

SWAT 137: A factorial embedded randomised controlled trial to test the impact on recruitment of a pen incentive and a brief participant information sheet (PROMETHEUS in MSS3)

Objective of this SWAT

To evaluate the effectiveness and cost effectiveness of a brief participant information sheet (PIS) provided in addition to a standard length PIS, with or without the addition of a trial logo branded pen, on recruitment and response rates in the Multiple Symptoms Study 3 (MSS3) host trial (ISRCTN57050216).

Study area: Recruitment

Sample type: Participants, Patients

Estimated funding level needed: Low

Background

A common method of recruiting participants to trials from general practices and other registries of patients is to send a letter to potentially eligible people inviting them to participate in the trial, along with the trial's Participant Information Sheet (PIS). However, PISs are lengthy and increasingly complex - often about 8 pages long (1). There is a hypothesis that being asked to read such a large document in one go may deter potential participants from becoming involved in the research (2). A shorter PIS may be more appealing to patients initially, because it is likely to provide a more manageable volume of information, which may encourage more potential participants to contact the trial team to be screened and subsequently recruited into the trial (2). The latest Cochrane review of recruitment interventions (3) identified two trials that have evaluated a brief PIS compared with a full PIS (2, 4). It found that the brief PIS makes little or no difference to recruitment compared with a full PIS (RD: 0%, 95% CI: -2% to 2%; GRADE: moderate). However, it would be useful to conduct this SWAT in different populations, in order to end uncertainty about whether to use a brief or standard PIS when initially contacting participants to invite them into a trial. This SWAT will also contain a factorial randomisation for the addition of a pen (see SWAT 37).

Interventions and comparators

Intervention 1: A pen with the trial logo within the standard trial recruitment pack.

Intervention 2: A pen with the trial logo and a brief PIS (in addition to the standard length PIS), within the standard trial recruitment pack.

Intervention 3: A brief PIS (provided in addition to the standard length PIS), within the standard trial recruitment pack.

Intervention 4: The standard trial recruitment pack contents only, with no additional interventions

Index Type: Incentive, Participant Information

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: The effectiveness of the SWAT interventions based on the recruitment rate (the proportions of participants in each SWAT intervention group who are randomised into the host trial).

Secondary: 1. Proportion of patients in each SWAT intervention group who return an expression of interest form; 2. Cost-effectiveness of the interventions for the host trial; 3. Proportion of patients in each SWAT intervention group who return an expression of interest form but do not go on to be randomised into the host trial due to a) ineligibility or b) non-consent; 4. Time taken to respond to an invitation to participate in the host trial in each SWAT intervention group.

Analysis plans

Analyses will be conducted on an intention-to-treat basis, including everyone randomised to receive the initial invitation letter on the basis of the group to which they were randomised. Reply forms returned following a reminder letter will not be included in the analysis. Analysis will be conducted using 2-sided significance tests at the 5% significance level. For analysis of the primary

outcome, logistic regression will be used to produce odds ratios and their associated 95% confidence intervals and p-values. Cost effectiveness will be presented as a cost-per-additional recruited participant.

Possible problems in implementing this SWAT

References

1. National Research Ethics Service. Information sheets and consent forms: guidance for researchers and reviewers. 2018.
2. Brierley G, Richardson R, Torgerson DJ. Using short information leaflets as recruitment tools did not improve recruitment: A randomized controlled trial. *Journal of Clinical Epidemiology* 2012;65(2):147-54.
3. 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.
4. Chen F, Rahimi K, Haynes R, Naessens K, Taylor-Clarke M, Murray C, et al. Investigating strategies to improve attendance at screening visits in a randomized trial. *Trials* 2011;12(Suppl 1):A111.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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