SWAT 141: Does patients' guided self-reflection on their illness increase engagement with and recruitment to clinical trials

Objective of this SWAT
To use a mixed-methods sequential explanatory design to establish if a one-to-one patient consultation, which helps the patient to reflect on and self-contextualise the impact of the specific disease area under study, using a bio-psycho-social approach, will increase their engagement with a clinical trial.

Study area: Recruitment
Sample type: Patients
Estimated funding level needed: Medium

Background
Successful clinical trial recruitment is an unresolved challenge (1) with fewer than 50% of trials meeting their targets (2). The recent PRioRiTy study (3) ranked “what information should trialists communicate to members of the public who are being invited to take part in a randomised trial in order to improve recruitment” as the second most important unanswered issue.

This SWAT will seek to establish if a one-to-one patient consultation with a researcher, which helps the patient to reflect and self-contextualise on the impact of the specific disease area under study and the importance of research in this area, using a bio-psycho-social approach, will help motivate them to participate in clinical trials. The “bio-psycho-social” model of health allows for the understanding that health and illness are influenced by complex interactions between biological, psychological and social factors (4-6). It is important that practitioners and researchers consider the patients’ psychological experiences and social context as it leads to a greater understanding of the illness (4-6). Using patient centred interviewing (7,8) through the lens of the “bio-psycho-social” model, provides a more holistic description of the patient (8). Face-to-face interviews with patients are the most important method of obtaining bio-psycho-social information (8).

Decision aids are tools designed to help patients participate in healthcare decisions (9), they provide evidence-based information about a health condition, treatment and care options and associated harms and benefits. All are individually tailored to help decision making. A systematic review on the use of patient decision aids found high quality evidence that decision aids improve patient’s knowledge on their care options, and help them feel better informed (10)

The intention of the patient guided self-reflection is to give potential research participants a greater understanding of clinical trials, of the impact of the medical condition on the individual and how engaging in clinical research could be of benefit to them. Ultimately, we aim to increase patient recruitment to clinical trials and their engagement with the research.

Potentially eligible participants will be approached by the PI or designated representative, as per standard recruitment processes for their host trial. The SWAT researcher will be present and will be introduced by the PI or designated representative. The SWAT will be introduced to the eligible participant. If they agree to participate (participants will also tick a box if they agree to a 10-minute interview, on the same day, following the consent visit for the host trial) they will sign the SWAT consent, and the SWAT researcher will randomise the participant to either active SWAT or control SWAT.

Interventions and comparators
Intervention 1: The SWAT researcher will take the patient to a consultation room and conduct the one-to-one consultation involving a patient guided self-reflection on their illness. This will take place before host trial consent. The participant will then be asked to complete an anonymous SWAT questionnaire on trial knowledge and confidence in trial participation. If they proceed into the host trial, the relevant researcher will be alerted and the questionnaire will be administered again after the trial’s consenting process, regardless of whether or not the person agrees to join the host trial. The one-to-one consultation with the SWAT researcher, through the lens of the bio-psycho-social model of health, will specifically reference the host trial, and will provide probing questions to encourage self-reflection, engagement and empower patients to better understand the

subsequent consent process, as well as how the potential trial could impact on their specific illness. This one-to-one consultation should take no longer than 15 minutes in duration.
Intervention 2: The participant continues with the host trial screening and consent process with the host trial personnel (research nurse or PI). Regardless of the participant's response to the consent for the host trial, the research nurse will alert the researcher who will administer the anonymous SWAT questionnaire to the patient after the consent process for the host trial.

Index Type: Method of Recruitment, Participant Information

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Host trial recruitment: Proportion of subjects meeting the eligibility criteria and who consent to participate in the host trial.
Secondary: Confidence in ability to consent to a trial measured on a 5-point LIKERT scale and factors influencing the agreed participation or refusal from the host trial

Analysis plans
Proposed sample size is 30 (with 15 in each SWAT arm), with two or three people (15%) from each SWAT arm being randomly sampled for a qualitative study.

Quantitative analysis
Descriptive statistics will be produced, means and proportions where appropriate, along with inferential statistics (chi-squared analysis for proportions and t-test to calculate the means between two groups, or ANOVA for the mean between more than two groups) for normally distributed data.

Qualitative analysis
A qualitative study will be done of five participants (or until saturation is reached), who will be randomly selected as two or three from each SWAT arm. This will use semi-structured interviews after the host trial consent visit (only those who have ticked the yes box in the SWAT consent to say they agree to be interviewed will be selected for interview). The interview will be recorded for transcription purposes, but no patient names or identifiable information will be recorded. Topics will include an examination of the patient's basic trial knowledge, confidence in making a decision on trial participation, assessment of and reported benefits of the one-to-one consultation involving patient guided self-reflection on their illness (if in active SWAT arm), and willingness to recommend participation in a clinical trial to other members of the public etc. Analysis of the qualitative data will be by thematic analysis.

Data will be stored in compliance with all applicable GDPR regulations and local guidelines.

Possible problems in implementing this SWAT
We are dependent on the availability of a sufficient number of host trials.

References
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Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of idea: 10/JAN/2020
Revisions made by:
Date of revisions: