SWAT 121: What are the effects on retention and follow-up of courtesy telephone calls versus postcards to trial participants following enrolment?

Objective of this SWAT
To evaluate the effect on response rates to subsequent follow-up questionnaires of making a courtesy introductory telephone call to newly recruited participants in a randomised trial compared with a written card with equivalent information.

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

Background
Randomised trials are the bedrock of testing healthcare treatments. However, achieving high retention of trial participants can be difficult. Trial teams often experience difficulties with maintaining follow-up and high questionnaire response rates from participants, which can introduce bias, reduce the available sample size and statistical power, and affect the validity, reliability and generalisability of findings [1-5].
Therefore, there is a need to develop and test interventions to improve retention of participants. One way to do this is to 'embed' trials of retention interventions in ongoing randomised trials. Testing interventions in ongoing trials ensures causality of intervention effectiveness is assessed [4] and avoids limitations associated with testing in a quasi- or non-randomised trial.
In the UK in 2017-18, 85% of households had a landline telephone [6], whilst 95% had a mobile telephone [7]. Courtesy telephone calls are routinely used in commercial and service settings to engage customers and are perceived to be 'good customer service', helping to remind customers of upcoming appointments or to check on the arrival of products.
In clinical research settings, there is evidence that telephone calls offer an effective method of data collection [8]. Advantages of speaking with research participants on the telephone include developing positive relationships between research teams and participants [8]. Some trial teams also routinely telephone newly recruited participants as a courtesy or introduction to thank them for participating in the trial, and to remind them that they will be followed up at pre-specified times. It is unclear however, what impact these courtesy telephone calls have, whether they are cost effective and how they compare with a written thank you card containing a reminder about subsequent follow-ups.

This SWAT will be hosted in the 'Acute Rehabilitation following Traumatic anterior shoulder dISlocAtioN (ARTISAN): A Multi Centre Randomised Controlled Trial' (ISRCTN63184243). ARTISAN aims to establish if a course of physiotherapy is of clear benefit when compared to a single session of advice, following a first time traumatic anterior shoulder dislocation. 478 consenting participants will be randomly allocated to receive either a single session of advice or a course of physiotherapy. The primary outcome will be the Oxford Shoulder Instability Score (OSIS) at six months after randomisation. Complications resulting from treatment and implications on resources for participants and the NHS will also be studied up to 12 months after randomisation. Follow up of participants will be by postal questionnaires at six weeks, and then at 3, 6 and 12 months.

Interventions and comparators
Intervention 1: A courtesy introductory telephone call [within two weeks] of being randomised into ARTISAN. This telephone call will include the following content: a) thanks for taking part in the ARTISAN trial; b) reminder about how valuable their contribution is; c) reminder that they will be contacted by post at six weeks, and then at 3, 6 and 12 months post randomisation, and that these contacts are just as important as their first visit; d) information about when the trial results are expected; e) reminder that they can contact the ARTISAN team if they have any queries.
Intervention 2: A postcard-sized written card, with similar content as above, signed by the Chief Investigator and Trial Manager posted in an envelope to participants' homes within one week of being randomised.

Index Type: Method of Follow-up

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: The primary outcome is the questionnaire response rate at six months. This is defined as the proportion of participants who return the questionnaire by post at the 6-month time point within the response window.
Secondary: 1. Time to response to the questionnaires at all time points, i.e. 6 weeks, 3, 6 and 12 months (date of first posting to date of questionnaire received by study team) 2. Response rates at 6 weeks, and then at 3 and 12 months (as for primary outcome) 3. Response rates at 6 weeks, 3 months, 6 months and 12 months (return of questionnaire data at any point, including via telephone) 4. Completeness of responses. This will be counted as the number of missing items in the PROMS (OSIS, QuickDASH and EQ5D) and the complications section. 5. Number of reminder notices required. 6. Cost of intervention (phone call or postcard) per participant.

Analysis plans
All eligible participants will be included in the analysis on an intention-to-treat basis, using two-sided statistical significance at the 5% level. All statistical analyses will be conducted in R or SPSS. We will summarise baseline characteristics of participants in each SWAT intervention. For the outcomes of questionnaire response rates, the difference in proportions will be calculated with 95% confidence intervals, and the primary analysis will be a chi-squared test to assess statistical association. A logistic regression adjusting for age, gender and host trial treatment allocation will be performed to investigate the effects of these variables. A per protocol analysis will also be performed.
The secondary outcome of time to questionnaire return will be assessed by a Kaplan Meier curve and the SWAT interventions compared by log rank test. Cox regression will be applied, adjusting for participant age, gender and host trial treatment allocation, and the effect of the intervention reported. The requirement for any questionnaire return reminder will be analysed in the same way as the primary outcome.
An average cost per participant will be estimated for each SWAT intervention.

Possible problems in implementing this SWAT
The main challenge to this SWAT could be the extra staff resources needed to deliver the interventions, but the host trial team have mitigated this risk.

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 (7): MR000008.
6. Statista. Percentage of households with landline telephones in the United Kingdom (UK) from 1970 to 2018. Available from https://www.statista.com/statistics/289158/telephone-presence-in-households-in-the-uk/ (accessed on 24 February 2020).
7. Statista. Percentage of households with mobile phones in the United Kingdom (UK) from 1996 to 2018. Available from https://www.statista.com/statistics/289167/mobile-phone-penetration-in-the-uk/ (accessed on 24 February 2020).
8. Musselwhite K, et al. The telephone interview is an effective method of data collection in clinical nursing research: A discussion paper. International Journal of Nursing Studies 2007; 44(6): 1064-70.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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