SWAT 116: Impact on recruitment of adding an Infographic to a Patient Information Leaflet

Objective of this SWAT
To evaluate the effectiveness and cost effectiveness of an infographic provided in addition to a standard patient information leaflet on recruitment to a clinical trial.

Study area: Recruitment
Sample type: Patients
Estimated funding level needed: Low

Background
Randomised trials are the gold standard for testing the effects of interventions and treatments; but their validity and reliability is highly dependent on the recruitment of a sufficient number of participants (1). Reviews have shown that randomised trials have consistently struggled with recruitment; with some showing that approximately half of randomised trials do not achieve their required sample size (2-4). Given this context, evidence-based methods to increase recruitment to randomised trials are important.

Various strategies have been tested but a Cochrane Methodology Review showed that only a small number of these have provided strong evidence of their potential to affect recruitment and the review found that tailoring or shortening the patient information sheet given to participants made little or no difference to recruitment (5). None of the studies included in the review tested the use of information graphics ("infographics") to enhance recruitment. Infographics use a combination of text, images and data visualisation to provide key information in an engaging format and are increasingly used by funders and researchers to present an overview of their work (6). Evidence around the effectiveness of infographics in a health context is limited but persuasive. Infographics have been shown to improve patient knowledge; both in relation to personally relevant information such as discharge instructions, and statistical information such as the association of age with cancer risk (7, 8). Another study with patients, students and doctors found that infographics did not increase knowledge when compared to plain language summaries but the infographics did improve reader experience and user-friendliness (9).

These findings suggest that there may be the potential for infographics to improve the experience of potential participants and improve their understanding of health research, leading to increased recruitment. Embedding studies within ongoing randomised trials provides a useful and robust mechanism to evaluate recruitment methods (10) and this SWAT will test the use of an infographic in addition to the participant information leaflet to increase recruitment to an established trial.

Interventions and comparators
Intervention 1: An infographic (provided in addition to a patient information leaflet (PIL)) at the point of recruitment.
Intervention 2: Standard practice for the host trial (i.e. standard PIL only).

Index Type: Method of Invitation

Method for allocating to intervention or comparator
Randomisation (minimisation)

Outcome measures
Primary: Recruitment rate, defined as the proportion of participants in each SWAT group randomised into the host trial.
Secondary: 1. Proportion of patients who are screened for the study but do not go on to be randomised due to a) ineligibility or b) non-consent, according to each SWAT group
2. Cost-effectiveness of the intervention

Analysis plans

Primary analysis: The difference in recruitment rate between those receiving the infographic and those not receiving it will be analysed using logistic regression adjusting for the factors used in the minimisation, with site as a random effect.

Secondary analysis: The difference in the proportion of those responding to a recruitment invitation who received the infographic and those not receiving it who do not go on to be randomised will also be analysed using logistic regression adjusting for the factors used in the minimisation, with site as a random effect.

The difference in cost per recruited participant between those given the infographic and those not given it will be calculated. In addition to the direct costs of the infographic, it may also be necessary to include the cost of staff time spent administering the recruitment packs.

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 providing the infographic. However, because this is a non-invasive, low-risk intervention and the infographic will merely summarise information contained in the PIS, it is unlikely that this will pose a major ethical issue.

References

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Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Jennifer McCaffery; Catherine Arundel; Professor Ian Chetter; Caroline Fairhurst; Kalpita Joshi; Andrew Mott; Jackie Wilkinson
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Revisions made by:
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