WP7
Implementation Strategies, Processes, Outcomes and Costs
- Available data and code -

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

WP7 - Objectives

Phase 1

Phase 2

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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Phase1: study design

Participatory field study using **a) a questionnaire** and **b) qualitative interviews** in:

- Service users
- Clinicians
- Support network members
- Administrators

Data has been collected in all 4 countries.

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1) Survey data

Type	Participant	Source	Number of forms per time point
		Outcomes	
Self-report	Service users	Redcap (2 instances UMM, KULeuven)	8
Self-report	Support network	Redcap (2 instances UMM, KULeuven)	6
Self-report	Clinicians	Redcap (2 instances UMM, KULeuven)	8
Self-report	Admins	Redcap (2 instances UMM, KULeuven)	8

Example

Data Collection Instrument	Baseline (1)
ID (survey)	⬇
languages (survey)	⬇
Demographics (survey)	⬇
Technology Use (survey)	⬇
Privacy (survey)	⬇
Patient Specific Questions (survey)	⬇
PAM-MH (survey)	⬇
Shared Decision Making Patient (survey)	⬇
Shared Decision Making Clinician (survey)	
Clinician Specific Questions (survey)	
Supporter Specific Demographics (survey)	
Admin Specific Demographics (survey)	
ORCA (survey)	
PSS-I (survey)	⬇
Usability Self Tracking (survey)	⬇
Usability EHR (survey)	
Implementation Patient (survey)	✔
Implementation Supporter (survey)	
Implementation Clinician (survey)	
Implementation Admin (survey)	

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2) Interview data

Type	Participant	Source	Number of forms per time point	Example
		Outcomes		
Qualitative Interview	Service users	Codes according to common code book	-	
Qualitative Interview	Support network	Codes according to common code book	-	
Qualitative Interview	Clinicians	Codes according to common code book	-	
Qualitative Interview	Admins	Codes according to common code book	-	

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Phase 1 Overview

NASSS Domain	Questionnaire	Interview
Condition / illness	self-report; stress level (PSS-4); memory questionnaire (PRMQ); patient activation scale; clinician caseload	self report (case load / diagnosis / symptoms)
Technology	technology use and attitudes scales, SUS	experience with technology, sample task with DMMH
Value Proposition	special item; SDM-Q-9	sample task follow up
Adopter System	stakeholder-specific adaptation of questionnaire	as questionnaire
Organisation	ORCA - context component; experience with implementation	Interview prompts / vignettes
Institutional and Social Context	demographics; barriers / facilitators based on past experience; Privacy Concern	as questionnaire; vignettes
Interaction over time	not covered	prompts about history / past experience / developments

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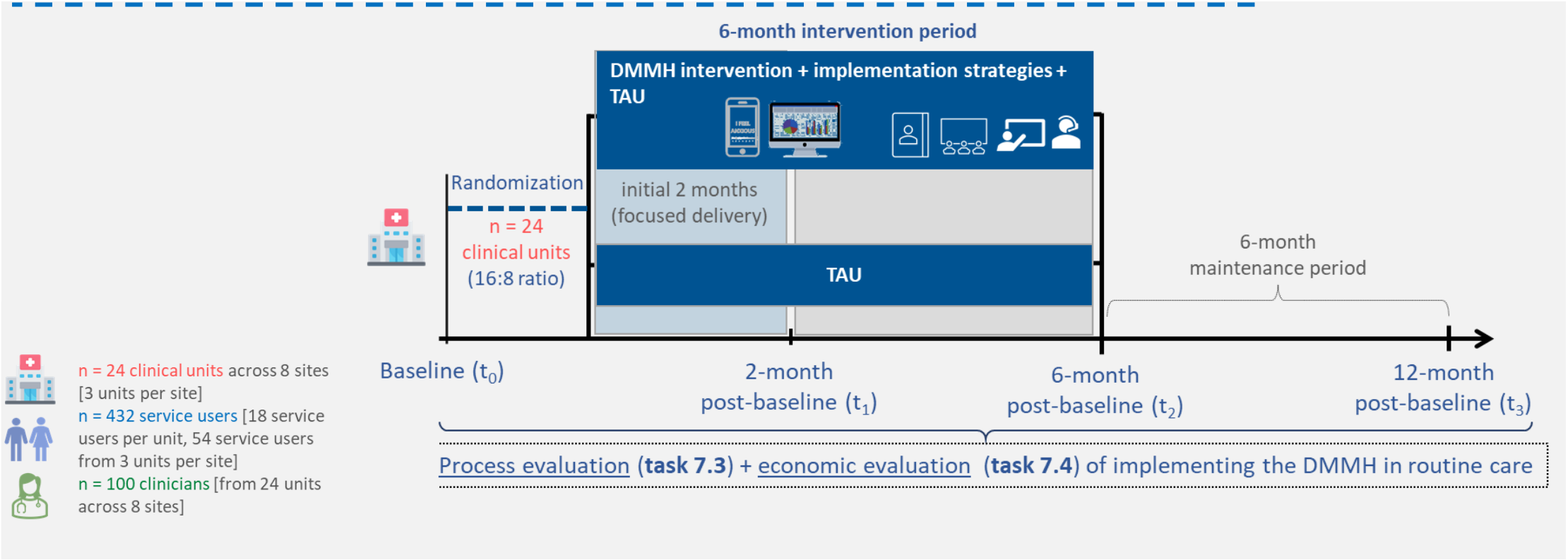
Trial design

Pragmatic, multi-centre, parallel-group cluster Randomized Controlled Trial (cRCT)



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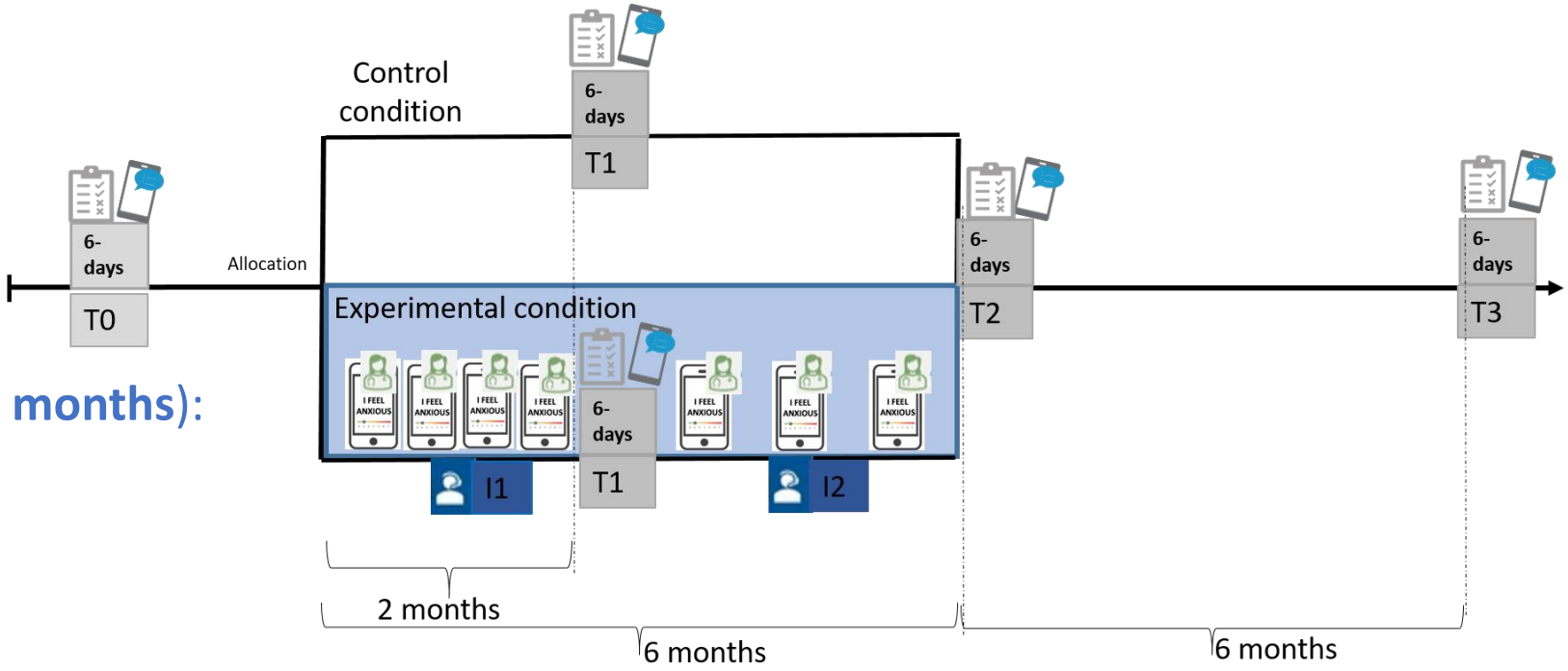
Trial design and data sources

eCRF (MaganaMed) to collect outcome data

MovisensXS in 50% of all participants to collect process Experience Sampling (ESM) data

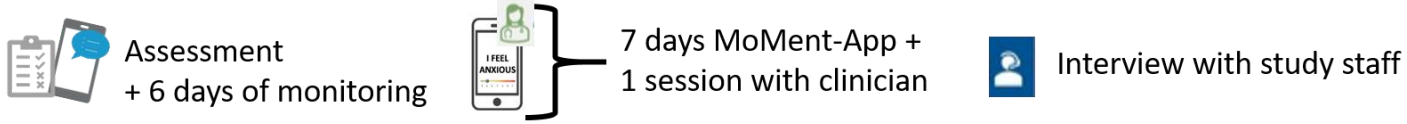


Experimental condition only (for max. **12 months**):

- TherapyDesigner to collect process data of the MoMent app + dashboard
- MovisensXS to collect fidelity data
- MovisensXS to collect mobile sensing data

Process evaluation interviews

Legend:



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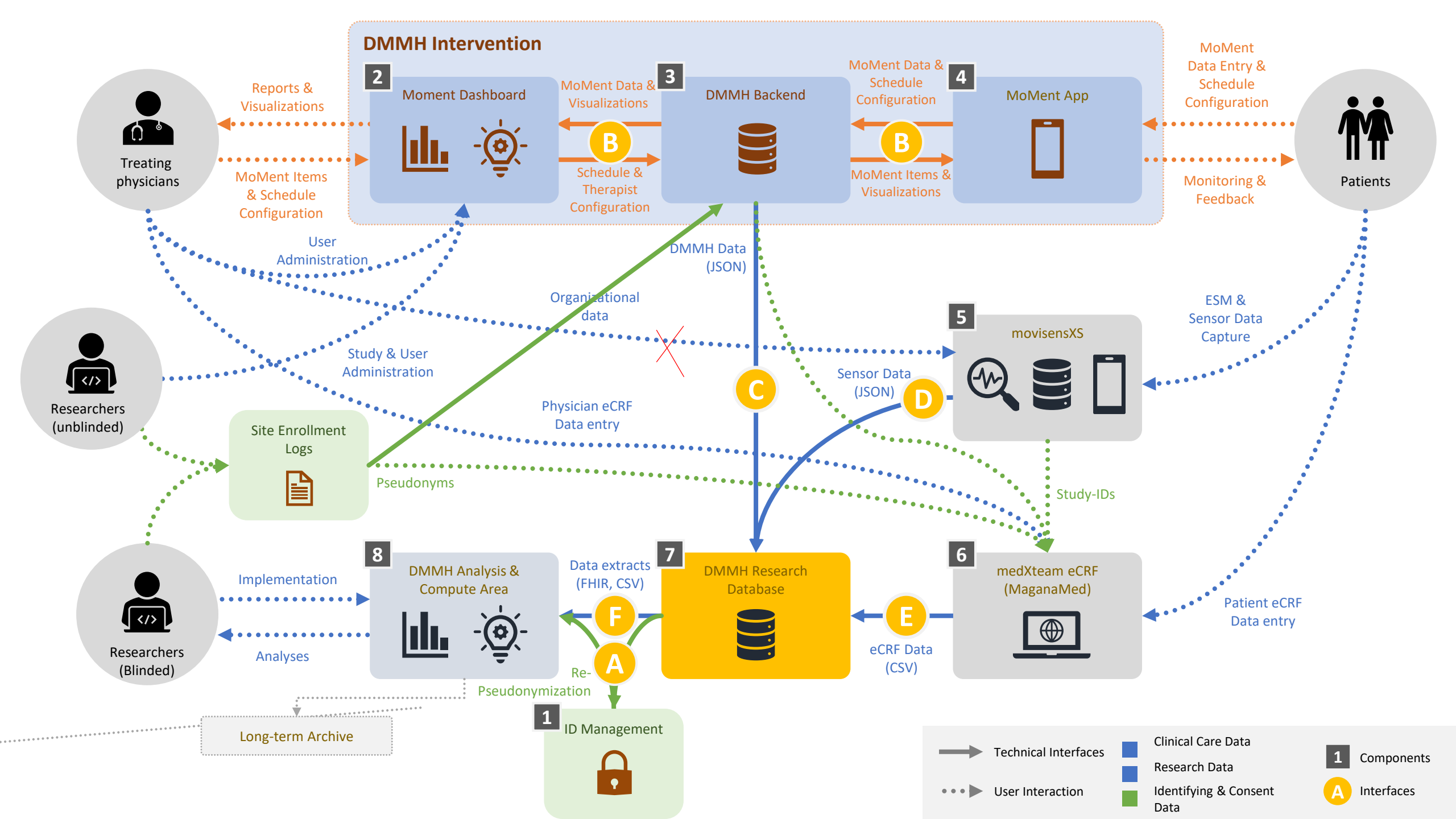
DMMH Intervention
2
Moment Dashboard
3
DMMH Backend
4
MoMent App
Reports & Visualizations
MoMent Items & Schedule Configuration
MoMent Data & Visualizations
Schedule & Therapist Configuration
MoMent Data & Schedule Configuration
MoMent Items & Visualizations
MoMent Data Entry & Schedule Configuration
Monitoring & Feedback
Treating physicians
Patients
User Administration
Organizational data
DMMH Data (JSON)
Study & User Administration
5
movisensXS
ESM & Sensor Data Capture
Researchers (unblinded)
Site Enrollment Logs
Physician eCRF Data entry
Sensor Data (JSON)
Pseudonyms
Study-IDs
Researchers (Blinded)
8
DMMH Analysis & Compute Area
Implementation
Analyses
Data extracts (FHIR, CSV)
7
DMMH Research Database
6
medXteam eCRF (MaganaMed)
eCRF Data (CSV)
Patient eCRF Data entry
Re-Pseudonymization
1
ID Management
Long-term Archive
Technical Interfaces
User Interaction
Clinical Care Data
Research Data
Identifying & Consent Data
Components
Interfaces

1) Outcome data

Type	Source	Number of forms per time point	Time points	Example
		Outcomes		
Patient self-report 	eCRF (1 MaganaMed data base for all countries)	19 Optional measures: 3	t0, t1, t2, t3	1 Primary outcome (Service Attachement Questionnaire) and secondary outcomes
Clinian-reported questionnaires 	eCRF (1 MaganaMed data base for all countries)	7	t0, t1, t2, t3	Secondary outcomes (e.g. Service Engagement Questionnaire)
Researcher ratings 	eCRF (1 MaganaMed data base for all countries)	2	t0, t1, t2, t3	e.g. Adverse events

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1) Outcome data: for economic evaluation

Type	Source	Number of forms per time point	Time points	Example
Outcomes				
Patient self-report 	eCRF (1 MaganaMed data base for all countries)	3	t0, t1, t2, t3	CSRI, EQ5D5L, SAQ

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2) ESM

- 50% of participants are randomly allocated (1:1) to participating in a 6-day ESM phase.
- As movisensXS runs on Android only, study smartphones will be provided in case it is necessary

Type	Source	Number of forms per time point	Time points	Example
		Outcomes		
Patient self-report 	MovisensXS studies: **7 „studies“** per time point (T0_GE, T0_BE, T0_UK, T0_SK, T0_SK_female, T0_Kosice, T0_Kosice_femal)	6-day ESM with 8 prompts per day <u>Measures:</u> Positive affect, negative affect, location, activity context, social context, social appraisal, quality of life	t0, t1, t2, t3	Secondary outcomes (Momentary quality of life, social functioning) Statistical analysis plan:

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3) TherapyDesigner data

- 66% of units are allocated to the experimental condition (2:1) and have *patients* that can use the MoMent app running via the app TherapyDesigner on Android and iOS.

Type	Source	Number of forms per time point	Time points	Example
		Process data		
Usage data (app usage by *patients* in experimental condition)	Therapydesigner	Based on ESM-principles with 8 prompts per day (i.e. 8 „interactions“): 30 items: a) Core items (20) b) Additional items (10)	Between t0 and t3 (i.e. for at least 4 weeks within the first 8 weeks, but then until end of study participation)	<u>e.g., core measures:</u> Positive affect, negative affect, location, activity context, social context, social appraisal, <u>e.g. additional:</u> therapy goals, main complaints, medication…

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3) TherapyDesigner data

- 66% of units are allocated to the experimental condition and their *clinicians* can use the TherapyDesigner dashboard.

Type	Source	Number of forms per time point	Time points	Example
Process data				
Usage data (Dashboard usage by *clinicians* in experimental condition)	Therapydesigner	Passive data: Configuration of items, display of visualisations	Between t0 and t3 (i.e. for at least 4 weeks within the first 8 weeks, but then until end of study participation)	Log-in information, duration of log-in

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4) Fidelity data

- We collect fidelity of using the TherapyDesginer in patients and clinicans allocated to the experimental condition

Type	Source	Number of forms per time point	Time points	Example
Fidelity data				
Patient self-report	MovisensXS	1	t1, t2, t3	Satisfaction with the app
Clinician self-report	MovisensXS	1	t1, t2, t3	Satisfaction with the dashboard

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5) Mobile sensing data

- In patients with a) in the experimental condition, b) with Android smartphone, and c) who agreed to it, we collect mobile sensing data over the course of the intervention period.

Type	Source	Number of forms per time point	Time points	Example
Mobile sensing data				
Passive data	MovisensXS	1	Between t0 and t3 (i.e. for at least 4 weeks within the first 8 weeks, but then until end of study participation)	Battery, screen on/off, Steps, movement, GPS, usage of TherapyDesigner App

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6) Process evaluation data

- Interviews are conducted with patients, clinicians and team leads per site
- Questionnaire is developped (and used?)

Type	Source	Number of forms per time point	Time points	Example
Process evaluation data				
Interview with patients	Codes of transcribed interviews	-	t1 or later	
Interview with clinicians	Codes of transcribed interviews	-	t1 or later	
Interview with team leads	Codes of transcribed interviews	-	t1 or later	
Self-report?	?	Questionnaire to be developped	-	-

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Trial design and data sources

eCRF (MaganaMed) to collect outcome data	✗ Access after „Last patient, last assessment“
MovisensXS in 50% of all participants to collect Experience Sampling (ESM) data	✗ Access after „Last patient, last assessment“

Experimental condition only (for max. **12 months**):

• TherapyDesigner to collect process data of the MoMent app + dashboard	✓ Access available
• MovisensXS to collect fidelity data	✗ Access after „Last patient, last assessment“
• MovisensXS to collect mobile sensing data	✓ Access available
Process evaluation interviews	✓ Access available

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Statistical Analysis Plan

- Preregistration with OSF

  Available at: https://osf.io/egpys

- Study protocol has been submitted to Implementation Science (08.02.2024)

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Discussion and questions?

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Thank you for your attention

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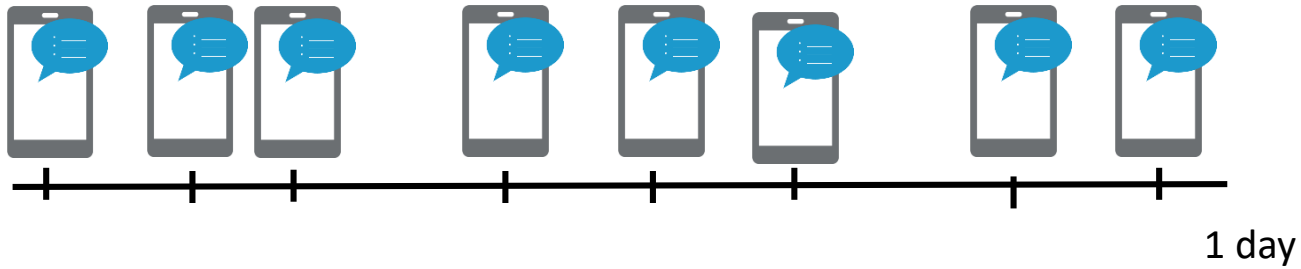
Data quality/ availability: ESM

- 50% of participants are randomly allocated (1:1) to participating in a **6-day ESM phase**:
  - Target sample: n=216
  - Allocated to ESM (by 8.4.24): n=150 (69% of target)



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Data quality/ availability: ESM

- Allocation to ESM or NoESM per site at Baseline:

Site	ESM	NoESM	Refused (%)
Bierbeek	20	23	1 (2%)
Leuven	8	16	0
Bratislava	11	17	6 (17%)
Kosice	20	23	5 (10%)
Lothian+CAMSH	33	32	0
Mannheim	31	32	0
Wiesloch	27	27	0
total	150	170	12 (4%)

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Data quality/ availability: ESM

- Coupled with movisensXS per site at Baseline:

Site	ESM coupled	allocated	Refused (%)
BI/LE	27	28	
Bratislava	11	11	
Kosice	19	20	
Lothian+CAMSH	22	33	
MA/WI	54	58	
total	135	150	15 (10%)

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Data quality: ESM

- Compliance with ESM per site at Baseline:

Novel digital methods for gathering intensive time series data in mental health research: scoping review of a rapidly evolving field

Anita Schick[1], Christian Rauschenberg[1], Leonie Ader[1], Maud Daemen[2], Lena M. Wieland[1], Isabell Paetzold[1], Mary Rose Postma[2], Julia C. C. Schulte-Strathaus[1] and Ulrich Reininghaus[1,3,4]

The majority of studies reported satisfactory compliance rates ranging from 52% to 98% of scheduled assessments. One third of publications reviewed did not report on compliance at all.

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Data quality: ESM

- Compliance with ESM per site at Baseline:

Site	Compliance
BI/LE	
Bratislava	
Kosice	
Lothian+CAMSH	
MA/WI	58%
total	

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RE-AIM table

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

Note: * Based on Reininghaus et al., 2022

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RE-AIM table

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	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.,

				service user at 2-months or 6-months post-baseline	mean rating on time >3 on a 7-point scale)
Adoption / implementation established	≥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	≥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**)	Use of **at least one** implementation strategy, on average, by clinicians or service users at 2-months post-baseline and/or 6-months post-baseline	Moderate to strong usage of MoMent app (i.e., ≥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 as intended (i.e., mean rating ≤ 3 for difficulty using the MoMent dashboard) and MoMent App use as intended (i.e., mean rating ≤3 for difficulty using the MoMent app). Moderate to strong progress (mean rating>3) toward treatment goal rated by patients at 2-months post-baseline and/or 6 months post-baseline	On average, ≥4 clinical decisions per service user made based on DMMH over 2-months period for focused delivery of the DMMH (at t_1); At least 1 shared decision made based on DMMH (i.e., >1 per clinician per service user) over 2-months period for focused delivery of the DMMH (at t_1); At least 1 change in healthcare practice made over 2-months period for focused delivery of DMMH (at t_1); Moderate burden (difficulty and time required for MoMent app/dashboard) assessed with the fidelity questionnaire for service users and clinicians (i.e., mean burden rating ≤ 3 on a 7-point scale)

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RE-AIM table

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 service users at 6-months post-baseline **(fidelity questionnaire)**;	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 MoMent at 12-months post-baseline **(fidelity questionnaire)**;

RE-AIM table

Moderate to strong willingness by service users **(mean rating≥3) to continue using the** MoMent **app with other clinicians at** 6-months post-baseline;	Moderate to strong willingness of clinicians (mean rating≥3) to continue using the dashboard at 12-months post-baseline **(fidelity questionnaire)**
Moderate to strong intended continuation of DMMH by clinicians (≥3) at 6-months post baseline	

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