

Round 2 Questionnaire (English Translation)

Adapting the Digital Health Navigator Role for Prescription-Based Digital Therapeutics in Germany: A Modified Delphi Study with Participatory Design Elements

Translator's note

This questionnaire was administered in German to participants in Delphi Round 2 of the DigiNavi study. The following is an English translation provided for reference. Response scales, which were identical for every item within a given table in the original instrument, are described once at the start of the relevant section rather than repeated for each item.

1. Introduction

Welcome

Dear Sir or Madam,

Welcome to the prioritisation of training content for Digital Health Navigators (DHNs).

This questionnaire draws on the findings of the first two adaptation workshops, held on 9 and 23 October. These workshops addressed, among other topics, the concept of the DHN, its implementation in Germany, and digital health applications (DiGAs).

Participation in the adaptation workshops is not a prerequisite for completing this questionnaire. Key terms used throughout are defined below.

Background and Purpose of the Questionnaire

The two preceding workshops already generated a wealth of insights into the concept of the DHN and the associated training. This questionnaire has two aims:

1. To determine which of these insights you consider particularly important.
2. To identify topics that still require further discussion.

There are no right or wrong answers - only your opinion matters.

The results of this questionnaire will inform the further development of the training content for DHNs and will shape the content of the third adaptation workshop on 6 November 2024.

Definitions

Digital health application (DiGA):

Digital health applications (DiGAs) are certified, CE-marked apps or web-based programmes that help manage mental or physical health problems, e.g. depression, anxiety disorders, or sleep problems. They are typically accessible via smartphone or computer. This study focuses specifically on DiGAs for mental health conditions. Whenever this questionnaire refers to DiGAs, it refers to those used to treat mental disorders (26 in total at the time of the survey).

Digital Health Navigator (DHN):

Digital Health Navigators (DHNs) are specially trained professionals (e.g. medical assistants) who support patients and clinicians in the selection and use of DiGAs. DHNs are available to both patients and clinicians for questions and (technical) problems, and provide continuous support to patients throughout DiGA use. DHNs are already established in the United States, whereas no comparable role currently exists in German healthcare.

Instructions

Participation in this questionnaire is anonymous. Your responses cannot be traced back to you. Please read each task carefully before responding.

2. Sociodemographic Data

Before addressing the workshop content, we ask for some sociodemographic information for the statistical analysis of the questionnaire.

Question	Response options
Which group do you represent in this study?	Patient
	Clinician (HCP)
	Prospective DHN (trainee)
How old are you?	under 20 years
	20–35 years
	36–50 years
	51–65 years
	older than 65 years
What is your gender?	Male
	Female
	Diverse

3. Part I: HDNT Training Content

The first section of the questionnaire addresses the training content for DHNs. This content is organised into five thematic modules. Each module is divided into individual competencies that a DHN should master, according to current evidence.

Rating scale used throughout this section. For each item, participants rated two criteria:

Relevance: “How relevant do you consider this item for the role of the DHN?” (not at all relevant / rather not relevant / unable to assess / rather relevant / very relevant)

Self-rated competence: “How would you rate your own competence in this item?” (not present / low / unable to assess / high / I am competent in this area)

Module 1.1: Basic smartphone skills

This part covers general smartphone basics. The competencies in this module may appear very simple or trivial; however, they represent the fundamentals of smartphone use on which many further DHN competencies are built. DHNs should also be able to support patients with these matters.

Item ID	Competency
1_H1_101	Understanding the difference between Wi-Fi and mobile data
1_H1_102	Connecting to Wi-Fi
1_H1_103	Downloading an app
1_H1_104	Making a call
1_H1_105	Answering a call
1_H1_106	Declining a call
1_H1_107	Writing a new message
1_H1_108	Replying to a message
1_H1_109	Sending pictures and videos
1_H1_110	Sending messages to a group
1_H1_111	Performing an internet search
1_H1_112	Navigating to a specific web address
1_H1_113	Viewing browser history
1_H1_114	Different apps for listening to music
1_H1_115	Playing a specific song
1_H1_116	Creating a playlist
1_H1_117	Taking a photo

Item ID	Competency
1_H1_118	Recording a video
1_H1_119	Creating a new note
1_H1_120	Editing a note
1_H1_121	Setting a reminder
1_H1_122	Setting an alarm
1_H1_123	Setting up “bedtime” mode
1_H1_124	Setting a timer
1_H1_125	Creating a new calendar entry
1_H1_126	Setting an alert for a calendar entry
1_H1_127	Editing a calendar entry
1_H1_128	Viewing steps taken
1_H1_129	Recording distance walked or run
1_H1_130	Viewing sleep data
1_H1_131	Creating user accounts
1_H1_132	Changing user account settings

Module 1.2 – Health-related smartphone skills

This part builds on Module 1.1 and addresses how basic smartphone skills can be applied for the purpose of mental health. As above, these competencies may appear simple, but they represent basics on which further DHN competencies are built.

Item ID	Competency
1_H1_201	Guided meditation via smartphone
1_H1_202	Talking to family
1_H1_203	Talking to telephone support services
1_H1_204	Watching videos
1_H1_205	Finding mindfulness exercises
1_H1_206	Researching reliable sources
1_H1_207	Finding podcasts

Item ID	Competency
1_H1_208	Creating playlists
1_H1_209	Photos and videos for mental health
1_H1_210	Notes for mental health
1_H1_211	Creating a routine
1_H1_212	Creating a schedule
1_H1_213	Exercise and mental health
1_H1_214	Creating an email account

Module 2: Digital troubleshooting

This module addresses solving digital problems. The competencies are named after the problems they address. Having completed a competency unit, a DHN should be able to independently resolve the problem in question, or assist patients in doing so.

Item ID	Competency
1_H2_001, 1_H2_002	Problems downloading an app
1_H2_003	Unknown user account or password
1_H2_004, 1_H2_005	Insufficient storage space on the smartphone
1_H2_006	App compatibility problems
1_H2_007, 1_H2_008	Internet connection problems
1_H2_009	Notification problems
1_H2_010	App crashes
1_H2_011, 1_H2_012, 1_H2_013	Bluetooth connection problems with other devices (e.g. headphones, smartwatch, ...)
1_H2_014	Resetting a password
1_H2_015, 1_H2_016	App permission problems

Module 3: App evaluation

This module addresses the evaluation of apps in general, not the evaluation of DiGAs specifically - the rationale being that DHNs should also be able to recommend other apps useful for mental health, such as meditation or nutrition apps. The competencies address individual criteria by which an app can be evaluated.

Item ID	Competency
1_H3_001	Cost of the app
1_H3_002	App developer
1_H3_003	Platforms on which the app can be used
1_H3_004	When the app was last updated
1_H3_005	User reviews of the app
1_H3_006	Test access for DHNs and HCPs
1_H3_007	Data protection provisions
1_H3_008	What data the app collects
1_H3_009	Option to opt out of collection of individual data
1_H3_010	Having data collected by the app deleted
1_H3_011	Sharing of collected data with third parties
1_H3_013	Compliance with data protection laws and regulations
1_H3_014	How collected data is used
1_H3_016	Where data is stored
1_H3_017	Who has access to which data
1_H3_018	Functions of the app
1_H3_019	Scientific evidence for the app's benefit (peer-reviewed evidence)
1_H3_020	Potential risks of using the app (e.g. potential for dependency, adverse effects when used with comorbidities, ...)
1_H3_021	Customisation options within the app (e.g. adapting exercises to the patient's abilities, creating an individual treatment plan, ...)
1_H3_022	Accessibility of the app for patients with impairments (e.g. colour-blind mode, read-aloud content, ...)
1_H3_023	Usability of the app (e.g. clarity, comprehensibility, intuitiveness, ...)
1_H3_024	Mechanisms within the app for patients' acute psychological emergencies
1_H3_025, 1_H3_015	How the DHN or HCP can access data collected by the app
1_H3_026	Option to download data collected by the app
1_H3_027	Options for interoperability with other applications (e.g. transferring data such as heart rate or sleep from a smartwatch into the app)

Module 4: Clinical knowledge and data

This module addresses both clinical knowledge and information on data.

Item ID	Competency
1_H4_004	Mental disorders and problems treatable with DiGAs, and their symptoms
1_H4_003	Common mental and somatic comorbidities
1_H4_005, 1_H5_011	Warning signs indicating an acute mental health crisis
1_H4_006, 1_H5_011	When DHNs need to seek help
1_H4_007, 1_H5_011	Where DHNs can seek help
1_H4_008, 1_H4_010	Working in compliance with data protection regulations
1_H4_011, 1_H4_012	Types of data and when they are collected

Module 5: Interaction techniques

This module addresses interaction techniques that DHNs may need when working with patients and the medical team.

Item ID	Competency
1_H5_001	How to politely ask patients to clarify or specify their concern
1_H5_002	How to ask open, non-leading questions
1_H5_003	Motivational interviewing, i.e. communication techniques to build intrinsic motivation for behaviour change
1_H5_004	Referring patients to appropriate services when problems arise
1_H5_006	Recognising and communicating one's own limits and the limits of the support provided
1_H5_007	Recognising when patients need help and providing assistance
1_H5_008	Understanding one's role as a DHN within the medical team
1_H5_009	Basics of trauma-focused therapeutic approaches
1_H5_010	Clear documentation of patient data and communication within the medical team

4. Part II: Discussion Results (Implementation Statements)

The second section of the questionnaire addresses statements collected during the first two adaptation workshops. These statements were grouped into five thematic areas: (1) training content on DiGAs for mental disorders; (2) collaboration between DHNs, patients, and the medical team; (3) course of DiGA-based treatment; (4) framework conditions for the DHN concept; and (5) website for DiGAs. The topics are addressed one at a time.

Rating scale used throughout this section. For each statement, participants rated two criteria:

Agreement: "To what extent do you agree with this statement?" (strongly disagree / disagree / neither agree nor disagree / agree / strongly agree)

Relevance: "How relevant do you consider the topic addressed by this statement?" (not at all relevant / rather not relevant / unable to assess / rather relevant / very relevant)

Training content on DiGAs

Unlike the original concept, the focus of DHNs in Germany is not on health apps in general but specifically on DiGAs, which therefore need to be integrated into DHN training. For the purposes of this study, DiGAs refer exclusively to those used to treat mental disorders (26 currently exist).

Item ID	Statement
2_1_001	DHNs should be familiar with the prescription and redemption process for DiGAs.
2_1_002	DHNs must know how to process data collected by DiGAs (e.g. to create reports for the medical team/HCP).
2_1_003	DHNs should be able to familiarise themselves independently with DiGAs.
2_1_004	It is sufficient for DHNs to have particularly good knowledge of at least one DiGA per condition for which a DiGA exists.
2_1_005	A basic understanding of data processing in DiGAs is entirely sufficient for the role of the DHN.
2_1_006	DHNs must be able to provide an overview of commonly used DiGAs.
2_1_006	DHNs must be able to provide an overview of all DiGAs.
2_1_007	DHNs must have knowledge of commonly used DiGAs that goes beyond a general overview.
2_1_007	DHNs must have knowledge of all DiGAs that goes beyond a general overview.
2_1_008	DHNs should know the content of commonly used DiGAs.
2_1_008	DHNs should know the content of all DiGAs.
2_1_011, 1_7_005	DHNs should be able to install and set up commonly used DiGAs.
2_1_011, 1_7_005	DHNs should be able to install and set up all DiGAs.
2_1_012, 1_7_003	DHNs should have gained personal experience with commonly used DiGAs.
2_1_012, 1_7_003	DHNs should have gained personal experience with all DiGAs.

Item ID	Statement
2_1_013	If a DHN has only limited knowledge of a DiGA, this reduces confidence in the DHN's competence.
2_1_014	DHNs should be familiar with the evidence base for a DiGA.
2_1_015	DHNs should have knowledge of the indications and contraindications of a DiGA.
2_1_016	DHNs should be required to know DiGA-specific information on data processing/security.
2_1_009	Given the large number of DiGAs, it is sufficient for DHNs not to have in-depth knowledge of all DiGAs.
1_7_001	DHNs should be able to support both Android and iOS devices.
1_7_002	Training for DHNs should focus on technical support related to DiGAs.
1_7_004	Beyond their training, DHNs should have access to a user account for all DiGAs in order to test and evaluate them.
1_7_006	DHNs should be able to explain treatment plans created within DiGAs.
1_7_007	DHNs should be able to recall knowledge about DiGAs without much deliberation.
1_7_008	Where there are gaps in their knowledge of DiGAs, DHNs should have the competence to fill them independently.

Collaboration between DHN, patients, and the medical team

The creation of a new role within the medical team raises the question of how this role should be integrated. Two aspects are relevant: collaboration between the DHN and patients, and collaboration between the DHN and the medical team. The following statements address both aspects.

Item ID	Statement
1_6_001, 1_6_003	Knowledge about DiGAs should be shared by the DHN within the medical team (e.g. during team meetings).
1_6_002	HCPs should have an overview of DiGAs, just as they have an overview of the medications they prescribe.
1_6_004	The DHN should be able to provide more in-depth knowledge about a DiGA on an individual, as-needed basis.
1_6_005	The DHN must not make decisions regarding diagnosis.
1_6_006	The DHN must not make decisions regarding treatment planning; this responsibility always lies with the HCP.
1_6_007	The DHN should maintain a neutral stance towards patients and their data.
1_6_008	The DHN should show a benevolent, supportive attitude towards patients.
1_6_009	The DHN should ensure a positive and motivating atmosphere during meetings with patients.
1_6_010	The DHN should be sensitive to patients' level of functioning and adapt their interaction accordingly.
1_6_011	The DHN should base their interaction with patients solely on the patient's diagnosis.
1_6_012	A good rapport and relationship of trust between the DHN and the patient is considerably more important than the DHN's knowledge of mental disorders.

Item ID	Statement
1_6_013	The DHN's technical competence is just as important as their interpersonal skills with patients.
1_7_009	DHNs are only obliged to provide technical support insofar as it contributes to treatment of the condition.
1_7_012	Patients should have access to information materials covering common technical problems and their solutions.

Course of DiGA-based treatment

In addition to the form of collaboration between the DHN, patients, and the medical team, the course of the shared treatment process is also relevant. This is addressed in the following statements.

Item ID	Statement
1_6_015, 1_6_014	Prerequisites patients need in order to use DiGAs include the necessary resources (e.g. a suitable device, internet connection) and motivation.
1_6_017	The possibility of patients' devices being incompatible with the DiGAs on offer is a realistic barrier.
1_6_018	It should be possible to lend devices to patients for the duration of DiGA-based treatment.
1_6_021	Before the first joint meeting, DHNs should have been briefed by the HCP about the patient and their condition.
1_6_022	Before the first joint meeting, the DHN should have been informed about the patient and their condition via a questionnaire completed by the patient.
1_6_023	The first meeting between the DHN and the patient should be used for installing, setting up, and introducing the prescribed DiGA.
1_6_024	Meetings between the DHN and the patient should be documented by the DHN.
1_6_025	Relevant data from the DiGA used by the patient should be documented by the DHN.
1_6_026	Documentation of meetings between the DHN and the patient should only take place with the patient's consent.
1_6_027	Forwarding information from meetings between the DHN and the patient to the HCP should only take place with the patient's consent.
1_6_028	Before meeting a patient, the DHN should be informed by the HCP about the patient's psychological wellbeing.
1_6_029	The DHN reviews the data collected via the DiGA together with the patient.
1_6_030	Before meeting a patient, the HCP should be informed by the DHN about the patient's psychological status.
1_6_031	There is no need for a fixed schedule for the HCP and the DHN to exchange information about the patient.
1_6_032	Data collected via DiGAs should inform the patient's treatment.
1_6_035	The patient, the DHN, and the HCP should meet together to select a DiGA.
1_6_033	The process by which a patient is enrolled in DiGA-based treatment should be determined individually by each clinic.
1_6_034	The following process would be a reasonable example for enrolling a patient in DiGA-based treatment: 1. The HCP identifies the patient's potential for DiGA-based treatment. 2. The DHN assesses the patient for the presence of the required technical competence.

Item ID	Statement
	4. The DHN reports back to the HCP and, where appropriate, provides a DiGA recommendation. 5. The HCP prescribes the DiGA. 6. Treatment with the DiGA begins.

Framework conditions for the DHN concept

A further aspect relevant to implementing the DHN role concerns the framework conditions of its establishment, including the organisation of training, the definition of content, and competency assessment. The following statements relate to these points.

Item ID	Statement
2_4_001	Attending training courses or continuing education is a fully sufficient qualification for the role of DHN.
2_4_002	Manufacturers of DiGAs should be expected to contribute, at least in part, to the training costs of DHNs.
2_4_003, 2_4_004	A competency assessment should take place as part of DHN training.
2_4_005	Combining DHN training with an assessment would reduce interest in the training.
2_4_006	A competency assessment would set too high a barrier for the role of DHN.
2_4_007	Case studies and scenario-based exercises during training already ensure the competence of DHNs.
2_4_009	Mandatory continuing education should ensure the ongoing competence of DHNs.
2_4_010	Competency assessments should take place as part of continuing education for DHNs.
2_4_011	Continuing education for DHNs should be delivered online.

Website for DiGAs

In addition to the role of the DHN, the design of a website for DiGAs was discussed. The following statements summarise the results of the workshop discussions and describe what an ideal website for digital health information (referred to below as 'the website') could look like.

Item ID	Statement
2_3_009	The website should also work well on smartphones.
2_2_014	The website should include information on the prescription and redemption process for DiGAs.
2_2_005	There should be a separate website for patients and professionals.
2_3_004	There should be a separate view of the website for patients and professionals.
2_3_021	There should be an option to display the website in plain language (e.g. no technical terms for conditions).

Item ID	Statement
2_3_005	The website's design should intuitively guide users on how to search for a DiGA.
2_2_001	The website should include an overview of the conditions for which DiGAs exist.
2_2_002	Selecting a condition should lead to an overview of all DiGAs used to treat it.
2_2_003	The website should allow DiGAs with the same indication to be listed together.
2_2_015	DiGAs should be findable via a search function.
2_2_016	DiGAs should be findable via a filter function.
2_3_001	A filter function should allow users to distinguish between different mental disorders.
2_3_002	A filter function should be designed so that all filter options are visible at a glance.
2_3_020	A filter function should be designed so that users can always see which filter settings they have selected.
2_2_017, 2_3_018	The website should allow direct comparison between DiGAs.
2_3_019	DiGAs should be comparable in a table based on hard facts such as platform, indication, and functions (e.g. similar to an Amazon product comparison).
2_3_006	The website should include recommendations for DiGAs.
2_3_022	An advisory function should guide users to recommended DiGAs by having them answer a series of questions.
2_2_004	There should be a detail view listing all relevant information about a DiGA.
2_3_010	The detail view of a DiGA should convey a sense of what using it is like, e.g. through a demo or screenshots.
2_2_006, 1_7_010	The website should include a pros/cons list for each DiGA.
1_7_011	The evaluation of DiGAs should preferably be presented in words rather than through point-based rating systems.
2_3_017	The PZN (German pharmaceutical central number) of a DiGA should be easy to find.
2_3_014	Stating the manufacturer's price of a DiGA is misleading/unsettling and should therefore be explained.
2_3_015	Stating the manufacturer's price of a DiGA is misleading/unsettling and should therefore not be listed.
2_2_007	The website should indicate any additional equipment required for a DiGA (e.g. VR headset, heart rate monitor, ...).
2_2_008	The website should indicate the time investment required to use a DiGA.
2_3_011	Descriptions of DiGAs on the website should not be written by their manufacturers, in order to avoid the risk of advertising.
2_3_012	Descriptions of DiGAs on the website should be as neutral and scientifically grounded as possible, presented in a sober manner.
2_3_003	Information for professionals should be listed after information for patients in the description of a DiGA.
2_2_009, 2_3_016	The website should display user reviews for each DiGA.
2_2_010	Displaying app-store user reviews for each DiGA on the website would be sufficient.

Item ID	Statement
2_2_011	User reviews displayed on the website should only be able to be submitted via the website itself.
2_2_012	User reviews displayed on the website should be verified beforehand to ensure their quality.
2_2_013	User reviews displayed on the website should have been verified beforehand by DHNs.

5. Closing

Thank you very much for your participation!

Should you have any questions or comments regarding this questionnaire, please contact the study team.