IMMERSE

Implementing Mobile MEntal health Recording Strategy for Europe

H2020 - 945263

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Document History

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1. Summary

The fourth and final live General Assembly meeting was held in Leuven, Belgium, on June 24th and June 25th 2025. Not all members were able to join the meeting in Leuven, due to a national strike in Belgium on June 25th, therefore some members joined online (see appendix 1, list of participants). See appendix 2 for the minutes of the meeting.

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IMMERSE: Implementing Mobile MEntal health Recording Strategy for Europe

APPENDIX 1: LIST OF PARTICIPANTS

at the General Assembly held on June 24th and 25th 2025 in Leuven

Name	Partner
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Zuzana Katrienkova (online)	UPJS
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Julia Schulte-Strathaus	CIMH
Inez Germeys	KU Leuven
Anita Schick	CIMH
Thomas Ganslandt	Erlangen
Lotte Uyttebroek	KU Leuven
Ulrich Reininghaus (online)	CIMH
Simon Krause	Movisens
Hoa Nguyen	UKHD
Jessica Gugel	CIMH
Daniel Dürstewitz (online)	CIMH
Manuela De Allegri	UKHD
Michel Wensing	UKHD
Matthias Schwannauer	UEDIN
Elisa Lievevrouw	KU Leuven
Joanne Beames	KU Leuven
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Steffie Schoefs	KU Leuven
Jan Boehnke (online)	CIMH
Nayeli Silva Preciado	Erlangen
Natalia Čavojská	UK BA
Marta Nemcikova	UPJS
Anton Heretik	UK BA
Isabell Hauswald	CIMH
Joerg Ottenbacher	Movisens
Ula Kolinska	UEDIN
Rowena Piers	UEDIN

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APPENDIX 2: MINUTES OF THE MEETING

at the General Assembly

held on June 24th and 25th 2025 in

Leuven

DAY 1 - Tuesday, June 24th 5
WP5 + WP7: Updates 5
Updates to deliverable 5.2. 5
Phase 1 updates: 6
Phase 2 data: 7
WP2: Movisens 8
WP3: Datamanagement & processing 10
WP7: Phase 2 - Papers 14
WP6 + WP8: White Papers 19
IMMERSE Policy White paper 19
White paper on Clinical Implementation 19
WP8: Dissemination 21
DAY 2 - Wednesday, June 25th 22
WP1: Finances and admin 22
Finances 22
SAB 22
Admin 22
Brainstorm potential hypotheses and research questions 24
Actions 26

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Appendix 2: minutes of the meeting

DAY 1 - Tuesday, June 24th

WP5 + WP7: Updates

Session by: Joanne Beames & Rowena Piers

Updates to deliverable 5.2.

Slides: https://www.immerse-project-members.eu/WP5%20D5.2%20Update.pdf

User experience (Joanne)

- QR Code in slides to see preregistration.
- Joanne starts by explaining UX = User's felt-sense of doing something with the product, all 5 senses involved. Three core elements of UX explained: user characteristics, context of use cases, clinical usability.
- Joanne explains the codebook process and framework; shows the codebook. Codes split between UX and Process Evaluation. Some of the codes overlap for both purposes.
    - First full coding aim: end of August. Coding team on track. QR code (Slide Activities & Timeline) for integrated process eval. & UX Codebook. Currently @ N=38 Service Users, N= 36 Clinicians across countries.
- Joanne presents preliminary results and some quotes.
    - Deliverable contingency plan: If the coding takes longer than expected, the focus will shift to one stakeholder group (clinicians).
- Joanne presents planned Masters projects. For consideration: re-coding based on specific papers.
    - Anita asks when the first draft of the deliverable report is planned. Answer: October/mid-November 2025. Recommendation to set internal deadline to 1. December.
    - Link to updated codebook https://3.basecamp.com/3635894/buckets/10764202/vaults/8748663871

Process Evaluation (across all countries) (Rowena)

Slides: https://www.immerse-project-members.eu/WP5%20Process%20Evaluation.pdf

- Rowena presents the timeline and intervention logic model. The codebook development is based on this model. DMMH in context - what works, for whom, when, and why. Micro and Macro-level outcomes explained.
- Rowena presents brief overview of the analysis plan for Qualitative and Quantitative data (dependent on available variables) (side note - what quantitative data in PE?)
- Rowena presents an update on progress (as of 23.06.2025): see slide for diff. countries status. The preregistration is still in process.
- Deadline coding set to end of August 2025
- Germany: new staff: Isabell Hauswald joined the Germany team for her Master thesis; will work on German coding.
- Slovakia: Coding team defined during question round:
    - Bratislava: Adam & Natalia for (11 interviews)

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    - Kosice: Marta codes 3 clinician interviews (total 8 interviews) – agreement with Matthias discussed. Rowena points out that the agreement was not known to the UK team.
- (Contingency plan Slovakia: potentially drop 5 remaining patient interviews OR Belgian Team codes remaining patient interviews)
- Coding priorities:
    - Clinicians
    - Patients
    - Team leads

Phase 1 updates:

Slides: https://www.immerse-project-members.eu/WP5%20Phase%201%20update.pdf

- Islay presents survey data: intention to adopt DMMH: SEM prelim. results. (See slides)
    - → Uli shares suggestion for mediation plan.

