



**PRESENT**

<b>WP1</b>	Inez Germeys Silke Apers	
<b>WP2</b>	Simon Krause	
<b>WP3</b>	Thomas Ganslandt	
<b>WP4</b>	Georgia Koppe	
<b>WP5</b>	Maria Wolters	
<b>WP6</b>	/	
<b>WP7</b>	Matthias Schwannauer Anita Schick Ulrich Reininghaus	Joanne Beames Iveta Nagyova Jan Boehnke
<b>WP8</b>	Jeroen Weermeijer	

**1. General Management**

- a. Value based health care prize: we won the collaboration prize!
- b. The protocol- and position papers were accepted
- c. Periodic reports
  - i. We are finalizing the last details. We are hoping to submit next week.
    - We would like to add in a citation or title + author list for the quantitative paper from phase 1 (Maria)
- d. Evaluation on June 19<sup>th</sup>: Silke will send the agenda points to the officer
  - i. There are 3 practice sessions scheduled: **let Silke know if you are not able to join on the day you were scheduled!**
    - No need to send in PowerPoints before hand
- e. Amendment: will be submitted after the evaluation, as advised by the EU evaluator

**2. WP2**

- a. Simon did another export of DMMH-data
- b. Provided two PhD-students with information on availability of data with regards to their preregistration. Coordinated this with WP3.

**3. WP3**

- a. Nailla Da Silva will help out temporarily, until Wolfgang's position can be refilled
- b. Will discuss the derived datasets with WP4 and organize the online workshop/hackathon shortly. Currently discussing the agenda for the hackathon.

#### 4. WP4

- a. Will organize workshop and analyze data, but no updates now since Manu just handed in his thesis and had to work on that mainly.
- b. Machine learning/methods paper has been accepted → Georgia will send the details to Inez & Silke to include in the progress report

#### 5. WP5

- a. two options for the main qualitative paper were discussed in the GA
  - i. Take Teresa's preregistration and divide the work amongst PhD students
  - ii. Take a qualitative paper that's already been registered by one of the PhD students (e.g. Lena, Julia & Adam). → Maria suggests to rather focus our resources and help them with these papers instead of rejigging Teresa's work
- b. Quantitative paper: in the works. Matthias has assigned someone to support. Maria to take on a more explicit coordinating role? Or focus on a 5.1 deliverable preregistration for now instead?
  - i. → Seems best to now focus on the more complicated paper, since we can then explain why it's not fully written up yet (i.e. due to the more complicated analyses).
    - Matthias: confirmatory models have been completed, so analyses are on track. Matthias will write up the methods part and discuss with Maria how to move further with the preregistration.
      - a. Inez needs a title + authors list to put in the report
      - b. Have the preregistration ready by the review (19/6/24)
  - ii. We need a PhD student to take on the qualitative secondary analysis (process evaluation interviews – user experience questions) → Lotte and Joanne (set up a meeting with Maria)
  - iii. Matthias & Michael will draft out two main papers for the process evaluation qualitative data → Jessica to help out here?
    - Is deliverable 5.2 covered in these papers? → Matthias will look into this and include Maria in this process
      - a. Send Inez 3 titles to include in progress report (we need additional core papers for Phase 2)
  - iv. Also need someone to take on the quantitative secondary analysis (TherapyDesigner data) → Jessica?

#### 6. WP6

- a. /

#### 7. WP7

- a. Thank you for making a final push in recruitment! We are now up to 77% of target sample and still going.
- b. According to preregistration, the database will be locked in March 2025, but PhD-students need access to the data. → Lock the database linked to primary outcome in September 2024? But then what about remaining data collection (T2 and T3 assessments)?

- i. Main reason to keep data locked is to not bias recruitment → but this doesn't play such a big role in T2 and T3. We can carry out the assessment and report the unblinding (in separate or same report). Clinicians will not know any of the results at this time so this can't bias/influence their engagement.
  - Jan: probably not so neutral → engagement could drop at T2 and T3 if results implicate that the intervention is not effective + this would raise the ethical question of continuing the trial if results implicate that the intervention is not effective + resource implications (performing multiple data locks + validations would require more effort).
- ii. Can we somehow provide the necessary information to PhD-students without having to officially lock the data already (e.g. make it available to parts of the team who can then run code?)
  - Jan: would have to look into current regulations, but in previous papers we for example used randomized subsets of data or dataset with information about condition removed
- iii. **Decision:**
  - We will continue T2 & T3 assessments until March 2025.
  - Inform students that data will be made available and that they can start preregistrations.
  - We will decide on how to exactly make data available later on → Jan to look into regulations and what possibilities there are concerning the data lock
- c. We can already mention that we will apply for 6-months no cost extension

## 8. WP8

- a. Maria to publish a summary of Teresa's preregistration to a non-archival computer science workshop? → ok
- b. Manuel requested data for deliverable 4.3 → request has to be adjusted because some of the requested data is embargoed. Anita will help out with this and Jeroen will inform Manu

## 9. AOB:

- a. Opinion piece: we have a good outline of all of the problems, but we have to think further about recommendations.
  - i. Instead of making specific suggestions on legal or regulatory advancements, maybe lay out more pragmatically what changes should be made and what is needed from a research or practice perspective (e.g. separate commercial from clinical evaluation, safe guarding of clinical interventions should allow for scientific evaluation both in development and post launch, safeguard around implementation rather than the level of intervention should dictate whether something can be evaluated).
    - Inez will try to finish this by the end of next week
    - There are representatives from all countries involved, so we will base authorship on this