SWAT 223: Impact of additional trial site training on managing participation changes and of participant information after stopping participation on the availability of primary outcome data

Objective of this SWAT
To establish whether specific site staff training about managing participation changes in trials and/or better informing of trial participants when they change their level of participation increase the proportion of participants with primary outcome data available for primary analysis.

Study area: Retention, Follow-up, Data Quality
Sample type: Participants, Healthcare Professionals, Sites in a Cluster Randomised Trial
Estimated funding level needed: Medium

Background
Participants in clinical trials have the right to withdraw their consent and stop taking part at any time. In many trials, it is possible for them to stop some aspects of participation (e.g. receiving trial intervention or attending trial-specific clinic visits) while continuing others (e.g. provision of primary outcome data). Evidence about why people stop taking part indicates it is often more to do with the burden of participating and practical factors, rather than because they no longer support the research [1-3]. Therefore, if participants are given the chance to continue contributing to a trial by providing outcome data but with less time commitment, they might be likely to accept this arrangement. There is, however, a persistent view – perhaps reinforced by language used in rules and regulations about research ethics – of 'withdrawal' in clinical trials as a binary phenomenon (i.e. each participant is either taking part or has withdrawn). This misconception, along with sensitivities around consent and its withdrawal, may prevent participants being offered a choice to continue contributing with less commitment.

This Study Within a Trial (SWAT) is aimed at both participants and staff at recruiting trial sites (i.e. those who are in direct contact with participants and would be involved in discussing their participation with them). A staff training intervention (randomised at site level) would aim to help recruiters to understand the possible complexity around participation changes and give them confidence to manage situations for the good of participants and trials. This might mean that site staff feel more equipped to explain participants' choices to them, which may lead to more participants accepting reduced participation, rather than stopping altogether, and a greater proportion of primary outcome data being available for analysis.

An information intervention for participants (randomised at individual participant level) would be given after a participant decides to stop or significantly reduce their participation. This would confirm how their participation would change (i.e. which elements had stopped and which would continue). This additional clarity might make it more likely that participants are properly involved in decisions about how their involvement in a trial will change, and more likely that the extent of the change aligns with their wishes.

All participants would get the best available information at initial consent about changing their participation (using recommended text from the "Persevere" project, where possible [4]), because there is no good justification to provide different information to different participants.

Interventions and comparators
Intervention 1: Site-level intervention: additional training for all staff who engage directly with trial participants about how to manage participation changes. This would be co-designed with relevant stakeholders (i.e. site staff and public contributors). Training would cover the possible complexity in participation changes, the need for a 'balanced' approach that protects participants' rights but does not unnecessarily impair trial integrity, and how to manage common and less common scenarios.
Intervention 2: comparator: no additional training (i.e. standard 'site initiation' training and courses available from, for example, NIHR about informed consent).
Intervention 3: Participant-level intervention: short information sheet to be given after a participant's decision to stop or significantly reduce their participation, confirming how their participation has changed and what will happen next. Previously developed guidance would be used to produce the communication materials [5].

Intervention 4: comparator: no information sheet.

Index Type: Participant Information, Training for recruiting site staff,

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Proportion of participants with primary outcome data available for primary analysis.
Secondary: Success of implementation (i.e. numbers of training sessions delivered and staff trained, and number of participant communications delivered); number of different sorts of participation change aside from those affecting primary outcome data (e.g. stopping intervention); acceptability and feasibility of the SWAT interventions; costs and/or resource use associated with the SWAT interventions.

We may also explore additional, related objectives using qualitative methods.

Analysis plans
Due to randomisation at the site and individual participant levels, the binary primary outcome will be analysed using a multilevel logistic regression with site and participant as random effects, and the two intervention factors as fixed main effects and a fixed interaction. Host trial will be included as a covariate.

Possible problems in implementing this SWAT
We anticipate the effect size to be relatively small, so a large number of clusters and a large number of host trials may be needed overall. This SWAT could only be implemented in trials where the primary outcome data can be collected with relatively little burden on participants (e.g. via routine healthcare data collection) and it may be less suited to trials where primary outcome is participant-reported. Delivering the SWAT interventions successfully and consistently could be a challenge. We may encounter resistance from research staff to the idea of giving information to participants after they have withdrawn from a trial. Significant work done on this topic recently (mainly through the PeRSEVERE project, perseverepriciples.org) may already have changed perceptions and practice in this area, reducing the scope for improvement. If site staff were to start getting additional training about managing participation changes as standard, this would affect the validity of the control in that comparison.

References
1. Skea ZC, Newlands R, Gillies K. Exploring non-retention in clinical trials: A meta-ethnographic synthesis of studies reporting participant reasons for drop out. BMJ Open 2019;9(6):e021959.
2. Henshall C, Narendran P, Andrews RC, et al. Qualitative study of barriers to clinical trial retention in adults with recently diagnosed type 1 diabetes. BMJ Open 2018;8(7):e022353.
3. Nakash RA, Hutton JL, Lamb SE, et al. Response and nonresponse to postal questionnaire follow-up in a clinical trial - A qualitative study of the patient's perspective. Journal of Evaluation in Clinical Practice 2008;14(2):226-35.
4. Persevere project (PRincipleS for handling end of participation EVEnts in clinical trials REsearch). Template wording for patient information sheets. Available at https://perseverepriciples.org/template-wording-for-patient-information-sheets (accessed on 19 February 2024).
5. Information to Support Participants Who Stop Taking Part: Guidance for Researchers. Available at https://ctru.leeds.ac.uk/information-to-support-participants-who-stop-taking-part (accessed on 19 February 2024).

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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