

SWAT 187: Impact on recruitment of adding a pictorial aid to a patient information sheet

Objective of this SWAT

To evaluate the effectiveness and cost effectiveness of adding a pictorial aid to a standard patient information sheet (PIS) on recruitment rates.

Study area: Recruitment

Sample type: Patients, Legal Representatives

Estimated funding level needed: Low

Background

Randomised trials are the keystone of evidence-based health care. However, recruitment and retention are major challenges to the success of a trial, particularly when trying to include participants from under-served groups.

Patients with low health literacy are less likely to participate in decisions about their own health [1, 2] and there is evidence that just under one in six adults in the UK have the literacy of an 11-year-old [3]. Systematic review evidence shows that the use of pictures with text can improve health communication [4] and that patients with low health literacy may gain a better understanding when being asked to consent to taking part in a trial if diagrams and pictures are used [5]. Therefore, the use of a pictorial aid with the patient information sheet (PIS) may improve a patient's understanding of the trial and boost recruitment. The need to resolve uncertainties about approaches to ensure inclusion of under-represented or vulnerable groups in randomised trials and optimisation of informed consent processes have been identified as priorities by the Prioritising Recruitment in Randomised Trials study (PRioRiT_y) [6]. This SWAT aims to contribute to resolving these uncertainties.

The SWAT will be embedded in the TIDE Trial, which is a 3-group, multi-centre, randomised non-inferiority and cost effectiveness trial comparing polyhexanide, chlorhexidine with neomycin and mupirocin for nasal methicillin-resistant *Staphylococcus aureus* (MRSA) decolonisation amongst adult hospital in-patients (ISRCTN12184897).

Interventions and comparators

Intervention 1: Pictorial aid with standard PIS

Intervention 2: Standard PIS

Index Type: Participant Information

Method for allocating to intervention or comparator

Cluster randomisation of sites

Outcome measures

Primary: Recruitment rate (proportion of eligible patients randomised to the host trial).

Secondary: Cost effectiveness of pictorial aid on recruitment

Analysis plans

For the primary analysis, the primary outcome of being randomised to the host trial will be analysed using a mixed-effects logistic regression model at the patient-level, controlling for recruiting site as a random effect and adjusting for relevant baseline covariates including SWAT allocation, host trial allocation and minimisation factors as fixed effects. Full analyses will be detailed in a SWAT statistical analysis plan.

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, the time and costs involved in staff administering the recruitment packs will be considered.

Possible problems in implementing this SWAT

To ensure there is no negative impact on overall recruitment to the host trial, both the standard PIS and the pictorial aid have been developed in conjunction with the trial's patient/public advisory group (PAG). No significant potential problems are anticipated.

References

1. Barragán M, et al. Low health literacy is associated with HIV test acceptance. *Journal of General Internal Medicine* 2005;20(5):422-5.
2. Mancuso CA, Rincon M. Asthma patients' assessments of health care and medical decision making: the role of health literacy. *Journal of Asthma* 2006;43(1):41-4.
3. Harding C, et al. The 2011 skills for life survey: A survey of literacy, numeracy and ICT levels in England, in London: Department for Business Innovation and Skills. 2012.
4. Houts PS, et al. The role of pictures in improving health communication: a review of research on attention, comprehension, recall, and adherence. *Patient Education and Counseling* 2006;61(2):173-90.
5. Burks AC, Keim-Malpass J. Health literacy and informed consent for clinical trials: a systematic review and implications for nurses. *Nursing: Research and Reviews*, 2019;9: 31.
6. Brunsdon D, et al. What are the most important unanswered research questions in trial retention? A James Lind Alliance Priority Setting Partnership: the PRioRiTty II (Prioritising Retention in Randomised Trials) study. *Trials* 2019;20: 593.

Publications or presentations of this SWAT design

NA

Examples of the implementation of this SWAT

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Date of idea: 4/JUL/2020

Revisions made by: NA

Date of revisions: