IMMERSE

Implementing Mobile MEntal health Recording Strategy for Europe

H2020 - 945263

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Document History

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1. Summary

The second live General Assembly meeting was held in Bratislava, Slovakia, on May 4th and May 5th 2023. Most of the members were able to join the meeting in Bratislava, some joined online (see appendix 1, list of participants). See appendix 2 for the minutes of the meeting.

Appendix 1: list of participants

IMMERSE: Implementing **M**obile MEntal health **R**ecording **S**trategy for **E**urope

LIST OF PARTICIPANTS

at the General Assembly

held on May 4th and 5th 2023

in Bratislava

Name	Participant
Michal Hajduk	UK BA
Maria Wolters	UEDIN
Islay Barne	UEDIN
Koraima Sotomayor-Enriquez	UEDIN
Zuzana Katrienkova	UPJS
Silke Apers	KU Leuven
Glenn Kiekens	KU Leuven
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Julia Schulte-Strathaus	CIMH
Inez Germeys	KU Leuven
Luca Marelli	KU Leuven
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Anita Schick	CIMH
Manuel Brenner	CIMH
Thomas Ganslandt	Erlangen
Martine van Nierop	KU Leuven
Lotte Uyttebroek	KU Leuven
Ulrich Reininghaus	CIMH
Irene Schluender	TMF
Adam Kurilla	UK BA
Johannes Schneider (online)	Movisens
Simon Krause (online)	Movisens
Hoa Nguyen	UKHD
Erica Niebauer	UEDIN
Simona De Folco (online)	UEDIN
Daniel Dancik	UK BA
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Klara Hagspiel	**UEDIN**
Elisa Lievevrouw	**KU Leuven**
Manuela De Allegri (online)	**UKHD**
Michel Wensing (online)	**UKHD**
Matthias Schwannauer (online)	**UEDIN**
Georgia Koppe (online)	**CIMH**
Lena de Thurah (online)	**KU Leuven**
Julius Evelley	**UPJS**
Laura Kundratova	**UPJS**
Theresa Ikegwuonu (online)	**UEDIN**
Jorg Ottenbacher (online)	**Movisens**
Jeroen Weermeijer	**KU Leuven**

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IMMERSE minutes May 4th/5th 2023
General Assembly Meeting Bratislava

(Day 1 morning)

Opening

See slides

- Phase 1 - Mid-term review:
  - Most deliverables have been approved
  - Mid-term review meeting with two external reviewers from the European Commission who were impressed with the work we've done and with the cohesion and collaboration within the consortium.
- **Action**: Email your PowerPoint presentation to Martine - everyone

WP1

See slides

- 3 deliverables were rejected:
  - D1.2: Website wasn't attractive enough and the use of twitter was too low.
    - The new website is already published.
      Action: Everyone should have a look and give feedback + incorporate feedback from PAB.
    - Twitter
      Action: Send content to Lena & Blijke – and retweet and tag the IMMERSE project.
- Budget: If you are underspending (e.g. EUDIN, TMF and UKHD) – please submit all your costs, or agree to re-shift the budget to other partners.

WP2

See slides

- Implementation of API is finalized but final data export is still missing, but the estimation is that this will be finished in May.
- Status of age restriction feature: WP7 provided a first draft for the argumentation for Apple and WP 2 did think about technical solutions but they take more time to implement.
  Action: Discuss further in WP6.

WP3

See slides

- New team member: Wolfgang Krebs will be joining the WP7 meetings – he can be involved in merging the data.

- Task 3.3: The extraction of the eCRF content is ongoing
  Action: needs to be discussed further
- DataquieR report: Develop dashboard for individual site visits and forms instead of on the level of items, so that we have an overview of the % of participants that have fully completed a form or a visit. Create an overview that links the data from RedCap with data from MaganaMed.
  Action: Schedule a meeting with Anita to design a prototype.
- Does the data checking tool need to be validated? – ask Medex?
- Can we double check our current setup or validated tools? With statistical software, might need to be changed for the main analysis. Question for Movisens: are the norms and IC's standards adhered to? – Identify were there is room for improvement.
  Action: Data management plan: XS and statistical software – build a quality system around MaganaMed – discuss further
- Dummy data: prepare simulated datasets, so that PhD students can write their analyses scripts. Risk of unintended disclosure of data content, regarding unblinding and open-science. PhD students can work on their pre-registration, think about analysis, defining variables and writing code, and then test this with the simulated dataset.
  Action: Implement simulated data: Thomas + statistician + Hoa Nguyen
  Action: PhD students need to think about their variables and what they need from the database.
  Action: WP3 can produce the MaganaMed prototype in June. For Movisens XS sensor data that would be harder. No access to the Moment data, but should be fairly easy to produce.
  Action: discuss timeline on Day 2.

SAB

Present: Lucia Valmaggia, Mario Alvarez & Tania Lincoln
Questions from SAB:

- Phase 1: the survey overrecruited – is this a problem?
  - We are preparing an ethics amendment to clarify this as the overrecruiment may even be an implementation outcome.
  - Because the survey was exploratory – the high recruitment is much less of an issue. The goal was to get enough people and a wide enough range of people. Recruitment in different countries was going at different paces. We wanted a perfect balance but this was more difficult, we thus started over-collecting in other countries to make up for this difference.
- Underrecruited supporters (service user support network members): we relied on service users to contact their supporters.
  - There were different strategies in different countries. In some countries, supporter organizations were specifically contacted. We broadened up the strategies after realizing the initial strategies of going via patients was not effective.
  - Patients also have reservations about sharing data with and involving their supporters.

- Contacting supporters separately has pros and cons. Interview data on privacy will reveal more on patient attitudes on this point. It may be interesting to set up a study for supporters and cross-examine with the exploration on patients. However, the patients have reservations about what to share with supporters.

Questions from consortium:
Primary outcome is to test the implementation of a clinical tool in routine clinical care pathways.

- How we can separate the impact of the trial from the implementation outcomes?
  - Reasons for refusal: what points of the trial made it less appealing for participants to enroll? Aspects on trial design. Whether this has more to do with the intervention itself vs. other characteristics?
  - Once people have been randomized to the intervention group – is this treated as a naturalistic part of the study? You could almost argue that regularly assessing outcomes is a desirable part of the trial anyway.
  - Take into consideration the "extras": who randomizes? Who conducts the pre and post assessments? Adding a member of staff or training staff to routine care.
  - Ensure that the implementation is simple and feasible: On the RE-AIM outcomes: we are currently preparing an ethics amendment to ensure that we continue to include participants in the study if clinicians are keen to continue using the tool beyond the trial period and drive down the trial elements. Once certain units have reached their target sample size, we could reduce the burden of trial design. The maintenance phase allows us to observe whether clinicians and service users continue to use the tool beyond the minimum usage. We should improve documentation on reasons for refusal. New participants joining a clinical unit that is randomized to the intervention condition could be especially informative and reduce selection bias compared to driving down the trial elements (i.e., study participation).

We have developed a new digital tool and are doing so under MDR as an "other clinical investigation". We have thus agreed that we will not bring our tool to the market until it is an official medical device. How can we deal with determining the impact (given limited prospects of bringing it to the clinical setting) - both clinicians and service users are quite keen on using the tool.

- How does the fact that people know they will not be able to use our tool after the trial impact our implementation study?
- Are there ways to work around this as we continue to reach more people and the more we present our results and tool. There is nothing we can do beyond the trial without a CE certificate.
  - Tania: Consider an intermediate research between the problem area and the market. The category is *effectiveness trial* – phase 4 of a clinical trial?

As long as our tool is not CE certified we are stuck within the limits of our investigation. To set up a new, true implementation study under the proper legal and ethical framework would require new resources. E.G., Dr. Amy Hardy (SlowMo Project) got the CE first and is now doing trials after. Collaborating with investor partners from the start who can plan the commercialization and market penetration is also a good strategy. Get the tool CE certified, keep it straight, and if asked, say it is for research purposes until further notice.
In the UK, the CE may not be valid much longer (brexit).
Action: Contact Dr. Amy Hardy and/or researchers from AVATAR.

- How do you make sure this does not contaminate the trial: leave this vague in a positive and hopeful way. E.G. “Bear with us until we work through the legal steps. The research we are currently implementing is a valuable and necessary step before entering the market.” E.G., TTA in Australia: evidence-based content and guidelines supported by clinicians helps the Australians get away with digital innovations without being medical devices and could even get a consultant to stress this if asked. However, EU guidelines may be too strict for this option. Bringing together all the expertise we gathered and making a comparison across countries may be a good step.
  Action: (Elisa & Inez? – ask advise from Mario) As part of WP6, write something on bringing together all the expertise that we gathered, and compare the different ways (Australia vs Europe) to think about alternative ways.

Service contexts are different across countries; service types and pathways to treatment are not comparable in our consortium.
Access to care, referral, ethics, and treatment pathways are essential factors in our study. How do we make clear that we are investigating the tool and not the layers surrounded the recruitment and “extras”?

- How do the context and environment interact with the outcomes? This will become interesting to explore in process evaluations.
  Action: Mario can send a grant with the process evaluation embedded in this and how that element influence uptake.

Technical aspect: the SAB also functions as the trial steering committee. We need to update the terms and conditions of the SAB to keep you in the loop in-between the steering meetings currently taking place.
Action: Send document of the terms and conditions, overview of the trial and the current status to the SAB.

(Day 1 afternoon)

WP5

Slides

General
-Theresa is extended until end of July this year, but then she really will be done, no more budget. Maria has switched from Edinburgh to OFFIS in Germany, but will still have a parttime contract at Edinburgh so no changes for the consortium or our DPA's.

-Maria will be coordinating the PABs, but will not be involved in the local PABs.

-D5.1 has been submitted, and all targets have been achieved or overshot. A full description of the data of phase one can be found in this deliverable report (to be found here).

Survey data
Complete raw data is available for quantitative survey data for Germany, UK, and Slovakia, including free texts, analysis scripts (e.g. data cleaning, scales) have been written. Coding of patient conditions has been done for Belgium, UK, and Slovakia. Anyone with some psychology training can do this coding (doesn't have to be a clinician).
Still needed: (1) complete raw data from Belgium, (2) transformation into dataset for WP3 (computing scores on scales, rather than just the items), (3) still need to think about how ethnicity/nationality can be harmonized, needs to be decided before it gets loaded into central database, (4) further free text coding.
Creation of dataset was blocked because Maria didn't have the full Belgium data including the free text, to confirm that there are now identifiable data in the free text (edit 24/5 should be done by now?).
Maria now needs to have a meeting with WP3 about the codebook and data storage, and to get some support from them (someone who knows R well) in creating R scripts for data delivery (only needed for phase 1, not phase 2). The postdocs and PhD students need to keep coding the free texts.

Interview data
Transcriptions are done everywhere. Coding is done in UK, but Bratislava, Belgium and Germany are still working on it, Kosice still needs to start, but that will be fine. Theresa will help in Germany.
If someone is using data from a certain location in qualitative papers, there should always be a co-author from that site on it. Also because a native speaker is needed to be able to pick up on details and context.
Anyone interested in a workshop on reusing existing high level codes on the qualitative data please contact Maria.

Main WP5 papers
-Quantitative paper on effect of aspects of NASSS (nonadoption, abandonment, scale-up, spread, and sustainability framework) covered by survey on intention to adopt and perceived potential benefit (expected submission September 2023).

This includes what was reported in D5.1, but also includes the full dataset, inclusion of condition variables, improved selection of variables representing NASSS, and possibly some structural equation modeling. Will be submitted to DROPS this Friday (May 5th). Authorships still need to be discussed. And Maria needs a SEM specialist.

-Qualitative paper on overall qualitative content analysis findings, using top down codes derived from NASSS (expected submission March 2024).
So this is about what we can learn from stakeholder contexts, views, and requirements from NASSS-led coding of the interviews. Authors also still need to be discussed, and Maria needs help merging everything in single NVivo file (not all sites have access to NVivo, although importing should work).

-Maybe also a descriptive data set paper in December 2023, which includes (e.g.) differences between countries, and how the sample might differ from people normally seen in services

Task 5.3
Is about interpretation of usage patterns, interested in looking for unexpected use of dashboard/app. For the quantitative analyses Maria will work together with WP4, and for the qualitative analysis with WP7.

Discussion
All activities within WP5 has been for research purposes, not for implementation purposes (that part is done in WP7) – this is important for the economic evaluation.

WP4

Slides

WP4 has finalized the simple statistics and visualisations, and is now working on RNN-based (Recurrent Neural Network) AI models for multimodal data integration and prediction. For the later they would like input from the consortium on what they could be looking at, from a clinical perspective.

RNN-based AI models
For example can be used for complex pattern extraction or forecasting. The basic idea of it is that it tries to build a model that best represents a complex pattern/network found in nature (for example the weather). The main challenge was to get these models to work on IMMERSE data (that could be categorical, discrete, sparse, etc, all with different underlying statistical assumptions). They developed a framework to make it all work! (developed and applied on non-IMMERSE data) With this model they can do long term forecasts, but also short term predictions. It also allows to investigate whether underlying processes are 'non-stationary' (so for example if people's processes are influenced by treatment). Furthermore it can show if there are recurring periodic patterns, for example in NA, or predictability of items.

Deliverable 4.3
Is a report on big data integration framework. They will be increasing the predictive strength by preprocessing, feature extraction, and integration across multiple modalities (not just ESM data but also sensor data). As the timeseries are very short it's hard to robustly estimate models on that data. To account for that they are now working on making use of group level parameters to get to better subject level parameters. An example is using GPS data to extract psychological relevant data (if they are at home, or in nature). It is still possible to extract these data and add them to the raw data.

Milestone 14
They are looking into how that can integrate interventions and external inputs into the framework. This can lead to knowing which intervention will have the best mental health outcome, and who much control the intervention will have (on an outcome).
What is needed for IMMERSE is a way that we can inform clinicians on where they should actually look in the data, to see the relevant changes. So if there are for example the biggest changes in anxiousness scores, this should be pushed forward on the dashboard to help clinicians see these changes easier (as we are not doing a clinical treatment intervention). And to see which items influence others, so for example that if people are feeling anxious they will not benefit from social activities. This is possible. So the data will show for example which node should be influenced that, with the least amount of effort, will have the strongest effect on a desired outcome, it doesn't have to rely on interventions. This will be a very important added value for clinicians, which will help with implementation.

WP4 will start with application of IMMERSE data probably late 2023 or 2024. They are thinking (if there is interest) to include text data in the model, where interesting data could be extracted from. They are not sure whether timeseries text data is then needed. But also from the patient/clinician point of view it is a highly requested feature to have a text box after each measurement (so to have more information on why they filled out certain scores).
They need input on interesting analysis/applications tailored to IMMERSE data, and what interesting questions are from a clinical perspective.

Delays in data collection also has consequences for WP4, as Manuel can't be on the project for the entire duration. So they need to know when the data will be available, so Georgia can make sure he will be available at that time. Will be discussed further tomorrow.

Patient Advisory Boards

In December they had a meeting and drafted a document (was circulated, and to be found on Basecamp) on guidelines. They have been reaching out to organisations to promote the PABs. In the UK only 2 patients signed up, and then they stopped recruiting because it was unclear how to move forward (and what needs to happen). In Belgium there are around 7 who would like to be involved in the PABs.
(sorry, recording failed here for a few minutes, please add any relevant info by emailing to Martine)
Belgium and Germany had 1 meeting with their PAB. Not sure if one happened in Slovakia?
Now we need integration and coordination, which Maria will take on (there hasn't been

much time between that decision and now so she still needs to get started). Maria will organize a first meeting with everyone who has been recruiting participants. She would also like someone to be there with experience in doing PABs.
Some ideas on topics:
-feedback on how the trial is run
-run papers by them while still in developmental phase (so on main questions in that paper), on papers where we can get meaningful input from them (for example on the process evaluation to be used for the update), not so much the primary analyses. Maria would like to discuss the WP5 main papers, also to discuss the language used in these papers.
-Ask them how best to involve the PAB with our questions.
-Looking at the data that comes out of the process evaluation, and how that will be used for the update of DMMH.
-(ongoing) social media and newsletters

There will be an enquiry form, which anyone in the consortium can use to add very specific questions/topics to be discussed in the PABs. The use of this form should not be too voluntary, but will also be filtered in case of too many topics. The SC will have this as a standing topic on the SC meetings, to keep coming up with relevant topics, and to do a selection of the available topics from the enquiry form. There will be one chosen every SC meeting.
Elisa will send Maria a link to a project that describes ways of approaching PABs for further ideas.
Lena/Simona are working on a PAB guidelines document (also on Basecamp in the PAB folder) which is a brief description of what is expected of the PAB members and can be used for recruitment, and in the same folder there are also some additional documents that were used in Belgium (free to use for anyone). But we need a clearer focus of what the PABs are going to do, not just a list of possible topics. Final decision will be made Friday May 5th.

Paper presentations

Islay Barnes, Daily avoidance as a mechanism of change. Slides
Is reliant on moment app, so depends on whether clinicians pick those items, but Islay also has another sample available. They don't have to pick an entire module, only a few items are needed.
Islay will develop a state measure to capture avoidance, but is not sure yet what (state measure?) it will be compared with.
Suggestion of Inez to also look at IMMERSE as an intervention (so looking at your own symptoms may also have an effect). Inez has INTERACT data available that could be used.
Koraima Sotomayor-Enriquez, Mentalization as a key factor in psychological change: a longitudinal study in clinical population. Slides
Mentalization will be measured once per day (overall reflection of the day, is optional). Inez has data on emotion regulation available, but not related to mentalization. Uli has code for mediation analyses in MPlus available (lagged multilevel mediation/moderation).

Lena de Thurah, Usage behavior, drivers and barriers for digital self-tracking among mental health care service-users in four European countries: A mixed-methods study. Slides

There is no overlap with a WP5 main paper, this paper serves as background. We also have a unique perspective available via the administrators (not just service-users and clinicians).

Rafael Bonnier, general overview of his PhD. No slides available
For whom ESM and EMI's work best – who benefits more, who uses it and keeps using it, for whom is it burdensome? He will try to find clinical factors that influence treatment outcome, to (1) improve clinical guidelines, and (2) use that information to improve EMIs. He now has 2 IMMERSE papers planned, one on compliance and maintenance (looking at characteristics of different types of therapists, and of patients), and one on clinical outcomes (in which first paper will be used as measure of compliance).

Main analyses will be decided on soon: structured around the deliverables ([1] Main outcomes implementation, [2] process evaluation, [3] economic evaluation. For all papers pre-registration, code (on dummy data), introduction, and methods can be prepared, so that as soon as data becomes available it shouldn't take too long to get papers out.

Jessica Gugel, Exploring the implementation of a digital mobile mental health intervention in four European countries – a process evaluation. Slides
Both models (on intervention and one on implementation) will be based on qualitative data of the interviews that they will do.
Suggestion of Jeroen to check while they are interviewing when they get enough data saturation, so it might not be necessary to do all the now planned interviews. They now planned 40 interviews per group (1 hour each) in total, of which 10 per group in Germany – so they are looking for (non-blind) people from the other countries to team up with (Rafael would like to join, also Laura, and someone else said yes but have no idea who, sorry).
Possibly the papers will not be written country per country, but maybe instead looking at specific factors where there are differences between countries, or type of service, etc. However, planning cross-country analyses could be challenging, because of these differences.

Julia Schulte-Strathaus, 2 papers planned. Slides
In the high frequency behavior model she assesses liked activities by an item appraising an activity. Daily QoL is an aggregated set of moments in this study. Maria suggests to also use the results of the usability tests to look at what was changed in the visualizations and the Think Aloud protocol.

(Day 2)

Quick updates:

1. Jessica and Uli will take a look if more questions can be added to the Process Evaluation (request from steering committee)
2. All sites, except BE: Provide feedback on website and communication strategies at PAB's. Jessica and Lena are going to provide an overview to have everything the same for all PAB's.
3. Anita will now be member of the Project Management team.

WP7

See slides
There is a draft for an amendment. All sites: think about changes you want to make e.g. update in PI's.
All sites: check ISF's and see if all signatures, documentation are correct
Jeroen and Lena: set up newsletters for participants to keep them motivating for the study.
PAB Belgium: next meeting about process evaluation, the one after about retention
PAB other sites: next meeting about broader communication (BE has done this already).
These meetings need to be translated (Germany: Julia; Edinburgh: Koraima; Kosice: Slovakia: to be determined).
Jan will look into the different software in the next few weeks for the Statistical Analysis Plan. For now STATA and R seem not to be validated (there is too little documentation about how the software works). SAS is a possible solution. People who have experience with process validation can contact Jan to help.
Age restriction Apple store: a document has been created to send to Movisens. They will contact Apple about the issue. Matthias will check this document and add a paragraph about the procedure in the UK.
Increase recruitment

- Focus on months before summer break to keep things going over summer
- Give a small present to clinical teams to keep them motivating (Belgian chocolates)
- Do another workshop in September to show preliminary results

Anita will add an item in Redcap about reasons for refusal.
It is not an option to release data sooner for PhD students. They can use Phase I data now.
WP8: look into pre-prints about main analysis.
Economic evaluation of DMMH: primary objectives
Costing: Hoa will discuss this with Anita, Uli, Manuela and maybe Jeroen and Jan. WP2, 8 and 7 needs to be involved.

WP6
Slides

All sites: send all documentation (approvals, protocols, amendment etc.) to Luca asap.
WP6 (Elisa) will help coordinating the upcoming amendment by being present in the WP7 meetings.

Age restriction: Matthias will meet with Luca and Elisa about a practical approach (end of May). There will also be a discussion on a more higher level (Apple)
Data Collection White Paper: invitations for expert conversations will be sent from September (IMMERSE members). Focus groups can also include members of the PAB.
Elisa will look into AI regulations.

WP8
Slides

Sharing the protocol in Movisens with other researchers:

- Technically it's not a problem, Movisens can make a copy. Technical documentation would then also be very similar.
- Regulations: other groups will need to set this up themselves. There is difference between using the app for assessment and intervention. Regulations also differ per country/region.
- Intellectual property: We need a discussion about having a usage fee/license → Exploitation Steering Group / Jeroen. Movisens is also look into what the costs can be.

Internal continuous use → Exploitation Steering group

Closing

Steering committee meeting in Edinburgh in the fall
Next GA in Mannheim

Actions

Who	**What**
Everyone	Email presentations to Martine
Everyone + PAB	Give feedback on the new website
Everyone	Send content for Twitter to Lena & Blijke and retweet and tag the IMMERSE project.
Everyone	Inform WP1 when you will not be able to spend your budget before the end of the study!
WP2	Finish final data export
WP2 + WP6 + WP7	Discuss age restriction feature in Apple
WP3	Discuss extraction of the eCRF content
WP3 + Anita Schick	Develop dashboard for individual site visits and forms to see % of participants
WP3 + Medex	Validated software needed?

WP3	Data management plan: XS and statistical software – build a quality system around MaganaMed
Thomas + Hoa Nguygen + statistician	Implement simulated data
PhD students	Think about their variables and what they need from the database.
Thomas	Redcap - Maganamed
WP7	Define timeline simulated data
Inez?	CE certificate: contact Dr. Amy Hardy and/or researchers from AVATAR.
Elisa + Inez + Mario	Combine and compare expertise and document this.
Mario	Send a grant as an example
Anita	Send document of the terms and conditions, overview of the trial and the current status to the SAB.