IMMERSE minutes
31/3/22 – 1/4/22
General Assembly Edinburgh

Present

WP1	Inez Germeys Martine van Nierop Silke Apers	
WP2	Jörg Ottenbacher Johannes Schneider Simon Krause	
WP3	Thomas Ganslandt Tariq Elahi Geun-Hyun Kim	
WP4	Georgia Koppe Manuel Brenner	
WP5	Maria Wolters Theresa Tikegwuonu	
WP6	Ine van Hoyweghen Luca Marelli Irene Schluender Stefanie Hampel	
WP7	Uli Reininghaus (online) Matthias Schwannauer Anton Heretik Michel Wensing (online) Manuela de Allegri Glenn Kiekens Lena de Thurah Iveta Nagyova Lotte Uyttebroek Matej Hrabovsky Valerie Louis	Julia Schulte-Strathaus Rafael Bonnier Simona DiFolco Anita Schick Daniel Dancik Adam Kurilla Koraima Sotomayor Enriquez Islay Barne Dagmar Breznoscakova Hoa Nguyen
WP8	Evelyne van Aubel (online)	

DAY 1

WP1

See slides: https://immerse-project-members.eu/onewebmedia/IMMERSE_GA_WP1.pdf

For travel that is not part of a bigger meeting (e.g. visiting another consortium member) you need to fill out a working visit report. An example like it's used at KU Leuven can be found here: https://public.3.basecamp.com/p/1KXAs5244ee3LbgwdU1bDbT5

WP2

See slides: https://immerse-project-members.eu/onewebmedia/GA_presentation_WP2.pdf

Objectives: visualizations

- ➔ *Action*: Movisens will keep working on the visualizations (as there are other priorities at this point)

MoMent App:

Participants scan a QR code and allow access to their smartphone camera to log in to the IMMERSE study. Advantage: no other login or password details are needed. In case a participant gets a new phone, the dashboard deletes the access to old phone. There is a unique QR code for each participant.

Participants can scroll back in the chat metaphor to change their previous answers if necessary.

Current chat metaphor setup might raise some confusion as participants are supposedly talking to an avatar in the chat, but at the same time are answering 'I statements' in that chat. Are they talking to an avatar or talking to themselves?

- ➔ *Action*: **Test this in usability face**, and reformulate questions if necessary from I statement to third person to make it consistent or formulate something like 'how much do you agree with that statement', followed by the ESM question: 'I currently feel happy'. Then you keep the standard ESM formulation in the current chat metaphor.
- ➔ *Action*: Site leads of WP7 will first give feedback on the dashboard in week 15 or 16, followed by feedback on the visualizations and app.

Current status of documentation:

Risk management:

- ➔ *Action*: risk indication implementation

Requirements files:

- ➔ *Action*: creating finalized version of the software requirements

Usability testing: Usability evaluation plan in place

- ➔ *Action*: create test protocol for different usability testing and documentation of usability tests, followed by a report in the end.

Test-specification and test reports: Is implementation in our system correct? Are mood items implemented? Is the timing correct when you select time frame for questions? Does activation of add on items work?

- ➔ Action: Conducting tests: pass or no and remediate if necessary

MDR Annex I Checklist: Checklist of fundamental security and performance requirements to provide prove that we did that correctly.

All documents are completely or partially required for ethical application.

➔ Deadline: End of June.

WP3

See slides: https://immerse-project-members.eu/onewebmedia/2022-03-31%20IMMERSE%20GA%20-%20WP3%20Update%20%28Ganslandt%29.pdf

If the Data Management Plan changes (as it will throughout the project) the Consortium Agreement does not have to be changes – the CA just references the DMP.

Thomas will discuss with medX which part of the data management goes into the DMP and which part goes into the CIP.

Right now there are several different numbers for the same participant as patients are re-enrolled. For now we have to register these numbers manually but we'll find out whether there's a technical solution to this.

Thomas only had a meeting with 1 clinical site (in Leuven) – he needs contact details of IT departments!

Audio files for phase 1 are locally stored, transcripts can be in FIHR. The format for this will be discussed soon.

Thomas has made the reduced version of FIHR (original version was meant for clinical use, too much info for our purposes.

WP4

See slides: https://immerse-project-members.eu/onewebmedia/Immerse%20Edinburgh%20Meeting_WP4.pdf

Currently there is not enough data for AI models to highlight certain visualizations for clinical use, but this might be possible using the data we collect during the project (so with results outside of this funding period).

WP5

See slides: https://immerse-project-members.eu/onewebmedia/GA%20Edinburgh%20WP5%20Presentation.pdf

We have smaller but more heterogeneous sample than expected, which is not great for the stats. But these can be adjusted, and then planned sample sizes could be smaller. But we need to decide urgently when all sites stop active recruitment for surveys and interviews of

phase 1. If the numbers will be different than what we said in our proposal we need to as a general assembly have a good rational for this.

The main problem for patient recruitment does not seem to be the length of the questionnaire, but getting people past the flyer and actually fill the questionnaire out (so we need more ways to approach patients).

Overrecruiting on some sites and underrecruiting in others is problematic as the samples within sites are already so heterogeneous, so we'll lose balance. And if sites have more questionnaires they will also have more interviews, which means a lot of extra work to code that.

We need to start with the preregistrations for the analyses, **for this Maria needs to know in the next two weeks of all sites whether recruitment will continue or stop**. But recruitment can continue after preregistration.

Before any (local) analyses can start we need to do preregistrations first (which is mandatory before we can access any data).

We still need a stakeholder / patient advisory board.

WP6

See slides: https://immerse-project-members.eu/onewebmedia/WP6_IMMERSE_Edinburgh_2022.pdf
See overview of allowed data processing operations: https://docs.google.com/document/d/10VzfwOrWh6F_r0_PDfXoL-96Fpa6VGaO/edit

Right now the DGF is unsigned – Martine will find out how to get this to be a legally binding document.

We need to write an ethics report for the EC at the end of the 1st Period (September 2022) and the 2nd Period (31/3/24), which has to be countersigned by our independent ethics advisors.

All local sites have to submit an amendment to the phase 1 protocol to allow for clinician workshops this Summer. NB: contact earlier the Ethics Committees to understand the requirements and timing for amendment submission (!)

End of May: submission ethics approval for Phase II. NB: contact earlier the Ethics Committees to understand the requirements and timing for submitting clinical trial study (!) [all local sites]

Luca will plan another Ethics Advisory Board meeting end of April, together with WP6 and Mannheim. Please let Luca know if you also want to be involved!

When are data is anonymised and shared this is still considered pseunonymised (as there is a codebook available at another site). Everyone make sure that this is described correctly in your ICF!

WP7

See slides: https://immerse-project-members.eu/onewebmedia/WP7_GA%20meeting_allmerged.pdf

Outcome assessment:
-6 days of mobile sensing is enough for analyses, but 6 days of ESM might be too much and can contaminate the intervention. But both conditions need tob e similar, in the sense that if there is now ESM monitoring in the control group we won't know what effect we're measuring. Number of days could be reduced though, but this is an issue for WP4. → ask participants to have longer period of collecting sensing data (6 months). Android phones are preferred for this. If people hardly fill out any ESM they don't have to be excluded from the study, this is included as attrition in the power calculations.
-Selection of measures needs to be finished soon.

Implementation strategies:
Maybe also do something like workshops etc at the unit level, rather than only separate clinicians. We should be flexible in terms of how many things the clinicians have done in preparation (workshop, online material, etc) – if some only read the manual they shouldn't be excluded.

Thomas needs to finalize DMP section in CIP for ethics.

WP8

See slides: https://immerse-project-members.eu/onewebmedia/IMMERSE_GA_WP8_March2022.pdf

ESG will work on establishing what exactly is our IP. Part of the implementation strategies are also part of dissemination. We'll start on other types of implementation (newsletters etc) after recruitment has started, Evelyne will then start a small group from someone from each site to also establish the different stakeholders and how to reach them.
Evelyne has started a Dissemination Network google sheet (WP8 folder basecamp) to create an overview of all different channels and stakeholders.

Instead of whitepaper a sort of mixed-method paper – combine with WP6 white paper. Evelyne and Luca will discuss.

Closing

The Wednesday cross-WP meetings will not be every week anymore, Anita will set up an agenda to indicate which WPs are needed at which meetings.

DAY 2

Main papers
-Inez will take the lead on a paper on the overall idea of the consortium based on the proposal.
-Uli will take the lead on a trial protocol paper
-Maria will lead paper(s) on phase 1, but can only start when she gets feedback on when the sites will stop recruitment. Then she can start the preregistrations of the qualitative analyses. The preregs of the qualitative analyses can be done earlier.
-Luca + Maria will lead a paper on recruitment barriers.
-(?) on visualizations / questionnaires (process papers)

Conference abstracts can only be submitted **after preregistration**.

Main deliverables could also be papers (this is what WP7 is already doing). E.g., implementation strategies.

Dissemination plan + authorships

See slides dissemination plan + link to authorships slide: https://immerse-project-members.eu/onewebmedia/IMMERSE_GA_dissemination%20plan.pdf

No IMMERSE authorship, they will be listed in the acknowledgements (and can be mentioned in the title).

Analysis plans can still change after preregistration – just describe clearly why things have changed. There is also a template on qualitative preregistrations on OSF.

Evelyne will look into how this preregistration will work with the machine learning data.

All papers have to be OA. We save the gold route for the main papers, via KUL there is a repository available which is green OA with publications at any journal. Contact Martine for questions.

PhD topics

https://3.basecamp.com/3635894/buckets/10764202/uploads/4796890740

Scientific Advisory Board

- Uneven sample sizes and distribution of recruitment patients / supporters etc across sites. For surveys we need larger numbers (quantitative analysis), and some sites are far below target. We have enough interview (qualitative) data. How do we deal with this? Combine data across sites, so leaving out site as a variable in analysis? (but no DTA in place yet)

-Mario: Exclude a site if not enough data was collected (set a threshold). Look at variability in responses. Amendment ethics to be able to send a link to more people.
-Lucia: consent for consent (which exists in NHS). Use social media, but be careful of bots (you can target specific audience).

Maria: assess effect of combining data of the different sites by assessing heterogeneity proxies (demographics, caseload, etc).

- How do we define clusters, as the different sites / teams are very different from each other?

-Mario: Establish aspects that the teams share, and cluster based on that (minimal common denominator). Stratify the teams. Make sure to have a strong process evaluation.

- ESM monitoring may influence outcome of intervention study. So it may also enhance the effect of TAU.

-Mario: You could argue to remove ESM from the control group. But the current design is good and clean, keep it. Add qualitative data on experiences of users.
-Lucia: Don't worry too much about it, with good sample size. Even if you don't find an added effect of the intervention on top of ESM is interesting. Or there may be classes within the groups with different effects.

Actions

Who	**What**
All local sites	Send Thomas contact details for IT departments
All local sites	Submit an amendment to the phase 1 protocol to allow for clinician workshops this Summer. NB: contact earlier the Ethics Committees to understand the requirements and timing for amendment submission (!)
All local sites	End of May: submission ethics approval for Phase II. NB: contact earlier the Ethics Committees to understand the requirements and timing for submitting clinical trial study (!)
All local sites	When are data is anonymised and shared this is still considered pseunonymised (as there is a codebook available at another site). Everyone make sure that this is described correctly in your ICF!
All	Data transfer agreements need to be signed urgently! Please all reach out to your legal department if your institution has not signed yet
All local sites	Decide on when to stop recruitment phase 1

All local sites	Work on setting up patient / stakeholder advisory board
Thomas	Finalize DMP in CIP
All	Add info on stakeholders and channels for dissemination on Evelyne's google sheet on Basecamp