SWAT 114: Effects of telephone calls or postcards to trial participants following enrolment on retention in a randomised trial

Objective of this SWAT
To evaluate the impact of courtesy introductory telephone calls to newly recruited trial participants on their response to follow-up questionnaires compared with a written card with equivalent information, or neither.

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

Background
Randomised trials often experience difficulties with maintaining follow-up from participants, which can introduce bias, reduce the sample size and statistical power and affect the validity, reliability and generalisability of findings.[1-5] Trial teams often use telephone calls to collect data or as a courtesy to thank participants for participating in the trial, and to remind them of future follow-up. It is unclear however what impact these courtesy telephone calls have, whether they are cost effective and how they compare with alternatives, such as a written thank you card with a reminder about subsequent follow-ups.

This SWAT is funded by the PROMoting THE USE of SWATs (PROMETHEUS) programme (Medical Research Council Grant number MR/R013748/1) (www.york.ac.uk/healthsciences/research/trials/research/swats/prometheus).

Interventions and comparators
Intervention 1: Courtesy introductory telephone call within one month of being enrolled into the host trial. These phone calls will include the same content: (a) Participant will be thanked for taking part; (b) reminded how valuable their contribution is; (c) reminded of future follow-up arrangements; (d) informed when the trial results are expected; (e) asked to contact the trial team if they have any queries or asked if they would like the trial team to contact them.
Intervention 2: Postcard-sized written card, with similar content to the above, signed by the host trial's chief investigator, trial manager or both; posted in an envelope to the participant's home within one month of being randomised.
Intervention 3: Neither of the above.

Index Type: Reminder

Method for allocating to intervention or comparator
1:1:1 block randomisation

Outcome measures
Primary: Proportions of participants who complete and return the questionnaire at 6 weeks, 12 weeks, and 6-month time points.
Secondary: Time to response (length of time taken to return the questionnaires); completeness of response (average percentage of questions completed for all applicable questionnaires) at the 6-month time point; 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 the 6-month time point; cost of SWAT intervention per participant retained.

Analysis plans
For the primary outcomes of questionnaire response rates, a logistic regression will be performed, and the effect of the SWAT intervention reported as an adjusted odds ratio (OR) with its associated 95% confidence interval (CI) and p-values. Data from this SWAT will be analysed as two separate comparisons of an intervention with control (i.e. telephone call versus control and postcard versus control).

The secondary outcome of ‘time to 6-month questionnaire return’ will be assessed by a Kaplan Meier curve. Cox regression will be applied, and the effect of the interventions reported. Completeness of response will be analysed using linear regression and reported. The requirement for any questionnaire return reminder will be analysed and reported using logistic regression.

Possible problems in implementing this SWAT
None anticipated.

References
(1) Brueton VC, et al. Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2013; (12): MR000032.
2. Fewtrell MS, et al. How much loss to follow-up is acceptable in long-term randomised trials and prospective studies? Archives of Disease in Childhood 2008; 93(6): 458-61.
(3) Schulz KF, Grimes DA. Sample size slippages in randomised trials: exclusions and the lost and wayward. Lancet 2002; 359(9308): 781-5.
(4) Waller R. Principles of exposure measurement in epidemiology. Occupational and Environmental Medicine 1994; 51(11): 790.
(5) Edwards P, et al. Methods to increase response to postal and electronic questionnaires. Cochrane Database of Systematic Reviews 2009; (3): MR000008.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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