

Update WP7



SC 15.09.2022



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

Update WP7



- Trial is (prospectively) registered with ISRCTN registry

<https://doi.org/10.1186/ISRCTN15109760>

- Prototype of the medical device is now available (usability tests completed, verification of the medical device)
- Submission to ethics committees and competent authorities

	22.09.20	05.10.20	12.10.20	2022	09.11.20	19.12.20	26.01.21	03.02.21	02.03.21	22.03.21	10.04.21	22.04.21	17.05.21	02.06.21	22.06.21	07.07.21
Approval in Bratislava		x														
Reply to ethics in Germany (45 days for response, till 23.10.22)					x											
Reply to ethics UK till																
Request from CA in BE (3.10)								x								
Reply to request in BE (23.10)													x			
Final approval in BE (9.11.)																x
Ethics Kosice?																

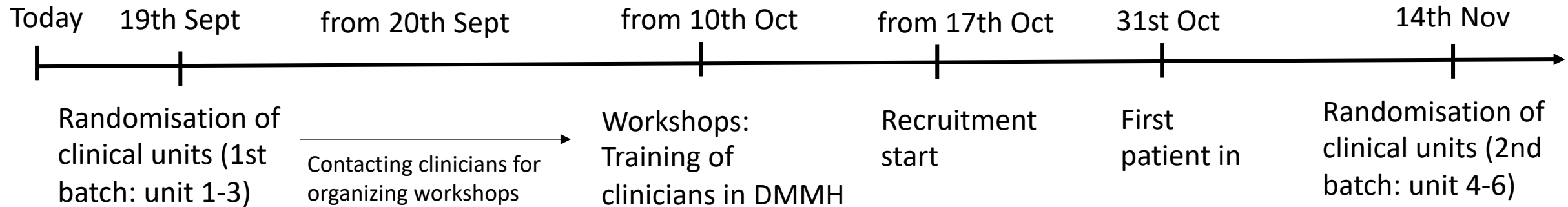
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Ongoing preparation, timeline until recruitment start



IMMERSE



Role out of further implementation strategies (e.g., video clips, manual)



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Next steps (summary)



1. Randomization of clinical units: 19.9.22
2. Meeting with each site to organize the conduct of the trial
3. Finalize all material (eCRF, SOP, training)
4. First workshop: 10th Oct
5. First patient in the trial: 31st October
6. Recruitment until summer 2023 (last patient in)
7. DMMH intervention completed by last participant: autumn 2023



WP7 – Deliverables & Milestones

	Task	Deadline
MS 9	Tailoring and optimization of DMMH intervention and implementation strategies and guidelines for semistructured interviews finalized	16.9.22
D 7.1	Consolidated description of intervention and implementation strategies	16.9.22
MS 10	Preparation of clinical trial completed	16.9.22
D 7.2	Completion of First study subject approval package	16.9.22
MS 11	First patient, first assessment	10/ 22
	216th patient in (50% of full sample)	12/22
D 7.3	Completion of Midterm recruitment report	18.7.23
	First patient last outcome assessment	10/23
MS 17	DMMH usage completed by last patient (sample complete 100%)	12/23



WP7 – Deliverables & Milestones

	Task	Deadline
MS 18	Data checking and cleaning for 50% of sample completed	12/23
MS 23	Last patient, last assessment (100% of sample completed)	06/24
MS 20	Data quality checking and cleaning (completed for 100% of the sample)	08/24
	Completion of statistical analysis	12/24
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

