

SWAT 12: Projected accrual as part of effective site selection for a multi-centre randomised trial

Objective of this SWAT

To assess the effects on recruitment of different methods to identify sites which will be good recruiters in a multi-centre randomised trial.

Study area: Recruitment.

Sample type: Trial team; Healthcare professionals.

Estimated funding level needed: Medium.

Background

Recruitment targets made in the early stages of a study's set up period are not always being reached.[1] As well as affecting the scientific value of the study, financial penalties may be incurred through setting overambitious targets which are not achieved at individual sites. For example, in the UK, NHS Trusts are monitored by the Department of Health and all recruitment data must now be reported.[2] In addition to recruitment fines, there is a significant financial and resource cost required to set up a multi-centre randomised trial. Setting up multiple sites for a study is costly for the lead site: covering monitoring costs per site, the time and resource spent helping on the set up of the trial, providing and supplying trial treatment to sites. Therefore, it is important to ensure that sites have the necessary resources and enthusiasm, and have thought carefully about their recruitment strategy before choosing to take part in a study. All these issues could be discussed either at a site visit or included on a feasibility form, to check that a site is capable of recruitment to the study. This SWAT will compare two methods of collaboration between the lead site and participating site teams, during the set-up of a trial, to see which method best aids in improving recruitment for the trial and enables the lead site to identify sites which will be good recruiters.

Interventions and comparators

Intervention 1: Face-to-face feasibility meeting with the Trial Manager before accepting a site into the trial.

Intervention 2: Feasibility is assessed through a posted or emailed form, with no face-to-face meeting.

Index Type: Site Selection, Visit

Method for allocating to intervention or comparator

Randomisation.

Outcome measures

Primary outcomes: Achievement of the target number of recruited participants within a specific time period (70 days in the UK).

Secondary outcomes: Number of sites that do not join the trial (and reasons); reasons for sites withdrawing during the study.

Analysis plans

The primary analysis will be the rate of success in the two types of site. This might be used in the first year of a multi-year study to allow the lead site to determine the best way of selecting future sites.

Possible problems in implementing this SWAT

The feasibility meeting may lead some sites to decide not to take part in the trial. For example, the meeting may highlight that the site does not have enough staff to complete assessments required in the trial or they do not have enough patients that fulfil the eligibility criteria. If the feasibility meeting results in a site not joining the trial, it will not be possible to determine whether the site would have recruited to target. It is also difficult to decide on the duration for the assessment of success in the main trial. For example, if recruitment is monitored for the first 70 days only, this may not be an accurate depiction of recruitment to the trial at that particular site. Sites in the trial might join the trial at different times, which will slow down the time needed to have sufficient power to use the findings of the SWAT within the same randomised trial.

References

1. O'Dowd A. Target to start clinical trials within 70 days of approval will take time to achieve, admits minister. *BMJ* 2013; 346: f3649.
2. Bayes S. Faster, Easier, Clinical Research. 2014. Available from <http://www.nihr.ac.uk/policy-and-standards/Performance-in-initiating-anddelivering-research.htm>

Person to show as the source of this idea: Joanna Peel.

Contact email address: joanna.peel@gstt.nhs.uk.

Date of idea: 8 December 2014.