

SWAT 76: Sending pre-notification cards to trial participants before outcome measurement to improve retention.

Objective of this SWAT

To evaluate the effect on retention of sending pre-notification cards to trial participants one month before trial outcome measurement points.

Study area: Retention

Sample type: Participants

Estimated funding level needed: Very Low

Background

Many trials struggle with trial retention. A recent UK study found that the median loss-to-follow up in a sample of 151 trials was 11% [1]. Reminders are generally an effective way of increasing response rates to questionnaires and there is some evidence that pre-notification (contacting a participant to let them know that the trial team will be sending a questionnaire to them soon) also has some evidence of benefit, although it is not high certainty evidence [2] but there is currently no clear evidence that pre-notification is effective for trial retention [3]. It is also possible that trial participants' reactions to pre-notification cards will differ depending on who and how the cards are signed (e.g. on behalf of trial team or lists specific names, handwritten (or e-signatures) or typed). This could be investigated across different implementations of this SWAT of in sub-randomisations for the intervention group.

Interventions and comparators

Intervention 1: Pre-notification card sent one month before a trial measurement point (e.g. one month before the 6-month follow-up questionnaire is sent).

Intervention 2: No pre-notification card.

Index Type: Reminder

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Number of trial participants who complete the outcome measurement (i.e. are retained).

Secondary: Cost per participant retained.

Analysis plans

The primary analysis is the difference in retention rate between those receiving the pre-notification card and those receiving no incentive.

Similarly, the secondary analysis is the difference in cost per participant retained between those sent the pre-notification card and those not. In addition to the direct costs of the pre-notification card and postage, it may also be necessary to include the cost of staff time spent administering the mail out (for example filling and labelling envelopes).

Software such as Cochrane's RevMan can be used to do this analysis.

Possible problems in implementing this SWAT

The main barrier in implementing this SWAT relates to staff time to complete the mail out. There may be resistance from trial staff if a Clinical Trials Unit or trial team has always sent out pre-notification cards but this might be addressed by being clear that currently there is no evidence of benefit and that taking part in the SWAT could provide that evidence.

References

1. Walters SJ, Bonacho dos Anjos Henriques-Cadby I, Bortolami O, Flight L, Hind D, Jacques RM, et al. Recruitment and retention of participants in randomised controlled trials: a review of trials funded and published by the United Kingdom Health Technology Assessment Programme. *BMJ Open* 2017; 7(3):e015276.

2. Edwards PJ, Roberts I, Clarke MJ, DiGiuseppi C, Wentz R, Kwan I, Cooper R, Felix LM, Pratap S. Methods to increase response to postal and electronic questionnaires. Cochrane Database of Systematic Reviews 2009;(3): MR000008.
3. Brueton VC Tierney J, Stenning S, Harding S, Meredith S, Nazareth I, Rait G.. Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2013;(12):MR000032.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

The SWAT is being evaluated in the ActWELL trial (<http://www.actwellstudy.org>)

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