Piloting Digital Navigators to Promote Acceptance and Engagement With Digital Mental Health Applications in German Outpatient Care: Protocol for a Mixed-Method Interventional Study

Julian Schwarz, Kelly Chen, Martin Heinze, Julia Schönbeck, Darja Schubert, Justin Speck, John Torous, Jan Wolff, Laura Uchtmann, Eva Meier-Diedrich

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Abstract

Background: In Germany, patients often have to wait several months for a psychotherapeutic treatment. Digital therapeutics (DTx) offer a promising approach to providing timely mental health support. However, their use is still limited. Digital navigators (DNs) are specially trained advanced practice providers who support health care professionals (HCPs) and patients in the selection and use of DTx. This can improve digital health literacy, increase engagement and reduce the burden on HCPs.

Objective: The DigiNavi study is the first pilot study to test the feasibility of implementing DNs in general practice and outpatient psychiatric care in Germany.

Methods: I) In order to explore the acceptance and expectations of HCPs and patients towards DNs, a qualitative study will be conducted. II) The Harvard Digital Navigator Training will be adapted and advanced practice providers will be trained to become DNs at n=6 study sites. III) The DNs will guide a total of n=48 patients in the use of DTx for mental health. The patients' digital health literacy and the severity of their psychological symptoms will be assessed quantitatively in a pre-post comparison. In addition, user experience and barriers to implementation will be explored qualitatively.

Results: The study provides important insights into the acceptability and feasibility of human-facilitated competency development for mental health apps in multi-professional health care teams and their patients.

Conclusions: The successful implementation of DNs can promote the use of DTx in Germany and thus enhance the provision of healthcare for individuals with mental health conditions. Clinical Trial: German Clinical Trials Registry (DRKS), registration number: DRKS00034327, https://drks.de/search/de/trial/DRKS00034327

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Keywords: digital therapeutics, digital health applications, digital navigators, eHealth, mHealth, digital health literacy, mental health

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Introduction

The prevalence of mental health conditions is increasing worldwide [1]. Conditions such as depression and anxiety have a significant impact on an individual's quality of life and, if left untreated, can lead to the development of chronic conditions [2]. This can result in a burden on health care systems and society as a whole [1]. Effective treatment typically involves psychological interventions. However, there is a significant treatment gap, particularly in low- and middle-income countries [2,3]. Lack of psychotherapy and the resulting long waiting times are structural barriers to treatment [2]. In addition, general practitioners (GP) often do not have the resources to provide adequate treatment, even when mental disorders are recognized [4]. Personal attitudes toward psychotherapy also contribute to this gap, as many patients have a high threshold for seeking treatment and may not recognize their condition as requiring professional intervention [4].

Low-threshold digital services such as digital therapeutics (DTx) for mental health offer scalable, evidence-based, and easily accessible solutions that can reduce waiting times and provide initial relief [5–9]. An increasing number of countries have already introduced the possibility to prescribe DTx or financially support the purchase of mental health apps [10–12]. However, despite the growing availability of mental health apps, the use of DTx internationally remains below expectations [13,14].

The reasons for low engagement are complex [15]: A user-friendly design and interface are essential for application adoption [16]. However, a significant proportion of users lack the digital and technical literacy to use the applications intuitively and effectively [17,18]. This so-called digital divide particularly affects already underserved patient groups, such as elderly or educationally disadvantaged patients [19,20]. In addition, many patients often do not have sufficiently modern smartphones or the necessary digital health literacy to use digital health apps effectively [21]. Acceptance of digital health services by health care professionals (HCPs) is an important factor influencing the adoption of digital interventions by patients [17,22]. However, HCPs often lack the time to keep abreast of developments in DTx and how to effectively integrate them into treatment processes. [6,7,17,23,24]. Furthermore, both HCPs and patients frequently perceive digital apps as inadequate for addressing mental health problems [21].

However, research suggests that human guidance - defined as personal assistance in the selection, installation, and use of DTx - can improve both acceptance and engagement with DTx and achieve lasting positive health outcomes [25–29]. A promising approach in this context is to train selected HCPs in medical teams to become so-called digital navigators (DNs) [30–32]. The core tasks of DNs are threefold: first, to increase digital competence within psychiatric and GP treatment teams through training initiatives; second, to expand the knowledge base of HCPs and patients regarding DTx for mental health; and third, to support and accompany patients in the use of DTx. The guided use of DTx is intended to improve the care of the target group of people suffering from mental health conditions.

In Germany, DTx are called "Digitale Gesundheitsanwendungen" ("Digital Health Applications") (DiGAs) and have been available since the implementation of the Digital Health Care Act (Digitale-Versorgung-Gesetz) in December 2019 [33]. This legislation established the framework for the approval and reimbursement of digital health applications. DiGAs must meet specific standards set by the German Federal Institute for Drugs and Medical Devices (BfArM) to ensure safety, quality, functionality, privacy, data security and effectiveness [34]. Once approved, DiGAs can be prescribed by physicians and psychotherapists and are reimbursed by statutory health insurances. Currently,

there are n=55 DiGAs available, of which n=26 are focused on mental health conditions (e.g,. n=7 for depression and n=7 for anxiety). All approved DiGAs can be found at the publicly available German DiGA directory of the BfArM [35].

While DNs have been successfully implemented in several countries [17,29], no such role or training program currently exists in Germany. In addition, evidence from abroad cannot be easily transferred to Germany due to significant differences in the healthcare system [29].

The aim of this study is to (1) explore the acceptance and expectations of HCPs and patients in Germany towards DNs (2), adapt the Harvard Digital Navigator Training for the German Health Care system, (3) evaluate the trial implementation of DNs including their impact on patients and HCPs, and (4) investigate options for perpetuating DNs in the German healthcare system.

Methods

Study Setting and Design

Within the framework of the DigiNavi study (duration: July 2024 - July 2025), DNs will be piloted in GP practices and psychiatric outpatient clinics in different rural and urban regions of the federal state of Brandenburg, Germany, based on the DN model of the Harvard Medical School [36,37].

The DigiNavi study employs a mixed-methods approach, incorporating elements of participatory design and is divided into four research phases (see Figure 1). The following research questions will be addressed in the four phases:

1. **Phase I:** What are the levels of acceptance and expectations of HCPs and patients towards DNs?
2. **Phase II:** What responsibilities and specific skills should DNs have in the German healthcare system?
   How can these findings contribute to the needs-based introduction of this new role?
3. **Phase III:** What impact does the advice and support provided by DNs have on the digital health literacy of patients and HCPs?
   What impact does the increased integration of DiGAs into treatment have on their use and the therapeutic relationship between patients and HCPs?
   What are the challenges and barriers that arise when piloting DNs?
4. **Phase IV:** What measures are necessary to ensure the long-term implementation of DNs in the German health care system?
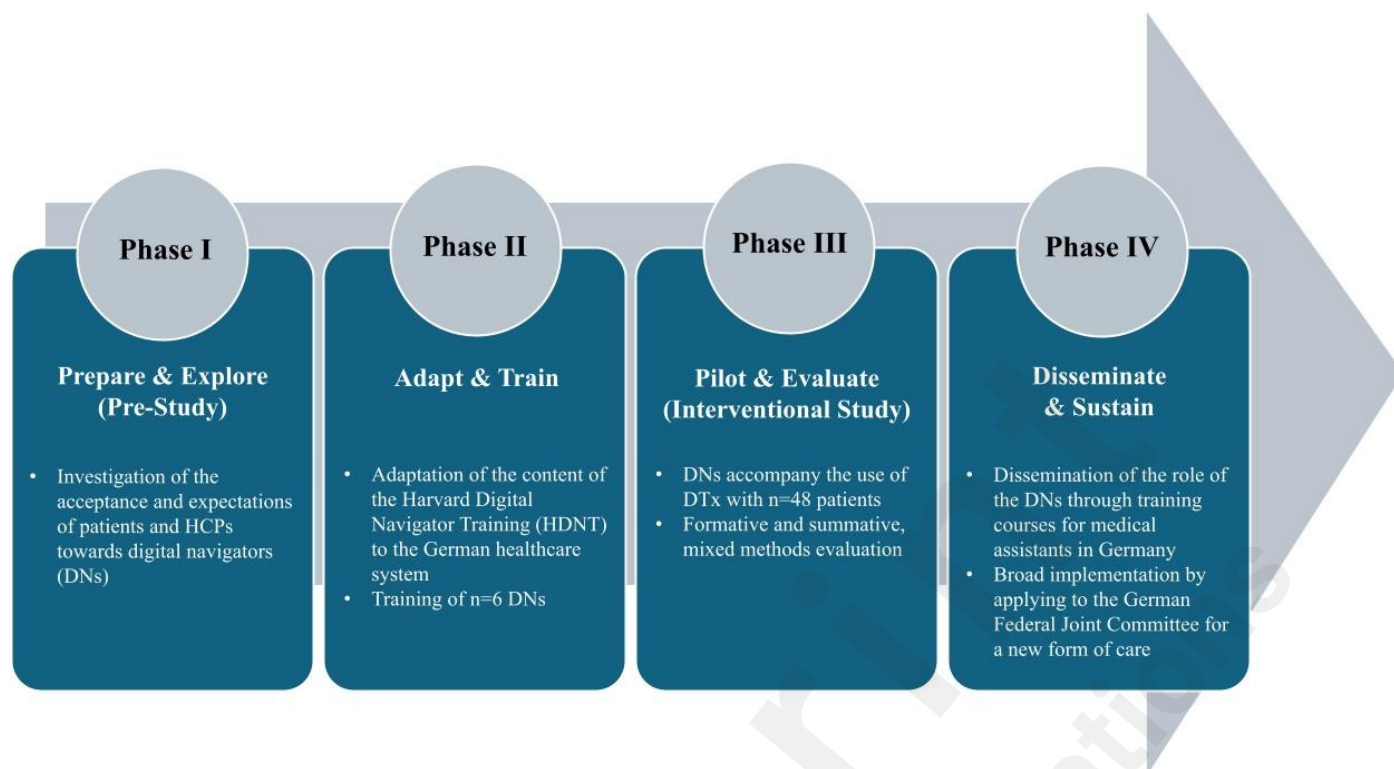
Figure 1. Research phases of the DigiNavi study. HCP: health care professional. DN: digital navigator. HDNT: Harvard digital navigator training. DTx: digital therapeutics.

The Role of Digital Navigators

According to Perret et al [17], DNs have at least three distinct roles (see Figure 2): First, it is their task to keep their knowledge of available mental health apps up to date and to evaluate these apps based on the available evidence. For this purpose, DNs can refer to MindApps.org of Harvard University. In this way, DNs can advise HCPs on the selection of suitable health apps and provide ongoing assistance to patients in using the app. Second, DNs are responsible for teaching the multiprofessional care team the technical and digital basics and skills, as well as informing team members about available mental health apps and their specific features. This requires constant availability to team members and patients in case of questions or problems (troubleshooting). Third, it is the DN's responsibility to process the data generated by the patient's use of the mental health app and prepare it for the HCPs in a way that is useful for treatment.

In the context of this study, so-called advanced practice providers are selected to perform the role of DNs. In Germany, these occupational groups often work as receptionists, who usually work at the registration desk of healthcare facilities and perform mainly administrative and partly nursing tasks (e.g. administering depot medication or carrying out treatments ordered by a HCP). The advanced practice providers know the patients well and work closely with HCPs, which predestines them to take on the role of a DN.
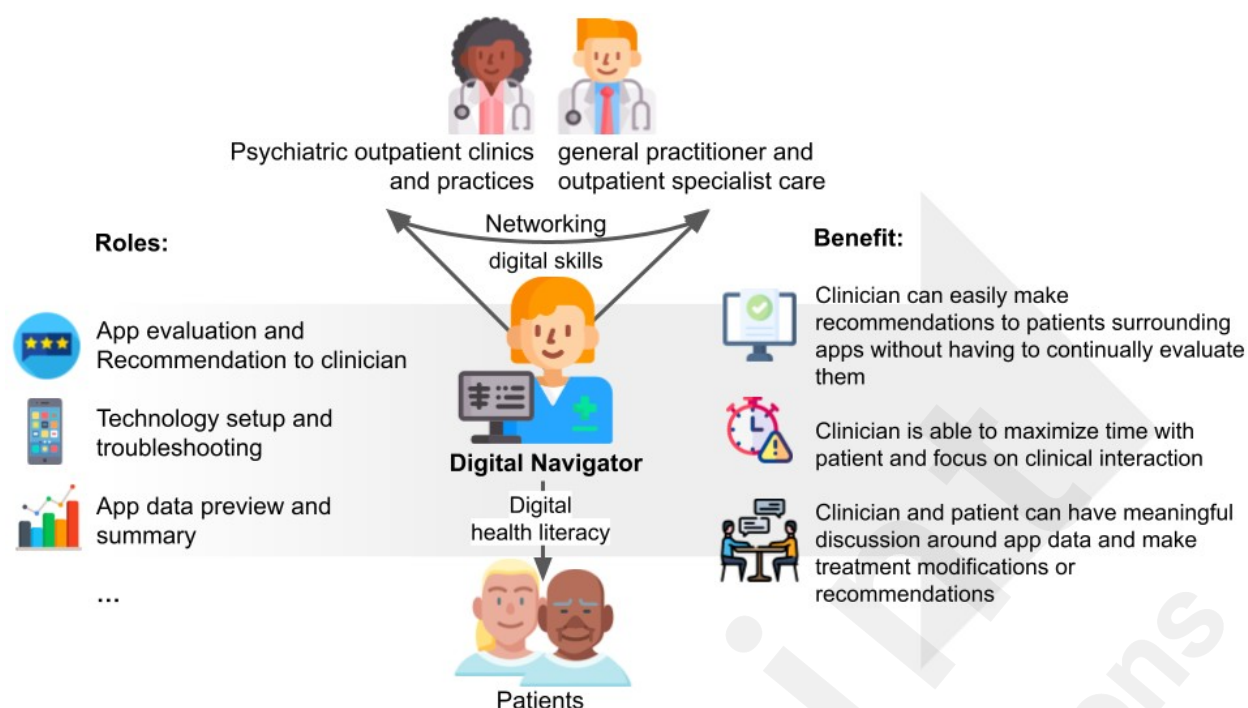
Figure 2. Role and tasks of digital navigators adapted from Wisniewski and Torous 2020 [31].

Complex Health Care Intervention

The use of DNs in multiprofessional care teams is a complex intervention. A complex intervention is defined as a health care intervention or program that consists of a number of interacting components, each of which may contribute to the overall outcome in different ways [38]. The impact of the intervention typically depends on the interaction between these different components. The introduction of DNs corresponds to a complex intervention with several interacting components, as the role of DNs comprises several components in terms of content (see Fig. 2).

Process Evaluation

In order to evaluate complex interventions such as the pilot of DNs and to gain insight into the impact of the intervention in practice, elements of process evaluation were incorporated into the study design [38]. In this sense, the design of the present study follows the fundamental recommendations of the UK Medical Research Council (MRC) for process evaluation [39]. Accordingly, the intervention, any prior assumptions, contextual factors, implementation processes, influencing factors and outcomes are carefully observed, analyzed and described in order to facilitate an informed interpretation of the study results [39]. A mixed methods approach was adopted, using both quantitative and qualitative methods for data collection and analysis to provide a comprehensive picture of the implementation of the intervention.

Ethical Considerations

The study was approved by the Ethics Committee of the Brandenburg Medical School (MHB) (reference number: 218062024-BO-E). The study was registered at the German Clinical Trials Registry (DRKS) (DRKS00034327) and at ClinicalTrials.gov (NCT06575582).

Study Population

Recruitment

The pilot project will be conducted in psychiatric outpatient clinics (n=3) and GP practices (n=3) in Germany. Specifically in the Brandenburg districts of Märkisch-Oderland, Oder-Spree, Barnim, Brandenburg an der Havel, and Dahme-Spreewald. Both patients and HCPs (GPs, outpatient psychologists and psychiatrists, advanced practice providers) will be collaborating with DNs and are therefore considered as relevant stakeholders and will be included in this study. Study sites were selected to ensure proximity between a primary care practice and a psychiatric outpatient clinic to facilitate networking. New participants will be recruited in each phase of the study, and the pool of previously recruited participants will be used in subsequent phases. HCPs and DNs (usually advanced practice providers at each study site) are recruited by the study team. Participating patients will be recruited by the DNs and HCPs (n=1 DN and at least n=1 HCP per site). In addition, raters (n=6, typically psychologists) will be assigned to each study site to conduct the data collection.

All study participants will receive written information about the nature of the study and will be asked to provide informed consent for their participation, which will include data collection, storage, and processing. Written informed consent will be obtained from each participant.

Inclusion and Exclusion Criteria

All patients undergoing treatment at one of the study sites and meeting the following DigiNavi study inclusion criteria will be approached for participation in the study:

- Diagnosis according to ICD 10 F[1-6]x.x and/or F06.7
- No recent (<= 3 weeks) qualified psychiatric or psychotherapeutic treatment
- Ability to give informed consent
- Minimum age of 18 years
- No acute danger to self or others
- No disturbance of orientation or reference to reality
- Absence of significant cognitive deficits as indicated by severe organic brain disease
- No diagnosis of intellectual impairment
- Sufficient language skills to complete an interview in German
- Sufficient modern hardware (e.g. smartphone, tablet, or PC) available
- Basic knowledge of how to use a smartphone

DNs and HCPs to be surveyed must be at least 18 years of age and provide informed consent to participate.

Sampling

A report on digital health applications by the German Association of Statutory Health Insurance Funds (GKV-Spitzenverband) indicates that in Germany in 2023, users of DiGAs for mental health conditions were on average 43 years old and 70% female [40]. Internationally, socio-demographic factors appear to be similar, as shown by a study examining diversity in clinical trials of digital therapeutics, which found that the median reported mean age across studies was 43.3 years, with 65% of participants being female [41]. To better address the specific needs of younger, older, and male patients, convenience sampling with a balanced gender ratio will be used for all patient-related surveys conducted as part of this study. In addition, marginalized groups in the German health care

system will be prioritized for recruitment to address inequalities in mental health care through the use of DNs [42]. This will include the selection of at least one non-white (n≥1), non-native German speaking (n≥1), LGBTQIA+ (n≥1) and older than >65 years (n≥1) [43] individual for study participation.

Study Implementation

Phase I: Prepare *and* Explore (= Pre-Study)

A first exploratory pre-study will examine the acceptance of and expectations of DNs from the perspective of patients and HCPs. This qualitative study will involve 10 GPs, 10 outpatient psychiatrists and psychologists, and 20 of their patients from the service areas of the study sites. Specifically, 12 semi-structured interviews (n=4 GPs, n=4 outpatient psychiatrists/psychologists and n=4 patients each) and 4 focus groups will be conducted. Two focus groups with patients (n=8 each), one focus group with GPs (n=6), and one focus group with outpatient psychiatrists/psychologists (n=6) will be conducted. In addition, the sociodemographic characteristics of the participants will be collected [44]. The developed survey instruments and interview guides will be pre-tested before implementation. The collected qualitative data will be transcribed, pseudonymized, and analyzed using MAXQDA software following a thematic analysis to elaborate stakeholders' acceptance and expectations of DNs [45].

Phase II: Adapt *and* Train

Three researchers from the study team will participate in a multi-day training and coaching program on the implementation of DNs during field visits at Harvard Medical School [46]. Furthermore, the content of the certified "Harvard Digital Navigator Training" (HDNT) will be translated into German and adapted to the German context through a participatory process. This process will involve patients (n=5) and HCPs (n=5) in discussion groups at three time points, following the levels of the European Commission's Digital Competence Framework for Citizens (DigComp 2.0) [47]. A key tool for DNs is the MindApps.org website, which will be translated into German and made available at DiGAnavigator.de for this study. Initially, all DiGAs for mental health approved by the BfArM [35] in Germany will be listed on the website. In addition, detailed psychoeducational content on the use of DiGAs for mental health conditions will be developed and incorporated into the website. Subsequently, clinical staff (preferably advanced practice providers) will be trained as DNs at the six study sites. In addition, 6 psychologists will be trained as raters to conduct participant recruitment and data collection.

Phase III: Pilote *and* Evaluate (= Interventional Study)

In the intervention phase, the trained DNs will train the multi-professional teams at the six study sites to select and integrate DiGAs for mental health into the treatment of N=48 patients (n=8 per site). The selected patients will be supported and guided by the trained DNs for a period of 12 weeks, during which time they will be encouraged to regularly use a DiGA tailored to their individual needs. Data collection will be conducted by the trained raters (n=6) at each study site. The evaluation will include a formative assessment of implementation barriers and a summative evaluation of eHealth literacy among patients (n=48) and professionals (n=18; 3 per site) before and after the 12-week intervention. For this purpose, the validated instruments eHealth Literacy Scale (eHEALS) and

Digital Health Literacy Index (DHLI) will be used [48,49], which can already detect changes in smaller samples [50]. eHeals is the most widely used international questionnaire for the assessment of digital health literacy. It is a self-assessment tool that focuses on digital information-seeking skills [48]. The DHLI complements the eHEALS in assessing interactive skills such as the use of (web-based) health applications [49]. In addition, both patients and staff will be assessed for their digital and technical literacy as well as their readiness and ability to change before and after the intervention. The following instruments will be used for this purpose: the Information and Communication Technology (ICT) Self-concept Scale related to Information and Communication Technology [51], the Brief Scale of Technological Readiness [52] and the Readiness for Change [53]. In addition, the severity of the patient's disease will be assessed and compared before and after the intervention using validated scales. Furthermore, socio-demographic parameters (e.g. age, gender) are collected to adjust the statistical analysis. Table 1 provides an overview of the instruments used.

The collected socio-demographic characteristics will be analyzed using descriptive statistics and presented in an appropriate format such as age distribution and gender ratio. Quantitative primary data collected will be analyzed using descriptive statistics in a pre/post comparison. Qualitative data will be obtained through interviews and focus groups with a total of n=25 participants (patients, HCPs and DNs). The data collection and analysis methods used in the exploratory preliminary study will be used to document the effects and impact of the guidance and support provided by DNs on the digital health literacy of stakeholders. The methodological implementation is strictly based on the UK Medical Research Council guidelines for the evaluation of complex interventions [39].

Table 1. Instruments used for pre and post assessment of the interventional study.

Participants	Construct	Instruments
Patients and staff		
	Digital health literacy	Digital Health Literacy Index (DHLI) eHealth Literacy Scale (eHEALS)
	Digital and technical literacy	Information and Communication Technology (ICT) Self-Concept Scale Brief Scale of Technological Readiness
	Readiness and ability to change	Readiness for Change
Patients		
	Severity of disease	Global Assessment of Functioning (GAF) Clinical Global Impression (CGI) Beck Depression Inventory (BDI) Hamilton Depression Scale (HAMD) Hamilton Anxiety Rating Scale (HAMA)

		Insomnia Severity Index (ISI)

Phase IV: Disseminate and *Sustain*

This study phase includes the dissemination of the study results as well as the development of strategies to ensure the long-term integration of the pilot innovation into the German health care system. This includes the continuation of the pilot project beyond the end of the study by maintaining the DiGAnavigator.de website, training advanced practice providers at the Federal State of Brandenburg's Medical Association (LAEKB) and applying for a new form of care from the Innovation Fund of the German Federal Joint Committee. Preliminary scenarios for the remuneration of DN activities are currently being formulated.

Results

The study will provide important insights into the acceptance of DNs by HCPs and patients (Phase I), which, in combination with the participatory coordination of the digital navigator training, will contribute to an address-oriented implementation in the pilot region (Phase II) and beyond. The open-access publication of the adapted and field-tested manual and all training materials for the DN training (including the website MindApps.org) in German will facilitate the independent implementation of the innovation by outpatient care providers and enable its extension to other disciplines and settings (e.g. day clinics or even inpatient care). In order to ensure a broad implementation and continuation of the innovation, the project team is preparing the accreditation of the training programme for advanced practice providers to become DNs by the LAEKB. At the end of the project period, a roll-out phase is planned, during which the innovation will be transferred to the member practices of the Brandenburg General Practitioners Association.

Discussion

International studies indicate the great potential of digital mental health tools to improve the quality of and access to care [17]. However, the actual use and integration of these applications is still limited, even in an international context, due to a lack of relevant technical and digital literacy among HCPs and patients alike [31]. DNs have the potential to mitigate these barriers, promote digital health literacy, and ultimately lead to improved care outcomes [17,30].

The role of the DN is a complex intervention that requires evaluation at multiple levels. In this regard, its evaluation must include questions about digital health literacy, implementation conditions, the role and function of DNs, treatment processes, and impact factors, in addition to clinical endpoints. In addition, the evaluation process should consider the perspectives of patients, HCPs, and DNs themselves.

The role of the DN in multi-professional medical teams is a novel approach within the German healthcare system, which is why it has not yet been researched. The DigiNavi study will adapt, pilot and evaluate the role of DNs in a participatory manner for the German healthcare system. The planned study will provide valuable insights into the acceptance, expectations, challenges and opportunities associated with the role of DNs in improving health care.

Limitations

The present study is limited by the size and composition of the sample, which was selected on the

basis of convenience rather than random sampling. Consequently, the findings cannot be generalized to the entire population of patients with mental health conditions in Germany. In addition, the focus on patients with mental health conditions is a limitation in itself, so that the results cannot be generalized to patients with somatic conditions or to individuals without illnesses. In addition, it can be assumed that the study will attract a larger number of technologically proficient HCPs and patients (self-selection). This may result in overrepresentation of this particular patient and HCP group.

Other potential limitations arise from the outpatient setting of the study. In the inpatient setting, the ability to prescribe DiGAs is limited. The aforementioned factors, along with the nature of the pilot study, preclude the possibility of incorporating these elements into the investigation.

In addition, the present study is conducted without a comparison group, i.e. with only one condition. This makes it difficult to identify and control for confounding factors. However, the primary goal of the DigiNavi study is to investigate the feasibility of the innovation, not to provide evidence of its effectiveness. The sample size and composition chosen are therefore justified by the exploratory nature of the planned study and are appropriate for a pilot project. The implementation of a randomized controlled trial may be a future goal for research efforts.

Furthermore, the limited funding period of only twelve months has resulted in the intervention phase being constrained to a duration of three months. As a result, the study design does not include a follow-up component, precluding any assertions regarding the evolution of the outcomes of interest over a six- or twelve-month period.

Further studies are needed to test DNs in inpatient and outpatient settings, or in the somatic field, to determine whether the hypothesized effects of DNs can be confirmed in other settings and patient groups and whether DNs can be established as a sustainable tool for improving the care of patients with mental health conditions. In addition, further international studies involving different health care systems would be of great value. The findings of this study, together with the easily accessible training materials on the project website (www.diginavi.de), should encourage and facilitate further research.

Acknowledgments

Authors' Contributions

JS designed the study and applied for funding. DS and EMD were involved in developing the main documents regarding ethics approval. JS, EMD and LU drafted the study protocol. Successive drafts were revised by LU, EMD, JT and JS. All authors have approved the submitted version. All authors have agreed both to be personally accountable for the author's 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.

Conflicts of Interest

None declared.

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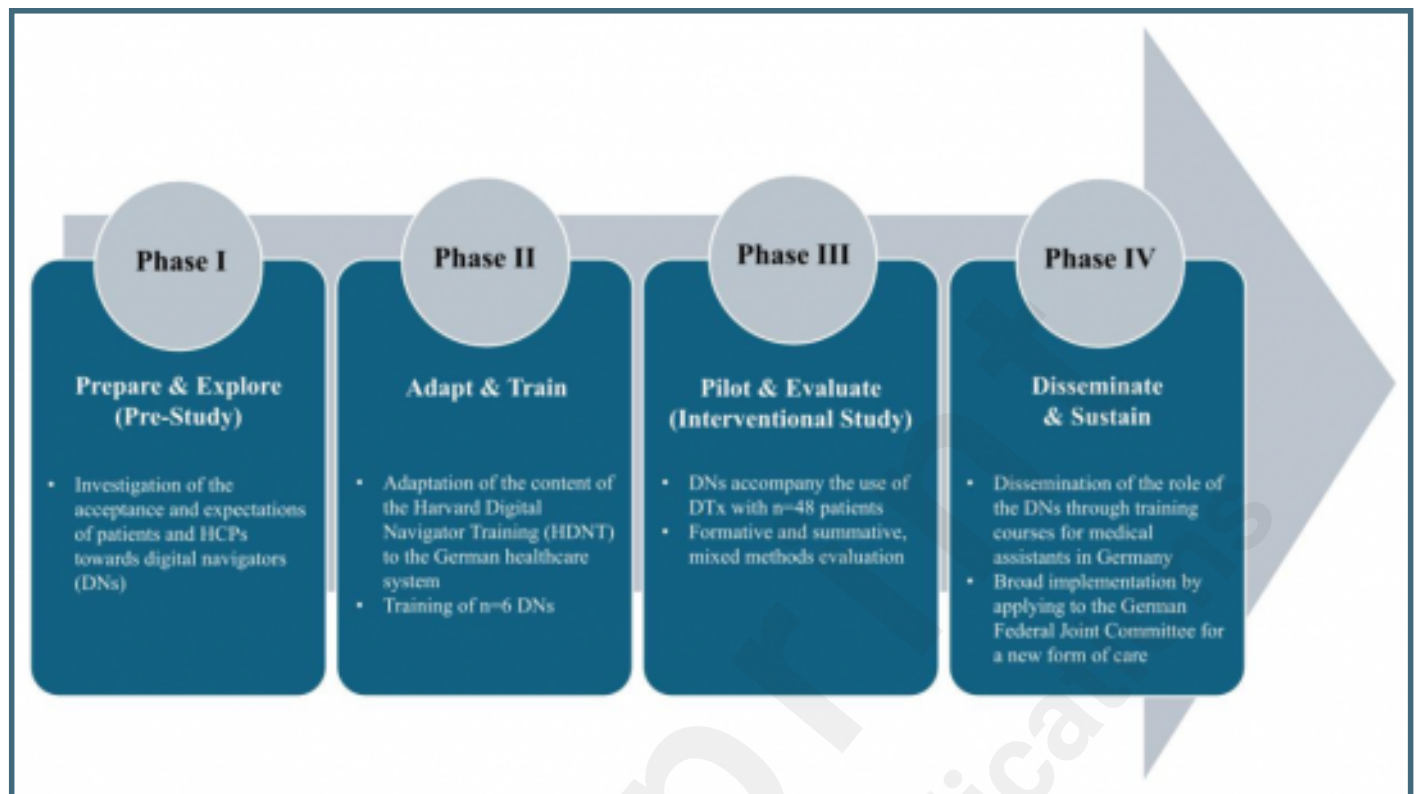
Abbreviations

BfArM	German Federal Institute for Drugs and Medical Devices
DiGA	Digital Health Applications
DN	Digital Navigator
DTx	Digital Therapeutics
GP	General Practitioner
HCP	Health Care Professional

Supplementary Files

Figures

Research phases of the DigiNavi study.

Role and tasks of digital navigators adapted from Wisniewski and Torous 2020.