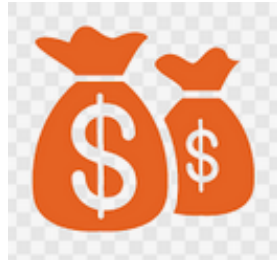# Study protocol and data analysis plan of IMMERSE economic evaluation

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# Economic evaluation of DMMH: Objectives

- To assess the economic costs of **implementing** DMMH intervention in routine mental health care in Europe

- To assess the **cost-effectiveness of DMMH** compared to treatment as usual considering both the intervention costs and changes in care service costs (cost-saving analysis)

- To assess the **utility benefits** of DMMH and its **cost-utility** compared to treatment as usual

Study design and overall approach: trial-based economic evaluation

Multi-center, parallel-group cluster-randomized controlled trial (cRCT)

Experimental condition:

- DMMH intervention
- Implementation support strategy
- Treatment as usual
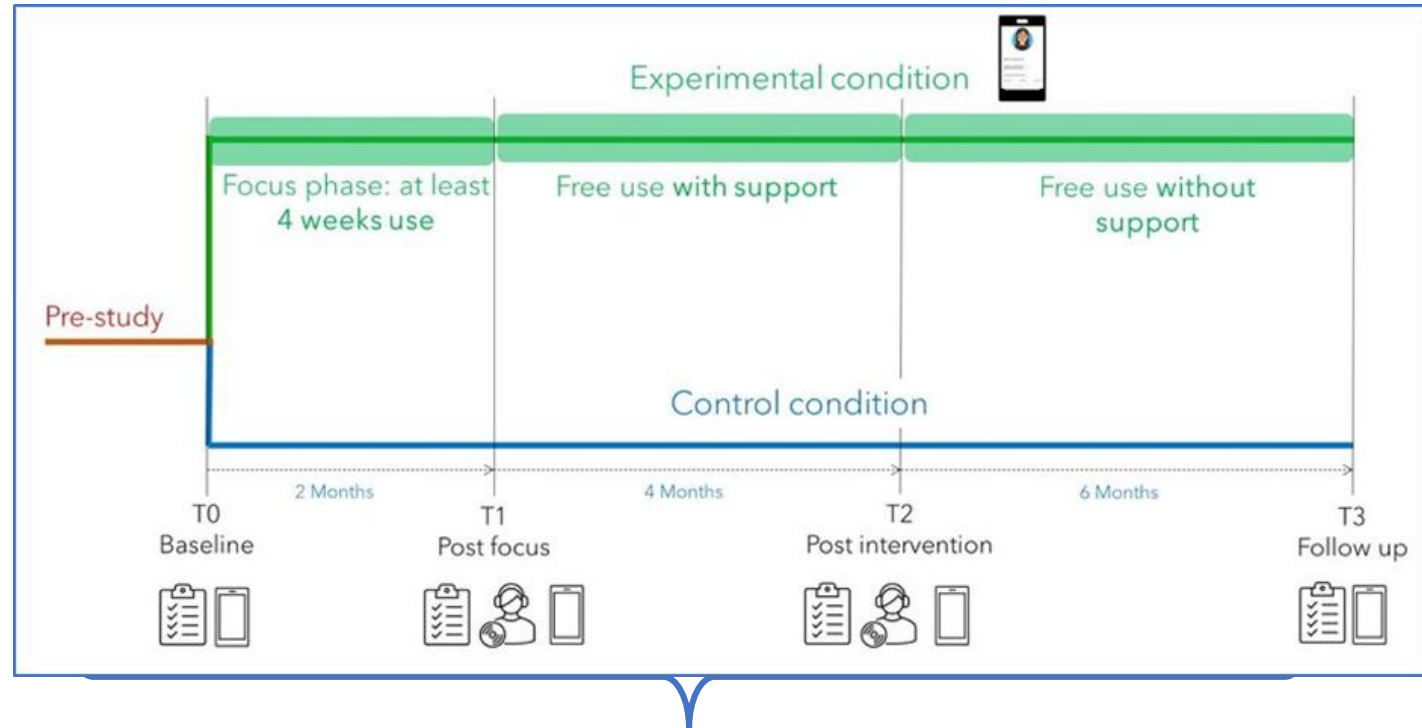
Control condition:

- Treatment as usual per country standard and guideline

- Societal perspective, assessing **costs and effects from Oct 2022 to Dec 2024**
- **Costing implementation of DMMH** in 4 countries, 8 clinical sites, 24 clinical units, 108 service users per country, 432 service users in total
- **Cost-effectiveness and cost-utility analysis of DMMH** compared to treatment as usual

Hypotheses

- Hypothesis 1: Compared with the control condition (TAU), **the economic costs of delivering DMMH in routine mental care will be higher in the experimental conditio**n (DMMH + implementation support strategies + TAU) due to the additional costs of implementing DMMH.

