SWAT 1: Site visits by the principal investigator to improve recruitment in a multicentre randomized trial

Objective of this SWAT
To assess the effects on recruitment of site visits by the principal investigator in a multicentre randomized trial.

Study area: Recruitment.
Sample type: Trial team; Healthcare professionals.
Estimated funding level needed: None.

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.

Interventions and comparators
Intervention 1: Visit by the principal investigator to a site responsible for recruiting trial participants.
Intervention 2: No site visit.

Index Type: Visit

Method for allocating to intervention or comparator
Randomisation, or other methods (including a retrospective analysis of recruitment data).

Outcome measures
Primary outcomes: 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 plans
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 in implementing this SWAT
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.

Publications or presentations of this SWAT design

Smith V, Clarke M, Devane D, Begley C, Shorter G, Maguire L. SWAT 1: what effects do site visits by the principal investigator have on recruitment in a multicentre randomized trial? Journal of Evidence-Based Medicine 2013; 6(3): 136-137.
Smith V, Clarke M, Begley C, Devane D. SWAT-1: The effectiveness of a 'site visit' intervention on recruitment rates in a multi-centre randomised trial. Trials 2015;16:211

Examples of the implementation of this SWAT

Smith V, Clarke M, Begley C, Devane D. Embedding research into research, SWAT-1 assesses the effectiveness of a 'site visit' on recruitment rates in a multicentre randomised trial. Cochrane Database of Systematic Reviews 2014; Supplement: 39-40 (P10).

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Revisions made by: Declan Devane, Cecily Begley, Gillian Shorter and Lisa Maguire.
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