

# **SWAT 105: Effects of a patient-designed-and-informed participant information sheet versus a standard, researcher-designed information sheet on recruitment to a randomised trial**

## **Objective of this SWAT**

To examine the effects of a (patient) PPI-designed-and-informed participant information sheet (PIS) in comparison with a standard, researcher-designed information sheet on recruitment to the trial, rate of consent and relationship with participant retention, and understanding regarding the two PIS.

Study area: Recruitment, Retention

Sample type: Participants, Patients

Estimated funding level needed: Very Low

## **Background**

Recruitment is a critical process for randomised trials and the participant information sheet (PIS) is a key source of information for potential participants during the recruitment process. Although the PIS is crucial to ensuring that participants understand the implications of what they are consenting to,[1] such ethical consideration does not necessarily account for quality of the PIS. Understanding of the PIS is often poor amongst participants in health-related research,[1,2] because PIS are often lengthy and lack accessible language.[3,4] On the other hand, reducing length has been found to be ineffective and may negatively impact comprehension.[5] A small body of limited research has evaluated the effects of various PIS manipulations, generating mixed results on recruitment and comprehension.[3,6,7] In addition, some of these manipulations can be impractical and costly. As a result, research is still needed to identify a practical, feasible means of enhancing PIS clarity and comprehension, as well as subsequent participant retention.

It is hypothesised that a PIS developed in light of Public and Patient Involvement (PPI) may enhance trial understanding, recruitment and participant retention. PPI is an effective means of enhancing the likelihood of a successful trial by involving people with lived experience of a particular condition as partners throughout the research process.[8,9] Having design input, from the outset, of an individual eligible to participate in the randomised trial (e.g. someone living with the chronic illness), but without any personal bias involved with actually participating, may yield positive effects on recruitment and comprehension. Thus, this SWAT aims to compare the effects of a (patient) PPI-designed-and-informed participant information sheet versus a standard, researcher-designed information sheet on recruitment to the trial, rate of consent and relationship with participant retention, and understanding regarding the two PIS.

## **Interventions and comparators**

Intervention 1: Standard, researcher-designed Participant Information Sheet

Intervention 2: PPI-designed-and-informed Participant Information Sheet

Index Type: Participant Information, Method of Recruitment

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

Randomisation

## **Outcome measures**

Primary: Recruitment

Secondary: Understanding, Retention and Likeability

## **Analysis plans**

Two chi-square tests of independence will be performed to examine the relationship between the two groups (i.e. patient-designed-and-informed participant information sheet versus standard, researcher-designed information sheet) and recruitment and retention (i.e. completion versus non-completion of the trial). A series of analyses of variance will examine the effects of the PIS on level of retention, understanding and likeability for the two PIS.

## **Possible problems in implementing this SWAT**

As this SWAT will be implemented in a feasibility trial, the sample size may be too small to detect an important effect.

## **References**

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6. Knapp P, Raynor DK, Silcock J, et al. Can user testing of a clinical trial patient information sheet make it fit-for-purpose? A randomized controlled trial. *BMC Medicine* 2011;9(1):89.
7. Manley AJ, Lavender T, Smith DM. Processing fluency effects: Can the content and presentation of participant information sheets influence recruitment and participation for an antenatal intervention? *Patient Education and Counseling* 2015;98(3):391-4.
8. Crocker JC, Ricci-Cabello I, Parker A, et al. (2018). Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis. *BMJ* 2018;363:k4738.
9. Crocker J, Rees S, Locock L, et al. No. 3 PIRRIST: A patient and public involvement (PPI) intervention to enhance recruitment and retention in surgical trials (oral presentation). *International Journal of Surgery* 2018;59:S1-S2.

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

None

## **Examples of the implementation of this SWAT**

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