SWAT 79: Effect of a birthday card on retention and data completion rates in trials involving children

Objective of this SWAT
To evaluate whether sending a birthday card improves retention and data completion rates in trials involving children

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

Background
A low response rate to trial follow-up questionnaires adversely impacts on the validity and generalisability of findings. Participant retention in trials involving children has been identified as particularly challenging [1]. The Cochrane Methodology Review of retention interventions, albeit tested mainly in adults, identified a range of non-monetary incentives such as certificates of appreciation, pins, pens and offer of study results that have been tested [2]. Another Cochrane Methodology Review, by Edwards et. al., [3] also identified a range of non-monetary incentives intended to increase response to postal and electronic questionnaires. The odds of response were increased by more than one tenth when a non-monetary incentive was used (OR 1.15; 95% CI 1.08 to 1.22). Birthday cards are non-monetary incentives often used in longitudinal studies and paediatric trials to enhance participant retention [4-6], but to date their impact on retention rates has not been robustly evaluated.

This SWAT will be suitable for host trials with a minimum of a 12 month follow-up period. The SWAT can be used in trials using any method of follow-up, including face-to-face and/or postal. For logistical reasons and to avoid contamination between randomised groups, it would be easier to do a single randomisation for each participant and then that participant will either receive or not receive birthday cards for the whole trial.

Interventions and comparators
Intervention 1: Birthday card.
Our PPI (patient and public involvement) group felt that the birthday cards should not have anything on the front that could be offensive. The front will therefore have a gender neutral image linked to the trial.
Intervention 2: No birthday card

Index Type: Method of Follow-up, Birthday Cards,

Method for allocating to intervention or comparator
Participants will be randomly allocated 1:1 to one of the two groups using block randomisation stratified by main trial allocation using randomly permuted block sizes. Allocation will take place at the time of allocation to the main trial so as not to miss any participants whose birthdays are shortly after their randomisation date. The allocation sequence will be generated by a statistician who is not involved in the recruitment of participants.

Outcome measures
Primary: Response rate to the participant follow-up questionnaire at the first time point following receipt of the birthday card.
Secondary: 1) Response rate to the participant follow-up questionnaire at the 12-month follow-up:
2) Time to response (number of days from date due to date returned)
3) Completeness of primary outcome measure (defined as providing sufficient data to produce a valid summary score)
4) Need for a postal reminder
5) Cost per participant retained

Analysis plans
The sample size for this embedded trial will be constrained to the number of participants recruited into the host trial. All participants recruited into the host trial and who are currently participating in

the study, at the point at which their birthday card is due to be sent out, will be eligible to take part in this embedded trial. The host trial aims to recruit 478 participants. With this sample size, we would have 90% power to detect a 10 percentage point increase in response rate between the no birthday card (control) group and the birthday card group assuming a response rate of 80% in the no birthday card group, using a two-sided alpha of 0.05.

Analyses will follow the principles of intention to treat, including all participants in the groups to which they were originally allocated. Response rates, completeness of response and need for a postal reminder will be analysed using mixed-effect logistic regression adjusting for main trial allocation, and recruitment site as a random effect. Time to response will be compared between the groups using Cox proportional hazards regression.

Subgroup analyses for age and gender will be undertaken for the primary outcome to see if response rates differ in these groups. This will be undertaken by including an interaction between the factor (age/gender) and embedded trial allocation in the logistic regression model.

Possible problems in implementing this SWAT

The main challenge in implementing this SWAT relates to staff time to complete the mail out. Religious groups such as Jehovah's Witnesses might be averse to having their birthday acknowledged, so we will ask the clinicians to let us know if they can think of anyone who would be offended, and care must be taken to create a birthday card which is inoffensive to diverse populations. The costs associated with the SWAT will relate to 1) design and printing, 2) postage and stationary, and 3) staff time for randomisation, and administering.

References

1. Huntington C, et al. Lessons learned on recruitment and retention in hard-to-reach families in a phase III randomised controlled trial of preparatory information for children undergoing general anaesthesia. BMC Oral Health 2017;17(1): 122.
2. Brueton VC, et al. Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2013;(12):MR000032.
3. Edwards PJ, et al., Methods to increase response to postal and electronic questionnaires. Cochrane Database of Systematic Reviews 2009;(7):MR000008.
4. Brueton VC, et al. Use of strategies to improve retention in primary care randomised trials: a qualitative study with in-depth interviews. BMJ Open, 2014.4:e003835.
5. Abshire M, et al. Participant retention practices in longitudinal clinical research studies with high retention rates. BMC Medical Research Methodology 2017;17(1):30.
6. Funkhouser E, et al. Where are they now? Retention strategies over 25 years in the Coronary Artery Risk Development in Young Adults (CARDIA) Study. Contemporary clinical trials communications 2018;9:64-70.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Date of idea: 1/AUG/2018
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