- Hypothesis 2: Compared with the control condition (TAU), **the secondary outcome on patient self-reported quality of life (QALYs)** assessed with the EQ-5D-5L questionnaire at 2-month, 6-month and 12-month post-baseline **will be higher in the experimental condition**, while controlling for the QALY scores and clinical unit at baseline.

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Hypotheses (con.)

Hypothesis 3: Compared with the control condition (TAU), **the economic costs of service use** including health care, social care and informal care at 2-month, 6-month and 12-month post-baseline, **will be lower in the experimental condition**, while controlling for the cost of service use and clinical unit at baseline.

Hypothesis 4: Compared with the control condition (TAU), **the incremental cost effectiveness ratios (ICERs)** per one SAQ unit (the primary outcome) and per one QALY gained in the experimental condition at 2-month, 6-month and 12-month post-baseline, **will be positive**

Activity-based miro-costing study: steps and data sources

Costing steps	Tasks involved	Data sources/data collection tools
1. Identification of resources	- Identify **key activities:** e.g., trainings for clinicians, administration of DMMH, implementation supports - Identify **type of resources** for each activity: e.g. time spent by clinicians, mobile devices	- Trial protocols and project documentations (e.g. training manuals, reports) - Direct observation

2. Measurement of resource uses	- Measure **quantity of resource consumption** for each identified resources
	  - Time of clinicians and project staff
	  - Care service use by patients
		- Multiple data sources and tools
		  - Time recording templates, invoices, financial reports, interviews
		  - CSRI questionnaires

3. **Valuation** of costs	- Collect information **on local unit price** or charge of medications and care services
	- Combine **information on resource use with local unit prices** to compute costs
		- Different sources of unit prices
		  - Invoice, market prices
		  - Salary scales
		  - Open sources and existing publications

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Micro-costing study: statistical analysis

- Deterministic analysis
  - Compute total implementation costs of all sites and per country
  - Compute average implementation cost per patient on the pooled sample and per country

- Sensitivity analysis (SA)
  - Conduct one-way SA on major cost drivers which entail large uncertainty
  - Scenario analysis on different assumption: e.g. inclusion and exclusion of costs of implementation supports

Assessing utility benefits of DMMH

- Data collection tools
  - EQ-5D-5L questionnaire, digital version, self-administration with support of researchers

- Statistical analysis
  - Compute QALYs using the information collected by EQ-5D-5L and country specific value sets or proxy value set
  - Compare QALYs at T1, T2 and T3 versus T0 on the pooled sample and per country
  - Conduct the regression analysis to ascertain the utility benefits in QALYs

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Cost-effectiveness analysis and cost-utility analysis

- **Deterministic analysis**
  - Calculating **incremental cost-effectiveness ratios** (ICERs)

  $$\text{ICER} = (\textbf{Cost}_{\text{Intervention}} - \textbf{Cost}_{\text{Control}})/(\textbf{Effect}_{\text{Intervention}} - \textbf{Effect}_{\text{Control}})$$

  - **Cost-effectiveness analysis**: compute ICER per SAQ unit at T1 on the pooled sample and by country
  - **Cost-utility analysis**: compute ICER per QALY gained at T1, T2, and T3 on the pooled sample and by country
  - Reference to **country-specific thresholds** to determine the cost-effectiveness

- **Sensitivity analysis**
  - One-way SA to assess the influence of individual estimates
  - Probabilistic SA to assess the join uncertainty of all included parameters

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Current progress and supports needed

- **Study protocol and data analysis plan** developed and circulated for feedbacks
- **Time recording template for clinicians** developed and administered
- **Time recording template for researchers and professionals** developed and circulated for data collection
- **Unit cost database on care services monitored by CSRI** prepared for Germany
- **Manuscript outline on the analysis of prescriptions and costs** of mental health drugs in the UK prepared
- **Supports needed from all project staff, partners** for on-going data collection on costs of implementing DMMH and implemenation support strategies

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Thank you for your attention and support!