

SWAT 25: Two-by-two factorial randomised trial to evaluate strategies to improve follow-up in a randomised prevention trial

Objective of this SWAT

To evaluate the effects of a text message notification on questionnaire response and timing of monetary payment for a home/clinic visit in a randomised prevention trial.

Study area: Follow-up, Outcomes, Retention

Sample type: Participants

Estimated funding level needed:

Background

Failure to collect outcome data in randomised trials is inefficient and can result in bias and loss of statistical power. A great deal of effort is often expended in recruiting participants to trials. Ensuring that as many of these participants as possible are retained and provide outcome data can greatly improve research efficiency and minimise the risk of bias resulting from incomplete data.

A Cochrane Methodology Review has reported on the effect of strategies to improve retention in randomised trials [1]. Most of the 38 included studies were concerned with collection of outcome data via postal or electronic questionnaires rather than return of participants to study sites. There was evidence that monetary incentives (for postal questionnaires, relative risk (RR): 1.18, 95% CI: 1.09-1.28) and offer of monetary incentives (for electronic questionnaires, RR 1.25, 95% CI: 1.14-1.38) were effective in increasing response to questionnaires, but there were no studies that compared an upfront monetary incentive with an incentive conditional on questionnaire completion. The review concluded with a plea for the conduct of more well planned, adequately powered, and better reported evaluations of strategies to increase retention in trials. The primary aim of this SWAT is to estimate the effectiveness of two strategies for participant retention on the collection of primary outcome data in the host trial (BEEP). This is a randomised controlled trial to determine whether application of emollient from birth can prevent eczema in high risk children, which includes a choice between the use of a postal or electronic questionnaires for the follow up at 3, 6 and 12 months. The SWAT uses a two-by-two factorial design to allow the simultaneous comparison of the effects of a monetary payment and advance contact with the study participants by SMS text.

Interventions and comparators

Intervention 1: Monetary payment. A £10 voucher included with the invitation to attend the 24 month follow up versus a £10 voucher to be given after the 24 month follow up is due (regardless of whether this follow-up is completed).

Intervention 2: Contact by SMS versus not, prior to sending questionnaires at 3, 6 and 12 months.

Index Type: Incentive, Method of Follow-up

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: There are two co-primary outcomes:

(1) Collection of the BEEP trial primary outcome at 24 months during a home or clinic visit with a research nurse.

(2) Collection of data via the chosen method of questionnaire (postal or electronic) at interim follow up times (3, 6 and 12 months).

Secondary: (1) Time to questionnaire completion.

(2) Number of reminders required to obtain questionnaire completion.

Analysis plans

We plan to conduct one interim analysis of the data for each of the two co-primary outcomes, for the first 400 participants in the host trial. If there is strong evidence of an effect, one or both of the factorial interventions will then be applied for the remainder of the host trial, otherwise the embedded randomised trial will continue until the end of the host trial. Analyses will include appropriate descriptive analyses, and between-group comparisons for each retention strategy using multivariable logistic regression models. Interaction between strategies for the 24 month

follow up for the BEEP trial primary outcome will be investigated by inclusion of an interaction term in the regression model. In the absence of any evidence for such an interaction, the main effects for each of the factorial elements will be estimated, along with their 95% confidence intervals.

Possible problems in implementing this SWAT

Additional strategies to improve questionnaire response may be introduced if the response rates are poor. The effect of SMS contact prior to sending the questionnaire may be diminished if additional strategies are introduced.

References

1. Brueton VC, Tierney J, Stenning S, Harding S, Meredith S, Nazareth I, et al. Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2013; (12): MR000032.

Publications or presentations of this SWAT design

Bradshaw LE, Montgomery AA, Williams HC, Chalmers JR, Haines RH. Two-by-two factorial randomised study within a trial (SWAT) to evaluate strategies for follow-up in a randomised prevention trial. *Trials* 2020;21:529.

Examples of the implementation of this SWAT

People to show as the source of this idea: Alan Montgomery, Hywel Williams, Lucy Bradshaw, Joanne Chalmers

Contact email address: lucy.bradshaw@nottingham.ac.uk

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Revisions made by:

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