SWAT 182: Impact of a return postage strategy on retention in randomised trials

Objective of this SWAT
1) To evaluate the effects of different types of return postage on retention in randomised trials that use a participant self-reported postal questionnaire
2) To evaluate the cost-effectiveness of different types of return postage on retention in randomised trials that use a participant self-reported postal questionnaire

Study area: Retention, Follow-up
Sample type: Participants
Estimated funding level needed: Low

Background
Retention is a common problem for randomised trials and many participants leave trials before trial completion, sometimes more than 20%. In the UK, 50% of trials have been found to have attrition above 11% (1, 2). Retention is important because poor retention rates lead to missing data which introduces bias and causes the trial to become underpowered. Thus, the effect detected for the tested intervention might not be believable or implementable. Attrition is a large contributor to research waste. If retention difficulties arise in a trial, the efforts to design, establish it and recruit to it are wasted. More importantly, participants' time is wasted with no return for their input.

The updated Cochrane review of retention strategies for clinical trials (3), made recommendations for future methodological research and prioritised this research into Categories, A, B and C, which include eight recommended interventions, in 2021. Category A covers interventions with multiple existing evaluations that currently provide low-certainty evidence but for which rigorous replication could upgrade the evidence to moderate or high certainty. One of these interventions is "Return postage strategies (e.g. such as free post versus second class stamp; high-priority mail stamp versus usual postage; and personal form) compared to usual practice for return postage". This SWAT protocol was developed to help researchers to contribute to the evidence base to establish the effects of various return postage strategies on retention in randomised trials.

Interventions and comparators
Intervention 1: Freepost business reply envelope provided to the trial participant.
Intervention 2: Pre-addressed return envelope on which there is a second class postage stamp provided to the trial participant.
Intervention 3: High priority mail stamp (at least higher than the comparator, e.g. first class versus second class) on the pre-addressed return envelope provided to the trial participant.
Intervention 4: "Personal format letter" in which the participant's mailing address and the return address are hand written and a traditional stamp is on the envelope provided to the trial participant.
Intervention 5: "Business format letter" in which the address is typed and the postage is affixed by a commercial stamp-machine on the return envelope provided to the trial participant.

Index Type: Method of Follow-up

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Retention rate, defined as the proportion of participants who return the follow-up questionnaire.
Secondary: 1) Cost-effectiveness (cost per participant retained for each comparison); 2) Questionnaire completeness (to be defined as appropriate to the host trial); 3) Number of days to return of the questionnaire; 4) Number of reminders sent to participants before completion of follow-up assessment; 5) Impacts of the retention strategy on all subsequent follow-up time points. Where possible, the effects of the strategies in different patient populations will be explored, including sex, age and ethnicity.

Analysis plans

Demographic characteristics, including sex, age, and ethnic group (if available), will be presented descriptively, as mean (standard deviation) or number (%), as appropriate. An 'intention-to-treat' analysis will be performed, with all randomised participants analysed in the SWAT group to which they were randomised. Any randomised participant who does not return the questionnaire for any reason (including participants who had died or were withdrawn from the host trial) will be categorised as 'No' for the primary outcome.

Primary outcome analysis:
Comparison of the questionnaire response rate between the SWAT groups using logistic regression. The regression model will include the randomised group factor and any stratification or minimisation factors (e.g. host trial intervention group). The between-groups difference will be presented as number (%) and as both adjusted absolute (i.e. risk difference) and relative (i.e. odds ratio or relative risk) effect estimates, with 95% confidence intervals from the logistic regression model.
Secondary outcome analysis
For questionnaire completeness, the analysis will be as above. The between-groups difference in time taken to return the questionnaire will be analysed using techniques suitable for time to response (event) data such as Kaplan-Meier curves, log-rank test or Cox regression (adjusted for stratification/minimisation factors). Time zero will be set as 'day before expected completion date' (equivalent to adding 1 to the time variable to avoid exclusion from the analysis set).

The incremental cost per retained participant will be calculated for the comparisons under evaluation as the difference in costs between the groups, divided by the difference between groups in return rates. Direct costs of the retention strategies, and indirect costs associated with administering the strategies and the comparators will be included.
The following sensitivity analyses will be performed for the primary analysis:
• Excluding participants who did/could not receive allocation as allocated
• Excluding participants who were retrospectively found to have died or withdrawn from host trial before the expected completion date.
Subgroup analysis may also be performed for key demographic subgroups (e.g. age group, gender) by adding interaction terms to the logistic regression or Cox regression model, where sample sizes are deemed sufficiently large.

Meta-analyses will include data from existing SWATs and will estimate differences in retention rates between the SWAT groups.

Possible problems in implementing this SWAT

References
1. Brunsdon D, Biesty L, Brocklehurst P, Brueton V, Devane D, Elliott J, et al. What are the most important unanswered research questions in trial retention? A James Lind Alliance Priority Setting Partnership: the PRioRiTy II (Prioritising Retention in Randomised Trials) study. Trials 2019;20:593.
2. Walsh M, Devereaux PJ, Sackett DL. Clinician trialist rounds: 28. When RCT participants are lost to follow-up. Part 1: Why even a few can matter. Clinical Trials 2015;12(5):537-9.
3. Gillies K, Kearney A, Keenan C, Treweek S, Hudson J, Brueton VC, et al. Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2021;(3):MR000032.

Publications or presentations of this SWAT design
Sharp L, Cochran C, Cotton SC, Gray NM, Gallagher ME, TOMBOLA group. Enclosing a pen with a postal questionnaire can significantly increase the response rate. Journal of Clinical Epidemiology 2006;59(7):747-54.
Kenton L, Dennis CL, Weston J, Kiss A. The effect of incentives and high priority mailing on postal questionnaire response rates: a mini-RCT (P 136). Clinical Trials 2007;4(4):446-7.
Dinglas VD, Huang M, Sepulveda KA, Pinedo M, Hopkins RO, Colantuoni E, et al. Personalized contact strategies and predictors of time to survey completion: analysis of two sequential randomized trials. BMC Medical Research Methodology 2015;15:5.

Examples of the implementation of this SWAT

Sharp L, Cochran C, Cotton SC, Gray NM, Gallagher ME, TOMBOLA group. Enclosing a pen with a postal questionnaire can significantly increase the response rate. Journal of Clinical Epidemiology 2006;59(7):747-54.
Kenton L, Dennis CL, Weston J, Kiss A. The effect of incentives and high priority mailing on postal questionnaire response rates: a mini-RCT (P 136). Clinical Trials 2007;4(4):446-7.
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People to show as the source of this idea: Frances Shiely, Katie Gillies
Contact email address: f.shiely@ucc.ie
Date of idea: 1/JUN/2021
Revisions made by:
Date of revisions: