

## **SWAT 107**

- 1. Any further information on the design of the intervention available? I am copying here more detailed information from the original grant application. Consent procedures will be different in the UK compared to Ireland as has been the case for SWATs I've been involved in.**

### **Intervention (N=60)**

An audiovisual programmable animation lasting 5-6 minutes in five sections:

- 1) Rationale for trials and key concepts (importance of trials, randomisation, placebo control, blinding etc.)
- 2) Participant selection (main entry criteria, voluntary basis, ability to withdraw).
- 3) Calendar of events and explanation of typical activities at each visit.
- 4) Visual illustration of risk probabilities, e.g., common vs rare events.
- 5) Illustrative animation of relevant intervention e.g., exercise programme or patient testimonial).

The animation will explain general trial issues including things known to be important to potential participants(2). It will not specifically reference the primary trial, but will provide basic education, encourage engagement and empower patients to better understand the subsequent consent process. The intervention can be web based, to support recruitment in clinics or at home. The content will be individualized by the researcher, in advance, using a series of menu options e.g., *[show 'placebo explanation']* or *[show 'patient testimonial']* or *[show 'visual depiction of different risk probabilities']*.

### **Intervention Conduct**

During prescreening, clinician briefly mentions possible target trial and enquires about interest. He/she will further explain SWAT and ask patient if willing to participate. If agreeable to SWAT participation, the researcher obtains consent, randomises the patient and in active SWAT arm provides a tablet that shows the bespoke animation. A post-animation questionnaire on trial knowledge and confidence in participation will be obtained. If patient proceeding to primary trial, the trial nurse will be alerted, and the post-animation questionnaire will be administered again after the trial consenting process.

### **Control Conduct (N=60)**

During prescreening, the clinician briefly mentions a possible trial and enquires about interest. Regardless of answer he/she will additionally explain SWAT and ask patient if willing to undertake. If agreeable, the researcher will obtain consent, and randomize subject. In control SWAT arm there is no SWAT intervention and the usual care pathway is followed. The SWAT researcher will alert trial nurse if the patient is interested in the primary trial and ask the trial nurse to administer the SWAT questionnaire, post the primary trial consenting process.

### **Qualitative Study (N = 12 or until saturation is reached)**

A random selection of participants, 10% from the active SWAT arm and 10% from the control SWAT arm, will participate in a semi-structured interview after the primary trial consent visit. Topics will include an examination of their basic trial knowledge, the confidence in making a decision on trial participation independent of clinician's recommendation, assessment of and reported benefits of video (if in active SWAT arm), willingness to recommend participation in a clinical trial to other members of the public etc.

- 2. Analysis plan taken from original grant application.**

**Mixed-methods: Sequential explanatory design – Quantitative followed by qualitative with integration at the results and/or interpretation phase**

**Sample size: N=120 (SWAT active arm = 60; SWAT control arm =60). 10% random sample for qualitative study.**

### **Quantitative Analysis**

Data will be recorded on paper based case-report forms and entered into an electronic database. Exploratory data analysis will be conducted and outliers will be reconciled against the original paper records. Analysis will be conducted on an intention-to-treat basis using the stratified randomization scheme (stratified by primary trial). Analyses will be conducted using R and in all cases a 2-sided type I error rate of 0.05 will be taken as statistically significant.

The primary analysis will be based on test and confidence intervals for two proportions – difference in proportions that consent to the primary trial. An independent sample t-test comparison of active vs. control SWAT arms for self-reported VAS following consenting (or at last visit prior to this) of participant's confidence in their ability to make the right decision regarding trial participation, independently of clinicians recommendation.

Secondary analysis as per above for proportions. Secondary analysis of the VAS scales will be replicated using a Generalised Linear Model (GLM) but will adjust for patient demographics, primary study and research study nurse taking primary study informed consent. Analyses of quantitative secondary outcomes will mirror that of the primary analysis. Additional non-specified analyses will be clearly indicated as post-hoc.

### **Qualitative Analysis**

Qualitative interviews will be transcribed and entered into NVivo software (supported by UCC) and thematically analysed.