

# SWAT 200: Development of an interactive application tool for trial recruitment planning and monitoring

## Objective of this SWAT

To develop a tool to serve as a computerised decisions-support system to aid the planning and management phases of the trial recruitment process.

Study area: Recruitment, Retention

Sample type:

Estimated funding level needed: This work was supported by the South African Medical Research Council. The Project MIND trial received joint funding from the British Medical Research Council, Wellcome Trust, the Economic and Social Research Council, the Global Challenges Research Fund, and the Department of International Development (MR/M014290/1).

## Background

When developing a protocol for a clinical trial, a sample size calculation is done in advance of the trial using conventional statistical tools. This provides a fixed number, which would be the target for the trial. Alongside this, investigators planning the practical management of a clinical trial need to calculate how many sites, facilities and staff they will need to ensure that the required sample size is obtained. The amount of time available to reach the required sample size may be fixed (e.g. by a funding cycle) or may be flexible, which will influence the amount of funding required and the study's duration. Investigators can also estimate in advance how long the eligibility assessment process will take, how many follow-up-assessments are required and the length of time for each of these assessments. The number of assessments that can be done at a site and facility is thus dependent on these times, how many staff are available to do assessments and the size of the facility (e.g. number of rooms to accommodate assessments).

In the academic sector, investigators determine sample size and might then fit this into a fixed duration using a tool such as MS Excel or white-boards. The numbers of staff and facilities are then dropped into the flow using general estimates. However, experience is that after rapid recruitment, staff and facility become over-whelmed as trial participants return for follow-up assessments beyond capacity and additional staff need to be hired at short notice.

Several trial management software packages are available but these are costly and investigations with several local South African trial investigators and trialists based at the UK Medical Research Council revealed that none of the packages were optimal. All required additional customisation. Therefore, it was decided that an app which will allow investigators to calculate how many staff and facilities are required either over a fixed time for the fixed sample size or the duration required for a trial if the number of staff and facilities are fixed would be helpful. Such a tool was developed and tested in this SWAT, within the Project MIND cluster trial (PACTR201610001825403).[1] The tool is available for use from <https://github.com/spiesruan/TrialRecruitmentTool>.[2]

## Interventions and comparators

Intervention 1: Interactive application tool to help with trial recruitment planning and monitoring.

Index Type:

## Method for allocating to intervention or comparator

Single group study.

## Outcome measures

Primary: Usefulness of the interactive application tool.

Secondary:

## Analysis plans

Evaluation of the usefulness of the interactive trial recruitment tool (TRT) in the host trial. A Poisson process simulation model was formulated and incorporated in the TRT to predict the recruitment duration. The assumptions underlying the model were made in consultation with the trial team at the start of the project and were deemed reasonable. Real-world data extracted from

the Project MIND cluster trial, based in 24 sites in South Africa was used to verify the simulation model and to develop the monitoring component of the TRT.

### **Possible problems in implementing this SWAT**

The SWAT is complete.[2]

### **References**

1. Myers B, Lombard CJ, Lund C, Joska JA, Levitt N, Naledi T, Petersen Williams P, van der Westhuizen C, Cuijpers P, Stein DJ, Sorsdahl KR. Comparing dedicated and designated approaches to integrating task-shared psychological interventions into chronic disease care in South Africa: a three-arm, cluster randomised, multicentre, open-label trial. *Lancet* 2022;400:1321-33. doi: 10.1016/S0140-6736(22)01641-5.
2. Spies R, Siegfried N, Myers B, Grobbelaar SS. Concept and development of an interactive tool for trial recruitment planning and management. *Trials* 2021;22:189. doi: 10.1186/s13063-021-05112-z.

### **Publications or presentations of this SWAT design**

Spies R, Siegfried N, Myers B, Grobbelaar SS. Concept and development of an interactive tool for trial recruitment planning and management. *Trials* 2021;22:189. doi: 10.1186/s13063-021-05112-z.

### **Examples of the implementation of this SWAT**

Spies R, Siegfried N, Myers B, Grobbelaar SS. Concept and development of an interactive tool for trial recruitment planning and management. *Trials* 2021;22:189. doi: 10.1186/s13063-021-05112-z.

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