**Project title: Inclusive designs for superiority studies in mental health**

Applicants:

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Budget: £18,620

Aim

This research project evaluates an innovative design, called inclusive design, that aims to expedite intervention evaluations with high completion rate and enhance the validity of RCTs by including a broader range of participants in trial (who might otherwise be excluded from participating).

Objective 1*. Conduct computer experiments to establish the design and analysis strategy for the inclusive design.*

What was achieved:

We have identified several analysis methods for making inference when an inclusive design is considered. These includes methods that make inference based on the data of two arms that are involved in a single pairwise comparison, and the modelling approaches that pool all data together in a single analysis for all pairwise comparisons. We do not include Bayesian analysis methods that pool external data as the inference has different interpretation. We consider different covariate and outcome relations for participants who have different randomization eligibility. We also explore the impact of using different randomization ratios.

A simulation study plan was drafted and reviewed by the team, according to the output from the meetings with the patient and practitioner groups. The computing code was reviewed by another person prior to implementing the simulation for all the considered scenarios.

The project finding is under-preparation for submission to a peer-reviewed journal.

Objective 2. *Identify barriers on promoting the inclusive designs through discussions with patient and practitioner groups in mental health trial settings.*

An advertisement to recruit stakeholders who are related to mental health research was sent to

* The PPI lead of the NIHR Research Support Service Hub delivered by King’s College London and Partners
* The PPI group at the NIHR Maudsley Biomedical Research Centre
* The health and care professionals and patient representatives who received support to attend ICTMC 2024
* The monthly all staff update email (February 2025), School of Mental Health & Psychological Sciences, King’s College London
* The weekly news & event email (January- February 2025), Institute of Psychiatry, Psychology & Neuroscience, King’s College London
* Personal network with health and care professionals

Output one:

A clinician, whose research interests include psychiatry and psychology, agreed that there is a potential to implement the inclusive design in certain areas of mental health. He described a three-arm trial which has been funded and was at the set-up period at the time of discussion, as a potential example where the inclusive design would be more efficient than the conventional three-arm design. Specifically, this trial has a placebo arm, an active comparator arm and an intervention arm. Recruitment to this three-arm trial may be more challenging than the inclusive design as the active comparator have been used by some of the patients, who may then be unwilling to participate in this three-arm study especially when they have had negative experiences with the active treatment. This real trial will be used as a motivating example in the manuscript that is under-preparation.

As opposed to an adaptive version of the inclusive design, this clinician suggested a two-stage design where stage one uses a three-arm design and stage two uses an inclusive design, with the goal of improving recruitment. The statistical design and analysis strategy of this option is yet to be explored.

Output two:

A community-based nurse, who helps patients with mental health conditions in the community setting, suggested that trial participants are willing to participate in a randomized trial when they know there is a higher chance of receiving an active intervention. This has led to the exploration of the randomization ratio used in the inclusive design.

She suggested the nature of the intervention would affect the participation of patients more than the types of trial design. Many patients would not know the subtlety between a two-arm and a three-arm trial. She emphasised that transparency is crucial, regardless of the type of trial design.

Future work:

* Publication on the simulation study results of the analysis strategies of inclusive design.
* Seek opportunity to disseminate the findings from the simulation study, e.g., present a talk at CTUs.
* Recruitment of stakeholders to discuss the applicability of the inclusive design has not been successful. We seek funding support to organise a knowledge exchange event to gather feedback from health and care professionals on the inclusive design. This may not be limited to the mental health area.
* Apply funding to explore the statistical aspects of inclusive design that allows for pre-specified design adaptations after the knowledge exchange event.