SWAT 152: A qualitative investigation of patient recruitment to a perioperative feasibility randomised trial

Objective of this SWAT
To understand patient recruitment to a perioperative randomised trial and to formatively use these findings to optimise recruitment processes.

Study area: Recruitment
Sample type: Patients, Trial Team
Estimated funding level needed: Very Low

Background
This is a linked sub-study of a feasibility randomised trial exploring the use of intra-operative octreotide infusions to reduce post-operative renal failure (henceforth referred to as 'the host trial').

Recruitment to perioperative trial is acknowledged to be difficult. One of the principal aims of this SWAT is to evaluate if patients can be recruited at a rate which makes the study feasible. Qualitative methods may offer insights into barriers to and optimisation of recruitment.[1] For example, previous research has found that barriers to participation may include concern over the concept of randomisation, incomplete explanations of trial methodology or a lack of balance in the way that treatment arms are explained to patients by recruiters.[2] Evaluating barriers (and enablers) to trial recruitment in a formative way will enable us to use this information to modify the participant information materials and/or the information discussed during the consent process, with the aim of providing better information to patients and therefore improving recruitment rates.

Interventions and comparators
Intervention 1: All patients approached for enrolment to the host trial will afterwards be asked to complete a validated questionnaire [3] exploring their perceptions of the information sent to them and their motivations for agreeing or declining to participate.
Intervention 2: If recruitment rates fall below pre-specified thresholds, up to 12 consecutive patients will be asked to have their recruitment consultations recorded and subsequently be interviewed by telephone.
Intervention 3: If recruitment rates fall below pre-specified thresholds, up to 6 members of the trial team will be interviewed to explore their perceptions of barriers & enablers to patient enrolment in the host trial.

Index Type: Method of Recruitment, Participant Information, Method of Invitation

Method for allocating to intervention or comparator
Non-Random

Outcome measures
Primary: (1) Barriers and enablers to patient participation; (2) patient motivation(s) to participate; and (3) trial team perceptions of recruitment processes
Secondary:

Analysis plans
Questionnaire responses to closed questions will be analysed using descriptive statistics and thematic analysis for the open-ended question.
Recruitment consultation recordings will be analysed according to the Q-QAT methodology,[2] which involves summarising recruitment consultations both quantitatively (time taken to present the information about the trial and the details of each arm), and qualitatively, (thematic analysis using a framework designed to incorporate concepts identified from the relevant literature).
Patient and trial team interviews will be professionally transcribed, imported into NVivo and analysed using Framework analysis. This analysis will focus on themes from our research questions and will also explore additional themes which emerge from the growing dataset. A codebook will be developed to enable team-based analysis via rapid assessment procedure sheets and subsequent timely formative feedback to the trial team.

The researchers will engage in a continuous process of reflexivity by documenting their own assumptions and viewpoints.

Possible problems in implementing this SWAT
Due to changes in trial recruitment processes necessitated by the COVID-19 pandemic, recruitment consultations and patient interviews may need to be conducted remotely. This may impair SWAT recruitment rates. Data connectivity and patients' familiarity with technology may impair data collection.

References
1. Elliott D, Husbands S, Hamdy FC, Holmberg L, Donovan JL. Understanding and Improving Recruitment to Randomised Controlled Trials: Qualitative Research Approaches. European Urology 2017;72(5):789-98.
2. Paramasivan S, Strong S, Wilson C, Campbell B, Blazeby JM, Donovan JL. A simple technique to identify key recruitment issues in randomised controlled trials: Q-QAT - quanti-qualitative appointment timing. Trials 2015;16(1):88.
3. Jenkins V, Fallowfield L. Reasons for accepting or declining to participate in randomized clinical trials for cancer therapy. British Journal of Cancer 2000;82(11):1783-8.

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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