SWAT 172: Qualitative study within a randomised trial to explore the uncertainties surrounding perioperative cancer trial methodology

Objective of this SWAT
To address important methodological issues in perioperative cancer trials by exploring the acceptability, facilitators, and modifiable barriers regarding various aspects of trial methodology to participants and clinical staff.

Study area: Recruitment, Outcomes, Follow-up
Sample type: Patients, Healthcare Professionals,
Estimated funding level needed: Low

Background
Embedding qualitative methods into a clinical trial could provide deeper understanding of uncertainties surrounding various aspects of clinical trial methodology.(1,2) The key uncertainties surrounding perioperative cancer trials to be addressed in the SWAT include:

1. Are clinicians willing to recruit and randomise patients to perioperative cancer trials?

Previous qualitative studies have described some positive attitudes towards clinical trials among clinical staff. Many felt that patients could benefit from treatment outside standard care and by closer monitoring by health professionals that could lead to an overall better outcome.(3-7) Some felt involvement in clinical trials positively challenged their professional intellect.(6,7) However, a significant barrier to recruitment is the extra time required to deliver the research study, on top of regular clinical commitments, which is not necessarily compensated.(4-7) Poor understanding of the concept of randomised trials, the objectives and the detailed procedure of the trial, and reasoning behind inclusion criteria makes it challenging for clinical staff to communicate about the trial and could cause barriers to recruitment.(9) It is also essential to explore the extent to which equipoise exists among clinical staff and to what extent they are willing to set their personal preferences aside in seeking reliable and robust evidence.

2. Are patients happy to participate and would agree to randomisation?

For some patients, the feelings of contributing to the advancement of science and helping others are significant motivations for joining a clinical trial.(9,10) However, a significant barrier to recruitment includes a lack of understanding of the trial's potential benefits and harms, and misconceptions about randomisation, blinding and placebo that need to be addressed appropriately in the participant information.(10)

3. Are informed consent procedures, information, and recruitment practices appropriate and acceptable to patients?

The presentation of the study information and the informed consent procedures need to be tailored to the individual circumstances of potential participants.(11) Other factors such as avoiding medical jargon, using concise and easy-to-read information, and ways to reduce the burden of information will affect the acceptability of the trial to patients.

4. Are outcomes being measured important to patients?

Study designs that use multiple endpoints or outcomes can intimidate potential participants.(12) Consultations with patients to ascertain the outcomes important to them can help prioritise the most relevant outcomes that potential participants find essential and which would make their participation in the trial worthwhile.

5. Does follow up and frequency cause burdens to patients?

The inconvenience that might be caused by participating in clinical trials, such as the need for extra travel, invasive procedures and time-consuming interviews or questionnaires, are major barriers to recruitment and retention.(10,13,14) It is important to streamline the follow-up procedure with standard care to minimise the burden to participants.

This SWAT is a qualitative study nested in a randomised trial evaluating a perioperative intervention to improve cancer outcomes following surgery. The SWAT will explore potential issues

specific to perioperative cancer trials and establish how to address patients' and clinicians' concerns to ensure successful study conduct.

Interventions and comparators
Intervention 1: A brief interview before hospital discharge to explore patients' experience of being asked to participate and being randomised into the host trial's treatment or placebo group, the informed consent procedures, the information given and any suggestions for improvement.
Intervention 2: A further qualitative semi-structured interview will be conducted three months after hospital discharge, which should last approximately 30 minutes.
Intervention 3: Patients who refuse consent to the host trial will be asked for their reasons for doing so at the point of recruitment only
Intervention 4: Clinician interviews will be at times that suit them. Clinicians will be asked their reasons for recruiting and not recruiting patients to the study.
Intervention 5: All participants and clinicians in the host trial will be given a questionnaire with 10 close-ended questions (measured on a Likert-type scale) and an opportunity for free text feedback.

Index Type: This SWAT is to obtain feedback regarding aspects of trial methodology from both patients and clinicians.

Method for allocating to intervention or comparator
The sampling strategy will involve a range of participants, taking into account gender, age, ethnicity, and co-morbidities to ensure diversity.

Outcome measures
Primary: To explore the roots of uncertainties surrounding aspects of clinical trial methodology in perioperative cancer trials from the perspectives of patients and clinical staff.
Secondary: 1. To explore potential mitigating factors for barriers to perioperative cancer trials from the perspectives of patients and clinical staff.
2. To explore if the qualitative approaches provide additional benefits for obtaining valuable information compared to a standard close-ended patients' and clinicians' feedback questionnaire.

Analysis plans
This study will involve individual, semi-structured interviews, face-to-face or virtual methods, which will be digitally recorded and transcribed verbatim for analysis. Participants will select the interview setting that is convenient to them. A maximum of 10 patients and five clinicians will be interviewed. Interview schedules will be developed with the PPI group and will guide data collection. Any potentially identifiable information, including locations and characteristic turns of phrase, will be masked. The interview transcripts will be reviewed to identify facilitators, barriers and steps to address these barriers.

The transcripts will be analysed using content analysis. The analysis will involve familiarisation of the data, constant comparison, identification of initial codes and iterative development of themes and relationships between themes. NVivo qualitative data management software will be used to facilitate the management of the dataset. An audit trail will be used to ensure rigour and minimise bias.

Data from feedback questionnaires will be summarised using descriptive analysis with frequencies and percentages. The Likert-type scale responses will be expressed as mean and standard deviation.

Possible problems in implementing this SWAT
Patient and clinician recruitment to the SWAT could be challenging. For example, recruitment and interviews might need to be performed remotely, which may require technologies that are not available to some potential participants. People who decline trial participation might also refuse to answer questions about why they declined to join the trial.

References
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Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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