SWAT 250: Investigate whether watching a patient testimony video clip, available in English, Polish, Romanian and Punjabi in addition to reading the written participant information sheet increases consent rates compared to written information alone.

Objective of this SWAT
To investigate whether watching a patient testimony video clip, available in English, Polish, Romanian and Punjabi in addition to reading the participant information sheet increases consent rates compared to written information alone, in a randomised trial of interventions to reduce problematic bleeding when using a contraceptive implant.

Additional SWAT Details
Primary Study Area: Recruitment
Secondary Study Area: EDI
Who does the SWAT intervention target: Participants
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:
Primary Outcome Findings:
Cost:

Background
The written participant information sheets that are provided to potential participants in a randomised trial are often in English only. This may limit trial participation for people who have difficulty understanding written English. It is important to make participation in clinical trials as inclusive as possible and researchers are exploring the best ways to do this.[1] Media tools are increasingly used to engage potential participants, but there is limited data on their effectiveness. Testimonies from previous participants show that media tools probably increase recruitment [2], because they provide potential participants with evidence that people like them engage with research. No comparable data exists for the use of video clips, which are ubiquitous on social media.

This cluster randomised Study Within a Trial (SWAT) [3] will investigate whether watching a patient testimony video clip, available in English, Polish, Romanian and Punjabi in addition to reading the written participant information sheet increases consent rates compared to written information alone.

The sample size for the SWAT will be predicated by that of the DEBI trial (ISRCTN10116165), which is comparing interventions to reduce problematic bleeding when using a contraceptive implant. We anticipate including at least 17 sites in the SWAT. More detailed information on the sample size will be detailed in the SWAT statistical analysis plan.

Host Trial Population: Adults
Host Trial Condition Area: Sexual and Reproductive Health

Interventions and Comparators
Intervention 1: Group 1: Written participant information only
Intervention 2: Group 2: Written participant information followed by patient video testimony

Method for Allocating to Intervention or Comparator: Randomisation

Outcome Measures
Primary Outcomes: Proportion of eligible patients who consent to join the trial.
Secondary Outcomes: Proportion of randomised participants who provide the primary outcome.

Analysis Plans
Detailed analysis of this SWAT will be documented in the trial's SWAT statistical analysis plan. Analysis will be based on cluster-level summaries. Unpaired t-test, with each cluster weighed by its sample size, will be used to provide 95% confidence intervals for the between-group effect measures.

Possible Problems in Implementing This SWAT

References Cited in This Outline
1. Dawson S, Banister K, Biggs K, et al. Trial Forge Guidance 3: randomised trials and how to recruit and retain individuals from ethnic minority groups practical guidance to support better practice. Trials 2022; 23: 672.
2. Free C, Hoile E, Robertson S, Knight R. Three controlled trials of interventions to increase recruitment to a randomized controlled trial of mobile phone based smoking cessation support. Clinical Trials 2010; 7(3): 265-73.
3. Treweek S, Bevan S, Bower P, et al. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)? Trials 2018; 19: 139.

References to This SWAT

Source of This SWAT
People to show as the source of this idea: Professor Kate F Walker
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Date of idea: 20/03/2025
Revisions made by:
Date of revisions: