

# **SWAT 120: The impact of audio-recording study discussions on recruitment rates: the audio study**

## **Objective of this SWAT**

The aim of this study is to investigate the association between being provided with an audio-recorded research consultation and consenting to the trial.

The secondary research aim is to assess the extent to which patients are willing to be audio-recorded.

Study area: Recruitment

Sample type: Participants

Estimated funding level needed: Low

## **Background**

Recruitment is one of the most important challenges for trials. Various techniques have been developed and tested to try to help [1] and new methodologies are continuing to be developed. Providing an audio-recorded research recruitment consultation to the patient may help with the way the information is provided and therefore improve the likelihood that they will consent to join a trial [2]. This will be evaluated in this SWAT, which is embedded in the GAP trial (ISRCTN63614165). It might also be embedded in other trials (to be confirmed).

## **Interventions and comparators**

Intervention 1: Audio-recorded research recruitment session

Intervention 2: Standard research recruitment session, without audio-recording

Index Type: Method of Recruitment, Participant Information

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

Randomisation

## **Outcome measures**

Primary: Consent to the host trial

Secondary: Consent to the Audio SWAT

## **Analysis plans**

The primary analysis for the audio study will compare numbers and proportions of participants who agree to join the host trial in each of the two intervention arms (audio-recorded research consultation versus standard research consultation). The outcome will be summarised descriptively by allocated group and overall. The outcome will be modelled using linear mixed effects methodology with the treatment group fitted as fixed effects and recruiter as random effects. Intervention effects and 95% confidence intervals will be reported.

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

Audio-recording of trial participants is integral to a number of studies run through the Bristol Clinical Trials Unit to identify obstacles during recruitment. There are very limited additional potential harms associated with participating in the SWAT, because it only involves talking to hospital staff (as is routine practice for the trials). Previous studies involving audio-recordings have suggested that it might raise some discomfort and distress. If this happens, participants will be asked if they wish to have the audio-recorder turned off or to stop the consultation.

## **References**

1. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. *Cochrane Database of Systematic Reviews* 2018; (2): MR000013.
2. Rogers C, Paramasivan S, Elliott D, et al. Audio-recording recruitment consultations - an exploratory study in two RCTs to investigate the impact on randomisation rates. *Trials* 2017; 18 (Suppl 1): O54.

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

Rogers C, Paramasivan S, Elliott D, et al. Audio-recording recruitment consultations - an exploratory study in two RCTs to investigate the impact on randomisation rates. *Trials* 2017; 18 (Suppl 1): O54.

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

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Date of idea: 1/JAN/2017

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Date of revisions: