SWAT 165: Rapid qualitative study of patient consent in co-recruiting studies

Objective of this SWAT
This formative qualitative study will be conducted within the VITAL trial to examine ways of consenting patients to two complementary studies with the following objectives:
1. Explore patient, carer and staff views and experiences with different recruitment approaches
2. Examine patient and carer experiences of participating in VITAL and PQIP
3. Identify barriers and enablers to trial set-up, recruitment and trial delivery

Study area: Recruitment, Retention, Patient and staff experience
Sample type: Healthcare Professionals, Patients, Carer/Parent
Estimated funding level needed: Low

Background
Improving outcomes after surgery is a major public health research priority for patients, clinicians and health systems. It will require efficient clinical trials and one way to achieve this might be to co-enrol patients into multiple studies.

The host trial for this SWAT is the VITAL trial (ISRCTN62903453), which will specifically address the effect of anaesthetic technique on key patient outcomes: speed and quality of recovery after surgery (quality of recovery after anaesthesia, patient satisfaction and major perioperative complications), survival and patient safety. VITAL proposes an efficient trial design partnering with an existing national cohort study hosted by the Royal College of Anaesthetists: the Perioperative Quality Improvement Programme, PQIP (https://pqip.org.uk/content/home). Using PQIP's prospective clinical dataset and existing NHS data sources, VITAL will limit the burden of research for participants and data collection requirements. As a result, participants in VITAL will also be participating in PQIP. This SWAT will explore these issues through an assessment of the process of recruitment and the gathering of experiences during the trial.

Interventions and comparators
Intervention 1: Process of recruitment
Intervention 2: Experiences during the trial

Index Type: N/A

Method for allocating to intervention or comparator
Non-Random

Outcome measures
Primary: Best methods of consenting participants into VITAL, and evidence to develop site training materials, Site Initiation Visits and consenting materials (i.e. Patient Information Sheet and Consent Form).
Secondary: N/A

Analysis plans
Transcripts and key documents will be imported into NVivo and analysed using framework analysis. The framework will be shaped by the research questions, published qualitative research and additional topics emerging from the data. Data collection and analysis will be carried out in parallel as emerging findings will be shared with the trial team at monthly meetings of the Trial Management Group to inform trial design and delivery.

Possible problems in implementing this SWAT
Potential problems include barriers accessing sites and potential study participants. Delays in the implementation of the VITAL trial would also impact on the timely delivery of the SWAT.

References

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of revisions: