SWAT 66: Site visits to initiate recruitment in a clinical trial: Does it matter who conducts the visit?

Objective of this SWAT
To investigate whether site visits intended to get recruitment started in sites that have not yet recruited a patient to the host trial are more effective when conducted by a clinical peer rather than by a non-clinical member of the research team.

Study area: Recruitment
Sample type: Trial Team
Estimated funding level needed: Low

Background
The results of SWAT-1, showing the effects of a 'site visit' intervention on recruitment rates in a multi-centre randomised trial were published in 2015 (1). The site visit and scheduled meeting had the sole purpose of discussing trial recruitment and the authors compared recruitment rates pre- and post-intervention in a site that was visited, against sites that did not receive a visit. They found a significant increase in recruitment in the site that received the visit versus the controls, indicating that this may be a useful method for addressing under-recruitment in trials.

This SWAT extends SWAT-1 by examining whether site visits not only have the potential to improve recruitment, but also to initiate recruitment in those sites which have not yet started. But, the main aim of this SWAT is to answer the question: does it matter who conducts the visit? The visits in SWAT-1 were made by the Principal Investigator (PI). PIs are usually either clinical practitioners who also conduct research (eg. GPs, hospital consultants) or non-clinical researchers (ie. members of the research team who do not have a clinical background), such as the Trial Manager.

Support for the design of this SWAT is a systematic review of the impact of feedback on physicians' clinical performance, which found that the source of the feedback was important (2). Feedback had more effect on performance if it came from a professional or administrative group, than if it came from a researcher.

Interventions and comparators
Intervention 1: A face-to-face site visit and meeting by a clinical peer to sites that fail to recruit a participant within a specified time frame following site initiation. The choice of clinical peer will be study specific and reflective of the personnel at the site to be visited. For instance, if GPs are the main recruiters of patients for a trial, a GP trained in the study procedures and working with the trial team would be asked to visit the non-recruiting site.
Intervention 2: A face-to-face site visit and meeting by a non-clinical research member of the trial team, for example, a Trial Manager or the PI (providing that they are not a clinical peer).

Index Type: Visit

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Number of days to first recruit following the site visit.
Secondary: Total number of participants recruited by the end of the trial.

Analysis plans
The primary analysis would be a survival analysis comparing sites receiving a visit from a clinical peer versus those where the site visit was by a non-clinical member of the research team. Hazard ratios with associated 95% confidence intervals would summarise the results. Comparative statistics will be to assess differences in the total number of recruits between the two types of site visit.

Possible problems in implementing this SWAT

Host trials would need to be large enough to have enough sites to randomize non-recruiting sites to two arms. This may be more feasible in large primary care studies than in secondary or tertiary care studies with fewer sites. However, whilst small trials may not be able to definitively demonstrate effectiveness, they could contribute to a meta-analysis, which is an important reason for using a standard protocol such as this one in each host trial. Another challenges is that the research teams will need an available peer clinician, willing and able to make site visits.

References

1. Smith V, Clarke M, Begley C, and Devane D. SWAT-1: The effectiveness of a 'site visit' intervention on recruitment rates in a multi-centre randomised trial. Trials 2015; 16: 211-7.
2. Veloski J, Boex J, Grasberger M, Evans A, Wolfson D. Systematic review of the literature on assessment, feedback and physicians' clinical performance: BEME Guide No 7. Medical teacher 2006; 28(2): 117-28.

Publications or presentations of this SWAT design

Nollett C, Kelson M, Hood K. Site visits to initiate recruitment in a clinical trial: does it matter who conducts the visit? Protocol for implementation in trials. Journal of Evidence-Based Medicine 2016; 9(4), 225-7.

Examples of the implementation of this SWAT

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