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.

Index Type: Participant Information

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
1) Wray RJ, et al. Do cancer patients fully understand clinical trial participation? A pilot study to assess informed consent and patient expectations. Journal of Cancer Education 2007;22(1):21.
2) Knapp P. The TRECA study: TRials Engagement in Children and Adolescents https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/142121/#/
3) Dresden GM, Levitt MA. Modifying a standard industry clinical trial consent form improves patient information retention as part of the informed consent process. Academic Emergency Medicine 2001;8(3):246-52.
4) Cockayne S, et al. An optimised patient information sheet did not significantly increase recruitment or retention in a falls prevention study: an embedded randomised recruitment trial. Trials 2017;18(1):144.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Rachelle Sherman, Graham Johnson, Andrew Tabner
Contact email address: rachelle.sherman@nhs.net
Date of idea: 7/DEC/2018
Revisions made by: Adwoa Parker, Apostolos Fakis
Date of revisions: 22/MAR/2019