

WP7

Implementation strategies, processes, outcomes, and costs

Ulrich Reininghaus, Anita Schick

Department of Public Mental Health, CIMH

Michel Wensing

*Department of General Medicine and Health Services Research,
UKHD*

Live Steering Committee meeting Edinburgh, 16/11/23



Work package 7: Overview

- Update on recruitment and assessment
- Participant flow and retention
- Strategies for improving recruitment and retention (each site)
- Discussion



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

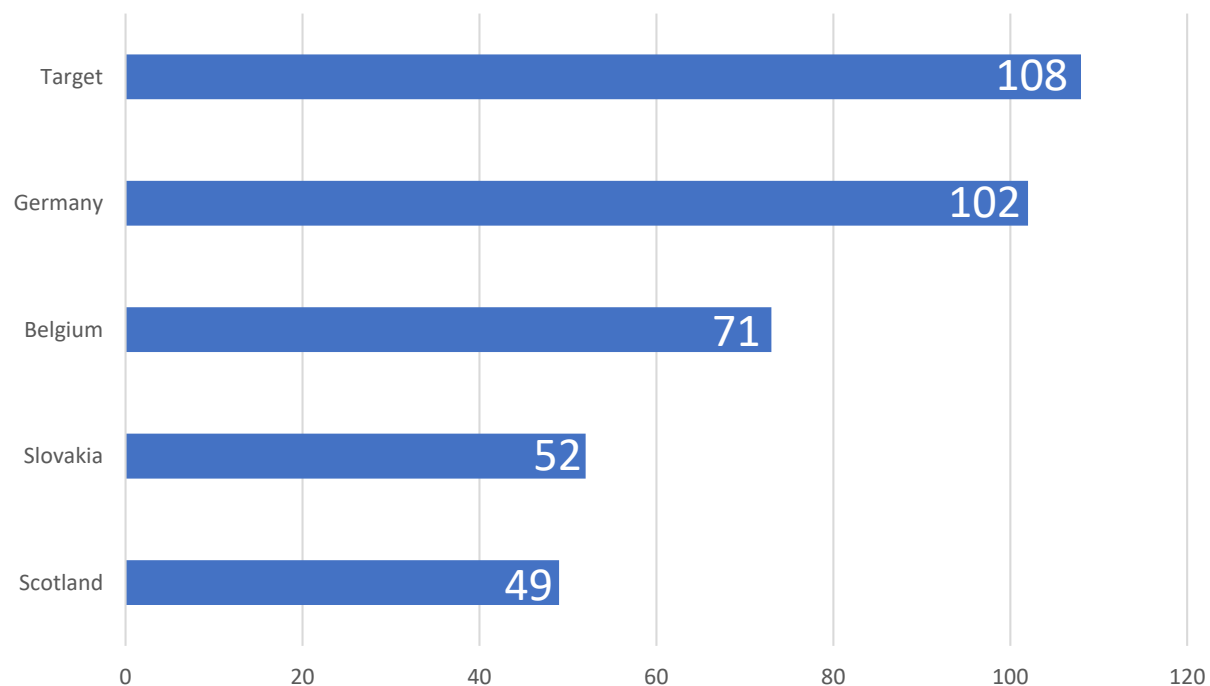


Recruitment status (13.11.23)



Overall n (% target sample size, n=432) to date: n=243 included (56%), n=276 screened (i.e. 64%)

Recruitment numbers, 13.11.23



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



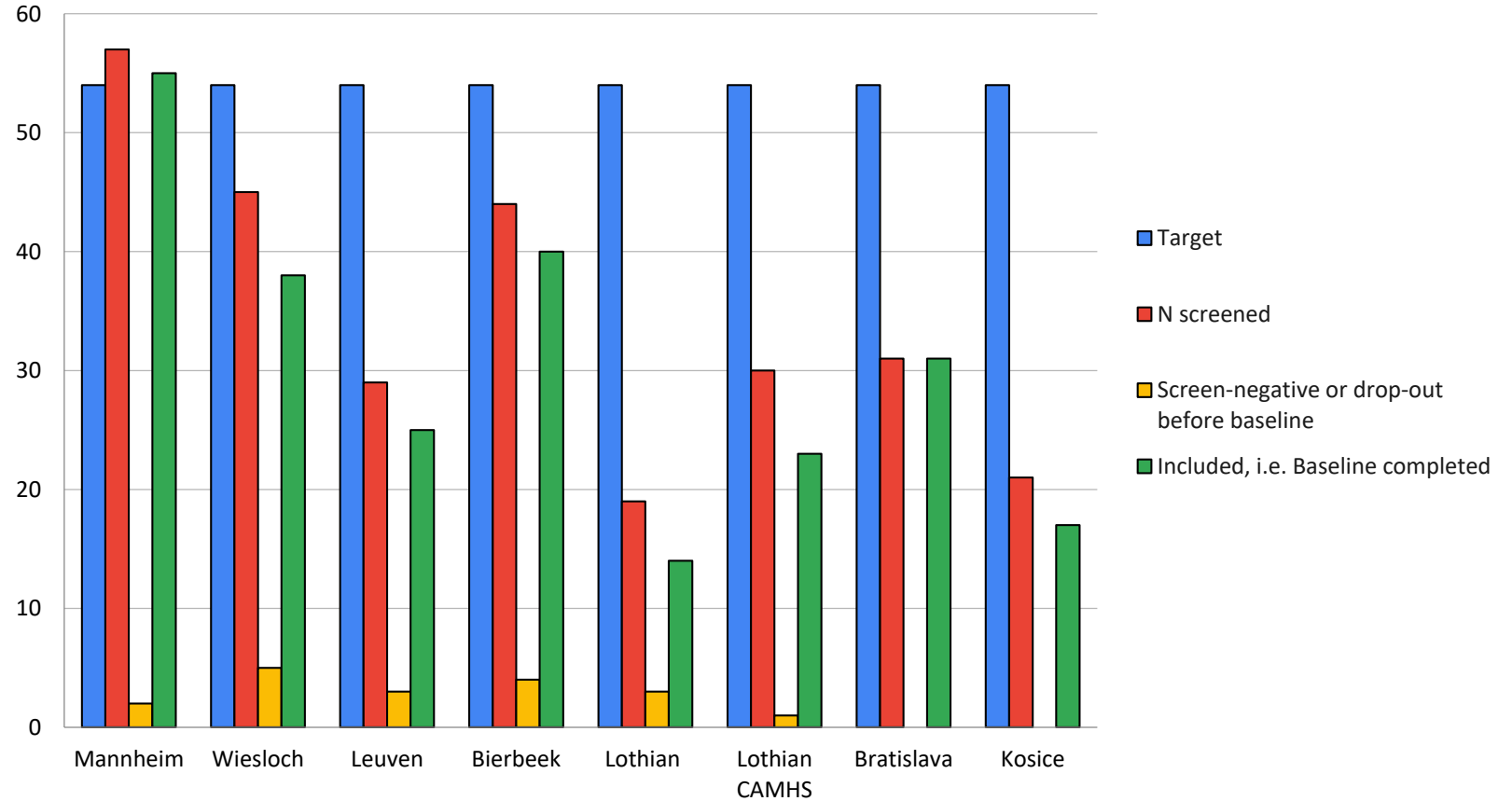
Recruitment status (13.11.23)



Recruitment numbers in all sites (13.11.23)

Patients	Target	N screened	Included, i.e. Baseline completed
Mannheim	54	57	55
Wiesloch	54	45	38
Leuven	54	29	25
Bierbeek	54	44	40
Lothian	54	19	14
Lothian CAMHS	54	30	23
Bratislava	54	31	31
Kosice	54	21	17
Total	432	276	243

56% of the target



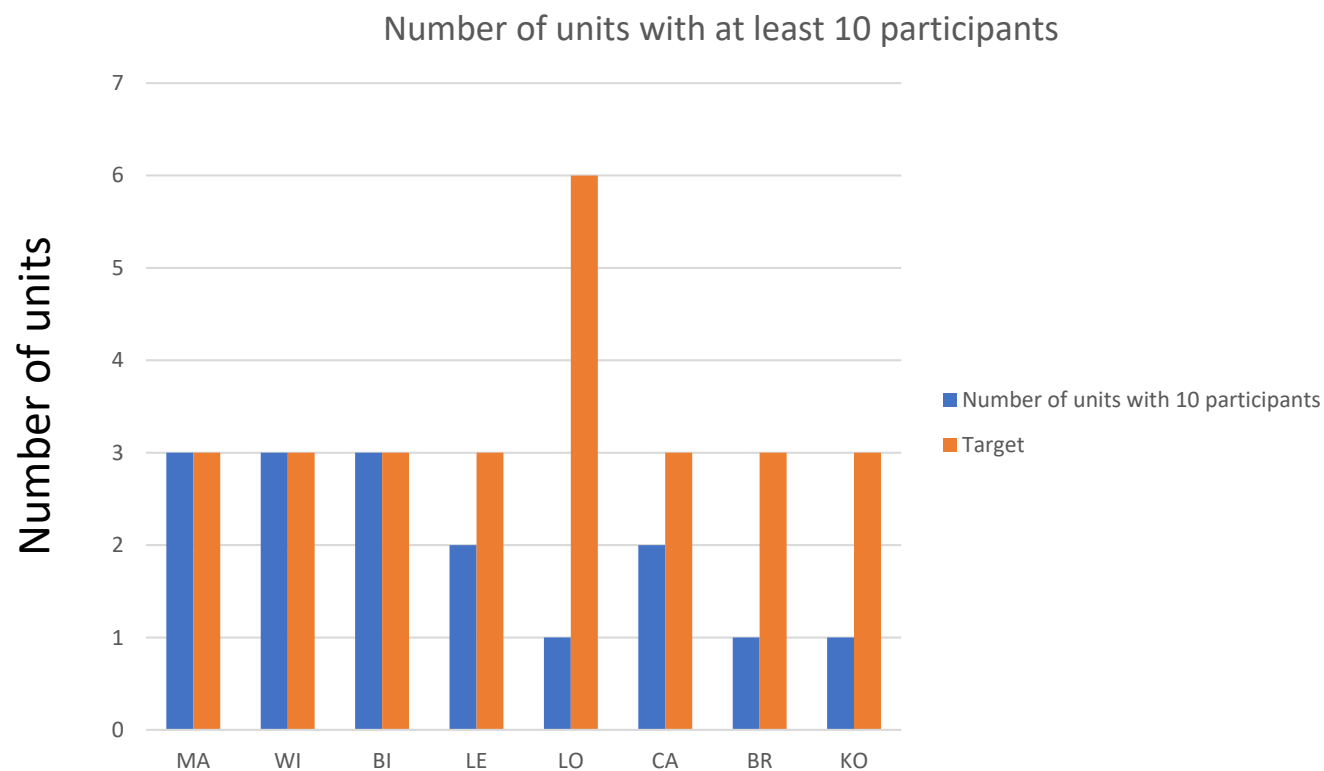
This project has received funding from the European Union's Horizon 2020 research and innovation Programme under grant agreement 945263 (IMMERSE)



Recruitment status (13.11.23)



Required sample size per unit:



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



Monthly recruitment

- CIP: recruitment of 3 participants per unit per month, i.e. 9 participants/month per site
- THE ACTUAL recruitment since August 2023:

	actual n recruited in Aug/Sept/Oct/Nov	Mean recruitment over last 3 months	Target per month to finish till 12/23	Target per month to finish until 04/24
Mannheim	11	2,75		
Wiesloch	5	1,25	4	2
CAMHS	10	2,5	11	5
Bratislava	5	1,25	9	5
Lothian	9	2,25	15	7
Kosice	8	2	14	7
Bierbeek	4	1	5	2
Leuven	1	0,33	9	4

Sounds high, but:
n=1-2 per week across 3-6 units

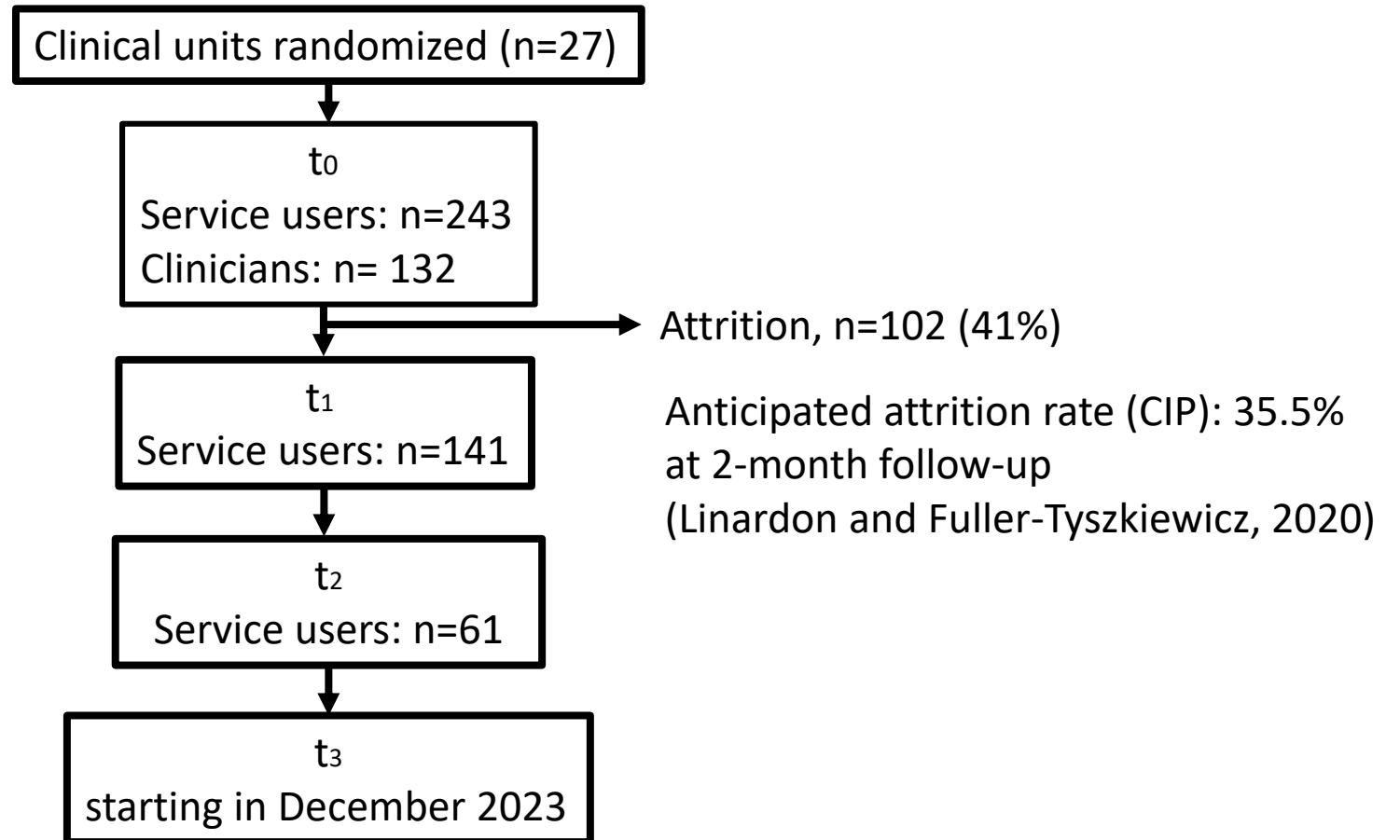


Summary: recruitment

- Focus on recruitment of units with <10 participants: LO, CA, KO, BR, LE
- Continue with recruitment at all sites until at least March 2024
- NB: n=432 is the target sample size for primary outcome (service user engagement) at t_1



Participant flow



Participant flow

Retention at the sites

	t1 due	t1 retention rate
Mannheim	46	89.1
Wiesloch	35	54.3
Leuven	29	44.8 ←
Bierbeek	39	76.9
Lothian	10	80.0
Lothian CAMHS	20	40.0 ←
Bratislava	24	91.7
Kosice	11	0 ←

- retention rate not corrected for t1 data that is still to be collected
- completion of Redcap for tracking recruitment and retention continues to be an issue (even though we need to ensure sponsor oversight according to MDR 2017/745)



Update: process evaluation (Germany, Belgium)

Category	Stakeholder Group	Target	Leuven	Bierbeek	BE To Do	Mannheim	Wiesloch	GE To Do
Number of Interviews conducted	P - Service User	10	0	1	9	2	0	8
	C - Clinicians	10	0	0	10	8	3	-1
	A - Administrators	10	0	0	10	4	4	2
Number of interviews transcribed	P - Service Users		0	0	10	0	0	10
	C - Clinicians		0	0	10	0	0	10
	A - Administrators		0	0	10	1	2	7
Number of transcripts coded with top/down codebook in Nvivo	P - Service Users		0	0	10	0	0	10
	C - Clinicians		0	0	10	0	0	10
	A - Administrators		0	0	10	0	0	10
	sum to be coded		0		30	0	0	30

Process evaluation (Scotland, Slovakia)

Category	Stakeholder Group	Lothian CAMHS	Lothian	UK To Do	Bratislava	Kosice	SK To Do	Sum
Number of Interviews conducted	P - Service User	2	0	8	4	0	6	6
	C - Clinicians	0	1	9	3	0	10	15
	A - Administrator	0	0	10	1	0	10	9
Number of interviews transcribed	P - Service Users	0	0	10	0	0	10	0
	C - Clinicians	0	0	10	0	0	10	0
	A - Administrator	0	0	10	0	0	10	3
Number of transcripts coded with top/down codebook in Nvivo	P - Service Users	0	0	10	0	0	10	0
	C - Clinicians	0	0	10	0	0	10	0
	A - Administrator	0	0	10	0	0	10	0
	sum to be coded		0	30	0	0	30	30

WP7 – Year 3: Upcoming activities

- Statistical Analysis Plan published: <https://doi.org/10.17605/OSF.IO/EGPYS>
- Study protocol: draft completed, needs shortening, circulate for comments
- Complete recruitment: March 2024 (NB: n=432 is the target sample size for primary outcome (service user engagement) at t_1)
- Complete focused delivery (for target n): May 2024
- End of intervention period: Nov. 2024
- Complete process evaluation Nov/Dec 2024
- End of 12-month post-intervention assessment: March 2025
- Analyse data on main outcomes: April 2025
- Draft manuscript on main outcomes: July 2025



WP7 – Tasks and Deliverables



	Task	Deadline
MS 18	Data checking and cleaning for 50% of sample completed	02/24
MS 23	Last patient, last assessment (100% of sample completed)	03/25
MS 20	Data quality checking and cleaning (completed for 100% of the sample)	03/25
	Completion of statistical analysis	03/25
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

WP3 Data
management



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

Discussion



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