SWAT 15: Video presentation of trial information to potential patient participants in a randomized trial

Objective of this SWAT
To evaluate the effectiveness of hand-held video presentation of trial information to potential patient participants on recruitment and retention to a randomised trial.

Study area: Recruitment.
Sample type: Healthcare professionals.
Estimated funding level needed: Low.

Background
Primary care trials often fail to achieve adequate sample size as demonstrated in a recent study of primary care trials in which only three (23%) recruited successfully compared to eight (62%) mental health trials.[1] This SWAT will add to the limited evidence base on recruitment to trials, and specifically, to trials in primary care by investigating the effects of different ways to provide information to potential participants. It will add to existing evidence on different ways to provide trial information to patients.[2] A version of this SWAT will be conducted by the Health Research Board-Trials Methodology Research Network (HRB-TMRN), in collaboration with the MRC START Programme, and forms part of the research activity of the Irish Primary Care Trials Network (IPCTN) where it will be embedded within the host SATIN trial. To minimize contamination, the SWAT would need to use a cluster design in which general practices are randomized and all potential participants in each site receive the same intervention.

Interventions and comparators
Intervention 1: The original SATIN participant information sheet will be given to potential participants. This will be written in adherence to good research ethics practice and will invite participation of the patient in SATIN. It will include a description of the SATIN trial, ethics information including risk-benefit assessment congruent with the scientific purpose of the SATIN trial and a consent form.
Intervention 2: A handheld, tablet device containing a hard-installed, hand-held video presentation of the trial information will be given to potential participants. The video information will contain generic information on trial participation and SATIN trial specific content.

Index Type: Participant Information

Method for allocating to intervention or comparator
Randomisation.

Outcome measures
Primary outcomes: Number of patients who are recruited to the main trial, and proportion of the potential participants who are recruited.
Secondary outcomes: Proportion of patients who agree to participate in the SATIN trial (in case this differs from the number actually recruited, for example because of exclusion criteria); proportion of recruited patients who are retained to the end of the trial; proportion of patients who decline to participate by ticking the ‘not understanding enough about the study’ as a reason on the ‘Decline form’; level of GP satisfaction with recruitment.

Analysis plans
Comparative analyses of outcomes between groups.

Possible problems in implementing this SWAT
Possible challenges include recruiting GPs to participate in the study; the need to avoid a separate information leaflet for the SWAT as well as the information leaflet for the host trial.

References
1. Sully BGO, Julious S, Nicholl J. A reinvestigation of recruitment to randomised, controlled, multicenter trials: a review of trials funded by two UK funding agencies. Trials 2013; 14(1)**:** 166.

2. Synnot A, Ryan R, Prictor M, Fetherstonhaugh D, Parker B. Audio-visual presentation of information for informed consent for participation in clinical trials. Cochrane Database of Systematic Reviews 2014; (5): CD003717.

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