

WP7

Implementation Strategies, Processes, Outcomes and Costs

Ulrich Reininghaus

Department of Public Mental Health, CIMH

Michel Wensing

Department of General Medicine and Health Services

Research, UKHD

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WP7 Overview



- Ethics, research governance
- cRCT design, methods
- DMMH intervention
- Data management
- Recruitment
- Deliverables, milestones
- Next steps



This project has received funding from the European Union's Horizon 2020 research and innovation Programme under grant agreement 945263 (IMMERSE)

WP7: new staff



KU Leuven:

Inez Myin-Germeys

Glenn Kiekens

Ana Teixeira

Lena de Thurah

Rafaël Bonnier

Lotte Uyttebroek



UEDIN:

Matthias Schwannauer

Simona DiFolco

Koraima Sotomayor-Enriquez

Islay Barne

Erica Niebauer



CIMH:

Uli Reininghaus

Anita Schick

Julia Schulte-Strathaus

Jessica Gugel

Jan Böhnke

UHEI:

Michel Wensing

Manuela de Allegri

Hoa Nguyen

Valerie Louis



UK BA:

Jan Pecenak

Michal Hajdúk

Anton Heretik

Adam Kurilla

Natalia Cavojska

Daniel Dancik

UPJS:

Iveta Nagyova

Zuzana Katreniakova

Andrea Pavlickova

Dagmar Breznoscakova

Laura Kundratova

Julius Evely



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WP7 Update



Ethics, research governance

- SUKL approval!!
- Ethics amendment in preparation
 - Additional contingencies
 - Clarify usage by service users/clinicians as implementation outcome
 - Use of validated statistical software (e.g., SAS)
 - Potential update PIs (e.g., Wiesloch) – any others?
- Monitoring request by regional authority in Mannheim (potential indication for audit)
- Trial Master File, Investigator Site File
 - Updates to delegation logs (e.g., Kosice)



WP7 Update



cRCT design, methods

- SOPs
 - Initial recruitment and retention of participants (in control condition) – newsletters, social media - support by WP8?
- Measures
 - Importance of collecting measures to assess Reach, Adoption, Implementation, Maintenance
- Statistical Analysis Plan:
 - close to final version
 - procedure for database lock (prepare code, simulation – recommended for all)



WP7 Update



DMMH intervention/implementation strategies

- age restriction in Apple app store as implementation barrier (with WP2)
- maintenance: use of platform after completion of cRCT (cost model for internal and external clinical partners)
- opinion leaders – identified in each site?

Data management

- Implementation of architecture for research database by WP3 – by when?
- Implement ongoing data checking and cleaning procedures – SOP by WP3?
- Simulation of data access prior to completing data collection – with WP3?

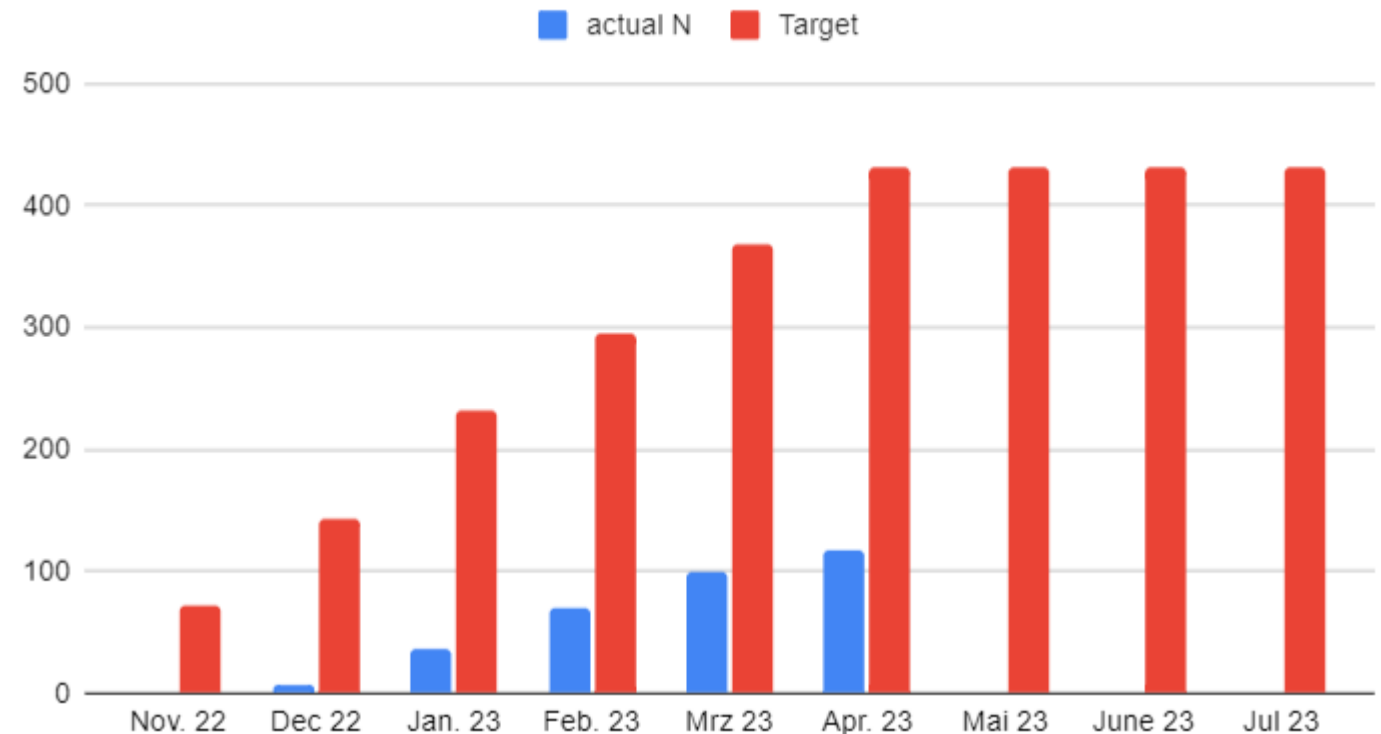


WP7 – Recruitment

1.5.23

- Recruitment started in Nov 2022 in 4 sites (Mannheim, Wiesloch, Bierbeek, Leuven)
- Lothian, Lothian CAMHS started in March 2023
- Bratislava, Kosice started in April 2023
- total n included: 120 of 432 (27%)
- Number of participants included per month: around n=20 (on average)
- Contingencies in place in 5 sites from April 2023 (Mannheim, Wiesloch, Bierbeek, Leuven, Lothian)
- **Based on current recruitment rate, we would require 20 additional months until completion of recruitment (last participant, first assessment)**

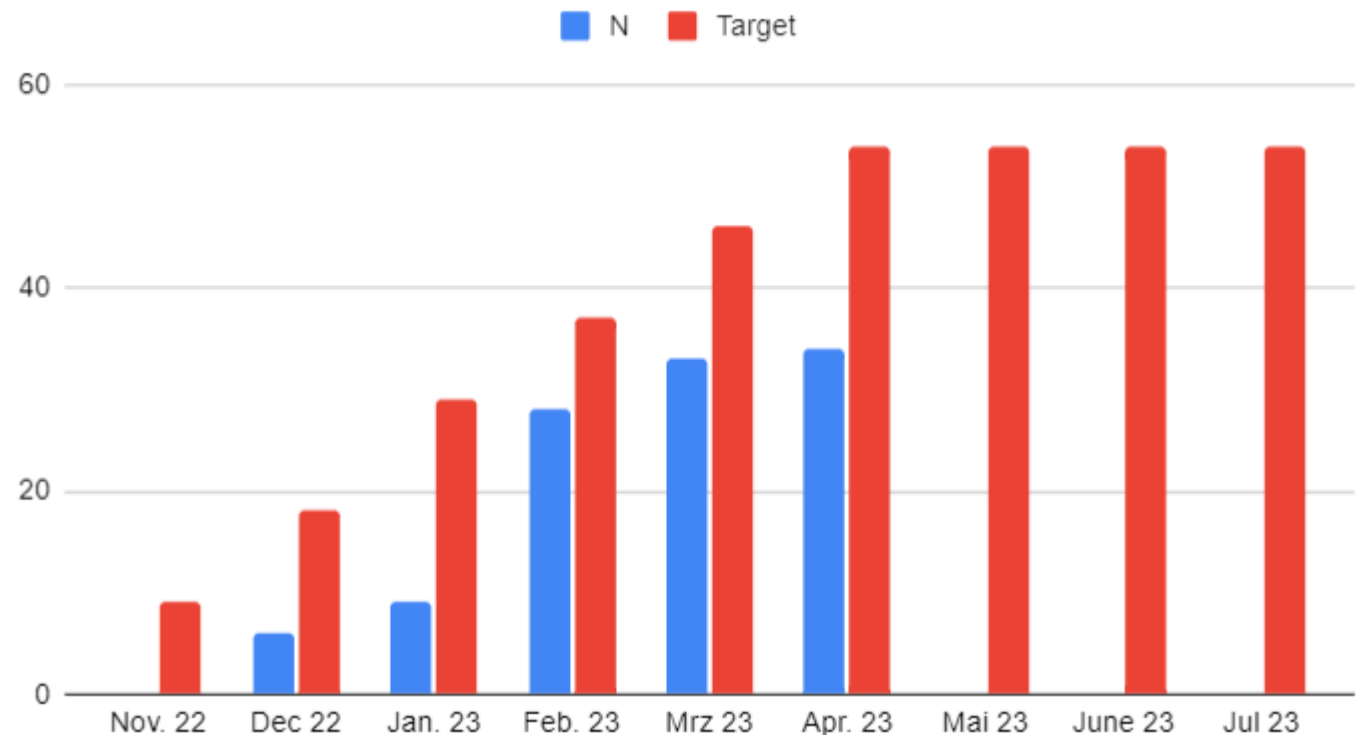
All sites



WP7 – Recruitment Mannheim

- N=34 of 54
- Mean recruitment: 8 participants per month
- Contingency rule in place: recruitment until end of July
- Based on current recruitment rate, 2.5 additional months would be required until completion of recruitment (last participant, first assessment)
- **Measures to improve recruitment:**
 - On-boarding of additional staff, increase flexibility in meeting demands
 - Increase n identified and retained until completion of baseline (communication)

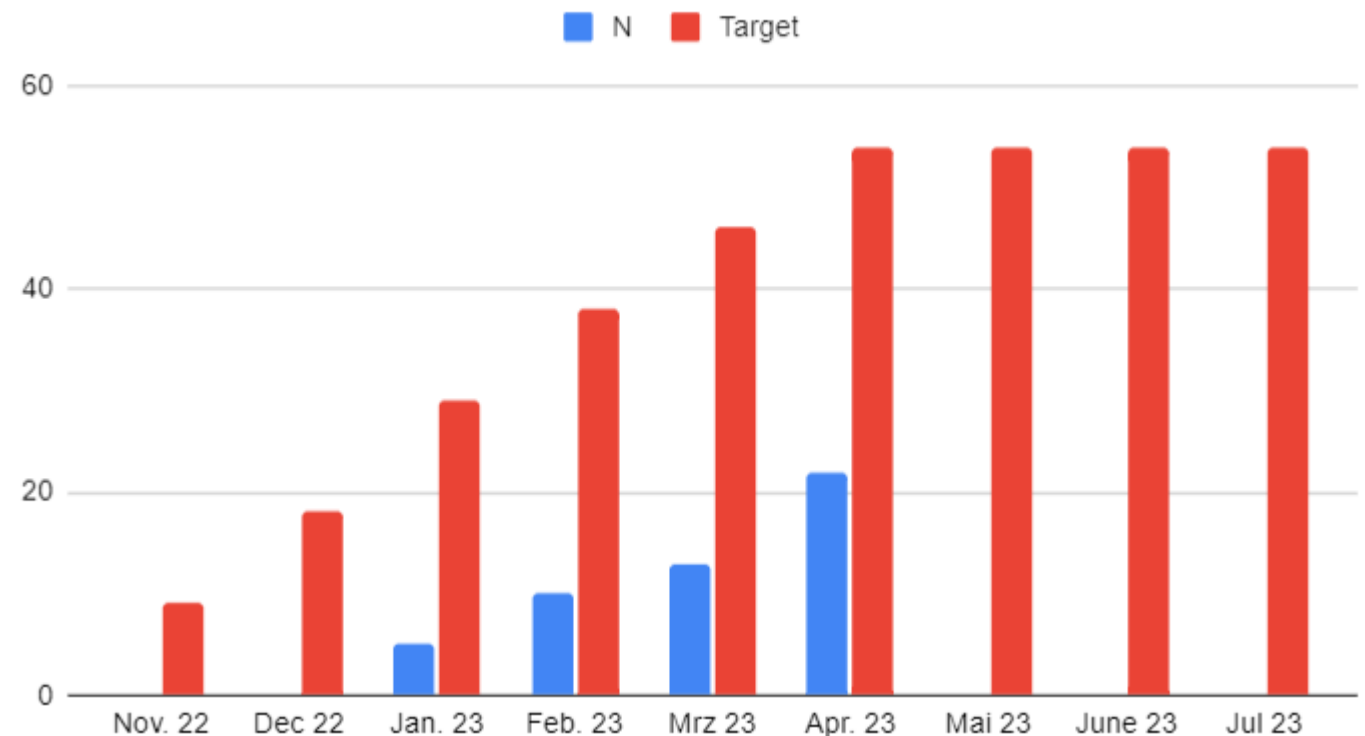
Mannheim



WP7 – Recruitment Wiesloch

- N=22 of 54
- Mean recruitment: 5.5 participants per month
- Contingency rule in place: recruitment until end of July
- **Based on current recruitment rate, 5.8 additional months would be required until completion of recruitment (last participant, first assessment)**
- **Measures to improve recruitment:**
 - More presence on site, on-boarding of additional staff, increase flexibility in meeting demands
 - Increase n identified and retained until completion of baseline (communication)

