WP7
Implementation Strategies, Processes, Outcomes and Costs

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General Assembly meeting Edinburgh, 31/3/22

This project has received funding from the European Union's Horizon 2020 research and innovation Programme under grant agreement 945263 (IMMERSE)

Work package 7: Overview

Time	Topic	Speaker
14:30- 14:40 min	Timeline, deliverables, milestones	Uli
14:40- 14:50 min	Data collection: outcome assessment (7.1.3)	Anita
14:50- 15:00 min	DMMH (7.1.1), Implementation strategies (7.1.4)	Simona/Matthias
15:00- 15:10 min	Ethics approval (D7.2.1), cRCT (D7.2.2)	Uli
15:10- 15:20 min	Economic evaluation	Valerie/Hoa
15:20- 15:30 min	Timeline, next steps	Uli

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WP7 – Deliverables & Milestones

	Task	Deadline
D 7.1	Consolidated description of intervention and implementation strategies	**16.09.22**
MS 9	Tailoring and optimization of DMMH intervention and implementation strategies and guidelines for semi-structured interviews finalized	16.09.22
7.1.1	Finalize DMMH intervention manual	15.12.21
7.1.2	Prototype development: Requirements document (led by WP2!)	15.12.21
7.1.3	Data collection: outcome assessment	**30.05.22**
7.1.4	Development and optimization of implementation strategies	**30.05.22**
D7.2	Completion of "First study subject approval package"	**16.09.22**
7.2.1	Ethics application (phase II) (Clinical Investigation Plan, IC, PIS)	30.05.22 (TBC, WP2)
7.2.2	Implementation cRCT	16.09.22

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WP7 – Deliverables & Milestones

	Task	Deadline
D7.2	Completion of "First study subject approval package" (cont.)	**16.09.22**
	(…)	
MS 11	Preparation of clincial trial completed	16.09.22
MS 12	First patient, first assessment	16.09.22
	216th patient included (50% of full sample, 27 patients per site)	31.12.22
D 7.3	Completion of Midterm recruitment report	18.07.23
	(…)	
MS 19	DMMH usage completed by last patient (sample complete 100%)	31.12.23
	(…)	
D7.4	Completion of “Report on status of posting results”	31.03.25

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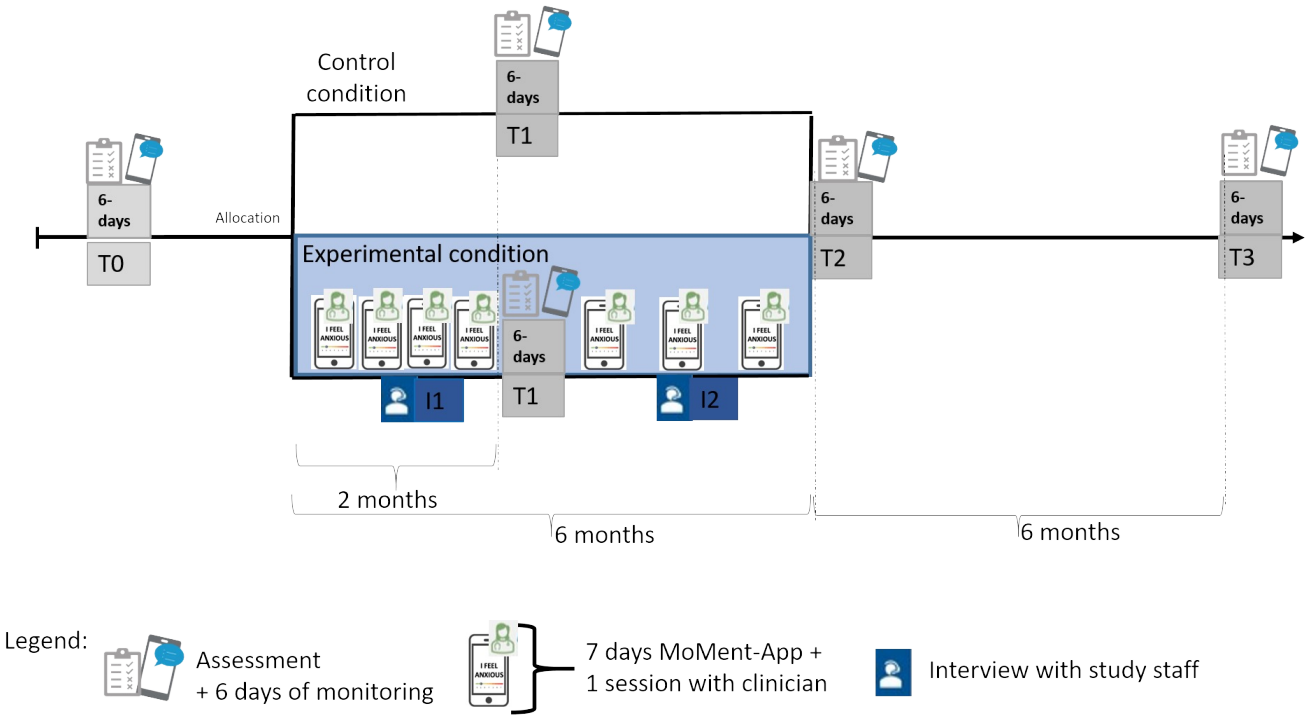
D7.1.3 Data collection: outcome assessment

Outcome assessment (Michal; due: 30.05.22)

- Questionnaires at timepoints see basecamp
- For ethics submission: full list of questionnaires

Decisions:

1. Additional/ other questionnaires (due: 22.10.21)
2. Translation of measures (due: 31.1.22)
3. Implementation in eCRF (due: 30.06.22)
4. 6 days of ESM + mobile sensing? → Workgroup on ESM programming + testing
5. Mobile sensing over the course of the intervention (always only 6 days on)? → Workgroup
6. Qualitative and quantitative measures for process evaluation (Matthias; due: 30.05.22)



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Implementation strategies

WP7

Slides by: SDF, KS,IB

Working group

Anita Shick, Simge Celik, Julia Schulte- Strathaus, Adam Kurilla, Matej Hrabovsky, Lena de Thurah, Koraima Sotomayor-Enriquez, Islay Barne, Simona Di Folco

The University of Edinburgh

General Assembly meeting 30th of March 2022

Theoretical framework: Shared Decision Making

“It is a person-centred approach to care which encompasses all health professions and fields and includes "...a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care. It could be care the person needs straightaway or care in the future, for example through advance care planning.

It involves choosing tests and treatments based both on evidence and on the person’s individual preferences, beliefs and values. It means making sure the person understands the risks, benefits and possible consequences of different options through discussion and information sharing. This joint process empowers people to make decisions about the care that is right for them at that time (with the option of choosing to have no treatment always included)." (NICE, 2021)

The DMMH as a tool at the centre of a new innovative way of promoting and enhancing shared decision making in clinical practice

https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making#:~:text=Shared%20decision%20making%20is%20a,individual%20preferences%2C%20beliefs%20and%20values

Promoting and Supporting Shared Decision Making in clinical practice with the DMMH intervention

Vision & Objectives

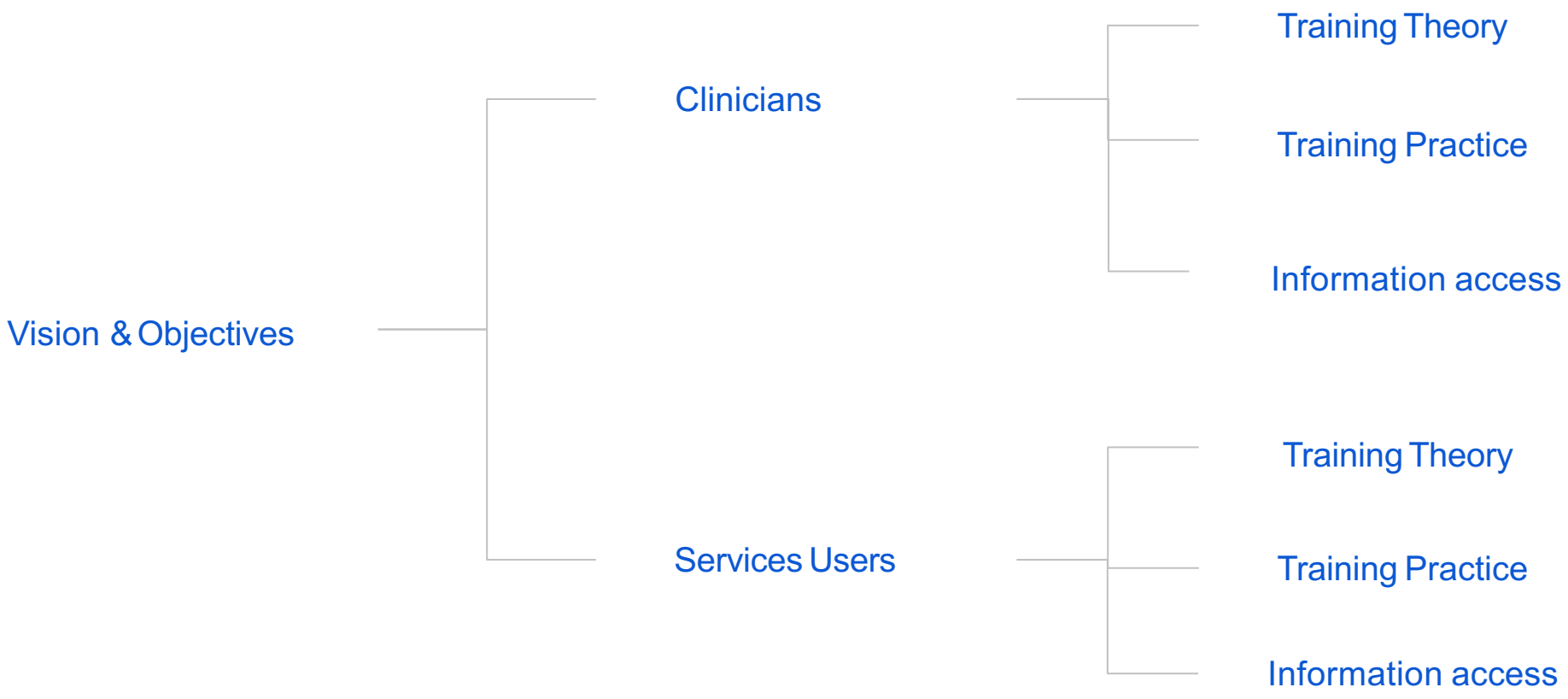
Enable clinicians to use the DMMH with service users in a beneficial way

C1	Provide initial training to the clinicians that allows them to master therapeutic and technical aspects of the DMMH	• 1.1) Training clinicians to master the essential therapeutic aspects of the DMMH • 1.2) Train clinicians to master the technical aspects of the DMMH.
C2	Establish long term support for the use of the DMMH that allows its use without support from the research team.	• 2.1) Provide easy to access and easy to navigate information platform • 2.2) provide direct research-participant support (first 2 months)
SU1	Provide them with sufficient support to start using the DMMH	• 3.1) Service users understand the purpose of the DMMH • 3.2) Service users master the technical skills to use the DMMH app

C: Clinicians, SU: service users

Vision & Objectives

Enable clinicians to use the DMMH with service users in a beneficial way



Essential skills for each objective- Clinicians

Training theory	Training practice
• Introduce and explain the DMMH • Practice collaborative Shared Decision Making (SDM) • Review treatment based on ESM data • Interpret and present data to the client • Discuss how to use the information obtained from the data • Set personal goals	• Creating an account and logging in • Make a new ESM intervention • Personalize the ESM intervention • Navigate the visualizations tabs

Essential skills for each objective- Service users

Training theory	Training practice	Information access
• Being aware of own agency when discussing decisions during the therapeutic treatment • Discuss the DMMH data with the clinician • Review treatment • Set goals to work on during the DMMH	• Creating an account and logging in • Navigate the app	• Troubleshooting guide • Cheat sheets • Refreshment material • Videos • Researchers support

Materials to be created

- **Workshop (problem-focused and interactive)**
- **Vignettes**
- **Cheat sheets**
- **Manual**

- Webpage
- Video clip with use cases
- Newsletter with tips and progress monitoring (TBD)
- Coffee catch up with the researcher

Miro board: https://miro.com/app/board/uXjVOGpOOgc=/

Next steps

- Screenshots and Videos using the prototype
- Discuss differences for each site
  - What would clinician's preferences influence our implementation strategies?
  - What about availability times?
  - What about different settings?
- Offer a variety in the strategies proposed (having a core material, essential, and additional resources that can be used at local sites, depending on the setting and needs)

Deadlines

- First draft of the implementation strategies material: 15th of April
- Second draft of the material translated at the local sites: 15th of May
- Roll out of the implementation strategies: June 2022.

D7.2 Ethics approval (D7.2.1), cRCT (D7.2.2)

Ethics application (phase II; submission, 23.05.22, TBC with WP2/movises)

- Amendment, phase I ethics (submission: 30.04.22 , approval: 31.05.22)
- CIP: draft reviewed by medX (28.01.22), finalized as much as possible, some open points (final draft: 23.05.22)
- Informed Consent (IC) forms and Participant Information Sheets (PIS) (final draft: 08.04.22)

Completion of "First study subject approval package" (by 16.09.22)

- finalize IFU and IB (30.04.22)
- Standard Operating Procedures (SOPs), Trial Master File (TMF) (final draft: 23.05.22)
- Registration with competent authority (BfArM), incl. MDR course certificates, submission of ethics application (23.05.22)
- Investigator Site File (ISF) (23.05.22)

Statistical Analysis Plan (final: 30.05.22)

- Randomization strategy (clarify cost, external/in eCRF)
- Publish SAP prior to randomization (i.e., by 30.05.22)

Develop/finalize recruitment strategies (16.09.22)

- Ongoing issues: Tayside (PI TBC), Kosice (Clinical Department, TBC), Bratislava (blinding, TBC)

Implementation of outcome measures (eCRF system) (test version: 30.06.22, final: 16.09.22)

START: cRCT Implementation Outcomes Evaluation (on 16.09.2022)

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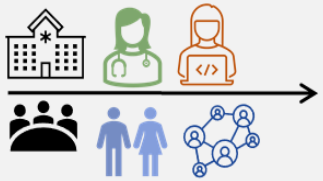
Economic evaluation of DMMH: objectives

- To assess the economic costs of development and implementation of the DMMH intervention
- To assess the cost-utility of the DMMH vs the satus quo of standard service provision

Study design and overall approach

Phase I

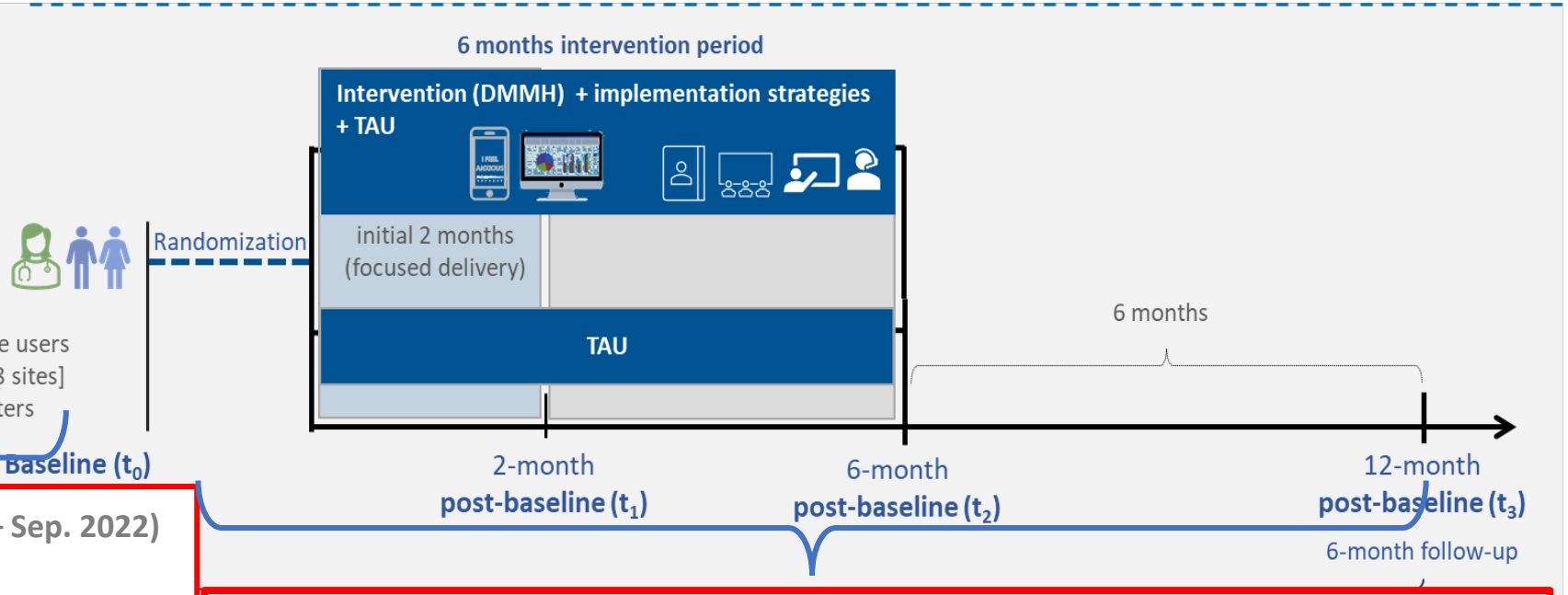
Participatory field study



Service users
Clinicians
Service users' network
IT / health care management

Phase II

Pragmatic, multi-centre, parallel-group cluster randomized controlled trial (cRCT)



Design Phase: Apr. 2021 – Sep. 2022)

Costing development of

- DMMH information technology system (MoMent App + management console
- Intervention manual, training and support packages
- Package of tailored information for service users

Implementation Phase (Oct. 2022 – Sep. 2024)

- Costing implementation of DMMH in 4 countries, 8 clinical sites

- Assessing utility of DMMH measured in QALYs & estimating cost utility of DMMH versus status quo

Zentralinstitut für Seelische Gesundheit
Landesstiftung des öffentlichen Rechts

What has been done so far?

- Costing study
  - Develop the activity list and identify data needs
  - Interview staff in charge in WP7 and WP2 to understand roles and tasks of various personnel involved in the design and early implementation
  - Compile contacts to support with collecting cost information
  - Identify the most up-to-date version of CSRI to collect resource consumption at patient level

- Cost utility analysis
  - Identify information required to register for use of EQ-5D-5L
  - Identify the value sets of EQ-5D used for the study countries
  - Examine the validity of EQ-5D for mental health patients
  - Have an overview of the outcomes measured in the main trial

What are the next steps?

- Adaptation of CSRI
  - Streamline CSRI: Identify all necessary questions
  - Integrate in full questionnaire: ensure all needed background information is included
  - Adapt and translate for each country: versions already available in English, Dutch, German
- Additional interviews of key information to trace the remaining information on costs of the design phase
- Development of tools to trace the program cost during the implementation phase
- Registration and integration of EQ-5D

What supports are needed?

- **Adaptation of CSRI**: seeks meetings and inputs from the study leads in each study country to make sure the CSRT questions are comparable across sites and well integrated in the patient survey questionnaire

- **Validity of EQ-5D**: supports to connect with experts who have used EQ-5D for mental health patients

- **Activity list and data needs**: final round of inputs will be sought to finalize the activity list and data needs which serve as the basis to develop tools to collect cost data of the implementation phase

WP7 – Year 2: Upcoming activities

- Complete field study for a priori assessment of contextual factors and tailor implementation strategies
- Consolidate the description of intervention and implementation strategies
  - DMMH information technology system
  - Intervention manual, training and support package for clinicians and services
  - Package of tailored information, counselling, and reminders for service users
- Prepare cRCT (e.g., training of research staff, prepare eCRFs/database, address regulatory requirements etc.)
- Obtain ethics approval for cRCT / inform competent authority

- Recruit first participants: September 2022
- 50% of participants enrolled: December 2023

} i.e. 27 participants per site (around 9 per month)

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Thank you for your attention!

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DMMH (7.1.1), Implementation strategies (7.1.4)

DMMH Intervention Manual (finalize based on phase II: 30.05.22)

Development and optimization of implementation strategies (**Deadline: 30.05.22**) -> Matthias/Simona

- Documentation of meetings with clinical leads (all, always): Meeting 28.4.22
- Identify commonalities and differences across sites / service contexts
- Develop training manual etc. for clinicians (first draft: 15.12.21)
- Develop counselling package etc. for service users (first draft: 15.12.21)
- **Optimize and finalize based on findings from phase I (30.05.22)**
- Roll out of implementation strategies (after randomization of units) to **clincians**: 1) manual, 2) workshops (August), other material (videos) 4)provide monthly feedback (16.9.22)

Discussion:

1. How to identify and approach line managers, opinion leaders?
2. Unblinded staff: training of practical support teams

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