

SWAT 77: TYPhoon (Thank You and Pre Notification) SWAT Protocol: sending pre-notification emails to trial participants before outcome measurement

Objective of this SWAT

To evaluate the effect on retention of sending a combined thank you and pre-notification email to trial participants before the next trial outcome measurement point.

Study area: Retention

Sample type: Participants

Estimated funding level needed: Low

Background

Many trials struggle with trial retention and a recent UK study found that the median loss-to-follow up in a sample of 151 trials was 11%.^[1] Reminders are generally an effective way of increasing response rates to questionnaires and there is some evidence that pre-notification (contacting a participant to say that they will be sent a questionnaire soon) is of benefit, although it is not high certainty evidence.^[2] However, there is no clear evidence that pre-notification is effective for trial retention.^[3]

This SWAT will tackle this uncertainty, drawing on the fact that electronic methods of contacting participants and capturing data generally save money and trial resources, compared to the use of paper forms and telephoning participants. The SWAT is embedded in the UKSTAR study, which collects data from participants at 3, 6 and 9 months after randomisation using a questionnaire sent directly to participants, either via an online link in an email or SMS text message, by post, or by telephone.

It may be considered intuitively that all participants should receive a courteous acknowledgement for their participation. However, it is important to establish in a SWAT whether such emails sent as pre-notifications have a beneficial effect on retention and whether there can be a financial and quality benefit to introducing them in trials that adds to the courteous treatment of trial participants. Separately from the SWAT, the host study will implement a courtesy thank you communication to all participants after their final study time-point, whether or not they have completed questionnaires at the various time-points.

Interventions and comparators

Intervention 1: A combined thank you and pre-notification email (called: "pre-notification email") sent around 2 weeks after a participant has completed a 3 month or a 6 month questionnaire. (Because of the wide time range during which UKSTAR responses are received, this email may be between one and 10 weeks before the next study time-point (i.e. the 6 month or 9 month follow-up questionnaire, respectively). Emails are sent to participants who have supplied an email address, irrespective of whether they completed the earlier questionnaire through an email link, mobile link, on paper or by phone.

Intervention 2: No pre-notification email.

Index Type: Incentive

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Proportion of participants who provide data at the next study time-point by electronic means (email or mobile link).

Analysis plans

The primary analysis is the difference in response rate by electronic means (email or mobile link) between those receiving the pre-notification email and those receiving no incentive.

Possible problems in implementing this SWAT

The main barrier in implementing this SWAT relates to the staff time needed to prepare and send the email pre-notification. However, sending the emails can be added to a weekly scheduled follow-up administration in UKSTAR.

PLEASE NOTE:- This SWAT is not being implemented as an embedded study within the UKSTAR trial, due to delays in approvals and implementation.

References

1. Walters SJ, Bonacho dos Anjos Henriques-Cadby I, Bortolami O, Flight L, Hind D, Jacques RM, et al. Recruitment and retention of participants in randomised controlled trials: a review of trials funded and published by the United Kingdom Health Technology Assessment Programme. *BMJ Open* 2017;7(3):e015276.
2. Edwards PJ, Roberts I, Clarke MJ, DiGuseppi C, Wentz R, Kwan I, et al. Methods to increase response to postal and electronic questionnaires. *Cochrane Database of Systematic Reviews* 2009;(3):MR000008.
3. Brueton VC Tierney J, Stenning S, Harding S, Meredith S, Nazareth I, Rait G. Strategies to improve retention in randomised trials. *Cochrane Database of Systematic Reviews* 2013;(12):MR000032.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Susan Wagland

Contact email address: susan.wagland@ndorms.ox.ac.uk

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Revisions made by: Susan Wagland

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