

# **SWAT 203: The effect of patient testimony videos on recruitment to a clinical trial**

## **Objective of this SWAT**

The primary aim of the SWAT is to determine if adding a brief video patient testimony on the benefits of trial participation to the standard participant information sheets increases recruitment rates in a clinical trial. The secondary aim will be to determine if tailoring the video's content to the specific health area of the trial brings any additional benefit on recruitment.

Study area: Recruitment, Retention

Sample type: Participants

Estimated funding level needed: Very Low

## **Background**

A key research priority for trials' methodology research is to find ways to improve recruitment rates (1). A crucial part of the recruitment pathway to focus on is how to prevent the loss of potentially eligible participants early in the process.

The use of patient testimonies about the experience of taking part in research could be a powerful motivator to encourage others to consider participating in trials. This may partly have an effect through engendering a sense of group identity, because wanting to improve care and treatment for people with similar difficulties in the future is a key motivator for people to take part in trials (2, 3). Previous embedded methodology studies have investigated the effect of adding video clips and additional multimedia materials to standard information sheets, with both finding no evidence that this increased the likelihood of participation in the trial (4, 5). However, only one of these studies included patient testimonies in the additional material (4), and there was limited engagement by patients with the multimedia resource, which may explain why it was not found to have a beneficial effect on recruitment rates. No previous embedded studies have examined the effect of specifically tailoring patient testimonies to the patient population, and none have been conducted in mental health trials. Further research into the use of patient testimonies and/or multimedia materials in the recruitment process is needed across a wider range of trials, because the effectiveness will likely vary according to the trial context (e.g., setting, healthcare area). This SWAT will be embedded in the STOP (Successful Treatment Of Paranoia) trial (ISRCTN17754650).

## **Interventions and comparators**

Intervention 1: usual procedure, whereby the research assistant informs the patient they are potentially eligible for the main trial and offers a standard online participant information sheet (PIS).

Intervention 2: the research assistant offers a PIS with an embedded brief participant testimony video (general health conditions).

Intervention 3: the research assistant offers a PIS with an embedded brief participant testimony video (tailored to mental health conditions).

Index Type: Participant Information

## **Method for allocating to intervention or comparator**

Randomisation

## **Outcome measures**

Primary: Participants' intention to participate in the STOP host trial (captured as a binary outcome of 'yes' or 'no').

Secondary: proportion of participants who a) gave consent; b) were randomised into the host trial; c) dropped out after randomisation.

## **Analysis plans**

SWAT participants' intention to participate in the host trial will be analysed using a multi-level mixed-effects linear regression model, using the binary outcome as the dependent variable and SWAT allocation status as the independent variable. The proportion of SWAT participants who a) gave consent; b) were randomised into the host trial; and c) dropped out after randomisation will be calculated for the three SWAT intervention groups (standard PIS, health-general testimony video

and mental health specific testimony video). The difference between the three proportions will be calculated alongside the corresponding 95% confidence interval.

### **Possible problems in implementing this SWAT**

The SWAT was designed to minimise additional burden on researchers and participants alike by embedding the patient testimony videos in the online PIS for the host trial. However, it will be unknown if the videos are watched by participants because the patient testimony videos will be accessed outside the presence of a researcher. To mitigate this risk, the online PISs were designed to prevent SWAT participants from manually skipping the testimony videos. Instead, study information can only be accessed by SWAT participants after the conclusion of the videos.

### **References**

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4. Jolly K, Sidhu M, Bower P, Madurasinghe V, Eldridge S, Graffy J, et al. Improving recruitment to a study of telehealth management for COPD: a cluster randomised controlled 'study within a trial' (SWAT) of a multimedia information resource. *Trials* 2019;20:453.
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6. Treweek S, Bevan S, Bower P, Campbell M, Christie J, Clarke M, et al. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)? *Trials* 2018;19:139.

### **Publications or presentations of this SWAT design**

### **Examples of the implementation of this SWAT**

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