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Implementing digital mobile mental health in routine care

Submission date
20/07/2022

Recruitment status
No longer recruiting

Registration date
03/08/2022

Overall study status
Completed

Last Edited
25/06/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Digital technology provides a unique opportunity to involve service users in their clinical care. Digital Mobile Mental Health (DMMH) is an innovative, evidence-based digital health tool, which is based on the Experience Sampling Method, a method similar to that of a structured daily diary. It offers the opportunity for service users to be at the center of their therapy by providing patients the ability to be more involved in the shaping of their therapy goals, as well as the opportunity to lead discussions with their clinicians about their complaints, recovery, and well-being. As part of the Implementing Mobile MEntal health Recording Strategy for Europe (IMMERSE) consortium, we aim to evaluate the implementation of the DMMH tool into routine mental health care in 4 countries in Europe.

DMMH is a web- and app-based software system that consists of a health app (the “MoMent app”) that lets users of mental health services document how they feel throughout the day. With this app, service users together with their practitioners can view the information collected, discuss and use a secure feedback website (the “MoMent dashboard”) to better understand their treatment and condition.

In addition to this, we want to identify key aspects which contribute to the successful and effective implementation of the DMMH in routine mental health care. We will do this by talking to, and observing, service users and clinicians. We aim to establish what works, for whom, in what circumstances, in what respects, to what extent, and why.

Who can participate?
Help-seeking service users and clinicians in charge of their treatment within the mental health services at the participating clinical units and their care pathways will be eligible.

What does the study involve?
In this clinical trial, the use of the MoMent app in conjunction with standard care will be compared to standard care without app use. Participants will either have the opportunity to use the MoMent app or not based on which clinical unit they are admitted to. Clinical units will be allocated to either the experimental group or the control group, with an equal chance of being in either group (like tossing a coin). Participants and researchers will not have a choice in the

treatment given. The participants admitted to clinical units which are allocated to the experimental group will have the opportunity to use the MoMent app for a maximum period of 6 months, which will be offered to service users by the clinician in charge of their treatment (i.e. psychiatrists, psychologists, specialist mental health nurses, or other key workers) during their admission. During the intervention period, participants using the MoMent app will be asked a range of questions daily related to mental health symptoms, mood, current activity, and social activity. These can be chosen by the clinician alongside the participant. In the first 2 months, various implementation strategies will be provided including a manual. The participants admitted to clinical units which are allocated to the control group will receive their standard treatment as usual.

The study will consist of one baseline and three follow-up assessments conducted by the research team who will not be aware of whether a participant/clinician is in the control or experimental condition. The baseline assessment will involve a phase of 6 consecutive days of ESM monitoring and the completion of questionnaires. Follow-up assessments will be completed at 2, 6, and 12 months post-baseline.

What are the possible benefits and risks of participating?
There are no direct benefits to participants from participating in this study. However, this study is important because it aims to improve our understanding of how the MoMent app and similar technologies can best be used to help people with mental health problems and those who treat them. Smartphone apps for monitoring mood and mental health have been used in research for about 20 years. The use of these technologies has been shown to be feasible in different patient groups and no worsening of complaints occurred. The risk of adverse effects or discomfort is very low.

Where is the study run from?
The study is sponsored by the Central Institute of Mental Health (Germany) and led by the following clinical sites within mental health services in Belgium, Germany, Scotland, and Slovakia:
1. Central Institute of Mental Health in Mannheim, Germany
2. Psychiatric Centre Nordbaden in Wiesloch, Germany
3. KU Leuven University Hospital UZ in Leuven, Belgium
4. Psychiatric Hospital Sint-Kamillus in Bierbeek, Belgium
5. NHS Lothian Mental Health Service, Scotland
6. Psychiatric Clinic of Faculty of Medicine and University Hospital in Bratislava, Slovakia
7. Faculty of Medicine, PJ Safarik University in Kosice, Slovakia

When is the study starting and how long is it expected to run for?
From July 2022 to March 2025

Who is funding the study?
European Union’s Horizon 2020 Research and Innovation Programme

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
318332

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2022-07-IMMERSE, V.1.5, EU Horizon 2020 research and innovation programme grant agreement: 945263, IRAS 307153, CPMS 53732

Study information

Scientific Title
Strategies, processes, contextual factors, outcomes, and costs of implementing Digital Mobile Mental Health in routine care in four European countries: a parallel-group cluster randomized controlled trial

Acronym
IMMERSE

Study objectives
Primary hypothesis:
Compared with the control condition (TAU), patient-reported service engagement (primary outcome) assessed with the total score of the Service Attachment Questionnaire (SAQ), will be higher in the experimental condition (DMMH + implementation strategies + TAU) at 2-month post-baseline, while controlling for service engagement and clinical investigation site at baseline.

Secondary hypotheses:
Compared with the control condition (TAU), personal recovery, self-management, shared-decision making, personalized therapy goal attainment, social functioning, symptom improvement, reflective functioning, emotion regulation and quality of life will be higher and symptom severity will be lower in the experimental condition (DMMH + implementation strategies + TAU) at 2-, 6- and 12-month post-baseline, while controlling for respective secondary outcome scores and clinical investigation site at baseline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 24/10/2022, Ethics Committee II of the Medical Faculty Mannheim, Heidelberg University (Theodor-Kutzer Ufer 1-3, Mannheim, 68167 , Germany; +49 (0)62138371770; ethikkommission-II@medma.uni-heidelberg.de), ref: 2022-414MF
2. Approved 21/10/2022, Federal Agency for Medicines and Health Products (Avenue Galilée - Galileelaan 5/03, BRUSSELS, 1210 , Belgium; +32 (0)2 528 4000; ct.rd@fagg-afmps.be), ref: CIV-22-08-040547
3. Approved 20/02/2023, West of Scotland REC 4 (Edinburgh, EH7, UK; +44 (0)141 314 0213; WoSREC4@ggc.scot.nhs.uk), ref: 22-WS-0125 318332
4. Approved 31/08/2022, Etická komisia Lekárskej fakulty Univerzity Komenského a Univerzitnej nemocnice Bratislava Nemocnica Staré Mesto (Mickiewiczova 13, Bratislava, 811 01, Slovakia; +421 (0)259 357 669; eticka.komisia@pe.unb.sk), ref: 71/2022
5. Approved 10/01/2023, Ethics Committee of the Presov Self-Governing Region, Presov, Slovakia. (Urad Presovskeho samospravneho kraja, Presov, 08001, Slovakia; +421 (0)517081639; zdravotnictvo@psk.sk), ref: 03891/2023/OZ-4

Study design
Multicenter parallel-group cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Mental disorders

Interventions
In a multi-centre, parallel-group cluster randomised controlled trial (cRCT), service users and clinicians in clinical units (as the cluster and unit of randomization) randomly allocated to the experimental condition will receive the Digital Mobile Mental Health (DMMH) intervention and implementation strategies. The control condition will be treatment as usual. A validated and concealed procedure for randomisation will be applied independently of the research team using an unbalanced 2:1 ratio for allocating clinical units to the experimental and control condition stratified by the eight sites.

The Digital Mobile Mental Health (DMMH) intervention consists of the following:
1. The MoMent App, a digital application for mobile devices based on Experience Sampling Methodology (ESM), to systematically monitor service users' self-reported momentary mental state, mood, symptoms, activities, context, therapy goals, key problem areas, and momentary quality of life in daily life
2. The MoMent Management Console that allows clinicians to tailor the idiosyncratic treatment goals and questionnaires that are presented by the MoMent App (together with the individual service user), and generate reports that provide meaningful information from the self-report data using the integrated MoMent dashboard, an interface to visualize and distill the collected data into tailored feedback to the service users and their clinicians

The DMMH intervention and implementation strategies will be delivered over a 6-month intervention period, including an initial 2-month period for focused delivery of DMMH and implementation strategies (in the first two months of the intervention period), in which service users and clinicians will receive the implementation strategies and will be required to use the DMMH in the form of ESM-based monitoring via the MoMent App in service users and feedback for service users and clinicians on the MoMent dashboard for visualization. In the remainder of the 6-month intervention period, service users and clinicians will continue to have access to the DMMH and implementation strategies.

Intervention Type
Mixed

Primary outcome(s)
Patient-reported service engagement measured using the Service Attachment Questionnaire at 2 months

Key secondary outcome(s))
1. Clinician, researcher-rated, and patient-reported service engagement measured using the Service Engagement Scale (SES) at 2, 6, and 12 months
2. Patient-rated accounts of recovery measured using the Questionnaire about the Process of Recovery (QPR) at 2, 6, and 12 months
3. Patient-rated self-management measured using the Mental Health Self-management Questionnaire (MHSEQ) at 2, 6, and 12 months
4. Patient- and clinician-rating of the extent of shared decision making in clinical encounters measured using the 9-item Shared Decision-Making Questionnaire (SDM-Q-9) at 2, 6, and 12

months
5. Extent to which patient goals are achieved measured using Goal Attainment Scaling (GAS) at 2, 6, and 12 months
6. Patient-rated social functioning measured using the Social Functioning Scale (SFS) at 2, 6, and 12 months
7. Patient-rated loneliness measured using the UCL Loneliness Scale at 2, 6, and 12 months
8. Researcher-rated illness severity and change measured using the Clinical Global Impression (CGI) scale at 2, 6, and 12 months
9. Patient-rated general health measured using the General Health Questionnaire (GHQ-12) at 2, 6, and 12 months
10. Patient-rated quality of life measured using Manchester Short Assessment of Quality of Life (MANSA) at 2, 6, and 12 months
11. Health-related quality of life measured using the EuroQol 5-dimension 5-level questionnaire (EQ-5D-5L) at 2, 6, and 12 months
12. Service use measured using the Client Service Receipt Inventory (CSRI) at 2, 6, and 12 months
13. Reflective Functioning and emotion regulation measured using the Reflective Functioning Scale (RFS) and the Difficulties in Emotion Regulation Scale (DERS) at 2, 6, and 12 months

Completion date
30/03/2025

Eligibility

Key inclusion criteria
Service users:
1. Aged between 14 and 64 years
2. Help-seeking for mental health problems and deemed sufficiently unwell to be accepted for specialist mental health treatment
3. In contact with local inpatient, outpatient, or community mental health services at the participating clinical sites
4. Able to provide informed consent

Clinicians:
1. Providing care and being the clinician in charge of treatment for included service users in one of the clinical units at the participating clinical sites

Participant type(s)
Health professional, Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
14 years

Upper age limit
64 years

Sex
All

Key exclusion criteria
Service users:
1. Evidence that psychiatric symptoms are precipitated by an organic cause (incl. a diagnosis of ICD-10 F00-F09)
2. Significant risk to themselves or others
3. Clinical diagnosis of intellectual disability (ICD-10 F70-79) or disorders of psychological development (ICD-10 F80-89) that are sufficiently severe to impair a person's ability to provide informed consent
4. Medical or psychological contra-indication (as judged by the clinician in charge)
5. Self-reported inability or unwillingness to use a smartphone to collect ESM data
6. Not fluent and literate in German (Germany), Dutch (Belgium), Slovak (Slovakia), or English (Scotland)
7. Short life expectancy/terminal illness

Date of first enrolment
01/11/2022

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
United Kingdom

Scotland

Belgium

Germany

Slovakia

Study participating centre
Central Institute of Mental Health
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Study participating centre
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Sponsor information

Organisation
Central Institute of Mental Health

ROR
https://ror.org/01hynnt93

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
Access to data generated in the IMMERSE consortium can be requested via the following link https://redcap.gbiomed.kuleuven.be/surveys/?s=4EYK9J7TLNMJ7FJY when data collection has been completed.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		24/06/2024	25/06/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Statistical Analysis Plan	Study website	30/10/2023	11/12/2023	No	No
Study website		11/11/2025	11/11/2025	No	Yes