

SWAT 86: Advance notification of trial participants before outcome data collection to improve retention

Objective of this SWAT

To evaluate the effects of a pre-notification letter or email on completion and return of outcome questionnaires.

Study area: Follow-up, Retention

Sample type: Participants

Estimated funding level needed: Medium

Background

Many trials struggle with participant retention and completion of follow-up questionnaires. A recent study found that the median (IQR) retention rate across 151 UK trials was 89% (79%-97%).^[1] Reminders are generally an effective way of increasing response rates to questionnaires, with some evidence that pre-notification (contacting a participant in advance to say that they will be sent a questionnaire) also provides some benefit, although it is not high certainty evidence.^[2] Therefore, there is no clear evidence that pre-notification is effective for trial retention,^[3] nor whether any particular method (telephone, text, postcard, letter) of pre-notification confers any benefits over any other, although researchers have reported a lower odds of response following a postcard reminder than following a postal reminder to a survey, albeit after rather than preceding the original questionnaire mailing.^[4]

There is also research on the content of contacts with participants, much of which relates to cover letters and post-reminders, although some relates to pre-reminders. Recent research on the content of cover letters by Duncan and colleagues developed a theory-based response letter intervention^[5] using Michie's Theoretical Domains Framework (TDF)^[6] and associated Behaviour Change Techniques (BCTs).^[7,8] Evidence on the effectiveness of this approach is still inconclusive and has been included as a SWAT idea in the PROMETHEUS project (SWAT24).

It is therefore important to use what evidence is available to develop pre-notification interventions that might improve questionnaire return rates in trials and to evaluate these. Such pre-notifications should be developed using best current evidence in terms of mode of delivery and content, whilst practical considerations should, as ever, also be taken into account in the design and delivery.

This SWAT will test a pre-notification communication sent two weeks before participants are due to be sent their 6-month follow-up questionnaire in the WORKWELL Trial, which is a pragmatic, multi-centre individually-randomised trial of job-retention vocational rehabilitation for employed people with inflammatory arthritis. The intervention to be tested is similar to that in SWAT 76, but will use a letter rather than a postcard in order to provide as consistent a form of pre-notification as possible between participants who opt to complete questionnaires postally and those who opt to complete electronically, whilst maintaining the patient choice of mode of communication.

The text in the pre-notification communication was informed by the theory and associated text used in the IQuad trial SWAT (SWAT 24). The reminder letter (or email) will be personalised to include the (typed) name of the participant because there is some evidence that personalising may improve response rates in surveys.^[9]

Interventions and comparators

Intervention 1: Pre-notification communication in advance of follow-up questionnaire. Participants who elect to complete follow-up questionnaires online will be sent a personalised pre-notification in an email two weeks prior to the mailing of this. Participants who elect to complete follow-up questionnaires in hard copy form and return by post will be sent a personalised pre-notification letter. Similar wording and layout will be used in the email and letter.

Intervention 2: No pre-notification communication.

Index Type: Method of Follow-up

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Valid response for WORKWELL trial primary outcome (yes/no) (i.e. usable outcome data for the primary outcome measure (WLQ-25 total score[10]) obtained by any means, no more than 56 days after the scheduled 6-month follow-up time-point.

Secondary: 1. Valid response for WORKWELL trial primary outcome (yes/no) without reminder; 2. Number of reminders sent; 3. Time to response [or ceasing follow-up] (days); 4. Costs per participant retained.

Analysis plans

Baseline participant data, and the primary and secondary outcome measures will be summarised, using frequency (%), mean (SD) or median (IQR), as appropriate) both overall and by SWAT group allocation. For the analysis of the effect of the intervention, all randomised participants will be included in the analysis. Comparison of the primary outcome between the pre-notification letter group and the no pre-notification group will use binary logistic regression, including the randomised group factor and adjusting for stratification variables (WORKWELL trial treatment allocation; chosen mode of response). Odds ratios and 95% confidence intervals for the between-groups difference in proportions completing the questionnaire will be estimated, and presented in conjunction with descriptive statistics of the number and percentage of respondents in each group. Analysis of the corresponding secondary outcome (valid response for WORKWELL trial primary outcome without reminder) will be performed using the same method.

Time to response will be compared between the groups using Cox regression, adjusted for WORKWELL treatment allocation and chosen mode of response. Data will be presented as a hazard ratio and related 95% confidence interval; median time to response in each group will also be presented. For the analysis of the difference in costs per participant retained (i.e. with a valid response for WORKWELL trial primary outcome) between those randomised to pre-notification and those randomised to not be sent the pre-notification, costs will include the direct costs of printing the pre-notification letter, envelopes and postage, and the cost of staff time spent administering the mail out (for example filling and labelling envelopes for those who choose to receive questionnaires by post, sending emails to those who choose to receive questionnaires electronically). We will present a crude analysis of the ratio of the estimated between-groups difference in costs, divided by the corresponding difference in proportions providing valid responses for WORKWELL trial primary outcome.

A meta-analytic framework will be undertaken by the PROMETHEUS team to explore variability across different implementations of the pre-notification SWAT. Proportions of participants responding in each trial of a pre-notification card/letter/text intervention will be entered into a meta-analysis, and the heterogeneity of the intervention effect will be assessed using the I² statistic. If substantial heterogeneity is demonstrated (I² of 50% or greater), we will explore differences between trials that might explain that variation. The power of any such analyses may be limited if there are small number of trials, but in such an instance we will explore this issue qualitatively using data collected on the trial, the patient population, and the trial context.

Possible problems in implementing this SWAT

Recruitment to the host (WORKWELL) trial and the introduction of additional strategies to improve questionnaire response if there are poor response rates, which might diminish the effect of the intervention being assessed in this SWAT.

References

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Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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