SWAT 160: An enhanced participant information leaflet and multimedia intervention to improve the quality of informed consent in a randomised clinical trial enrolling people living with HIV and obesity

Objective of this SWAT
To investigate whether an enhanced Participant Information Leaflet/Informed Consent Form (PIL/ICF) and access to an informational website improves potential participants' understanding of a clinical trial. The enhanced PIL/ICF and website have been optimised to improve participant understanding, by using plain language, infographics, and animation to explain the clinical trial to participants.

Study area: Recruitment
Sample type: Participants
Estimated funding level needed: Low

Background
Recent systematic reviews indicate that research study participants often have a poor understanding of the important concepts of a clinical trial (1, 2). This lack of understanding impairs research participants' ability to make informed decisions and undermines their autonomy. Paper-based PIL/ICF contain key information about the study including study objectives, design, procedures and information on insurance and data protection but are becoming longer (3) and are often too complex for many participants (4, 5). Multimedia interventions and enhanced PILs have been tested to determine whether they improve participants' understanding and the rate of recruitment (6). However, there is currently insufficient empirical evidence to determine how effective they are on improving participants' understanding (7-11).

The host trial for this SWAT is the SWIFT trial (EudraCT: 2019-002314-39; NCT04174755) is a prospective, multi-centre, randomised, open-label, controlled trial investigating whether semaglutide helps people living with the HIV and obesity to lose weight (12).

The enhanced PIL/ICF and website which will be used in this SWAT were co-designed with a representative from a patient advocacy organisation, and in line with the available best practice guidelines for patient-facing materials.

Interventions and comparators
Intervention 1: Control: standard participant information leaflet/informed consent form (PIL/ICF)
Intervention 2: Intervention: enhanced PIL/ICF and access to an educational website

Index Type: Participant Information

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Quality of consent, as measured by the modified Deaconess Informed Consent Comprehension Test (DICCT) questionnaire scores, assessed 48 hours after consent to the host trial.
Secondary: Recall, as measured by the DICCT questionnaire scores two weeks after consent to the host trial.

Analysis plans
Descriptive statistics will be used to outline educational level and ethnicity of participants and the rate of recruitment to the host trial (SWIFT) across the two arms of the SWAT. Depending on the distribution of data gained from the primary outcome of the SWAT, the appropriate test (parametric or non-parametric) will be selected to compare DICCT scores in the two arms of the SWAT: an independent samples t-test or a Mann-Whitney U test.

Possible problems in implementing this SWAT
None anticipated.

References

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Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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