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: Number of patients recruited; time to reach half recruitment target from greenlight
Secondary: Could include the following if applicable: Time to full recruitment target, proportion of eligible patients who were recruited, time from greenlight to first recruit, attendance rate and people (role) attending at monthly calls (intervention group only), length of scheduled calls (intervention group only), 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.

Analysis plans
All analyses will be conducted on an intention to treat basis by including all sites based on the group they were assigned to at randomisation. All outcomes will be summarised descriptively overall and by allocated group. Group differences and 95% confidence intervals (CI) will be reported. Owing to the small number of anticipated sites per host trial (around 10 sites per SWAT group in the initial version of this SWAT), no formal statistical tests will be undertaken on site-level outcomes. Group differences will be summarised descriptively and reported using 95% CI. The statistician will remain blind to the intervention group until all data summaries and results are finalised. 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, but 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 randomised groups for important characteristics that may impact on a site's ability to recruit (e.g. site size). Studies 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 the proposed host trial before adopting the SWAT.

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:
Date of revisions: