Reviewer's report

Title: Study protocol: a randomised controlled trial of invitation techniques to improve men's uptake of faecal occult blood test screening for colorectal cancer.

Version: 3 Date: 23 May 2013

Reviewer: Sarah Damery

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This is an interesting study that has good potential to show how changes in screening behaviour can be brought about through targeted interventions. On the whole, the protocol is very clear, and the background section and justification for the study were particularly well written.

Major compulsory revisions:

1. Background para 1. The authors state that "Australia has a comparatively high incidence of colorectal cancer". Compared to where?

2. Background para 3. In the paragraph beginning "In order to identify strategies", the authors cite their own unpublished work. More detail is needed on the nature of this study and its population i.e. was data collected via interviews? From whom?

3. The authors might like to say something about how their intervention dovetails with the screening programme. There is no mention of the study being undertaken in collaboration with the screening programme, and I wonder whether there could be bias introduced into the study from the fact that in their study population, a fair number of individuals may have recently received an 'official' invitation to participate in screening, or may be due to receive such an invitation shortly after receiving the trial intervention. Have the authors done anything to take this into account in their analyses, as the recency of other screening invitations has been shown to impact on the likelihood of undertaking screening on subsequent occasions.

4. The authors describe how randomisation will be carried out, but do not say by whom (e.g. members of the research team?)

5. I would suggest moving the section about ethical considerations to the end of the methods section rather than inserting it midway through as is currently the case.

6. The authors state that individuals who formally opt out of the study will not receive any further correspondence about it. As individuals can opt out at any stage of the research study, will data that has already been collected on or provided by individuals still be included, or will these individuals be removed from the study completely?
7. The description of the sub-groups to receive the survey is confusing and it is not clear how the survey fits in with the rest of the study. This is probably because of the way the text is currently phrased rather than there being any problem with the research design, but it seems that in each arm, 1100 men will receive the screening invitations. Of the additional 600 in each arm selected for the survey, only those who return a baseline survey will be sent a screening invitation. Is it ethical to withhold the opportunity to participate in screening from those individuals on the basis that they have not returned a survey when the rest of the cohort in the relevant trial arm will receive the screening invitation?

8. Why was a 6% difference in uptake between groups chosen as the difference that the trial is powered to detect? Is there any particular rationale for a 6% difference being especially significant from a screening uptake point of view?

9. In the section on secondary outcomes (immediately before the discussion section), the authors note that they will assess "change scores for psychosocial variables". It is not clear what is meant by 'change scores'. This is presumably the change in psychosocial variables between the baseline and endpoint surveys for the cohort who respond to both surveys. If this is the case, then this needs to be clarified.

Minor issues not for publication:
1. Background paragraph 2, sentence beginning "Consequently, population screening", don't capitalise the The before United Kingdom

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
I declare that I have no competing interests.