

FINAL REPORT

CULTURAL COMPETENCY PROJECT, 4th May 2023

FUNDER:

Trial Research Methods Partnership; awarded September 2020, open-ended no-cost extension until publication provided in May 2022

Principal Investigator:

Dr Nandi Siegfried, South African Medical Research Council

1. Summary of achievements against planned objectives

Our study aimed to evaluate the utility of, and comparability between, the Gibbs and GRIPP-2 tools, when applied to a complex trial, Project MIND, conducted in an African setting.

Planned Objectives stated in Proposal	Achievements
Conduct of a secondary data source analysis by identifying and collating trial documentation	Completed
Preparation of a trial process diagram specific to Project Mind with the responsible investigator linked to each stage	Completed
Completion of a 2007 Gibbs framework and GRIPP-2 checklist against each stage of the trial process by interrogating the secondary data where this exists	Completed
Production of a graphical representation of tool comparability	Completed
Publication in the peer-reviewed literature describing the methodology as it applied to Project Mind and our findings regarding the utility and comparability of both checklists	Completed
Dissemination of our findings to the Project Mind trial team in a dedicated workshop setting	Not done
Communication of our findings to the CONSORT executive for possible consideration in future CONSORT extensions dependent on our findings.	Completed through engagement directly with Prof Sally Hopewell and participation in the revision and subsequent meetings of the Stakeholder Group for the updating of SPIRIT and CONSORT Statements in March 2023.

2. Reasons for non-achievement of objectives and plan for completing project (if relevant)

Due to administrative delays in finance and legal departments bilaterally, and the prioritization of COVID-19-focused work within the organization and individually, the project start was delayed from 1st May to 1st October 2020. The timeline was adjusted accordingly.

COVID-19 resulted in the cancellation of all unnecessary in-person interviews and focus groups within clinical facilities for the immediate future. As a result we did not communicate our finding in a workshop setting in the clinic facilities.

3. Outputs (e.g. publications, presentations, reports) and/or plan (including timelines) for outputs

- a) Siegfried NL, Hopewell S, Erasmus L-A, Myers B. Evaluation of cultural competency in a South African cluster randomised controlled trial: lessons learned for trial reporting standards. *Trials* 2022 Oct 29;23(1):918. doi: 10.1186/s13063-022-06767-y
- b) Erasmus-Claassen, L., Hopewell, S., Myers, B., and Siegfried, N. November 2022 *Cultural Competency: An evaluation of secondary data analysis from a South African clustered randomised controlled trial and the implications for trial reporting standards*. [Poster]. *Global Health Network Conference*, University of Cape Town, Cape Town.
- c) Registered study as a SWAT (Study within a Trial) with the SWAT STORE Repository hosted by the Northern Ireland Hub for Trials Methodology Research in April 2023. Planning media release for study as SWAT will be 200th.

4. A separate financial report detailing expenditure under the budget headings set out in the project plan.

Please see attached report.