

SWAT 136: Impact on Recruitment of Using an Invitation Letter Informed by Self-Determination Theory

Objective of this SWAT

To evaluate the effects of a Self-Determination Theory informed invitation letter on recruitment to a randomised trial

Study area: Recruitment

Sample type: Participants

Estimated funding level needed: Low

Background

Randomised trials are the gold standard for testing the effects of interventions and treatments; but their validity and reliability is highly dependent on the recruitment of sufficient participants (1). Reviews have shown that randomised trials have consistently struggled with recruitment; with some reporting approximately half of all randomised trials failing to achieve their required sample size (2-4). Given this context, evidence-based methods to increase recruitment to randomised trials are important.

Various strategies have been tested but a Cochrane Methodology Review showed that only a small number of these have provided strong evidence of their potential to improve recruitment (5).

Self-Determination Theory (6) is a theory of human motivation, and what moves people to act. The theory outlines three core needs, which facilitate self-determined (autonomous) motivation. These are autonomy (having choice), competence (feeling effectant), and relatedness (feeling connected to others). The invitation letter to be tested in this SWAT has been designed with an aim to make people feel (i) they have choice and are pursuing the research because it suits their values, (ii) they are competent to undertake the study and they could do this well, and (iii) that they feel connected to other people taking part.

Any participant identified by the host trial (the FIREFLI study, NCT04717258) as eligible to receive a host trial invitation pack will be randomised into the SWAT. Participants allocated to the SWAT intervention group will be sent an invitation letter informed by Self-Determination Theory with their trial invitation pack, whilst SWAT control participants will receive the 'standard' invitation letter used within York Trials Unit (YTU) to recruit participants via the post. Participants will be randomised using block randomisation with randomly varying block sizes in a 1:1 ratio. The allocation schedule will be generated by a YTU statistician otherwise not involved in the recruitment of participants. As is usual with an embedded trial within a trial, no formal power calculation will be undertaken for the study, as the sample size will be constrained by the number of participants available to mail out to.

Interventions and comparators

Intervention 1: Invitation letter informed by Self-Determination Theory with the trial invitation pack sent to potential participants for the FIREFLI study.

Intervention 2: 'Standard' invitation letter used within YTU to recruit participants via the post.

Index Type: Method of Invitation

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: The proportion of participants in each SWAT group who go on to be randomised into the host trial (the FIREFLI study).

Secondary: Proportion of patients who are screened for the FIREFLI study. Proportion of participants who are eligible for randomisation. Proportion of participants who remain in the FIREFLI study at three months post-randomisation (defined as returning at least the first three months' worth of falls calendars from the date of randomisation).

Analysis plans

Primary analysis: The difference in recruitment rate between those receiving the Self-Determination Theory informed invitation letter and those not receiving it will be analysed using logistic regression, with site as a random effect.

Secondary analysis: The secondary outcomes of being screened for the study, being eligible and being retained in the FIREFLI study for the first three months will be analysed as described for the primary outcome. The retention outcome model will also be adjusted for host trial allocation.

Possible problems in implementing this SWAT

Participants will not have opportunity to provide informed consent for their involvement in this SWAT because consent for the main clinical trial will not have been obtained at the point of sending them the invitation letter. However, because this is a non-invasive, low-risk intervention and the Self-Determination Theory invitation letter aims to make people feel more supported, it is unlikely that this will pose a major ethical issue.

References

1. Ioannidis JPA. Why most discovered true associations are inflated. *Epidemiology* 2008;19(5):640-8.
2. McDonald AM, Knight RC, Campbell MK, Entwistle VA, Grant AM, Cook JA, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials* 2006;7:9.
3. Sully BGO, Julious SA, Nicholl J. A reinvestigation of recruitment to randomised, controlled, multicenter trials: a review of trials funded. *Trials* 2013;14:166.
4. Walters SJ, Bonacho Dos Anjos Henriques-Cadby I, Bortolami O, Flight L, Hind D, Jacques RM, et al. Recruitment and retention of participants in randomised controlled trials: a review of trials funded and published by the United Kingdom Health Technology Assessment Programme. *BMJ Open* 2017;7(3):e015276.
5. Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, et al. Strategies to improve recruitment to randomised trials. *Cochrane Database of Systematic Reviews* 2018;(2):MR000013.
6. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *American Psychologist*. 2000;55(1):68.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Revisions made by:
Date of revisions: