

WP7

Implementation Strategies, Processes, Outcomes and Costs

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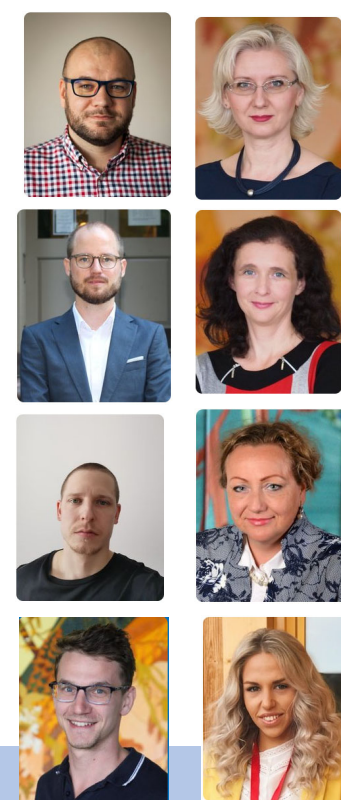
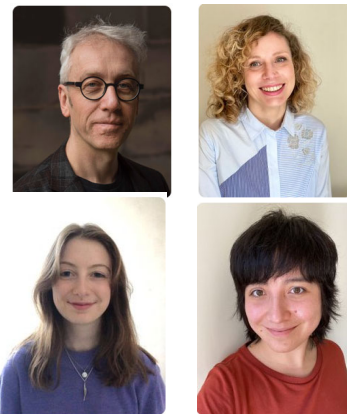
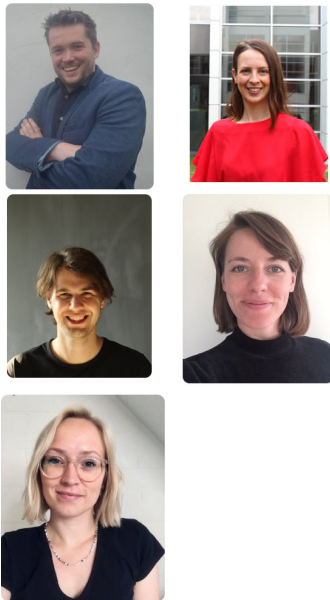
*Department of General Medicine and Health Services
Research, UKHD*

EC Evaluation, 19th June 2024



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

WP7 - Staff



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WP7 - Objectives



1. To tailor and optimize detailed strategies for implementing ESM-based monitoring, reporting and feedback (incl. the Digital Mobile Mental Health intervention (DMMH) and other strategies) in routine care at each site and identify putative contextual factors (barriers, facilitators) of implementation (**task 7.1**)
2. To investigate i) **Reach**, ii) **Effectiveness**, iii) **Adoption**, iv) **Implementation** and v) **Maintenance** of implementing ESM-based monitoring, reporting and feedback in routine care via the DMMH and other implementation strategies (**RE-AIM**) as a basis for assessing **public health impact** and **scale-up** (**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**)
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**)

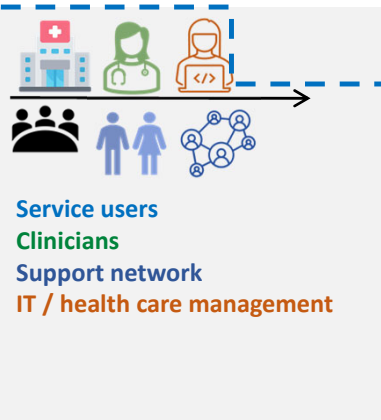


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Phase I

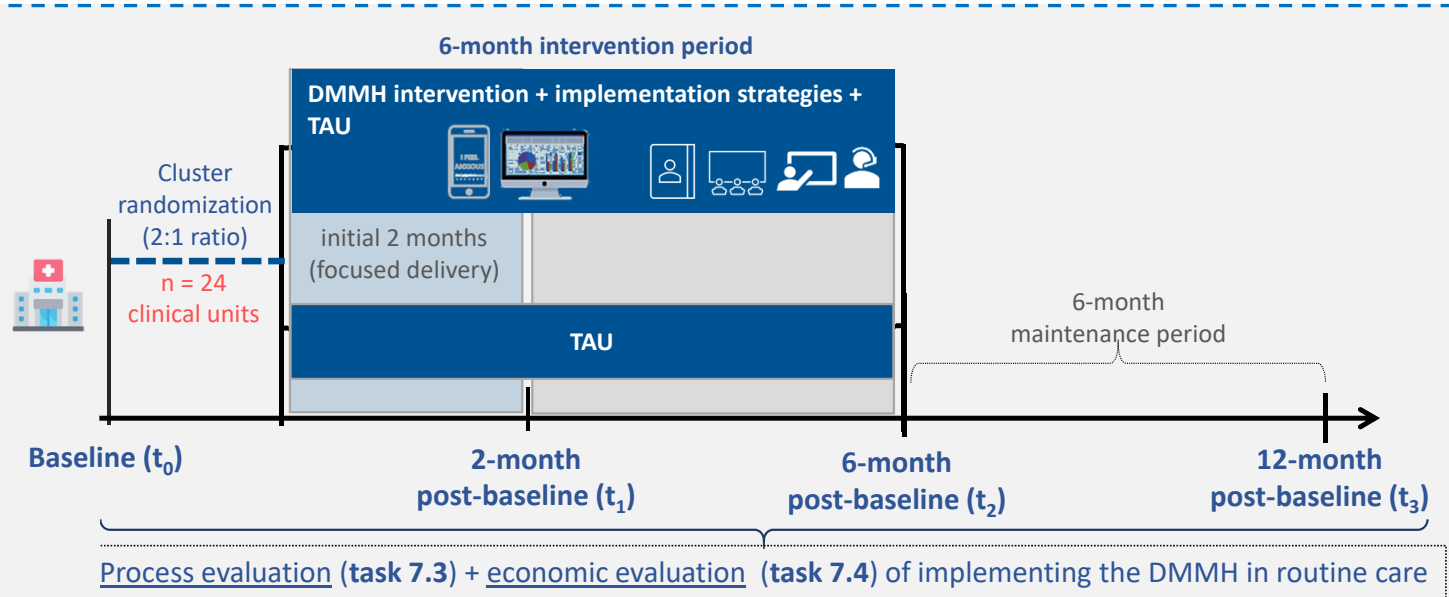
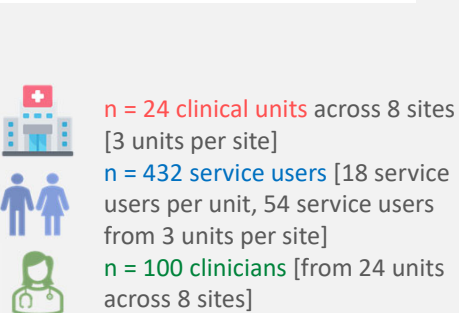
Participatory field study
(task 7.1, month 1-18)

WP7 – Design, Methods



Phase II (M19-54)

Pragmatic, multi-centre, parallel-group cluster randomized controlled trial (cRCT; task 7.2)



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WP7 – Delivery of task 7.1 (completed)

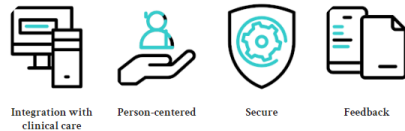


Task 7.1 Optimizing the implementation strategies

- Getting started
- Basic configuration
- Personalization of Add-ons
- Visualizations
- FAQ

Let's take a MoMent!

Thank you for taking part in the IMMERSE study. By participating in the study you are contributing with the integration of digital mobile mental health into clinical routine care.



CHEAT SHEET Dashboard Page 1

A. Registration & Login

Enter the following link:
<https://therapymanager-staging.movisens.com/>

B. Patient overview

1. Select the overhead button „Participants“.
2. Select the pseudonym of interest.
3. Set the therapy period and check Status.

Participants	Actions
[Table with columns for participant details and status]	[Buttons for actions]

C. Explanation of the Status

UNCOUPLED: Smartphone is not paired. Scan QR code to pair.

WAITING: Smartphone is paired, therapy period not yet started.

RUNNING: DMHM active. I.e. smartphone is paired and the current time is between the start and end of the therapy period.

PAUSED: Smartphone is paired, therapy period has ended.

Contact us

Should you encounter any issue when using the MoMent App or MoMent Dashboard, please contact a member of the research team:
Phone: 0131 431 7112
Email: immerse@ed.ac.uk
On the web: <https://immerse-project.eu> or (ADD the implementation website)
Mail: Contextual Mental Health Centre of University of Edinburgh, 24 Buccleuch Pl, Floor 2, Flat 10
Primary investigator: Prof. Matthias Schwartze



Manual for Clinicians

Version 2.0-27.09.2022



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WP7 – Delivery of task 7.2 (ongoing)

Task 7.2 Implementation outcomes evaluation (cRCT)

- Completion of complex research ethics, regulatory, and governance process for other clinical investigation (MDR 2017/745, §82)
- Compilation of Investigator Site Files (ISFs) and Trial Master File (TMF) for cRCT as other clinical investigation (MDR 2017/745, §82)
- Completion of Site Initiation Visits (SIVs)
- Completion of ‘first study subject approval package’ (**deliverable D7.2**)
- Implementation of trial methodology and intervention delivery
- Completion of ‘midterm recruitment report’ (**deliverable D7.3**): inclusion of 216th participant



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WP7 – Delivery of task 7.2 (ongoing)

Task 7.2 Implementation outcomes evaluation (cont.)

- Completion of audit (by external consultant) and inspection (by regional authority) at CIMH as sponsor and clinical investigation site (MPDG, §77)
 - TMF, all ISFs (ISF of CIMH in detail)
 - Sponsor responsibilities/oversight (DIN EN ISO 14155)
 - Quality assurance system, sponsor SOPs
 - Monitoring, vigilance
 - Risk and deviation management (CAPA)
 - Investigational device (IFU, risk policy DIN EN ISO 14971)
 - eCRF, data management (e.g. primary data fusion)
 - Archiving (primary archiving, DB lock, long-term archiving)
- Outcome: positive (only recruiting §82 MDR 2017/745 investigation in the region)
- We have pioneered this type of clinical investigation with an immense team effort (special thanks to WP1, WP2, and WP3)

AUDITED



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WP7 – Delivery of task 7.3 (ongoing)



Task 7.3 Implementation process evaluation

- Prepare the process evaluation to provide insight into the implementation and maintenance of the DMMH intervention
 - Development of programme theory
 - Development and piloting of interview guide
 - Conduct interviews with service users, clinicians and administrators (ongoing)
 - Transcribe interviews (ongoing)
 - Development of codebook and coding of data (ongoing)
 - Several planned outputs: conferences, papers



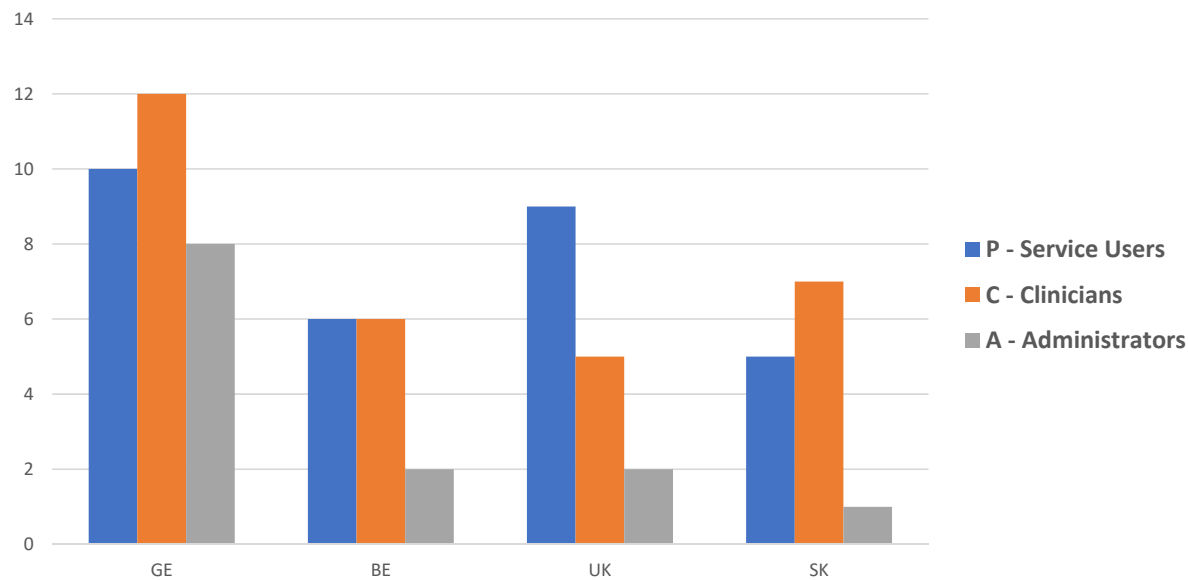
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WP7 – Delivery of task 7.3 (ongoing)



Task 7.3 Implementation process evaluation

Number of qualitative Interviews (12.6.24)



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WP7 – Delivery of D7.4 (ongoing)



D7.4 Report on posting of results

- Recruitment progress: cRCT
 - **currently included: n=350** (target n=432; **81%**)
 - all sites reached 50% of the target sample (milestone)
 - some sites: already met recruitment targets, continue to recruit (contingency)
- Final extension of recruitment (last participant in): **30th June 2024**
 - expected final sample size: **n=363 (i.e., 84%)**
 - last participant, last assessment at t_1 : 09/2024
 - last participant, last assessment at t_2 : 12/2024
 - **last participant, last assessment at t_3 : 03/2025** (earliest point in time for completing t_3)

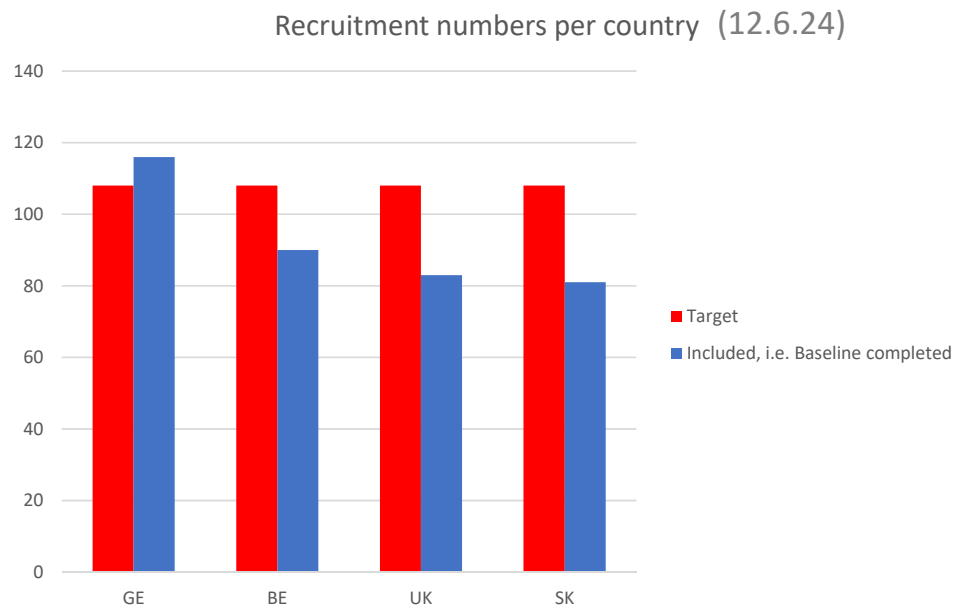


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WP7 – Delivery of D7.4 (ongoing)



D7.4 Report on posting of results: Recruitment



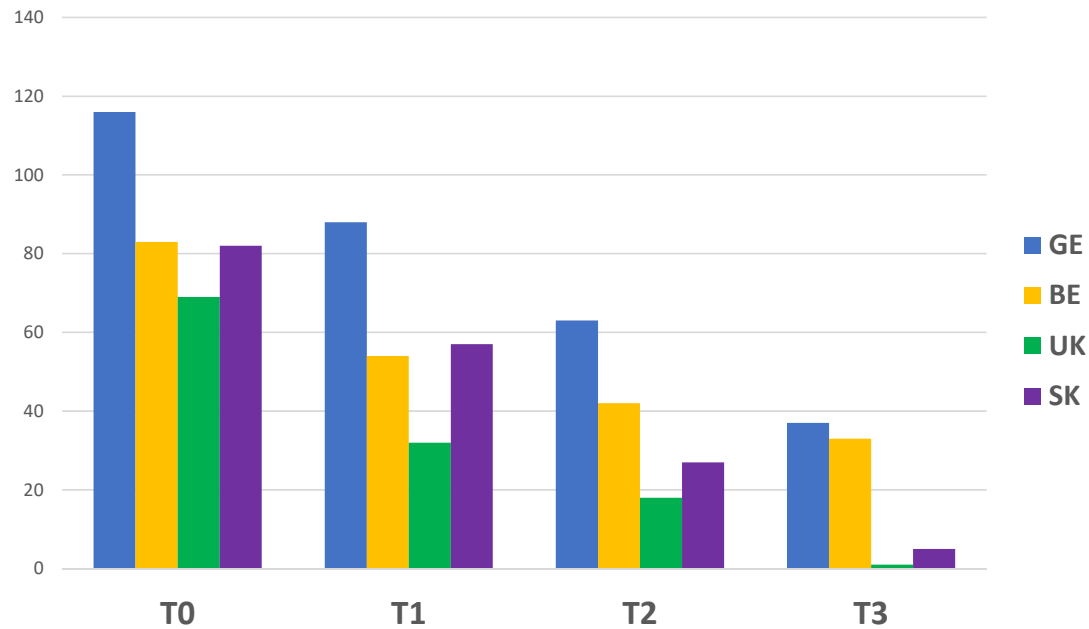
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WP7 – Delivery of D7.4 (ongoing)



D7.4 Report on posting of results: Data collection

Data collection per country (12.6.24)



Sample size calculation (CIP):
expected attrition rate= 35.5 % (i.e.,
153 participants lost to t_1)
planned sample size at t_1 : n=278



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WP7 – Delivery of task 7.4 (ongoing)



Task 7.4 Economic evaluation

- Selection of measures for the assessment of costs
- Implementation in eCRF in all languages
- Assessment of time of clinicians using the DMMH, and of researchers applying implementation strategies
- Completion of statistical analysis plan and preregistration



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WP7 – challenges and solutions



- limited resources to be used across sites and WPs
 - regular meetings: setting priorities, managing researcher time (across sites)
 - substantial in-kind contributions
- complex ethics and governance procedures in 4 countries
 - close monitoring of contracts and amendments
 - version, training etc. trackers
- strong regulatory requirements (e.g., audit/inspection)
 - close collaboration with other WPs (esp. WP1, WP2, WP3) – real team effort!
 - further in-kind contributions
- recruitment
 - iterative process of refining and extending recruitment strategies
 - several contingencies
 - strategies to minimize burden



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WP7 – Dissemination

- ISRCTN registry: <https://doi.org/10.1186/ISRCTN15109760>
- Preregistration and Statistical Analysis Plan completed and published: <https://osf.io/egpys>
- Protocol paper is accepted for publication in BMC Psychiatry
<https://www.researchsquare.com/article/rs-4293471/v1>
- Website for clinicians and service users (implementation strategy)
- Number of publications: 7
- National presentations (for clinicians) / international presentations: 21 / 19
- Preregistrations and planned papers: 11
- Social media/ twitter (X): @IMMERSE



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WP7 – Conferences



For example:

Bonnier, R (2022, September) IMMERSE: Implementing Mobile MEntal health Recording Strategy for Europe. Poster presentation at Belgian GGZ congress (<https://www.tegek.be/kenniscentrum/ggz-congres/ggz-congres-2022>), Antwerpen BE

Ulrich Reininghaus (2023, March). Digital opportunities for shared decision making in psychiatry: supportive interventions. Presented at EPA, Paris, France.



Willkommen	Programm	Teilnehmende	Unterstützer	Kontakt	LIVESTREAM
Workshop Sponsoring					

WiS-3503 – Implementierung des digitalen mobilen Monitoring und Feedback in der psychotherapeutischen Routineversorgung (#813)

A. Schick, G. Kiekens, M. Hajdúk, A. Heretik, I. Nagyova, M. Wensing, M. Schwannauer, I. Myin-Germeys, U. Reininghaus

Session: WiS-35 - Feingranulare Assessments in der Psychotherapie: Neue Erkenntnisse aus Ecological Momentary Assessment und Smart Sensing Forschung

Datum: Donnerstag, 13. Juni 2024, 15:00

Ort: Estrel Saal C8 (Estrel C8)



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WP7 – Next steps



	Task	Original deadline	New deadline	Potential extension
MS 18	Data checking and cleaning for 50% of sample completed	12/2023	07/2024	-
MS 19	DMMH usage completed by last patient (sample 100% complete)	12/2023	12/2024	-
MS 20	Data quality checking and cleaning (completed for 100% of the sample)	08/2024	03/2025	-
MS 23	Last patient, last assessment (100% of sample completed)	06/2024	03/2025	-
	Completion of statistical analysis	12/2024	03/2025	04/2025
D 7.4	Completion of Report on status of posting results	18.3.25	03/2025	09/2025
D 7.5	Report on implementation process evaluation	18.3.25	03/2025	09/2025
D 7.6	Report on economic evaluation	18.3.25	03/2025	09/2025



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Thank you for your attention!



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