Topics, analyses PhD students, Postdocs

Wednesday 29-09-2021, 14:00-15:30

Present: Uli Reininghaus, Inez Germeys, Anita Schick, Glenn Kiekens, Iveta Nagyova, Matthias Schwannauer, Michal Hajdúk, Manuela de Allegri, Michel Wensing, Julia Schulte-Strathaus, Lena de Thurah, Rafaël Bonnier, Matej Hrabovsky, Islay Barne, Koraima Sotomayor Enriquez, Simon Krause, Simona Di Folco, Yvonne Beauge, Adam Kurilla, Daniel Dancik, Theresa Ikegwuonu, Maria Wolters, Anton Heretik, Zuzana Katreniakova, Ján Pečeňák.

TOPIC	Action points	Who	By when

1. PhD/PostDoc/PI topic interest round

- Iveta
  - Focus on affective disorders and behavior change
  - Comparing different health facilities
- Matej
  - Mindfulness and stress
- Adam
  - Substance use disorders - prediction of relapse and craving
  - Service attachment, shared decision making and recovery
- Michal
  - Sleep
- Maria/Theresa
  - Deliverable 5.1. Qualitative analysis phase I
- Koraima
  - Cognitive/Psychological flexibility
- Islay
  - Service user engagement with technology. Negative reactivity to technology.
- Simona
  - Clinicians experience of using DMMH
- Julia
  - Quality of life assessed with ESM
  - Interpretation of data visualizations
- Uli
  - Implementation strategies

- Manuela
    - Economic evaluation
- Rafael
    - What works for whom. Trauma. Therapeutic alliance. Adverse effect of using DMMH.
- Lena
    - User technology engagement. Stigma reduction. Self-monitoring behavior and motivation.
- Glenn
    - Non-suicidal self-injury. Recovery based approach.

2.	**Summary of topic round**		

• Four overall topics when looking at the interest of PhDs and postdocs.
  ○ **Patient characteristics** *(affective disorder, substance abuse, NSSI, psychosis)*
  ○ **Psychological constructs** *(quality of life, psychological flexibility, stress*
  ○ **User experience** *(Clinicians, service users, visualizations, usability)*
  ○ **Process evaluation** *(Barriers, facilitators, implementation strategies, economic evaluation)*
• It is important that all young researchers are involved and benefit from the project.
• PhDs/Postdocs interested in similar topics should try to **coordinate specific interests** in order to avoid overlap, and allow for collaborations to be formed. Coordination should happen within the four overall topics to the extent that this makes sense.
• Expressing interest in a topic now, does not mean that this cannot be changed later.
	• Decide how to divide main outcomes/ central topics amongst PIs and Postdocs	PIs and Postdocs	2nd December?

- Central topics for the project should be covered by post docs/PIs. Final decisions still need to be made regarding how main outcomes are divided.

- When settling on a topic PhDs and ECRs should think about the following:
    - integrating **data collected in Phase I and at baseline of Phase II,** as final outcome data for Phase II will only be available in 2023. There will be a rich qualitative dataset from Phase I.
    - That the possibility to add new questionnaires to Phase I and II is limited (to keep burden low for participants).
    - Consider using data that will already/automatically be collected (e.g. app usage data).
    - Data blinding should be maintained.

3.	**Central abstract system**		
• To avoid overlap in the work being produced, the consortium will use a **central abstract system.** • To get access to data PhDs/postdocs/PIs should **submit an abstract** describing specific research objectives, analysis plan and data needed. For this an **abstract template** will be available and should be used. • **Data governance board** will review and approve abstracts. • After approval of an abstract, authors should submit a **detailed pre-registration** to the Open Science Framework (OSF). • An **abstract monitoring system** will be put in place to monitor whether the submitted proposals are being carried out.	• Make abstract templates available + submission procedure. • Make a central overview of all submitted abstracts.	? ?	2nd December? 2nd December

- Researchers in the consortium are free to **submit and retract abstracts at any time** (NB: submitted abstract that will not be carried out, should be retracted to allow other people to work on these topics/objectives).

- Researchers are encouraged to **start the process of writing abstract as soon as** possible, to make it more clear where people's interests lie.

- A **central overview of all submitted abstrac**t will be made available to all researchers in the consortium. This overview should also allow researchers to show interest in collaborating on ongoing work.

4. Authorships and publication strategy			
• General **rules for co-authorship** will be discussed and decided upon in the meeting in Leuven in december. • The **steering committee will prepare suggestions** for guidelines for assigning co-authorship. • The consortium should be aware that there are different rules for awarding co-authorship within different scientific fields, and that shared 1st authorship can be an issue for some PhD students.	• Sketch guidelines for co-authorship	Steering group	2nd December

WORK PACKAGE 7

Wednesday 29-09-2021, 16:00-18:30

TOPIC	Action points	Who	By when
1. DMMH intervention: manual, requirements (working group)			
Core questionnaire: 17-18 items in the core. Maximum of 20 items. ● 8 fixed mood items (PA, NA). Additional list of 10 items where patients and clinicians can select 2 more items. ● Context items: location, activity, social. 6 or 7 items ● Key problem items: 1-3 items	● Make a **review** on this. Balance between being comprehensive and being feasible, otherwise we might end up with a very long list.	Joint effort: PhD students or different groups.	
Possibility of adding 10 add-ons ● Morning (2-3) and evening (3-7) questionnaires are separate entities ● **Symptom-based** ○ Adhd, OCD, Psychotic symptoms (+,-), NSSI and Suicidal thoughts/behaviours, Substance abuse, Eating disorders, Depression, (hypo)mania, Anxiety, PTSD. ● **Transdiagnostic-based** ○ Therapeutic alliance*, Shared-decision making*, Self-efficacy, Emotion-regulation behaviour, Social functioning, Self-esteem, Intimacy, Physical activity. ● How often should each of these add-on items be asked? Daily vs. Weekly*. ● Which groups are interested in which add-ons? ○ Which items are most used? Psychometric qualities of these items could be interesting. ● Not all items in a specific category will be selected. ● Network approach, every symptom stands for itself and has important connections with other symptoms. Interesting to compare to dimensional approaches to the DSM. ● Consistency between the modules, balance between thoughts,	● Make decisions on being comprehensive as well as balanced. ● Think about how to formulate adherence, engagement with therapy/treatment to the evening questionnaire.	ESM items working group.	

behaviours, emotions.
- Simon has added comments to requirements document - please do not resolve!

- **Scales** - Most literature uses 7 or 5 -point scales. Not much difference to VAS scales. Not much research to ESM items about this. Most of the items are from 1 to 7 scales. Measuring from -3 to +3 is also an option; difference in how engaging the scale is. - Visual scale is always better? Slider might be difficult on phones. - Importance of anchor points? - Iveta: boring for the patients to answer with the same response formats. ○ Different issues with this: we know that it is not very helpful to use a lot of different answer formats. The simpler it is the higher the chance questions are answered properly. - **Gamification** element would be very interesting to include, especially for engagement.	- Inez adds a preliminary copy of her ESM book: chapters 3 and 4	Inez
	- Change response formats to 7-point likert scales.	PhDs
	- Analysis idea: do some psychometric analyses; CFA or item response models.	
	- Clarify who is responsible for which tasks: how much do the users do vs. how much the clinicians do.	
→ Inez: Doing all the setting up work for the clinicians will not give us a lot of new information on implementation. One outcome could be that these types of implementation are too difficult for clinicians.	- MoviSens: Translation of the app and dashboard, create a general working force.	
- Service user provides access to the clinician, this needs to reflected in the technology too. For some service users this will require support from the research team. Would every S.U be able to provide access; would technical skills are required? Training to S.U. = implementation strategy. Done jointly.	- Talk to colleagues in Edinburgh specialised in security.	Maria
- Two-factor authentication. This is important as a security measure. Find a balance between security and burden for clinicians to access the dashboard. - Logging data. Some logging data already exists, e.g. who adds modules. Idea to add meta-usage data, how long the clinician uses the dashboard. Usability analysis.	- Priority list on tasks and timeline for requirements.	Simon

2. DMMH Visualisations (working group)

- Currently have 7 categories of visualisations, coming from DiSERVE@home and IMPROVE.
- Data science approaches are required to optimize the algorithms selecting relevant feedback for each individual (WP4).

- It remains open which data is represented in which graph, and how to represent add-ons:

    - Timeline graph
    - Pie chart / donut
    - Box Plots*
    - (Horizontal) bar chart
    - Text output
    - Correlation Matrix*
    - Simple trend line

- Complexity of graphs is discussed. We do not want to simplify too much either.

- It would be useful to have a summary sentence e.g., “in the last 7 days, anxiety tripled”.

- Idea: present this to novice psychiatrists and gauge a reaction.

- Use phase I to find out what clinicians want.
- Training clinicians on dashboard usage is an implementation strategy (workshops, manuals, training/…)

- Customizable graphs would require a lot of clicking.
- Personalization is important but complex.
- Feasibility trial Thomas Ganslandt / Preetha/ Julia-DiSERVE@home.

- Overview of categories, first draft with data suggestions. — Julia, Lena
- Share presentation to Basecamp. — Julia
- Set up next meeting to discuss next steps.

3. Data collection/assessment of outcomes (Michal, working group)

- Michal prepared an overview of questionnaires, point about translations from last WP7 meeting.
- Some scales raised concerns. SAS, CRSI were specifically designed for UK context. Need to be adapted to specific health system. Scales should be as uniform as possible.
- Birchwood insight scale designed for people who are inpatients.
- Copyright protected: EQ5D, GHQ-28
    - Other scales are not problematic
- Cultural aspects, translations.
    - Cross-site team should take a look?

- Pilot some scales further. E.g. SAS in patients with psychosis.
- Michal adds this table to basecamp, PIs comment. — Michal, PIs

4. Economic evaluation (Yvonne, Manuela)

- Overall objective is to assess the costs of the DMMH intervention.
- Which cost is included?
    - Economic costs; value of all resources consumed by the intervention.
- What is the cost perspective?
    - Societal perspective; assessing costs within and beyond the health system.
- Which health outcome?
    - Quality adjusted life year (QALY)
- Framework of Cost Data Collection:
- Highlighted in red where input is needed
- Activities for programmatic implementation of the DMMH intervention
    - Log time spent by various stakeholders.
    - Time sheet: researcher will have to fill out sheet: time spent with movisens regarding design.
    - RedCap survey: whenever meeting with external collaborations

- Yvonne shares slides to Basecamp — Yvonne
- Identifying the data sources to assess costs. Local PIs assign a contact person. — PIs

• Meeting in October with country leads and local PIs to discuss upcoming activities for economic evaluation.
  ○ Responsibilities for filling time sheets or RedCap survey; discussion and collection of unit cost information and country-specific wage information.
  ○ Discussion of reimbursement of services of healthcare and social service provider
  ○ Data collection team: 1 PhD student per site?
  ○ Medications/ can we use clinical records- if so, to what extent?
  ○ What about co-morbidities?
• Outcomes are assessed at baseline and then 2-month, 6-month, and 12-month post-baseline
	• Reminder: Doodle Link October Meeting		

5. Tasks, deliverables, timeline, and next steps			
• Starting next September 2022 with data collection. Stick with timeline. WP7 tasks: • T7.1 Optimizing DMMH implementation strategies • T7.2 Evaluation of implementation outcomes • T7.3 Implementation process evaluation • T7.4 Completion of 'Report on status of posting results'	→ Create a **working group**: Development and optimization of implementation strategies.	Uli, Matthias, Inez, Rafael, **and others**	30.05.2022
T7.1	• Conduct a rapid review		
	• Documentation of meetings with clinical leads	All	Always
	• Identify communalities and differences across all sites/ service contexts		
	• Develop training manual etc. for clinicians. First draft.		15.12.2021

	● Develop counselling package etc. for service users. First draft	15.12.2021
	● Optimize and finalize based on findings from Phase I	30.05.2022
	● Determine timeline: start cRCT, randomization of clinical units and delivery of implementation strategies	30.05.2022 (finalized implementation strategies)
	● Prepare/organize workshops with clinicians (after randomization of clinical units)	
	● Implement other implementation strategies	30.05.2022
T7.2	**Ethics application (phase II)** ○ Study protocol/CIP ■ First draft ■ Final draft ○ Informed consent forms	 22.10.2021 01.12.2021 01.12.2021
	Completion of "First study subject approval package"	16.09.2022
	● Investigator Site File (ISF)	10.01.2022
	● Trial Master File (TMF), SOPs ○ First draft ○ Final draft	 01.12.2021 31.01.2022

	• medX: Review/validation of study documents	04.02.2022
MDR courses • Who needs it? • Quite a high cost per person • We have a budget • As many people as possible • All PIs (and postdocs?) • Training of staff is responsibility of PI Budget for 10 people being trained (2 per site)	• Registration with competent authority (BfArM), incl. MDR course certificates, submission of ethics application.	23.05.2022
	• Statistical Analysis Plan	16.09.2022
	• Clarify randomization strategy, blinding, primary outcome etc.	16.09.2022
	• Develop/finalize recruitment strategies	16.09.2022
	• Implementation of outcome measures (in eCRF system)	16.09.2022
	START: cRCT Implementation Outcomes Evaluation	On 16.09.2022
6. Distribution of responsibilities and tasks		
• We have a lot of working groups	• Create overview of working groups on Basecamp	

WORK PACKAGE 5
Thursday 30-09-2021, 08:30-10:30

Topic	Action points	Who	By When
Topic: 5.1 **Coordination requirements**:			
• Information: Skim through literature for state of the art and then convey this in an easy way on Basecamp. We need to collect information from everyone working in user usability. References are as valuable as questions! • Movisens has a masterstudent working on the visualisations and user experience. Vital to have this information available on to WP5. • Data: Phase 1 will have crucial information for other WP's and individual PhD's. (patient characteristics, psychological constructs, user experience and process evaluation). • Input for WP 2, 4 and 7	Literature review Working on visualisations	 Maria will contact Preetha	
Topic: Timeline WP5			
WP5.1 Questionnaires M1 (April 21) – M9 (December 21)	Coming up: Data collection Analysis Write up		
WP5.2 Interviews M3 (June 21) – M18 (September 22)	Coming up: Training Data collection Analysis Write up		

Topic: Bottlenecks and how to overcome them.			
• Main reasons for hold-ups are that everyone is stretched to the limit due to COVID. • Translations take a while • Ethic approvals consume a lot of time	• Early deliverable of D5.1 • Centralise Phase 1 documents in the WP5 BC folder (now its scattered in different folders) • PI's and Postdocs should focus on the core analyses, because new PhDs are still onboarding. • USE Basecamp TO-DO list, this way we have a centralised way of communicating tasks and responsibilities • Track progress using Kaban-Style. • List Phase 1 data in a living document on BC so everyone has easy access to the data.		
Topic: Early warning systems			
• We will place fortnightly catch ups and urgent notifications via BaseCamp • We will have a Recruitment tracker to have a quick overview of where we are with that. • Write up a document where we keep track of issues identified during data collection. This way we can easily keep track of each other and the general progress, jump in where needed.	Recruitment tracker document	Not specified, Maria?	
Topic: Master students in BaseCamp (BC)			
• Preetha works with Thomas Ganslandt. She mainly works for DiSERVE@home and indirectly informs IMMERSE. • Maria W.: suggestion: as long as a master student is working in our	• External individuals who work on the project will be provided with access to IMMERSE BC.		

teams, we should have everything they produce available on BC. So we can keep track of what is going on and get access to valuable information. • Some master students will be working with IMMERSE data for their thesis.	• Facilitate a meeting between Preetha and WP5		
Topic: Ethic approval Mannheim			
• Mannheim ethics approved! • We have a centralised task tracker on BaseCamp. We will use this to distribute and check on individual (work group) tasks • We will have a 'flagged' document where WP6 can work with.	• Use BC to distribute and check on individual (work group) tasks		
Topic: Discussion 2			
• Upload to Redcap needs to be as smooth as possible. Lena W. has provided an Excel file, but this is very prone to error when copied straight into RedCap. Mannheim will upload in their own RedCap and then export to Heidelberg RedCap (they don't allow outsiders)	• Upload RedCap Document		
Topic: Recruitment strategies			
• Service users: Email mail shots, postal mail shots, in clinic (leaflets, posters via clinician) • Supporters: via service users and supporter organizations • Clinicians/Administrators: via sites, in particular staff mailing lists • Document what each site is doing for recruitment in the WP5 folder (recruitment materials)	• Document to keep track or progression in WP5 in each site.		
Topic: Ethics Issues			
• Ethics is not in place in certain sites, so slightly different timelines in different sites are happening. • See update section for more detail. • Michel: For a scientific point of view it is important to keep track of how	• Edit draft of the interviews/ questionnaires. The draft is available but still needs piloting and input from different sites.		

many people were **approached** by researchers. So we need to keep track of this to get a 'response rate' to publish in papers. • Matthias: How much of the pilot informs the final version. This might lead to site variations and necessary amendments. • ⇒ Interview materials are in WP5 BC, every site has piloted and provided feedback in this doc and this has been adapted in the final interviews/questionnaires. Important to get some form of Ethics approved in all sites, later when adaptations are made we can put in amendments. : https://docs.google.com/document/d/1xYbht2_S1qctFnep2urGk1IlJUwJ7Cx9j-4YMYkWx1w/edit#heading=h.g03u3ha1kge2			
Topic: Task assignment			

• WP5 task assignment
• Interview group
  ○ Data collection is responsibility of the local sites and PI
  ○ Analysis: align with core tasks of phase 2
  ○ Theresa holds analysis, training needs to be done with people of different sites. Every site has PhD's interested so this should not be a problem. Also Theresa needs to know who will do the interviews to plan the training accordingly.
• Questionnaire group:
  ○ Data collection is responsibility of the local sites and PI
  ○ Analysis: align with core tasks of phase 2
  ○ Glenn: will take on an advisory role. Prioritization is not possible because of own projects and part-time appointment
  ○ Yvonne has experience with quantitative data and offers to help.
  ○ New postdoc in Mannheim can help or lead in this.
• Instrument Design team:
  ○ Who is doing analysis on data once it is available, being prepared for this we will cut back on time.
• Discussion: to assign tasks or not to assign tasks. We will assign tasks, but agree that these might change due to day-to-day events.
	Assignment Document
	
	• Decisions were made to have PhD or Post-docs, so core tasks should be divided according to these decisions. Then we can add from local sites or from the wider consortium.
	• Centralise documents with core tasks, timelines, workgroups.
	  ○ Prioritising will be done on the weekly wednesday-meetings.
	  ○ Put names to it for now, can be changed when other people come in or real life asks for more resources.
		Maria	

WHO keeps track of the working groups?

TOPIC	Action points	Who	By when
1. How will we organise and divide the tasks?			
• Someone needs to coordinate and keep an overview of who is working on what and what responsibilities they have. ⇒ decision: Theresa (Edinburgh) for WP5 and the Mannheim post-doc WP 7 play a vital role in this. We will keep a **centralised list** of who is working on what! (Maria will create one for WP 5, Anita will concoct a document for WP 7). This overview will also feed agenda points for our (weekly) meetings. Take an open view towards staff 'belonging' to only one WP. It is a joint-effort so people will work on different WP when needed. It is the task of the PI of the WP to coordinate and keep track of deliverables. It is everyone's responsibility to flag any issues or concerns (workload, task division, questions, involvement,...) they have with the wider consortium, we are an open and transparent group!	Create list with who is working on what	Maria and Anita	Not specified, but soon.
• Slovak site: Has little experience with the size of this project and asks if it is possible to include them more by assigning direct tasks and meeting groups. • Weekly coordination meetings			
2. Comment Michel Wensing			
• Simplify our working groups. IMMERSE has many meetings and shared docs which slow down the process. Suggestions: • Have a decision flow-chart • Have working groups assigned to certain teams, not per task. So work groups can work on multiple topics and focus on this and then contribute to the whole consortium. This way work is more distributed and decisions can be made faster.			

UPDATE OF LOCAL SITES & TOPICS, ANALYSES (PHDs/POSTDOCS)

Thursday 30-09-2021, 11:00 -13:00

TOPIC	Action points	Who	By when
1. Bratislava			
• Translation of British questionnaires and interviews completed (issues with context and cultural adoption but this is being looked at) • Utilise universal coding for education • Ethics submitted by next week (WB 04/10/21) and evaluated by mid October • Ideally interviews would be conducted on both Slovak sites but if one struggles to recruit the other may pick up the numbers • In general on time with all the work • Will adopt outlined strategies to begin recruitment (mainly through personal contact but also online recruitment to see which is preferred). • Bratislava mainly recruiting through clinicians • Detailed feedback on the questionnaire is available in the Slovak folder	Need local speakers to translate the interviews. Perhaps this could be done by someone in the qualitative interviews for their research? Keep a note of recruitment strategies used.	Maybe a PhD student who is interested in user experience	
2. Edinburgh			
• Further along in NHS Lothian site compared to NHS Tayside, contact forms uploaded. Many services are keen to participate so can include different services and specialities across mental health sites • Ethics will be submitted next week with a following meeting within the month (4 - 6 week expected turnaround on ethics) • Recruitment to begin in the next month but is looking good for phase 1 • NHS Tayside, some specialty services have agreed. Slower to participate as finding a new head. Even if this is delayed enough can happen through NHS Lothian. • Questions over whether personalised feedback for each site can be provided, this is a question that needs answered at some point • NHS digital - can ESM be incorporated into patient records, what happens to the app after the project, another question to be answered in the future	Submit ethics Keep a note of recruitment strategies when applicable		In the WB 04.10.2021

3. Leuven		
● Ethics has been formally submitted, answer expected in the next 28 days (by the end of October). Post comments etc. interviews and questionnaire must be finalised ● Local sites are willing to collaborate and are fully onboard with phase 1 ● Recruitment strategies under discussion ● Questions on how to get entire teams onboard, a challenge on the Leuven side as clinical teams are at their current limits. ● (Suggestion) Offer continuous professional development slots - helps them feel as though they are getting something back from their participation (careful not to influence their practice). ● Also can leave something behind, such as recruitment videos, that the teams can use.	Keep a note of recruitment strategies when applicable	
4. Mannheim		
● Ethics has been approved! ● Now to implement recruitment strategies for the questionnaire ● It poses a challenge engaging local site teams as clinicians concerned about participation affecting productivity ● Interviewed for the postdoc position (will hopefully have someone soon) ● Contingencies - what to do if we have no participants after three months etc. ● NB. certain recruitment strategies might pose issues in recording data for example when putting up a poster you cannot record the number of people seeing and reading the advert vs those who respond ● Best to know from which sources people have been sampled more than how many see the recruitment study vs how many respond ● Try to approximate sample frames	Set up redcap form to record recruitment strategies (this will help with heterogeneity across sites)	Anita

PhD topics and analyses - Revisited

Topic	Action points	Who	By When
Potential reviews and papers		**bold = who made the suggestion**	
• Those interested in user engagement can align with Maria and Theresa on aspects of phase 1		One person from each language: Lena and Raphael, Julia, Islay, Adam	
• Protocol paper (suggestion that phase 1 protocol paper is published separately to the main trial)		**Uli, Anita, new postdoc** together with everyone working on WP7	
• Position paper on grant application		**Inez**	
• Economic evaluation (H/E must be looked at whether there is space for such a review as a recent one has been done		**Manuela**	
• Psychometric evaluation (too much to consider all modules so perhaps certain core modules considered)		**Uli**	
• Implementation strategies (although many exist so need to check if there is space for this)		**Uli**	

• Review mindfulness apps on google store. Past reviews have looked at how they might help with mental health. Again important to check if this is necessary as there are many similar reviews to this exist		**Matej**	
• User contribution to design in ESM		**Lena and Maria**	
• Implementation Strategies/ science		**Michel**	
• To what extent have old people been reached/ is their a selection bias/ which people have not ended up in the sample (those with different diagnoses, those from different SES', different genders, different ages)		**Michel**	
• Comparison of different recruitment strategies		**Michel**	
• To what extent had the app design been user centered, what is the user experience		**Maria,** Lena, Adam	
• In depth look at QoL scales used in ESM		**Julia**	
• Position paper on not hiding behind paywalls		**Glenn**	
Further points discussed/ mentioned			
• The more papers align with the goals of the project the more useful they may be. • For those working on projects not fully aligned with the goals of IMMERSE it would be useful to acknowledge IMMERSE. • Templates are included in the templates folder of deliverables, PowerPoint's etc.	Need to start working on the protocol (especially important if some using baseline data before the project is done) Add Phase 2 protocol to the agenda of Dec. meeting Leuven.		

		Discussion of publications and papers that are being worked on also to be added to the agenda	
		Living document to be created outlining PhD project topics and papers/ reviews that are in discussion to help with collaboration	Islay and Julia
		Provide on basecamp an indication of authorship rules specific to different fields. (This might be added as a living document to the WP8 dissemination plan)	