- Maria shares phase 1 numbers:

Interviews	Survey
Belgium: 45	Belgium: 47
Germany: 42	Germany: 216
Slovakia: 26	Slovakia: 103
UK: 12	UK: 120

- Julia: phase 1 qualitative paper on how clinicians perceive ESM visualizations: about to submit revision after first round of peer review. https://osf.io/mjqd7

Use case Presentation

- Lotte: presents plan to develop hands-on workshop guide based on use-case Implementation strategies - desires and needs clinicians shared.
    - → Julia asks how we can contribute; a lot of information across the consortium.
    - → Michel points out that this is projects is an essential part of the IMMERSE project. Everyone agrees. Clinicians need to understand how to use the data. Ref. Julia's paper.

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Phase 2 data:

Slides: https://www.immerse-project-members.eu/WP5%20Use%20case%20presentation.pdf

- Rafael: presents preregistration on DMMH engagement, phase 2 data. Looked at proportion of answered beeps/ total beeps sent out during initial 4 weeks. Rafael explains prelim. data and analysis plan. Sustained use and liberal use differentiated and explained. Predictors: age (pos. rel) and childhood trauma (neg. rel) significant predictors of patient ESM engagement.
    - Anita asks if childhood trauma was split into subscales. Answer: no
    - Manuela asks about the logic of using thresholds. Answer: thresholds are arbitrary, unclear if this can be clinically useful. Cut-off based on protocol (33% ESM)
    - Maria points out that phase 1 data UK patients expressed desire for reduced number of beeps.
    - Michel asks why continuous data has been categorized, reduced information. Discussion moved to phase 2 slot on how to define different variables.

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Appendix 2: minutes of the meeting

WP2: Movisens

Session by: Simon Krause

Slides: https://www.immerse-project-members.eu/WP2%20Movisens.pdf

- Improvements on the platform
  - updates of Manager & App directly benefit the IMMERSE project
  - interventions can now be updated in a separate project & tested directly in Manager
  - new data entry types (e.g. multiselect, vertical Likert)
  - calculations based on prior input
  - additional interactions on demand & notification patterns
  - new visualizations
- planned improvements
  - multiple chats (and studies) in parallel
  - exploration of mobile sensing, including GDPR compliant audio capture (local analysis on the phone, raw data discarded afterwards)
    - not a transcription, but e.g. mood analysis
  - data entry via visualization to mark important events
- demo system for non-medical purposes
- preparation of certifications towards Medical Device development (e.g. QM system, IT-Security Management system)
- next steps for WP2
  - discussion on intellectual property
  - reimbursement scenarios
    - insurance companies (however would require effectiveness data)
    - individual contracts with hospitals
  - marketing options
  - options for integrating DMMH into routine clinical systems (e.g. hospital electronic health record)
- Discussion
  - screen usage by vertical scales: will take up the full screen – not more space than now
  - movisens strategy towards regulation - certification of a platform vs. certifying individual products?
    - movisens had consulting on this issue:
      - criteria for defining individual products were narrowed down in the MDR
      - there would be issues with defining the medical purpose of the base platform vs. the specific products, especially in the context of research & teaching use cases
  - intellectual property - Leuven transfer department advised not to fix IP issues at this stage (there is no final product yet; there may be follow-up projects with different partners)
    - IP discussion should be narrowed to specific aspects (e.g. licensing costs)

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- regarding integration with EHR systems - has interaction with the Gematik (German agency for interoperability) been initiated?
  - not yet, concrete interfaces still need to be defined
  - the Medical Informatics Initiative is currently partnering with the German National Center for Mental Health (DZPG) to standardize FHIR profiles for patient-reported outcome measures that could be a very good fit for the DMMH data

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Appendix 2: minutes of the meeting

WP3: Datamanagement & processing

Presented by: Thomas Ganslandt

Slides: https://www.immerse-project-members.eu/WP3%20Data%20Management%20&%20Processing.pdf

- Distributed data from multiple data systems making it more
- Data harmonization
    - Export flattening
        - automated
        - manual
    - Pre-processing
        - flattening
    - Validation
        - alignment of participant IDs (some easy to spot and fix and some harder)
        - alignment of site & visit IDs with plausibility checks
        - Individual item checks
    - Derived measures
        - completeness measure for forms
        - Handling of missings for each measure need to be discussed and clearly defined
        - specific data protection requirements for certain items (e.g. GPS)
    - Integration into research database
        - one database with all data

- Status of data harmonization
    - Magana Med: generating derived measures needs to be rechecked (due to unclear handling of missings) - **TODO ALL**: input from clinical partners needed who have provided the definitions - please add info on handling missing values for each score
    - TherapyDesigner: completeness measure needs to be added
    - movisensXS Sensing: Finished
    - movisensXS ESM: ID validation, derived measure and integration outstanding
    - ReadCAP Mgmt: Finished

- Data use process
    - optimizing the handling of data requests
        - more detailed (item-level) definition of datasets for DROPS proposal in order to determine data availability and ensure minimization of datasets delivered to users by WP3
        - Discussion regarding Codebooks for different data sources
            - Process evaluation requires DMMH codebook - initial information provided by movisens to Matthias
            - Main outcome requires fidelity data codebook from movisens ESM data
            - Magana Med codebook is available in basecamp but WP3 uses annotated more technical version which could be uploaded as well

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- **TO DO WP3**: provide overall codebook covering all data sources

- Inclusion/Exclusion criteria for requests are given as free text, which in some cases allows different interpretations; they should be precise enough to ensure that the expected data is exported for each request
  - Free text vs. more options on the DROPS website
  - providing more options requires large effort to reflect in DROP thus free text preferable
  - Requires clarification in a short webconf for ambiguous cases of criteria description with the person submitting the request and have them sign-off the understanding of the criteria
- Ulrich Reininghaus is concerned of an unexpected number of data deviations from maganamed and these causing issues further down the analyzation pipeline and cause should be identified in a collaborative approach. Be careful which data is provided to Anita for checking plausibility and to Jan for analyzing ensuring correct data being analyzed.
  - the initial release for the main trial analysis was provided on June 16th; inconsistency noted by Anita regarding participant counts across the visit schedule
  - This problem might affect economic evaluation as well and thus they should be kept in the loop
  - the flowsheets prepared by Anita could be useful to check plausibility of participant counts throughout the visits; WP3 is already in discussion with her
- Michel Wensing suggests to provide basic characteristics across data sources (i.e. patient and record count per data item) to inform plausibility checks & feasibility

  Decision: provide the data volume via basecamp
  - **TO DO WP3**: include participant/record count in the codebook

- data preparation
  - How to check plausibility & utility of datasets (including cohort)
    - requires input from other WPs, especially WP7 to provide domain knowledge regarding plausibility

- data use
  - data users will create derived datasets, requires adding to database to make analysis reproducible

- archiving
  - all data users need to provide metadata descriptions of newly generated/derived datasets
  - option: use of external broad (e.g. Zenodo) or domain-specific research data repositories for data instead of archiving at Erlangen to achieve higher data visibility

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- Thomas does not see a problem having dataset in domain-specific repositories, as long as it does not contain person-relatable data (covered by GDPR) or is subject to embargo periods defined by the consortium
- This option concerns only meta-data and non-person-relatable datasets, but not raw (person-relatable) original data
- OSF with only textual description would not be structured enough in accordance with FAIR-Requirements thus other repositories should be considered
- **TO DO all**: if you know domain-specific (e.g. psychiatry, psychology, or health economics) research data repositories, please inform WP3

- Next steps
  - German NFDI4Health consortium to implement standardized research data management. currently launched LocalHub project to establish local research data registries at sites that are involved in trials
    - Erlangen is participating in the LocalHub project and now has the opportunity to publish a set of studies with Erlangen participation through the LocalHub
    - question: can IMMERSE be a candidate study for this, to create more visibility?
      - Only Meta-data would be published
    - Decision: It is ok to participate increasing visibility

- General discussion
  - Question from Manuela De Allegri regarding publishing data after project end:
    - clarification that for all datasets, metadata will be registered in a publicly available catalog; non-person-related raw data can be made available on a public archive, but person-related data needs to be archived securely, with a Dataset cannot be completely published after project end due to personal identifiable information but only meta-data describing
  - Question from Inez: How data release works and how resources are available after project ends and how can this be done by UKER
    - currently still a much larger than expected effort to align participant identifiers mismatched between data capture systems
    - after resolving all participant ID & validation issues effort for exporting data is much lower
    - UKER has already expended its staff funding through IMMERSE & is supporting the consortium through local funds. Going forward being part of publications to increase visibility of UKER would be helpful to justify efforts
  - Question to include coded interviews into the research database? -> No (only structured data)
  - Question whether pseudonymization of interviews should happen by researcher before submitting to data management
    - Yes - all datasets delivered for archiving to Erlangen must be cleared of any directly identifying data; fully-identified datasets must be archived locally at the sites which acquired the datasets.

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- Prioritization of next steps for data management
  - 1st: clarifying the issues noted by Anita in the main trial analysis dataset (probably regarding inclusion of missings in the SAQ score calculation)
  - 2nd: finalizing the remaining ID mismatches & add the movisensXS ESM data to the research database
  - 3d: data releases that are required for project deliverables
  - 4th: data releases for PhD students in contract limitation situation
  - 5th: any other data releases

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WP7: Phase 2 - Papers

Session by: Uli Reininghaus & Anita Schick

Uli's presentation

Slides: https://www.immerse-project-members.eu/WP7%20RE-AIM.pdf

- Uli gives an overview of the WP7 objectives; focus of this session on RE-AIM; effectiveness part; from the second objective (RE-AIM) two main papers will be published: one by Inez looking at RAIM, and one on Efficacy (primary and secondary outcomes of the cRCT) primary outcome: service engagement
- Uli gives an overview of the primary and secondary outcomes (including EMA outcomes) and the cRCT Design.
- Flow chart based on Redcap data is presented (numbers are not final! cross-checking with Maganamed data needs to be done). In total 27 units were randomized, 722 potential participants identified; drop outs are explained, at t2 237 participants were assessed (62%); total n recruited and assessed with primary outcomes not clear yet → see slides
    - The original plan was to present initial findings, however due to processes in the data processing, no findings are presented but will be shared soon.
- Learnings from the trial are presented. Uli concludes that regarding data management, you cannot start too soon, experiences with MedX - close out visits are discussed. Uli talks about the discussions the IMMERSE team had to consider both effectiveness and implementation aspects in the study design. Another learning was considering EU guidelines and formalities.
- For WP7 Deliverables & Milestones see slides. MS23 and MS20 completed. D7.4, D7.5 and D7.6 are not completed yet and are all due by 31.12.2025, Uli is optimistic that we can meet these deadlines.
    - Questionnaire data will be released 13.06.2024 (no ESM); Draft for the manuscript in September.
    - → Inez agrees that the numbers look amazing and emphasizes that we are progressing well

Inez' presentation

Slides: https://www.immerse-project-members.eu/WP7%20RAIM%20paper.pdf

- Inez talks about her work on RAIM (all aspects of RE-AIM except for efficacy): reach, adoption, implementation, maintenance of the DMMH. Inez explains that the data is so rich, that it would be too much for one paper, this is why for efficacy, there will be a separate paper. The goal of the discussion in this session is to discuss what aspects belong to which paper (also e.g. in the process evaluation). For definitions of reach, adoption, implementation, and maintenance → see slides
- Inez refers to the table in the protocol paper defining when the goals of RE-AIM are reached and repeats these goals → see slides; Inez also refers to the discussion that was shortly held after Rafael's presentation about the categories of EMA compliance

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- Reach: A reach criterium that is currently not included is representativeness of users: Discussion whether this should be added.
    - Anita mentions that we cannot compare between people who agreed and who did not agree since we have not collected sociodemographic data of people who did not agree, only of people who dropped-out. Anita mentions that we might also compare participants who are using their own phone vs. a study phone
    - Inez asks if it is still useful to compare participants who dropped out vs. did not drop out.
    - All agree that this would be useful, it is still a (limited) approach to examine representativeness.

    - Discussion
        - Inez raises the question whether it would be a good idea to move some items (see slides)
            - Uli mentions that we should consider how we can justify this, since we agreed to keep changes to a minimum. Uli asks whether we move things around or adapt items, all while aiming at the best possible paper.
            - Inez mentions that right now she thinks it is still possible to move things around, but these decisions should be made now. She agrees that as little changes should be made as possible, but some changes need to be made.
            - Michel mentions that moving items makes a difference if you calculate sum scores, otherwise, especially since those are not primary outcomes, this should not have big impacts. Adoption and implementation are in many practical cases combined, since they cannot be separated easily. Michel asks whether those questions are only asked for clinicians but also for patients.
            - Inez answers that Reach is more for service users / from the perspective of them
            - Michel notes that RE-AIM comes from public health, so in the sense of reaching a population. In terms of reach it is also important why some clinicians might not have participated.
            - Anita added that it is also interesting to examine whether they only signed in or whether they actually actively participated and used the intervention
            - Michel mentions that all this is called process evaluation in wider international literature, which differs from our wordings.
            - Inez agrees, that we need to be clear, what we are presenting (which story we are telling)
            - Uli: reminder that we wrote a CIP and protocol paper, we agreed on some things before. If things need to be changed and that can be justified, it is ok.
            - Inez: if you are looking at things now there is overlap. No need to change everything

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    - Inez: Question: Is acceptability (= satisfaction with the DMMH) better covered in the process evaluation?
        - Michel: For him, acceptability does not fit well with RE-AIM, since RE-AIM is about observable behaviour.
        - Rowena: Will check in with Matthias and adapt this accordingly

- Maintenance
    - Inez asks whether the number of drop-outs, compliance in the first 6 months and sustained over 6 months should be moved to maintenance; the question is: When does maintenance start?
        - 12-month time point is a main outcome of the economic evaluation
        - In Reach number of drop-outs in the first 2 months is already included
        - Michel: some overlap cannot be avoided, that a few items will be in two papers; it doesn't change much
- Adoption:
    - Inez presents the criteria that are already included in the CIP and protocol paper → see slides. What was not included was representativeness of services and staff. Inez suggests to add comparisons between academic and peripheral institutions
        - Anita: We could calculate the percentage of staff per site that participated (when this system information is available); however, there is not much information about non-users. We have information on caseload by clinicians and on how many participants they included in IMMERSE
        - Inez: Reach is often used to describe patients, adoption and implementation for clinicians; Joanne mentions that this is how it is defined in the RE-AIM framework
        - Michel mentions that the separation between adoption and implementation is very arbitrarily
        - Inez asks what the difference between adoption at 12 months and maintenance is, therefore the idea is: 2 months is implementation, 6- and 12-months maintenance
        - Michel mentions that some studies include questions about expected maintenance, we also have this data.
        - Uli agrees that this is confusing. Uli also concludes that there is no nominator data to differentiate between different services

- Implementation fidelity
    - At 2 and 6 months: same question, is this maintenance?
        - See slides for original definition of implementation criteria Inez mentions that there are criteria for implementation, reach, and intervention fidelity that are all compliance. So, she asks: Why do we use this number in one definition and another number in another definition?
        - Uli mentions that the focus for implementation was on extent, so quantifying extent rather than a yes/no answer. He cannot answer ad hoc why especially these numbers have been chosen.
    - Inez refers to Rafael who differentiated between liberal and strict criteria

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        - Michel states that we do not know what figures lead to what outcomes, so without a rationale this is unclear. He would not throw away information in the analyses if there is NO clear rationale (i.e., something happens at this figure)
        - Anita: Cut offs were included for when more implementation strategies were needed
        - Inez states that numbers are more for descriptive purposes. She agrees that for analyses, it doesn't make sense to categorize, so we should not compare high vs. low XY, if we have continuous variables.
        - Rowena mentions that from the process evaluation it could be helpful to be able to differentiate between high and low users
        - Uli: idea was to categorize between low and high users, that has been done before, there is a root to it. You need some benchmarks to compare. You could also calculate confidence intervals.
        - Inez agrees and includes that in further analyses we would still include the continuous variable to not lose information. Question: Does it make sense to have this information spread out across different boxes? It could be confusing in the paper if information comes back but with different definitions.
        - Uli: it is important to be clear and specific in the definitions of the criteria. Also, important information for future studies, i.e. are there aspects that need to be improved.
            - Inez will reorder items and send that updated list around.

- Maintenance:
    - Inez shows the criteria for maintenance → see slides. Shye repeats the question whether we should put the maintenance everything from 6 months here. That is intended maintenance of service users and clinicians measured at 2, 6, and 12 months. She asks the question:
        - Would this already be maintenance if you have intended maintenance of 2 months?
            - Michel questions whether intention and action will correlate. You should just make sure to clearly describe what you have/report.
    - Inez states that we do not expect them to use the app in the same frequency as in the first two months, but that is not clearly spelled out. Questions are:
        - a) When do we say it is maintenance? is it 1 or 2 weeks?
        - b) What is a compliance then within those weeks? Those two components have not been defined yet
    - Julia asks whether we are differentiating between different types of use of the app, so e.g. if opening the app once is enough?
        - Inez answers that that is really open right now.
        - Uli mentions that the intention there was to know whether users use the DMMH at all. It could be many weeks without use, but if they then open that app and use it, this would be a crude indicator of continuous use. The question was: Is it used at all? Uli agrees that this is a very crude indicator.

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- Anita asks Simon whether it is even recorded if the app has just been opened.
    - Simon states that that data is recorded, but not part of the app data that is exported by now. That could be exported if it is useful. It is not recorded when the app is closed but everything else is entered.
    - Inez: Might be useful to distinguish between that. Would be useful to think about whether we can refine that. Agrees with Uli that it is important to see whether they use it at all; but to also think further than that. Idea: If they started an interaction (after a pause), what happens than? Could we see whether they then filled out beeps and continued using it? How can we refine compliance in respect to how much they interact?
- Manuela asks about center and site differences and whether we should report heterogeneities by country in the Appendix?
    - Anita mentions that site effects will not be reported, but controlled for (fixed effects). She adds that we are not powered for analyses of heterogeneities by country
    - will be discussed with Jan

<u>Hoa's presentation</u>

Slides: https://www.immerse-project-members.eu/WP7%20Economic%20Evaluation.pdf

- Hoa talks about the objectives of the economic evaluation as well as the hypotheses of the economic evaluation → see slides
    - Hypotheses (see slides), main focus of the 3 hypotheses:
        - 1) economic cost
        - 2) patient-reported quality of life
        - 3) incremental cost-utility ratio at 12-month post-intervention
    - Cost and effect data have been collected from Oct 2022 to Dec 2024. Cost-effectiveness will be compared with treatment as usual. For methods and procedures, as well as the current progress → see slides
    - Information about time spent by clinicians only uploaded by Germany and Slovakia.
        - Uli: comments in the Zoom call that there is also a section on handling of missing data in the SAP (section 22.3)

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WP6 + WP8: White Papers

Session by: Elisa Lievevrouw & Jeroen Weermeijer

IMMERSE Policy White paper

Slides: https://www.immerse-project-members.eu/onewebmedia/WP6%20Policy%20White%20Paper.pdf

- Submitted on 31/12/24
- Aim was to examine the key regulatory challenges within the context of the development and implementation of digital mental health tools
- Overview of the different challenges and recommendations that were described in the white paper (cfr slides)
    - 1. Limited access to Research Based Digital Health Tools
    - 2. Fragmented alignment between EU regulations and member state frameworks
    - 3. Misfits between the adaptive nature of digital health tools and regulatory classifications

- Discussion/questions
    - What is the expected impact of the white paper? → Structure of the white paper did not allow for adding in quotes or interview segments of the expert interviews, which is unfortunate. We did try to be very specific and concrete. Hopefully, by addressing three main issues and three possible solutions, this will increase feasibility of potentially implementing the proposed changes.
    - Deliverable 6.13 internal deadline moved up to December 1st
    - There are currently no remaining questions or concerns that have to be discussed with the ethical board.

White paper on Clinical Implementation

Slides: https://www.immerse-project-members.eu/WP8%20White%20Paper%20on%20Clinical%20Implementation.pdf

- Part of Deliverable 8.4
- Jeroen presents structure of white paper: history of ESM, including an example to make it clear and understandable for people without ESM experience - will use input from WP5 and 7 for barriers to case study and adoption section of white paper
- Today we will mainly focus on the 'Hurdles to Commercialization' (cfr slides)
    - 1. Reimbursement Challenges
    - 2. Financial constraints and Long-term sustainability
    - 3. Lack of Clinical Validation and its impact on Credibility and Commercialization
- Comparisons with other Digital Health Services: lessons for mental health app commercialization

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Appendix 2: minutes of the meeting

- Discussion/questions
    - Is ‘commercialization’ the correct term? We do not intend to make profit from this, but to help developers make their mental health apps more sustainable and viable. People might interpret that the intent is to make profit. Jeroen will investigate wording.
    - Why the division between mental health apps and physical health apps? Apps that are currently in the top layer are more focused on well-defined (clinical) populations, which is more clear-cut for physical health issues. But they also share some hurdles.
    - ‘Digital therapeutics’ seemed to be a reaction to regulatory hurdles, but this seems to feed into the division between ‘lifestyle’ and ‘medical’ ‘labeled apps.

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Appendix 2: minutes of the meeting

WP8: Dissemination

Session by: Jeroen Weermeijer

Notes & full overview (living document):
https://docs.google.com/spreadsheets/d/1eL5Jw5yAcenCZhUgJf-TGJFG5Nwuf7eetuzWzTYUguE/edit?gid=0#gid=0

- At the previous GA, Jeroen asked to write down tasks for the dissemination plan. He made a google sheet overview with all of the tasks that he has been tracking in the meantime (i.e. what the current status is).
    - → Breakout rooms per site to discuss status of these dissemination tasks (full overview in google sheet, but we will go over some of the dissemination tasks here – not exhaustive).

- KU Leuven:
    - IMMERSE symposium in Leuven in May 2026
    - Reach out to national media when WHO piece gets published
    - Add white papers + infographic to website
    - Promote IMMERSE at other universities + within KUL

- Slovakia:
    - Adam wrote a blog related to his PhD thesis + published on website
    - Daniel is teaching that course for Master students (2nd year) + presentation for PhD students of Faculty of medicine - Bratislava (2nd year). -- Kosice site included the topic of mHealth/ IMMERSE/ ESM into elective course 'Behavioural Medicine' (Study program: General Medicine, 2nd-5th year, Faculty of Medicine, UPJS; reach: 50-70 international students each year) and the topic is also disseminated within compulsory course 'Social Medicine' (Study program: General Medicine, 2nd year; reach: over 250 Slovak students and over 300 international students each year).
    - User case task was initiated within KU Leuven, Lotte will invite other sites
    - Adam will present a poster in October
    - Local clinician meeting will take place in November

- Germany
    - Workshop by Georgia & Daniel on machine learning
    - Anita will give a course on the use of DMMH in Clinical practice
    - Jessica will present at SPR in Poland
    - Uli will present at IEPA

- UK
    - National summary on the utilization of the DMMH
    - Engage with Festival of Social Science 2025 (pending on approval)
    - IMMERSE phase 1 paper to be submitted for publication
    - Submit Process evaluation for publication
    - Analyze Phase I qualitative data and submit Privacy Concerns paper for publication
    - Arranging DMMH demonstrations at local events.

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DAY 2 - Wednesday, June 25th
WP1: Finances and admin

Presented by: Inez Myin-Germeys

Finances

- Almost all partners are overspending, mostly to cover personnel costs during no cost extension period
    - CIMH: overspending but put staff on other budgets
    - Matthias overspending +/- 10% (20k) + can't see transfer yet internally (informatics budget not yet) → will send budget overview to Steffie
    - UK BA: actual spending is higher but difficulties allocating money because of person months. Would be able to pay for any open access fees etc.
        - Sites that are overspending should look at budget and see if things can be paid from Bratislava budget
    - Kosice: contact Martina for financial information

SAB

- SAB members could not make it
- Set up meeting to present results to SAB?
    - At IEPA Berlin? (Mario, Matthias, Tania, Inez, Uli, ask Andreas (organizer) to give a room for IMMERSE meeting) → schedule the meeting there.

Admin

- RAIM, Effectiveness and Process evaluation papers
    - Preferred journals:
        - Lancet Psychiatry could also be an option (but they require very specific format) so send them the abstracts
        - Approach JAMA Psychiatry when we have the manuscripts (3000 words format)
            - one editor with strong focus on digital mental health
        - BMJ
        - Psychological Medicine
        - British Journal Psychiatry
        - European journals: Journal Psychiatry? Nature mental health? IPS? Psychotherapy and Psychosomatics? Implementation sciences?
            - → Approach editors to see if they are in principle interested so that we have quick feedback and can move in if needed
            - → Compile longer list in shared google sheet
    - Timeline
        - Send abstracts to Lancet in a bit later phase (we can upgrade abstracts even more when working on the papers).
        - We are meeting at IEPA so aim for that date to start sending out to the journals. So, prepare first drafts of the papers by then
        - Start with JAMA format

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Appendix 2: minutes of the meeting

- Jeroen will end his contract at the end of July or August. Someone in KUL team will take over DROPS and Steffie/Silke will follow up on dissemination
- Data & pseudonymization
    - 2nd pseudonymization should not happen yet before main papers because it will make things more complicated and not yet needed. Will be needed for main data file
    - Priorities:
        - Always communicate the number ID of the DROPS abstract
        - Phase 1 data can be released → Do Barbara & Thomas have access to Phase 1 data?
        - Priority 1: solve problem with Phase 2
        - Priority 2: 3 main outcome papers + economic evaluation

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Appendix 2: minutes of the meeting

Brainstorm potential hypotheses and research questions

Part 1 (non steering committee members)

Notes & full overview (living document):
https://docs.google.com/spreadsheets/d/1rhXxnTPt7f6BpuDZcc4RuBHKLYsfyfL7CQSZxoWwS_4/edit?gid=1149212912#gid=1149212912

- All potential research questions will be added to the google sheet 'IMMERSE Papers overview'. Some rough drafts of the questions are noted here.
- Cost Heterogeneity -, comparative analysis of service use: What is the cost of the services across the four countries and what patient characteristics drive service use costs across the countries? This could be two research questions potentially but Hoa thinks they could be one.
- How different measures of health related QofL relate to each other and to the main outcomes - this could be a PhD research question but would be dependent on sample size. Looking at how well QofL measures are associated with other measures of mental health and wellbeing.
- Looking at changes in ESM variables throughout the intervention period. Do changes in ESM variables differ between the intervention and the non-intervention? Could this help identify potential mechanisms?
- Mixed methods papers
    - Exploring the effectiveness of the intervention looking at the role of different service user characteristics
    - Exploring the effectiveness of the intervention looking at the role of differences in service characteristics
    - Maybe considering the role of service user and service characteristics in user experience to better understand the role of context on user experience.
- Role of app engagement on outcomes, looking at whether participants who actually engaged in the app, dashboard, and who accessed the feedback information saw more benefits on the main outcomes. This would depend on usage data and how specific this information is.
- Can service user outcomes be related to the way in which they complied to the app i.e. those who were consistent vs inconsistent responders. What is the minimum number of beeps answered, length of time taken to answer the beep (i.e. are they thinking about the questions fully), time of day the beeps are answered, and how this relates to outcomes.
- Validation of ESM items using the IMMERSE data, could the immerse data help try and validate some ESM items that are commonly used in ESM studies.
- DMMH ESM data: using the ESM core items from the intervention period has the benefit of bigger sample sizes
    - associations between mood post clinician session assessed with EMA and therapy outcomes, e.g. mental health effects, therapeutic alliance, and shared decision-making
    - Do we find clusters in the ESM items and therapy goals chosen based on diagnoses? Like item profiles, maybe based on ideas of HITOP
    - Bidirectional relationship between anxiety add-on and context ESM items

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Appendix 2: minutes of the meeting

- Context data and associations with mood; ESM outcomes
  Are there effects of the duration of the EMA on outcome measures and immediate outcomes like the next EMA
- IT data (usage data):
  - Associations between the amount of times that clinicians logged on and outcomes
    Associations between the amount of time spent on the Dashboard by clinicians and outcomes
- Did looking at the feedback in the App make a difference on outcomes for service users?
- Assessment measures
  - Parameters that can be individualized: Differences in outcomes by the amount of individualisation of the App; some clinicians did not individualize the App, sometimes it was done by the study team - how often, who logged on, … related to better use// more compliance? who (EDITOR ID, raw data) logs onto the system can be assessed via info on clinician IDs vs. researcher IDs. Do people look more at data? → Do outcomes/a.o. differ when the App was individualised more?
- GHQ/ MHSEQ/ ETC. // NA, PA/ social functioning etc….
- Does your level of symptom severity / general health at baseline predict intervention outcomes, controlled for working status, inpatient/outpatient, age
- Factors influencing outcomes
  - mediation analyses to explore pathways to outcomes: putative mechanisms might be emotion regulation, substance medication, loneliness/social functioning, paranoid thoughts, list of threatening events, experiential avoidance; e.g. already at baseline
- Specific diagnoses: e.g. depression
  - mediators/pathways to/from depression
  - maintenance factors, e.g. loneliness, emotional regulation, DMMH core items, sleep
  - → but 'diagnosis' difficult to include due to different data entry in UK
- Factors influencing compliance besides age and childhood trauma: does the number of kids, working situation, symptom severity, etc., predict compliance?
  - Does compliance predict outcomes?
  - Does service characteristics predict compliance/fidelity for clinicians?
- Group differences between participants using their own phone vs. study smartphone → does compliance differ?
- Can we predict *at what time points people dropped out the most?*

Part 2 (whole group)

- Status overview of papers based on google sheet (make sure all papers are assigned)
- Brainstorm with entire group (cfr notes brainstorm in smaller groups + google sheet overview with research question ideas).
- Manuela will have a course on mixed methods next year and is always happy to help with mixed methods!
- Only add Individual funding if main authors want to mention it
- All papers have to go through DROPS!

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Appendix 2: minutes of the meeting

Actions

Who	What
Everyone	Upload presentations to the Basecamp folder
WP2	Make additional export of data on how many times app was opened by participants
WP5	Make sure interviews are coded by end of August
WP3	Upload more detailed/technical codebook to Basecamp
WP3	Submit IMMERSE candidacy for German NFDI4Health LocalHub Project
Everyone	Follow up on dissemination tasks that were discussed during session by Jeroen (cfr google sheet overview)
Lotte + Jeroen	Invite other sites to join user-case project if interested
WP1	Set up new SAB meeting to present them results (at IEPA Berlin?)
Anita	Create google sheet to make an overview of potential papers to review three main papers
Everyone	All papers have to go through DROPS! If your paper didn't, please add it.
Everyone	Update the potential RQ's in the paper google sheet
WP5	Matthias to send financial overview to Steffie
WP8	Jeroen to add prizes and awards into dissemination overview
WP5, WP6, WP7, WP8	Internal deadline for deliverables moved from Dec 17th to Dec 1st, so that there is enough time for WP1 to curate and submit to portal
Everyone	if you know domain-specific (e.g. psychiatry, psychology, or health economics) research data repositories, please inform WP3
WP3	include participant/record count in the codebook
WP1	Inez will reorder items for RAIM and send that updated list around.
WP2	Simon will export data on how many times app has been opened
Everyone	Compile longer list potential journals for main papers in shared google sheet
WP1, WP5, WP7	We are meeting at IEPA so aim for that date to start sending out to the journals → prepare first drafts of the papers by then + Present results to SAB at IEPA

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