

# **SWAT 30: Use of a leaflet containing information about healthcare research for recruitment to a randomised trial**

## **Objective of this SWAT**

This SWAT evaluates the effectiveness of providing prospective trial participants with a leaflet about healthcare research, prior to their receiving a consent pack.

Study area: Recruitment

Sample type:

Estimated funding level needed: Unfunded

## **Background**

There is substantial information to indicate that recruitment to randomised trials can be problematic and that there are many uncertainties about the most appropriate ways to boost recruitment. For example, McDonald et al indicates that 45% of trials “failed to recruit to within 80% of target” [1] and a systematic review highlighted the need for further research [2]. Research by Ellis et al, in relation to public understanding of health research, has found poor levels of understanding amongst the general public of (a) the need for randomised trials and (b) the way in which these trials are enacted [3]. Furthermore, this research found that participants would be “more willing to consider participating in a clinical trial once they were better informed” [3]. Additional research relating to information booklets and understanding of clinical trials has found that participants are often unable to recall information relating to the trial they are participating in after general informed consent procedures [4]. This research however showed that patients have found trial information sheets and booklets useful; enabling patients to read the literature in their own time, equipping them with knowledge of what might be involved in a trial should they decide to consent and enabling them to refer back to this information at any point. Prospective and current trial participants may therefore benefit from clear concise information on research and what their involvement can mean and involve; making their involvement in a clinical trial more informed.

A number of studies have discovered that pre-notification increases questionnaire response rates [5]. This suggests that pre-notification is worthy of investigation as a means to improve consent response rates in randomised trials. Studies by Ellis et al and Ives et al both investigated the provision of additional information in relation to participant’s decisions to be involved in primary research [3, 4]. In both cases, consent was obtained prior to information being provided and both involved participants experiencing complex conditions. These trials indicated there was little difference between the intervention and control groups in terms of understanding or willingness to consent to a future study. However, these studies may not have been sufficiently powered for detecting a significant difference due to their small sample sizes. This SWAT investigates the use of pre-notification to provide information to prospective participants in advance of invitation to consent to join the trial. It was implemented in the REFORM (REducing Falls with ORthoses and a Multifaceted podiatry) Trial.

## **Interventions and comparators**

Intervention 1: Participants are sent a leaflet providing information on, and detailing the importance of, taking part in research. The leaflet will be sent to the participant approximately two weeks before the consent pack for the clinical trial.

Intervention 2: Participants receive no literature regarding research. They will be contacted when recruitment packs are mailed to prospective participants for the clinical trial.

Index Type: Method of Recruitment

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

Randomisation

## **Outcome measures**

Primary: Recruitment rate (defined as the proportion of people who are randomised into the clinical trial).

Secondary: Time to response (defined as the number of days elapsed between the consent pack being sent by the study site and the completed consent form being returned and recorded as such at the central trial facility).

Rate of retention in the follow up phase of the clinical trial (defined as the proportion of people who were provided with a research leaflet remaining in the study during the follow up phase of the clinical trial).

### **Analysis plans**

A chi squared test will be used to test for any statistically significant differences in the proportion of participants who responded between the two randomised groups and in the proportion of participants who are retained in the clinical trial. Logistic regression will be used to calculate odds ratios and corresponding 95% confidence intervals and P values. Cox's proportional hazards models for time to return will be used to analyse the differences between intervention and control groups for the secondary outcome, time to response.

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

Participants will not have opportunity to provide their informed consent for their involvement in this SWAT, because consent for the main clinical trial will not have been obtained at the point of sending out the pre-notification leaflet. However, because this leaflet is designed to be non-invasive and will contain generalised literature about healthcare research, it is unlikely that this will pose a major ethical issue.

### **References**

1. McDonald AM, Knight RC, Campbell MK, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials* 2006; 7: 9.
2. Treweek S, Mitchell E, Pitkethly M, et al. Strategies to improve recruitment to randomised controlled trials. *Cochrane Database of Systematic Reviews* 2010; (4): MR000013.
3. Ellis PM, Butnow PN, Tattersall MHN. Informing breast cancer patients about clinical trials: a randomized clinical trial of an educational booklet. *Annals of Oncology* 2002; 13: 1414-23.
4. Ives NJ, Troop M, Waters A, Davies S, Higgs C and Easterbrook PJ. Does an HIV clinical trial information booklet improve patient knowledge and understanding of HIV clinical trials? *HIV Medicine* 2001; 2: 214-9.
5. Edwards PJ, Roberts I, Clarke MJ, et al. Methods to increase response rates to postal and electronic questionnaires. *Cochrane Database of Systematic Reviews* 2009; (3): MR000008.

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

Arundel C, Torgerson D, Jefferson L, Cockayne S. A nested randomised controlled trial of a leaflet, containing information on research, to increase the recruitment rate of reform (reducing falls with orthoses and a multifaceted podiatry) trial participants. *Trials* 2013; 14(Suppl 1): O109.

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

People to show as the source of this idea: Catherine Arundel, David Torgerson, Laura Jefferson, and Sarah Cockayne

Contact email address: catherine.arundel@york.ac.uk

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