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Process evaluation in practice based research networks: a study protocol for a mixed-methods implementation study

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ABSTRACT

Introduction General practitioners often criticise clinical trials for their poor applicability in primary care, which may at least partially explain why their engagement in primary care research remains limited. In order to enhance primary care research, the German government has funded six regional practice based research networks (PBRNs). Within the Bavarian PBRN (BayFoNet), two cluster-randomised pilot trials will be conducted. This paper presents the protocol of the process evaluation accompanying both trials, which aims to explore relevance, feasibility, acceptability and credibility of clinical research in primary care from the perspectives of BayFoNet researchers, general practitioners, and patients.

Methods and analysis The BayFoNet will be established by recruiting general practices (GPs) as prospective research collaborators in two cluster randomised pilot trials. Research teams will provide training in good clinical practice, and support practices in patient recruitment, data collection and documentation. Our process evaluation explores barriers and facilitators in the set up of the BayFoNet PBRN and both cluster randomised pilot trials, under the application of the consolidated framework for implementation research and the theoretical domains framework. In a mixed-methods concept, we will use qualitative and quantitative approaches to evaluate both pilot cluster-randomised trials as well as the BayFoNet itself: focus groups with researchers, semi-structured interviews with general practitioners and questionnaires for patients participating in the pilot cluster-randomised trials at three different time points.

Ethics and dissemination Research ethical approval for this study was granted by the Ethics Committee of the Medical Department, Ludwig-Maximilians-University Munich (AZ 21-1135). Results will be published in international peer-reviewed journals and summaries will be provided to the funders of the study as well as other PBRNs, GP teams and patients.

Trial registration numbers DRKS00028805, NCT05667207.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This comprehensive multi-centre process evaluation will examine all perspectives of the involved key stakeholders in research within primary healthcare.
⇒ The longitudinal mixed-methods study design will elaborate information concerning maintenance of study participants over time and development of research processes within primary healthcare.
⇒ A multi-professional research team (ie, general practice (GP), pharmacy, nursing, sociology and health service research) will combine quantitative and qualitative methods to provide multiple perspectives and analyses.
⇒ Access to GPs and their patients might be challenging.
⇒ The generalisability of findings is likely to be compromised by participation bias.

INTRODUCTION

Primary care plays a key role in the provision of medical care in healthcare systems globally. However, it faces a number of challenges, which are mainly attributable to an increasing demand due to ageing societies with an increasing prevalence of chronic diseases and multi-morbidity. First, such patients are often under-represented in clinical trials that inform clinical practice guidelines, which limits its applicability in primary care. Second, there is a need for service innovations to meet increasing demands in primary care, which require evaluation. The implication is an urgent need for both clinical and health services research in primary care, for which the engagement of general medical practices is a pre-requisite.

PBRNs are networks of general practices (GPs), which cooperate closely with specific coordinating centres, often academic departments of GP or specific publicly funded research institutes for primary care research.[1] They enable primary care practices to conduct studies with complex designs, disseminate results and implement evidence-based strategies in daily clinical practice.[2] Practice based research networks (PBRNs)

have demonstrated increasingly high-quality research output, but also improvements in the quality of patient care[3–5] by 'shifting efforts from a single disease focus per study to practice systems transformation'.[6]

In comparison to countries with a longer history of PBRNs (including the UK, the Netherlands, the USA and Australia[3–6]), the research output from GPs in Germany remains unsatisfactory, which is at least partly attributable to deficits in research infrastructure.[1 7] As German GPs work in a market-based, competitive setting of small private practices, they have no protected time or funding for research. Furthermore, they have typically no or little research training or experience. Academic departments of GP mainly depend on public research funding, which has traditionally been scarce.[1] A further practical barrier is that GPs in Germany use a wide variety of practice software systems, which are generally poorly suited to support the efficient identification of eligible research participants and data collection.

In order to enhance primary care research, the German government has funded the set up of six regional PBRNs, each with a coordinating university department of GP and research staff to conduct pilot studies. The Bavarian PBRN (BayFoNet) initially comprised four university departments and conducts two pilot cluster-randomised trials within the initial 5-year funding period.[8]

Aim of the study

This paper presents the protocol for the process evaluation accompanying the set up of the PBRN BayFoNet as well as the implementation of two pilot cluster-randomised trials. The aim is to explore the barriers and facilitators to recruitment and research processes from the perspective of key stakeholders (research teams, GP teams, patients) to identify opportunities for improving PBRNs in Germany and beyond.

METHODS/DESIGN

Setting

At the start of the funding period, the initial four regional network centres (RNCs) (ie, two departments of GP at two universities in Munich, and one each at the universities of Würzburg and Erlangen) had established working relationships with local GPs. However, the collaboration had focused on teaching of medical students, and none of the RNCs had a formal research network with defined qualification programmes and contractually bound practices. Each RNC had access to clinical trial centres providing methodological support in the design and conduct of clinical trials. The RNC Augsburg became part of BayFoNet as it was founded in November 2022. The main characteristics of the RNCs are described in table 1.

Implementation of the PBRN BayFoNet

Infrastructure of the PBRN BayFoNet

As patient care in German GP is solely carried out in private outpatient practices, academic departments depend on a trustful relationship with local GPs when performing research. Therefore, BayFoNet has to operate at regional level but cooperate closely across Bavaria. Each RNC has its own research team for operational tasks. They are responsible for practice recruitment, ongoing contact and equipment for educational courses, trainings and study material. The coordinating unit (located in Würzburg) is responsible for the overall network activities in BayFoNet and manages any requests to the network, for example, collaboration, patients, publicity and funding.

Recruitment, accreditation and incentives for GP teams

Some of the already collaborating practices had previously participated in primary care research. In the first step, these practices are invited to participate as partners in BayFoNet by invitations letters. In the second step, practices will be invited to participate in the pilot cluster-randomised pilot trials and other projects in each RNC.

Table 1 Characteristics of all participating RNCs of BayFoNet

Location of the RNC	Description of the regional network sites
Munich (TUM)	Founded 2009, existing network of 280 teaching practices; conducted already more than 15 research studies (RCTs, diagnostic studies, observational longitudinal and cross-sectional studies) with about 50 practices. The team currently consists of 14 scientific employees
Erlangen	Founded 2013, existing network of 120 teaching practices; very good relationship and experiences with recruiting practices for a research project together with the Bavarian Association of General Practitioners. The team currently consists of 13 scientific employees
Munich (LMU)	Founded 2014, existing network of 267 teaching general practices; 20 of these conducted already more than 10 research studies (RCTs, observational and cross-sectional studies). The team currently consists of 30 scientific employees
Würzburg	Founded 2017, existing network of 126 teaching general practices and 20 research practices. The team currently consists of 19 scientific employees
Augsburg	Founded 2022, no existing network of general practices for teaching or research. Up-to-date the team consists of 9 scientific employees.

RCTs, randomised controlled trials; RNCs, regional network centres.

Table 2 Applied research questions referring to the CFIR domains concerning the focus groups of researchers and the coordinating unit

