SWAT 37: Improving trial recruitment using pens as an incentive

Objective of this SWAT

To evaluate the effects of adding a pen printed with the trial logo to the trial invitation.

Study area: Recruitment Sample type: Participants, Patients Estimated funding level needed: Low

Background

There is a need to develop and rigorously evaluate strategies for improving recruitment into trials by embedding them in real-life host trials. There is some evidence that using pens as a non-monetary incentive increases response rates and time to response for trial follow-up questionnaires [1, 2]. One trial in the U.S. embedded in an observational study, showed that including a pen with the study logo to a questionnaire mailed to women who had previously not responded significantly improved recruitment rates [3]. However to our knowledge, there have been no trials which have evaluated the impact of using a pen to increase recruitment to trials which use face-to-face recruitment procedures. It is already intended that this SWAT will be implemented in three or more host trials to obtain a heterogeneous sample by recruiting host trials involving participants from a diverse range of ages and both genders. This methodology of embedding trials across multiple host trials is guided by methodology developed and published by MRC START [4].

Interventions and comparators

Intervention 1: A pen with the study logo printed on is given to potential participants in the host trial, in addition to the standard host trial invitation (intervention group) Intervention 2: Potential participants in the host trial receive the standard host trial invitation alone (control group)

Index Type: Method of Recruitment, Incentive

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Proportion of potential participants who give their consent and are enrolled into the host trial.

Secondary:

Analysis plans

Analysis will use the intention-to-treat principle. Graphical and tabular examination of the data will explore baseline comparability of randomised groups and representativeness of the sample in terms of the overall eligible population. The proportion of participants who gave their consent and were recruited will be calculated for the two groups (Pen and no Pen). The difference between the two proportions will be calculated along with the corresponding 95% confidence interval (CI). Outcomes will firstly be described separately by group, and then compared using logistic regression to estimate the between-group odds ratio (OR) and corresponding 95% CI. Secondary analysis will explore whether the impact of the intervention is moderated by age and gender. A meta-analytic framework would be used to explore variability across host trials. Proportions of participants responding in each trial will be entered into a meta-analysis, and the heterogeneity of the intervention effect across trials will be assessed using the I2 statistic. If there is evidence of significant heterogeneity, differences between trials that might explain that variation would be explored. The power of any such analyses may be limited if there are a small number of trials but, if so, this issue can be explored qualitatively using data collected on the trial, the patient population, and the trial context.

Possible problems in implementing this SWAT

1) Recruiting host trials and delivering the intervention in time with their timelines.

2) Additional strategies to improve trial recruitment may be introduced if there are poor recruitment rates, which may diminish any effect of the pen intervention.

References

1. Brueton VC, Tierney J, Stenning S, et al. Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2013; (12): MR000032.

Bell K, Clark L, Fairhurst C, et al. Enclosing a pen reduced time to response to questionnaire mailings. Journal of Clinical Epidemiology 2015 [Epub ahead of print 29 December 2015]
White E, Carney PA, Kolar AS. Increasing response to mailed questionnaires by including a pencil/pen. American Journal of Epidemiology 2005; 162(3): 261-6.

4. 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(1): 407.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Adwoa Hughes-Morley and David Torgerson Contact email address: adwoa.hughes-morley@york.ac.uk Date of idea: 20/FEB/2016 Revisions made by: Date of revisions: