- Advisory Board -
WP7 Implementation Strategies, Processes, Outcomes and Costs

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WP7 - Objectives

1. To tailor, optimize and evaluate detailed implementation strategies for the Digital Mobile Mental Health intervention (DMMH) at each site and identify putative contextual factors based on an a priori assessment using the NASSS framework (task 7.1, with WP5, task 5.1, 5.2)
2. To investigate i) **R**each, ii) **E**ffectiveness, iii) **A**doption, iv) **I**mplementation and v) **M**aintenance of implementing the DMMH in routine care **(RE-AIM)** as a basis for assessing the **public health impact** of implementation and **scale-up** of the DMMH (task 7.2)
3. To examine the process of implementing the DMMH in routine care and identify in vivo configurations of contexts, mechanisms of change, and how these are associated with outcomes of implementation and intervention (task 7.3, with WP5, task 5.3)
4. To investigate the economic costs of implementing the DMMH intervention, determine cost-utility and extended cost-utility of the intervention vis à vis standard care (task 7.4)

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Design, methodology

- Effectiveness-implementation design: parallel-group, assessor-blind, multi-centre cRCT, combined with a process and economic evaluation
- 4 time points:
  - Baseline (t_0)
  - **2-month post baseline (t_1)**
  - 6- month post baseline (t_2)
  - 12-month post baseline (t_3)
- Primary outcome: Service Attachement Questionnaire (SAQ) at t_1 as user-level implementation outcome
- Target sample size: **n=432 service users** from 24 units (clusters) at 8 sites
  - Based on ICC=0.05; **attrition rate of 35.5%** at t_1
- Allocation ratio: 2:1 (experimental vs. control condition)
- Secondary outcomes: reach, effectiveness, adoption, implementation, maintenance (set of criteria)

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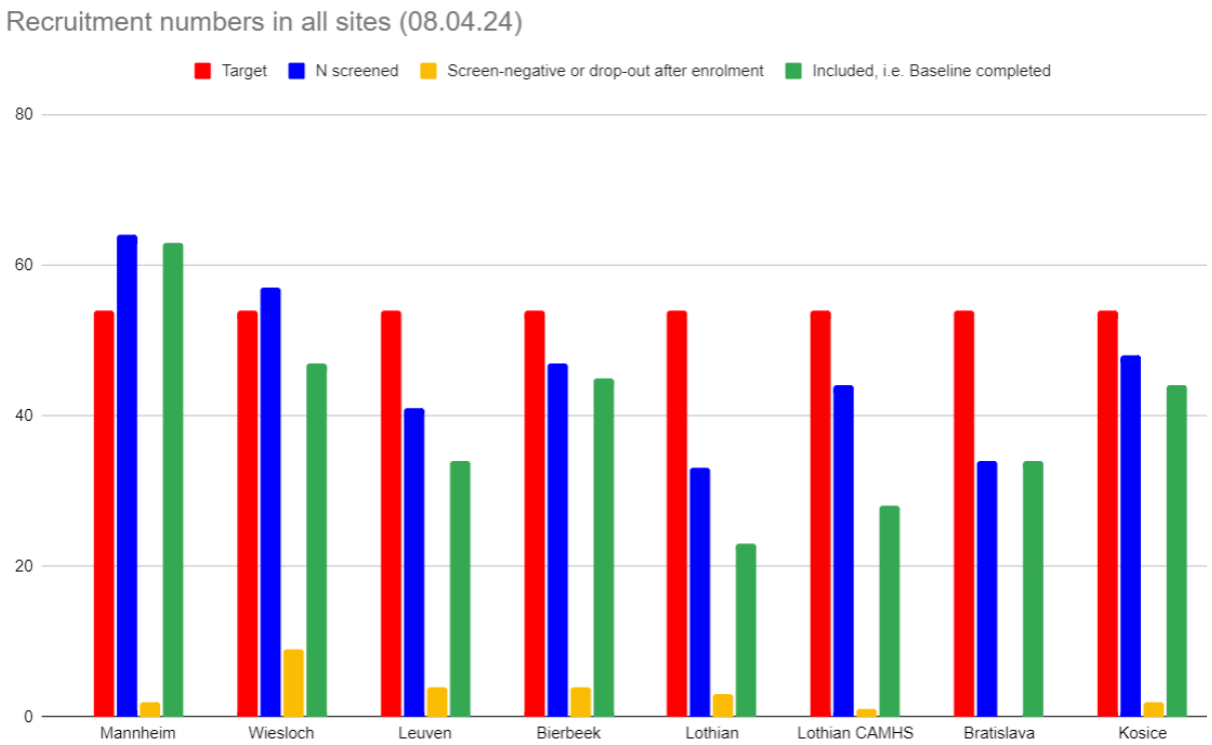
Recruitment numbers

Overall number of included individuals (08.04.2024): **n=318** (target: n=432; **73.6%**)

- range: n=23-63 per site (target: n=54)
- units n<10: in 5 sites, at least 1 unit (5 units in 1 site)

Sites	Target	N screened	Included, i.e., baseline completed
Mannheim	54	64	**63**
Wiesloch	54	57	47
Leuven	54	41	34
Bierbeek	54	47	45
Lothian	54	33	**23**
Lothian CAMHS	54	44	28
Bratislava	54	34	34
Kosice	54	48	44
Total	432	368	**318**
% of target		85.2	**73.6**



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Projections

- **n=117** participants still need to be **included**
- if each site recruits an additional **14-15 participants**, we would meet the target
- in last 6 months, we screened on average **n=20** participants per month across all sites
- If we continue in this pace, then we would need **7 months** to reach the target

  (i.e. end of 10/2024)

Month	N included	delta
9/23	212	
10/23	230	18
11/23	246	16
12/23	265	19
1/24	278	13
2/24	302	24
3/24	**315**	**13**
4/24	332.2	
5/24	349.3	
6/24	366.5	
7/24	383.7	
8/24	400.8	
9/24	418	
10/24	435.2	

On average: n=17 participants have been included (i.e. baseline assessed)

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End of recruitment: June 2024

- as in other trials (e.g., INTERACT, SELFIE etc.), further extensions were envisaged with in-kind contributions
- however: termination of recruitment by June 2024 decided by IMMERSE Steering Committee
- now need to consult with TSC and DMEC (admittedly beforehand better)
- also: MDR requires us to carry out the clinical investigation according to DIN EN ISO 14155:
  - 9.2.3 conduct of clinical investigation: mitigate risks that 'significantly affect reliability of clinical investigation results' (chapter 9.2.3)
- implementation of CAPA (DIN EN ISO 14155, chapter 9.2.3):
  - higher number of participants identified in each investigational site
  - higher conversion rates: identified/screened, screened/included
  - lower attrition rate at 2-month follow-up (i.e., **lower than 35.5%**)

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End of recruitment: power considerations

- Original power calculation

Table 2. Scenarios allowing for different effect sizes *d* and intra-class correlations *ICC*; increased for an expected attrition of 35.5% presenting the corresponding recruitment targets to meet $N0^{+}$

	$d = 0.50$	$d = 0.40$	$d = 0.30$
$ICC = 0.00$ $(DEFF = 1.00)$	198.4	311.6	544.2
$ICC = 0.05$ $(DEFF = 1.22)$	241.4	426.5	914.9
$ICC = 0.10$ $(DEFF = 1.43)$	284.3	541.4	1285.6

- Potential additional steps from consulting with trial statistician
  - determine power based on actual/observed ICC
  - interim analysis (DMEC)
  - however, value of both (ICC, interim analysis) is limited given…
    - end of recruitment is pre-set (June 2024)
    - by the end the data is processed and the interim analysis is completed, recruitment will have ended
    - this is an effectiveness-implementation trial: want to facilitate further exposure in exp condition

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Timeline for recruitment and assessment

- End of recruitment: June 2024
- Last patient, first assessment: June/July 2024
- End of intervention phase: December 2024
- Last patient, last assessment: March 2025
  - lock of database as per sign-off by trial statistician (as detailed in the statistical analysis plan published on OSF)

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Feasibility vs. implementation aspects

- planned as high-quality, a priori hybrid effectiveness-implementation trial
- however, recruitment end date now set
- urgent need to disentangle feasibility of trial methodology from implementation aspects
- e.g., need to carefully assess:
  - number of participants identified for screening (e.g., lower than expected?)
  - conversion rates, proportion of recruitment target met etc. in the control vs. experimental condition
  - effect sizes are as expected or smaller than expected
- conclusions about implementation of DMMH depend on exposure to intervention and implementation strategies
  - inability to disentangle feasibility/implementation of trial methodology from implementation of the DMMH intervention
  - units/sites with larger sample size particularly informative for implementation

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Discussion

- focus of recruitment:
  - higher number of participants identified in each investigational site
  - higher conversion rates: identified/screened, screened/included
  - lower attrition rate at 2-month follow-up (i.e., **lower than 35.5%**)
- report findings on hybrid effectiveness-implementation trial as preregistered on OSF and in (submitted) study protocol: Reach, Effectiveness, Adoption, Implementation, Maintenance
- process evaluation: contexts, mechanisms of change, and how these are associated with outcomes of implementation and intervention
- health economic evaluation
- **Any advice much appreciated!**
- Thank you!!

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