SWAT 61: Telephone reminders to people who do not respond to a postal invitation to join a trial

Objective of this SWAT
a) To evaluate the effect of telephoning people who do not respond to a postal invitation on recruitment to randomised trials.
b) To calculate the cost per recruited participant.

Study area: Recruitment
Sample type: Participants
Estimated funding level needed: Medium

Background
See also SWAT 17. A common trial recruitment strategy is to invite people to take part in the trial by sending an invitation letter to them in the post. However, a large proportion of people do not respond to these letters.

A Cochrane Methodology Review had shown that reminders increase response rates to questionnaires [1], but this evidence does not generally come from research in the context of clinical trials. One way to deliver the reminder is by telephone and the Cochrane Methodology Review on recruitment interventions finds that this is effective in increasing recruitment to trials with low (<10%) baseline rates of recruitment (risk difference = 6% (95% CI = 3% to 9%)) [2]. However, there remains uncertainty as to whether the intervention is effective for higher baseline rates of recruitment or on how to operationalise the reminder (including its content) and, indeed, whether using telephone reminders at all before a person has consented to take part in the trial.

Interventions and comparators
Intervention 1: Telephone call to individuals who have been sent a postal invitation to take part in a trial but who have not responded. How long the trial team waits before making the call and the number of attempts made to call a non-responder if there is no answer to the first call, is at the discretion of the trial team. The trial team should be clear about the content (or purpose) of the phone call, which should be well-described so that others can understand what was actually delivered. For example, the reminder might be a scripted check that the invitation letter had been received, an opportunity to record that the person does not want to participate, or the offer of a further letter. The call might also provide additional information about the study, or offer to discuss it. Care would also be needed with regard to what to do if the call was directed to voicemail, because any message left would have to be clear and recognise that it may be listened to by someone other than the person being contacted. The intended content of the call will affect who can make it and who makes the call may have ethical implications depending on the jurisdiction (see 'Possible problems in implementing this SWAT').

The trial team should be clear about the content (or purpose) of the phone call, which should be well-described so that others can understand what was actually delivered. The reminder could be a scripted check that the invitation letter had been received, the recording of decline to participate, or the offer of a further letter if the person didn't decline. The call could also provide more information about the study, or offer to discuss it in some degree of detail. Care would also be needed with regard to what to do if the person contacted was not in but there was the option of voicemail; the message left would have to be clear and recognise that it may be played back by someone other than the person being contacted.
The content of the call will affect who can make the call. Indeed, who makes the call may have ethical implications depending on the jurisdiction in which you work: see 'Possible problems in implementing this SWAT'.
Intervention 2: No telephone reminder.

Index Type: Method of Recruitment

Method for allocating to intervention or comparator
Randomisation

Outcome measures
Primary: Number of people recruited to the host trial.
Secondary: Cost per recruited participant.

Analysis plans
The primary analysis is the difference in recruitment rate between those receiving the telephone reminder and those not receiving the reminder. Similarly, the secondary analysis is the difference in cost per recruited participant between those receiving the telephone reminder and those not receiving the reminder. Note that the direct costs of telephone calls may not be so great but the cost of staff time needed to make them could be considerable.

Possible problems in implementing this SWAT
Firstly, ethical committees and trial teams may be concerned about the intervention having an adverse effect on recruitment. There is very little high-quality evidence supporting any recruitment strategy but the evidence in favour of telephone reminders is better than almost all other recruitment interventions [2]. However, this evidence comes from two trials both with very low baseline recruitment so the evidence supporting telephone reminders at other baseline recruitment levels is uncertain. Secondly, some ethical committees may be worried about cold-calling potential participants, while other ethical committees have concluded that the ethical balance between calling people who have not declined to take part in the trial and failing to recruit enough participants to answer the trial research question falls in favour of allowing telephone reminders. Moreover, the postal information sent to potential participants can say that the research team may contact them if there is no response, which makes it clear that this is a possibility. Without more evaluations, such as this SWAT, trial teams will continue to have little evidence on which to base decisions about using telephone reminders in their recruitment strategies. In the UK, the Health Research Authority/National Research Ethics Advisors' Panel guidance on "Follow-up contact of potential participants who have not responded to an initial invitation to take part in research" makes the point that (particularly where an initial contact has been made): "RECs [research ethics committees] should be wary of being too paternalistic and overprotective of patients' rights in this regard [unsolicited follow-up], particularly where initial contact had already been made and potential participants have not indicated that they would not wish to be contacted again. Maximising access to a public good such as ethically approved clinical research is an important aim, grounded by the principle of justice involving the distribution of research benefits and burdens, and that non-coercive communication aimed at facilitating this is desirable." [3]. Thirdly, trial teams may want some reassurance that the intervention is not having an adverse effect before the SWAT reaches its planned end. They could be reassured by an interim analysis but this should be pre-planned with pre-defined stopping rules.

References
1. Edwards PJ, Roberts I, Clarke MJ, DiGuiseppi C, Wentz R, Kwan I, Cooper R, Felix LM, Pratap S. Methods to increase response to postal and electronic questionnaires. Cochrane Database of Systematic Reviews 2009; (3): MR000008.
2. Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, Jackson C, Taskila TK, Gardner H. Strategies to improve recruitment to randomised controlled trials. Cochrane Database of Systematic Reviews (update submitted).
3. http://www.hra.nhs.uk/documents/2013/10/nreap02-guidance-national-research-ethics-advisors-panel-v1-4-04-october-2011.pdf

Publications or presentations of this SWAT design
Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, Jackson C, Taskila TK, Gardner H. Strategies to improve recruitment to randomised controlled trials. Cochrane Database of Systematic Reviews (update submitted).

Examples of the implementation of this SWAT

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