SWAT 101: Design of the patient information leaflet: does Participant Information Sheet Design affect the recruitment rate into an interventional trial (OPTIMISED)?

**Objective of this SWAT**
To explore whether improving the readability of a participant information leaflet (PIL) has an effect on the recruitment rate into an interventional trial.
To assess the impact or "value" of the PIL in the patient's decision making.

**Study area:** Recruitment
**Sample type:** Patients
**Estimated funding level needed:** Low

**Background**
The information provided to participants in clinical research plays an important role as a point of reference for them [1] and long and complex information leaflets may affect their decision to enter a trial. Problems in recruiting to studies can extend their duration making them more expensive or requiring agreement of collaborators to continue to work on the project with little or no additional funding. If recruitment is helped by improving the readability and design of these information leaflets, this may ease some of these problems. This SWAT is an embedded, randomised study within the NIHR-funded SARC trial to assess if improving readability impacts on recruitment into this interventional trial, which is being done in an emergency setting. An additional qualitative component will assess the impact or "value" of the information sheet in patients' decision making.[2]

**Interventions and comparators**
Intervention 1: Patient Information Leaflet A (PIL A) - "Optimised" information sheet, developed based on similar "improved information sheets" [3,4]
Intervention 2: Patient information leaflet B (PIL B) - "Conventional" information sheet based on Health Research Authority (HRA) example.

**Method for allocating to intervention or comparator**
Randomisation

**Outcome measures**
Primary: Proportion of patients who consent to take part in the interventional trial.
Secondary: Qualitative outcomes assessing the impact/value of the PIL in the decision making.

**Analysis plans**
Proportion of patients who consent to take part will be compared across both groups.

**Possible problems in implementing this SWAT**
Adherence to the randomisation schedule: because the randomisation is at a participant level and not at a site level, managing the allocation (and ensuring adherence) may be challenging. Ensuring the details of which PIL the patient received is recorded may also be challenging.

**References**
Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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