SWAT 195: Pre-notification of trial participants by newsletter to improve response rates to questionnaires

Objective of this SWAT
To assess the effects of pre-notification using a newsletter to increase response rates to questionnaires in the RAPSODI-UK randomised trial.

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

Background
Attrition in randomised trials can affect the statistical power of the analyses and introduce bias. It is a particular challenge in studies where the primary outcome is patient-reported and reliant on patients returning a postal questionnaire. Response rates in the older population are estimated to be 60% or less, and this is especially relevant for the RAPSODI-UK trial (ISRCTN12216466), given that participants will be aged 60 and older. Therefore, testing methods to improve response rates of postal questionnaires in an older population are highly applicable to this trial, and to health research more widely.

RAPSODI-UK is comparing anatomic total shoulder replacements with reverse total shoulder replacements in patients who have been diagnosed with osteoarthritis of the shoulder, who are aged 60 and older with an intact rotator cuff. Baseline data collection will be done in person at a routine clinic appointment or remotely, but follow up data (3, 6, 12, 18 and 24 months) will be collected via postal questionnaires sent to the patient's address (or collected in clinic where feasible).

We will undertake a SWAT to test whether sending newsletters to participants six weeks before the 18 and 24-month follow ups (24 months is the primary endpoint) can improve the return of questionnaires at these two time points. This is based on a registered SWAT (SWAT 28) from the SCOOP trial.[1]

Interventions and comparators
Intervention 1: Newsletter sent approximately six weeks before participants are due to receive their 18-month and 24-month questionnaires. The newsletter will be an A4 booklet providing an update on the host trial's progress and a reminder about the importance of returning questionnaires.
Intervention 2: Same newsletter sent eight weeks after the questionnaire is sent (regardless of whether the questionnaire is returned), unless the participant withdraws beforehand.

Index Type: Method of Follow-up, Participant Information

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Overall questionnaire response rate at 24 months, calculated as the number of patients who return the 24-month follow-up questionnaire (primary endpoint) divided by the number of patients who were sent a questionnaire.
Secondary: (1) Overall questionnaire response rate at 18 months, calculated as the number of patients who return the 18-month follow-up questionnaire divided by the number of patients who were sent a questionnaire; (2) whether a reminder was required (i.e. 2 or 4-week postal reminder, 6-week telephone/video reminder); (3) completeness of the primary outcome (number of patients with a complete primary outcome divided by number of patients returning a questionnaire); and (4) time to response (length of time taken to return the questionnaire).

Analysis plans
The host trial (RAPSODI-UK) aims to recruit and randomise 430 participants. Assuming that 5% withdraw from follow-up before the 24-month time point, questionnaires would be sent to 408 (204 in each SWAT group). This would give 80% power at the 5% significance level to detect a

difference in return rates of at least 9%, assuming a control rate of 85%. As with all retention SWATs, we are limited by the sample size of the host trial. Therefore, we plan to combine this SWAT with the SCOOP study and other related SWATs in a meta-analysis.

Baseline characteristics of the participants of the SWAT and the host trial will be compared descriptively.

The primary outcome will be analysed using logistic regression adjusting for age (60-69; 70+ years), gender and RAPSODI-UK treatment allocation. The odds ratio (OR) and associated 95% confidence interval (CI) and p-value will be reported. This will include reporting the OR and 95% CI for age and gender to assess whether these variables were predictors of questionnaire return. The secondary outcomes of response to the 18-month questionnaire, 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 regression adjusting for age (60-69; 70+ years), gender and RAPSODI-UK treatment allocation. The incidence rate ratio, 95% CI and p-value will be reported. Questionnaire return times will be censored at 3 months (91 days) for the time to event analyses.

Return rates will be compared descriptively between participants recruited into the SWAT and participants who were recruited into the host trial before the SWAT was initiated.

Possible problems in implementing this SWAT
Pre-notification with a newsletter may increase the cost of the study, and therefore, if the absolute difference in response rates is small, might not be a cost-effective solution for low additional return rates.

References
1.
www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/FileStore/Filetoupload,604630,en.pdf

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Prof Joseph Dias and Prof Ian Trail
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Date of idea: 9/JAN/2023
Revisions made by:
Date of revisions: