Author's response to reviews

Title: CanPrevent: A telephone-delivered intervention to reduce multiple behavioural risk factors for colorectal cancer.

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Author's response to reviews: see over
Response to Reviewers Comments

We thank the reviewers for their valuable and very helpful feedback. We trust we have addressed all of the reviewer’s comments and believe the manuscript has been greatly improved based on their advice.

Editorial Comment

Include the clinical trial registration number
This has now been included following the abstract.

Reviewer#1: Annie Anderson

1. Recruitment and response

No mention is made of increasing mobile telephone use and the limits this may create for a one hour counselling session.

The telephone counselling sessions were at the expense of the study. There are no associated costs with receiving mobile telephone calls in Australia. This has been clarified in the text (para 1, page 9).

Response rate is very small considering the incidence of CRC. It is unclear why 28 were approached and what the number 28 is based on. It is unclear what the study period was.

The research team have conducted studies with colorectal cancer patients (n=430 and n=1996) and agree that the incidence rate is very high, however the purpose of this study was to test the feasibility and short-term effectiveness of a novel intervention for first degree relatives of colorectal cancer survivors. The recruitment period was 8 weeks which has been indicated in the text (para 4, page 4).

The first 28 potential participants who expressed interest in taking part in the study were screened for eligibility. This number was sufficient for a small feasibility and short-term effectiveness trial which has been indicated in the text (para 4, page 4; para 2, page 10).

The small sample size and lack of control group has been acknowledged as a study limitation (para 2, page 13).

2. Assessment methods

All results are self-reported and whilst reported as being derived from valid and reliable measures are they all tested in this age group and tested for longitudinal validity? In cross sectional analysis there is less need to worry about social bias in reporting, but when an intervention has taken place, social bias in follow up may well be increased.

This intervention aimed to primarily improve health behaviours (e.g physical activity, diet) as a wide range of studies have demonstrated that improvements in health behaviours can improve health outcomes and reduce risk of colorectal cancer. Further, the intervention was telephone-delivered so it was available to all people at risk of colorectal cancer across the state of Queensland, Australia. Consistent with this delivery method, data were also collected...
by telephone interview. Therefore, data were self-reported and this is included as a study limitation (para 2, page 14). Further, we have noted where measures have been used previously in cancer patients (pages 5-7).

*There is much in the literature about under reporting body weight (and indeed over reporting height in the elderly) which makes attaining valid BMI measures challenging.*

As mentioned above, we have acknowledged the limitations with self-reported data in the study limitations section (para 2, page 13). Further, participants were instructed on how to measure height and weight and this has been detailed in the text (para 4, page 6).

*Waist circumference is known to vary considerably through measurement error in finding the correct part of the body to measure and repeating it in the same place some weeks later. There is no mention of specific instruction being provided to participants e.g. photographic instructions etc.*

Participants were provided with an instruction sheet prior to the telephone interview with clear instructions on how to measure their waist. The telephone interviewers also assisted if necessary. This has been detailed in the text (para 5, page 6).

3. **Intervention**

*This section merits further detail.*

The intervention section has been expanded as suggested (page 8-9).

4. **Follow up**

*Why were the follow up measures done at 6 weeks? This is a very short period and there is no evidence that changes that are reported at 6 weeks are continued over a longer period... they indicate initiation of change but neither short nor long term maintenance. In a feasibility study it would not necessarily be appropriate to undertake long term follow up (that may be for full RCT) but undertaking short term follow up after the intervention has ended would be useful e.g if the intervention runs for 6 weeks what happens at the end of 6 weeks and after intervention withdrawal at the end of 12 weeks?*

The intervention continued for 6 weeks, hence participants were assessed at the completion of the intervention period (6 weeks). We acknowledge the limitation of the 6 week follow up in the study limitations section. The need for a large-scale randomised controlled trial to confirm the study findings has been included in the conclusions (para 2, page 14).

*The short follow-up period does not take account of seasonal effects. Indeed mention of dates of collection might be useful. The lack of control group needs discussion.*

The dates of data collection have now been included (para 4, page 4). The lack of control group has been acknowledged as a study limitation (para 1, page 14) and the conclusion highlights the need for a large-scale randomised controlled trial of the approach to confirm effectiveness (para 2, page 14).
5. **Feasibility perspectives**

If this is a feasibility study to inform a future RCT then the reporting could usefully take a systematic report (see for example Anderson et al. Live Well).

The study findings are now reported in line with the recommendations from reviewer #1 and #2. We trust they are now consistent with the aim of this small feasibility and short-term effectiveness study and the reviewer’s recommendations.

### Reviewer #2: Miriam Morey

**Major Compulsory Revisions**

1. **The results of this study should be scaled back considerably.**

   The results of the study have been scaled back as suggested. The abstract and results sections have been revised to reflect the purpose of the study, which was to test the feasibility and short-term effectiveness of a novel intervention. The results have been described as improvements in health outcomes and the emphasis on statistical significance has been reduced (pages 10-12), with p values removed from the abstract as recommended.

2. **Abstract: Eliminate all t tests and control for baseline value for each outcome.**

   P values have been removed from the abstract and descriptive comparisons from baseline to six weeks have now been reported. The statistical tests have been included in the results section for further information, however the emphasis on the results has been reduced. The conclusions now reflect these changes (para 3, page 14).

3. **Methods: Data collection. Were interviewers different from the interventionists?**

   Yes, interviewers were different from the interventionists/health coaches and this has been clarified in the text (para 2, page 5).

4. **Data Collection: Explain why the measures were chosen.**

   Measures were chosen to assess change in the health behaviours and health outcomes that were targeted by the intervention. CanPrevent was a multiple health behaviour change intervention that targeted a range of health behaviours including physical activity, sedentary behaviour (TV viewing), diet, alcohol intake and weight management (BMI and waist circumference). Measurement of health-related quality of life was included as a widely-used generic measure of health status that has been used in cancer populations. Measurement of perceived risk of CRC was included as this is relevant for those at high risk of the disease and was also targeted by the intervention. An explanation of the data collection has been included in the text (para 3, page 4; para 2, page 5).

5. **Were weight and height by self-report?**

   Weight and height were by self-report. Participants received written instructions on how to measure themselves correctly and telephone interviewers confirmed this if necessary (para 4, page 6).
6. **Intervention:** Expand on the training the health coaches received and their background.

Information has been included on training and background for the health coaches (para 1, page 8).

7. **Statistical Analyses:** You should present the raw data with no statistical analyses performed.

We have revised the abstract and results sections to describe the improvement in outcomes from baseline to 6 weeks. We have retained the statistical analyses as further information, but changed the emphasis to be more descriptive (abstract and results sections).

8. **Results, paragraph 1:** Clarify what is meant by reaching the required sample size.

This statement referred to the fact that the study was a small feasibility and short-term effectiveness study; hence we required a small sample size (approximately 20). The text has however been revised for clarity (para 2, page 10).

9. **Results:** Revise based on recommendations for data presentation.

The results section has been revised and now refers to the improvements in health outcomes, and the statistical significance is secondary (pages 10-12). The results of statistical tests have however been included in the tables for further information.

10. **Discussion:** Consider the clinical vs statistical significance of some of the change scores. Be very cautious in interpreting the results of your study and comparing with findings of other well-designed studies.

The discussion has been revised to refer to clinical significance of the intervention effects, and the study limitations have been noted before drawing comparisons with large-scale RCT’s (para 2, page 13).

**Discretionary Revisions**

1. **Introduction, para 7:** clarify that telephone-delivered interventions have been shown to be acceptable for short-term interventions.

The introduction has been revised to emphasise that telephone-delivered interventions have been shown to improve health behaviours in the short-term (Para 2, page 4).

2. **CRC screening:** Perhaps given the nature of the intervention, future studies can include a question that asks ‘what proportion of people in the general population are diagnosed with CRC due to lifestyle?’

The discussion has been revised to refer to the importance of investigating beliefs about lifestyle factors and perceived risk of CRC (para 1, page 13).
3. **Minor issues: please consider another word for trialling and manualised.**

These changes have been made (para 2, page 2; para 3, page 9).

<table>
<thead>
<tr>
<th>Additional Changes by the Authors</th>
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<tbody>
<tr>
<td>1. The authors have noted that many abbreviations were used throughout the manuscript, so this has been changed to include fewer abbreviations for ease of interpretation.</td>
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<tr>
<td>2. References have been added and included in the reference list. This change has also been tracked in comments boxes.</td>
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