing interests.

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Figures

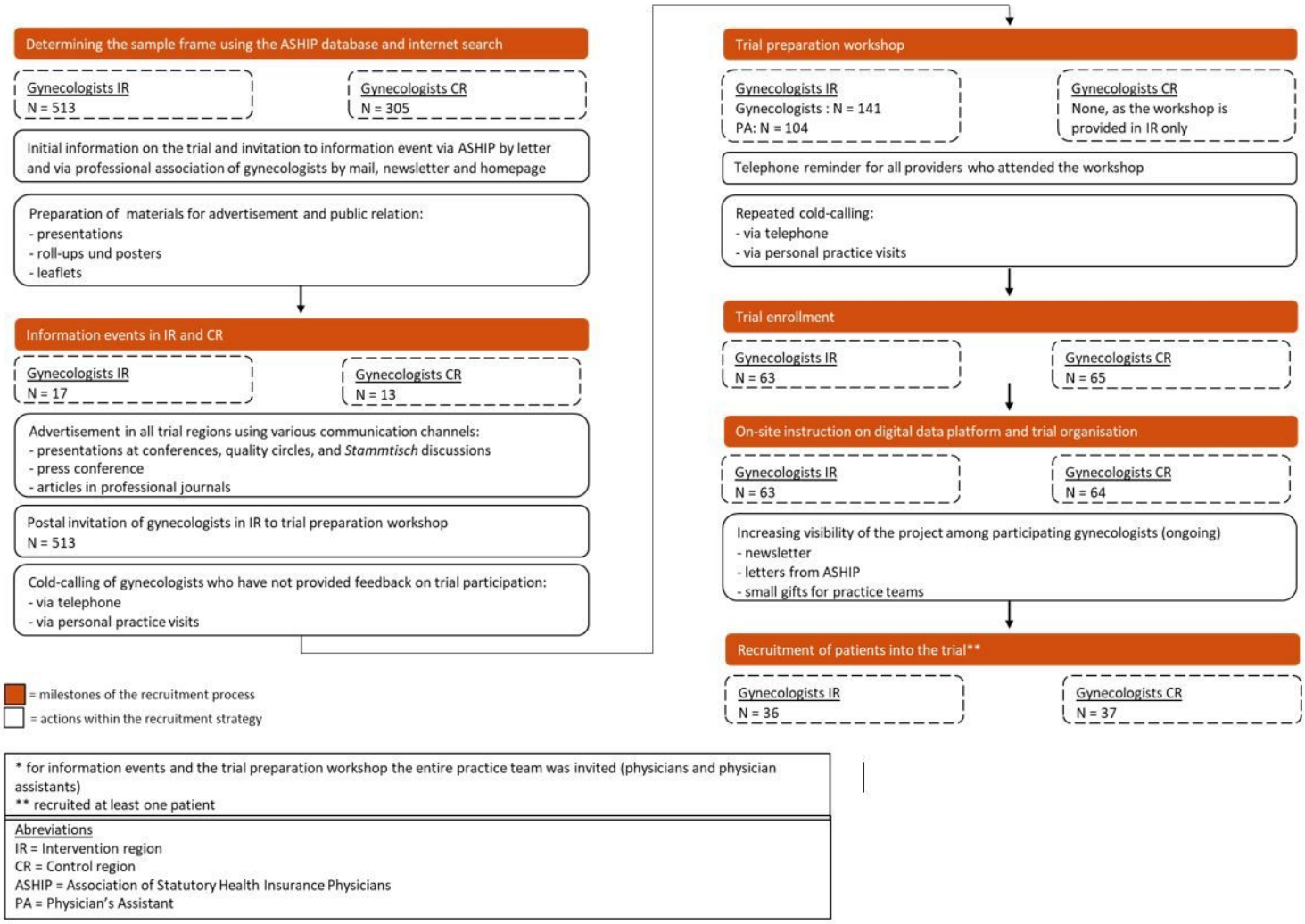

Figure 1

Flowchart for the recruitment process in the GeMuKi trial.

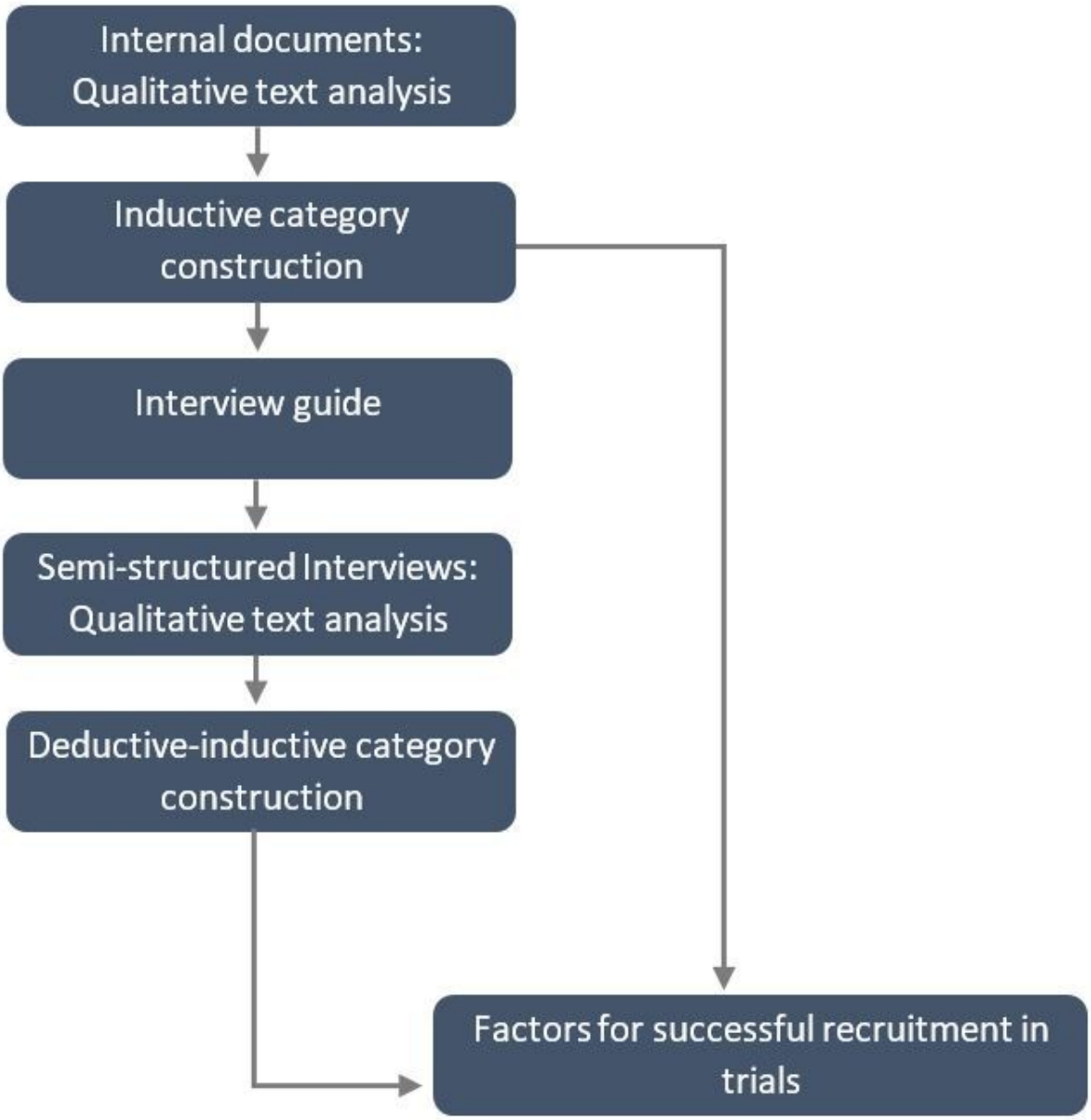

Figure 2

Iterative data collection and analytical approach.

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