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Adapting the digital health navigator role for prescription based digital therapeutics in Germany: a modified Delphi study with participatory design elements

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Abstract

Background

The role of the Digital Health Navigator (DHN) supports medical teams and patients in their use of mental health applications. Evidence suggests that competent implementation of this role can improve patient adherence and treatment outcomes in psychological and psychiatric settings. However, as the concept originated in the United States, it requires contextual adaptation to the German healthcare system, where digital health applications (DiGAs) represent a specific form of prescription digital therapeutics integrated into statutory healthcare. We therefore adapted the Harvard Digital Navigator Training (HDNT), the US-based training programme underlying this role, to the German context.

Objective

This study aimed to adapt the HDNT to the German healthcare context and to develop Delphi-derived recommendations for its implementation.

Methods

A modified three-round Delphi process was conducted with patients and healthcare professionals (HCPs) from participating study sites. Beyond rating predefined items, participants co-developed training and implementation content in moderated discussions and contributed to the user-centred specification of a DiGA information resource. Round 1 adapted the HDNT and generated implementation-related content, Round 2 prioritised competency and implementation items through an online survey, and Round 3 refined contested implementation recommendations through a moderated group discussion.

Results

The original HDNT required only limited adaptation. Most original content was retained, while changes primarily concerned German legal and regulatory requirements, DiGA-specific care pathways, and mental health-specific additions. The final catalogue comprised 174 recommendations, including 97 competency and 77 implementation recommendations. App evaluation was rated as highly relevant but showed the lowest self-rated competence, whereas basic smartphone skills showed high self-rated competence despite limited consensus on relevance. Implementation recommendations emphasised organisational integration, communication with HCPs, and access to reliable DiGA information. Formal competency assessment remained contested; participants instead supported competency assurance through training design, practical exercises, and continuing professional development.

Conclusions

The findings suggest that implementing DHNs in Germany requires less the development of a new role than the contextualisation and operationalisation of an established model. Future DHN training should prioritise the critical evaluation of digital interventions and should be embedded within existing treatment structures. The resulting recommendation catalogue provides a framework for subsequent feasibility testing and evaluation in routine care.

Trial Registration:

German Clinical Trial Register: DRKS00034327, https://drks.de/search/en/trial/DRKS00034327;

Background

Globally, incidence rates of mental illnesses have been rising in recent years [1]. This trend is significantly influenced and amplified by ongoing global crises, including pandemics, armed conflicts, and the climate crisis [2–5]. In parallel with these crisis-driven developments, the digital landscape has been evolving at a rapid pace: today, 67.9% of the world's population are internet users [6].

In Germany, there has been an observed increase in the prevalence of mental disorders from 17.4% to 26.1% in recent years [7]. However, there has been no corresponding expansion of outpatient or inpatient psychotherapeutic care to meet this growing demand [8, 9]. Mental health clinics and psychotherapy practices are generally experiencing high demand, often resulting in extensive waiting lists with an average waiting time of approximately 142 days and more [10, 11]. During this waiting period, individuals diagnosed with mental health disorders frequently remain untreated, a circumstance that can result in the exacerbation and chronicity of symptoms [12, 13].

While an intensified political focus on improving the population's (mental) healthcare is urgently required, the reality is that, in the absence of structural improvements in routine care, digital innovations can provide interim support and act as a form of "first aid" during the waiting period before psychotherapeutic treatment becomes available [14, 15]. Since 2020, prescription-based digital health applications (Digitale Gesundheitsanwendungen, DiGAs) have been available in Germany [16, 17]. DiGAs are a uniquely German category of prescription based digital therapeutics (DTx). They are evidence-based mobile interventions, which are reviewed and approved by the Federal Institute for Drugs and Medical Devices (BfArM) and reimbursed by statutory health insurance upon prescription [18]. This regulatory integration into routine care differentiates DiGAs from DTx in most other healthcare systems, including the United States. At present, 30 prescription-based DiGAs for mental health disorders, including depression, anxiety disorders and ADHD, have

been approved in Germany (as of 08/2026). DiGAs have the potential to enhance mental well-being and make mental healthcare accessible to patient groups that have no immediate access to psychotherapeutic treatments [19].

It is generally thought that digital literacy is mainly a problem for older patients since they are less likely to be digital natives and may have difficulty in using these tools on their own [20]. However, even among younger people who are digitally literate, adoption of DiGAs is still low [21, 22], which indicates that digital skills by themselves are not enough to guarantee their use. More generally, implementation difficulties still constitute a major obstacle to incorporating digital mental health interventions into routine care [23]. As a result, continued engagement usually requires extra human support. To provide such support and ensure equitable access across patient groups, the role of the Digital Health Navigator (DHN) was established in the United States [24]. DHNs are members of a clinical care team (e.g., medical assistants) who help healthcare professionals (HCPs) select suitable DTx for their patients and support patients throughout their use, assisting with installation, troubleshooting, and continued engagement [24, 25]. This form of human guidance may be especially valuable i for disadvantaged and marginalised groups [26].

The role of the DHN may offer a suitable model for the German healthcare context, particularly for the implementation of DiGAs. In order to facilitate the training of DHNs, Harvard University has developed the Harvard Digital Navigator Training (HDNT) programme [24, 27]. Despite the fact that the role of the DHN has been examined in several international studies, at the outset of the DigiNavi project the role of the DHN and DHN training has not yet been applied within the German healthcare system [24, 26, 28]. To introduce the role of DHN in the German healthcare system, the U.S.-based DHN training needs to be adapted to align with the German patient population and healthcare structures.

The objective of the present adaptation study is to customize the HDNT modules to the German routine care setting and to develop a set of recommendations for the implementation of the DHN role into German healthcare.

Methods

Study Design

This study is part of the DigiNavi project (Digital Navigators for Acceptance and Competence Development with Mental Health Apps; Medical School Brandenburg; 15.07.2024–30.09.2025), which investigates the feasibility of DHNs in German outpatient care [29, 30]. It builds on a preceding qualitative study within the DigiNavi project that explored expected competencies and personal attributes of DHNs from patient and HCP perspectives [31].

The present study focused on adapting the HDNT to the German healthcare system and developed recommendations for its implementation into routine care. A modified three-round Delphi design was used to generate, prioritise, and refine training and implementation recommendations iteratively [32–36]. Across the three rounds, the expert panel generated and evaluated content, and their assessments were analysed and fed back between rounds to develop consensus iteratively [33]. The design incorporated participatory elements: patients and HCPs participated as equal members of the expert panel and contributed both to the generation of content and to its subsequent evaluation and refinement.

The study follows the SRQR (Standards for Reporting Qualitative Research; see Additional file 1) and Reporting Guidelines for Delphi-Techniques by Spranger and colleagues [37].

Participants and Recruitment

The DigiNavi study was conducted at six study sites in the rural region of Brandenburg, comprising three psychiatric outpatient clinics and three general practitioner practices and followed a purposive sampling strategy. At each study site, HCPs (general practitioner, psychiatrists, psychologists and prospective DHNs, who were typically medical assistants) were recruited by the study team. These HCPs, in turn, recruited patients who were interested in participating in the study. Participants (see Table 1) formed an expert panel for the Delphi process (round 1 and 3) that represented key stakeholders of the DigiNavi study including HCPs and patients.

Table 1
Participants in the three rounds of the Delphi study.

Round	Method	Participants
Round 1 (Session 1 & 2)	Group Discussion	Patients and HCPs, including prospective DHNs
Round 2	Survey	Patients and HCPs, including prospective DHNs
Round 3	Group Discussion	Patients and HCPs, including prospective DHNs

Legend: DHNs: Digital Health Navigators; HCPs: healthcare professionals.

To be eligible for participation, patients had to be 18 years of age and have a diagnosed mental disorder according to the German version of the International Classification of Diseases 10 (ICD-10, F[1–6]x.x and/or F06.7).

Individuals with acute risk of harm to self or others, or with severe cognitive impairments, were excluded from the study. No prior knowledge of the concept of DHNs or DTx was required to participate in the adaptation study. All relevant information was provided prior to each round of the Delphi process.

Delphi Procedure

The modified Delphi process comprised three rounds with complementary aims. Rounds 1 and 3 were conducted as moderated online group discussions using WebEx, while Round 2 consisted of an online survey hosted in LimeSurvey.

Round 1 focused on adapting the HDNT to the German healthcare context and generating additional content relevant to the implementation of the DHN role. Because of the breadth of topics, Round 1 was divided into two sessions: one addressing DHN competencies and one addressing implementation-related requirements. The discussions were semi-structured and guided by topic-specific prompts. All sessions were audio-recorded, transcribed, and anonymised.

Round 2 was used to prioritise and evaluate the content generated and adapted in Round 1. Competency statements were rated for relevance and self-assessed competence, while implementation items were rated for relevance and agreement.

Round 3 focused on items still controversial after Round 2. The panel discussed selected items again and refined the wording where they reached agreement for the final recommendation catalogue.

Delphi Round 1: Adaptation and Content Generation

Round 1 consisted of two moderated online group discussion sessions. The initial session addressed the adaptation of the HDNT competency framework. Prior to the session, participants were provided with two scientific articles on the DHN role [24, 25]. After a brief introduction to the DHN concept and the HDNT, participants reviewed the original training content and discussed which competencies and skills should be retained, modified, or supplemented for the German mental healthcare context. Proposed changes and additions were discussed by the panel and, where appropriate, decided by vote.

The second session addressed four implementation-related topics, which were outlined on the basis of prior research and collaboration with the study team: integration of DHNs into patient care, DiGA-related training content, adaptation of the MIND database to the German context, and structural considerations for DHN training (Table 2). Topics 1, 2, and 4 followed the same semi-structured discussion format as the competency session.

Table 2
Thematic areas discussed in the implementation session of Delphi Round 1.

Topic	Content	Origin
1) Integration of DHNs into patient care	Role of the DHN within the clinical care team Design of care processes involving DHNs	New
2) Prescription-based digital health applications (DiGAs)	Structure and content of a potential DHN training component on DiGAs (including regulatory basis and prescription pathways)	New
3) Adapting the MIND Database to the German Context	Adaptation of the M-Health Index and Navigation Database (MIND), a U.S.-based resource available via mindapps.org, to the German healthcare context	Existing DHN resource
4) Structural considerations for DHN training	Training structure and quality assurance mechanisms for DHNs	HDNT

Legend: Origin indicates whether a topic was newly introduced for the German healthcare context, derived from the Harvard Digital Navigator Training (HDNT), or based on an existing Digital Health Navigator resource. DHN: Digital Health Navigator; DiGA: prescribable digital health application; MIND: M-Health Index and Navigation Database.

For the adaptation of the MIND database, a user-centred procedure was used. Participants initially discussed their requirements for a DTx information resource without prior exposure to existing platforms. They then tested the official DiGA directory, followed by an introduction to the MIND platform and a study team-developed mock-up that combined features from both MIND and the DiGA directory. Their feedback informed the requirements for a German-language information resource [38].

All Round 1 discussions were transcribed and analysed using qualitative content analysis. Contributions were summarised into discrete statements that reflected either consensus or differing views within the panel. Coding and condensation were performed by JSP. As the researchers involved in data collection and analysis were members of the DigiNavi study team and familiar with the DHN concept, potential influence on interpretation was addressed by reviewing the resulting statements within the study team for accuracy and completeness. Statements that were repeatedly mentioned, explicitly emphasised, or generated extensive discussion were additionally flagged as particularly relevant to inform subsequent prioritisation. These relevance ratings were later used to inform training priorities for DHNs. The resulting material formed the basis for the Round 2 questionnaire.

Delphi Round 2: Prioritisation and Evaluation

Round 2 was conducted as an online survey. A five-point Likert scale was used to assess two criteria per item. Negatively worded items were reverse-coded. Participation was independent of participation in Round 1. The link to the survey was circulated through the participating clinics, and was open to patients and HCPs. The questionnaire collected sociodemographic information and comprised two sections corresponding to the two Round 1 strands: DHN competencies and implementation of the DHN role. The questionnaire was developed specifically for the present study and was not a previously published instrument. An English-language version is provided in Additional file 2. For the competency section, the original HDNT structure was retained. For the implementation section, the Round 1 content was reorganised into five subtopics for the Round 2 survey: DiGA-related training content, integration into patient care, the course of DiGA-based treatment, information resources, and the training framework.

Before inclusion in the questionnaire, overlapping content from Round 1 was consolidated. The 109 skills in the adapted HDNT were grouped into 97 broader competency statements, while 113 implementation statements were consolidated into 103 survey items. Competency statements were rated for perceived relevance as a training topic and for participants' self-assessed competence. Implementation items were rated for relevance to DHN implementation in the German healthcare system and for agreement with the statement.

Ratings were converted to numerical values and analysed using medians and standard deviations. Predefined thresholds for relevance, agreement, and consensus were used to determine inclusion and recommendation levels, as shown in Tables 3 and 4. No competency statement met the exclusion criterion and all 97 were therefore retained. Implementation items were classified according to their combined relevance, agreement, and level of consensus.

Table 3
Criteria for assigning recommendation levels to competency recommendations (based on relevance and consensus).

Recommendation level	Relevance (median)	Consensus on relevance (SD < 1.0)
1	> 2.5	yes
2	> 2.5	no
3	≤ 2.5	irrespective
Excluded	< 2	yes

Legend: Recommendation levels reflect the strength of each recommendation. Exclusion and level assignment were applied as two separate steps: a competency was first excluded only if rated irrelevant by consensus (relevance median < 2 and SD < 1.0); all remaining competencies were then assigned to levels 1–3 based on their relevance median (threshold 2.5) and consensus (SD < 1.0). Relevance was rated on a 0–4 scale. SD: standard deviation.

Table 4
Criteria for assigning recommendation levels to implementation recommendations (based on relevance, agreement, and consensus).

Recommendation level	Relevance (median)	Agreement (median)	Consensus (SD < 1.0)
1	> 2.5	> 2.5	On both relevance and agreement
2	> 2.5	> 2.5	On agreement only
3	> 2,5	> 2.5	On relevance only
Excluded	-	-	Consensually irrelevant (rel. median < 2, SD < 1), consensually not agreed (agr. median < 2, SD < 1), or no consensus on either criterion (SD ≥ 1 on both), or if relevance or agreement median did not exceed 2.5

Legend: Recommendation levels reflect the strength of each recommendation. Exclusion and level assignment were applied as two separate steps: a statement was first excluded if rated irrelevant or not agreed by consensus (relevance or agreement median < 2 with SD < 1.0), or if no consensus was reached on either criterion (SD ≥ 1.0 on both); all remaining statements were then assigned to levels 1–3 based on their relevance and agreement medians (threshold 2.5) and consensus (SD < 1.0). Relevance and agreement were rated on 0–4 scales. SD: standard deviation.

For five linked pairs of implementation items within the training-content topic area, the items addressed closely related aspects of the same implementation question. These pairs were therefore reassessed jointly when interpreting relevance and agreement ratings. Where one item in a pair met the predefined relevance criterion (median > 3, SD < 1), this relevance classification was also applied to the corresponding item. This procedure did not affect which items were ultimately included in the final recommendation catalogue.

Delphi Round 3: Consensus Refinement

Round 3 focused on implementation items for which consensus had not been reached in Round 2. Items with a standard deviation greater than 1 were considered non-consensual. Given the limited duration of the Round 3 session, a study team member (JSP) selected eight implementation items for further discussion based on the magnitude of disagreement and their thematic relevance. The selected items were discussed in a moderated online group session. For each item, the moderator presented the statement and the relevant survey results, followed by participant discussion of potential revisions. When the panel reached consensus, the wording of the corresponding recommendation was refined. No entirely new statements were generated in Round 3; however, previously excluded Round 2 items could be reformulated and retained if consensus was achieved. The session was audio-recorded and transcribed. Agreed-upon revisions were incorporated into the final recommendation catalogue. Recommendations with modified wording in Round 3 were assigned recommendation level 3, as the revised wording had not been quantitatively re-rated.

Results

Study Sample

Participation varied across rounds (see Table 5). Because participation in each round was voluntary and the Round 2 survey was completed anonymously, individual participants could not be tracked across rounds. Consequently, the total number of unique individuals could not be determined. Some participants contributed to several rounds, while others participated in only one round. The Round 2 survey, with the broadest participation, was completed by 26

respondents, 17 HCPs (65.4%) and 9 patients (34.6%). Sociodemographic data and digital health-related baseline characteristics could be obtained for 18 respondents who subsequently disclosed their survey participation (see Table 6). Most disclosed respondents reported little or no prior knowledge about DiGAs: 17 of 18 respondents (94.4%) rated their knowledge as none, very low, or rather low. At the same time, two thirds (12/18; 66.7%) had previously used self-management or wellbeing apps, and most respondents (14/18; 77.8%) rated their general competency in using digital applications as rather or very secure.

Table 5
Participant distribution across Delphi rounds.

Delphi Round	**Participants**		
	HCPs (incl. DHNs)	**Patients**	**Total**
Round 1			
Session 1	7	5	12
Session 2	6	3	9
Round 2 (survey)	17	9	26
Round 3	8	3	11

Legend: Overall participant numbers for Round 1 are not reported because participation overlapped across Session 1 and Session 2. DHNs: Digital Health Navigators. HCPs: healthcare professionals.

Table 6
Sociodemographic and digital health-related baseline characteristics of disclosed participants.

Characteristics	HCPs (n = 9)	Patients (n = 9)	Total (n = 18)
Gender			
Male	3 (33.3%)	4 (44.4%)	7 (38.9%)
Female	6 (66.7%)	5 (56.6%)	11 (61.1%)
Age			
<20 years	1 (11.1%)	0 (0%)	1 (5.6%)
20–35 years	2 (22.2%)	4 (44.4%)	6 (33.3%)
36–50 years	3 (33.3%)	2 (22.2%)	5 (27.8%)
51–65 years	3 (33.3%)	3 (33.3%)	6 (33.3%)
Ethnicity			
White	9 (100%)	8 (88.9%)	17 (94.4%)
PoC	0 (0%)	1 (11.1%)	1 (5.6%)
Subjective knowledge about DiGAs			
None	2 (22.2%)	3 (33.3%)	5 (27.8%)
Very low	2 (22.2%)	5 (55.6%)	7 (38.9%)
Rather low	4 (44.4%)	1 (11.1%)	5 (27.8%)
Rather high	1 (11.1%)	0 (0%)	1 (5.6%)
Usage of self-management or wellbeing apps			
Yes	6 (66.7%)	6 (66.7%)	12 (66.7%)
No	3 (33.3%)	3 (33.3%)	6 (33.3%)
Subjective competency level in using digital applications			
Very low	1 (11.1%)	0 (0%)	1 (5.6%)
Rather low	2 (22.2%)	1 (11.1%)	3 (16.7%)
Rather high	4 (44.4%)	6 (66.7%)	10 (55.6%)
Very high	2 (22.2%)	2 (22.2%)	4 (22.2%)
Subjective competency level in dealing with technical problems			
Try to solve it myself	3 (33.3%)	4 (44.4%)	7 (38.9%)
Seek help from others	2 (22.2%)	4 (44.4%)	6 (33.3%)
Use online help sources	2 (22.2%)	4 (44.4%)	6 (33.3%)
I rarely or never have technical problems	2 (22.2%)	0 (0%)	2 (11.1%)
Subjective competency to learn how to use new digital health applications			
Rather low	1 (11.1%)	4 (44.4%)	5 (27.8%)
Rather high	7 (77.8%)	2 (22.2%)	9 (50.0%)
Very high	1 (11.1%)	3 (33.3%)	4 (22.2%)

Legend: DiGA: prescribable digital health application; HCPs: healthcare professionals. PoC: person of color.

Among the 9 HCPs who disclosed their data, the most frequent professional group was nursing (4/9; 44.4%), followed by licensed psychological psychotherapists (2/9; 22.2%), with one trainee, one physician in training, and one medical assistant. Professional experience ranged from under five to more than 30 years (median 10–20 years). Notably, two-thirds had never prescribed a DiGA (6/9; 66.7%). Among the 9 patients, educational background varied, the most common being a (technical) university degree (3/9; 33.3%). Full-time employment and inability to work were equally frequent (each 3/9; 33.3%). Just over half reported current or prior psychiatric or psychotherapeutic treatment (5/9; 55.6%), and none had ever received a DiGA prescription (9/9; 100%).

Development of the recommendation catalogue

Figure 1 provides an overview of the three-round Delphi process. Overall, the process yielded 174 recommendations, comprising 97 competency and 77 implementation recommendations.

Legend: The competency pathway was based on the Harvard Digital Navigator Training (HDNT). Skills refer to observable behaviours and knowledge required for the Digital Health Navigator (DHN) role. In Round 1, the original 96 HDNT skills were adapted through replacement and addition of content, resulting in 109 skills overall, a net increase of 13. For Round 2, closely related skills were consolidated into 97 broader competency statements and rated for relevance; all 97 met the inclusion criteria and were retained. In parallel, 113 implementation statements generated during the Round 1 group discussions were consolidated into 103 survey items and evaluated for relevance and agreement in the Round 2 online survey. Based on predefined inclusion criteria, 73 survey items were retained and 30 were excluded. In Round 3, contested implementation items were revisited: three statements that had not met the Round 2 inclusion criteria were retained following reformulation, and one already represented item yielded an additional, differently worded recommendation. The final catalogue comprised 97 competency recommendations and 77 implementation recommendations (174 in total). DHNs: Digital Health Navigators; HDNT: Harvard Digital Navigator Training.

The HDNT required only minor adaptation

The original HDNT required only minor adaptation to the German healthcare context. In Round 1, participants agreed that all modules and competency areas of the original HDNT were relevant and should be retained. Of the 96 original skills, 92 (95.8%) were adopted without modification. Four skills were replaced by three new ones: the two HIPAA-related skills were replaced by skills on compliance with German data protection law, while the separate skills for depressive and anxiety disorders were consolidated into a single skill covering all mental health conditions addressed by DiGAs. Participants also proposed additional content in six existing competency areas and identified three new competency areas: account management, app authorisations, and behaviour in emergency situations. These additions resulted in nine new skills within existing competency areas and five skills within newly created competency areas. Following these adaptations, the revised HDNT comprised five modules, 49 competency areas and 109 skills (compared with 46 competency areas and 96 skills in the original HDNT; Fig. 2). Overall, the adaptations primarily focused on aligning with the German legal and regulatory context, expanding the clinical scope to encompass the diverse conditions addressed by DiGAs, and incorporating practical competencies relevant to app-based care.

A detailed overview of all adaptations is provided in Additional file 3.

- **Legend**: The competency framework was based on the Harvard Digital Navigator Training (HDNT). During Round 1, the original HDNT content was reviewed and adapted to the German healthcare context, yielding 5 modules, 49 competency areas (previously 46), and 109 skills (previously 96).

Perceived training needs differed markedly across competency areas

- In Round 2, almost all competencies were considered relevant, although consensus varied markedly between modules. Average item medians ranged from 3.1 to 3.9 on a 0–4 scale (Table 7), and 59 of 97 competencies (60.8%) met the predefined consensus criterion (SD < 1.0). Consensus was highest for app evaluation, basic technology troubleshooting, clinical terminology and data, and engagement techniques (80-88.9% of competencies), and lowest for basic smartphone skills (28.1%). Only nine competencies (9.3%) received a relevance median of 2 or lower. These competencies were limited to basic smartphone functions (e.g., creating playlists or playing media content) and highly specific app-related knowledge. Although a number of competencies did not reach consensus, no competency met the predefined exclusion criterion (consensus that the competency was irrelevant) and all 97 competencies were retained for the adapted training programme.
- Self-rated competence showed a contrasting pattern. Competencies related to app evaluation were rated as highly relevant but showed the lowest self-rated competence, whereas basic smartphone skills showed the highest self-rated competence despite lower consensus regarding their relevance. Average self-rated competence was 3.9 for basic smartphone skills and 2.0 for app evaluation. Within app evaluation, the lowest competence ratings concerned deletion of collected data, knowledge of data storage practices, and appraisal of scientific evidence supporting an application. Competence ratings for the clinical terminology and data and engagement modules were obtained from HCPs only.
- Based on the predefined inclusion criteria, all 97 competencies were retained in the recommendation catalogue: 59 (60.8%) were assigned to recommendation level 1, 28 (28.9%) to level 2, and 10 (10.3%) to level 3. Detailed results are provided in Additional file 4.

Table 7
Round 2 ratings by HDNT module and implementation topic.

HDNT modules	Items, n	Relevance ∅ median	Relevance consensus, n (%)	Self-rated competence ∅ median	Self-rated competence consensus n (%)
M1.1: Basic smartphone skills	32	3.1	9 (28.1%)	3.9	27 (84.4%)
M1.2: Health-related smartphone skills	14	3.3	8 (57.1%)	3.4	5 (35.7%)
M2: Basic technology troubleshooting	10	3.6	8 (80%)	2.9	0 (0%)
M3: App evaluation	25	3.6	20 (80%)	2.0	1 (4%)
M4: Clinical terminology & data	7	3.9	6 (85.7%)	2.9	6 (85.7%)
M5: Engagement techniques	9	3.8	8 (88.9%)	2.8	9 (100%)
Implementation topics	**Items, n**	**Relevance ∅ median**	**Relevance consensus, n (%)**	**Agreement ∅ median**	**Agreement consensus, n (%)**
Teaching content on DiGAs	26	3.1	14 (53.8%)	2.9	14 (53.8%)
Integration into patient care	14	3.4	12 (85.7%)	3.0	10 (71.4%)
Course of DiGA-based treatment	18	3.3	12 (66.7%)	2.9	8 (44.4%)
Information website	36	3.3	29 (80.6%)	3.3	27 (75%)
Training framework	9	3.0	5 (55.6%)	2.7	3 (33.3%)

 Self-rated competence assessed among HCPs only.

- **Legend**: Consensus = standard deviation < 1.0; ∅ median = mean of item medians (0–4 scale). DiGA: prescribable digital health application; HDNT: Harvard Digital Navigator Training; HCP: healthcare professional.

Implementation requirements extended beyond technical support

The implementation discussions in Round 1 centred on four themes: *Integration of the DHN into patient care, Integration of DiGAs into DHN training, Requirements for a DiGA information website*, and *Framework conditions for DHN training*. Across the discussions, a total of 113 statements were collected (n = 35, 16, 39, and 11 across the four themes, respectively, plus 12 additional statements), of which 51 (45.1%) were identified as particularly relevant. Participants noted that the DHN role should not be expected to provide unrestricted technical support. At the same time, they discussed basic patient-level technical competencies as a potential prerequisite for effective participation, highlighting a tension between feasibility and equitable access. They also discussed the breadth and depth of DiGA-specific knowledge required for the role. Patients generally favoured broader knowledge than HCPs considered feasible, while all groups agreed on the importance of hands-on experience with DiGAs. Regarding information resources, participants, particularly following the self-test on the official DiGA directory, recommended including user reviews (ideally from verified patients), a comparison function, and the ability to filter by all listed mental health conditions. Many participants indicated that existing information resources were challenging to navigate and frequently overwhelming. The primary area of disagreement involved competency assessment. Patients generally preferred structured assessment, while HCPs expressed concerns regarding feasibility. Case-based role plays were identified as a potential compromise.

An additional 12 statements addressed aspects beyond the predefined thematic areas, including the perceived motivational potential of DHN support and its influence on users' confidence in engaging with digital mental health applications. Detailed results are provided in Additional file 5.

Implementation recommendations showed broad support but persistent disagreement

In Round 2, implementation statements were generally considered relevant, with average relevance medians ranging from 3.0 to 3.4 on a 0–4 scale (Table 7). Consensus on relevance was reached for 72 of 103 statements (69.9%) and was most frequent for integration into patient care (85.7%) and information website requirements (80.6%). Agreement ratings showed greater variability, with consensus achieved for 62 of 103 statements (60.1%) and average agreement medians ranged from 2.7 to 3.3 across topics. Disagreement centred mainly on the expected scope of DiGA-related knowledge and on formal competency assessment. The requirement that DHNs should provide an overview of all available DiGAs received lower ratings and did not reach consensus, whereas a general overview of commonly used DiGAs received strong support and consensus. Similarly, statements on mandatory competency assessments generated divergent ratings. Applying the predefined inclusion criteria, 73 of 103 statements (70.9%) were retained in the recommendation catalogue, whereas 30 statements (29.1%) were excluded. Among the retained statements, 53 (72.6%) were assigned to recommendation level 1, and 20 (27.4%) to levels 2 and 3 combined. Detailed results are provided in Additional file 6.

These contested issues were revisited in Round 3 (Additional file 7). For reporting purposes, the eight most contested statements were grouped into five topics (Table 8). For four topics (the scope of DiGA-related knowledge, the boundaries of DHN technical support, information sharing between DHNs and HCPs, and communication routines within the care team) the statements were retained and reformulated for clarity. For the fifth topic, the assurance of DHN competence, no consensus was reached on formal assessment. The three examination-related statements had not met the inclusion criteria in Round 2 and were therefore not adopted to the catalogue. Instead, two already-retained recommendations were reworded to emphasize training design, practical exercises, and continuing professional development. The total number of implementation recommendations thus increased from 73 to 77. Three statements that had not met the Round 2 inclusion criteria were retained following reformulation, and one statement already represented in the catalogue yielded an additional, differently worded recommendation. The resulting recommendations are summarised in Table 8. The final catalogue is provided in Additional file 8.

Table 8
Final recommendations for contested implementation topics in Delphi Round 3.

Topic	Final recommendation
Scope of DiGA knowledge	DHNs should maintain a general overview of available DiGAs and possess detailed knowledge of at least one DiGA per indication.
Technical support responsibilities	DHNs should provide technical support only when directly related to the use of a DiGA.
Information sharing	Information may be shared with treating healthcare professionals based on patient consent obtained at the beginning of DiGA treatment.
Communication between DHNs and healthcare professionals	Communication should occur regularly but remain flexible and adapted to individual treatment needs.
Competency assurance	Competence should be ensured through training design (e.g., case-based simulations and practical exercises) and maintained through continuing education rather than formal examinations.

Legend: DHN: Digital Health Navigator; DiGA: prescribable digital health application.

Discussion

Principal findings

- This study adapted the HDNT to the German healthcare context and developed stakeholder-informed recommendations for implementing DHNs in mental healthcare. A central finding is that the core DHN model [24, 25] required only minor adaptation: most original content was retained, while modifications primarily concerned country-specific legal requirements, particularly regarding data protection, alongside several mental-health specific additions. This suggests that many core DHN competencies may be relatively stable across healthcare settings, whereas regulatory, organisational, and care-pathway-related competencies require local adaptation. This is consistent with the international expansion of the DHN concept across diverse settings and health systems [26, 28, 39].

Additionally, the findings indicate that the DHN role encompasses responsibilities beyond technical support. Participants highlighted the importance of coordination, communication, and facilitation within digital mental healthcare. These results are consistent with previous descriptions of DHN roles, which emphasize their function as facilitators of digital care rather than solely as providers of technical assistance [25, 40]. This is particularly relevant given that current mental health DiGAs frequently lack manufacturer-provided human guidance, with DHNs proposed as a means to address this support gap [41]. In practice, DHNs may help bridge the gap between prescribing a DiGA and its sustained use by supporting onboarding, addressing barriers, and maintaining communication between patients and treatment teams. However, whether this leads to higher uptake, adherence, or clinical benefit requires empirical evaluation.

- A second key finding concerns the mismatch between perceived relevance and self-rated competence across competency modules. App evaluation was rated as highly relevant, yet participants reported the lowest self-rated competence in this area, particularly regarding data deletion, data storage practices, and appraisal of scientific evidence. In contrast, basic smartphone skills were associated with high self-rated competence although there was lower consensus regarding their relevance. This finding aligns with previous research indicating that general technology use does not necessarily translate into the knowledge needed to identify and evaluate mental health apps [42]. These results suggest that future DHN training should prioritize the critical evaluation of DTx over basic technology use. This focus is particularly important given the rapidly changing quality and availability of mental health apps [43].
- The Delphi process also revealed unresolved questions about the scope of DiGA-related knowledge and competency assurance. Participants supported a general overview of commonly used DiGAs combined with detailed knowledge of at least one DiGA per indication, but no consensus emerged for formal examinations. Instead, participants supported ensuring competency through training design, practical exercises, and ongoing professional development. This approach aligns with recent DHN training methods which emphasize practical exercises and competency-based assessment [44] The disagreement appears to concern the form of competency assurance rather than its necessity. The recommendation favors integrating competency

assurance into training and professional development instead of relying on separate examinations. However, the effectiveness of this approach in maintaining consistent competence across various training settings remains unproven. Future research should therefore examine how training-based competency assurance can be operationalised and whether additional assessment or certification mechanisms are needed to ensure comparable training quality across settings.

- Taken together, the findings largely confirm existing international work on DHN roles [24, 28] while extending it through detailed recommendations for implementation within a publicly funded mental healthcare system. Implementing DHNs in Germany does not require the development of an entirely new role, but the operationalisation of an existing model within local care structures. The competency framework required minimal adaptation. Greater uncertainty remains regarding DHN training, integration into treatment teams, and support for evaluating rapidly changing digital interventions. The primary contribution of this study is not the definition of new DHN competencies, but the development of a structured implementation framework that connects individual competencies with training requirements, organisational processes, and information infrastructure. This framework serves as a foundation for future feasibility testing and evaluation in routine care.

Implications for practice

- Three priorities have been identified for implementing DHNs in routine mental healthcare. First, DHNs should be integrated into existing treatment structures rather than functioning as independent technical support roles. Implementation models must define communication routines between DHNs and HCPs, clarify role boundaries, and establish procedures for managing patient-related information generated through the use of DiGAs. Second, future DHN training programmes should emphasise competencies in app evaluation, data management, and evidence appraisal. Although basic smartphone skills remain important for ensuring a minimum level of technical competence, the most significant training need identified in this study is the ability to critically evaluate DiGAs. Third, DHNs require accessible, user-oriented information resources to facilitate comparison and selection of DiGAs. Overall, these findings indicate that successful implementation will rely more on organisational integration, evidence appraisal, and access to reliable information than on basic technical proficiency.

Implications for research

- The practical feasibility and effectiveness of these recommendations remain to be evaluated. A companion feasibility study within the DigiNavi project offers initial evidence for the role: trained medical assistants provided DHN support with limited time investment, and more frequent DHN contact correlated with higher DiGA use and improved clinical outcomes [45]. However, the single-arm, exploratory design does not allow for causal conclusions. The next step is to determine whether the prioritised competencies and implementation strategies lead to better DHN performance and increased patient engagement with DiGAs. Future controlled studies should assess uptake, adherence, continued use, clinical outcomes, and workload, as these outcomes address the implementation gap identified in this study. Several implementation questions remain, including the optimal scope of DiGA-related knowledge, the effectiveness of training-based competency assurance, and the need for additional formal assessment or certification. Future research should examine which quality assurance approaches are both acceptable and effective, and how different training models influence DHN competence, implementation success, and workload. While many recommendations may apply beyond Germany, some are specific to the German DiGA framework. Comparative studies across healthcare systems could help identify which DHN competencies are broadly transferable and which require adaptation to local regulations or organisational structures.

Strengths and limitations

- This study has several strengths. First, the Delphi process included both patient and HCP perspectives, ensuring recommendations reflect lived experience and professional expertise. Second, combining qualitative and quantitative Delphi methods allowed participants to generate, prioritise, and refine recommendations over multiple rounds. Third, the study produced a concrete recommendation catalogue to directly inform future training and implementation.
- Several limitations should be noted. The sample size was relatively small, participation varied across rounds, and purposive recruitment limits generalisability. Because the Round 2 questionnaire was anonymous, participants could not be fully tracked across rounds, resulting in a partially overlapping Delphi panel. Competence ratings for the clinical terminology and data and engagement modules were obtained from HCPs only. Most participants of Round 2 who had available baseline data had little or no prior experience with DiGAs. This may have affected their assessment of DiGA-specific competencies, although this itself reflects the implementation gap that motivated the study. Additionally, the discussions indicated that patients might require a minimum level of technical competence for effective participation, thus leading to a possible conflict between the feasibility of implementation and equitable access for patients who have lower digital skills. Some HCPs and prospective DHNs were recruited from settings involved in the subsequent implementation of the DHN role, potentially introducing implementation-related bias. Furthermore, the study was conducted within a specific regional and organisational context, limiting transferability to other settings. Finally, the recommendations have not yet been evaluated in clinical practice.

Conclusion

- The HDNT could be adapted to the German mental healthcare context with only minor modifications, suggesting that it may be broadly transferable across healthcare systems. Successful implementation, however, appears to depend less on basic technical skills than on the ability to evaluate digital interventions, support patients during use, and integrate the DHN role into existing treatment structures. The resulting recommendation catalogue provides a practical framework for implementation. Future research should test whether these recommendations improve DHN competence, patient engagement with DiGAs, and integration of digital interventions into routine care.

Declarations

Ethical approval and consent to participate

The study was approved by the Ethics Committee of the Brandenburg Medical School (MHB) (reference number: 218062024-BO-E) and registered at the German Clinical Trials Registry (DRKS) (DRKS00034327), and at ClinicalTrials.gov (NCT06575582). The study was conducted in accordance with the Declaration of Helsinki and all relevant guidelines and regulations. All participants were informed about the content of the study (both verbally and in writing) as well as the possibility to withdraw their consent at any given time. Written informed consent to participate was obtained from all participants prior to study participation.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Author Contribution

All authors contributed to planning, analysis, and the critical interpretation of the findings. JS developed the study design and supervised the study. JSp was responsible for data collection. JSp contributed to the data analysis. EMD and LF wrote the first draft of the manuscript. Successive drafts were revised by LF, EMD 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.

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Data Availability

The data supporting the findings of this study are included within the article and its additional files. Further data are available from the corresponding author on reasonable request.

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Figures

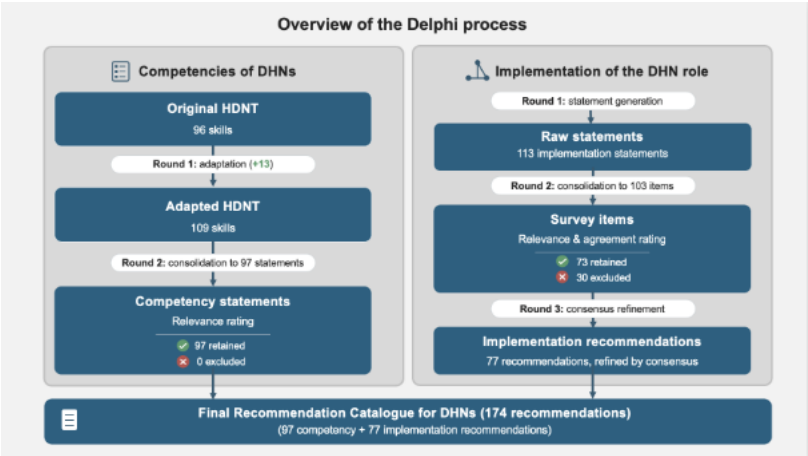

Figure 1

Overview of the Delphi process and development of the final recommendation catalogue.

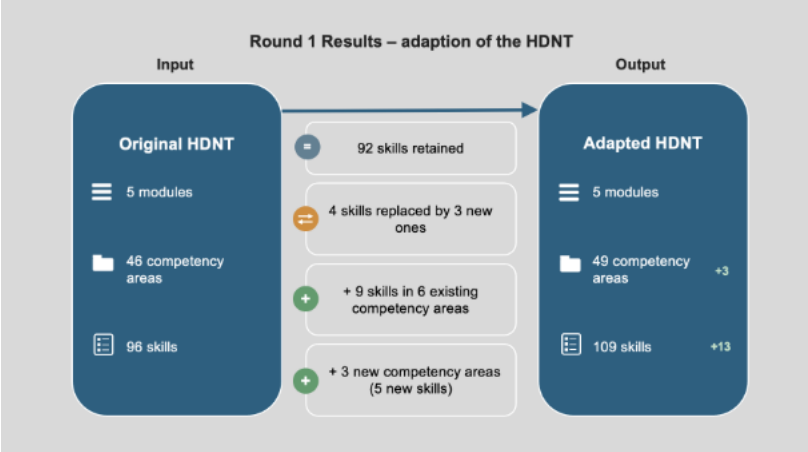

Figure 2

Summary of the results of the HDNT topic block from the first Delphi round.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Additionalfile1SRQRChecklist.pdf
- Additionalfile2Round2QuestionnaireEN.pdf
- Additionalfile3ResultsDelphiRound1Competencies.pdf
- Additionalfile4ResultsDelphiRound2Competencies.pdf
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