SWAT 231: Implementation of an AI Avatar digital communications technology in secondary care sites to facilitate recruitment of participants from ethnic minority groups in the TADPOLE Trial.

Objective of this SWAT
To monitor, describe and evaluate the implementation of a novel Artificial Intelligence (AI) training video in a breast cancer surgical trial to facilitate the recruitment of ethnic minority groups with: a) limited English proficiency; b) low levels of literacy in their own language; or c) a preference to speak to someone in their own language at their trial site.

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: Medium
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 UK National Institute for Health and Care Research (NIHR) 'Innovations in Clinical Trial Design and Delivery for underserved groups' (INCLUDE) project (1) was initiated because many groups of patients in the UK were identified as being under-served by clinical trials and by the healthcare services that are influenced by these trials. Ethnic minorities are one of the under-served groups. An INCLUDE Ethnicity Framework was developed to assist trial teams to think about how their health condition, the interventions in the trial and the trial's design can influence the ability of people from different ethnic backgrounds to take part in a trial (2). The third Trial Forge guidance paper (3) provides practical guidance for researchers on how to recruit and retain individuals from ethnic minority groups, including a recommendation to 'ensure trial materials are developed with inclusion in mind'. This could include translated study materials and offering verbal interpretation when needed. Verbal interpretation can enable individuals with limited English proficiency, low literacy in their own language, or both, and those who simply prefer to speak to someone in their own language to consider trial participation.

Whilst the framework and associated guidance may be a useful tool for researchers, there is little robust evidence to help researchers consider which recruitment strategies are most effective in increasing recruitment of ethnic minority groups to trials (4). As such, this Study Within a Trial (SWAT) aims to evaluate the use of a novel digital communications technology to facilitate the recruitment of adults from ethnic minority groups presenting at secondary care sites for a randomised trial of surgery for patients with breast cancer: TADPOLE.

Synthesia (5) is an AI video communications platform which enables users to create videos using AI avatars and voiceovers across 130 different languages. For this SWAT, avatars, each representing a different ethnic minority group will be created and the study information will be translated and spoken via the avatar. This, with visual graphics in the background, will be presented as a video to potential participants at breast clinics during the recruitment consultation for the host trial. Alongside this, potential participants will receive the relevant translated patient information leaflets and informed consent forms and offered an interpreting service.

Both resource use and costs of the communications technology will be recorded, and we will use qualitative interviews with research staff at secondary care sites, the study team and the patient participants to explore the implementation of the technology at sites. An interim review of the SWAT data will be carried out and the emerging findings might be used to further refine the implementation of the SWAT intervention. Our diverse trial 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: Access to Synthesia AI avatar videos alongside an interpreting service and translated study documents when required.
Comparator: Access to interpreting services and translated documents when required.

Method for Allocating to Intervention or Comparator: Randomisation

Outcome Measures
Primary Outcomes: Proportion of potential participants and participants from ethnic minority backgrounds recruited following the SEAR framework (6). Proportion of potential participants and participants from ethnic minority backgrounds accessing Synthesia digital avatar videos (resource use) and cost spent in total for the enhanced services, to calculate cost per ethnic minority participant recruited.
Secondary Outcomes: Acceptability, facilitators, and barriers of using the Synthesia digital avatar videos at secondary care sites from the perspectives of research staff, the study team, and patient participants.

Analysis Plans
Interim and final analyses will include descriptive statistics and between SWAT group comparisons using regression models with analysis at the cluster level for recruitment outcomes and participant level for other outcomes. We will use mixed effect models to take account for clustering by research site.

The number and proportion of potential participants and participants accessing the AI avatar videos at each secondary care site will be obtained from screening logs and baseline case report forms. Cost per participant recruited from an ethnic minority background will be calculated by collecting total costs incurred for the use of the technology and the total number of participants recruited from an ethnic minority background. Total number of participants screened, eligible, approached and recruited from an ethnic minority background will be collected from the participant screening logs following the SEAR framework (6).

This study will also involve individual, semi-structured interviews (each lasting up to 45 minutes), most of which will be done online. These interviews will be digitally recorded and transcribed verbatim by a University of Bristol approved supplier, coded, and analysed thematically using Framework analysis (7) to understand contrasting perspectives, context, and barriers/ facilitators to the implementation of the AI Avatar videos. Interviews will be conducted at a time which is most convenient for the interviewee. We will reimburse participants for taking part in the interviews. A maximum of 12 research staff at sites, three members of the study team and 10 participants will be interviewed. Patient participants taking part in qualitative interviews for the host trial will be asked about their views and experiences of recruitment, specifically the use of the Avatar digital video. We will use a purposeful sampling strategy to interview ‘information-rich’ participants (8) in order to represent all the key groups involved in recruitment.

Two researchers (qualitative researcher and SWAT 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) (8).

Possible Problems in Implementing This SWAT

None foreseen.

References Cited in This Outline

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4. Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018;2(2):MR000013.
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6. Wilson C, Rooshenas L, Paramasivan S, Elliott D, Jepson M, Strong S, et al. Development of a framework to improve the process of recruitment to randomised controlled trials (RCTs): the SEAR (Screened, Eligible, Approached, Randomised) framework. Trials 2018;19(1):50.
7. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Medical Research Methodology 2013;13:117.
8. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. BMJ 2000;320(7227):114-6.

References to This SWAT

None yet

Source of This SWAT

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