SWAT 119: Effects on retention of giving trial participants a thank you card following each study visit.

Objective of this SWAT

To evaluate the effects of giving trial participants a thank you card following each study visit, compared with not giving them a thank you card.

Study area: Retention, Follow-up Sample type: Participants Estimated funding level needed:

Background

Reliable testing of the effects of interventions in randomised trials is fundamental to decision making about health care. Approximately a quarter of trials experience attrition, resulting in greater than 10% of primary outcome data being unavailable for use in the end analysis.[1] Problems with trial retention can limit the internal and external validity of the study.[2]

There is therefore a need to identify interventions that improve retention of participants and one method for developing and testing interventions is to 'nest' trials of retention interventions in ongoing randomised trials. Testing interventions in ongoing trials ensures causality of intervention effectiveness is assessed [3] and avoids limitations that would arise if the intervention was tested in a setting other than a randomised trial.

Many recruitment and retention strategies routinely include some element of thanks within them. But there is little evidence to suggest that these are effective. Recent evidence suggests that those saying thank you often undervalue its effect [4]. There is therefore a need to test the impact of thanks in the context of trial recruitment and retention, and this SWAT complements others, such as SWAT 54 and SWAT 114. It is embedded in the SWHSI-2 trial of interventions to treat surgical wounds (ISRCTN26277546).

Interventions and comparators

Intervention 1: A Thank You card is sent to trial participants at 4.5 and 9 months after randomisation. The host trial includes routine weekly clinical follow up assessments (if the participant's wound is yet to heal) and participants in this SWAT group will also be sent questionnaires for the next outcome assessment time point (at months 6 and 12) when due. Intervention 2: Standard practice for the host trial (i.e.no thank you card). The host trial includes routine weekly clinical follow up assessments (if the participant's wound is yet to heal) and participants in this SWAT group will receive no further contact until the next outcome assessment time point (at months 6 and 12).

Index Type: Method of Follow-up

Method for allocating to intervention or comparator

Block randomisation stratified by the host trial's treatment arm using randomly varying block sizes to avoid imbalance between the SWAT groups.

Outcome measures

Primary: Questionnaire response rate, defined as the proportion of participants in each group who complete and return the questionnaire at the 6-month follow up visit.

Secondary: 1) Completeness of response (percentage of questions completed) at 6 months.

2) Whether a reminder notice is required (number of participants requiring a reminder mailing divided by the number of participants who were sent a questionnaire) at 6 months.

3) Cost of SWAT intervention per participant retained at 6 months.

4) Completeness of response, whether a reminder notice is required, and cost per participant retained at 12 months.

Analysis plans

Primary analysis: The difference in retention rate at 6 months between those allocated to the thank you card and those not allocated to it will be analysed using logistic regression adjusting for main trial allocation and site, as a random effect.

Secondary analysis: The difference in completeness of response between those in the two SWAT groups will be analysed using logistic regression, adjusting for main trial allocation and site as a random effect. The difference in the proportion of participants requiring a reminder letter in the two SWAT groups will be analysed using logistic regression, adjusting for main trial allocation and site as a random effect.

The difference in cost per retained participant between those allocated a thank you card and those not allocated to receive one will be calculated. In addition to the direct costs of the thank you card and postage, it may be necessary to include the cost of staff time spent administering the mail out (for example filling and labelling envelopes).

The secondary outcomes at 12 months will be analysed as described above for the 6-months outcomes.

Possible problems in implementing this SWAT

None anticipated.

References

1. Hewitt CE, Kumaravel B, Dumville JC, et al. Assessing the impact of attrition in randomised controlled trials. Journal of Clinical Epidemiology 2010; 63: 1264-70.

2. Torgerson DJ, Torgerson CJ. Designing randomised trials in health education and the social sciences: an introduction. Basingstoke: Palgrave MacMillan 2008.

3. Bowling A. Research methods in health: investigating health and health services (3rd edition). Maidenhead: The Open University Press 2009.

4. Kumar A, Epley N. Undervaluing gratitude: expressers misunderstand the consequences of showing appreciation. Psychological Science 2018; 29(9): 1423–35.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: Ms Catherine Arundel, Professor Ian Chetter, Ms Caroline Fairhurst, Ms Kalpita Joshi, Dr Jenifer McCaffery, Mr Andrew Mott, Ms Jackie Wilkinson Contact email address: catherine.arundel@york.ac.uk Date of idea: 1/NOV/2019 Revisions made by: Date of revisions: