

SWAT 150: Anaesthesia Choice for Creation of Arteriovenous Fistulae (ACCESS Study): A Qualitative Study within a Trial (SWAT)

Objective of this SWAT

A process evaluation will run in parallel with the host trial, using a rapid feedback evaluation approach to combine qualitative data from semi-structured interviews with patients, carers and staff and documentary analysis (reports, meeting minutes etc) to:

- * Explore staff views and experiences with different approaches to recruitment
- * Examine patient and carer experiences of participating in the host trial (understanding of trial literature; experience with treatment options; reasons for withdrawal)
- * Examine patient and carer experiences of declining to take part in the host trial
- * Identify barriers and enablers to trial set-up, recruitment and delivery from the point of view of staff

Study area: Recruitment, Retention, Patient and staff experience

Sample type: Healthcare Professionals, Patients, Carer/Parent

Estimated funding level needed: Medium

Background

Qualitative research is used to inform various aspects of clinical trial design and delivery including identification of barriers to recruitment; problems with trial set-up and management; and potential difficulties with trial scale-up. The Rapid Research Evaluation and Appraisal Lab (RREAL) at the Department of Targeted Intervention, University College London (UCL) has developed a rapid feedback evaluation approach to collect, analyse and share findings with trialists at a time when they can be used to inform within trial decision-making processes. We will use this approach for this qualitative SWAT, within the ACCESS study (ISRCTN14153938).

Interventions and comparators

Intervention 1: Process of recruitment

Intervention 2: Experiences during the trial

Index Type: Experience

Method for allocating to intervention or comparator

Non-Random

Outcome measures

Primary: Interviews with staff will focus mainly on documenting their experience setting-up or implementing the host trial, the main barriers encountered during these stages and strategies used to overcome them. These experiences will be understood by taking into consideration the context of each of the sites where the ACCESS study is delivered. Interviews with patients/carers who have decided to take part in the trial will focus on their experiences with the trial, their understanding of trial information, reasons why they decided to take part in a trial, reasons for withdrawal and experiences with treatment options. These interviews will take place at least 1 week after entering the trial to be able to capture a wide range of experiences. In the case of patients who decline the invitation to take part in the trial or decide to withdraw, the interview will take place right after decline/withdrawal. If the withdrawal happens after the interview has been carried out, the researcher will carry out a short follow-up interview with the patient/carer to explore the reasons for withdrawal.

Secondary:

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 literature on qualitative research during trial implementation 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 on a monthly basis 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 ACCESS study 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 idea: 23/JUN/2020

Revisions made by:

Date of revisions: