SWAT 199: Impact of monetary rewards added to both trial arms on participant retention in a randomised trial

Objective of this SWAT
1) To evaluate the effects of different amounts of a monetary award on participant retention in randomised trials
2) To evaluate the cost-effectiveness of different amounts of a monetary award on participant retention in randomised trials

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

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 tools for collecting participant outcome data in health services research.[2] However, the failure of participants to return completed questionnaires is a major drawback of such methods and low return rates impact adversely on study validity by introducing bias and reducing effective sample size.[2,3] Similar issues occur when other approaches to collection of outcome data are used, such as when this is collected as part of a clinic visit by a trial participant, whether as self-report or clinical assessment. It is important to identify effective interventions to improve participant retention or, equivalently, reduce attrition.

The addition of a monetary reward at least at the first follow-up time point for the primary outcome is one approach that may improve the retention of participants. Monetary rewards are conditional on behaviour and are intended to be received when a participant has completed a follow-up procedure that aims to collect data (e.g., self-report information, weight measurements, blood tests).The latest version of the Cochrane methodology review of retention interventions[3] identified one trial[4] that evaluated the addition of a monetary reward to both groups in a randomised trial, delivered either with the prenotification or with the reminder letter, to assess the impact on participant retention (response rate to a self-report questionnaire completed remotely by trial participants). The Cochrane methodology review identified no trials that investigated the use of monetary rewards for other forms of participant follow-up, such as via clinic visits. It concluded that there is merit in conducting replication of interventions evaluated in single studies, especially where the single studies have moderate-certainty evidence and potentially large overall effect sizes, such as the addition of monetary rewards to both trial arms.

The implementation of standardised SWATs featuring this intervention in both randomised groups in a trial have been categorized as relatively easy to integrate into a host clinical trial. However, an intervention of this type may be relatively costly if the host trial has numerous assessment time points for the primary outcome and monetary rewards are provided at all time points associated with the primary outcome. 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: Monetary reward 1 (Value X) The provision of this monetary reward should use methods suitable for the host trial (e.g. by post, web-link, email or mobile phone message). The monetary reward will be sent to participants in the host trial who have completed the target follow-up assessment (e.g. return of a completed questionnaire or attendance at a clinical assessment). Information about the monetary reward will be sent via similar means before the target date for the assessment, including details about the monetary reward being provided after the target follow-up assessment is completed. The monetary reward intervention will normally be implemented for each time-point included in the schedule of assessments in the host trial that provides data for the primary outcome.
Intervention 2: Monetary reward 2 (Y, value less than X). This intervention will be administered in the same way as intervention 1.

Other strategies for maximising retention rates are also allowable provided they are the same across both SWAT groups.

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 for the target assessment time-points for which a monetary reward was provided.
Secondary: 1) Cost-effectiveness (cost per participant retained for monetary award X compared to monetary award Y); 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) 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 group to which they were randomised, regardless as to whether their allocated monetary reward was sent or received. 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.

Primary outcome analysis: Comparison of the retention rate between the two monetary award groups 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 or 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 in the monetary reward X group compared to the monetary award Y 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 monetary rewards and the cost associated with pre-notification, it may also be necessary to include the cost of staff time spent on designing and integrating the system into the host trial database system.

The following sensitivity analyses will be performed for the primary analysis: 1) Excluding participants who did or could not receive allocation as allocated (e.g. due to missing or invalid electronic contact details); 2) Excluding participants who were retrospectively found to be deceased 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 monetary reward groups. Within the meta-analysis, remote self-completion of questionnaires by trial participants and face to face data collection will be evaluated in subgroups and a combined treatment effect should be presented 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 implementation of the SWAT is likely to be 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 within 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 such a system may be of limited generalisability to trials in which the intervention would be delivered in that way.
3. Uptake of monetary rewards delivered by electronic notification means, voucher link codes and QR scans will depend on trial participants having access to the appropriate technology and being conversant with the software needed to receive their monetary reward.

References

1. Dumville JC, Torgerson DJ, Hewitt CE. Reporting attrition in randomised controlled trials. BMJ 2006;332(7547):969-971. doi: 10.1136/bmj.332.7547.969
2. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018;(2):MR000013. doi: 10.1002/14651858.MR000013.pub6
3. 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.
4. Hardy P, Bell JL, Brocklehurst P, Epidural and Position Trial Collaborative Group. Evaluation of the effects of an offer of a monetary incentive on the rate of questionnaire return during follow-up of a clinical trial: a randomised study within a trial. BMC Medical Research Methodology 2016;16:82. doi 10.1186/ s12874-016-0180-9

Publications or presentations of this SWAT design

1. Hardy P, Bell JL, Brocklehurst P, Epidural and Position Trial Collaborative Group. Evaluation of the effects of an offer of a monetary incentive on the rate of questionnaire return during follow-up of a clinical trial: a randomised study within a trial. BMC Medical Research Methodology 2016;16:82. doi: 10.1186/ s12874-016-0180-9

Examples of the implementation of this SWAT

1. Hardy P, Bell JL, Brocklehurst P, Epidural and Position Trial Collaborative Group. Evaluation of the effects of an offer of a monetary incentive on the rate of questionnaire return during follow-up of a clinical trial: a randomised study within a trial. BMC Medical Research Methodology 2016;16:82. doi: 10.1186/ s12874-016-0180-9

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