CFIR domain	Research questions
Time point	**Before intervention**
Intervention characteristics	What is the possible added value/benefit of 'BayFoNet'?
	How could an added value/benefit be realised/increased?
	What additional support do you need to make working on 'BayFoNet' even more attractive for you?
Outer setting	Which external influences (barriers and facilitators) do you perceive around 'BayFoNet'?
	How can these external influences be used/overcome?
	To what extent does participating in 'BayFoNet' give your institute an advantage over other institutes/chairs for general medicine that are not part of a PBRN?
	To what extent do you independently network with colleagues or people in similar professions/positions outside of your institute?
Inner setting	Which internal influences (barriers and facilitators) do you perceive around 'BayFoNet'?
	How can these internal influences be used/overcome?
	Do you assume that you already have enough resources to set up and implement 'BayFoNet' as initially planned?
	To what extent have the roles and responsibilities of the institute employees been clarified for their active participation in 'BayFoNet'?
Characteristics of the individual	Do you recognise an individual added value/need for you to actively develop and implement 'BayFoNet'?
	Do you have the feeling that you can achieve the planned goals in 'BayFoNet'? What difficulties or barriers could/do you expect to arise?
Process	What are you planning specifically at your location in order to be able to actively develop and implement 'BayFoNet'?
	How should the results of 'BayFoNet' be communicated to the network partners and the general public?
Time point	**During intervention**
Intervention characteristics	What is 'BayFoNet' for you?
	Which culture do you perceive? Do you think 'BayFoNet' is successful? What is the overarching goal?
	Which further measures would be expedient? What additional support do you need to make working on 'BayFoNet' more attractive/easier for you?
Outer setting	Which external factors do you perceive? Where is 'BayFoNet' embedded?
	What/who influences 'BayFoNet'? Who is a possible multiplier?
Inner setting	Do you have enough resources to set up and design 'BayFoNet' as planned?
	To what extent have the roles and responsibilities of the institute employees been clarified during the development and implementation of 'BayFoNet'?
	How is 'BayFoNet' anchored at your location, what role does the network play at your location?
Characteristics of the individual	How do you use 'BayFoNet' in your daily work? Do you recognise any individual added value/benefit/need for you from the implementation of 'BayFoNet'?
	Which moment in working with 'BayFoNet' do you remember negatively? What moment did you enjoy?
Process	How have you perceived the development of BayFoNet so far?
	How are the results of 'BayFoNet' being communicated?
Time point	**After intervention**
Intervention characteristics	Did we reach our goals and aims within 'BayFoNet' until now?
	How should 'BayFoNet' be adjusted after the first 5 years in order to be/remain an attractive network for everyone involved?

Continued

Table 2 Continued

Time point	After intervention
Outer setting	Which external barriers and facilitators were conducive to the development and implementation of 'BayFoNet'?
	What influences and multipliers have played the biggest role in BayFoNet so far? Why?
Inner setting	Do you have enough resources to keep 'BayFoNet' a lively and sustainable network as planned?
	Were the roles and responsibilities of the institute employees clarified concerning 'BayFoNet'?
	Has 'BayFoNet' changed something at your location, what role does the network play at your location?
Characteristics of the individual	How do you use 'BayFoNet' in your daily work? Do you recognise any individual added value/benefit/need for you from a sustainable implementation of 'BayFoNet'?
	Which moment in working with 'BayFoNet' do you remember negatively? What are you looking forward to in the future cooperation within the network?
Process	What further developments do you expect regarding 'BayFoNet'?
	How did you communicate the results of 'BayFoNet' so far?

CFIR, consolidated framework for implementation research.

Invitation to participate in a project will comprise an additional invitation to participate in BayFoNet. Participating in high-quality clinical research can place a heavy burden on GPs. To be accredited, physicians and staff members need to obtain the necessary qualifications in training courses, prepare for studies, adequately inform patients, document according to standards, host monitoring visits, etc. All of these activities compete with the conduct of routine care. In order to establish a sustainable network performing high-quality research, high motivation of practices has to be maintained over years. Financial compensation will primarily be implemented for additional efforts within the studies by paying case-based allowances.

Training of GP teams

We will develop and implement a comprehensive training programme for participating GPs and their teams. The aim is to achieve common levels of research competency in order to enable practice teams to conduct high-quality research including clinical trials and to enable particularly engaged GPs to develop their own research questions. To reach rural GP teams in underserved areas, we will use e-learning facilities.

Data management within the PBRN BayFoNet

So far, there is no publicly available data repository on practice characteristics across RNCs. BayFoNet will develop a central dataset on practice characteristics, research experience and qualification of practice staff as well as on current research activity.

Pilot cluster-randomised trials

Apart from the primary purpose of informing a possible definitive evaluation of intervention effectiveness, the pilot cluster-randomised trials will provide opportunities to identify current weaknesses in the infrastructure to support the implementation of this challenging but important study design in German primary care. Each pilot trial has a coordinating RNC, which will collaborate with the other RNCs in the recruitment and training of GPs, data collection and data management. The latter will use an established software system for electronic data capture including electronic case report forms. All trial procedures and data will be handled according to national and international clinical trial standards. The following paragraphs briefly describe the two pilot trials. Both trials are registered as followed: IMONEDA is registered at the German Register of Clinical Trials, MicUTI is registered at Clinical Trials.gov.

Pilot cluster-randomised trial 1: dipsticks and microscopy to reduce antibiotic use in women's urinary tract infections (MicUTI)

The aim of the microscopy to reduce antibiotic use in women's urinary tract infections (MicUTI) is to evaluate the effects of a point-of-care diagnosis and treatment algorithm on antibiotic use in women with symptoms of an uncomplicated urinary tract infection. Twenty GPs affiliated with BayFoNet will be randomly assigned to the intervention arm (women with symptoms of an uncomplicated urinary tract infection will be diagnosed using phase-contrast microscopy and urinary dipsticks) or to the usual care arm. In total, 200 patients should be included and followed up using a patient diary completed until day 7–14 and through telephone calls at day 28 to assess antibiotic prescriptions (number, dose and appropriateness), as well as symptom burden, relapses and recurrence of urinary tract infections, need of re-consultations due to urinary tract infections and the occurrence of upper urinary tract infections.

Pilot cluster-randomised trial 2: implementation of an online education programme for asthma patients in GP (IMONEDA)

The aim of this study is to examine the effectiveness of an online asthma education programme in terms of asthma

knowledge, asthma control and unplanned emergency treatment of patients suffering from bronchial asthma in primary care. Twenty GPs affiliated with BayFoNet will be randomly assigned to the intervention arm (patients will have access to the online training) or to the usual care arm. In total, 100 patients should be included and followed up using a patient questionnaire on asthma knowledge, asthma control, patient autonomy, and attitudes and attitudes towards asthma medication after 3 and 6 months.[9 10]

Design of the process evaluation

In order to elicit the perspectives of key stakeholders (research teams, GPs and patients) on the set up of BayFoNet and the implementation of the pilot trials, we have designed a longitudinal mixed-methods study. Data collection will take place at three time points[1]: at the point of recruitment (where we also aim to elicit the main reasons for declining an invitation to participate in BayFoNet),[2] during the implementation of the pilot cluster-randomised trials and[3] after the completion of both pilot cluster-randomised trials.

Applied frameworks to examine barriers and facilitators

In order to elicit barriers and facilitators from the perspectives of research staff and GPs, we will draw on the consolidated framework for implementation research (CFIR). The CFIR provides a conceptual model of implementation drivers across five domains, namely intervention characteristics, inner setting, outer setting, characteristics of the individual and process.[11]

In order to elicit barriers and facilitators from the perspectives of patients, we will draw on the theoretical domains framework (TDF). This framework assumes that three key drivers (namely motivation, opportunity and capability) determine individual behaviour (such as participation in research). The TDF is very useful to examine domains of behaviour change in individual persons and will be applied to analyse the patients' perspectives towards participation in pilot cluster-randomised trials.[12] Unfortunately, we do not have the possibility to contact patients who refused an active invitation to participate in a pilot cluster-randomised trial. The process evaluation will be conducted between August 2022 and December 2025.

The study protocol follows the reporting guidelines of Standards for Reporting Implementation Studies to differentiate the intervention and implementation strategy of interest[13] (online supplemental additional file 1).

Exploring the perspectives of researchers

The research teams and coordinating unit of the PBRN BayFoNet will meet online for a focus group at three-time points: before, during and after the interventions of both pilot cluster-randomised trials. For logistic reasons, the number of participants may vary between 6 and 15 participants, with at least one participant representing each regional study centre of BayFoNet. An experienced scientist (HK) in qualitative data collection will moderate the discussion and display the previously developed key questions (see table 2). After informed consent of the participants, the discussion will be recorded to support the subsequent transcription.

Exploring the perspectives of GP

To examine the perspective of the GPs, a convenience sample of GPs will be interviewed until data saturation (we expect 3–4 GPs per regional location; about n=16) before, during and after the interventions of both pilot cluster-randomised trials (see table 3). The semi-structured interviews will be conducted via telephone or web-based video conference, based on the GP's preference to enable a high degree of feasibility and acceptability in daily practice.

In addition to qualitative data collection, we will also collect data on practice characteristics. We will examine the practice size and rurality of the GP, as well as experience in teaching, further education of medical students and medical doctors and postgraduate training status of the practice owner. We hypothesise that practice organisational characteristics and adoption will be associated with the level of reach, delivery to the patient and maintenance achieved. Lower levels of these might be associated with lower effectiveness of the delivered interventions. The specific hypotheses to be tested will be based on findings from the interviews with the GPs. Participating and non-participating practices will be compared using organisational information, as far as possible.

Exploring the perspectives of patients

We will conduct a parallel process evaluation, where data will be collected simultaneously to the implementation of both pilot cluster-randomised trials. The paper-based questionnaires will be provided to every enrolled patient (n=300) of both pilot cluster-randomised trials after informed consent by the GP team before, during and after the interventions of both pilot cluster-randomised trial (see table 4). Patients are invited to send their completed questionnaires to the study centre (LMU). The questionnaires for the subsequent time points are sent from this study centre directly.

For this purpose, we have developed a paper-based questionnaire through iterative procedures and discussion between three researchers (LS, TD and AH). These discussions were informed by specific domains of the TDF.[12 14] Answers will be provided on a 5-point Likert scale (from '1=I do not agree' to '5=I totally agree') and a descriptive, exploratory data evaluation is planned for data analysis.

Data analysis

The recorded interviews and focus groups will be transcribed using the transcription software 'F4-audio transcription (Windows)'. Established transcription rules will be applied, which focus on a semantic-content transcript and smoothing of the language.[15] In view of

Table 3 Applied research questions referring to the CFIR domains concerning the interviewed general practices

CFIR domain	Research questions
Time point	**Before intervention**
Intervention characteristics	What would make 'BayFoNet' successful for you?
	What tools and support are currently available and how do you use them?
Outer setting	What can others do to make 'BayFoNet' successful?
Inner setting	Do you know of any other practice-based research networks?
	Do you know other 'BayFoNet' practices?
Characteristics of the individual	Why do you participate in 'BayFoNet'?
	What can you contribute to make 'BayFoNet' successful?
	What are your hopes and wishes for 'BayFoNet'?
	What previous research experience do you have?
	What kind of support do you need?
Process	How was 'BayFoNet' introduced to your practice team?
	Where do you see 'BayFoNet' in 5 years?
Time point	**During intervention**
Intervention characteristics	What is the added value of participating in 'BayFoNet' for your practice?
	What characteristics must clinical trials have to make them attractive and feasible for patients?
	How can 'BayFoNet' support practices even better in the implementation of clinical studies?
Outer setting	What external barriers and facilitators do you recognise to date when conducting clinical studies?
Inner setting	What changes have you experienced in your practice by conducting clinical studies?
	Is there an exchange with colleagues from other practices regarding research?
	What internal barriers do you recognise to date when conducting clinical studies?
Characteristics of the individual	How do you actually like 'BayFoNet'?
Process	Can you imagine integrating clinical studies into your everyday practice in the long term?
Time point	**After intervention**
Intervention characteristics	Based on your experience: what do you think makes the network 'BayFoNet' attractive for general practice teams?
	How should 'BayFoNet' be improved in the future to create a sustainable added value for primary healthcare research?
Outer setting	Which external barriers and facilitators (eg, health policy) were conducive to your active participation in 'BayFoNet'?
Inner setting	Looking back, has your active participation in 'BayFoNet' changed anything in your own practice? For example, role allocation, processes, social culture, etc
	Did you perceive 'BayFoNet' as a lively network that promoted the exchange with academic general medicine and other general practitioners?
Characteristics of the individual	What qualities should a researching general practitioner have? How would you describe suitable colleagues?
	What kind of study designs would you like to implement in your practice in the future? Are there any research questions that particularly interest you?
Process	What have you already done in your practice to make future clinical trials easy to conduct, feasible and attractive?

CFIR, consolidated framework for implementation research.

the research interest and the data to be generated, the evaluation will be carried out applying a qualitative content analysis according to Kuckartz and Rädiker.[16] Especially with larger amounts of text, this rule-based procedure allows a qualitative evaluation, but also opens up possibilities for quantifying partial aspects. Within Kuckartz's qualitative content analysis, the CFIR framework will be applied. In addition to these deductively obtained categories, there will be the possibility of forming categories inductively in order to make aspects of implementation practice that have not yet been described accessible to theory building.

Table 4 Applied research questions referring to the theoretical domains framework concerning the patient questionnaires

Sources of behaviour	Research questions
Time point	**Before intervention**
Reflective motivation	I accept the planned assignment to one of the two participants groups randomly as part of the clinical study
	As an affected patient, I feel towards other patients obliged to participate in the presented clinical study
	I look forward to actively participating in the presented clinical study
	By participating in the clinical study presented, I am pursuing clear goals
	By participating in the clinical study presented, I would like to help to improve medical care for other affected people
	By participating in the clinical study presented, I will make an important contribution to better patient care
Automatic motivation	There are effective incentives (financial or non-financial) to participate in the clinical study
Psychological capability	I know what the presented study is about and what I can contribute here
	I can remember the correct implementation and the planned process of the clinical study that I was informed about
	I can arrange/plan my everyday life in such a way, that I can participate in the clinical study as discussed with the practice team
Physical capability	I am physically able to participate in the clinical study presented
Social opportunity	My relatives/my partner/my family support me in participating in the presented clinical study
Physical opportunity	I have the required material or technical support (eg, internet) to participate in the clinical study presented
Time point	**During intervention**
Automatic motivation	I am satisfied with the content and process of the study
Psychological capability	I know why it's important in the clinical study presented to participate continuously until the end
	I can organise/plan my everyday life in such a way, that I continuously can participate in the clinical study
Physical capability	I am physically able to continuously participate in the clinical study
Physical opportunity	I have the required material or technical support to continuously participate in the presented study
Time point	**After intervention**
Reflective motivation	With the participation in the completed study, I have clear goals pursued
Automatic motivation	I was satisfied with the content and process of the study up to the end
	There were effective incentives until the end of the clinical study for me to participate continuously
Psychological capability	I was able to organise/plan my everyday life in such a way that I could take part in the clinical study
Social opportunity	My relatives/my partner/my family supported me in participating until the end/completion of the clinical study

Two different researchers (LS and TD) will read and analyse the data, the third researcher (JG) will solve disagreement. Both the intracoder and the intercoder reliability will be checked, above all to eliminate any ambiguities in the categorisations and thus support the reliability of the analysis. Different stakeholders will be interviewed and analysed independent from each other.

Quantitative data analyses will be performed in IBM SPSS Statistics V.19.0 using descriptive methods.

Patient and public involvement

Patients and/or the public were involved in the conduct and dissemination plans of this research.

DISCUSSION

With our process evaluation study, we aim to gain insights concerning expectations and experiences of all potential stakeholders in primary care research during the development of the PBRN BayFoNet. Both pilot cluster-randomised trials investigate areas of uncertainty about the feasibility of future definitive randomised controlled trials in this setting.[17] Our process evaluation will be performed alongside and reported separately. The comprehensive longitudinal mixed-methods study design considers individual-level behaviour change aspects (assessed by the TDF) as well as organisational aspects (assessed by the CFIR) at different time points of a healthcare intervention. We are aware, that both frameworks might address constructs at the individual and collective levels.[18] By combining them during data collection and analysis, we aim to define the multi-level nature of behaviour change in healthcare organisations than either of these frameworks alone. We did choose the TDF to understand the patients' behaviour, whereas the CFIR is a valuable tool to get information about the implemented interventions from the perspective of primary care providers and researchers.

Strengths and limitations

The study design of upcoming interventions and studies will sufficiently benefit from our insights, besides the organisational infrastructure of BayFoNet itself. Our multi-professional research team (ie, GP, pharmacy, nursing, sociology and health service research) will provide multiple perspectives about the research processes within primary healthcare.[19] Possible limitations could occur due to different

effectiveness in the simultaneous implementation of the cluster-randomised pilot trials and the accompanying process evaluation by the GP. Whether the effectiveness in these practices will be higher or lower cannot be estimated prospectively. A post-hoc analysis will not be sufficient, as the effectiveness will be already known and this trial would be conducted sometime after both pilot cluster-randomised trials were completed. Consequently, we decided to use this prespecified protocol for our process evaluation, as the proposed methods are flexible to unexpected findings in the planned qualitative data collection and analysis will be iterative in nature. Furthermore, it will influence the choice of the actual hypotheses to be tested quantitatively. Another limitation of our process evaluation is that some of the quantitative data might be scarce due to variable access to GPs and their patients. For example, we will not be able to evaluate patients that are not interested in participating in both pilot cluster-randomised trials. Understanding causation will be limited as differences between practices may reflect different attitudes towards medical research in general. This participation bias will compromise the generalisability of our findings.

Next steps

These insights will be shared on a low-threshold level with other regional PBRNs to be able to derive indicators for the successful development of a Germany-wide PBRN in primary care. Based on the data obtained from the process evaluation, recommendations for the development and implementation of clinical studies in German primary care should be developed in accordance with good clinical practice. Furthermore, two sets of indicators for identification of 'suitable research practices' as well as criteria for 'good research practice' in German primary care are to be derived using a Delphi consensus process involving primary care researchers.[20] To this end, we will assemble a list of candidate indicators (eg, appropriate study designs, needed resources, etc to conduct clinical studies in primary care) followed by each expert individually scoring each indicator for importance using a Likert scale. First round results will be discussed again with those experts before second round ratings are placed. In a final face-to-face meeting, the experts will consent the most important indicators and make final recommendations (eg, which types of GPs are needed for a sustainable PBRN and describe features of clinical studies for German primary care to make them relevant, accepted, credible and feasible for healthcare professionals and their patients).

Ethics and dissemination

This study protocol conforms to the Declaration of Helsinki.[21] Research ethical approval for this study was granted on 21 February 2022 by the Ethics Committee of the Medical Department, Ludwig-Maximilians-University Munich (AZ 21-1135). Participating general practitioners and their patients receive both verbal and written information explaining the purpose of the study and provide informed consent. Participating general practitioners and their patients receive a minor compensation for answering interview question or for filling the research questionnaires. The interviews with the general practitioners are expected to take about 30–60 min; the research questionnaires for the patients will take 5–10 min to complete. Results will be presented at scientific meetings and published in international peer-reviewed journals. Summaries will be provided to the funders of the study as well as other coordination centres of PBRNs, GP teams and their patients.

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Contributors LS and TD contributed equally to this paper and have drafted the manuscript and developed the concept of the process evaluation under the supervision of JG. They contributed substantially to the conception of the work and will mainly analyse the resulting data. AH developed the questionnaire for the quantitative data collection as well as the semistructured interview guideline (qualitative data collection) and discussed these materials with LS and TD. HK piloted the semistructured interview guideline and items for our focus groups. She will serve as an expert in qualitative data collection, moderate the discussion sessions and will acquire focus group data. IG and PKK developed and implement MicUTI and revised the manuscript substantially. TK and LB supported the development of the items for the upcoming focus groups and revised the manuscript. SE developed and implement IMONEDA and revised the manuscript substantially. MR contributed to the conception of the study and will support the analysis and interpretation of resulting data for the work, he revised it critically for important intellectual content and approved the final version to be published. All authors have approved the submitted version of the manuscript and have agreed both to be personally accountable for their own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved and the resolution documented in the literature.

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