SWAT 256: Evaluation of translation and interpretation services to facilitate recruitment of participants from ethnic minority groups with Low English Proficiency (LEP) in the TADPOLE surgical trial

Objective of this SWAT
To monitor, describe and evaluate the implementation of translation and interpretation services in a breast cancer surgical trial to facilitate the recruitment of ethnic minority groups with Low English Proficiency (LEP).

Additional SWAT Details
Primary Study Area: Recruitment
Secondary Study Area: EDI
Who does the SWAT intervention target: Participants; Researchers; Trial Team
Estimated resources needed to conduct the SWAT: High
Estimated cost of the SWAT (£): 30,000

Findings from Implementation of this SWAT
Reference(s) to publications of these findings:
Primary Outcome Findings:
Cost:

Background
In 2017, the NIHR launched the INCLUDE project to address the under-representation of certain groups, including ethnic minorities, in clinical trials in the UK (1). The INCLUDE Ethnicity Framework was developed to help trial teams consider how a condition, an intervention to address it, and the corresponding trial design may affect participation across ethnic groups (2). In 2022, Trial Forge Guidance 3 included practical strategies for improving recruitment and retention of ethnic minority participants, including the development of inclusive trial materials (3), which may involve translating study documents and providing verbal interpretation to support individuals with limited English proficiency, low literacy, or a preference for communication in their native language. Since then, further recommendations and resources on using translation and interpreting services in trials have been published (4,5,6). Whilst these and the Trial Forge guidance may be useful tools for researchers; there is little robust evidence to help researchers consider whether these strategies are effective in increasing recruitment of ethnic minority groups in trials (7). Furthermore, the ACCESS study highlighted key challenges in implementation of language support services and a lack of consistency and standards. Whilst the costs for language support services are frequently included in research proposals, little data exists on how often these services are used or their success in facilitating trial participation (8). As such, this Study Within a Trial (SWAT) (9) aims to evaluate the use of translated study materials and interpreting services at sites to facilitate the recruitment of ethnic minority groups with low levels of English in a randomised trial of surgery for patients with breast cancer: TADPOLE (ISRCTN71954670).

Both resource use and costs of the translation and interpretation services will be collected, and we will use qualitative interviews with patient participants, research staff at sites and the study team to explore the implementation of the language support services at sites. SWAT data will be monitored and used to further refine the implementation of language support services if required. Our diverse Patient and Public Involvement and Engagement group and Patient Advisory Group will provide input on the delivery of the SWAT and dissemination of its findings.

Host Trial Population: Adults
Host Trial Condition Area: Oncology

Interventions and Comparators
Intervention 1: Translation and interpretation services provided for each site when required. The use of the translation and interpreting services will be discussed with sites at their site initiation visits and its use encouraged throughout the duration of the trial period by the trial team.

Method for Allocating to Intervention or Comparator: Not applicable, all sites to receive the intervention.

Outcome Measures
Primary Outcomes: Proportion of potential participants and participants from ethnic minority backgrounds using translation and interpretation services (resource use) and total cost for the services to calculate cost per ethnic minority participant recruited.
Secondary Outcomes: Acceptability, facilitators and barriers of the translation and interpretation services used at sites from the perspectives of participants, research staff and the study team.

Analysis Plans
Analyses will be descriptive. The number and proportion of potential participants and participants using the translation and interpretation services at each site will be reported on screening logs and baseline case report forms. Cost per participant recruited from an ethnic minority background will be calculated by collecting the total costs for the translation and interpretation services and the total number of participants recruited from an ethnic minority background in host trial. The total number of participants screened, eligible, approached and recruited from an ethnic minority background will be collected and reported from the participant screening logs following the SEAR framework (10).

The SWAT will involve individual, semi-structured interviews (each lasting up to 45 minutes), most of which will be done online or by telephone and with an interpreter if required. A maximum of 10 research staff at sites, 10 patient participants, and 3 members of the trial team will be interviewed. We will use a purposeful sampling strategy to interview 'information-rich' participants to represent all the key groups involved in recruitment at sites. The interviews will be conducted at a time which is most convenient for the interviewee. We will pay each participant £10 for taking part in the interviews.

The interviews will be digitally recorded and transcribed verbatim by a University of Bristol approved supplier. We will use framework analysis (11) to understand contrasting perspectives, context, and barriers/ facilitators to the implementation of the translation/ interpretation services. Two researchers (qualitative researcher and lead) will independently code a proportion of the data, discuss discrepancies, and develop a coding frame based on anticipated and new themes. The qualitative researcher will then apply the framework to the whole dataset and ensure that newer themes identified are compared against previously coded transcripts. We will give particular attention to dissonant data (or negative data, i.e., data that differs from the main themes and helps revise and refine those themes) (12).

Possible Problems in Implementing This SWAT
None foreseen.

References Cited in This Outline
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References to This SWAT
None yet

Source of This SWAT
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Date of revisions: 26/09/2025