

SWAT 23: Systematic Techniques for Assisting Recruitment to Trials (MRC START)

Objective of this SWAT

(1) To develop recruitment interventions; and (2) to test the impact of the interventions using embedded methodology trials in 'host' clinical trials.

Study area: Recruitment, Retention

Sample type: Patients, Researchers

Estimated funding level needed:

Background

Randomized controlled trials play a central role in evidence-based practice, but recruitment of participants, and retention of them once in the trial, is challenging. Moreover, there is a dearth of evidence that research teams can use to inform the development of their recruitment and retention strategies. As with other healthcare initiatives, the fairest test of the effectiveness of a recruitment strategy is a trial comparing alternatives. For recruitment, this would mean embedding a recruitment trial within an ongoing host trial. Systematic reviews indicate that such studies are rare [1]. Embedded trials are largely delivered in an ad hoc way, with interventions almost always developed in isolation and tested in the context of a single host trial, limiting their ability to contribute to a body of evidence with regard to a single recruitment intervention and to researchers working in different contexts. The START programme is funded by the UK Medical Research Council (MRC) to develop interventions that might assist recruitment to clinical trials and to facilitate their evaluation. It has identified several different interventions, which are being tested in a variety of host trials.

Interventions and comparators

Intervention 1: Optimised Patient Information Material: Research ethics committees want to ensure that participants receive appropriate information and are able to provide fully informed consent. However, a long and complex participant information sheet (PIS) may impact negatively on recruitment, particularly if it is also visually unappealing or raises inappropriate levels of anxiety [2]. This is especially critical when patients are initially approached by a letter from their health professional, which occurs in a significant proportion of trials in primary care and community settings, especially for patients with long-term conditions. A systematic review has identified evidence that involving consumers in the development of patient information results in higher relevance and readability, without increasing anxiety [3]. To test the impact of involving consumers in the development of patient information, a revised version of the PIS will be prepared for each host trial. The process involves optimization of PIS readability through expertise in writing for patients and improved presentation via graphic design [4]. The revisions are informed by user testing [5-7], where the ability of patients to locate and understand key pieces of information is evaluated objectively to provide an assessment of the ability of the PIS to provide information in a way that can be understood. Initially the original PIS is tested, and then versions of the optimized PIS are tested (followed by further revision), until the resultant PIS is judged to be better able to inform potential trial participants. The optimized PIS would cover the same topics as the original version but the optimized version would likely differ in appearance, structure, and wording.

Intervention 2: Multimedia Patient Information: At present most information about trial participation is presented in written form, but this is not necessarily the best way to communicate complex messages to all segments of the targeted population, particularly as so much communication now happens via the internet, often using video. Multimedia interventions may offer a useful strategy to improve communication about participation and may therefore facilitate greater accrual and retention rates. We therefore set out to design and test multimedia approaches for delivering information to potential research participants alongside the standard, written PIS.

Intervention 3: Advertising patient and public involvement (PPI) in the trial and the design of the trial materials.

Intervention 4: Optimised consent forms.

Index Type: Method of Invitation, Participant Information

Method for allocating to intervention or comparator

1:1 individual randomisation or cluster randomisation, depending on design of host trial.

Outcome measures

Primary: Primary outcome for interventions 1, 2 and 3: randomisation rates.

Primary outcome for intervention 4: correctly completed consent forms and error rates.

Secondary: expressions of interest.

Analysis plans

These will vary for each START study.

Possible problems in implementing this SWAT

These will vary for each START study.

References

1. Treweek S, Mitchell E, Pitkethly M, et al. Strategies to improve recruitment to randomised controlled trials. *Cochrane Database of Systematic Reviews* 2010; (4): MR000013.
2. Gillies K, Huang W, Skea Z, et.al.: Patient information leaflets (PILs) for UK randomised controlled trials: a feasibility study exploring whether they contain information to support decision making about trial participation. *Trials* 2014,15(62):1–10.
3. Nilsen E, Myrhaug H, Johansen M, Oliver S, Oxman A: Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. *Cochrane Database Syst Rev* 2006, 3:CD004563
4. Raynor T, Dickinson D: Key principles to guide development of consumer medicine information - content analysis of information design texts. *Ann Pharmacother* 2009, 43:700–706. 10.1345/aph.1L522
5. Knapp P, Raynor D, Silcock J, Parkinson B: Performance-based readability testing of participant information for a Phase 3 IVF trial. *Trials* 2009,10(79):1–15.
6. Knapp P, Raynor D, Silcock J, Parkinson B: Performance-based readability testing of participant materials for a phase I trial: TGN1412. *J Med Ethics* 2009, 35:573–578. 10.1136/jme.2008.026708
7. Knapp P, Raynor D, Silcock J, Parkinson B: Can user testing of a clinical trial patient information sheet make it fit-for-purpose? - a randomised controlled trial. *BMC Med* 2011, 9:89. 10.1186/1741-7015-9-89

Publications or presentations of this SWAT design

Rick J, Graffy J, Knapp P, et al. Systematic techniques for assisting recruitment to trials (START): study protocol for embedded, randomized controlled trials. *Trials* 2014; 15: 407.

Man M-S, Rick J, Bower P. Improving recruitment to a study of telehealth management for long-term conditions in primary care: two embedded, randomised controlled trials of optimised patient information materials. *Trials* 2015; 16: 309.

Examples of the implementation of this SWAT

This SWAT has been implemented in the ECLS trial: Parker A, Knapp P, Treweek S, et al. The effect of optimised patient information materials on recruitment in a lung cancer screening trial: an embedded randomised recruitment trial. *Trials* 2018;19(1):503.

MRC START studies have also been implemented in the following trials: REFORM, Healthlines, Help Diabetes, ISDR, GH2K, PSM COPD, STOP ACEi, HI-Light and SeAFood.

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