- Recruitment -
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

- 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)

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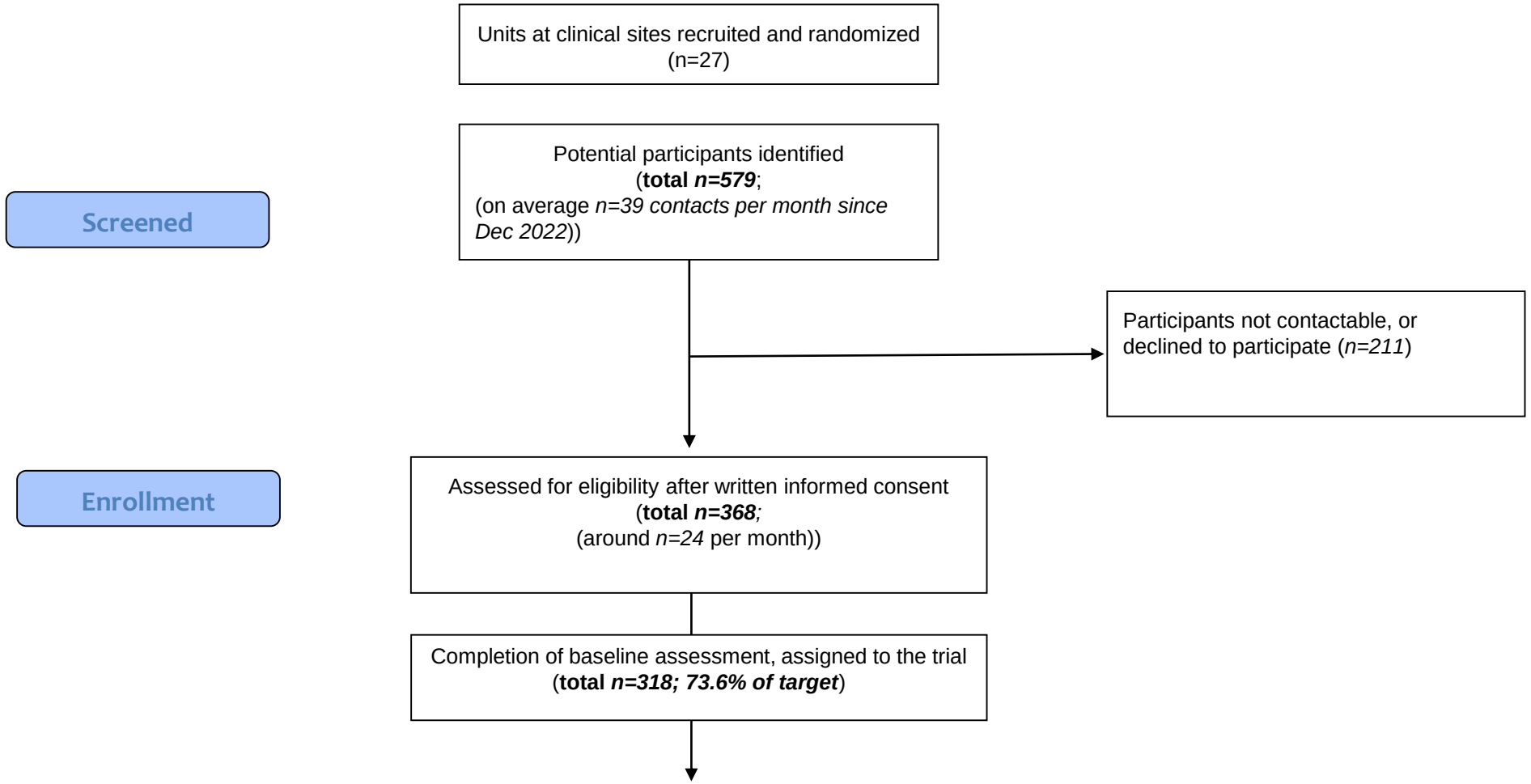
Flow chart



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Conversion rates

	in contact	screened	conversion rate: in contact/screened	Baseline assessment	conversion rate: in contact/baseline
Mannheim	112	64	1.75	63	1.78
Wiesloch	109	57	1.91	47	2.32
Leuven	46	41	1.12	34	1.35
Bierbeek	67	47	1.43	45	1.49
Lothian	62	32	1.94	23	**2.70**
CAMHS	57	39	1.46	28	2.04
Bratislava	38	34	1.12	34	**1.12**
Kosice	88	48	1.83	41	2.15
total	579	362	1.57	315	1.87

- contact-to-screened: 1.1-1.9
- contact-to-baseline: range 1.1-2.7
  - at some sites, **every 1st** contact resulted in inclusion
  - at other sites, only **around every 3rd** contact resulted in an inclusion

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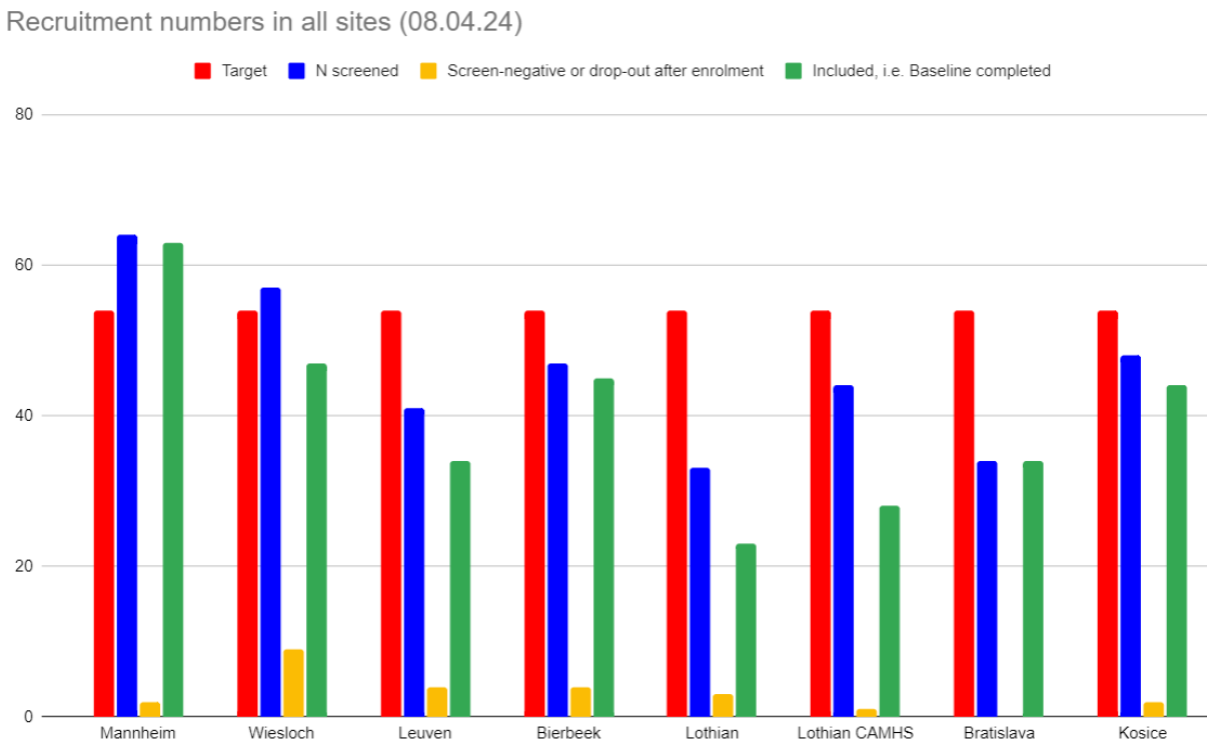
Recruitment numbers

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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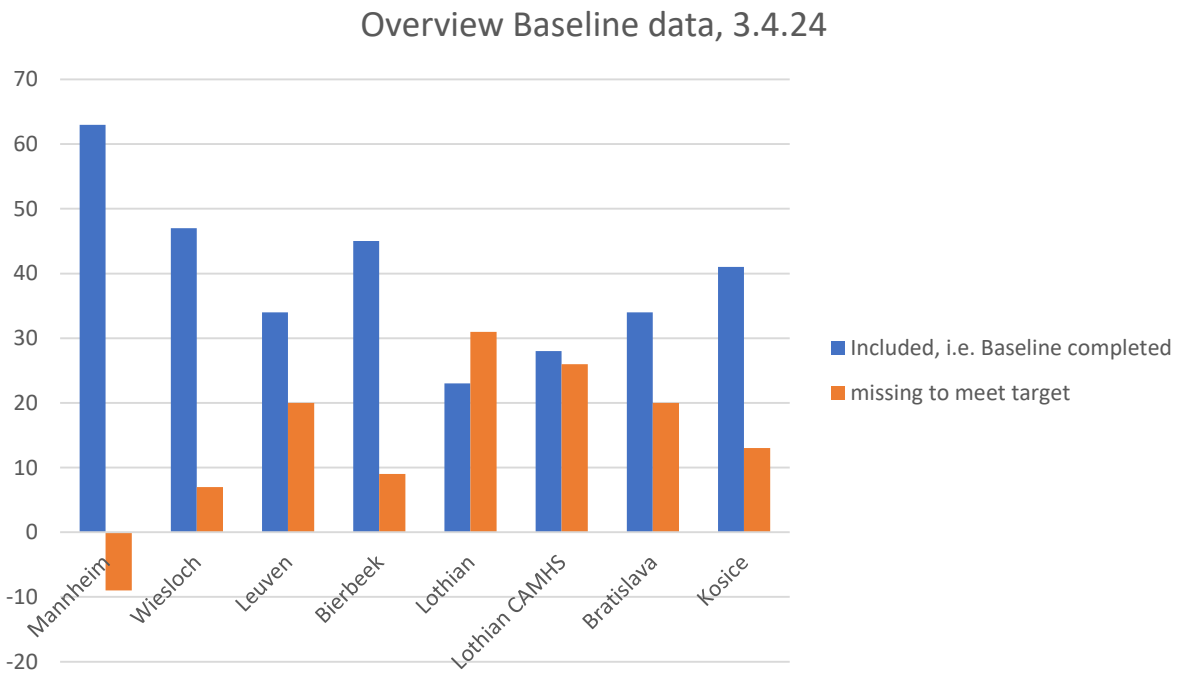
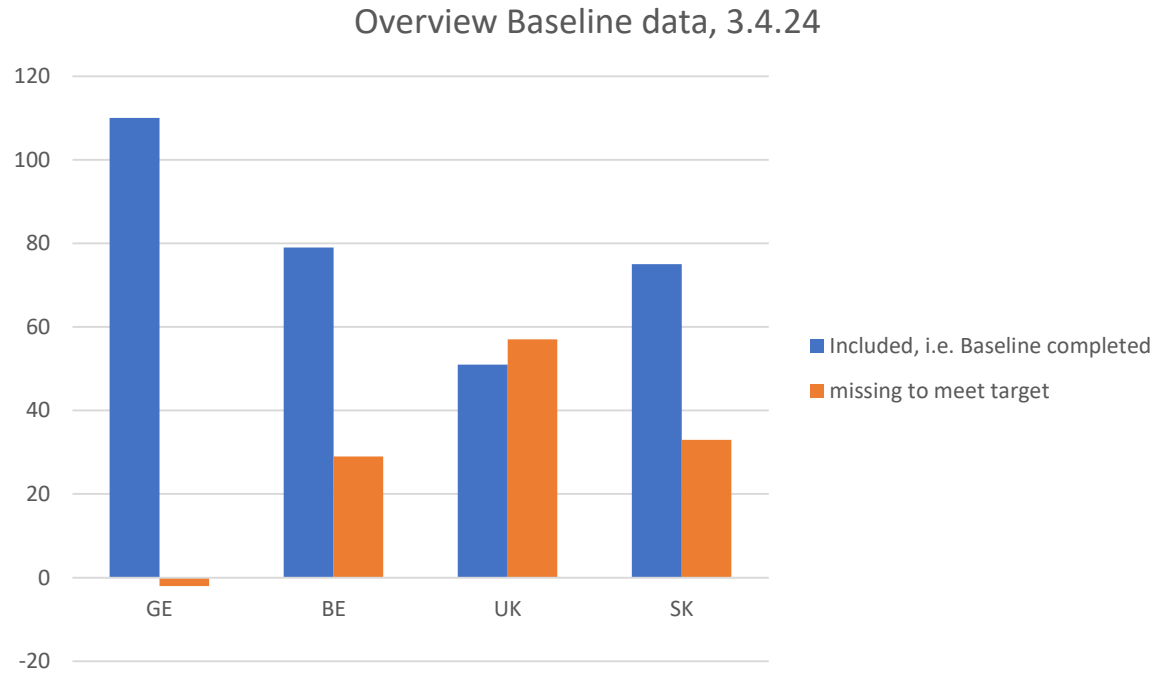
Recruitment numbers

Outstanding data per site:



Outstanding data per country:



Milestone: 50% of sample recruited

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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
- termination of recruitment by June 2024 decided by IMMERSE Steering Committee
- now need to consult with TSC and DMEC
- 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)
- CAPA to mitigate risks (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
  - 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 analysis is completed, recruitment will have ended

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Feasibility vs. implementation aspects

- planned as high-quality, a priori hybrid effectiveness-implementation trial
- 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?)
  - reach of recruitment targets, conversion rates 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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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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Reach, Adoption, Implementation, Maintenance: requires exposure in experimental condition

Table 1. *Reach* of service users (service user participation)

	Recruitment/ number of service users consented in experimental condition	Interest in using the DMMH	Actual participation after consent/baseline	Number of participants dropping out from the DMMH during the intervention period	Usage of/ compliance with the DMMH	Acceptability*
Strategies for ensuring *Reach* need further optimization	Less than 288 participants recruited (less than 100% of target sample size in clinical units of experimental condition) over the study period	Less than 75 % of individuals approached agree to participate / use DMMH	Less than 75% of participants initiate usage of DMMH after written consent obtained and baseline completed	A drop-out rate of more than 30% over the 2-months period for focused delivery of the DMMH (at t_1).	Poor DMMH usage/compliance (<60% of participants participating in at least four weeks of DMMH during the 2-months period for focused delivery of the DMMH)	Low satisfaction with the DMMH (MoMent app and/or dashboard) in the debriefing questionnaire (i.e., mean satisfaction rating <3 on a 7-point scale) at t_1 **and** limited willingness to recommend the DMMH to others (service users / clinicians), i.e. rating <3 on a 7-point scale
Reach established	Successful recruitment of at least 288 participants recruited (i.e. 100% of target sample in clinical units of experimental condition) over the study period	≥75 % of individuals approached about DMMH agreed to participate	≥75% of participants initiate usage of DMMH after written consent obtained and baseline completed	A drop-out rate of ≤30% over the 2-months period for focused delivery of the DMMH.	Poor usage/compliance (≥60% of participants participating in at least four weeks of DMMH during the 2-months period for focused delivery of the DMMH)	Moderate to strong satisfaction with the DMMH (MoMent app and/or dashboard) in the debriefing questionnaire (i.e., mean satisfaction rating ≥3 on a 7-point scale) at t_1 **or** willingness to recommend the DMMH to others (service users / clinicians), i.e. rating ≥3 on a 7-point scale

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Table 2. Adoption and implementation of the DMMH in routine clinical care settings

Adoption | **Implementation**

	Adoption by service users	Adoption by clinicians	Implementation fidelity	Intervention fidelity	Health care practice
Strategies for adoption and implementation need further optimization	Less than 70% of service users in the experimental condition having used the MoMent app at least once per week in at least 4 weeks over the 2-months period for focused delivery of the DMMH as indicated by MoMent app usage data	Less than 70% of participating clinicians (trained in the DMMH) in the experimental condition having used the dashboard at least once per week in at least 4 weeks over the 2-months period for focused delivery of the DMMH (based on dashboard log-in data)	No use of any implementation strategy (multiple choice item) by clinicians or service users at 2-months or 6-months post-baseline	Limited usage of MoMent app (i.e., less than 70% of service users having completed ≥30% of DMMH assessments in the MoMent app in at least 4 weeks over the 2-months period for focused delivery of the DMMH) Delivery of the DMMH not as intended (i.e., mean rating > 3 for difficulty using the MoMent dashboard) and MoMent App use not as intended (i.e., mean rating >3 for difficulty using the MoMent app). No/sow progress (<3) toward therapy goal rated by service user at 2-months or 6-months post-baseline	On average, <4 clinical decisions based on DMMH over 2-months period for focused delivery of the DMMH (at t_1); No shared decision made based on the DMMH data over 2-months period for focused delivery of DMMH (at t_1); No changes in healthcare practice made over 2-months period for focused delivery of DMMH (at t_1); High burden in the fidelity questionnaire of patients (i.e., mean rating on the items on time>3 on a 7-point scale) High burden in the fidelity questionnaire of clinicians (i.e., mean rating on time >3 on a 7-point scale)

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Table 3. Maintenance of the DMMH in routine clinical care settings

	Intended maintenance	**Actual/intended maintenance between t_1 and t_2**	**Actual/intended maintenance at t_3**
Strategies for ensuring maintenance need further optimization	Low intended use of the MoMent app or dashboard (mean rating <3 on a 7-point scale) by service users or clinicians at 2-months post-baseline **(fidelity questionnaire)**	No use of MoMent app (on average, <1 week for focused DMMH assessment) by service users at 6-months post-baseline; No use of MoMent dashboard (on average, <1 log-in) by clinicians with any service user **(based on dashboard log-in data)** at 6-month post-baseline; Intended use of the MoMent app or dashboard rated, on average, <3 on a 7-point scale by service users at 6-month post-baseline **(fidelity questionnaire)**; Low willingness by service users (mean rating<3) to continue using the MoMent app with other clinicians; Low intended continuation of DMMH usage by clinicians (mean rating<3) at 6-months post baseline	No use of MoMent app (on average, <1 week for focused DMMH assessment) by service users between 6-months and 12-months post-baseline; No use of MoMent dashboard (on average, <1 log-in) by clinicians with any service user **(based on dashboard log-in data)** between 6-months and 12-months post-baseline; Low willingness by service users (mean rating <3) to continue using the MoMent app at 12-month spost-baseline **(fidelity questionnaire)**;Low willingness of clinicians (<3) to continue using the dashboard at 12-month post-baseline **(fidelity questionnaire)**
Maintenance established	Moderate to strong intended use of the Moment app or dashboard (mean rating ≥3 on a 7-point scale) by service users or clinicians at 2-months post baseline **(fidelity questionnaire)**	Any use of MoMent app (on average, ≥1 week for focused DMMH assessment) by service users at 6-months post-baseline; Any use of MoMent dashboard (on average, ≥1 log-in) by clinicians with any service user **(based on dashboard log-in data)** at 6-months post-baseline; Intended use of the Moment app rated, on average, 3 or higher on a 7-point scale by	Any use of MoMent app (on average, ≥1 week for focused DMMH assessment) by service users at 12-months post-baseline; Any use of MoMent dashboard (on average, ≥1 log-in) by clinicians with any service user **(based on dashboard log-in data)** at 12-months post-baseline; Moderate to strong willingness by service users (mean rating≥3) to continue using the

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Reach, Adoption, Implementation, Maintenance: requires exposure in experimental condition

1. Establish, in a pragmatic cRCT of the DMMH and other implementation strategies to support its use in service users and clinicians in routine care settings, **i) R**each (i.e., service user participation), **ii) E**ffectiveness (defined as the interaction of efficacy and implementation in real-world settings), operationalized as greater service user engagement at 2-month post-baseline in the experimental than control condition as primary outcome, **iii) A**doption (i.e., proportion of service users and clinicians having used DMMH components in routine care), **iv) I**mplementation (defined as delivery of the DMMH as intended in routine care) and **v) M**aintenance (defined as the extent to which the DMMH becomes sustainable part of routine care at 6-month and 12-month post-baseline). Consistent with the **RE-AIM** framework (Glasgow *et al.*, 1999), this will provide the basis for assessing the public health impact of implementation and scale-up of ESM-based monitoring, reporting and feedback via the DMMH and other implementation strategies. The primary hypothesis will be that, compared with the control condition (i.e., Treatment-As-Usual (TAU)), patient-reported service engagement, assessed with the total score of the Service Attachment Questionnaire (SAQ) at 2-month post-baseline (primary outcome), will be higher in the experimental condition (DMMH + additional implementation strategies + TAU), while controlling for service user engagement and clinical unit at baseline (please see our preregistration published

Discussion

- the question that remains: how can we achieve a final push in recruitment and assessment?
- focus(!):
  - 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%**)
- What strategies can we use in each site to facilitate this focus?
- Discuss in cross-site groups

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