SWAT 171: Use of an additional video link of an informed consent conversation to improve recruitment into perioperative cancer trials

Objective of this SWAT
To evaluate if supplementing the participant information sheet (PIS) with a video link of an informed consent conversation can overcome some challenges in recruiting patients into perioperative cancer trials. The content and style of the video clip will be developed with help from a group of patients and public users.

Study area: Recruitment, Retention, Randomisation
Sample type: Participants, Patients, Carer/Parent
Estimated funding level needed: Low

Background
The perioperative period is increasingly recognised as a critical time that could influence cancer outcomes, such as recurrence-free survival.(1) To address this, a growing number of perioperative cancer trials are being undertaken. However, there are recognised challenges in conducting such randomised trials, including funding, regulatory approval, study set-up, recruitment, trial retention, and follow up. On top of this, recruiting patients newly diagnosed with cancer about to have major surgery poses its own struggle. Indeed, patient accrual in cancer research, including perioperative oncological trials, could be lower than 10% and very slow.(2)

The willingness of healthcare professionals and researchers to provide potential research participants with individualised attention and approach are essential, along with using empathetic language and addressing the individual concern.(3) The behavioural aspect and the style of communicating study information could influence understanding, retention of information and willingness to participate.(4) Although the presentation of the written participant information (PIS) and the actual conversation is crucial, it is possible that the visualisation of what the study might involve and what happens during the informed consent process could overcome some challenges in recruiting to perioperative cancer trial.

In a previous cancer randomised trial, video clips improved knowledge and overcame some barriers to recruitment compared to the text form.(5) However, a Cochrane review of the use of video clips to supplement the standard information in cancer trials, shows that the available evidence is insufficient for a recommendation.(6)

We hypothesised that the visualisation of a conversation between the person in charge of the study (i.e. the chief investigator (CI)) and a potential participant might enhance the personalised approach to recruitment. Therefore, this SWAT will evaluate the addition of a video clip of this conversation to the written form of the PIS. It is planned to be embedded into a future definitive trial evaluating perioperative intravenous lidocaine for colorectal cancer outcomes following surgery.

Interventions and comparators
Intervention 1: The clinician will give the original PIS for the trial to the potential participant following a brief introduction to the study.
Intervention 2: The original PIS with a link to a video clip of an example of what happens during the informed consent conversation will be provided. In this video, the CI will explain the study to a potential participant, covering the information in the PIS and the exchange of informed consent.

Index Type: Participant Information, Method of Recruitment

Method for allocating to intervention or comparator
Cluster randomisation across the NHS sites for the host trial. Each site will be randomised to deliver one of the SWAT intervention groups such that all potential participants at each site will receive the same SWAT intervention.

Outcome measures
Primary: Proportion of eligible patients recruited to the host trial in each SWAT intervention group.

Secondary: 1. Participant satisfaction with the information they were given and the informed consent process, measured on a Likert-type scale in a 10 question feedback questionnaire.
2. Proportion of potential participants who agree to have a conversation following PIS in the subsequent pre-operative clinic, which may differ from the number recruited.
3. Number of potential participants in SWAT intervention group 2 who report watching the video.
4. Retention of participants in the host trial.

Analysis plans
Demographic and participant characteristics will be summarised using the mean and standard deviation or median and interquartile ranges, as appropriate for continuous variables. Categorical variables will be summarised using frequencies and percentages.

Participant recruitment, the proportion who agree to have the conversation, the number who watch the video and retention rates will be summarised and reported as frequencies and proportions. The Mann-Whitney-U test will compare the variance of the results between the two SWAT interventions.

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
There is a potential for bias if the informed consent delivery standard differs across sites and this may be difficult to standardise. To minimise this potential bias, the principal investigator at each site will need to ensure that the study process is delivered to an acceptable Good Clinical Practice standard. There will be an ongoing review of recruitment rates and participant satisfaction with the study process to address any potential barriers.

References
1. Hiller JG, Perry NJ, Poulogiannis G, et al. Perioperative events influence cancer recurrence risk after surgery. Nat Rev Clin Oncol 2018;15(4):205-18.
2. Cata JP, Kurz A. Challenges in research related to perioperative cancer care and cancer outcomes. Best Pract Res Clin Anaesthesiol. 2013;27(4):457-64.
3. Thorne S, Taylor K, Stephens JM, et al. Of Guinea pigs and gratitude: the difficult discourse of clinical trials from the cancer patient perspective. Eur J Cancer Care 2013;22(5):663-72.
4. Albrecht TL, Eggly SS, Gleason ME, et al. Influence of clinical communication on patients' decision making on participation in clinical trials. J Clin Oncol 2008;26(16):2666-73.
5. Meropol NJ, Wong YN, Albrecht T, et al. Randomized trial of a web-based intervention to address barriers to clinical trials. J Clin Oncol 2016;34(5):469.
6. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. Cochrane Database Syst Rev 2018;(2):MR000013.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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