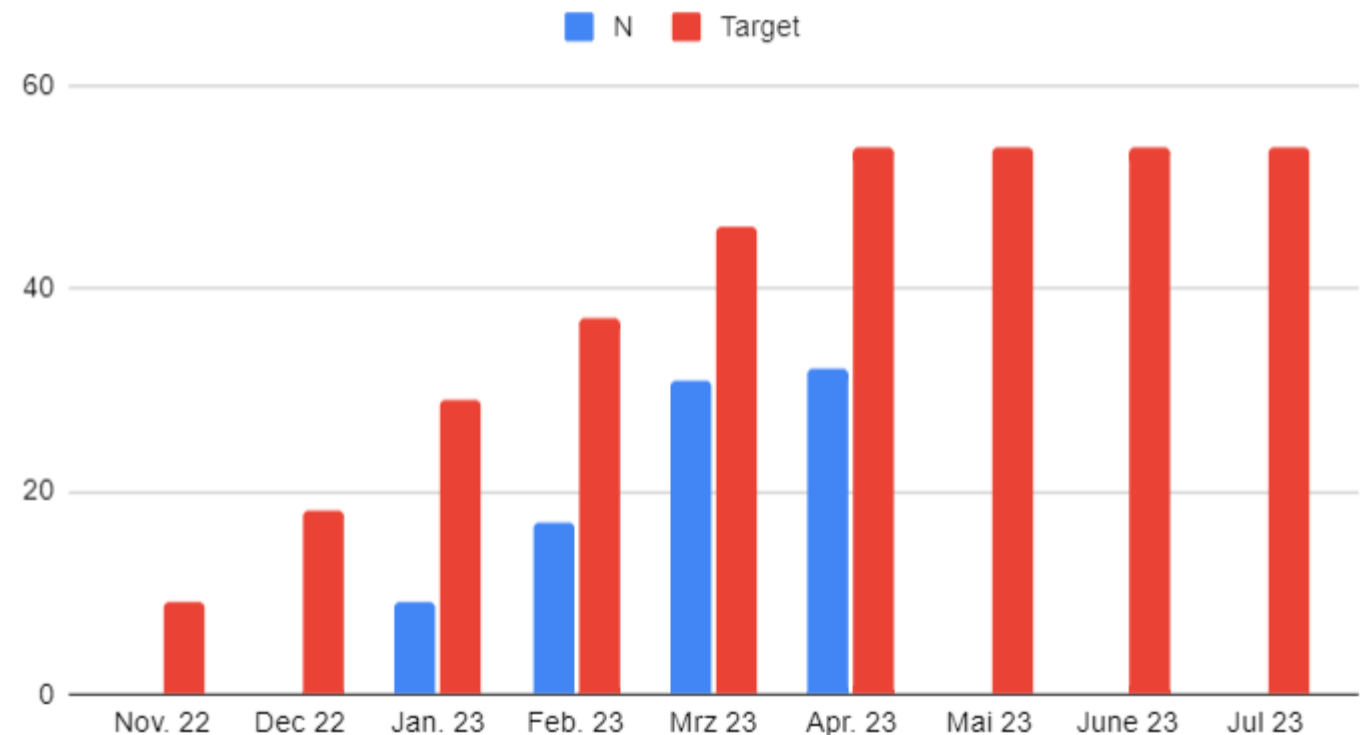
Wiesloch



WP7 – Recruitment Bierbeek

- N=32 of 54
- Mean recruitment: 8 participants per month
- Contingency rule in place: recruitment until end of July
- **Based on current recruitment rate, 2.8 months would be required until completion of recruitment (last participant, first assessment)**
- **Measures to improve recruitment: N/A**

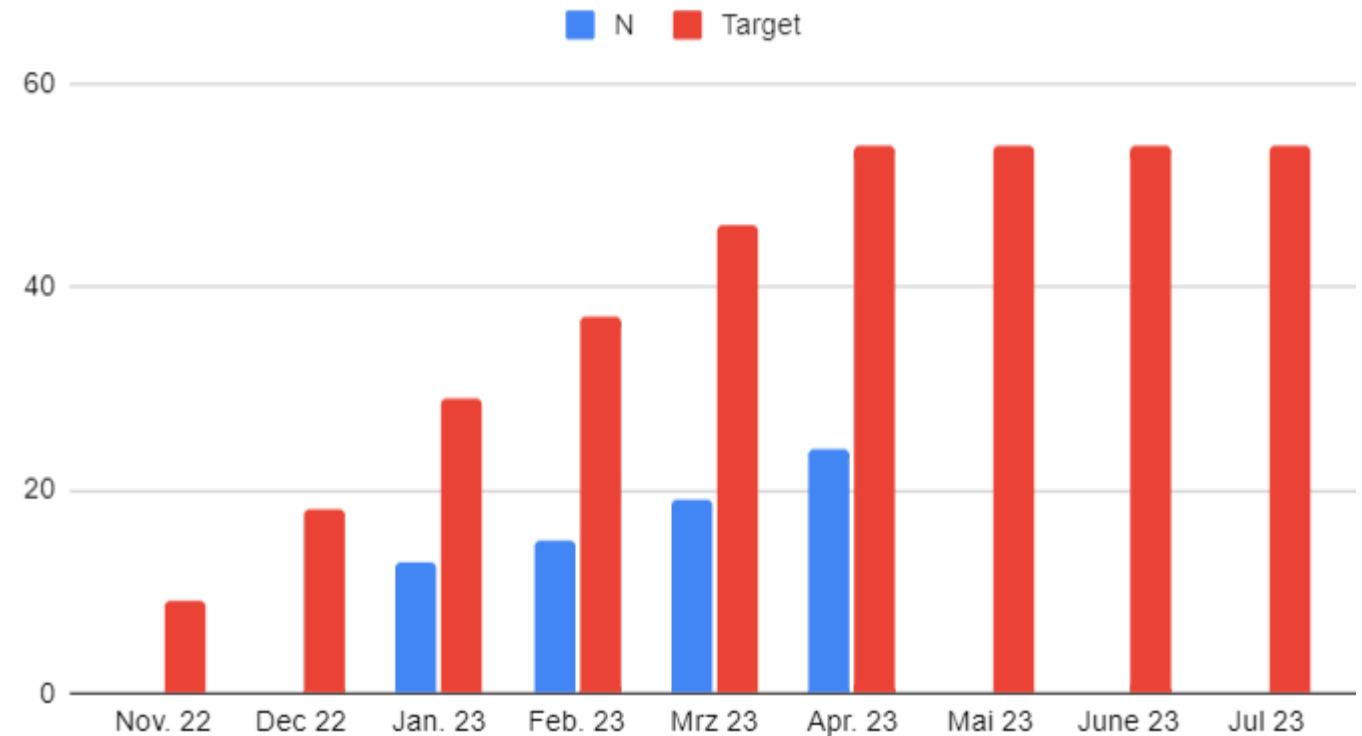
Bierbeek



WP7 – Recruitment Leuven

- N=24 of 54
- Mean recruitment: 6 participants per month
- Contingency rule in place: recruitment until end of July
- Based on current recruitment rate, 5 additional months would be required until completion of recruitment (last participant, first assessment)
- **Measures to improve recruitment** (see next slides)

Leuven



Lessons learned: Recruitment of participants

- **Being 'present'**

We are at the hospital 1 day a week to troubleshoot, recruit and test participants

- **Being 'flexible' and determine what works best for the unit:**

- In some units we give presentations to potential participants
- In other units, clinicians introduce the study and procedures and notify us
- For one unit, we wrote a template mail that they use to send to all of their patients, they then contact us when they show interest and we plan a date for signing and testing.

Lessons learned: Motivating patients

- We are **available** via mail and mobile during working hours
- Small **'casual' moments** on the units for troubleshooting and asking about the study and to motivate them.
- Reminding them of the **benefits** (financial rewards, personal information, and scientific importance)

Lessons learned: Motivating clinicians

- **Having a contact person/’go to clinician’**
- **Regular visits to motivate and respond to questions**
 - For some units we have a planned meeting to catch up and discuss strategies for recruitment.
 - In one case we planned a moment where we would share recruitment numbers / compliance, and provided cakes and coffee.
- **Monthly updates**

We also show the graphs of the other units (positive competition)

Difficulties

■ Clinicians

- Number of questionnaires/participant is burdensome. Hard to fill out on time.
- Psychologists and psychiatrists have a positive attitude about the dashboard and the data it generates. Other professions seem to struggle and are beginning to show demotivation towards the study, which we notice in the recruitment numbers and ESM-dropouts. Here we try to offer support in interpreting (using) the tools, yet so far we did not have a request.

■ Patients

- 10 beeps a day is too burdensome is the most heard critique we face.
- Participants are very reluctant to use MovisensXS and often get confused as to why and how we do this. Especially if they need to carry a study phone (happens more than expected).
- Participants often come with great features to add, but are somehow disappointed they are not integrated. One very recurrent requested feature is to add free text at the end of a questionnaire.

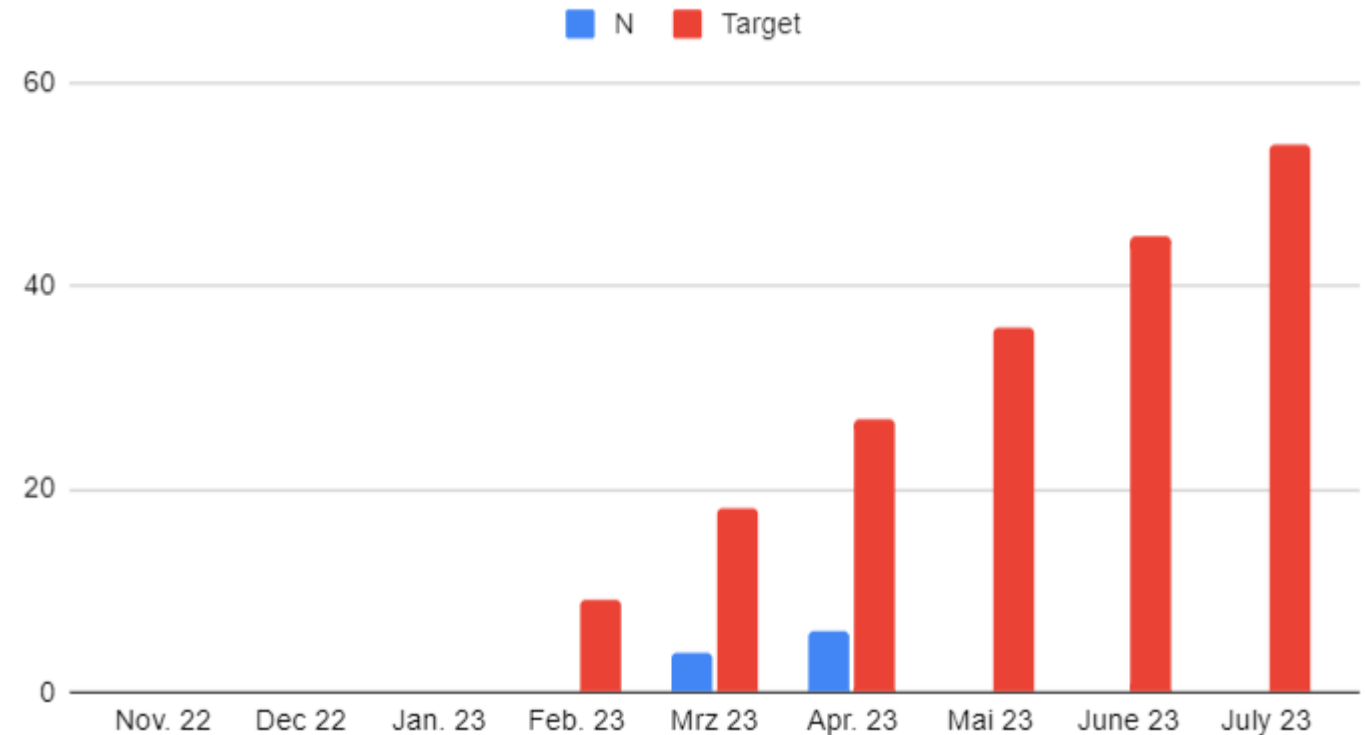
Questions

- How to ensure recruitment numbers keep up during summer?
- How to intervene when the entire team becomes demotivated?
- From inclusion to keeping them in the study: how to best approach this?

WP7 – Recruitment CAMHS

- R&D approval in Feb 2023
- N=6 of 54
- Mean recruitment: 2 participants per month
- No contingency rule in place
- **Based on current recruitment rate, 24 additional months would be required until completion of recruitment (last participant, first assessment)**
- **Measures to improve recruitment:**

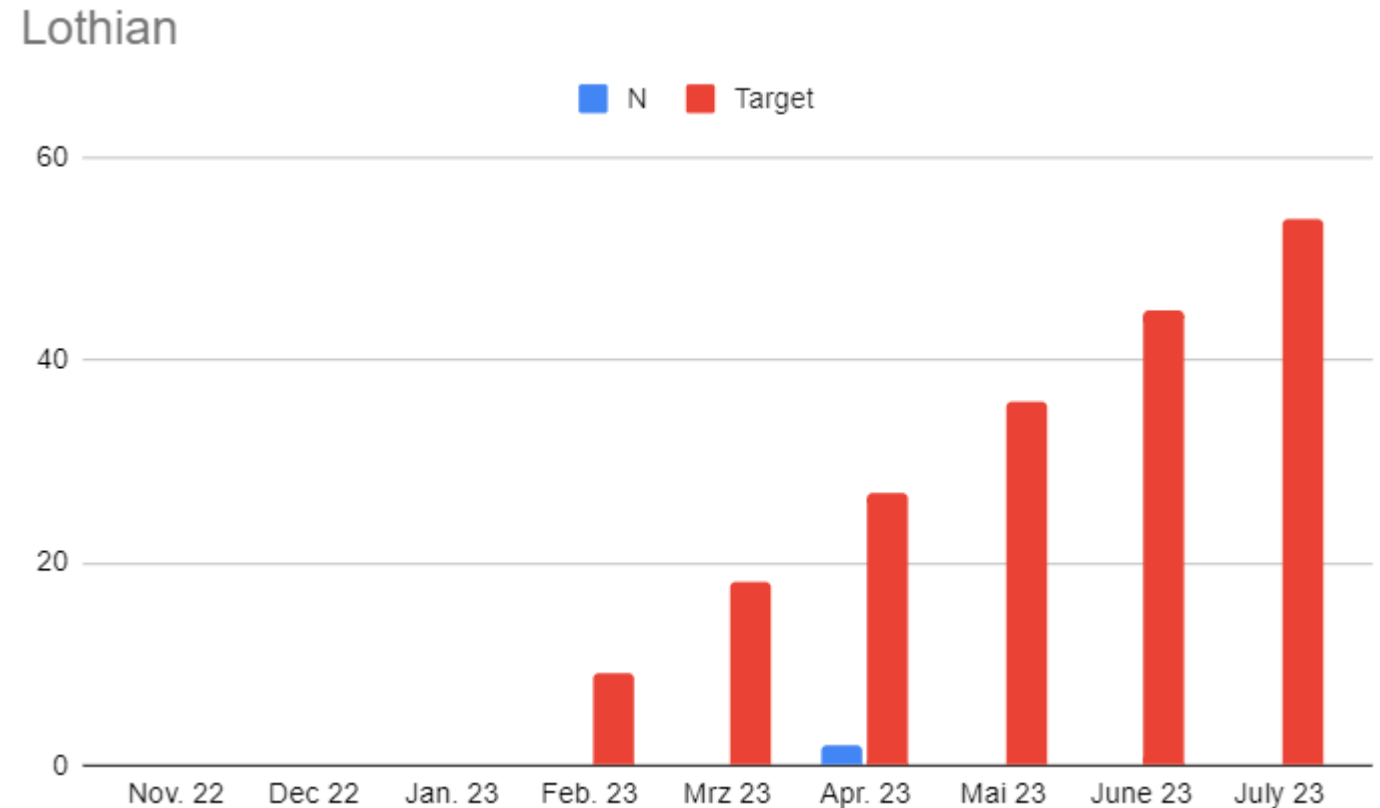
CAMHS



WP7 – Recruitment Lothian

1.5.23

- R&D approval in Feb 2023
- N=2 of 54
- Mean recruitment: 0.67 participants per month
- Contingency rule in place. 6 units randomized
- **Based on current recruitment rate, 18 additional months would be required until completion of recruitment (last participant, first assessment)**
- **Measures to improve recruitment:**



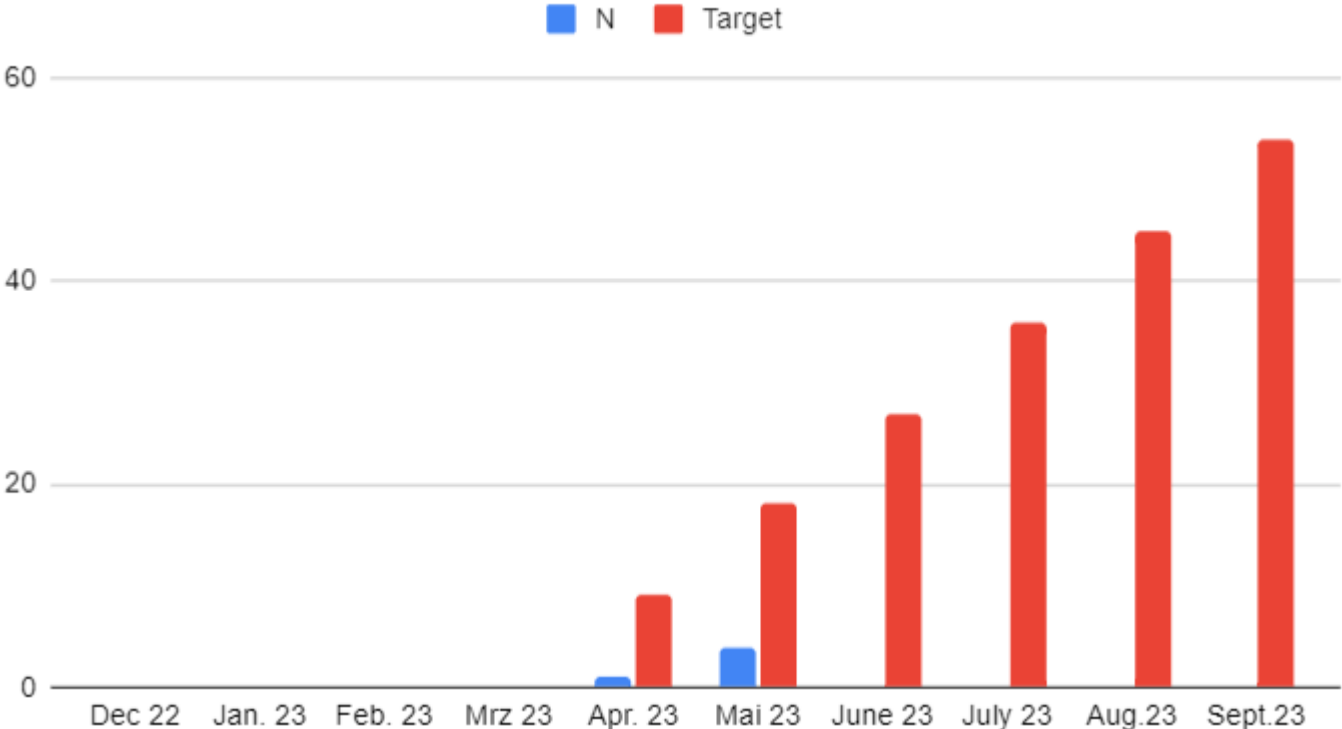
WP7 – Recruitment Bratislava



4.5.23

- SUKL approval in 24.04.2023
- N=4 of 54
- No contingency rule in place
- **Barriers:**

Bratislava



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WP7 – Recruitment Kosice

- SUKL approval in April 2023
- N=0 of 54
- No contingency rule in place
- **Measures to improve recruitment: N/A**



WP7 – Deliverables & Milestones 2022

	Task	Deadline	
MS 9	Tailoring and optimization of DMMH intervention and implementation strategies and guidelines for semistructured interviews finalized	16.9.22/ 31.10.22	✓
D 7.1	Consolidated description of intervention and implementation strategies	16.9.22 / 31.10.22	✓
MS 10	Preparation of clinical trial completed	16.9.22 / 31.10.22	✓
D 7.2	Completion of First study subject approval package	16.9.22 / 31.10.22	✓
MS 11	First patient, first assessment	10/ 22 / 28.11.22	✓
	216th patient in (50% of full sample)		



WP7 – Deliverables & Milestones 2023

	Task	Deadline
D 7.3	Completion of Midterm recruitment report	18.7.23
	216th patient in (50% of full sample)	07/2023
	First patient, last outcome assessment	10/23 Approx. 12/23, i.e. 2 months delayed
MS 17	DMMH usage completed by last patient (sample complete 100%)	12/23
MS 18	Data checking and cleaning for 50% of sample completed	12/23



WP7 – Deliverables & Milestones 2023

	Task	Deadline
MS 23	Last patient, last assessment (100% of sample completed)	12/24
MS 20	Data quality checking and cleaning (completed for 100% of the sample)	12/24
	Completion of statistical analysis	01/25
D 7.4	Completion of Report on status of posting results	18.3.25
D 7.5	Report on implementation process evaluation	18.3.25
D 7.6	Report on economic evaluation	18.3.25



WP7 – Delivery of task 7.3/7.4 (ongoing)



Task 7.3 Implementation process evaluation (Jessica)

- Prepare the process evaluation to provide insight into the implementation and maintenance of the DMMH intervention
 - Development of programme theory based on focus group data
 - Development and piloting of interview guide

Task 7.4 Economic evaluation (Hoa)

- Measures for the assessment of costs
- Implementation in eCRF in all languages



WP7 – Year 3: Upcoming activities

- Data collection
- Amendment of phase 2 ethics
- Ongoing training of research staff
- Implementation of contingency rules in case of slow recruitment
- SOP: Data checking, cleaning, simulation (with WP3)
- Develop a clear timeline and contingencies for primary and secondary analyses (incl. planned analyses for all PhD students)

