SWAT 221: What is the effect of time critical wording of text message reminders on completion of electronic participant case report forms (CRFs)?

Objective of this SWAT
This SWAT aims to evaluate the effects of time critical SMS wording on the completion of responses to electronic questionnaires in the DIDACT randomised trial.

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

Background
Attrition affects most randomised trials and it varies across time periods, data sources, and outcomes. Self-reported questionnaires are a common data collection method. They can be received postally or electronically, and a wide range of strategies have been tested to improve response rates across many sectors [1]. Many clinical trials use self-reported questionnaires and increasing response rates and data completeness is essential for maximising their statistical power and for minimising bias, because this can affect the generalisability and validity of results. A systematic review has looked specifically at methods used to reduce attrition in clinical trials by increasing response to postal questionnaires [2]. There is evidence that giving participants a deadline versus no deadline increases the response rate but few trials have tested the effects of time critical wording in a SMS electronic prompt to increase response rate with electronic questionnaires. As health research moves towards more electronic data capture, there is a need to focus on how to reduce attrition and increase response rates using this mode of data collection.

This SWAT will be embedded in a host randomised trial called DIDACT (**DI**splaced **D**ist**Al C**lavicle Trial, ISRCTN11981704), which is comparing surgery versus sling immobilisation for adults with a displaced fracture of the distal clavicle. The trial will use Research Electronic Data Capture (REDCap), which is a secure browser-based web application to collect participant responses to questionnaires. We will undertake a SWAT to evaluate the effect of time critical wording of a SMS reminder on the return of electronically completed questionnaires at 6 weeks, 3, 6 and 12 month after randomisation. For all follow-up data collections, two email reminders (after 2 and 4 weeks) will be sent to non-responding participants, with a final attempt to obtain data by a telephone/video call at 6 weeks. Our population for the SWAT will be all participants in DIDACT who provided an email address at randomisation into that host trial with the intention of completing the follow-up questionnaires online.

Interventions and comparators
Intervention 1: Time critical text message sent on the day the request to complete questionnaires is emailed to the participant, with the same text message at each time-point. The text will say "Collarbone study: You had an email today about a survey. Your answers are important; so please try to complete it within the next seven days. Thanks."
Intervention 2: Standard text message sent on the day the request to complete questionnaires is emailed to the participant, with the same text message at each time-point. The text will say "Collarbone study: You had an email today about a survey. Your answers are important; so please try to complete it as soon as you can. Thanks."

Index Type: Retention

Method for allocating to intervention or comparator
Participants recruited into the host trial will be randomised 1:1 to receive either: 1) a SMS reminder with time critical wording (intervention) or 2) a SMS reminder with standard wording (control) at each follow-up time point. We will use block randomisation stratified by the host trial treatment arm using randomly varying block sizes to avoid imbalance between the SWAT intervention arms. Randomisation for the SWAT will take place at the same time as randomisation for the host trial. The allocation sequence will be generated by a statistician at York Trials Unit (YTU), who is not involved with the recruitment or follow-up of participants.

Outcome measures
Primary: Questionnaire response rate at the host trial primary endpoint (12 months), calculated as the number of patients who return the 12-month questionnaire divided by the number of patients sent the questionnaire.
Secondary: (1) Questionnaire response rate as calculated above at 6 weeks, 3 and 6 months follow-up. (2) Time to response (defined as the number of days between the text message being sent and the questionnaire recorded as being returned) at each time-point. (3) Whether a reminder was required (i.e. REDCap email reminder at 2 or 4 weeks, or a telephone/video reminder at 6 weeks) at each time-point. (4) Completeness of the primary outcome (number of patients with a complete DASH score divided by number of patients returning a questionnaire) at each time-point.

Sample size calculations
The host trial (DIDACT) aims to recruit 214 participants. All participants who agree to complete the questionnaires electronically as part of the DIDACT trial will be eligible to be randomised into this SWAT. There are no additional inclusion or exclusion criteria. Any participant who subsequently withdraws fully from the host trial, withdraws from SMS contact, or dies will be excluded from the analysis at the time-point corresponding to their withdrawal or death.

As this is an embedded SWAT, the sample size is constrained by the number of participants recruited and randomised into the host trial. The host trial (DIDACT) aims to recruit 214 participants. We anticipate 5% of participants will need the questionnaires in an alternative language or don't have a mobile number and email address and therefore will be collected postally. In addition, it is estimated that 20% of all participants will not complete questionnaires by the 12-month follow-up (primary end-point). With this sample size (n=162, 5% loss to follow-up in an alternative format and 20% attrition), we would have 80% power to detect a 16% increase in response rate between the standard wording SMS reminder (control) group and the time critical wording SMS reminder (intervention) group assuming a response rate of 80% in the standard wording SMS reminder group, using a two-sided alpha of 0.05. As with all retention SWATs, we are limited by the sample size of the host trial. With a sample this size, a signal of an effect may be shown but it is unlikely to demonstrate a statistically significant result. Therefore, we plan to include this SWAT in a meta-analysis of the most current systematic review published about SWATs on retention.

Analysis plans
This SWAT will be reported according to the CONSORT guidelines for clinical trials. A CONSORT diagram will be produced to show the flow of participants through the SWAT, providing reasons for non-participation and withdrawal where available.

Baseline characteristics of the participants included in the SWAT and the host trial will be compared descriptively, by group. Baseline data of participants included in the SWAT will be summarised by group, as randomised and as included in the primary analysis. Continuous variables will be summarised using a mean and standard deviation, and categorial variables will be summarised using a count and percentage. No formal baseline testing for imbalance will be conducted.

Outcome analyses will be conducted following the principles of intention-to-treat with participant's outcomes analysed according to their original, randomised SWAT group irrespective of deviations based on noncompliance. Any deviations will be reported descriptively (e.g. consented to electronic data collection but then switched to providing it by paper).

The primary outcome, the difference in response rate at 12 months between those receiving the time critical wording SMS reminders and those receiving standard wording SMS reminders will be analysed via logistic regression adjusting for host trial allocation, age at randomisation (<65 or ≥65 years) as a fixed effect and site as a random effect. The odds ratio (OR) and associated 95% confidence interval (CI) and p value will be reported. This will include reporting the OR and associated 95% CI for age (<65; ≥65) and treatment allocation to assess whether these variables predict questionnaire return. The secondary outcomes of response to the 6 week, 3 and 6 month questionnaires, need for a reminder, and completeness of the primary outcome will be similarly analysed.

The secondary outcome of time to questionnaire return will be analysed using a Kaplan-Meier curve and a Cox Proportional Hazards model with a shared centre frailty adjusting for age (<65; ≥65) and DIDACT treatment allocation. The hazard ratio, 95% CI and p-value will be reported.

Questionnaire return times will be censored at each time-point for the time to event analyses. If a questionnaire is completed on or before the date it was due, return time will be recorded as 0.1.

Return rates for each time-point will be compared descriptively between participants in the SWAT and participants who are in the host trial.

Our population for the SWAT is all participants in the host trial who provided an email address at randomisation into that trial with the intention of completing questionnaires online. However, some of these participants might switch their preference from online to postal follow-up before being sent their questionnaires and these people would not be sent their allocated SMS message. We will conduct a CACE analysis to investigate the impact of receiving the allocated SMS message; which will include all SWAT participants but will account for whether or not the allocated text message was sent.

Possible problems in implementing this SWAT
REDCap will send out email reminders after 2 and 4 weeks, and someone from YTU will conduct a telephone or video follow-up reminder after 6 weeks if a participant does not return their questionnaire, which may diminish the effect of the text message intervention. (2) Fewer DIDACT patients than expected might opt for electronic questionnaire collection, which will reduce the sample size for the SWAT.

References
1. Edwards PJ, Roberts I, Clarke MJ, et al. Methods to increase response to postal and electronic questionnaires. Cochrane Database of Systematic Reviews 2023;(11):MR000008.

2. Gillies K, Kearney A, Keenan C, et al. Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2021;(3):MR000032.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Dr Stephen Brealey, Mrs Sam Swan, Mrs Kalpita Baird, Dr Hannah Rodrick, Ms Fi Rose, Mrs Maggie Barratt
Contact email address: ytu-didact@york.ac.uk
Date of idea: 03/FEB/2023
Revisions made by:
Date of revisions: