SWAT 229: Impact on recruitment of a brief compared with a standard participant information leaflet

Objective of this SWAT
This Study Within a Trial (SWAT) aims to evaluate the effectiveness of a shortened participant information leaflet (PIL) compared with a standard length PIL on recruitment and retention rates in the IBD BOOST host randomised trial (ISRCTN71618461).

Additional SWAT Details
Primary Study Area: Recruitment & Retention
Secondary Study Area: Document design and delivery, Participant identification and consent
Who does the SWAT intervention target: Participants, Patients
Estimated resources needed to conduct the SWAT: Low
Estimated cost of the SWAT (£): £4,962

Findings from Implementation of this SWAT
Reference(s) to publications of these findings: N/A
Primary Outcome Findings: N/A
Cost: N/A

Background
Randomised trials delivered via the internet are an increasingly common and acceptable form of generating research evidence [1, 2]. A common method of recruiting participants into internet-delivered trials is from registries or databases, where potentially eligible patients are invited to participate in the randomised trial and provided with the trial's PIL. However, PILs are often lengthy and complex – typically about 8 pages long [3]. There is a hypothesis that being asked to read such a large document in one go may act as a deterrent to potential participants becoming involved in the research [4]. In one trial comparing an electronic interactive information leaflet versus a standard length, Research Ethics Committee (REC) approved, PIL, only 9% of people accessed the detail presented on the standard length REC approved PIL [5]. A shorter PIL may be more appealing to patients initially because it is likely to provide a more manageable amount of information, which may encourage more potential participants to contact the trial team and subsequently be recruited into the trial [4].

The Cochrane Review of recruitment interventions identified two trials that have evaluated a brief PIL compared with a full length PIL [4, 6, 7], and found the brief PIL made little or no difference to recruitment compared with a full PIL (risk difference = 0%, 95% CI = -2% to 2%, GRADE: moderate). It would be useful to replicate this comparison in an online setting, where people typically read the minimal information provided [8], to determine whether a brief or a standard length PIL is more effective in this setting. We will do so in this SWAT and we will also compare retention between the SWAT groups, because of the potential for people who have received more information to be more motivated to remain in the trial.

Host Trial Population: Adults
Host Trial Condition Area: Gastrointestinal

Interventions and Comparators
Intervention 1: Shortened online PIL, with hyperlinks for more detailed information that potential participants can access to read.
Intervention 2: Standard length PIL, with all required details provided in a single online document.

Method for Allocating to Intervention or Comparator: Randomisation

Outcome Measures
Primary Outcomes: 1) Recruitment rate (proportion of participants in each SWAT group who are randomised into IBD BOOST).
Secondary Outcomes: 1) Proportion of patients in each SWAT group who express an interest in participating in IBD BOOST; 2) Proportion of participants in the shortened PIL group who access

the full PIL information; 3) Number of follow up queries received before randomisation by the study team; 4) Retention rates of participants at 6 and 12 months.

Analysis Plans
All analyses will be conducted by intention to treat. Participants will be analysed according to the group they were randomised to, irrespective of which PIL they received. A two-sided p-value of <0.05 will be taken to indicate a statistically significant result.

The numbers and percentages in each SWAT group will be reported for categorical outcomes and means (with SD) will be reported for continuous outcomes. Proportions of people approached who are subsequently randomised will be compared using logistic regression adjusting for entrance pathway and reported as an adjusted odds ratio with 95% confidence interval. Secondary outcomes will be analysed in the same way.

Possible Problems in Implementing This SWAT

References Cited in This Outline
1. Mathieu E, et al. Internet trials: participant experiences and perspectives. BMC Medical Research Methodology 2012;12:162.
2. Mathieu E, et al. Internet-based randomized controlled trials: a systematic review. Journal of the American Medical Informatics Association 2013;20(3):568-76.
3. https://www.hra-decisiontools.org.uk/consent/docs/Consent%20and%20PIS%20Guidance.pdf (accessed 22 June 2024)
4. Brierley G, Richardson R, Torgerson D. Using short information leaflets as recruitment tools did not improve recruitment: A randomized controlled trial. Journal of Clinical Epidemiology 2012;65(2):147–54.
5. Kirkby HM, et al. Informing potential participants about research: Observational study with an embedded randomized controlled trial. PloS One 2013;8(10):e76435.
6. Chen F, et al. Investigating strategies to improve attendance at screening visits in a randomized trial. Trials 2011;12(supplement 1):A111.
7. Treweek S, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018;(2):MR000013.
8. Antoniou EE, et al. An empirical study on the preferred size of the participant information sheet in research. Journal of Medical Ethics 2011;37(9):557-62.

References to This SWAT

Source of This SWAT
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