

WP7

Implementation Strategies, Processes, Outcomes and Costs

Ulrich Reininghaus, Anita Schick

Department of Public Mental Health, CIMH

Michel Wensing

*Department of General Medicine and Health Services
Research, UKHD*

Live Steering Committee meeting Leuven, 18/04/22



Work package 7: Overview

- D7.2 Completion of 'First study subject approval package'
- D7.1 Consolidated description of intervention and implementation strategies
- Status: contracts and regulatory aspects
- Timeline: recruitment and assessment
- Next steps
- Discussion





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D 7.2 Completion of 'First study subject approval package'

- Submitted on 31.10.22
- Obtained ethical approval in all countries

Site	Ethics approval	Notification of competent authority	Site Initiation Visit
Bratislava	31.08.22	Done	8.11.22
Lothian	24.10.22	N/A	8.11.22
Leuven	21.10.22	21.10.22	9.11.22
Bierbeek	21.10.22	21.10.22	9.11.22
Mannheim	26.10.22	14.11.22	9.11.22
Wiesloch	14.11.22	14.11.22	TBC
Kosice	To be obtained	To be notified	TBC

Deliverable

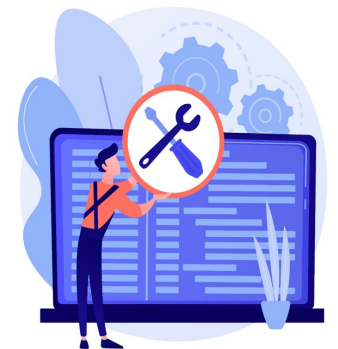


This project has received funding from the European Union's Horizon 2020 research and innovation Programme under grant agreement 945263 (IMMERSE)

D 7.1 Consolidated description of intervention and implementation strategies



- Submitted on 31.10.22
- Implementation strategies:
 - Technological: DMMH
 - For clinicians: IFU, manual, cheatsheet, workshop, webpage, videos, support
 - For users: IFU, (manual), webpage, support
 - Organizational: clinical lead meetings (within/across sites), newsletter
- Developed and adapted to local needs



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Tailoring/status: implementation strategies

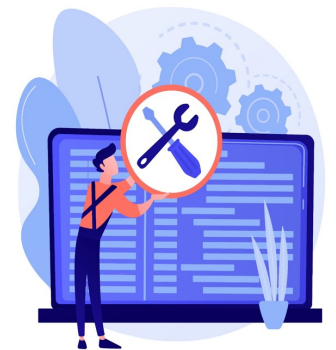


Workshops:

- Duration 60 min, 90 min and 4h
- Remote or in person
- Optional practice/monitoring phase

Status workshops:

- Germany: 2 workshops delivered (n=14)
- Scotland: 2 workshops delivered (n=13)
- Belgium: 4 workshops delivered (n=22)
- Slovakia: ? workshops delivered (n=?)

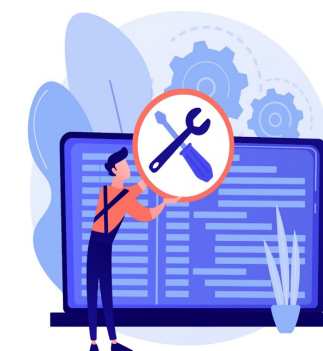


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On contracts...



Site	JCA	DPA MedX	DPA MaganaMed	DPA Movisens	Investigator Site Contract
Bratislava	Currently signed	N/A	N/A	N/A	Waiting for legal (CIMH)
Lothian	Currently signed	N/A	N/A	N/A	Waiting for R&D (Lothian)
Leuven	Currently signed	Currently agreed	Currently agreed	N/A	Signed
Bierbeek	Currently signed	N/A	N/A	N/A	Waiting for legal (Bierbeek)
Mannheim	Currently signed	N/A	N/A	Currently signed	N/A
Wiesloch	Currently signed	N/A	N/A	N/A	Signed
Kosice	Currently signed	N/A	N/A	N/A	Waiting for legal (Kosice)



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Trial registration, start



cRCT is (prospectively) registered with ISRCTN registry

<https://doi.org/10.1186/ISRCTN15109760>

1. Randomization of clinical units: 19.9.22
2. Planned start of recruitment: from 17th October 2022 (at least 1 month delay)



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WP7 – Deliverables & Milestones

	Task	Deadline	
MS 9	Tailoring and optimization of DMMH intervention and implementation strategies and guidelines for semi-structured interviews finalized	31.10.22	
D 7.1	Consolidated description of intervention and implementation strategies	31.10.22	
MS 10	Preparation of clinical trial completed	31.10.22	Original deadline
D 7.2	Completion of First study subject approval package	31.10.22	
MS 12	First patient, first assessment	11/ 22	09/22
	216th patient in (50% of full sample)	02/23	12/22
	Last patient, first assessment	05/23	03/23
D 7.3	Completion of midterm recruitment report	18.7.23	
	First patient, last outcome assessment	11/23	09/23
MS 19	DMMH usage completed by last patient (sample complete 100%)	12/23	09/23



WP7 – Next steps

- Recruit first participants: **November 2022 (instead of September!)**
 - 50% of participants enrolled: **February 2023 (instead of Dec!)**
 - **randomize 3 further units per site where contingency is necessary**
 - **decision: January 2023, if recruitment targets not met**
- } i.e. 27 participants per site
- Recruitment until May 2023 (last patient, first assessment): midterm recruitment report (18.07.)
 - DMMH intervention completed by last participant: Dec 2023
 - Discontinue implementation strategies requiring active support by research team
 - Last patient, last assessment: June 2024!
- Complete and publish Statistical Analysis Plan (January 2023)
 - Submit protocol paper (January 2023)



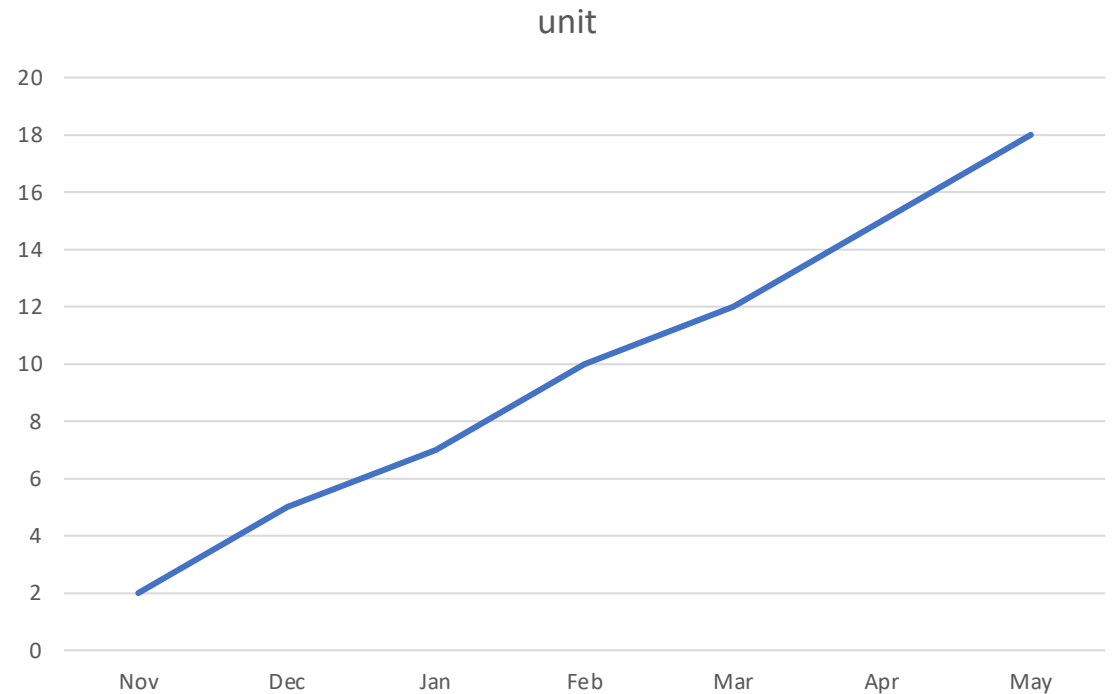
Recruitment – per site

- Target: n=54
- Recruitment per site:
 - 9 per month over 6 months (Dec-May 2023; recruitment target for Nov will not be met in any site)
 - previously: 6-7 per month over 8 months (Oct-May 2023)



Recruitment – per unit

- Target: n=18
- Recruitment per unit:
 - 3 per unit, rather 3
 - 3 per unit over 6 months (Dec-May 2023; recruitment target for Nov will not be met in any site)
 - previously: 2-3 per month over 8 months (Oct-May 2023)
- need to finalize strategies for controls



WP7 – Deliverables & Milestones

	Task	Deadline
MS 18	Data checking and cleaning for 50% of sample completed	12/23
MS 23	Last patient, last assessment (100% of sample completed)	06/24
MS 20	Data quality checking and cleaning (completed for 100% of the sample)	08/24
	Completion of statistical analysis	12/24
D 7.4	Completion of Report on status of posting results	18.3.25
D 7.5	Report on implementation process evaluation	18.3.25
D 7.6	Report on economic evaluation	18.3.25



Discussion

- @Thomas: Redcap user access established in all sites (incl. Adam, Matej and Rafael)?
- Debugging DMMH
- Additional training needs, site-specific SOPs?
- Cross-site, cross-WP communication
- Upcoming evaluation (Dec): how to fill one hour?
- Questions and comments?



WP7 - Objectives

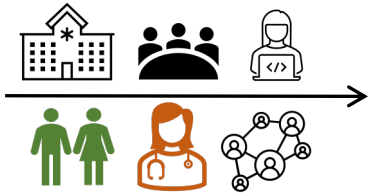


1. To tailor, optimize and evaluate detailed implementation strategies for the Digital Mobile Mental Health intervention (DMMH) at each site and identify putative contextual factors based on an a priori assessment using the NASSS framework (**task 7.1**, with WP5, task 5.1, 5.2)
2. To investigate i) **Reach**, ii) **Effectiveness**, iii) **Adoption**, iv) **Implementation** and v) **Maintenance** of implementing the DMMH in routine care (**RE-AIM**) as a basis for assessing the **public health impact** of implementation and **scale-up** of the DMMH (**task 7.2**)
3. To examine the process of implementing the DMMH in routine care and identify in vivo configurations of contexts, mechanisms of change, and how these are associated with outcomes of implementation and intervention (**task 7.3**, with WP5, task 5.3)
4. To investigate the economic costs of implementing the DMMH intervention, determine cost-utility and extended cost-utility of the intervention vis à vis standard care (**task 7.4**)



WP7 – Design, Methods

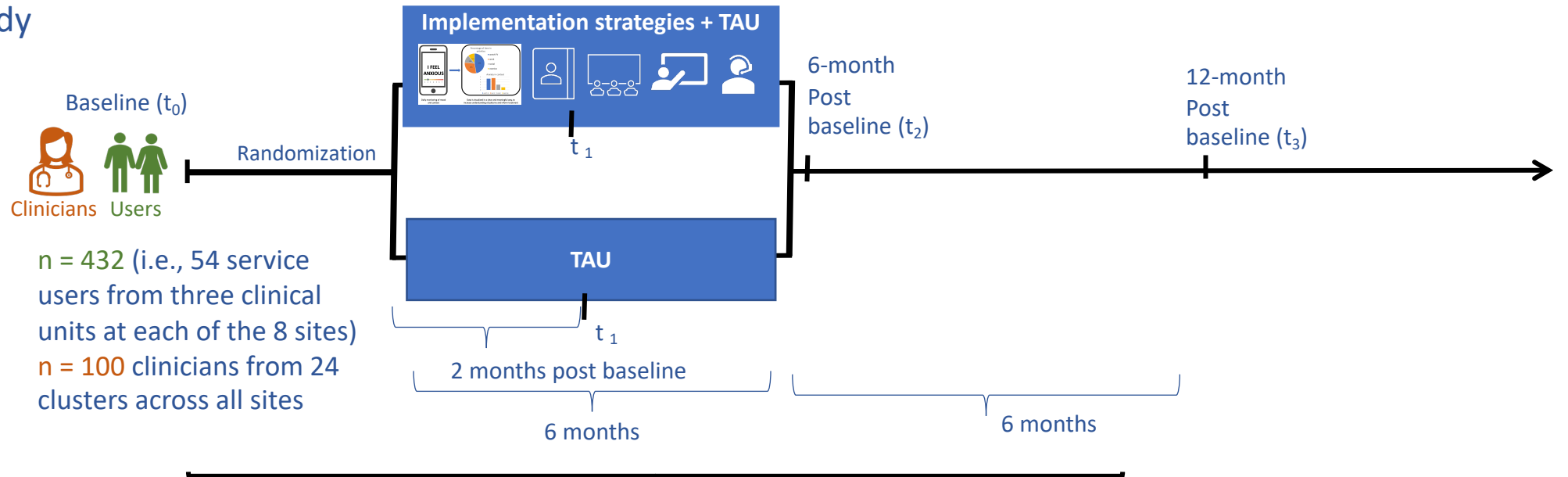
Phase I Participatory field study (month 1-18)



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

(with WP5)

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



Process evaluation of implementing the DMMH in routine care **(with WP5)**

Economic costs of implementing the DMMH

