Author's response to reviews

Title: A randomized controlled trial of the effectiveness of a pre-recruitment primer letter to increase participation in a study of colorectal screening and surveillance.

Authors:

Christine L Paul (chris.paul@newcastle.edu.au)
Ryan J Courtney (ryan.courtney@newcastle.edu.au)
Rob W Sanson-Fisher (rob.sanson-fisher@newcastle.edu.au)
Mariko L Carey (mariko.carey@newcastle.edu.au)
David J Hill (david.hill@cancervic.org.au)
Jody Simmons (jody.simmons@cancervic.org.au)
Shiho K Rose (shiho.rose@newcastle.edu.au)

Version: 2 Date: 14 February 2014

Author's response to reviews: see over
Dear Ms Pura,

RE: “A randomized controlled trial of the effectiveness of a pre-recruitment primer letter to increase participation in a study of colorectal screening and surveillance” (1039571604965392).

Thank you for the opportunity to revise and re-submit the above manuscript. Please find below our responses to the reviewers suggestions. We have attempted to make all changes suggested and provide explanations where we felt a change was not appropriate or possible. Amendments to the revised manuscript have been done using track changes.

Reviewer 1:
1. Consider distinguishing between types of research, various incentives may have different effects for these types of research participation.
   Paragraph 2 under the heading “Background” addresses the possible strategies (including incentives) shown to have an effect in recruiting a cancer cohort for cross-sectional research. This discussion is continued further in paragraph 3, across a more general scale. The systematic reviews referred to explored recruitment in intervention studies including cancer treatment trials. The manuscript has been amended to indicate that the review focuses on cancer treatment trials.

2. SAMPLE & PROCEDURE: In paragraph 2, you state eligible participants must be within 3 months of diagnosis, however you later suggest that randomisation took place approximately 2-6 months post diagnosis.
   Eligible patients were required to be within 3 months of diagnosis, with those identified outside this timeframe subsequently excluded. To avoid confusion, the statement “…which was approximately 2-6 months post diagnosis” has been removed.

3. SAMPLE & PROCEDURE: In paragraph 2, you state that “the VCR contacted remaining patients for permission.” It would be useful to clarify by what means.
   Remaining patients were contacted by mail. This detail has now been added.

4. It would be useful to signpost figure 1 in the text.
   Figure 1 has now been signposted, with reference added at the end of paragraph 2 under the heading “Sample and procedure”.
5. **FIGURE 1: has this been merged into the PDF incorrectly?**
   Figure 1 has not been uploaded correctly. The correct version has been now uploaded, containing the explanatory note for the asterisk.

6. **FIGURE 1: It suggests that all patients who gave consent to the Registry also consented to participate in the study.**
   Of the 1,062 that were contacted by the Registry, 425 had consented to being contacted by researchers for study participation. The text “consent from” has been removed in all instances within the final box of the flow chart to reduce confusion.

7. **Please clarify if there were two stages where consent was sought.**
   Consent was a two stage process: i) firstly via the VCR to release patient’s contact details to the researchers and; ii) secondly via researchers to participate in the study trial. This has been further clarified in the manuscript.

**Reviewer 2:**

1. **Is there a reason why participants within 3 months of diagnosis were considered eligible?**
   A sentence has been added to paragraph 2 under the heading “Sample and Procedure” clarifying the reason for the eligibility criteria.

2. **Please specify how allocation concealment was achieved and implemented.**
   This has been further clarified in the manuscript under “Sample & Procedure”, paragraph 2. Allocation into study arms was achieved via a computer generated random number sequence. Random allocation was performed by the VCR who did not disclose the outcome of the assignment of participants to researchers until completion of the trial.

3. **SAMPLE & PROCEDURE: In paragraph 2, it is not clear whether all participants were contacted by the VCR for permission to release contact details to researchers.**
   All eligible participants were contacted by the VCR. The word “remaining” has been replaced by “eligible” to clarify this.

4. **Please add the primer letter as an appendix.**
   The primer letter has been included as appendix 1.

5. **STATISTICAL METHODS: Please clarify if participation rates mean “consent” or “completion of study baseline measure” or “completion of 12-month follow-up measure.”**
   Participation rate is in reference to consent to be contacted by researchers. This has now been clarified in the manuscript.

6. **STATISTICAL METHODS: Specify the primary and the secondary outcomes.**
   The primary outcome has now been specified.
7. **RESULTS: Do you have information on the socio-demographic characteristics of the participants?**
The available data regarding characteristics of consenters has now been included.
(Results and Discussion paragraph 1)

8. **TABLE 1: Please clarify what is meant by “refusal” and “no response”.**
Table 1 details the outcomes of contact made by the VCR in seeking permission to release contact details to researchers. “Refusals” meant that the patient did not wish to release their contact details to researchers. “No response” meant that the patient did not reply to the contact (and follow-ups) made by the VCR. The heading in Table 1 has been amended to better reflect this.

9. **TABLE 1: Please provide the numbers of those completing the baseline measure and the 12 month follow-up separately for both groups and present in another table.**
The results section has reported that there were no significant differences between experimental groups in completing baseline and follow-up measures. Given this, we do not feel it is necessary to provide these numbers in a separate table.

We hope the revised manuscript now meets the journal’s submission requirements.

Yours Sincerely,

Associate Professor Christine Paul (Corresponding Author)
Senior Research Academic
Priority Research Centre for Health Behaviour (PRCHB)

T +61 2 4042 0693
F +61 2 4042 0040
chris.paul@newcastle.edu.au