Promoting group identity to improve questionnaire return rates in a multicentre randomised trial.

Study Within a Trial (SWAT) Analysis Plan

Protocol /Study number:	20131DMcA-AS
Trial registration number:	ISRCTN17683568
SWAT registration numbers	SWAT 51
	ISRCTN16675252
Funder and number	National Institute for Health and Care Research Health Technology Assessment (NIHR HTA) Programme; NIHR130454
Sponsor:	Belfast Health and Social Care Trust, Northern Ireland
REC and number:	Yorkshire & The Humber - Leeds East Research Ethics Committee; 21/YH/0234
Protocol version:	Final 3.0 06/10/2023
SWAT analysis plan version:	Final 1.0 16/10/2024
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Background and study aims

When participants stay involved in a clinical trial after their treatment has finished, it allows researchers to collect important follow-up information about the effects of the trial treatments. Unfortunately, some participants drop out of the trial before the end. The reasons for this are poorly understood and there is uncertainty about the effects of interventions that might reduce or prevent it [1]. High levels of patient dropout are a particular problem in clinical trials that need to follow-up patients who were treated in critical care. This may be because participants are recruited when they are unconscious and lack capacity, or if they do not understand how important it is for the trial to collect information about their health several months after they have been discharged from critical care. According to self-categorisation theory [2], if a person identifies as a member of a particular group, they are more likely to cooperate and pursue the joint interests of the group. By applying this theoretical framework to clinical trials, it may be possible to influence participant retention. The aim of this Study Within a Trial (SWAT) [3] is to determine the effect of actively promoting group identity for participants using theory-informed study materials consisting of an adapted trial logo, thank you cards, a promotional item and letters. The resource use associated with delivering the SWAT (e.g. additional study materials, promotional items, and trial team time input) will be prospectively recorded.

Design

A randomised trial embedded within the MARCH trial. This host trial is a 2x2 factorial randomised trial testing the effects of two mucoactives (carbocisteine and hypertonic saline) for critical care patients with acute respiratory failure.

Participant eligibility

In order to take part in the SWAT, participants enrolled in the MARCH trial must have capacity, given consent to continue participation in the MARCH trial, and been discharged from hospital.

Outcome measures

Primary outcome measure

Proportion of participants in each SWAT group who return at least one of the two 6-month questionnaires for the MARCH trial.

Secondary outcome measures

1. Group identification at six months post-randomisation measured using the single-item social identification instrument [4] and a study-specific group membership Likert scale question.

2. Total costs associated with embedding the SWAT in the host trial, recorded via a spreadsheet of the resources (e.g. trial team time input, consumables) and related costs associated with the SWAT, which will be maintained prospectively over the study period by the trial team.
3. Cost per additional questionnaire returned.

Sample size

This embedded randomised trial is restricted to the maximum size of the host trial (n=1956) and no formal sample size calculation has been performed.

Randomisation

Participants will be randomised (1:1:1, using mixed block sizes) to one of three arms comprising two group identity intervention arms (S1 and S2) and one control arm (S3). The randomisation process will be separate from the host trial randomisation. The MARCH trial statistician will generate the SWAT randomisation sequence using NQuery Advisor. Participants in S1 and S2 will be sent the same correspondence (thank you card, letter and questionnaire incorporating theory-informed wording and adapted trial logo), but S2 will also be sent a promotional item (reusable coffee cup). Participants allocated to the SWAT control arm (S3) will be sent the standard MARCH trial follow-up correspondence (letter and questionnaire incorporating standard trial follow-up wording and standard trial logo) and will not be sent a thank you card or reusable coffee cup. The wording of the SWAT correspondence was designed in consultation with the MARCH Patient and Family Advisory Group, consisting of former critical care patients and family members.

Analysis of outcomes

Number and proportion of participants returning one or both of the final MARCH questionnaires will be presented by SWAT group. We will compare proportions returning at least one of these questionnaires using logistic regression to estimate the odds ratio (95% confidence interval). Our primary analysis will be a comparison of the combination of S1 and S2 versus S3 to assess the impact of increasing the salience of the MARCH trial as a “group” on the return rate. We will also compare of S2 versus S1 to assess the additional impact on the return rate of sending a promotional item.

Mean (95% confidence interval) group identification scores will be presented by SWAT group and compared using linear regression. Mean SWAT costs (95% confidence intervals) will be presented by SWAT group and analysed using linear regression. The cost per additional

questionnaire returned will be calculated by dividing the incremental cost of embedding the SWAT by the incremental number of questionnaires returned at the end of the study.

For the analyses of the effects on group identification and costs, we will compare the combination of S1 and S2 versus S3 to assess the impact of increasing the salience of the MARCH trial as a "group". We will compare S2 versus S1 to assess the additional impact of sending a promotional item on group identification and costs. We will also compare S1 versus S3 and S2 versus S3 separately, to show the costs per additional questionnaire returned of each of the two strategies separately.

All analyses will be adjusted for participant's baseline age and APACHE II score.

Sensitivity analyses

We will repeat the above logistic and linear regressions including the host trial intervention group as a potential confounding variable.

References

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4. Postmes T, Haslam SA, Jans L. A single-item measure of social identification: reliability, validity, and utility. British Journal of Social Psychology 2013;52(4):597-617.