SWAT 28: Pre-notification of trial participants by newsletter to improve response rates

Objective of this SWAT
To assess the effects of pre-notification using a newsletter to increase questionnaire response rates within a randomized trial.

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

Background
Attrition in randomized trials is an important threat to their internal validity [1]. In addition, attrition also affects the statistical power of the study by decreasing the effective sample size. Many, if not most, randomised trials suffer some element of attrition. In particular, trials that rely on self-completed outcome measures from patients, often delivered by post, can have high levels of attrition and a 20% loss to follow-up in such trials is not uncommon [2]. Consequently, it is crucial that ways to keep attrition to a minimum are identified and implemented and several randomised trials have been done to test different strategies to reduce attrition or increase response rates to surveys [3]. The SCOOP trial is evaluating a screening program that aims to identify women aged between 70 and 84 years who are at high risk of osteoporotic fractures. One method of data collection in this trial is to send out six monthly questionnaires to ascertain incident fracture status as well as participants' quality of life and resource use. The trial has recruited more than 12,000 participants across seven centers and, for this SWAT, two centers (Norwich and York) developed a generic newsletter about the trial, which was tailored to each site.

Interventions and comparators
Intervention 1: Newsletter printed as an A5 single sheet, which was sent approximately 6 weeks before participants were due to receive their 24-month questionnaire. The sheet was folded into a booklet, giving the participants an update on the trials progress, and reminding them about the importance of returning their questionnaires whether or not they were in the control or intervention group. On the back of the newsletter, there was a brief description, with a photograph, of the local study team, with a reminder of the local trial coordinator's contact details if the participant had any queries or questions.
Intervention 2: Same newsletter sent after participants had returned their follow-up questionnaire

Index Type: Method of Follow-up, Participant Information

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Overall questionnaire response rate, calculated as the number of patients who returned the 24-month follow-up questionnaire divided by the number of patients who were sent a questionnaire.
Secondary: Whether a reminder was required (number of patients requiring a reminder mailing divided by the number of patients who were sent a questionnaire); completeness of the primary outcome (number of patients with a complete primary outcome divided by the number of patients returning a questionnaire); and time to response (length of time taken to return the questionnaire).

Analysis plans
Univariate odds ratios (ORs) for each response rate and the log rank test to compare the time to response between the two groups. Participants who withdrew consent for follow-up questionnaires or who did not want to receive a questionnaire at this time point were included in the analysis as nonresponders. Nonresponders in the control group who had not withdrawn from the trial received the newsletter after the study was complete.

Possible problems in implementing this SWAT

Pre-notification may have some drawbacks such as increasing the cost of the study, which, if the absolute difference is small, may mean that it is not cost-effective. In some studies, it may cause anxiety by unduly reminding patients of a condition which makes them at higher risk of poor health outcomes.

References

1. Torgerson DJ, Torgerson CJ. Designing randomised trials in health, education and the social sciences. Basingstoke, UK: Palgrave Macmillan; 2008.
2. Hewitt CE, Kumaravel B, Dumville JC, Torgerson DJ. Assessing the impact of attrition in randomized controlled trials. Journal of Clinical Epidemiology 2010; 63: 1264e70.
3. Edwards P, Roberts I, Clarke M, DiGuiseppi C, Pratap S, Wentz R, et al. Increasing response rates to postal questionnaires: systematic review. Cochrane Database of Systematic Reviews 2009; (3): MR000008.

Publications or presentations of this SWAT design

Mitchell N, Hewitt CE, Lenaghan E, Platt E, Shepstone L, Torgerson DJ, and SCOOP study team. Prior notification of trial participants by newsletter increased response rates: a randomized controlled trial. Journal of Clinical Epidemiology 2012; 65(12): 1348-52.

Examples of the implementation of this SWAT

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Date of idea: 1/FEB/2007
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Date of revisions: