SWAT 107: Effects of a multi-trial programmable animation platform on the efficiency and success of pre-screening and subsequent recruitment to a randomised trial

Objective of this SWAT
To use a mixed-methods sequential explanatory design to develop and test a novel approach of using a programmable multimedia animation to improve the success of pre-screening and enhance recruitment to randomised trial.

Study area: Recruitment, Pre-screening
Sample type: Patients
Estimated funding level needed: Medium

Background
Successful clinical trial recruitment is an ongoing challenge.[1] Fewer than half of all clinical trials meet their recruitment targets.[2] The PRioRiTy study of recruitment research prioritised "what are the best approaches for designing and delivering information?" to potential participants as the fourth most important unanswered issue.[3]

This SWAT will develop and test a novel approach (a programmable multimedia animation) to improve success of pre-screening, and enhance recruitment. It will use a mixed-methods sequential explanatory design. The content of the programmable multimedia animation can be readily tailored for different trials. The automated educational interface, which is deployable on a tablet computer, website or YouTube, will provide enhanced awareness of trial concepts using the structure of the host trial as an illustration. The intention is that enhanced understanding of trial processes will lead to better, more meaningful and efficient pre-screening; subsequent consent and, ultimately, better recruitment and retention.

During the pre-screening phase, a clinician typically identifies potentially eligible participants, briefly discusses the trial with them and asks if they would like more information. A lack of awareness regarding trials and the resulting uncertainty about joining one, may lead to refusal. While, even if someone is interested in joining the trial, the delay as they wait to meet a researcher may lead to disengagement. Even if the person progresses to the consent stage, they may be given a patient information leaflet that is highly legalistic, a poor educational tool and inadequate for good quality decision making.[4]

Data visualisation underpins comprehension and successful communication but is often ineffective in trials.[5] The Cochrane methodology review of recruitment strategies identified 35 studies focusing on information delivery, but almost all were low or very low methodological quality, including all those evaluating multimedia interventions. None examined the effects of interventions in the pre-screening phase for a clinical trial.[2]

In this SWAT, the audiovisual programmable animation lasts 5-6 minutes and has the following five sections:
1) Rationale for trials and key concepts (eg importance of trials, randomisation, placebo control, blinding)
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 (eg common versus rare events)
5) Illustrative animation of relevant intervention (eg exercise programme or patient testimonial)

The animation explains general trial issues including things known to be important to potential participants. It does not specifically reference the host trial, but provides basic education, encourages engagement and empowers patients to better understand the subsequent consent process. The intervention can be web-based, to support use in clinics or at home; and content can be individualized by the researcher using a series of menu options. These include [show 'placebo explanation'], [show 'patient testimonial'], and [show 'visual depiction of different risk probabilities'].

During the pre-screening phase for the host trial, the clinician would briefly mention that trial and ask the person about their interest in participating in it. They would also explain the SWAT and ask the person if they are willing to participate in this. If they agree to SWAT participation, the researcher obtains their consent for the SWAT, randomises them and, if the active intervention is allocated, provides access to the bespoke animation (perhaps on a tablet computer). The participant is then asked to complete a questionnaire on trial knowledge and confidence in participation. If the person proceeds 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 that trial. If the person is allocated to the SWAT control group, the usual care pathway is followed and the SWAT researcher alerts the host trial researcher if the person is interested in the host trial. They will ask the host trial researcher to administer the SWAT questionnaire after the consenting process for the host trial, regardless of whether or not the person agrees to join that trial.

Interventions and comparators
Intervention 1: Audiovisual programmable animation
Intervention 2: Control

Index Type: Participant Information, Method of Recruitment

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: 1. Host trial recruitment: Proportion of screened participants who meet the eligibility criteria who consent to participate in the host trial.
2. Self-reported visual analog scale (VAS) of participant's confidence in their ability to make the right decision regarding trial participation independently of the clinician's recommendation (assessed following the consent process for the host trial).
Secondary: 1. Pre-screening success. Proportion of pre-screened participants who agree to proceed at that point.
2. Self-reported assessment on VAS of adequacy of understanding regarding clinical trials (after the consent process for the host trial).
3. Effectiveness of the animation as measured using visualization effectiveness scales proposed by Few et al[5] and measured on the post-consent questionnaire.
4. Proportion of participants recruited to the host trial who are retained in that trial (assessable to the end of the funding for the SWAT).

Analysis plans
Proposed sample size = 120 (SWAT active group = 60; SWAT control group = 60) with 10% randomly sampled for a qualitative study.

Quantitative analysis
Analyses will be conducted on an intention-to-treat basis, in keeping with a randomization scheme, stratified by host trial. 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 host trial between the active and control SWAT groups. An independent sample t-test comparison of active versus control SWAT groups for self-reported VAS following the consent process for the host trial (or at last visit before this) of participant's confidence in their ability to make the right decision regarding trial participation, independently of clinician's recommendation.

Secondary analysis as above for proportions, with secondary analysis of the VAS scales replicated using a Generalised Linear Model (GLM) adjusted for patient demographics, host trial and researcher taking informed consent for the host trial. Analyses of quantitative secondary outcomes will mirror that of the primary analysis. Any additional non-specified analyses will be indicated as post-hoc.

Qualitative analysis

A qualitative study will be done of 12 participants (or until saturation is reached), who will be randomly selected as 10% of those allocated to the SWAT active group and 10% of those allocated to the SWAT control group. This will use semi-structured interviews after the person has been through the consent process for the host trial, and will include people regardless of whether or not they consent to the host trial. Topics will include an examination of their basic trial knowledge, their confidence in making a decision on trial participation independent of clinician's recommendation, assessment of and reported benefits of the video (if in the SWAT active group), willingness to recommend participation in a clinical trial to other members of the public, etc. The interviews will be transcribed, entered into NVivo software and thematically analysed.

Possible problems in implementing this SWAT

We are dependent on the availability of a sufficient number of host trials.

References

1. Rick J, Bower P, Collier D, et al. Systematic techniques for assisting recruitment to trials (START): developing the science of recruitment. Trials 2014; 15(1): 407.
2. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018; (2): MR000013.
3. Healy P, Galvin S, Williamson PR, et al. Identifying trial recruitment uncertainties using a James Lind Alliance Priority Setting Partnership – the PRioRiTy (Prioritising Recruitment in Randomised Trials) study. Trials 2018; 19(1): 147.
4. Gillies K, Huang W, Skea Z, et al. Patient information leaflets (PILs) for UK randomised controlled trials: a feasibility study exploring whether they contain information to support decision making about trial participation. Trials 2014; 15: 62.
5. Few S, Edge P. Data Visualization Effectiveness Profile. Perceptual Edge 2017; 1-11.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Revisions made by:
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