SWAT 181: What is the impact on participant retention when an electronic reminder is integrated into the design of a randomised trial?

Objective of this SWAT
1) To evaluate the effects of an electronic reminder, compared to no electronic reminder, on participant retention in randomised trials
2) To evaluate the cost-effectiveness of an electronic reminders, compared to no electronic reminder, on participant retention in randomised trials

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

Background
Attrition or non-response of participants, resulting in missing outcome data, is a serious issue in randomised trials, with the impact on trial validity being more serious with higher proportions of participants with missing outcome data.[1] Self-report questionnaires are commonly used for collecting participant outcome data in health services research.[2] However, the failure of participants to return completed questionnaires is a major drawback and low return rates impact adversely on study validity by introducing bias and reducing effective sample size.[2,3] Similar issues arise with other approaches to collection of outcome data, such as when it is collected by self-report or clinical assessment during a trial participant's clinic visit. It is therefore important to identify effective interventions to improve participant retention or, equivalently, reduce attrition.

A reminder is one approach to improving retention and is defined as a communication that is intended to be received after the target follow-up time-point for a participant is reached. The latest Cochrane review of retention interventions[3[identified three trials[4,5,6] that evaluated electronic reminders to assess whether they have an impact on participant retention, in terms of their response rate to a self-report questionnaire completed remotely by trial participants. No trials were found that had investigated the use of electronic reminders for other forms of participant follow-up, such as via clinic visits. The review concluded that there is currently low-certainty evidence for the benefits of reminders, but that rigorous replication could change this to moderate or high certainty. Therefore, the implementation of standardised SWATs featuring this intervention (versus a comparator of follow-up without electronic reminders) is a priority which could rapidly result in a recommendation for the future use of electronic reminders in randomised trials. Such SWATs could include not only trials for which outcomes are collected remotely via self-report questionnaires, but also when outcomes are collected by other means, such as evaluation by a clinician or questionnaire completion during a clinic visit.

Interventions and comparators
Intervention 1: Electronic Reminder
The 'test intervention' will be an electronic (or 'digital') reminder. The potential delivery mechanisms include telephone, email and web, and the 'system' for delivery of reminders may or may not be automated. The electronic reminder will be sent to any participant in the host trial who has provided the personal details (typically email address and/or mobile phone number) needed to deliver the electronic reminder. It will be sent at a specified time-point (e.g. 14 days) after the scheduled completion date of a participant self-report questionnaire if the questionnaire has not been returned by this time-point or if a participant fails to attend a clinic visit (or similar). Other strategies for maximising response rates are also allowable and may include non-electronic reminders at a later time than the scheduled electronic reminder. The electronic reminder(s) intervention will normally be implemented for each time-point in the schedule of assessments in the host trial protocol.
Intervention 2: No Electronic Reminder
The 'comparator' intervention will be 'No Electronic Reminder'. Other strategies for maximising retention are allowable and may include non-electronic reminders at a time subsequent to when the electronic reminders are scheduled for the 'test intervention' (for each 'assessment' time-point).

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.
Secondary: 1) Cost-effectiveness (cost per participant retained for electronic reminder compared to no reminder); 2) Time to collection of outcome data (days from scheduled date); 3) Number of reminders sent to participants before completion of follow-up assessment; 4) Impacts of the retention strategy on all subsequent follow-up time-points; 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.
Where possible, the effects of the strategies in different patient populations will be explored, including sex, age and ethnicity.

Analysis plans
Demographic characteristics, including age, sex 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 including all randomised participants analysed in the SWAT group to which they were randomised, regardless as to whether electronic reminders were sent or received. Any randomised participant who does not provide outcome data for any reason (including participants who had died or been withdrawn from the host trial) will be categorised as 'No' for the primary outcome.

Primary outcome analysis:
Comparison of the retention rate between the electronic reminders group and the no electronic reminders group will use logistic regression. The regression model will include the randomised group factor and any SWAT stratification or minimisation factors (e.g. host trial treatment 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:
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).

For self-report questionnaires, the analysis of questionnaire completeness will be as for the primary outcome.

The incremental cost per retained participant between the electronic reminder and comparator groups as the difference in costs between the groups, divided by the difference between groups in retention rates. In addition to the direct costs of providing electronic reminder push notifications (e.g. network charges), if an automated reminder system is used, it may also be necessary to include the cost of staff time spent designing and integrating the electronic reminder system into the host trial database system.
The following sensitivity analyses will be performed for the primary analysis:
• Excluding participants who did/could not receive allocation as allocated (e.g. due to missing or invalid electronic contact details).
• 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 and 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 intervention and comparator 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 treatment effect should be presented only if it is deemed that the effects are homogeneous between subgroups.

Possible problems in implementing this SWAT

1. In the case of a trial with an internal pilot, the SWAT is likely to be somewhat dependent on the success of the host trial progressing beyond the internal pilot. Should the host trial close after the internal pilot, the number of participants in the SWAT is likely be far lower than originally planned.
2. This SWAT will be more difficult to implement and be less efficient (and more costly) if not delivered via a fully-online, programmable data collection system. Moreover, findings from SWATs not delivered via a fully-online, programmable data collection system may be of limited generalisability to trials in which the intervention would be delivered via a fully-online, programmable data collection system.
3. There is an implicit assumption that all or the majority of trial participants who participate in the host trial will be able to utilise technology to receive electronic reminders.

References

1. Dumville JC, Torgerson DJ, Hewitt CE. Reporting attrition in randomised controlled trials. BMJ 2006;332(7547):969-71.
2. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018;(2):MR000013.
3. Gillies K, Kearney A, Keenan C, et al. Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2021;(3):MR000032.
4. Ashby R, Turner G, Cross B, et al. A randomized trial of electronic reminders showed a reduction in the time to respond to postal questionnaires. Journal of Clinical Epidemiology 2011;64:208-12.
5. Starr K, McPherson G, Forrest M, Cotton SC. SMS text pre-notification and delivery of reminder e-mails to increase response rates to postal questionnaires in the SUSPEND trial: a factorial design, randomised controlled trial. Trials 2015;16:295. Accessed 29 July 2021.
6. Keding A, Brabyn S, MacPherson H, et al. Text message reminders to improve questionnaire response rates. Journal of Clinical Epidemiology 2016;79:90-5.

Publications or presentations of this SWAT design

1. Ashby R, Turner G, Cross B, et al. A randomized trial of electronic reminders showed a reduction in the time to respond to postal questionnaires. Journal of Clinical Epidemiology 2011;64:208-12.
2. Starr K, McPherson G, Forrest M, Cotton SC. SMS text pre-notification and delivery of reminder e-mails to increase response rates to postal questionnaires in the SUSPEND trial: a factorial design, randomised controlled trial. Trials 2015;16:295.
3. Keding A, Brabyn S, MacPherson H, et al. Text message reminders to improve questionnaire response rates. Journal of Clinical Epidemiology 2016;79:90-5.

Examples of the implementation of this SWAT

1. Ashby R, Turner G, Cross B, et al. A randomized trial of electronic reminders showed a reduction in the time to respond to postal questionnaires. Journal of Clinical Epidemiology 2011;64:208-12.
2. Starr K, McPherson G, Forrest M, Cotton SC. SMS text pre-notification and delivery of reminder e-mails to increase response rates to postal questionnaires in the SUSPEND trial: a factorial design, randomised controlled trial. Trials 2015;16:295.
3. Keding A, Brabyn S, MacPherson H, et al. Text message reminders to improve questionnaire response rates. Journal of Clinical Epidemiology 2016;79:90-5.

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