

SWAT 26: Improving trial recruitment with a leaflet advertising patient and public involvement

Objective of this SWAT

The aim of this study is to evaluate the impact on recruitment of a leaflet advertising patient and public involvement (PPI) in mental health trials to potential participants. This study has been done within a mental health trial involving service users with severe mental health problems.

Study area: Recruitment, Retention

Sample type: Patients, Participants, Sites in a Cluster Randomised Trial

Estimated funding level needed: Low

Background

Evidence is emerging that patient and public involvement (PPI) may improve recruitment into trials, but the best methods to achieve improvement and the mechanism of action are unclear [1]. Although many trials use PPI to improve design and conduct, many do not clearly communicate this PPI to potential participants. Better advertising of PPI in trials might encourage patient participation. This study has been embedded in the EQUIP mental health trial, which involves service users with severe mental health problems. The EQUIP trial was a cluster randomised controlled trial, in which community mental health teams in NHS Trusts in England were allocated either to a training intervention to improve user and carer involvement in care planning or control (no training and care planning as usual). All participants in the EQUIP trial were recruited by postal invitation, sent via community mental health teams.

Interventions and comparators

Intervention 1: The recruitment intervention is the use of a leaflet to advertise patient and public involvement in the EQUIP trial to potential participants. The principles underlying the intervention were informed by a systematic review and a workshop. The intervention was developed with the EQUIP trial PPI partners (service users and carers). Professional graphic design optimised readability and impact. Potential participants in the intervention group received the leaflet communicating PPI, in addition to the standard trial invitation of a cover letter and participant information sheet.

Intervention 2: The standard trial invitation, comprising of a cover letter and a participant information sheet.

Index Type: Method of Recruitment, Participant Information

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Proportion of participants who gave their consent and were recruited in the EQUIP host trial after responding to the postal trial invitation.

Secondary: a) Proportion of patients who agreed to participate after responding to the postal trial invitation (this differs from the number actually recruited because of, for example, the application of the exclusion criteria)

b) Proportion of patients who gave their consent and were recruited after responding to both the postal trial invitation and telephone follow-up of initial non-responders

c) Proportion of patients who agreed to participate after responding to both the postal trial invitation and telephone follow-up of initial non-responders

Analysis plans

Preliminary graphical and tabular examination of the data will explore baseline comparability of randomised groups and representativeness of the sample in terms of the overall eligible population. The proportion of participants who gave their consent and were recruited will be calculated for the two intervention groups (PPI leaflet and no PPI leaflet). The difference between the two proportions will be calculated along with the corresponding 95% confidence interval (CI). Outcomes will be first described separately by group, and then compared using logistic regression to estimate the between-group odds ratio (OR) and corresponding 95% CI on the basis of the

intention-to-treat principle. A planned secondary analysis will be performed to explore whether the impact of the intervention is moderated by gender.

Possible problems in implementing this SWAT

- 1) Working with PPI stakeholders to develop an appropriate leaflet intervention advertising PPI
- 2) Recruiting host trial and developing recruitment materials in line with their recruitment timelines
- 3) Host trial is a cluster randomised trial with relatively small numbers of clusters. There is therefore a need to ensure that there is a balance between clusters randomised to the host trial intervention and host trial control, and the SWAT intervention and control

References

- 1) Hughes-Morley A, Young B, Hann M, Waheed W. Advertising patient and public involvement in trials as a way of improving participant recruitment: development of an intervention and its evaluation. *Trials* 2015; 16(Suppl 2):P100.

Publications or presentations of this SWAT design

Hughes-Morley A, Young B, Hann M, Waheed W. Advertising patient and public involvement in trials as a way of improving participant recruitment: development of an intervention and its evaluation. *Trials* 2015; 16(Suppl 2):P100.

Examples of the implementation of this SWAT

People to show as the source of this idea: Adwoa Hughes-Morley
Contact email address: adwoa.hughes-morley@manchester.ac.uk
Date of idea: 1/MAR/2014
Revisions made by:
Date of revisions: