SWAT 198: Impact of newsletters on participant retention in randomised trials

Objective of this SWAT
1) To evaluate the effect on participant retention of sending a newsletter, compared to not sending a newsletter, in randomised trials.
2) To evaluate the cost-effectiveness of sending a newsletter, compared to not sending a newsletter, in randomised trials.

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

Background
Attrition can threaten the validity of the results of randomised trials due to missing outcome data.[1] Unfortunately, retention can be challenging in many longitudinal studies, particularly those collecting self-report questionnaires. To improve the efficiency of trials, we need to identify and use strategies which are effective at improving participation retention.

Newsletters might be a method of maintaining participant engagement in a trial. However, the Cochrane review of retention strategies identified four studies (5622 participants) that compared the provision of a newsletter to no newsletter on trial retention and concluded that the certainty of the available evidence was very low, with a risk difference =-0% (95% CI -4% to 3%).[2] This highlights the need for further investigation of the use of newsletters as a retention strategy.

Interventions and comparators
Intervention 1: Newsletter designed to maintain contact with participants at any time between trial visits or activities, which might be in-person or remote (e.g. completion of a questionnaire by post). The mode of delivery for the newsletters might include paper newsletters sent by post or electronic newsletters sent by email or text message. The content might include images or text describing trial progress, participant testimony, study results or other work of the trial team. The content would not include participant-specific information (e.g. the individual's test results). The newsletter would be sent at one or more pre-specified timepoints (e.g. 6 months after each visit) and should be sent regardless of whether the participant had completed the preceding study activity unless they had withdrawn from the trial.
Intervention 2: No newsletter.

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 for whom outcome data are obtained at the activity following the date scheduled for the newsletter.
Secondary: (1) The cost per participant who completes outcome data; (2) Time to collection of outcome data (days from scheduled date); (3) Number of reminders sent to participants before completion of outcome data; (4) Impacts of the retention strategy on all subsequent follow-up time-points; and (5) Other outcomes, such as questionnaire completeness (e.g. primary outcome measure obtained) when data collection is via self-report questionnaire, to be defined as appropriate to the host trial.

Analysis plans
Descriptive statistics will be calculated for demographic characteristics including age, sex and ethnicity (where available). Categorical variables will be presented as frequency and percentage. Continuous variables will be presented as mean and standard deviation or median and interquartile range if skewed. An intention-to-treat analysis will be performed where all participants will be analysed according to the SWAT group to which they were randomised, regardless of whether the newsletter was sent or received or whether or not the participant had left the host trial. Any

randomised participant who does not provide outcome data for any reason (including participants who were deceased or withdrawn from the host trial) will be categorised as 'No' for the primary outcome. Where possible, the effects of the strategies in different patient populations will be explored, including sex, age and ethnicity.

Primary outcome analysis: Proportion of participants who complete the study activity following the date scheduled for the newsletter will be compared between the SWAT groups using logistic regression analysis. The model will include group allocation and any SWAT stratification factors (e.g. host group allocation). The between-groups difference will be presented as frequency and percentage, adjusted absolute effect estimate (i.e. risk difference) and relative effect estimate (i.e. odds ratio or relative risk) along with the 95% confidence interval. The following sensitivity analysis will be performed for the primary analysis:
- Excluding participants who did/could not receive their allocated intervention
- Excluding participants who were retrospectively found to have died or withdrawn from the host trial before the expected completion date.

Secondary outcome analysis: (1) The incremental cost per retained participant receiving a newsletter as the difference in costs between the groups divided by the difference between groups in retention rates. Direct costs of the retention strategies, and indirect costs associated with administering the strategies and the comparators will be included.
(2) The between-groups difference in time taken to collection of outcome data 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 SWAT 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).
(3) The average number of reminders sent for each group will be compared using logistic regression analysis. The model will include group allocation and any SWAT stratification factors (e.g. host group allocation) and be presented the same way as the primary outcome.
(4) The same analysis for the primary and above secondary outcomes will be repeated for each follow-up timepoint.
(5) Additional analysis should be undertaken according to the outcomes selected. For self-report questionnaires, the analysis of questionnaire completeness will be as for the primary outcome.

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 newsletter and no newsletter groups. Within the meta-analysis, remote self-completion of questionnaires by trial participants and face-to-face data collection should be evaluated in subgroups and a combined intervention effect should be presented only if it is deemed that the effects are homogeneous between subgroups.

Possible problems in implementing this SWAT
1. Email addresses of participants may be incorrect or the email service providers may block the newsletters. This would reduce the effect size of the newsletter and may limit identification of any true effect.
2. Participants may move and not receive the newsletter, similarly reducing any potential effect of the newsletter.
3. The content of the newsletter may influence its effectiveness but is difficult to standardise across host trials.
4. Study teams will need to ensure that all appropriate data sharing and communication regulations are met.

References
1. Dumville JC, Torgerson DJ, Hewitt CE. Reporting attrition in randomised controlled trials. BMJ 2006;332(7547):969-71. doi:10.1136/bmj.332.7547.969
2. Gillies K, Kearney A, Keenan C, et al., Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2021;(3):MR000032. doi: 10.1002/14651858.MR000032.pub3

Publications or presentations of this SWAT design

1. Goulao B, Duncan A, Floate R, et al. Three behavior change theory-informed randomized studies within a trial to improve response rates to trial postal questionnaires. Journal of Clinical Epidemiology 2020;122:35-41. doi: 10.1016/j.jclinepi.2020.01.018
2. Beasley M. MamMOTH trial. Personal communication in the Cochrane review cited above.
3. Mitchell N, Hewitt CE, Lenaghan E, et al. Prior notification of trial participants by newsletter increased response rates: a randomized controlled trial. Journal of Clinical Epidemiology 2012;65(12):1348-52. doi: 10.1016/j.jclinepi.2012.05.008
4. Rodgers S, Sbizzera I, Cockayne S, et al. A study update newsletter or Post-it® note did not increase postal questionnaire response rates in a falls prevention trial: an embedded randomised factorial trial. F1000Research 2019;7:1083. doi: 10.12688/f1000research.14591.2

Examples of the implementation of this SWAT

1. Goulao B, Duncan A, Floate R, et al. Three behavior change theory-informed randomized studies within a trial to improve response rates to trial postal questionnaires. Journal of Clinical Epidemiology 2020;122:35-41. doi: 10.1016/j.jclinepi.2020.01.018
2. Beasley M. MamMOTH trial. Personal communication in the Cochrane cited above.
3. Mitchell N, Hewitt CE, Lenaghan E, et al. Prior notification of trial participants by newsletter increased response rates: a randomized controlled trial. Journal of Clinical Epidemiology 2012;65(12):1348-52. doi: 10.1016/j.jclinepi.2012.05.008
4. Rodgers S, Sbizzera I, Cockayne S, et al. A study update newsletter or Post-it® note did not increase postal questionnaire response rates in a falls prevention trial: an embedded randomised factorial trial. F1000Research 2019;7:1083. doi: 10.12688/f1000research.14591.2

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