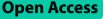
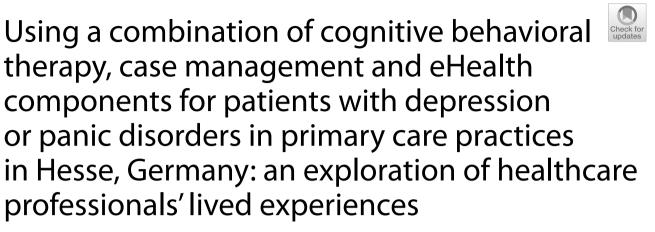
RESEARCH





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Abstract

Background Depression and panic disorders have high prevalence rates in primary care. Given the crucial role of general practitioners in diagnosing and treating mental disorders, the two-arm cluster-randomized, controlled PREMA trial was designed. PREMA was aimed at investigating a new intervention combining cognitive behavioral therapy, case management and eHealth components for patients with depression and/or panic disorder with or without agoraphobia in primary care practices in Germany. This qualitative study, embedded in the PREMA trial, explores primary healthcare professionals' lived experiences in using the new treatment program. Using a qualitative design, we conducted eleven interviews with general practitioners and medical assistants from Hesse, Germany, between July 2021 and March 2022. For both groups we relied on a semi-structured interview guide covering the following subjects: study procedures, implementation, practicality, and individual components of the treatment program. Interviews were audio-recorded, transcribed verbatim and analyzed by two researchers using content analysis. A deductive-inductive approach was used for the analysis according to Kuckartz.

Results We narratively summarized the facilitators and barriers from two different stakeholders across five key themes regarding experiences of feasibility and practicability of the new treatment program: study instruction materials, individual components of the treatment program, practicality, target population, and benefits of the treatment program. Facilitators to become familiar with the study include study instruction materials that are easy to understand and not too complex, considering the limited time resources available; barriers included text-heavy instruction materials, lack of collegial exchange, and issues especially with digital materials also involved access and log-in

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difficulties on the online platform. Facilitators for using the treatment program include the combination of face-toface consultations and the use of an online platform, enabling a structured approach and regularity; barriers included patients feeling unsupported in performing anxiety exercises independently at home. For practicality, the professional skills of medical assistants and their central role as points of contact for patients facilitated the implementation; barriers included time-intensive organization and planning of monitoring phone calls and consultations. Regarding the target population, general practitioners and medical assistants state that the treatment program would be most appropriate for patients with mild to moderate depression and for those waiting for psychotherapeutic treatment; it would be less suitable for older patients, and those with negative attitudes towards technological tools. For benefits of the program, facilitating factors included free and low-threshold access to the online platform and strengthening the relationship between medical assistants and patients; barriers included a preference for in-person conversations and the inability of some people to use online applications.

Conclusions The complexity of the new treatment program and the associated high workload underline the need for further adjustments to the treatment approach. Team-based care and the expanded responsibilities of medical assistants demonstrated promising results.

Trial registration The study was registered in the German Clinical Trials Register (DRKS00016622) on February 22, 2019.

Keywords Primary care, Health personnel, Mental health, Telemedicine, Cognitive behavioral therapy, Qualitative evaluation

Background

Depression and anxiety disorders (AD), including panic disorders (PD) often accompanied by the development of agoraphobia (AG), are the most common mental disorders worldwide [1-4]. In the US, the prevalence of depression has increased from 10.6% (2018) to 14.4% (2020) in primary care [5]. The lifetime prevalence of PD with or without AG ranges from 2.5% to 3.8% [6]. In Germany, depression has a prevalence of 9.2%, which is higher than the EU average of 6.6% [7]. Panic disorders with or without AG have a prevalence of 15.3% [8]. Depression and AD are challenging health conditions with high rates of comorbidity among patients [9, 10]. Both can ultimately result in incapacity to work [4, 11] and are associated with high direct and indirect costs [12]. As most people with mental disorders are diagnosed and treated in the primary care setting, general practitioners (GPs) play a central role [13–15]. There is a wide range of effective treatments for mental disorders, and the earlier patients receive treatment the greater its effectiveness [16]. In the primary care setting for the treatment of mental health disorders, the multimodal therapy approach, or collaborative care, has been proven effective, supported by numerous international studies [17-19]. In these studies, for example, a combination of medication management with psychological therapies and regular follow-up evaluations by a multidisciplinary team significantly improves standard treatment. Central to this model of care is the involvement of non-medical professionals, including nurse practitioners, who play an important role in structured patient care. As

demonstrated by Gilbody et al. [19], this comprehensive treatment model leads to significant improvements in the treatment of depression, both short-term and longterm. The results of these studies confirm the superiority of collaborative and multimodal therapy approaches over traditional methods and underscore their crucial importance in improving patient care with mental disorders in primary care settings.

The PREMA trial is an extension of the PRoMPT (Primary care Monitoring for depressive Patients) [20] and PARADIES (Patient Activation foR Anxiety DIsordErS) [21] trials. The findings from these RCTs showed that a general practitioner-centered case management approach can improve the treatment of depressed patients in an outpatient setting [22], while a practicebased, self-directed exposure training enhances efficacy for patients with panic disorder and agoraphobia in primary care [21]. The PREMA trial is a project funded by the German Innovation Fund, to improve the quality of healthcare in Germany. Administered by the Innovation Committee, the Innovation Fund is used to finance projects in the area of new forms of health care that go beyond existing standard care, as well as health research projects aimed at gaining knowledge to improve existing care in the statutory health insurance system [23, 24]. The trial is being conducted in accordance with the objectives of the Innovation Fund, with the idea of extending it to the entire statutory health insurance system.

The PREMA trial was designed to reliably detect depression and PD with or without AG at an early stage and to test a new combined treatment in primary care practices [25]. The trial is a two-arm cluster-randomized

controlled trial (cRCT) conducted in Germany and aims to evaluate the effect of a primary care team-based intervention with elements of cognitive behavioral therapy (CBT) and case management support through eHealth components in patients with depression and/or panic disorder with or without agoraphobia compared to treatment as usual. The study compares an intervention group with a control group to assess differences in clinical outcomes, including measures of depression, panic disorder with or without AG, and the quality of chronic care [26]. The central component of the new form of care was the collaborative care approach of GPs, medical assistants (MAs) and patients, which is assisted by the systematic use of eHealth. The online platform Embloom [27] that was used in the trial provided the eHealth components for assessing, monitoring, and treating mental health disorders [28, 29]. The central principle of the 12-month intervention was the application of a blended care approach, including a combination of traditional face-toface consultation in primary care practices and the use of a digital intervention [27]. The intervention consisted of four appointments with the GP (psychoeducational, interoceptive and situational exposure exercises, closing meeting/relapse prevention) and case management by the MA via 17 monitoring telephone calls in which MAs were guided by checklists [30, 31]. Through Embloom, GPs, MAs and patients had secure access to psychoeducational videos and texts, self-help exercises and diary functions. Outside of the GP appointments, patients could deepen or repeat therapeutic experiences through digitized exercises. They learn personal responsibility and independence. Parts of the treatment can take place in this way before or after the visit to the primary care practice.

For this study the research questions are the following: 1) How is the intervention being accepted and used from the point of view of the GPs and the MAs?, 2) To what extent is the intervention feasible and implementable from the perspective of the GPs and MAs?, 3) What are the facilitating and/or inhibiting factors with regard to daily practice routine, study implementation, study content and collaboration between GPs, MAs.

Methods

Setting and context

This present qualitative study was embedded in the PREMA cRCT, which was registered in the German Clinical Trials Register (DRKS00016622) on February 22, 2019. The trial was approved by the Ethics Committee of Goethe University Frankfurt (Germany). The study protocol of the PREMA trial has previously been published [25].

The recruitment of the primary care practices (approximately 3000 were eligible) within PREMA was carried out through the Kassenärztliche Vereinigung Hessen (KVH), an institution ensuring public health care [32]. Primary care practices in the federal state of Hesse (Germany) were eligible to participate if they were registered in the German statutory healthcare system as a GP, had a qualification in basic psychosomatic care [33], and the practice team includes at least one medical assistant. The randomization of the practices was conducted at cluster level (cluster = primary care practice) after the successful recruitment of ten patients, but at the latest after the end of the three-month screening phase. The main aim of this manuscript focuses on the implementation of the intervention; therefore, only practice staff of practices randomized in the intervention group were interviewed.

At the beginning of the study, all PHC professionals in the intervention group received paper-based and digital study instruction material from the study team. Paperbased materials comprised a study folder, which contained all relevant study and contract-related documents; information events were also held before the practice recruitment to provide information about, e.g., the purpose, content and procedure of the PREMA trial. Digital materials comprised webinars that were available on Embloom for becoming familiar with and learning how to use the online platform, as well as information provided about the treatment process, information for MAs on how to conduct patient screenings and telephone calls with patients using a monitoring checklist, and the Embloom helpdesk.

Study design

Qualitative interviews were performed because they are a low-threshold approach close to the everyday lives of participants and allow the exploration of subjective experiences that are not generally observable [34, 35]. Presenting patient perspectives in this qualitative study was not feasible due to limited patient engagement, as only one patient from the IG contacted us for an interview. Data protection regulations do not allow patients to be contacted directly for an interview. This article follows the Consolidated Criteria for Reporting Qualitative Research [36] (see Additional file 1).

Participant selection and recruitment

All PHC professionals in the intervention group, including general practitioners (GPs) and medical assistants (MAs), were invited for an interview. Specifically, invitations were issued to all GPs (n=9) and MAs (n=8) across the eight intervention practices. In case the study team was not contacted, participants received an additional reminder after two weeks. Participants were interviewed at the end of the study (12 months after the start of the intervention). This timeframe allowed study participants to fully experience the intervention and collect a wide range of experiences and perspectives on its use. GPs and MAs were eligible to participate if they were randomized to the intervention group (IG), and willing to participate. All participants were informed about the purposes of the study, were given sufficient time to think about participation, and submitted their written informed consent prior to the interview.

Data collection

The semistructured interviews were conducted in German via telephone from July 2021 to March 2022 by one of two of the authors (M.H. or C.K.) using the online portal DFNconf [37]. Due to the COVID-19 pandemic, individual telephone interviews were conducted instead of face-to-face interviews. These two female researchers performed the interviews separately. M.H., with expertise in qualitative research and experience in conducting interviews, carefully briefed and instructed C.K. (research assistant) before conducting the interviews. The interviewers used a semistructured interview guide (see Additional file 2) that was individualized to the participant group (GP or MA) but followed a similar structure and set of themes based on the predefined questions of the process evaluation. In the first process evaluation step, M.H. and M.v.d.A. developed the two interview guides. M.v.d.A. is a female health scientist, researcher, and professor of polypharmacy and health services research. In the second step, the guides were thoroughly discussed and approved by the study team as well as in the context of an interprofessional qualitative research group at the Institute of General Practice at Goethe University Frankfurt. Prior to conducting the interviews, the interview guides were pretested in pilot interviews with GPs and MAs and subsequently adapted by M.H. based on the pretest results [34]. At the beginning of each interview, either M.H. or C.K. introduced themselves as employees from the Institute but did not disclose any information regarding their personal goals or academic background. Interviews were audio-recorded and transcribed verbatim [38, 39] by C.K. The participants' data were pseudonymized, using unique IDs. Field notes were taken after the interviews. Interviews were not repeated. Transcripts were not returned to participants for comments or correction because we ensured the accuracy of the data collected by giving participants ample opportunity at the end of each interview to make further comments, withdraw statements, or suggest changes. In addition, all transcripts were reviewed by M.H. and C.K. Time and resource constraints also influenced our decisions. The interviews lasted between 27:48 and 53:27 min (on average: 35:37 min). The data collection was completed before the analysis started.

Data analysis

All transcripts of the interviews were imported into the computer-assisted data and text analysis software MAX-QDA, version 18.2.5 [40] and were analyzed by M.H. and C.K. using qualitative content analysis according to Mayring [41]. At the outset, a category system for coding transcripts from GPs and MAs was developed based on the topics of the interview guide, facilitating the initiation of data analysis. These topics provided a preliminary framework. Initially, both coders, M.H. and C.K., independently used these topics to code two GP and MA transcripts. Subsequently, a discussion meeting was held to check coding agreement. The researcher then independently coded blocks of two interviews from the outstanding transcripts, and further regular discussion meetings were held to compare coding and discuss discrepancies in findings until consensus was reached on a final analytic framework. During the coding process, additional relevant codes were inductively derived to ensure that all relevant content of the material was captured, beyond the predefined coding tree of the interview guide. After coding, all relevant citations were grouped according to themes and sub-themes to contextualize and highlight similar and different statements. Quotations from the interviews were selected by M.H. and C.K. as examples to illustrate the study findings. The quotes of the participants were translated into English by a native speaker. The translations were approved by M.H. and C.K.

Results

A total of eleven participants, five GPs and six MAs, agreed to participate in the qualitative interviews. Of these, a total of ten (90.91%) were female. The male participant belonged to the GP group. Six of the GPs and MAs invited were not interested in participation due to various reasons or were unable to schedule an interview appointment within the timeframe. Their reasons included time and personnel constraints related to the COVID-19 pandemic and administering vaccinations (both boosters and flu shots), opening new practices or second locations, practice closures due to illness within the practice team, and the typically high volume of patients in the practice.

Participants reflected on five key themes: 1) study instruction materials, 2) components of the treatment program, 3) practicality of the treatment program, 4) target population, and 5) benefits of the treatment program. These key themes represent the main categories of the coding tree. The findings of the analyses are summarized in Table 1. Each of the key themes can be further broken

Key theme	Facilitator	Barrier
Study instruction materials Pa	Paper-based information: sufficient, well prepared, easy to understand, mainly used for review and repetition of topics	Paper-based information: too complex, limited time resources
Ωă	Digital information: general satisfaction with the materials, including the inter- personal helpdesk provided by Embloom	Digital information: time-consuming, too text-heavy, access and log-in difficulties, lack of training
		Overall: lack of collegial exchange, limited human interaction
Individual components CC of the treatment program st ity	Combination of face-to-face consultation and online platform was most helpful, structured approach of the treatment program enabled regularity and continu- ity, and increased openness among patients	Patient screening results were not always in agreement with previous diagnosis
Ę	New responsibility for MAs was monitoring phone calls, which provided con- tinuous patient care without direct involvement of the GP	Patients felt unsupported in performing anxiety exercises independently at home, and standardized/repeated questions reduced patient attention and reflection during monitoring phone calls
Practicality M in of	MAs' professional skills and their role as a central point of contact for patients in order to support GPs and ensure the implementation and feasibility of the study	Time-consuming organization and planning of monitoring telephone calls and GP consultations, limited time, personnel and spatial resources
Target population N. ar te	No age limit; suitable for patients with mild or moderate depression and for patients' waiting for psychotherapeutic treatment; conscientiousness; technical expertise available	Unsuitable for older patients, and those with negative attitudes towards technological tools
Benefits of the treatment program Fr in pi	Free and low-threshold access to online platform, remote utilization, easy entry into therapy, strengthening the MA-patient relationship, and empowering patient engagement in self-care	Use of online platform by itself is insufficient, in-person conversations are pre- ferred, and not everyone is capable of using online applications

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down into subthemes, that were simultaneously regarded by different GP and MA participants as either a facilitator or a barrier based on their experiences. To present the results, we allocated the code "GP" for general practitioner and "MA" for medical assistant, plus an individual number. An ellipsis enclosed in square brackets [...] is used to signify omitted text.

Data saturation was reached after eight interviews, which was determined when no additional information brought new insights to the research questions, and further coding became redundant.

Study instruction materials *Facilitators*

GPs and MAs rated the clear and easily understandable paper-based study instruction material as adequate to conduct the study; it was often used for reviewing or revisiting topics.

"[...] the information was great, because it was well structured, that someone without having studied medicine can understand [...]."] (GP2)

"Id rather have something like the folder, where you can look again: "What was that again – what do I have to calculate?" or "What do I have to fill in there?" That's really good." (MA6)

The online webinars provided additional support for using the online platform; GPs also emphasized the critical role of the helpdesk in resolving technical challenges.

"I always call this beginner's mistake in using the computer [...] entered the wrong password in the wrong place. They were very simple mistakes. However, the Embloom support team could see that. Then, it worked." (GP5)

The fact that the technical support featured personal interaction was rated particularly favorably: "So, the human agents' support on the phone line made the difference; otherwise we would probably have dropped out of the study early." (GP2).

MAs expressed satisfaction with the webinars, particularly with the content on mental disease and studyspecific explanations, which served as a repetition and refresher.

Barriers

Some of the GPs and MAs expressed dissatisfaction with the complex preparation of the paper-based study folder that was intended for them to become familiar with the study. This was especially the case for those without prior study experience. Due to limited time and distraction in practice, the majority of the MAs were unable to concentrate sufficiently to work through the study instruction materials. They read the materials after work and partly at home. Furthermore, some MAs mentioned partial overlap between paper-based and digital materials, which was perceived as redundant and less useful.

"[...], that a person doing a study for the first time can't figure out what they are supposed to do with the study folder." (GP1)

"[...] the folder – that was really a lot too. [...] then I took some documents of it home with me. Because in the medical practice you don't always have time and to concentrate there too." (MA6)

Most of the GPs stated that they would have preferred to receive a summary of the relevant study contents and more intensive training in using the platform, in addition to the study instruction materials, in the form of a personal contact. Two of the MAs also noted the challenging familiarization process and highlighted the need for sufficient training or support from the study team.

"[...], that someone takes some time for me, explains the cornerstones to me a little, that's what I kind of missed." (GP5)

"We just got this folder sent to us and had to muddle through it ourselves." (MA1)

Some of the GPs experienced the webinars on the Embloom platform as too text-heavy, and the associated familiarization process was time-consuming. Moreover, the absence of interpersonal or peer exchange to discuss and debrief new study content was stated as a lacking aspect, which impeded the use of the treatment program.

"[...] I was actually a little disappointed because I understood something different from the training. We muddled through a bit at the beginning. Until we ourselves figured out how it works. That caused a bit of trouble." (GP3)

"[...] would have been nice, because then we would have also had direct contact with the trainer or with the other MAs. [...], this would definitely have given me another boost, to let it all sink in a bit." (MA3)

Four of the GPs experienced access or log-in difficulties among patients, MAs and themselves, which constituted a barrier that complicated the use of the online platform and required additional time and effort. This was also confirmed in interviews with MAs. The technical issues encountered constituted barriers that impacted the implementation of the intervention and required additional effort and time from the MAs to overcome these challenges. This situation was mainly observed in two GP practices, particularly with older patients, and required the MAs to solve technical problems not only for themselves and the GP, but also for the patients, in addition to their regular daily tasks. This increased their workload and the resulting dissatisfaction among two MAs led to the decision of the entire practice team not to include any more patients in the study.

"There were repeatedly major problems too for the patients with this electronic platform, that the patients can't log in. [...] didn't get it right and then the MAs had to help and then they didn't really know how to deal with it either. That was in fact the biggest hurdle in the end – all this electronics stuff, both for us and for the patients." (GP1)

"From the technical point of view, for instance, if something didn't work right in Embloom. One patient told me [...] but now, you always have to request a code by e-mail. Since then, the patient has had big problems logging in. And then I try to contact the technical people all the time, and that doesn't always work out so well." (MA2)

Another barrier mentioned by the MAs was that not all of them received the planned additional in-person training as part of the study. Two MAs suspected that this may have affected study conduction and emphasized that the resulting self-directed learning was complex and timeconsuming. To avoid study interruptions and ensure continuity of patient care, MAs desired adequate training by the study team for new MAs in case the first MA should drop out.

"[...] then I was just told to look at these materials, which are also on this platform, and that's how I then - also with the video and the material - more or less trained myself." (MA1)

Individual components of the treatment program *Facilitators*

One of the facilitators mentioned by GPs for using the treatment program was the combination of face-to-face consultation between the GP, MA and patients, and the use of the online platform, especially the disease-specific information materials. In particular, the diary function and physical exercises were valued as most helpful to the patients. Moreover, GPs expressed overall satisfaction regarding the opportunity for a low-threshold healthcare service.

"[...] [Patients] who kept a diary said afterwards: "Hey, that feels good." (GP2)

"[...] these physical exercises, that was incredibly helpful." (GP3)

The second facilitator mentioned by GPs and MAs was the continuity of consultations with the GP as well as of the monitoring telephone calls through the given structured treatment program. The provided structure offers an essential daily routine, particularly for patients with mental disorders, and reduces their responsibility of organizing their next GP practice consultations where they can talk about their feelings:

"It is never nice to have something psychological and to accept that, but that there was then a program that more or less already assumed that this would be regularly discussed. And not that the patient has to first come and say I want to talk about it, but that it was clear from the beginning that in four weeks or in six weeks I would talk to someone again." (MA1)

Furthermore, both GPs and MAs observed that regular and frequent consultations with patients helped them to better assess patients' well-being and rapidly notice any improvement or relapse. In particular, MAs noticed increasing openness among the patients. The length of time over which the phone calls took place allowed the MAs to closely monitor and recognize patients' progress and feelings using standardized questions.

"I almost had the impression that they told me more things on the phone that they wouldn't otherwise tell me if they were sitting across from me." (MA6)

"I believe that this effect alone of recurring engagement and, above all, also targeted engagement [...] that alone has considerable therapeutic consequences." (GP4)

"[...] You create a different relationship with the patients because you are naturally more in contact with them and deal with them more intensively and can then naturally understand the people more." (MA4)

Third, GPs viewed MAs' new responsibilities through phone monitoring as favorable because although GPs were less actively and directly involved in patients' treatment, patients continued receiving care.

"[...] I'm personally not so involved any more, but the treatment is still going on, which I find quite pleasant." (GP4) Finally, one GP commented that "almost all patients benefited from study participation, even though some of them became more unstable again after the study ended." (GP5).

Barriers

One of the barriers to using the treatment program, as reported by MAs, was that some patients had difficulty performing anxiety exercises independently at home because they felt *"abandoned"* and *"unsupported"* (MA1).

Another obstacle mentioned by MAs was the repetition of the same five items of the short questionnaire (OASIS-D [30]) during the telephone monitoring process, which was experienced as inappropriate and uncomfortable: Two MAs suggested a larger variety of questions for telephone monitoring to increase the attention and reflection of the patients. Furthermore, some felt uncomfortable asking questions regarding depressive feelings when patients were doing well.

"And a lot of people could already do that by heart and they sort of rattled it off to me and that's why I think that maybe a variety of questions would enable a different attention level [...]." (MA4)

"Questions 10 to 15, they are always only aimed at finding out whether administering medication worked, [...] But there was no option at all to select that the patient doesn't take any medication and that was always difficult to assess, because I have to answer the questions somehow so that I can move on to the end." (MA3)

Two MAs and two GPs assessed the patient screening process for depression or panic disorder \pm agoraphobia as unhelpful and inappropriate because some patients were assigned to a treatment path based on their screening results, which differed from PHC expectations and previous diagnoses.

Practicality

Facilitators

The GPs perceived the monitoring telephone calls conducted by MAs as a reduction in their own workload due to the regular interaction between MAs and patients, which ensured ongoing patient care without extended gaps. GPs described these monitoring phone calls as a *"continuity factor"* in patient care. GPs experienced workload relief due to the MAs serving as a point of contact for patients in case of any questions or topics that may arise during the phone calls. "[...] The MA proved herself by taking care of the respective appointments, which relieved me of some work. [...] assumed part of my role – namely, this continuity factor, taking an interest in the problems and answering questions [...]." (GP4)

This was confirmed by the MAs, who supported GPs and patients equally in the role of "mediator" or "intermediate contact", and rated their role as a "trusted contact for the patients".

"[...] you see how the patients also trust you: "Nah, I don't want to see the doctor straight away...", but see you as my contact person really and also trust you and also talk to you first." (MA4)

With regard to the organization and planning of the four GPs' consultations, GPs positively rated that they did not have to work out the content and structure of the appointments themselves, as this was already predetermined by the treatment program. In some cases, the consultation with the GP took place outside regular office hours to avoid disrupting the daily routine of the practice.

"[...] I then knew what I was going to talk to them about next. [...] didn't have to work out anything myself, but could use what was recommended in the program for the consultations." (GP2)

Furthermore, the professional skills of MAs, including previous knowledge or study experience, further training, and their motivational approach in interacting with individual patients, were indicated as beneficial for successful implementation of the study.

Barriers

From the point of view of the GPs and MAs, the extra workload resulting from study participation requires additional time resources, as the study-specific tasks had to be performed in addition to the regular practice routine. Due to various reasons (such as unreachable patients, missed appointments by patients or the practice, time constraints within the practices, and additional workload in the practices during the COVID-19 pandemic), deviations from the standard treatment program had to be made, which led to time-consuming organization and planning of telephone calls and GP consultations. During the pandemic, the priority of patient care initially focused on providing care to "COVID-19 patients" (GP3). Furthermore, GPs stated that the time and personnel resources in the GP practices were insufficient to recruit additional patients or to reach the desired sample size.

"[...] The MA's limits were exhausted because she

had to do everything else too, including taking blood samples, vaccinating people, making phone calls, and organizing things. You would then have to hire two or three MAs to do those things, and that can only be financed in the study. Nobody pays you. Besides, there are no MAs; even if I wanted to hire another one, there aren't any." (GP2)

"[...] So you couldn't have done it now with all the patients who would have needed it. That would simply not have been possible in terms of workload." (MA3)

MAs stated that there was limited space or no space at all available for conducting the monitoring phone calls with the patients.

"The problem was also that we are really a small practice. We have big rooms but there is only one multifunctional room, one registration area, one consultation room – so during the time when I was making the PREMA phone calls, this room could not be used [...]." (MA3)

MAs reported that the monitoring phone calls typically took up between 15 and 30 min, and many patients desired to have extended conversations with the MA in which they made *"small talk"* or *"discussed private matters"* (MA4).

In some cases, the GP consultation took up to 45 min, and this duration was necessary as the majority of patients wanted to address multiple topics. Additionally, it was a new experience for both GPs and patients, which required some time for adaptation and familiarization.

"[...] quite time consuming [...] doing all the exercises with patients, talking to them and making all the new experiences [...]."] (GP2)

Some GPs and MAs described it as challenging to motivate some of the patients to attend scheduled GP consultations and participate in monitoring phone calls or to perform the exercises in the treatment program, *"especially when patients were feeling unwell"* (GP1).

Target population Facilitators

Several disease-specific and personal characteristics of patients with mental disorders were identified for which the feasibility of the treatment program was rated as appropriate. Some PHC professionals set no age limit, and some preferred including younger patients.

"[...] I would accept 18-year-olds and I would also accept 70-year-olds." (GP2)

"Patients who were over 60 were already having difficulties, or over 50." (GP3)

Also mentioned were the technical expertise and the conscientiousness of patients – these were considered factors facilitating the use of the treatment program. Moreover, the treatment program was rated as particularly suitable for patients with mild or moderate depression.

"[...] Patients who are very meticulous, especially very obsessive personalities who actually exactly followed all the steps because that gives them a sense of security." (GP5)

"[...] if they are technically skilled people and their depression is not that severe and it concerns flareup problems, like professional conflicts or sleep disorders or anxiety problems, then this is a good component. "You're not in limbo somewhere. We've got something for you. You don't have to wait six months now before someone deals with it." It's also bad if it takes too long because then the problems might get worse or become entrenched." (GP4)

Additionally, the treatment program was found to be feasible for patients in transition of care, such as those awaiting therapy or their next session.

"[...] It depends on who we're talking about. Patients who have complex clinical pictures and a lot of trauma in their history, it has been very good as a transitional phase until they got a place in psychotherapy. [...]" (GP5)

"[...] I think also as a psychotherapeutically active doctor that such a program is quite useful in addition, because the people only go there every 14 days and if they have something they do 2 weeks in between, something would be gained too." (GP2)

It was also suitable for self-managed patients seeking to stabilize their own mental health, and was suitable whether or not a patient had prior knowledge of their mental illness.

"[...] Patients with prior knowledge are nice because then the program seems to have greater impact based on that prior knowledge." (GP2)

"[...] Patients who don't know anything about anxiety and depression yet, for them it's great." (GP3)

Barriers

Several disease-specific and personal characteristics of patients with mental disorders were identified as

hampering the implementation of the study program. Some PHC professionals mentioned that the treatment program was not feasible for elderly patients with limited digital experience or negative attitudes towards technological tools.

"Older patients, who are not that used to online activities – that they can then use their PIN to log in and send an e-mail [...]." (GP3)

"There are a lot of people who reject this for ideological reasons. This kind of mindset naturally leads to a lack of success, which is a negative attitude toward technical aids from the very start, which of course stands in the system's way, that you don't have any success in that case [...]." (GP4)

It was also considered unsuitable for patients who did not perceive or accept their mental illness or who had basically negative attitudes towards psychiatrists or psychotherapists. Moreover, the treatment program was not feasible for patients who lacked self-motivation, were too introverted, or had difficulties concentrating on performing exercises or "struggle to develop their own strategies for coping with their condition" (GP1).

Benefits of the treatment program *Facilitators*

GPs identified two key benefits of the free and lowthreshold accessible online platform. First, it offered the possibility for patients to more easily start therapy because the barrier of face-to-face interaction with a therapist was removed. Second, the need to physically travel to a therapist was eliminated, making therapy more convenient and accessible for patients with mobility or transportation issues.

"[...] I think that's the secret of the online version, that [...] the personal encounter with therapists is sometimes a psychological barrier too. And then that also dissolves. So it's easier to get started and then, because it happens in real time, you have the feeling that someone is there." (GP4)

Furthermore, the possibility of using the online platform provided some patients with the feeling *"of being cared for and interested in their mental health care"* until their next consultation. (GP3) In addition, GPs and MAs stated that the use of the online platform increasingly motivated patients to take an active role, engage in selfcare and become more involved in their own care.

"And to take care to get involved, to engage in selfcare as well and not always wait until I solve the problem. But then, for example, to independently

keep a diary." (GP2)

"[...] simply this evaluating the patient in a situation or an action or 'How has my feeling changed now?' or 'How has this now given me a boost that I also manage to engage in physical activity, even though I had no desire at all or was annoyed by it before?" (MA3)

GPs and MAs cautiously noted that some patients have seemed to show signs of progress since their participation in the study, which may have influenced their participation in their work life.

"[...] I now really had the feeling that we succeeded with the method in ensuring integration into work." (GP5)

Both GPs and MAs observed clear positive effects in the relationship between the patients and the MAs since study participation. GPs think that MAs could even take more responsibility if they were to receive specific training in advance. Similar to the GPs' observation, MAs also experienced a positive effect on the MA-patient relationship due to the increased level of interaction with patients and greater MA expertise in handling patients with mental disorders.

"[...] I can only emphasize repeatedly how important our MFAs are to our profession overall. [...] they make such an effort [...] and have been on the phone with the PREMA patients time and again. And I think the role of the women is significant." (GP1)

"In this respect, I do believe that as an MFA I was an important point and that the patients also obtained a completely different relationship to us as a practice because I was also an important pillar in this three-way alliance." (MA4)

Barriers

GPs highlighted that the use of an online platform by itself, without personal support from the practice team, would not help most patients. In this context, the majority of the GPs stated that almost all of their patients prefer personal conversations with them, both because not all patients were able to engage in the use of an online application and because they "don't want to sit at home alone and read a bit and that just on the PC". (GP2).

"After all, these are depressed patients. They have a certain resistance - also a certain shyness - to an Internet platform. And then sometimes they didn't really open up to it at all." (GP1) "[...], that there are also people who say: "No, that's too anonymous, I don't believe in that." [...] that is now, in principle, such a small psychological barrier for patients who, because of their preconception, assume that technical aids can't help to improve mental suffering." (GP4)

Discussion

This study explores PHC professionals' experiences regarding facilitators and barriers to using a new intervention that combines case management, CBT and eHealth components for patients with depression and/or panic disorder with or without agoraphobia in primary care in Germany.

Overall, we can conclude that there is a certain degree of consistency in the findings between GPs and MAs, but some elements are mentioned as barriers by some and as facilitators by others: The principal concept of the treatment program was generally rated favorably and considered important for the care of patients with mental disorders in GP practices, the consistently negative experiences expressed by participants indicated that the intervention was too complex, too time-consuming and not feasible. Similar to findings by Andersson et al. [42], one lesson garnered from our study was the importance of adequate training and study instruction materials, userfriendly handling of the online platform, and a certain level of human interaction, especially at the beginning of the study but also during the treatment period. Adequate consideration of all these factors may lead to improved outcomes and reduced dropout rates.

Based on findings from previous research, we recommend a user-centered design (UCD) approach that involves PHC professionals throughout the design process and development, especially for innovative, complex studies or studies that include digital health components [43, 44], to improve the implementation of the intervention. The UCD approach has the potential to enhance usability, reduce human support, improve user acceptance [43, 45], and identify barriers during the early stage of intervention development [46], among other benefits. In line with the findings of two German studies [47, 48], PHC professionals in our study were confronted with a high workload and shortage of personnel. Furthermore, our findings reinforce earlier studies' outcomes [49-51] that highlight the substantial impact of the COVID-19 pandemic around the world on primary care practices, resulting in an even greater workload and psychological distress among GPs. The dual burden of dealing with the COVID-19 pandemic, which was crucial to providing care to stressed and anxious patients, and participation in our study, had a negative impact, reflected both in deviations from the standard treatment program and in the small sample size, despite the need for care for patients with mental disorders. The pandemic-related increase in practice workload, combined with a prioritization of COVID-19 patient care, hindered the planned or intended use of the intervention. As a result, not all patients in need received the intervention. Furthermore, this led to PHC having less insight into how patients experienced and used the intervention. The sample size planned for the process evaluation was aligned with the sample size calculation of the PREMA trial. However, recruitment of GP practices proved difficult, resulting in a small number of participating GPs and MAs being recruited. Consequently, the sample size of the interviews embedded in the process evaluation was reduced.

The findings reported by Sheridan et al. [52] and aligned with our results indicate that team-based care and the additional responsibilities assigned to MAs result in increased direct interactions with patients and enhanced MAs' active role, which positions them as a valuable resource within the GP practice team. The increasingly close relationship between MAs and study patients was also reported by Gensichen et al. [53]. MAs take on the role of a trusted confidant and play a significant role in the continuity factor for patient care, resulting in a notable shift toward patients sharing more personal information. However, it is important to acknowledge that this positive effect is accompanied by a substantial time burden, as MAs are responsible for various tasks in the context on top of their other routine tasks. The intervention was perceived as excessively demanding and complex, requiring simplification to align with the daily practice routine [53]. Adequate allocation of additional resources, including personnel and offices, is crucial to address these challenges effectively. In our study, it becomes clear that medical assistants in primary mental health care are undertaking responsibilities beyond their routine tasks. Research on approaches such as Balint groups [54, 55], stepped care [56, 57], and collaborative care [17] (which are often part of stepped care strategies) found that specific training and supervision for MAs, as well as for GPs, are essential to meet the complex demands of the carer-patient relationship. Participation in Balint groups enhances empathy, improves patient-centered communication, and improves job satisfaction, while also contributing to the prevention of burnout among healthcare professionals. This integrated approach may help ensure that all healthcare professionals are well trained to manage the complexities of mental health care, thereby improving patient outcomes. The need for close collaboration between GPs, MAs, but also mental health practitioners, is recommended in stepped care approaches. In the context of the PREMA trial, the

study did not include regular ongoing professional training or supervision.

Our findings indicate that PHC professionals experienced CBT as a potentially useful treatment for mental disorders. In line with previous studies [58, 59], more interpersonal support and/or face-to-face CBT sessions, which were provided during GP consultations in our study, have the potential to provide more benefits. This, for example, led to increased openness among the patients, and both GPs and MAs perceived that consultations with patients helped them to better assess patients' well-being and to rapidly notice any improvement or relapse. However, our findings pointed out that the PHC professionals also perceived that evaluating the benefits, practicality and appropriateness of the treatment program must be considered individually for each patient and cannot be generalized. This is also reflected in the varied assumptions made by PHC regarding the target population, emphasizing the differentiated suitability of the treatment program based on disease-specific and personal characteristics of the patients. While some PHC emphasized the flexibility of the program by not setting an age limit and giving preferences to younger patients, the findings also point to barriers that restrict the program's implementation in certain patient groups. In particular, patients' technical competence and conscientiousness were identified as facilitating factors for use. Conversely, identified barriers, such as the limited digital experience of older patients, negative attitudes towards technological tools and lack of self-motivation, point to challenges. These limitations require careful consideration of implementation strategies to ensure that the new intervention effectively supports a broader range of patients with mental disorders. The observed discrepancy between facilitating factors and barriers to participation underscores the complexity of patient experiences and needs that must be considered when designing and adapting new treatment programs to increase both accessibility and acceptability. Nevertheless, these findings primarily reflect the perspectives of the interviewed PHC on patient experience and use of the intervention, revealing more about the views of healthcare providers than about the actual experiences of patients. Furthermore, we would like to note, that in our study, concerns were stated by two medical assistants and two general practitioners (n=4, 36%) regarding the alignment of the screening process with medical practices. These PHC professionals observed that the screening results led to treatment pathways that diverged from prior diagnosis or their expectations. This discrepancy suggests that while the PHQ-9 and OASIS are validated and generally effective [60-62], they may not always correlate well with the complex realities of individual patient cases.

The process evaluation shows that GPs and MAs feel responsible for their patients and generally feel able to handle patients with depression and/or panic disorders. The demand for caring for patients with mental illness in primary care practices remains high. Therefore, there is a desire to refer patients to appropriate and feasible treatment options. However, PHC professionals in our study recommend the treatment program only for patients with mild or moderate depression.

Strengths and limitations

One of the strengths of this study is that, through interviews, we explored various components of the treatment program simultaneously for the first time, including aspects such as the preparation and provision of the study instruction materials and the patient screening process. This forms the basis for enhancing subsequent studies, enabling a more comprehensive understanding and potential improvement of the entire approach. Second, to reduce recall bias, we conducted all interviews shortly after completing the treatment program (12 months after the start of the study).

However, the present study has some limitations. These qualitative findings are part of a proof-of-concept study. When interpreting the results, it is important to consider the small sample size, which may not fully represent the range of experiences among all GPs and MAs. In terms of representativeness, the interviews were conducted as part of the process evaluation of the PREMA trial, which restricts the sample to the GPs and MAs who participated in the PREMA trial. Additionally, the limited participation of GPs and MAs from the intervention group in an interview limits the extent to which the results can be considered reflective of the entire group. All participants in this study worked and lived in or near the Federal State of Hesse, Germany. Therefore, the results cannot be directly generalized to other regions in Germany and not to all GP practices. Moreover, the high representation of women among the participating GPs may not reflect the male perspective. We recommend that future studies explore the experiences of other GPs and MAs who provide care with a similar approach for patients with depression and/or panic disorder. In addition, it appeared that relying solely on practice teams for patient recruitment may not be an effective approach. Our experiences show that this approach can result in missing valuable patient insights. Future research should focus on patients' perspectives to assess their perspective on the intervention.

Conclusions

The findings of our study, which highlight the challenges and needs of the PHC professionals involved, may serve as valuable support for further developing the intervention approach to achieve positive effects in a follow-up study. These results are crucial for establishing a successful care structure for patients with mild or moderate depression and/or panic disorders with or without agoraphobia within GP practices.

Authors of future research with a similar study design of the PREMA trial should ensure that the intervention is not overly complex and can be integrated into the regular daily routine of GP practices, while being feasible given the available time, personnel, and spatial resources. This particularly concerns the requirements and tasks for MAs in the treatment program, who often had to manage the main part of the study implementation and the resultant additional workload. To reduce the complexity of the intervention, a reduction in the originally planned 17 MA-monitoring telephone calls could be considered. This adjustment could not only reduce the need for GPs to handle these calls but would also allow them to focus more on their primary task of performing the predetermined patient appointments. Essential for implementation is a realistic planning of staff resources to avoid overtime, but also appropriate remuneration for PHC to conduct the calls. While compensation was guaranteed for each call during the study, establishing a similar arrangement for routine care is critical to encourage GP practices to continue conducting the telephone calls without hesitation. In addition, in future adaptations, significant focus should be placed on the early testing of software applications. The goal should be to involve users in the adaptation process to prevent technical barriers from resulting in reduced utilization.

Based on the findings of the qualitative analysis of the process evaluation, a number of valuable suggestions (e.g., improving usability, practicality, simplicity, and conducting early testing of software applications) for enhancing the treatment program can be derived to support the implementation of eHealth interventions in primary care that include cognitive behavioral therapy and case management components to improve patient care and assist GPs and MAs.

Overall, this research highlights the need for a comprehensive approach to implementing similar innovative mental health interventions in primary care. Successful implementation requires not only technological innovation, but also comprehensive support for healthcare systems, training and support programs for healthcare professionals to ensure effective implementation. Despite the benefits of such an innovation new intervention, including eHealth, and the increased rates of mental disorders during the COVID-19 pandemic, the effective and widespread implementation remained lacking.

Abbreviations

7.001.011	Tibble Tiddloffs		
AD	Anxiety disorder		
AG	Agoraphobia		
CBT	Cognitive behavioral therapy		
COREQ	Consolidated criteria for reporting qualitative research		
cRCT	Cluster-randomized controlled trial		
GP	General practitioner		
IG	Intervention group		
MA	Medical assistant		
OASIS	Overall Anxiety Severity and Impairment Scale		
PD	Panic disorder		
PHC	Primary healthcare		
PREMA	EHealth supported case management for mentally ill patie		

REMA EHealth supported case management for mentally ill patients in primary care

Supplementary Information

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Additional file 1. COREQ checklist.

Additional file 2: Table S1. Interview guide GP. Table S2. Interview guide MA.

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Availability of data and materials

The datasets generated and analysed during the current study (audio files and written transcripts) are not publicly available due to privacy considerations. The datasets are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The PREMA trial was approved by the Ethics Committee of Goethe University Frankfurt (Germany) on April 24, 2019 (approval number 432/18), due to the nature of this study (qualitative interview analysis based on interviews with PHC professionals). Written informed consent was obtained from all participating GPs and MAs involved in the study. All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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