

METHODOLOGY

SWAT 1: what effects do site visits by the principal investigator have on recruitment in a multicentre randomized trial?

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Abstract

The SWAT (Study Within A Trial) programme has been established to develop a series of studies that would embed research within research, so as to resolve uncertainties about the effects of different ways of designing, conducting, analyzing and interpreting evaluations of health and social care. It was described in an Education piece in the *Journal of Evidence-Based Medicine* in 2012. We have now prepared the first example of the design summary for a SWAT, using the template that will be used for other SWAT. This is presented in this article.

Introduction

The SWAT (Study Within A Trial) programme has been established by the All-Ireland Hub for Trials Methodology Research, in collaboration with the MRC Network of Hubs in the United Kingdom and others, to develop a series of studies that would embed research within research, so as to resolve uncertainties about the effects of different ways of designing, conducting, analyzing, and interpreting evaluations of health and social care (1). This article describes SWAT 1, which tackles a challenge encountered by many multicentre trials: the slowing down of recruitment at one or more sites (2). It illustrates the template and shows the headings that will be used for other SWAT. This includes the background and design for the SWAT, and information about the specific version. The SWAT programme will be developed to provide an online library for these methodology studies and a data

repository into which people using the designs could log their study prospectively and deposit their findings to contribute to meta-analyses of each SWAT. This major collaborative effort will include mechanisms to allow people to propose new topics for SWAT, submit new designs, suggest modifications to existing ones, and report problems in implementing them.

Design for SWAT 1

Background

One challenge faced by many multicentre randomized trials is maintaining the interest of those responsible for recruiting participants, because a loss of interest can slow the recruitment of new participants. One solution might be for the principal investigator or other senior researchers to visit the sites

to regenerate or maintain interest in the trial. This SWAT assesses the impact of such a visit.

Intervention and comparator

The analyses would assess the effects of the site visit. This would be done through a before-intervention-after comparison in the visited site (where the date of the site visit provides the time point for the “intervention”) which could be contrasted with a before-control-after comparison in other sites (where the date of the visit to the intervention site is used to define the time point for the “control”). The content of the site visit is likely to vary across different implementations of this SWAT but, for this version of SWAT 1, the primary outcome would be recruitment to the randomized trial.

Allocation to intervention and comparator

If randomization is used to choose the site to visit, this will minimize the effect of other factors when comparing visited and nonvisited sites. However, if a site is targeted for a specific reason, in particular if this is related to its level of recruitment, the analyses might need to take account of this. This could be dealt with by, for example, matching sites, adjusting the analyses or acknowledging the potential for bias. The SWAT could also be done using other prospective designs such as an interrupted time series, or by a retrospective analysis combining details of site visits with the recruitment data for the trial.

Primary outcomes

The primary outcome measure is the change in recruitment after the visit compared to before the visit. The timing of the before and after visit measure might vary, as might the duration of the period over which recruitment is measured. For example, recruitment over a three-day period one month before the visit might be compared with recruitment over three-day periods at one, two, and three months after the visit. Recruitment might be measured in absolute terms (eg, the number of participants recruited) or in relative terms (eg, the proportion of eligible participants recruited).

Secondary outcomes

Secondary outcome measures might include satisfaction among the recruiters or others involved in the trial, recruiters’

knowledge of recruitment processes or barriers to recruitment, adherence to the trial interventions, retention of participants in the trial, and changes in the number of potentially eligible participants who are assessed or approached for the trial.

Analysis

The primary analysis is the comparison of the change in recruitment at a site that was visited versus the change at sites that were not visited.

Possible problems

As with all before and after studies, a major problem for this SWAT could be that something other than the site visit takes place between the before and after assessments, which affects the outcomes and introduces bias to the estimate of the effect of the site visit. Another problem is that a control site might become an intervention site during the period of follow-up for that site. For example, if a site is visited on 1 April and outcomes are to be measured three months after a site visit, one of the comparator sites might become an intervention site when it is visited on 1 June. This would impact on the three-month data for that site. Therefore, if multiple sites are to be visited in a short space of time, the length of follow-up for outcome measurement and comparison would need to be shorter than if site visits take place at much longer intervals.

Version information

Source of idea: Valerie Smith and Mike Clarke

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