SWAT 230: A mixed methods study exploring patients' decision making process in declining participation to a rehabilitation and nutrition based clinical trial

Objective of this SWAT
Reasons for declining to take part in clinical trials are often multi-dimensional but are not well understood. This qualitative SWAT aims to understand how patients who decline to participate in a rehabilitation and nutrition based clinical trial make this decision.

Additional SWAT Details
Primary Study Area: Data Collection/Quality, Recruitment
Secondary Study Area: Barriers and facilitators, EDI, Incentives and engagement
Who does the SWAT intervention target: Participants, Patients
Estimated resources needed to conduct the SWAT: Low
Estimated cost of the SWAT (£):

Findings from Implementation of this SWAT
Reference(s) to publications of these findings: Still recruiting
Primary Outcome Findings:
Cost: No additional cost for SWAT, included in main trial budget.

Background
Reasons for refusing to take part in clinical trials are often multi-dimensional but are not well understood. This qualitative SWAT will explore how patients who decline to participate in a rehabilitation and nutrition based clinical trial make this decision. We will create a survey using feedback from PPI members and the RESOLVE group. This survey will be offered to patients who decline to take part in the host F4S-2 trial (ISRCTN40412033), which is testing an app intended to help patients get fit for lung cancer surgery. The SWAT will collect information on the reasons for not wanting to participate in the trial, covering opinions on method of recruitment, method of invitation to the trial and participation information. Data will also be gathered about how the recruitment process could be improved, to make it more appealing to encourage patients from varied backgrounds to feel comfortable to take up the offer of rehabilitation and nutrition support through a research trial.

The questions will be a mixture of open and closed ended, including tick box options to learn what would encourage people to use the app or what barriers may be perceived by individuals.

Findings from the SWAT may guide future improvements in the study design and help develop strategies to increase participation in trials, especially from hard-to-reach groups.

Host Trial Population: Adults
Host Trial Condition Area: Oncology, Respiratory Conditions, Thoracic Surgery

Interventions and Comparators
Intervention 1: No intervention

Method for Allocating to Intervention or Comparator: Regardless of the route of approach, the patient will be asked if they wish to participate in the trial and, if not, whether they would be willing to share their reasons for declining, for purposes of the SWAT.

Outcome Measures
Primary Outcomes: Decision making process of patients who declined the host trial.
Secondary Outcomes:

Analysis Plans

Qualitative data will be analysed using thematic analysis; responses will be labelled with codes, and then grouped together into categories to create themes. Agreement on the final themes will be reached through discussion between the PPI co-applicants and the qualitative researcher.

Possible Problems in Implementing This SWAT

References Cited in This Outline

References to This SWAT

SWAT protocol development was presented as a poster at the Society for Cardiothoracic Surgery (SCTS) Conference, Newport, Wales 17-19 March 2024 .

Source of This SWAT

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