IMMERSE

Implementing Mobile MEntal health Recording Strategy for Europe
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Contents

List of Tables

List of Figures

List of Abbreviations

BE	Belgium
CIMH	Zentralinstitut für seelische Gesundheit, Mannheim / Central Institute for Mental Health
DE	Germany
DMMH	Digital Mobile Mental Health
DPA	Data Protection Act
ESM	Experience Sampling Monitoring
FAIR	findable, accessible, interoperable, reusable
ISCED	International Standard Classification of Education
IMMERSE	Implementing Mobile MEntal Health Recording Strategy for Europe
KUL	Katholieke Universiteit Leuven / Catholic University of Leuven
MTUAS	Media and Technology Usage and Attitudes Scale (Rosen, Whaling, Carrier, Cheever, & Rokkum, 2013)
NASSS	Non-Adoption, Abandonment, Scale-up, Spread, and Sustainability framework (Greenhalgh et al., 2017)
NHS	National Health Service
NPO	Non-Profit Organisation
ORCA	Organizational Readiness to Change Assessemnt Tool (Helfrich, Li, Sharp, & Sales, 2009)
PZN	Psychiatrisches Zentrum Nordbaden / Psychiatric Centre North Baden
PSS	Perceived Stress Scale (Warttig, Forshaw, South, & White, 2013)
SDM-Q	Shared Decision Making Questionnaire (Scholl, Kriston, Dirmaier, Buchholz, & Härter, 2012; Rodenburg-Vandenbussche et al., 2015)
SHARE	The Scottish Health Research Register and Biobank (McKinstry et al., 2017)
SK	Slovakia
SKH	Sint Kamillenhuis Hospital
SMHRN	Scottish Mental Health Research Network
SUS	System Usability Questionnaire (Brooke, 2013)
TCU CJ-PTN	Texas Christian University Criminal Justice Survey of Program Training Needs (of Behavioral Research, 2003)
TCU ORC-D4	Texas Christian University Organizational Readiness for Change (of Behavioral Research, 2009)
UEDIN	University of Edinburgh
UHEI	Ruprecht-Karls-Universität Heidelberg / Heidelberg University
UK	United Kingdom
UKHD	Universitätsklinikum Heidelberg / University Clinic Heidelberg
UNLP	Univerzitná nemocnica L. Pasteura Košice / Louis Pasteur University Hospital Košice
UPC	Psychiatric University Hospital, KU Leuven
UPJS	Univerzita Pavla Jozefa Šafárika v Košiciach / Pavel Jozef Šafárik University Košice

Summary

In this document, we describe IMMERSE Phase I, an extensive user consultation which consisted of two parts, a survey study (Part A) and an interview study (Part B). We outline the design of each part, discuss how the data were collected and prepared for further scientific analysis, and present preliminary findings that are relevant for the implementation of IMMERSE Phase II, a randomised controlled trial of DMMH. Overall, the implementation strategies that were designed for DMMH were validated by our findings. Some aspects, such as a detailed handbook, were not of interest to users, but are required as part of specifying the intervention. Having access to people who can support DMMH users, is crucial. Findings were contextualised using an implementation science framework that is specifically aimed at eHealth, the NASSS (Non-Adoption, Abandonment, Scale-Up, Spread, and Sustainability) framework (Greenhalgh et al., 2017). We end with a summary of lessons learned for Phase II. The deliverable will be complemented by documentation of the final data sets for Part A and Part B, released through the Open Science Framework, and our scientific publications, which are coordinated by the IMMERSE Steering Committee.

1. Introduction

Using Experience Sampling Methodology (ESM), people who live with mental illness can log their current mood and symptoms together with the context in which they experience them, such as activities or location. If the person is seeing a mental health care professional, the aspects that are logged can be easily adapted to align with important therapy goals and key problem areas in daily life (Myin-Germeys et al., 2009; Myin-Germeys et al., 2018). Within research settings, it has been shown that ESM can improve mental health and quality of life, encourage social participation, scaffold shared decision making in therapy, support the attainment of personalised therapy goals, and increase engagement with mental health services.

The IMMERSE team will deploy an ESM-based digital intervention, DMMH (Digital Mobile Mental Health), in four countries in a randomized controlled trial (RCT), to study the implementation of an ESM-based approach in routine mental health care.

In this deliverable, we report on an extensive user requirements study for DMMH that had three objectives:

1. To identify barriers, facilitators, and catalysts that might affect the implementation of DMMH in routine mental health care in four countries
2. To investigate planned implementation strategies for DMMH at each site where it will be deployed
3. To determine actionable requirements to ensure good user experience of the DMMH.

We developed a set of questionnaires and interview schedules that were used for data collection in all four countries of IMMERSE, covering all participating field sites and as many of the clinical units that will take part in the final RCT as possible. This approach allowed us to determine shared contextual factors and highlight differences that require context-specific tailoring.

The study covered four key stakeholder groups:

Service Users: Service users are adults who are able to provide informed consent and are treated for a mental disorder at one of the participating clinical sites.

Clinicians: Clinicians are mental health professionals that provide care for service users with a mental disorder at one of the participating clinical sites.

Supporters: Supporters are adults who provide informal care and support for a service user who is in treatment at one of the included sites.

Administrators: Administrators are people who are involved in the administration of the participating clinical sites. These can be managers, clinicians whose main responsibility is managerial (e.g., clinical team leads or directors), people who work in the administrative hierarchy, people who work on the sites' information technology infrastructure.

The study was designed to provide data for three tasks, T5.1 and T5.2 from work package 5 (Stakeholder Experience), and parts of T7.1 from work package 7 (Implementation). This combination allowed us to work more efficiently, since all relevant information was collected in one large study. We call this study **IMMERSE Phase I**, while the main RCT represents IMMERSE Phase II.

While the original versions of T5.1 and T5.2 were scoped to collect data by country through a wide variety of channels, the study reported in this Deliverable intentionally focused on the sites where we intend to deploy DMMH in the RCT, yielding richer information about each site. We coordinated applications to each site's Ethics Review Board with a joint protocol, a process which was managed by the team at CIMH led by Prof. Reininghaus and supported by the WP6 team.

1.1 Theoretical Framework

The main theoretical basis for the study was the Non-adoption, Abandonment, Scale up, Spread, and Sustainability (NASSS) framework (Greenhalgh et al., 2017). NASSS was developed specifically to assess technology-based interventions in health and social care. It allows integration of qualitative and quantitative data, and has been used and refined in many field studies. The framework has seven parts, the condition or illness, the technology, the value proposition, the adopter system, the organization(s), the wider institutional and social context, and the interaction and mutual adaptation between all these domains over time. Due to its emphasis on the adopter system and the organizational context, NASSS is highly suitable for exploring the stakeholder experience.

In the context of IMMERSE, the **condition or illness** is a mental disorder. We follow a transdiagnostic approach (Cuthbert & Insel, 2013; Beard et al., 2019), where the different aspects of mental ill health are modelled as continua. A person's specific symptoms locate their mental condition within this multi-dimensional space. The DMMH intervention can facilitate both a soft transdiagnostic approach, where certain parts of the multi-dimensional transdiagnostic space are linked to a traditional diagnostic term, such as depression or psychosis, and a hard transdiagnostic approach that fundamentally questions diagnostic categorisations. For the purpose of this study, we focus on adults and young people who are able to give informed consent, who do not have intellectual or learning disabilities, and whose mental health symptoms are not caused by organic damage to the brain (e.g., dementia, stroke, delirium).

The key **technology** is DMMH, as described in Deliverable D2.1. Clinicians interact with DMMH through a dashboard, while service users interact with it using a smartphone app. In this study, we also investigate related technologies because experience with such technologies is likely to affect how clinicians and service user view DMMH. For service users, we focus on their experience of tracking health and wellbeing using smartphones. For clinicians, we examine their experience with electronic health records.

The **value proposition** at this stage is hypothetical and based on participants' views after reading a brief description of DMMH (survey) or watching videos (interview).

The **organisation** domain was assessed for clinicians and administrators. We focused on organisational support for innovation and readiness for change, and specifically checked participants' views on components of the planned implementation strategies. Since participants were affiliated with the proposed RCT trial sites, existing documents about the sites can enrich the final analysis and prepare the implementation strategies set out in Deliverable D7.1.

The **wider context** was assessed in the study itself through demographic information and by eliciting information about participants' life and work environment. It is further enriched by data and documents about the health care systems involved and the regions in which the sites are situated.

Since this study was cross-sectional, it was not possible to study the **interaction between the domains over time**. However, we expected to gather some relevant information in the free text of the survey and the interviews, as participants reflect about relevant past experiences.

1.2 Main Contributions

Despite substantial disruption by at least two major waves of the Covid-19 pandemic, we have exceeded overall recruitment targets for service users and clinicians, and met recruitment targets for administrators, as reported in Chapters 4 and 5.

We ensured timely transfer of findings to the design of the implementation strategies using the qualitative analysis technique of writing memoranda. Writing memoranda as part of the data collection process is a well-established practice in qualitative research (Saldaña, 2022; Birks, Chapman, & Francis, 2008) that allows researchers to capture observations which might not be documented in the interview recording and subsequent transcript. Since the data collectors were also closely involved in the design of DMMH and the relevant implementation strategies, they used their memoranda to systematically reflect on key observations.

Data collected for this study have been cleaned, documented, and prepared for further in-depth analysis. For the interviews, we used a qualitative content analysis approach, where each transcript is annotated with codes that highlight aspects relevant to DMMH and the context in which it is deployed. As data collection ended for all sites in October 2022, we are still working on synthesising and preparing the survey and interview data sets for release. We will follow an open science approach and ensure that the data will be documented and shared using FAIR principles. Since the resulting data set is extremely rich, in this deliverable, we provide selected high level findings that are particularly relevant to the implementation of DMMH in the RCT.

The preliminary analysis reported here broadly validates the implementation strategies described in Deliverable 7.1. Most participants saw DMMH as potentially beneficial, and would be willing to use it in their practice. More in-depth analysis will follow in our scientific publications now that Phase I data collection has been completed in all four countries.

2. IMMERSE Phase I

2.1 Design

The study consisted of a questionnaire survey (Part A, c.f. Chapter 4) and an interview study (Part B, c.f. Chapter 5). Both components were designed to collect information about relevant contextual factors based on the NASSS framework as set out in Section 1.1. The core components of the survey and interview schedules were the same across all sites. The study covered implementation strategies that had been designed based on prior work, which are summarised in Table 2.2and further described in D7.1. In Germany, additional items regarding implementation strategies were administered as part of the survey.

The data collection sites are summarised in Table 2.1. Scotland was specified as country context since the organisational structure of the Scottish NHS differs from that of the English/Welsh and Northern Irish NHS. In the original design of the study, the Scottish sites were NHS Lothian and NHS Tayside. Since NHS Tayside is no longer participating (see Section 3.5 for details), the Scottish sites are now NHS Lothian (adult services) and NHS Lothian - Child and Adolescent Mental Health Services (CAMHS). Given the differences in mental health care systems across the four European countries, services will vary in structure and size, which will allow us to identify putative contextual factors (barriers, facilitators), implementation processes and tailor implementation strategies under a variety of conditions.

2.2 Participants

Due to uncertainty introduced by the Covid-19 pandemic, we defined two sets of target numbers for data collection, an ideal target and a minimum target. All participants were recruited from the sites summarised in Table 2.1.

For the survey study (Part A), we planned to recruit 400 service users (100 per country), 200 support network members (50 per country), 100 clinicians (25 per country), and 40 administrators (10 per country). The minimum target numbers were 25% of the original target.

Country	Short Form	Site
Belgium	be_kul	KU Leuven University Hospital UZ Leuven
	be_sk	Psychiatric Hospital Sint Kamillus
Germany	de_cimh	Central Institute of Mental Health Mannheim
	de_pcn	Psychiatric Centre Nordbaden Wiesloch
Scotland	sc_camhs	NHS Lothian CAMHS
	sc_lothian	NHS Lothian
Slovakia	sk_bratislava	University Hospital Bratislava
	sk_kosice	organisations linked to UJPS
		outpatient clinics in Vranov nad Toplov, Hanusovce, and Kosice

Table 2.1: Study Sites. For the UK, Scotland is specified as country context.

Strategy Number	Stakeholders	Description
Strategy 1	Clinicians and Service Users	Personalisation and tailoring of DMMH to needs of clinicians and service users
Strategy 2	Clinicians and Service Providers / Administrators	Tailored intervention manual
Strategy 3	Clinicians and Service Providers / Administrators	Tailored training and support
Strategy 4	Service Users	Tailored information, counselling, and reminders

Table 2.2: Key planned implementation strategies to be checked

For the interview study (Part B), we planned to recruit 40 service users (10 per country), 20 support network members (5 per country), 20 clinicians (5 per country), and 20 administrators (5 per country). As far as possible, interview participants were selected to maximise diversity of perspectives and backgrounds. The minimum target numbers were two interviews per stakeholder group and per country.

Inclusion criteria:

We included **service users** who were able to provide informed consent, aged between 18 and 64 years, and in contact with inpatient, outpatient, or community mental health services; **clinicians** who provided care for and/or were the clinicians in charge of treatment for service users with a diagnosis of a mental disorder; **supporters** who provide informal care and support for service users; **administrators** including managers and clinicians whose primary role is administrative.

Exclusion criteria:

For the interview study, we excluded service users for the following reasons:

1. evidence that psychiatric symptoms are precipitated by an organic cause (incl. a diagnosis of ICD-10 F00-F09)
2. clinical diagnosis of intellectual disability (ICD-10 F71-79)
3. clinical diagnosis of a disorder of psychological development (ICD-10 F80-89) that is sufficiently severe to impair a person's ability to provide informed consent
4. medical or psychological contra-indication, as judged by psychiatrist or clinical psychologist in charge
5. self-reported inability to use a smartphone to collect ESM data
6. not fluent and not literate in German (Germany), Dutch (Belgium), Slovak (Slovakia) or English (Scotland)
7. short life expectancy/terminal illness.

Due to anonymous data collection, it was not possible to assess clinical exclusion criteria for the survey study. However, whenever possible during recruitment, qualified research staff ensured that participants were able to provide informed consent. Where the survey invitation was distributed by an external agency, as was the case in the UK (c.f. Section 3.5), we also used the clinical exclusion criteria specified.

2.3 Data Curation and Analysis

The Data Sharing Agreement between all partners was not signed until September 2022, which delayed the joint analysis of results. This affected in particular the Belgian data collection for the survey study, which had to be done separately from the data collection for Germany, Slovakia, and Scotland. For the Belgian survey, we used a RedCap (Harris et al., 2019) instance hosted at KUL; for the other three countries, the RedCap instance was hosted at UHEI. In the UHEI RedCap instance, we created a single survey that branched by country and stakeholder group. While the landing page of UHEI RedCap was only for the survey, the KULRedCap landing page allowed participants to volunteer for the survey study, the interview study, or both. When KULparticipants opted-in for the interview they were redirected to a page hosted by the appointment scheduling service Calendly, where they could pick feasible time slots for them to take the one-hour interview. Researchers would receive an email with the timeslot and confirmed or rescheduled the appointment if necessary.

Once the Data Sharing Agreement had been signed, survey data were cleaned and curated centrally with the support of the KULteam, and a unified codebook and documentation were developed that took into account site-specific differences in the wording of some questions, and site-specific additions to the survey instrument. All statistical analysis scripts were written in R Markdown (Xie, Allaire, & Grolemund, 2018), led by the UEDINteam. R is a standard open-source statistical analysis environment in many sciences, including psychology. R Markdown is a literate programming environment for R that allows easy documentation of code.

The interview data were transcribed and analysed at the sites where the interviews were conducted. All analysis took place in the original language, to ensure that important nuances were not lost in translation. Common file naming conventions were established. The interviews were analysed using the standard computational analysis software provided by the host institutions, NVivo (UEDIN, UKBA, KUL) and MaxQDA (CIMH, UJPS). Both software packages support standard file exchange formats.

3. Recruitment

3.1 Overview of Sites

In planning, we paid particularly close attention to establishing feasible recruitment procedures and strategies at each of the clinical sites. While we already have good working relationships with all field sites, we used IMMERSE Phase I to allow the research assistants, who will work on Phase I and Phase II, to familiarise themselves with the needs of and constraints at each site, and to build relationships with staff. In this chapter, we briefly introduce the sites and discuss in detail the recruitment procedures, which were adapted to each context. We also outline changes in the clinical sites which emerged during recruitment for Phase I.

3.2 Belgium

3.2.1 Sites

We recruited service users from mental health services at two clinical sites in Belgium,

1. the KU Leuven University Hospital UZ Leuven (UPC), and
2. the Psychiatric Center Sint-Kamillus Bierbeek (SKH).

Both institutions are members of the Flanders Hospital Network. **UPC** is a large university hospital with a broad and longstanding research tradition and technological innovation, and serves both inpatient and outpatient populations across the psychopathology spectrum. Its services comprise regional coverage with a population in Leuven of 101,000 but as the largest university hospital in Belgium its coverage extends significantly beyond. The Psychiatric Center, spread over different locations in the province of Vlaams-Brabant, has 668 beds and provides ambulatory care, including 4 mobile teams. The yearly number of admissions is around 3500, and ambulatory treatment and follow up of around 10,000 service users. They have developed a patient data management system (MyNexus Health) that is now used in 27 hospitals in Flanders, and are keen to explore implementation of the DMMH into the system. **SKH** is a smaller regional psychiatric hospital with similar in- and outpatient mental health services. The center has 385 beds and 40 day center places. The yearly number of admissions is around 1000. Their patient data management system is provided by an external company based in Flanders (Obasi), who have equally expressed strong interest in collaboration with the current project.

3.2.2 Recruitment

Active recruitment of participants for IMMERSE Phase I was done over four months, starting in late January 2022 and ending in late May 2022. We initially recruited via clinical sites. When we did not reach our target numbers via this strategy, we contacted participants from previous relevant studies and recruited via patient organisations (Psychosenet, Ups&Downs, Similes and Uilenspiegel. We also wrote a blog post that was shared on Psychosenet's social media accounts. For each strategy, we would use emails or distribute posters and flyers.

Recruitment of service users via clinical sites was initiated by establishing contact with hospital management. For UPC, we received permission to distribute flyers into the clinics and

advertise on the intranet. For SKH, we contacted a research-associate, Saskia Bruyninckx, to coordinate recruitment efforts. We primarily contacted the clinicians and hospital admin personnel via email with a direct link to the survey. Clinicians and admin sometimes used direct email responses to schedule an interview.

Although we considered the idea of directly emailing patients, both UPC and SKH were reluctant toward this idea. This reluctance was twofold: first, there was a genuine privacy concern for the patients' data. Secondly, there was no easy way to retrieve and share these email addresses as each patient's email is only stored in their patient file and not in a single list. A similar problem occurred with the email addresses of a patient's support network. The supporter network's contact information is rarely stored in the patient files and is mainly limited to a phone number.

The study team printed 200 A5 flyers and 20 A1 posters to be distributed at the hospitals. The posters and flyers each had a QR code that led to the Redcap online survey. At UPC, a digitally animated version of the poster was also visible on the LCD information screens spread around the hospital ground. For UPC, we were allowed to go to the hospital ourselves. Due to Covid restrictions, for SKH, posters and flyers were distributed by a local research associate on the wards.

From the middle of March (18th) through April, we organised moments with the team leads to get most of the patients together in a meeting. These meetings often took place at the opening of the day or 'patient meetings', which are scheduled each week or month in their regular care. In these meetings we presented our study to patients using a PowerPoint presentation, answered their questions and distributed flyers with the message that they should share the flyer with their support network. In the PowerPoint, we incorporated the screen captures provided by Movisens of the app interface (avatar) and early versions of the visualisations visualisations. In these meetings, we saw that patients and some staff were genuinely interested in the study and were keen on involving their support network. To meet the growing demand for flyers, we first ordered 100 extra flyers, and then another 70. This strategy boosted our numbers immensely, resulting in 120 initiated surveys and 32 interviews in March and April. The increase in the number of interviews resulted in intensive days of three or four interviews per day, with sometimes two interviews in immediate succession. The last was interview conducted on April 28. We recruited some interview participants throuhg the patient and supporter networks, sometimes from remarkably distant locations.

By the end of April 2022, we had reached minimum recruitment targets and decided to no longer actively recruit participants. Interview scheduling was closed down at the end of April 2022, while the survey was closed to participants by the middle of July 2022.

3.3 Germany

3.3.1 Sites

In Germany, we recruited service users from mental health services at two clinical sites:

1. the Central Institute of Mental Health (**CIMH**) in Mannheim, Germany and
2. the Psychiatric Centre Nordbaden (**PZN**) in Wiesloch, Germany

The clinical programme at CIMH includes inpatient, outpatient and community mental health services provided in the three clinical departments of Psychiatry and Psychotherapy, Psychosomatic Medicine and Psychotherapy and Addictive Behaviour and Addiction Medicine offering treatment based on the national and international level of mental health care in their special fields. The CIMH serves a population of 308,000 in the city of Mannheim and currently has a total of 349 beds. In 2019, 3,072 patients were admitted to inpatient services and 12,222 patients were seen by outpatient services at CIMH. The PZN is a large clinical centre, which serves the population of 541,859 in the Rhine Neckar district with rural and mixed urban/rural

areas and consists of six clinical departments with a total of 1,070 beds and therapy places and around 9,000 admissions per year.

3.3.2 Recruitment

Active recruitment of participants for IMMERSE phase I was done in Germany over six months, starting in late January 2022 and ending late June 2022. We adopted three main recruitment strategies:

1. recruitment via clinical sites,
2. recruitment of previous study participants who consented to being recontacted for research purposes, and
3. recruitment via self-help groups and patient organisations.

For each target, we would use emails and physically distribute posters and flyers. These strategies largely took place in parallel and helped us avoid recruitment saturation at early phases.

Recruitment via clinical sites was initiated by establishing contact with clinical leads. Early emails were sent out to key contact persons to inform them of the IMMERSE project, with an emphasis on Phase I, and organise meeting opportunities. Contact took place both online and in-person. By going through a list of wards at CIMH, IMMERSE staff presented phase I of the IMMERSE project at nearly every floor of the CIMH hospital, spoke to people, hung up posters, and handed out flyers. Several presentations were given to clinicians (between 10-30 people at a time) whereas others were given directly to the patient groups of different sizes (between 1-15 people at a time). With every presentation, some type of physical material was handed out or presented with screen-share and then later handed out. The study presentation was most often conducted in-person, and only a few times virtually. One very important session where our representative attended was the so-called“morning round”, which included chief clinicians of the hospital. Direct contact with patients lasted much longer than direct contact with clinicians; after a pitch to a group, patients often approached individually to make an interview appointment or enter a conversation about the project. Service users at the CIMH were typically spoken to in groups before group sessions began in shared living spaces e.g., kitchens, TV rooms. Clinicians were usually, but not always, present for these interactive discussions lasting between 15 and 40 minutes.

Similarly, service users in recovery at PZN Wiesloch were approached with permission of respective clinical leads. Our team would first set up contact with a key person of a ward (or even the entire hospital), present the study to them, and subsequently set up an appointment for our representative(s) to present Phase I in more depth and recruit in parallel. In the case of PZN Wiesloch, our representative was able to first meet with the contact person (clinical head), and distribute as many recruitment materials as possible in waiting areas, mailing rooms, and hallways. This also included handing out flyers to clinicians met on the way, such that they could distribute the information further (to e.g., their patients). As some of the wards were closed due to COVID-19, and some wards are permanently limited to specific clinicians, only a selection of areas were visited in-person at the PCN Wiesloch for recruitment. The rest of the time was spent getting to know the institute with a tour and meeting patients in their free time (assisted living).

A pitch, or short-form of this presentation, was given when trying to spark interest to participate, e.g., to patients of one of our pilot studies, DiSERVE@home. Whenever patients, or any stakeholders, stated that an interview would take too long, the survey was presented in a foot-in-the-door strategy (the “easier task” between the two).

To communicate Phase I to potential participants, we developed several types of printed and digital recruitment materials describing part A and part B, target participant requirements, compensation, and included a QR code to access the anonymous online survey in Redcap as well as our contact information (name, email, and phone number) to set up an interview

appointment. We adjusted to the availabilities of participants and did not use an automatic scheduling tool (e.g., Doodle). Several interview appointments were scheduled in-person. To promote the study further, small business cards, flyers, and larger posters with the core information described above were hung up around the CIMH and PCN Wiesloch. We specifically thought of places on eye-level where our colleagues, visiting supporters, and patients might see them (e.g., above the water cooler, by the vending machines, cards placed on tables in waiting areas, posters hung up on walls). After communication with the media department of CIMH, we also designed a more interactive type of poster, which looked like (and was later printed as) the shape of a smartphone. The speech bubbles appearing on the poster represent a conversation, which informs the reader of the purpose, target sample, compensation, and contact information. A QR code to the survey was always included.

We also designed email templates to send out to individuals with a PDF of our flyer included in attachment. We prepared one template per stakeholder. Very rarely did we send out emails to groups of people, these were always individual emails, referring to someone by name. The majority of these emails went to participants of other studies at CIMH . We designed another email template that could be forwarded to other individuals we did not have contact with. For example, the first part of the message would be addressed to e.g., a clinical lead who recently participated in an interview, followed by a section stating “forward from this point onward” with information about the study, links to the survey and the CIMH website page describing IMMERSE, and contact information in case of interest. This way, the recipient was able to forward the relevant information to potentially interested participants. This was particularly useful in our final efforts to contact supporters of service users, whereby we reached out to a CIMH study specifically investigating support members to ask to forward the information email. Moreover, over 40 emails were sent to individual service users who already participated with a request to potentially identify their supporters and forward our contact details in case of interest. Service users were also explicitly asked if they could imagine their supporter(s) participating in Phase I and were given extra flyers and/or business cards to pass on to their supporters. Otherwise, supporters were addressed 1:1 in waiting rooms on ward floors or general waiting areas.

Next to supporter recruitment, another obstacle was maintaining and increasing our survey numbers. Generally, we always brought a laptop to interview appointments and appended the survey to the interview slot (in-person only) in case participants had not yet completed it. One further strategy to increase survey numbers was bringing printed versions of the survey directly to individuals (regardless of stakeholder group). This was first tested out at the PZN Wiesloch as we expected reduced network/internet and knew that mobile device rules for service users may differ while in treatment. Printed surveys were also handed-out at the CIMH and were meant to be returned via our house mailing service. However, more surveys were handed out than returned to us. Of the portion that did, we manually entered the data into Redcap. Recruitment at PZN Wiesloch was generally lower than at CIMH as we did not have paid IMMERSE staff working at this location at the time, the centre is more rurally located, and the centre does not have the same affinity for research as the CIMH . The German Redcap survey remained open until August 2022.

3.4 Slovakia

3.4.1 Sites

The Slovakian sites for DMMH consisted of inpatient and outpatient mental health services in two locations:

1. the Psychiatric Clinic at the Faculty of Medicine, Comenius University and University Hospital Bratislava, Bratislava and

2. outpatient clinics in Vranov nad Toplov, Hanusovce, and Košice as well as other collaborating organisations

These mental health services specialize in severe mental disorders and psychiatric care to adults and their families. Originally, we also planned to recruit from the Louis Pasteur University Hospital (UNLP) in Košice, but this proved more difficult than anticipated.

The Bratislava Psychiatric Clinic is part of the largest university hospital in the Slovak republic. It provides inpatient and outpatient services for a population of over 400,000 in the city of Bratislava and for patients with very severe mental health problems from the whole country. The clinic consists of acute departments for the treatment of psychotic, affective, and organic disorders, an open department for the treatment of less severe mental health problems, a specialized day care center for the treatment of non-acute psychotic disorders, and a department for specialized treatment of somatic comorbidities. The clinic has a capacity of 70 beds and 15 patients in the day care center. In 2019, 1,056 patients were admitted for inpatient care at the clinic, 700 patients to outpatient services with a total of 5,500 health examinations in these services. The city of Košice has a population of 240,000, while the region has 800,000 inhabitants. The outpatient clinics cover both city and region.

3.4.2 Recruitment in Bratislava

Active recruitment of participants for IMMERSE phase I was done over six months, starting in late December 2021 and ending in May 2022. We initially recruited via clinical sites. When we did not reach our targeted numbers via this strategy, we incorporated: recruitment via a private psychiatric clinic and two private psychiatric practices and recruitment via civil organizations providing services supporting people with mental health disorders. For each strategy, we would use personal communication with the lead of site and clinicians/social workers working with service users, emails to reach participants or distribution of flyers. After informal agreement to participation and providing an email address, we distributed to participants an uniform email with direct link to Redcap survey and an option to participate on interview after contact in research team.

Recruitment via clinical sites was initiated by establishing contact with clinic and centre management. For the Psychiatric clinic of University Hospital in Bratislava and Centre for Treatment of Drug Dependencies in Bratislava, the respective directors gave us permission to recruit managers and clinicians and cooperate with them in recruiting service users and members of their supporting network. The study team printed 100 A5 flyers to be distributed at the hospitals. The flyers were distributed to clinicians who than distributed them to interested service users.

Recruitment via private psychiatric practices was conducted by reaching one private psychiatric clinic. Calma Mental Health Clinic, Ltd. (represented by Mr. Martin Glézi) and two psychiatric practices in Bratislava, Dr. Barbora Vašečková and Dr. Andrea Heretiková. All three sites distributed an email prepared by the research team to their patients.

A gap in the data remained in the support network population. Therefore, we approached civic associations that systematically involve relatives and supporters of people with mental disorders in their activities: House of Social Services – MOST, NPO and Find yourself, NPO. We asked managers (Dr. Andrea Beňušková for MOST, NPO and Mr. Juraj Marendiak for Find yourself, NPO) to distribute our recruitment email using their contact list of supporters and via their clients.

During May, we reached our recruitment targets for the survey and decided to no longer actively recruit participants.

3.4.3 Recruitment in Košice

Recruitment started 1st of February. We recruited three outpatient clinics and four organizations focused on mental health. We used mainly personal contact for recruitment. Recruitment ended in May 2022 since our targets were met and no more subjects were needed.

For Part A (Survey), we asked 7 organizations, and 3 agreed to spread forward the survey through their networks. Due to a lack of responses, we sent the survey to clinicians and managers with whom cooperate with on other projects and tasks. They were asked to spread the survey to their patients and the informal carers of those patients. This strategy worked better. functional. Finally, members of our research team personally visit clinics and asked subjects for filling out the survey. This strategy also worked.

Recruitment for Part B (Interviews) was very efficient, as it was mostly done through the outpatient clinics mentioned in Section 3.4.1. These clinics are led by a member of the research team (dr. Dagmar Breznoscakova) Initially, 23 patients were chosen to achieve maximum variation in the sample. They were then invited via email or via personal contact. Many patients were also notified about the study by their clinicians. The clinician support was effective and helpful.

3.5 Scotland (UK)

3.5.1 Sites

Initially, we planned to recruit partcipants from mental health services in NHS Lothian (covering the city of Edinburgh and the surrounding area of East, West, and Midlothian) and NHS Tayside (covering the city of Dundee and the surrounding area). Tayside and Lothian are two of Scotland's 14 geographical Health Boards which are responsible for the delivery of services to residents in the area they cover. However, due to the retirement of the Head of NHS Tayside Psychological Therapies, recruitment in NHS Tayside proved more difficult than anticipated. Therefore, we focused on engaging with services in NHS Lothian. These services included inpatient, outpatient and community mental health services for service users of all ages provided in the clinical departments of adult clinical psychology, and children, young people and families mental health services.

The NHS Lothian Health Board covers a population of 800,000 people (NHS Lothian). The mental health population in active community treatment in Lothian at any point in time comprises 2800 individuals, split across 6 independent community mental health teams and 4 multi-disciplinary adolescent mental health teams as well as 4 intensive care psychiatric services in rehabilitation and acute mental health care. Services have current experience in implementing and evaluating mHealth interventions such as computerised Cognitive Behaviour Therapy (CBT) for depression.

3.5.2 Recruitment

Recruitment for Phase I of the IMMERSE study began in January 2022 and continued into September. The main strategy adopted was recruitment via clinical sites, including putting up posters, handing flyers to clinicians to be handed out to patients, and email shots to clinicians. When these strategies failed to help us reach the minimum targets, we expanded our recruitment strategy to use third-party recruitment channels. These were

1. SHARE (The Scottish Health Research Register and Biobank (McKinstry et al., 2017), and
2. SMHRN (Scottish Mental Health Research Network).

Initial contact was established with NHS Lothian sites via Dr Belinda Hacking, Director of Psychology Services NHS Lothian, and Professor Kevin Power, the Head of NHS Tayside

Psychological Therapies (prior to his retirement). The first issue with recruitment arose when Professor Kevin Power retired and the following acting Head of NHS Tayside Mental Health Services was less willing to actively engage with us to support the IMMERSE project. Despite this, we still had a significant number of NHS Lothian sites interested in taking part.

Initial recruitment started by emailing clinical psychologists directly with a link to the RedCap survey and an invitation to be interviewed. Clinicians were also emailed with reminders to fill out the questionnaire multiple times. Alongside this, emails were sent directly to individual clinicians who had shown interest in the project, inviting them to take part in the interview. At the start of recruitment, some of the clinicians provided feedback to us that the instructions to access the survey link were not clear. We had to re-design them several times, both in a written and visual form, before we could reach an agreement on the version that was later presented to participants. The SMHRN also provided feedback on this.

In terms of service user recruitment, the initial idea was to ask clinicians to advertise directly to their patients, put up posters in waiting areas and send out email shots to NHS patients. It soon became apparent that we would not be able to send out these email shots directly to NHS service users as this would require the storing of personally identifiable data outside of NHS data stores, which we did not have ethical approval for. We were also unable to be physically present on the units' wards, initially because of COVID-19 restrictions and because this would require a NHS Lothian contracts/Research passports which none of the researchers had. This meant we were heavily reliant on the clinicians inviting service users to take part in the study, which yielded no participants. Researchers applied for research passports as soon as the problem became evident, which have now been granted in time for Phase II of IMMERSE.

When it became evident that participant recruitment was at a standstill for all categories, we decided to recruit through the patient research register SHARE and we contacted the SMHRN. Using SHARE required a substantial amendment to our Ethical Approval, which was submitted in May 2022. We received approval to use SHARE and they sent out their initial mail shots and began phone calls in mid-July. This was of significant help to the numbers of participants completing the survey with the following weeks demonstrating a significant rise in the number of patient surveys being filled out. Setting up online interviews with patients also required separate permissions to use NearMe, NHS Scotland's videoconferencing service for online healthcare appointments.

As a result of the difficulties outlined above, UEDINfocused on recruiting a sufficient number of service users and clinicians. By the end of October 2022, targets for these stakeholder groups had been met or exceeded. In this report, we only consider surveys submitted before the end of the first week of August 2022. Findings from the full data set will be published in due course.

4. Part A: Survey Study

4.1 Survey Design

The primary aim of the survey was to identify putative contextual factors that may influence processes and outcomes, with a secondary aim of gathering information and feedback about implementation strategies for implementing the DMMH intervention. The design of the survey was informed by the NASSS framework, as summarised in Table 4.1. Except for additional implementation strategy-specific items used in Germany, the design was the same for all countries, with country-specific content in the demographics section. Country-specific ethnicity and education measures were harmonised following established best practice in EU projects (Jongsma et al., 2018). As far as possible, we used existing validated scales. As far as possible, official translations of existing scales were used, as long as the translation was of high quality as verified by the country's research team. Translation and back translation was used for scales that exist for English, but have not been validated for German, Dutch, or Slovak. Where those were not available, questionnaires were adapted from prior work, in particular from Albakry et al. (Albakry, Vaniea, & Wolters, 2020), a survey of around 2000 participants' ability to read URLs. Reading URLs is a basic skill for staying safe online, which is highly relevant in the eHealth context.

The survey was designed to require an average completion time of 10–15 minutes, with a completion time of 30 minutes in extreme cases where participants chose a long time to reflect on their answers. We minimised open-ended questions in order to increase completion rates. When several versions of a validated measure are available, the shortest one was chosen to minimise burden on respondents. The questionnaire covered the following components:

All respondents:

- Demographics (age, education, employment status, gender, ethnicity, whether participant lives in one of the eight study sites)
- Stress (Perceived Stress Scale – 4 item version) (Warttig et al., 2013)
- Brief measures of technology use (Albakry et al., 2020), technology self-efficacy (Albakry et al., 2020), attitudes to technology (Rosen et al., 2013) and privacy concerns online (Buchanan, Paine, Joinson, & Reips, 2007)

All respondents, but adapted to user type:

- Perceived value of DMMH, based on brief description of the tool. This is the main target item for inferential statistics
- Perceived barriers and facilitators for implementation of the DMMH, based on initial findings from the IMPROVE study and selected items from TCU ORC-D4 (of Behavioral Research, 2009) and TCU CJ-PTN (of Behavioral Research, 2003)
- Open-ended request for further comments

Service users and clinicians: Shared decision making scale (SDM-Q-9 (Kriston et al., 2010) / SDM-Q-DOC (Scholl et al., 2012))

Service users and supporters:

- Experience with and attitudes to self-tracking and health tracking technology
- usability of most frequently used tracking technology (System Usability Scale (Brooke, 2013))
- perceived value of planned implementation strategies for adopting a new self / health tracking tool
- open ended request for further comments

Clinicians and Health care system administrators / managers:

- experience with and attitudes to clinician-side electronic health records
- usability of the main electronic health record system used (System Usability Scale (Brooke, 2013))
- perceived value of planned implementation strategies for adopting a new app/software for clinical use
- ORCA (Helfrich et al., 2009) - Context Assessment sub-scales (senior leadership culture, staff culture, leadership behaviour, leadership feedback, opinion leaders, general resources)
- open-ended request for further comments

Service users only:

- self-reported diagnosis or self-reported main symptoms (assessed by open-ended question)
- patient activation scale for mental health (PAM-MH, (Green et al., 2010))
- open-ended request for further comments

Clinicians only:

- caseload
- experience with and attitudes to client self-report homework (e.g., diaries, worksheets)

Health care system administrators and managers only : experience with and attitudes to administration and management interfaces of electronic health records

4.1.1 Main Outcome Variables

Two main outcome variables were designed into the survey, perceived potential benefit and intent to adopt. Perceived potential benefit for the participant was measured using a slider that ranked from 0 to 100. The slider was anchored by “Very beneficial” on the left hand side, and “Not beneficial at all” on the right hand side. We treat this variable as an indicator of the value that participants ascribe to DMMH. We also asked participants whether they would like to use DMMH in their own life (service users) or clinical practice (clinicians) using a single item, with responses on a 5 step Likert scale, from “strongly disagree” to “strongly agree”. The value and adoption items were placed towards the end of the survey, after all relevant questions about condition, technology, organisation, and wider context had been answered, and after a short text describing the concept behind DMMH, which had been agreed with the WP7 team. The description was brief and in text form to ensure that it could be easily viewer.

4.1.2 Harmonising Demographics

All demographic categories except for age were difficult to harmonise across countries. We covered gender, occupation, education, and ethnicity. Below, we describe the strategies used.

Gender: While Germany has a well-established option “divers” (diverse) for people who are non-binary or genderqueer, in the UK, people who do not conform to the gender binary are usually asked to self-describe. For the survey, we used the “prefer to self-describe” option.

NASSS Domain	Survey
Condition / illness	self-report; stress level (PSS-4); patient activation scale; clinician caseload
Technology	technology use and attitudes scales, SUS special item
Value Proposition	special item, SDM-Q-9
Adopter System	stakeholder-specific version of survey
Organisation	ORCA - context component; experience with implementation; selected items from TCU ORC-D4 and TCU CJ-PTN
Wider Context	demographics; barriers / facilitators based on past experience; Privacy Concern
Interaction over time	not covered

Table 4.1: Mapping of NASSS Domains to Content of Survey Study

Since this option was erroneously translated as “do not wish to describe” into German, gender categories were collapsed into male, female, and other (prefer to self-describe / do not wish to say).

Occupation: For occupation, we merged options that were common in all countries into a single list. As a result, it contains categories such as “volunteer” that are rare in Anglo-American publications.

Education: Due to substantial differences in education systems, we harmonised the options into three categories following ISCED 2011 (for Statistics, 2012) based on the highest level of education completed:

1. at primary level or below, with up to 8 years of education
2. at secondary level, including vocational qualifications
3. at tertiary level, including university and college degrees

Ethnicity: Ethnicity is well recognised as a social determinant of health. However, relevant categories vary substantially between countries. Therefore, we adopted a dual approach. In Germany and Slovakia, we asked participants about their nationality, and whether they considered themselves to be migrants. In the UK and Belgium, we asked them about their ethnicity using a free text field, where they could specify how they would normally describe it in official forms.

4.1.3 Eliciting Diagnosis Information

The IMMERSE project works both with clinicians that issue standard diagnoses and with clinicians that follow a more flexible transdiagnostic approach. Similarly, we include a broad spectrum of patients, from those with a single, well defined diagnosis to those with multiple relevant conditions. Therefore, we asked clinicians about the composition of their caseload. Patients were asked whether they had a diagnosis, whether they were currently in treatment, and whether they had mental health issues that were not being treated yet. We also asked them to describe their mental health problems in free text.

4.2 Data Collection

The survey was implemented in RedCap. While RedCap lacks the polished user interface of Qualtrics or Surveymonkey, it is a standard data collection and data entry tool for clinical trials that makes it easy to organise data input for complex projects, especially those with longitudinal components and multiple arms, such as RCTs. RedCap is well supported at KULand will be used for data management in Phase II of IMMERSE. Data were collected at KULfrom

Country	Service User		Supporter		Clinician		Administrator	
	N	Complete	N	Complete	N	Complete	N	Complete
Belgium	67	47 (70%)	18	12 (67%)	63	45 (71%)	22	10 (45%)
Germany	231	164 (71%)	43	34 (79%)	62	42 (68%)	12	11 (92%)
Scotland	45	33 (73%)	0	0	15	12 (81%)	0	0
Slovakia	124	103 (83%)	15	12 (80%)	32	26 (80%)	11	10 (91%)
Total	467	347 (74%)	76	58 (76%)	175	125 (73%)	45	31 (69%)
Min. Target		100 ✓		50 ✓		25 ✓		10 ✓
Full Target		400 ×		200 ×		100 ✓		40 ×

Table 4.2: Completion of Survey as of August 5, 2022.
N: Number who completed the demographics questionnaire. Complete: Full completion (N/%)
✓: target reached. ×: target not reached

late January onwards and for the rest of the consortium from February 1, 2022 onwards (c.f. Section 2.3). All data that are not in free text fields were cleaned and merged into one file per stakeholder group. The end of data collection at each site is described in Chapter 3.

Table 4.2 summarises the data collection as of August 5, 2022, which is the data set used in this deliverable. We indicate rate of attrition among survey respondents by comparing the number of those who completed the initial unit, consisting of demographic questions, to the number of those who completed the entire survey. The minimum completion targets were achieved in all countries for all stakeholder groups, with the exception of supporters and administrators in the UK, where the team focused on recruiting a sufficiently large number of service users.

4.3 Statistical Analysis

In this deliverable, we only report on the quantitative results, with a focus on service users and clinicians who completed the full survey. Tables for descriptive statistics and summaries were generated using the `tidyverse` (Wickham et al., 2019) tools (Wickham et al., 2019). Percentages are rounded to the nearest full percent. Graphs were created using `ggplot` (Wickham, 2016). For the calculation of scales and indicators such as Cronbach's α, we used the `psych`(Revelle, 2022) package. Statistical tests were conducted using the implemention in the `coin` package, which provides more robust estimates. In addition to the standard R functions such as `polr` for ordinal logistic regression, we used the `arm`(Gelman & Su, 2021) and `lme4` (Bates, Mächler, Bolker, & Walker, 2015) packages for linear and generalised linear mixed models. The random effect variable for mixed models was "country", which covers the wider context of culture and health care system that unites all sites from the same country. We included both an overall intercept and an intercept by country. Significance testing for ordinal logistic regression predictors was conducted using the function `coeftest` from the `AER` package (Kleiber & Zeileis, 2008), which implements z-tests for estimated coefficients, while significance tests for the fixed effects in mixed models were conducted using `anova`.

4.4 Results

For the purpose of this Deliverable, we focus on the core **adopter system** of clinicians and patients. Results are grouped by five of the six remaining NASSS domains (c.f. Section 1.1), condition or illness, technology, wider context, organisation, and value proposition.

Country	Smartphone Use		Smart Watch Use		Fitness Tracker Use	
	Patients	Clinicians	Patients	Clinicians	Patients	Clinicians
Belgium	100%	100%	13%	20%	15%	22%
Germany	98%	98%	13%	7%	18%	14%
Slovakia	95%	100%	18%	38%	11%	19%
UK (Scotland)	91%	92%	15%	17%	24%	17%

Table 4.3: Percentage of Clinicians and Patients who use Smartphone, Smart Watch, or Fitness Trackers Daily Per Country

4.4.1 Wider Context and Technology: Demographics and Technology Use

As shown in Figure 4.1, demographically, the clinician and patient populations are quite heterogeneous across sites. German patients have a clear peak in the 20–29 age group, while Slovak patients show a peak in the 30–39 age group. Belgian and UK patients are spread more evenly across categories. Slovakia is the only country where the gender ratio between patients is 1:1 female:male. In all other countries, there are substantially more female participants. UK service users tend to be highly educated, with most having completed a tertiary degree. Slovak patients are split evenly between secondary and tertiary, while most of the German patients have only completed the equivalent to secondary education. In all four countries, clinicians are predominantly female. While Belgium, the UK, and Slovakia skew more towards younger age groups, there are two peaks in the age distribution of German clinicians, one in the 30–39 age group and one in the 50–59 age group.

Most clinicians and patients use smartphones every day. Around one in 5 respondents use smartwatches, such as the Apple Watch, or fitness trackers, such as a FitBit, with the exception of Slovak clinicians, where around a third use a smart watch every day. Relatively few patients have experience with tracking their mental health using an app, ranging from 11% (n=12) in Slovakia to 22% (n=11) in Belgium. Patients have a similar level of experience with tracking aspects of their health that affect their mental wellbeing, from 16% (n=22) in Germany to 26% (n=14) in Belgium. Only one in ten respondents would not be interested in tracking their mental health or other aspects of their health. Less than 10% of patients were actively tracking their mental health at the time of survey completion, with the exception of Belgium (19%, n=9). However, a considerable proportion of participants report having stopped tracking an aspect of their health in the past because it negatively affected their mental wellbeing (Germany: 46%, n=76, Slovakia: 33%, n=34, UK: 33%, n=11, Belgium: 19%, n=47).

4.4.2 Conditon/Illness: Treatment Context

We asked patients whether they were being treated for a mental disorder for which they had a diagnosis, whether they were being treated for a mental disorder without a specific diagnosis, or whether they were waiting to be seen for a mental disorder. Patients were allowed to select all options that applied to them. 81% of Belgian patients (n=38), 90% of German patients (n=147), 85% of Slovak patients (n=88), and 70% of UK patients (n=23) reported that they were being seen for a diagnosed disorder.

We asked clinicians how often they saw different types of mental health disorders in their practice. Specifically, we probed for anxiety, depression, eating disorders, postnatal depression, trauma-related disorders, substance abuse, psychosis, schizophrenia, phobias, and obsessive-compulsive disorder. The most prevalent disorders are summarised in Table 4.4. Clinicians in all four countries often saw patients with anxiety and depression. Clinicians from the Belgian sites also saw many patients with psychosis, while clinicians from Slovakia cover substance abuse. Clinicians also vary in their use of Electronic Health Records. All UK clinicians (100%),

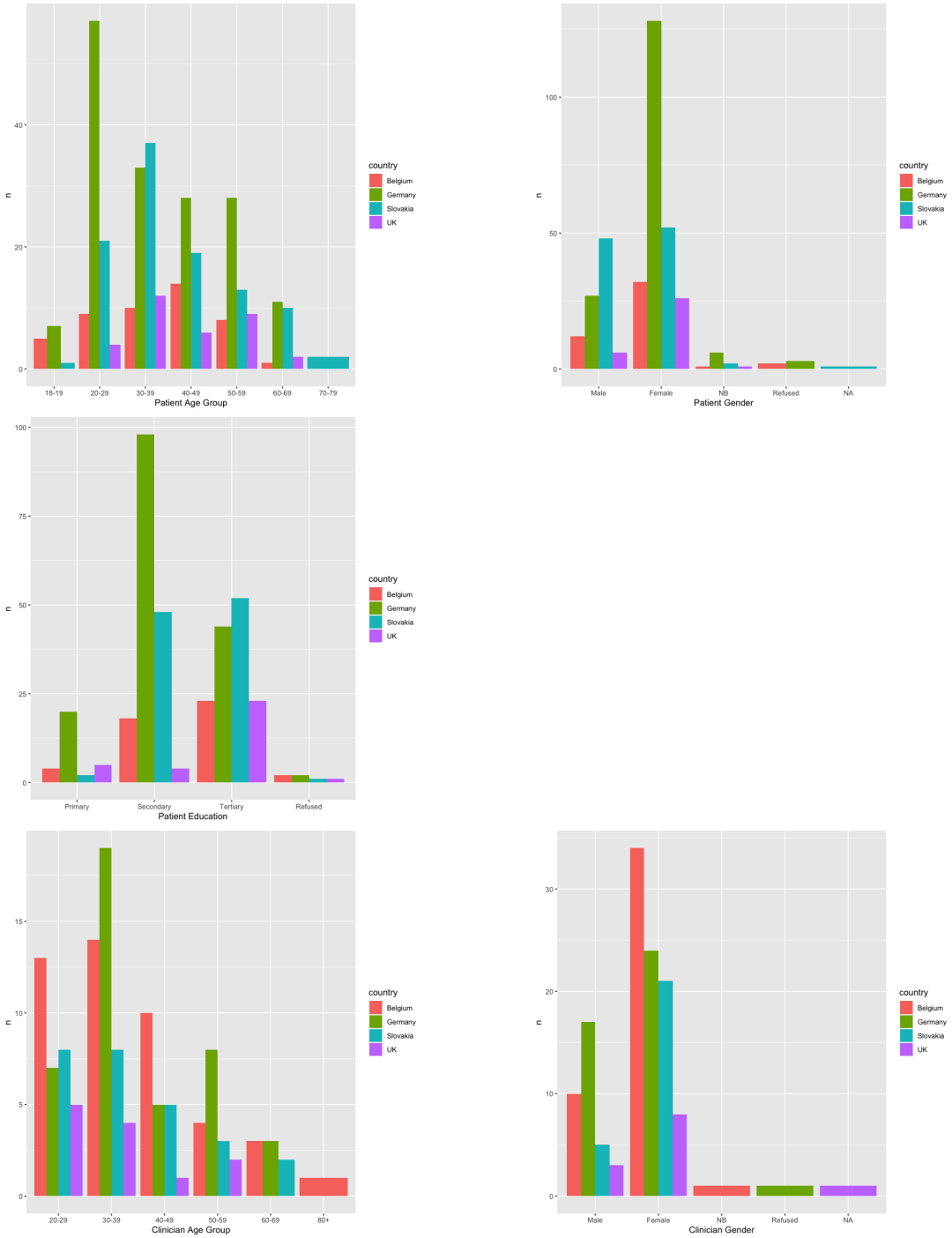

Figure 4.1: Age, Gender, and Education for Patients and Age and Gender for Clinicians. n: Count of category in data set.

Country	N	Top 3 Disorders Seen Often		
Belgium	45	depression (n=34)	psychosis (n=28)	anxiety (n=27)
Germany	42	depression (n=36)	anxiety (n=29)	trauma (n=19)
Slovakia	26	anxiety (n=23)	depression (n=22)	substance abuse (n=19)
UK (Scotland)	12	anxiety (n=12)	depression (n=9)	trauma (n=8)

Table 4.4: Top 3 Frequently Seen Disorders by Country

Implementation Strategy	Belgium	Germany	Slovakia	UK (Scotland)
Using a Cheat Sheet	✓✓	✓	✓	✓✓
Help from a Colleague	✓✓	✓✓	✓✓	✓✓
Handbook	×	×	✓	✓
In Person Training	✓✓	✓	✓✓	✓
Online Training	✓✓	✓	✓✓	✓
Online Help in App	✓✓	✓	✓✓	✓✓
Training Videos	✓✓	✓	✓	✓✓

Table 4.5: Importance of Implementation Strategies.
Symbols represent median judgements on the 4 point Likert scale. ✓✓: very important, ✓: important, ×: not so important

nearly all Belgian clinicians (98%, n=44), 85% of Slovak clinicians (n=22), and 79% of German clinicians (n=33) report using them.

4.4.3 Organisation and Technology: Implementation Strategies

Clinicians were asked to rate seven ways to help them learn and use new eHealth technology according to their importance with a four point Likert scale. Findings are summarised in Table 4.5. Getting help from a colleague was rated as very important across all countries, while using a handbook was rated least favourably. Clinicians preferred to use in-app help instead. They also appreciated in-person and online training, training videos, and cheat sheets.

Patients were asked about the importance of particular types of functionality to drive engagement with the app. Again, we used a four point Likert scale where patients could indicate the relative importance of each functionality. Findings are summarised in Table 4.6. The most important aspect across all countries was that the app was backed by scientific research. Patients also valued the ability to view their own data and to customise the app. Features beyond tracking, reminders, and the ability to share data with the therapist were seen as nice to have. In contrast, the ability to share data with supporters was deemed to be relatively unimportant.

4.4.4 Value Proposition: Perceived Benefit and Potential Adoption

Most patients and clinicians view DMMH as potentially beneficial. On a scale from 0 to 100, where 100 corresponds to very beneficial, patients give DMMH an average dating of 68.3 (SD 26.6), while clinicians rate it 65.1 (SD 21.7). Belgian patients (M=51.4, SD=23) and clinicians (M=58.8, SD=22) are the most sceptical, while participants from the other three countries are more positive (c.f. Figure 4.2). Overall, participants would be interested in using DMMH, regardless of stakeholder group or country (c.f. Figure 4.2; patients: M=3.8, SD=1.1, median=4; clinicians: M=3.6, SD=0.8, median=4; 5 = strongly agree that participant would use DMMH, 1 = strongly disagree).

We examined the effect of demographics (age and gender), experience with technology (smartphone use, fitness tracker use), online privacy concerns (privacy scale), positive and

Feature	Belgium	Germany	Slovakia	UK (Scotland)
Customisability	✓✓	✓✓	✓	✓
Features beyond tracking	✓	✓	✓	✓
Viewing own data	✓✓	✓✓	✓	✓✓
Reminders	✓	✓	✓	✓
Scientific backing	✓✓	✓✓	✓✓	✓✓
Sharing data with therapist	✓	✓	✓	✓
Sharing data with supporters	×	×	×	×

Table 4.6: Importance of App Features to Drive Engagement.
Symbols represent median judgements on the 4 point Likert scale. ✓✓: very important, ✓: important, ×: not so important

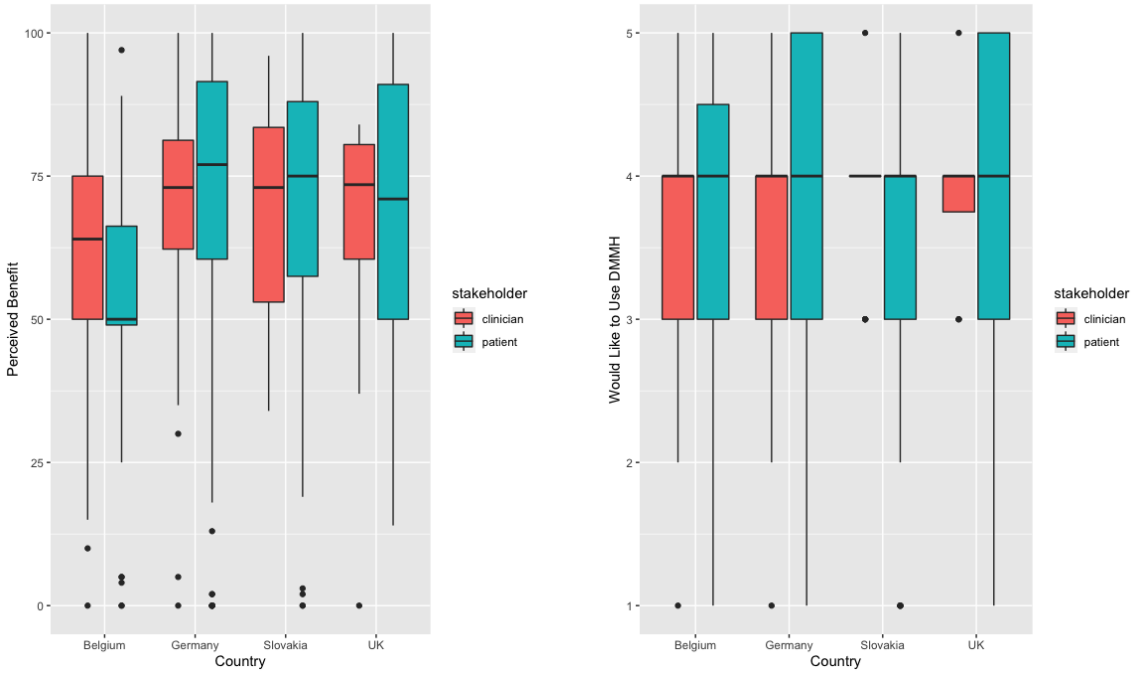

Figure 4.2: Left: Perceived Benefit of DMMH for Clinicians and Patients by country, rated using a slider. 100 = very beneficial, 0 = not beneficial at all. Right: Willingness to adopt for clinicians and patients by country, rated using a 5-point Likert scale, 5 = strongly agree, 1 = strongly disagree

Scale		Patient	Clinician
Privacy		0.93	0.92
MTUAS			
	positive	0.76	0.7
	negative	0.73	0.68
SDM		0.78	0.87
ORCA			
	Senior Leadership		0.79
	Staff Culture		0.79
	Leadership Behaviour		0.81
	Feedback from Leaders		0.7
	Opinion Leaders		0.71
	General Resources		0.81

Table 4.7: Reliability of Scales that enter into statistical models, measured using Cronbach's α

negative attitudes to technology (MTUAS, positive and negative attitude sub-scales), and shared decision making (SDM scale, patient and clinician version) on perceived benefit and intent to adopt. For patients, we added the Patient Activation Measure (PAM-MH); for clinicians, we added the six sub-scales of the ORCA context assessment scale. We chose these predictor variables as an initial parsimonious representation of the NASSS domains (c.f. Table 4.1). The validated scales entered into the models have acceptable reliability (c.f. Table 4.7).

We performed separate analyses for patients and clinicians. For intention to adopt, we used polynomial logistic regression and pooled findings from all countries, since there were no substantial differences in intention to adopt. For perceived benefit, we used linear mixed models, with country as random effect. The model had a country-specific intercept; all predictors were treated as fixed effects.

Intention to Adopt

For clinicians, the ordinal logistic regression failed to converge when the six ORCA variables were added. In the resulting model, the only significant predictor was a positive attitude to technology (Z=2.071,p$<$0.04)—clinicians with a positive attitude were more likely to adopt DMMH.

For patients, we saw significant effects of age (Z=-2.4817, p$<$0.02), experience with fitness trackers (Z=-3.0966, p$<$0.002), privacy concerns (Z=2.4618,p $<$0.002), and a positive attitude to technology (Z=2.4618,p$<$0.02). Younger patients who think positively about technology and have higher online privacy concerns are more likely to adopt DMMH; those who have experience with fitness trackers are less likely.

Perceived Benefit

The model for clinicians had to be modified by removing the predictor for negative attitude to technology, as the resulting model did not converge properly. We also removed the ORCA subscales, which had impeded the convergence of the adoption model. The only significant predictor was a positive attitude to technology (F(1)=4.12m p$<$0.05), which increased perceived benefit. There was very little variation by country, with random intercepts ranging from -0.65 (Belgium) to 0.32 (Germany).

For patients, positive attitude to technology (F(1)=6.8479, p$<$0.01), age (F(1)=7.576, p$<$0.007) and gender (F(1) = 6.304, p$<$0.02) were the only significant predictors of perceived benefit. Younger male patients with a more positive attitude towards technology tended to rate perceived potential benefits higher. Belgian participants rate perceived benefits lower (random

effect for intercept: -10.5), participants from the other countries are more positive (intercept for UK 1.4, for Slovakia 4.0, and for Germany 5.1).

4.5 Discussion

Recruitment targets were met or exceeded for patients and clinicians. Supporters proved to be far more difficult to reach than originally anticipated. All sites underrecruited this group of stakeholders. Administrators also proved difficult to access for some sites. One of the reasons is that clinicians often have substantial administrative roles, which means the boundaries between those two stakeholder groups are blurred.

Initial analysis shows that teams in the four countries work with different populations of patients and clinicians, which is as expected for a realistic implementation study. The resulting heterogeneity needs to be carefully addressed in statistical analyses of the full data set.

While almost all participants are daily smartphone users, relatively few use fitness trackers. Notably, around a third of patients mentioned that they stopped tracking aspects of their health at some point because it negatively affected their health and wellbeing. For clinicians, a favourable view of technology is the only significant influence on their assessment of the value of DMMH. The story for patients is more complex. Younger male patients with a positive attitude to technology are more likely to champion DMMH. While the positive effect of high online privacy concerns may appear paradoxical at first, this might be a sign of patients who are knowledgeable about technology. Interestingly, patients who use fitness trackers are less likely to adopt DMMH. This finding needs to be explored in Phase II interviews. Patients may feel that their existing fitness and health tracking practices are sufficient, and may need to be convinced that the added work of completing regular ESM questionnaires is worth it.

In all countries, the survey results validate the planned implementation strategies and the design of DMMH. They also point to an unexpected benefit of the personal contacts and presentations during Phase I: Having access to someone who is knowledgeable about a new intervention is crucial. The researchers, who are now known on the participating wards, build local capacity and knowledge through tailored training and support (Strategy 3, Table 2.2). While patients as the service users were positive about relevant proposed strategies, scientific backing turned out to be surprisingly important, and the substantial evidence for the utility of ESM will be crucial when providing tailored information (Strategy 4).

The analysis presented here is preliminary, since we imposed an artificial cut-off to data collection. This has affected most notably the UK team, who managed to recruit over 60 additional participants to the survey after the deadline. In our forthcoming scientific publications, we will present a more in-depth analysis of this substantial and rich data set. For these publications, we will also analyse the free text using the codebook developed for the interviews (c.f. Appendix A).

5. The Interview Study: The Context of ESM and Self-Tracking Practices

5.1 Interview Design

The primary aim of the interviews is to probe planned implementation strategies and elicit potential additional implementation strategies, with the secondary aim of gathering contextual information about respondents' use and experience of eHealth and eMentalHealth. At each field site, we will conduct semi- structured interviews with service users, support network members, clinicians, and health system administrators to explore:

1. Participant-specific context:

   All: technology respondents are comfortable using in their private and professional lives, their use of technology for self-care / patient care, their attitudes towards prompts and reminders, and relevant issues around privacy, security and trust

   Service users and supporters : mental health literacy and engagement with services

   Clinicians: interaction with clients, their preferences for the design and configuration of digital (mental) health tools, and intervention manuals and about their own training and support needs.

2. attitudes towards self-tracking physical and mental health in general and experience sampling methods in particular
3. potential barriers and facilitators to adoption of and adherence to the DMMH using technology probes (asking participants to work through a typical task using a DMMH prototype)
4. Vignettes to discuss:
   (a) potential contexts, mechanisms, and outcomes for the realist evaluation
   (b) potential implementation strategies for the DMMH (see Table 2), based on a brief description of the tool
5. relevant information for creating a pre-deployment initial NASSS assessment for each site

Vignettes for discussion were derived from qualitative work on the experience of using ESM in practice, while typical tasks will be based on the intervention manual.

Interviews were designed to take no longer than 1 hour. Interviews took place either in person using the same local Covid-19 safety protocols that are employed by clinicians who see patients in person or using secure video conferencing. All interviews were audio recorded with the permission of the participant.

5.2 Data Collection

Details of the interview data collection are covered in Chapter 3. Final numbers as of the end of October, 2022 are summarised in Table 5.1.

During data collection, interviewers were strongly encouraged to write memos after completing an interview. Sometimes, this was not feasible, especially when conducting several

Stakeholder Group	Belgium	Germany	UK (Scotland)	Slovakia
Service Users	20	19	6	13
Clinicians	9	14	9	10
Supporters	4	3	0	5
Administrators	5	4	2	6

Table 5.1: Completed interviews as of October 2022. All minimum recruitment targets were reached, except for supporters in the UK

interviews back to back. In these memos, interviewers were encouraged to reflect on their own impressions of the participant, the atmosphere of the interview, key lessons learned, and areas of improvement. Since most of the interviewers were also active in the team that designed the implementation strategies for WP7, they were encouraged to add detailed reflections about potential implementation strategies and areas for improvement, which they then fed back into their ongoing meetings.

5.3 Qualitative Content Analysis

The qualitative data analysis followed a directed qualitative content analysis approach. In content analysis, segments of text are associated with categories that can be summarised as a narrative or quantitatively. In this report, we use *directed* qualitative content analysis (Hsieh & Shannon, 2005), which starts with codes that are derived from a pre-defined theory. Qualitative content analysis is a very systematic 'a-priori' approach that starts with an initial coding framework (Williamson et al. 2018). This differs from qualitative thematic analysis, which follows a 'bottom up' approach that starts with the data (i.e. the researcher/s immersing themselves in the data and generating patterns and codes from there) (Ritchie & Lewis, 2003).

Based on NASSS (Greenhalgh et al., 2017), the components of DMMH, and the need to extract information about potential implementation strategies, an initial coding framework was developed. Each code carries information about a limited number of NASSS domains, and often, there will be a direct mapping. The initial codes were derived iteratively by expanding the definitions of the NASSS domains and testing coverage on transcripts of early UK clinician interviews. Thse codes were applied to a number of interview transcripts (n=12, see details below), and then further refined. Interview transcripts were kept in the original languages to ensure that the meaning and nuance captured during the interviews did not get lost during translation into English.

Coder Training

In-vivo coding was carried out as a first step of data analysis and to train coders. In-vivo coding is a form of qualitative data analysis that places emphasis on the actual spoken words of the participants and derives codes from the data itself (Saldaña, 2022). The coders/analysts read the qualitative data in-depth and identify segments of texts (short quotes) to summarize each paragraph. In-vivo coding represents a first cycle coding method in qualitative data analysis. Four transcripts, one per stakeholder group, were read thoroughly, paragraph by paragraph. Coders then summarised each paragraph to capture participants' perspectives making use of participants' own words. This allowed codes to reflect the perspectives, real-world context, and thoughts of the participants.

Codebook Development

The first version of the codebook was developed based on in-depth reading of the first five interview transcripts from Germany (A_CIMH_01, P_CIMH_02, P_CIMH_09, S_CIMH_01, S_CIMH_02), detailed interview notes from four UK interviews (C_Lothian_01, C_Lothian_02,

Belgium	Germany	Slovakia
Stage 1: Initial Codebook Testing		
A_SK_01	A_CIMH_02	A_Bratislava_01
C_SK_02	C_CIMH_07	C_Bratislava_01
P_SK_02	P_CIMH_09	P_Bratislava_01
S_UPC_04	S_CIMH_01	S_Bratislava_01
Stage 2: Application of Revised Codebook		
A_UPC_02	A_CIMH_01	A_Bratislava_03
C_UPC_05	C_CIMH_03	C_Bratislava_02
P_UPC_05	P_CIMH_08	P_Bratislava_02
S_UPC_01	S_CIMH_03	S_Bratislava_02

Table 5.2: List of Interviews Analysed during Codebook Development

C_Lothian_03, C_Lothian_04) and input from another, similar project (IMPROVE) in Belgium.

The codebook was tested and refined in two stages. In Stage 1, coding teams from BE, DE, and SK applied the codebook to four transcripts each. These four transcripts consisted of one from each stakeholder group (clinicians, admins, service users and supporters), and were coded by two coders each, following best practice in the development of content analysis codes. During this first round of coding, the coding teams had regular and detailed discussions (both within each country, as well as the whole team of coders) about any questions, discrepancies and disagreements. Following these discussions, there were several rounds of editing and refining the codebook. In Stage 2, the final, revised codebook was used to code four transcripts per country, one for each stakeholder group. These were coded independently by two coders that took part in the codebook development stage.

In the revised version of the codebook, which was used in Stage 2 and which is reproduced in Appendix A, several codes were renamed and defined more clearly. The following codes were added:

- Two sub-codes to Implementation: Barriers, facilitators
- Personal background, which includes personal identity / cultural background / religion
- Effect of DMMH on mental health
- Two sub-codes to functionality suggestion/changes: personalisation, gamification
- Data security / data privacy
- Visualisation

The following codes were merged:

- Work and employment situation merged into one code: “work”.
- Health care system and health care policy merged into one code: “health care system” with the definition edited to reflect that the code includes health care policy.
- Integration into clinical practice and Interpreting and making use of data merged into one code: “Integration into clinical practice” with the definition edited to reflect that the code includes interpretation and making use of data.

5.4 Results

The main outcome of this phase of the project was the creation of a codebook that can be used for fast initial analysis of interviews by the trained coders.

In this section, we provide a brief narrative summary of key findings from the first set of interviews to be analysed that are relevant for IMMERSE Phase II.

It is very important to stakeholders that the app runs smoothly, without crashing, and captures data reliably. The app should be easy to use and attractive. Participants asked for

personalisation options, such as different avatar pictures or bright colours instead of a neutral gray. The chat-like interface was very familiar. Participants also raised accessibility adjustments, such as making the font size larger, or having all prompts read out.

Personalised support and accessible online and in-person training were identified as key facilitators to implementation. The personalised support should be provided by someone who has got a good understanding of the app, and this person should be easy to contact. Long manuals were deemed off putting. The way in which the clinician introduces the app to the patient is also important. Finally, it should be clear who provides the app, and what the cost is.

Both patients and clinicians viewed sharing data with clinicians as a key functionality. Clinicians wanted to use the data in therapy to get a clearer picture of the patient's condition and improve decision making.

> "You said that the whole week was fine, but I see that this happened to you on Tuesday and this happened to you. Let us go back to that." (C_Bratislava_02, trans. DeepL)

Patients were keen to review their own data in order to help them make sense of their disorder, and to discuss their thoughts with clinicians. Patients and clinicians see DMMH as going beyond mere reporting and flagging issues.

Overall, a fine balance needs to be struck between capturing enough data so it will be useful for treatment and overburdening patients. While patients said that they spend a lot of time on their phone, they were also clear that they often silence or block reminders, and that there were context such as work where they would not be checking their phone and making entries. Some participants even suggested that instead of having pre-determined reminders (at specific times), patients should be able to complete the regular monitoring questionnaire when they want to or when they notice symptoms starting. This could be in the form of completing additional entries within the app. Participants also suggested adding free text fields that patients could use for reflections, notes, or messages to the clinician. Additional functionality should focus on helping patients adhere to relevant treatment suggestions, such as drinking enough water, or taking medication on time. Participants also suggested questions that stimulate reflection about positive or happy experiences. Finally, it was suggested to include information about coping skills and links to helpful services/resources.

Visualisations were deemed to be important, and more engaging than text. They should not contain too much information and be easy to interpret. Participants saw them as an important tool for digging deeper into the data, noticing patterns, and reflecting on what was going on for the patient.

> "I think, I mean, I'm feeling very good about the app and it's very interesting and so, so, so catchy I would say. And what I like about the app is that there are visualizations, that it's not so boring, just reading, but it also includes some graphics and such visualizations through which, as you were saying, the patient can understand that where they feel good and stuff like that. I liked that very much." (P_Bratislava_02, trans. DeepL)

The role of supporters and the relationships between supporters and patients were highly complex. Supporters can be friends, neighbours, family, or even coworkers. The work of supporters was manifold. They cared for people in crisis, supported engagement with therapy and treatment, and kept track of the condition of the patients they support. While patients were often happy to share their data with clinicians, they were conscious of setting and managing boundaries with those that support them. This is summarised well by supporter S_UPC_01, who reported that her daughter would say to her "It's my depression, mum." Patients viewed their data as private and were acutely aware that non-professionals might misinterpret what was actually going on.

5.5 Discussion

Overall, patients and clinicians welcomed DMMH as a meaningful addition to therapy. While shared decision making and patient activation did not emerge as significant predictors of perceived benefit or adoption in the analysis of the survey results (c.f. Section 4.4), the qualitative findings show that improved information sharing may lead to more insight and better evidence for treatment decisions. Importantly, patients tended to trust clinicians with the data collected using DMMH, but not supporters. The main issue that might affect successful implementation is the requirement for regular data collection throughout the day. It is likely that some contexts might be systematically underrepresented.

6. Lessons Learned

Recruitment

In several sites, researchers noted significant degree of support from clinicians for the project and especially for the premise of the app. This bodes well for Phase II as we are reliant on these clinicians to introduce the app to their patients. It is clear, however, that we cannot assume that clinicians will introduce the app to participants on their own accord, even though they see the benefit of DMMH. It is vital that we have some degree of presence in the wards in order to encourage clinicians to initiate the use of the app and to help them set up the app with the participant if they need it. Due to the frequent contacts and communications researchers had with the clinicians during Phase I of the study, we believe IMMERSE is now more present in their minds and this should facilitate their collaboration and support for Phase II recruitment. Phase I also allowed us to determine which of the sites that had provided strong support for the proposal in 2020 were still happy to proceed in 2022, after two years of the Covid-19 pandemic and the concomitant strain on health care systems across the world.

Recruiting supporters proved far more difficult than anticipated in the original planning. Originally, we planned to emphasise supporter recruitment, since they are a stakeholder group that is often neglected in the literature and yet closely involved in providing day-to-day care for outpatient service users. We intended for service users to recruit their supporters into the study. This happened only rarely; instead, we liaised with supporters and supporter organisations directly, and researchers worked very hard to ensure minimum targets were met. The data we do have suggests that the relationship between service users, their treating clinicians, and their supporters is complex, and boundaries around data access and data interpretation need to be carefully negotiated.

As a project, we tracked recruitment across all sites and all countries weekly during data collection for IMMERSE Phase I. A similar collaborative recruitment tracking should be implemented in Phase II, to identify any potential issues early and share best practices for improving recruitment across sites.

Ethics

Since we decided to recruit through clinics, Phase I served as a dry run for coordinating the Ethics Application across countries. In the process, sites ensured that researchers had the necessary permissions to enter wards and clinics for Phase II, such as UK Research Passports, tested mechanisms for data sharing, and established the legal requirements for this at each site. While the Data Sharing Agreement for Phase I took a long time to draft and agree between sites, it ultimately served as a starting point for the crucial Data Sharing Agreement that needs to be in place for the joint, planned analysis of Phase II RCT data.

Lessons for Implementation in Phase II

Since Phase I required us to work closely with all of the sites that were going to participate in Phase II, it allowed us to identify sites where we might struggle to recruit sufficient numbers of participants, and to adjust randomisation units accordingly. The close mapping between sites where we recruited for Phase I and sites where the Phase II RCT will take place will allow for a deeper understanding of site and country-specific context. We were also able to reuse

some of the instruments from Part A, notably the ORCA context assessment sub-scale, and the MTUAS attitude to technology scales. Key implementation strategies were validated. Although we identified potential barriers to service users reliably completing ESM data collection, these barriers were anticipated when designing the project and will be investigated in depth during the remainder of WP5 (Task T5.3).

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A. Interview Analysis Codebook

Code name	Definition	Group
Mental health	Participants talk about their own mental health in general.	All
Physical health	Participants talk about their own physical health.	All
Diagnosis	The condition or illness participants describe as having been diagnosed with. For clinicians and supporters, this covers the diagnoses that the people they treat / work with have.	All
Symptoms	Captures the symptoms participants describe.	P, S
Work	Participants talk about their work (including self-employment and volunteering), as well as employment situation (unemployment, precarity).	All
Study	Participants talk about their studies/education.	All
Family / Relationships	Participants talk about their family/partners etc.	P, S
Social life	Participants talk about their social life/friendships.	P, S
Personal background	Participants talk about their personal identity, cultural background or religious beliefs.	All
Exercise	Participants talk about any physical exercise they do.	All
Hobbies / Interests	Participants talk about their hobbies and interests.	All
Devices/use of technology	Captures participants' use of technology/devices/ access to technology.	All
App / Software	Participants talk about apps/software in general.	All
Attitude to technology	Participants' attitude towards technology.	All
Receiving Mental Health treatment	Participants talk about what mental health treatment they are receiving and their engagement in treatment etc.	P, S
Giving Mental Health treatment	Participants talk about what mental health treatment they are giving, their case load, etc.	C, A
Supporting Mental Health	Participants talk about the mental health treatment/support they are providing for somebody else in their life.	S
Other treatment	Participants talk about treatment for non-mental health related issues.	P, S
Health care system	Participants talk about the health care system and health care policy, the way they are organised, where they fit into the system, and their experiences with the system/policies. This includes attitudes towards mental health care.	All
Self-care for mental health	Participants talk about their self-care for mental health (e.g. meditation, psychological exercises, mindfulness practices).	All
Self-care for physical health	Participants talk about their self-care for physical health.	All

Code name	Definition	Group

Table A.1: Qualitative Codebook: General context of DMMH Use. Group: Stakeholder Group. A = Admin, C = Clinician, P = Service User / Patient, S = Supporter

Code name	Definition	Group
Reminders	Participants talk about the (number of) reminders/ beeps, receiving reminders, setting reminders, reacting to reminders.	All
Questions	Participants talk about the questions within the DMMH app.	All
User Interface	Participants talk about the user interface.	All
Infrastructure	Participants talk about the infrastructure needed to support the implementation of the app and their use of the app.	All
Data security / data privacy	Participants talk about data security or data privacy.	All
Purpose	Participants talk about the purpose of the app, i.e. participants describe how the DMMH can be used for specific people, situations and goals.	All
Learning technology	Captures what participants say about learning/ training for new technologies (i.e. how they would like to learn about DMMH).	All
Integration into clinical practice	Captures what participants say about how data generated from the DMMH app might be used in therapy sessions, including interpreting and making use of data. Also includes integration (present or future) with existing systems and technology available within the service.	All
Impact on therapy	Captures what participants say about how using the app might impact on their therapy. This also includes how the DMMH may fit within the interventions already delivered within the therapy.	All
Therapy engagement	Describes participants' views (both service users and clinicians) on how using the app might impact on their role in therapy.	All
Integration into daily life	Captures how using the app may impact on participants' everyday life/ how it fits into participants' daily life.	All
Effect of DMMH on mental health	Captures how using the app/DMMH might impact on participants' mental health.	All
Sharing data with clinician	Captures what participants say about sharing data with their clinician/what clinicians say about getting access to patient data/sharing data.	All
Sharing data with others	Captures what participants say about sharing data with people who are not their treating clinician/what non-clinicians say about getting access to patient data/sharing data.	P, S
Motivation to use app	Captures what participants say about their motivation to use the app.	P, S
Functionality suggestions / changes	Participants talk about making changes to the app (including adding questions, modifying questions, deleting questions). This code also includes suggestions for additional/passive data collection: e.g., daily step count or including a daily inspirational/motivational quote.	All

Code name	Definition	Group
Personalisation	Participants talk about personal configuration elements.	All
Gamification	Participants talk about gamification elements, e.g. collecting virtual points/ rewards.	All
Other stakeholders	Captures what participants say about other stakeholders.	All
Changes to work flow/ organisation	Participants describing changes to their work flow, their organisation, or their day (e.g. needing more time to prepare sessions/resources needed to support app infrastructure/ensuring that they are in an appropriate place to receive app reminder)	All
Implementation	Captures what participants say about implementation of the app.	All
Barriers	Captures things that make implementation difficult.	All
Facilitators	Captures things that make implementation easy.	All
Visualisation	Captures what participants who were shown examples of the visualisations say about them, and any suggestions for their improvement.	All
Future use	Captures participants' views on future use of the DMMH app.	All
DMMH	Content that is relevant to the DMMH, but not covered by one of the above codes	All

Table A.2: Qualitative Codebook: Codes Referring to the DMMH Itself. Group: Stakeholder Group. A = Admin, C = Clinician, P = Service User / Patient, S = Supporter