SWAT 155: Evidence-based enhanced participant information sheet (PIS) for recruiting caregivers to a multicentre randomised trial.

Objective of this SWAT
To determine the effects of an evidence-based enhanced participant information sheet (PIS) on recruitment and retention of caregivers to a multicentre randomised trial.

Hypothesis: Caregivers/support persons who receive an enhanced PIS will be more likely to agree to participate and more likely be retained in the REACH-HFpEF trial (host trial) (ISRCTN78539530) compared to caregivers/support persons receiving usual PIS.

Study area: Recruitment, Retention, Outcomes
Sample type: Carer/Parent, Participants
Estimated funding level needed: Very Low

Background
In SWAT 55, key motivators and challenges that influenced informal carers' when making decisions about participating in a randomised trial were identified and ranked in descending order. Based on the perspectives of 36 caregivers, 28 motivators and 17 challenges were presented (1).

A trial participant information sheet (PIS), depending on the depth, length and the user's perspective of the content (relevance, readability, complexity, etc.) has the potential to negatively or positively impact on recruitment. This has been recognised, and other SWATs evaluate the effect of PIS design on recruitment to trials (e.g. SWAT 32, SWAT 102). Current evidence, however, appears limited. In a recently updated Cochrane review on methods for enhancing recruitment to trials, three studies only comparing optimised PIS and standard PIS on recruitment to trials were included (2). The results overall showed no difference in recruitment rates between groups, although individual study results were conflicting. A second Cochrane review, that focused on strategies to improve retention in trials, also found no difference between optimised and standard PIS on retention rates; two studies only were included in this comparison and the evidence was of very low certainty (3). Notably, the studies included in these reviews all involved host trial 'primary' participants (i.e. those with the condition of interest) rather than caregivers of 'primary' participants, who are often also invited to take part in these clinical trials.

This SWAT (ISRCTN15757498) will be embedded as a cluster trial in the REACH-HFpEF trial, a multicentre trial involving 20 sites across England and Scotland. REACH-HFpEF will assess the effectiveness and cost-effectiveness of the home-based cardiac rehabilitation programme 'REACH-HF' plus usual care versus usual care alone in patients with heart failure with preserved ejection fraction (HFpEF). The effect of the intervention on patients' caregivers/support persons will also be formally evaluated as part of the trial. Although entry to the trial is not dependent on both patient and caregiver entering as a dyad (i.e. patients can enter the trial without identifying a caregiver/support person), the aim is to recruit and deliver the intervention to both patient and caregiver simultaneously. As part of trial recruitment, potential trial participants and their identified caregiver will be provided with separate and distinct PIS.

Interventions and comparators
Intervention 1: Enhanced caregiver PIS (conceptually developed using the findings of SWAT 55).
Intervention 2: Usual PIS (based on the standard caregiver PIS used in the REACH-HFpEF trial).

Index Type: Participant Information

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Proportion of caregivers who are approached and agree to participate in the REACH-HFpEF trial; and proportion of caregivers who provide trial outcomes at 4- and 12-months follow-up

Secondary: Time to recruit caregiver sample size estimates in each group; caregivers' level of satisfaction with the PIS (measured on a Likert scale of 1 not at all satisfied to 5 extremely satisfied) measured at baseline following randomisation to the trial, and at 4-months follow-up; and caregivers' priority motivators and barriers for participating in the trial (measured using a modified version of the SWAT 55 survey). We will also assess whether priority motivators and barriers change over time from baseline at trial entry and at 4-months post-trial follow-up as a measure of overall change, within group change, and between group differences.

Analysis plans
We will report odds ratios, mean differences, and hazard ratios with 95% confidence intervals for the comparison between SWAT intervention and SWAT control group for dichotomous, continuous, and time to event outcomes, respectively. We will also report the intra-cluster correlation coefficient of all primary and secondary outcomes.

Possible problems in implementing this SWAT
We do not anticipate problems with implementing this SWAT, nor should the SWAT have any negative implications for the host trial. Our cluster trial design will overcome any potential issues related to inaccurate PIS allocation or erroneous distribution of the allocated PIS to the SWAT intervention and control group personnel. There will be a small additional burden due to the collection of additional outcome measures (satisfaction and priority motivators and barriers) for caregivers. Given that we are recruiting caregivers and collecting their outcomes as part of the host trial, we would also expect this SWAT to be effectively cost neutral. We will seek ethical approval for the SWAT following approval of the host trial. A data sharing arrangement will be put in place so the Glasgow Clinical Trials Unit (overseeing the data management of the host trial) can allow data to be securely transferred to Prof Smith at Trinity College Dublin (overseeing the management of the SWAT).

References
1. Smith V, Corry M, Devane D, et al. Prioritising key motivators and challenges influencing informal carers' decisions for participating in randomised trials: An embedded Study Within A before and after Trial (SWAT 55) [version 1; peer review: 1 approved, 1 approved with reservations] HRB Open Res, 2020;3:71 https://doi.org/10.12688/hrbopenres.13125.1
2. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018;(2):MR000013.
3. 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

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Date of idea: 3/DEC/2020
Revisions made by:
Date of revisions: