SWAT 32: Effects of a re-designed Participant Information Sheet

Objective of this SWAT
To establish if the number of patients recruited and retained in a clinical trial is improved by the use of participant information sheets (PIS) with different input to their design.

Study area: Recruitment, Retention
Sample type:
Estimated funding level needed: Low

Background
During recruitment, potential trial participants are usually given a written patient information sheet (PIS) about the study. These are often long, complex and visually unappealing documents, which may have a negative impact on recruitment. Improving their readability by employing user testing, and their presentation by using graphic designers may improve patient understanding and aid recruitment. This SWAT has been done as an embedded randomised trial in the NIHR-funded REFORM study [1], as part of the MRC START initiative (Systematic Techniques for Assisting Recruitment to Trials) [2], to evaluate whether enhancing PIS improves trial recruitment and retention.

Interventions and comparators
Intervention 1: Original PIS, based on the NHS ethics template, plus a covering letter.
Intervention 2: Enhanced, user tested PIS, plus a user tested covering letter.
Intervention 3: 'Template' PIS developed using an enhanced PIS from another trial in a similar population, plus the original covering letter

Index Type: Method of Recruitment, Method of Follow-up, Participant Information

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Number of patients recruited to the clinical trial.
Secondary: Secondary outcomes will be:
1) Proportion of patients in each intervention group who go on to participate in the clinical trial (where this differs from the number actually recruited to the study due to, for example, exclusion criteria)
2) Proportion of recruited patients who are retained to the end of the clinical trial.

Analysis plans
The proportion of participants who return consent forms will be calculated for the three intervention groups (the original PIS and the two revised PIS). The difference between the three proportions will be calculated along with the corresponding 95% confidence interval.

Possible problems in implementing this SWAT

References
1. Cockayne S, Adamson J, Martin BC, et al. The REFORM study protocol: a cohort randomised controlled trial of a multifaceted podiatry intervention for the prevention of falls in older people. BMJ open, 2014; 4(12): e006977.
2. Rick J, Graffy J, Knapp P, et al. Systematic techniques for assisting recruitment to trials (START): study protocol for embedded, randomized controlled trials. Trials 2014; 15(1): 407.

Publications or presentations of this SWAT design
Cockayne S, Adamson J, Bower P, et al. The reform patient information sheet sub study - an embedded trial evaluating the enhancement of patient information sheets to improve recruitment. Trials 2015; 16(Suppl 2):P87.

Examples of the implementation of this SWAT

People to show as the source of this idea: Sarah Cockayne, Joy Adamson, Peter Bower, Belen Corbacho, Caroline Fairhurst, Lisa Farndon, Kate Hicks, Anne-Maree Keenan, Peter Knapp, Sally Lamb, Lorraine Loughrey, Caroline McIntosh, Hylton Menz, Anthony Redmond, Jo Rick, Sara Rodgers, Wesley Vernon, Jude Watson and David Torgerson
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