SWAT 177: Effects on recruitment rates of regular scheduled calls between the coordinating team and sites

Objective of this SWAT
To establish whether regular scheduled video/phone calls between the coordinating team and the site during the recruitment period improves recruitment rates in a clinical trial.

Study area: Recruitment, Retention
Sample type: Sites in a Cluster Randomised Trial
Estimated funding level needed: Low

Background
Most recruitment strategies in clinical trials continue to focus on methods directed at the trial participants rather than the recruiters. For example, the 2018 version of the Cochrane review of strategies intended to improve recruitment to randomised trials,(1) found only five studies evaluating interventions aimed at people recruiting participants compared with 63 studies aimed directly at trial participants, highlighting the gap in the evidence base. To date, no intervention focused on the recruiter has shown a significant effect on recruitment.(2)

Regular contact between the co-ordinating team and recruiting sites is a common part of trial management, although there is no evidence for the correct amount to maintain site motivation whilst not over burdening them. Monaghan et al reported that whilst additional site contact did not increase final recruitment, a non-significant increase in the speed with which participants were recruited was seen in the additional contact group.(3) When recruitment stalls, other reactive and potentially costly strategies are often employed such as research away days despite the lack of supporting evidence for these.(4) Therefore, an effective proactive approach to promoting recruitment at sites might reduce the need for further intervention.

Interventions and comparators
Intervention 1: Usual as needed communication between co-ordinating team and site during recruitment period.
Intervention 2: Regular scheduled phone/video calls between co-ordinating team and site during recruitment period to discuss progress and issues in addition to the usual as needed communication.

Index Type: Visit

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Patient level: Proportion of eligible patients recruited. Site level: Time to reach half recruitment target from greenlight.
Secondary: Could include the following if applicable:
Patient level: Cost based on time spent by members of the trial coordinating team communicating with each site regarding recruitment issues, rates of follow-up data collection and completeness.
Site level: Time to full recruitment target, time from greenlight to first recruit, attendance rate and people (role) attending monthly calls (intervention group only), and length of scheduled calls (intervention group only),

Analysis plans
All analyses will be conducted on an intention to treat basis by including all sites based on the SWAT group they were randomised to. All outcomes will be summarised descriptively overall and by allocated group. Group differences and 95% confidence intervals (CI) will be reported.

The patient level primary outcome, proportion of eligible patient recruited, will be analysed using logistic regression analysis, adjusting for group allocation and SWAT stratification factors (e.g. host group allocation). The between-groups difference will be presented as frequency and percentage,

adjusted absolute effect estimate (i.e. risk difference) and relative effect estimate (i.e. odds ratio or relative risk) along with the 95% CI.

The site level primary outcome, time to half target, will be reported with Kaplan-Meier curves. If sample size allowed (i.e. adequate number of sites for this analysis), we will also run log-rank test (unadjusted test) or Cox regression (adjusting for SWAT groups and stratification factors).

Cost and consequences for patient recruitment will be compared. If it is deemed appropriate, an incremental cost per patient recruited will be calculated. Primarily, estimates will be made using the researchers' records of time and costs associated with dealing with recruitment issues in each SWAT group.

Possible problems in implementing this SWAT

Time demands on site and coordinating staff in attending monthly calls may present an obstacle to arranging these calls. Recruitment targets may present a potential ceiling effect if sites recruit to their target then stop. However, having competitive recruitment with the option to over recruit may help to minimise this. Recruitment targets for each site would need to be pre-specified at the start of their participation in the trial to allow time to half this target to be analysed. Appropriate stratification would be required to ensure balance between the SWAT groups for important characteristics that may impact on a site's ability to recruit (e.g. site size). Therefore, others considering adopting this SWAT should consider the length of recruitment period, intervals of monthly calls, frequency of scheduled calls and if they have a sufficient number of sites in their host trial.

References

1. Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018(2):MR000013.
2. Fletcher B, Gheorghe A, Moore D, Wilson S, Damery S. Improving the recruitment activity of clinicians in randomised controlled trials: a systematic review. BMJ Open 2012;2(1):e000496.
3. Monaghan H, Richens A, Colman S, Currie R, Girgis S, Jayne K, et al. A randomised trial of the effects of an additional communication strategy on recruitment into a large-scale, multi-centre trial. Contemporary Clinical Trials 2007;28(1):1-5.
4. Jefferson L, Cook L, Keding A, Brealey S, Handoll H, Rangan A. "Away Days" in multicenter randomized controlled trials: a questionnaire survey of their use and a case study on the effect of one Away Day on patient recruitment. Journal of Evidence Based Medicine 2016;9(1):24-31.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of idea: 26/OCT/2021
Revisions made by: Matthew Northgraves
Date of revisions: 31/DEC/2023