Author's response to reviews

Title: Informing relatives about their hereditary or familial cancer risk: study protocol for a randomized controlled trial

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Version: 3
Date: 20 February 2014

Author's response to reviews: see over
To: Trials
Editors-in-Chief: Doug Altman, Curt Furberg, Jeremy Grimshaw

Regards: submission of revised manuscript ‘Informing relatives about their hereditary or familial cancer risk. A study protocol of a randomized controlled trial to assess the effectiveness of additional counseling.’

Amsterdam, 19 February 2014

Dear Editor,

Thank you for allowing us to submit a revised version of our manuscript, now entitled ‘Informing relatives about their hereditary or familial cancer risk. A study protocol for a randomized controlled trial.’ (original title: ‘Informing relatives about their hereditary or familial cancer risk. A study protocol of a randomized controlled trial to assess the effectiveness of additional counseling.’) to Trials.

We have tried our best to incorporate the reviewer’s constructive comments as suggested and believe that these changes have further improved our manuscript. This entire revised paper has been corrected by a native English speaker who has experience in checking scientific manuscripts. Changes made to the manuscript are indicted in yellow coloured text. Response to the reviewer is included below this letter.

We were pleased with your request to add information about additional files. However we now consider the additional files (proof of ethics approval and funding by a major funding body), which were submitted in order to make the manuscript eligible for publication without peer review, redundant.

In anticipation of your final decision, and on behalf of the co-authors,

Kind regards,

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Reviewer’s report

1. Background, para 4: The authors state that ‘Counselees may consider a relative to be too old, or too emotionally fragile, to burden them with genetic cancer information’. It may be more likely in the case of hereditary cancer risk that a counselee may think a relative is too YOUNG e.g. in cases where a mother may have to inform her daughters that they have an elevated risk of breast cancer due to genetic factors.

The reviewer is right in pointing out that counselees may also consider relatives to be too young. We adjusted the mentioned section to make it more complete (page 3, last paragraph).

2. Background, para 6: This paragraph is not very clearly worded – at first glance it appears to be describing the authors’ own intervention but I think it is actually describing work that others have done. This paragraph would benefit from being rewritten to make the description clearer, and it would also be useful to provide a more comprehensive overview of other similar research in order to distinguish the current study from what others have done.

To make this part of the paper more clear, we rephrased the paragraph and extended the information about similar interventions, to express more clearly what others have done and what our interventions aims to achieve (page 4, last paragraph).

3. Methods section: This would benefit from a clearer outline of standard care. In calling their intervention ‘an additional telephonic counselling session’, this suggests that standard care already includes telephone counselling sessions, and that the intervention will be the provision of an extra telephone counselling session. However, elsewhere in the methods section, standard care is described as consisting of a summary letter. It is also described as entailing face to face counselling sessions which the summary letter summarises. As it is important to know the difference between the care to be received by the control group vs. the intervention group, making clear exactly what comprises standard care is central to the reader’s understanding of the study.

We agree with the reviewer that we didn’t clearly describe current standard procedures. We have adjusted the sentence describing the aim of the intervention (page 5, 2nd paragraph) and the paragraph describing the control group (page 9, 1st paragraph).

4. Methods section: although the authors make an effort to describe the consent process for relatives, this is not clear, as the initial approach and transfer of study-related documentation will be made by the counselee. An extra sentence or two to describe exactly how this part of the study will be undertaken would be useful, especially as first, second and third degree relatives will potentially be approached by the counselee, which could encompass a large number of family members for a given counselee if they have a large family.

Following the reviewer’s suggestion we have now added some sentences to clarify what we intended to say about involving relatives into the study (page 9, 2nd paragraph).

5. Please clarify in the text throughout what is meant when you refer to a counselee’s ‘pedigree’.

Indeed, this may be unclear and has been specified (page 4, last paragraph).
6. **Methods, sample size section:** The sample size calculation section is not very clear. In particular, it is not clear what is being referred to when the authors state that they expect an effect size of 0, 0.5 and 0.5 at T1, T2 and T3 respectively.

. We have phrased this section differently in order to be more specific (page 14, paragraph 3).

**Minor comments**

- *Throughout, the tense of the text should be the future tense, i.e. describing things that ‘will’ happen rather than things that ‘do’ happen or ‘are’ happening.*

As suggested, we use future tense now in the manuscript.

- *In the methods section, the authors on a couple of occasions use the phrase “denounce participation”. In English, it would be more correct to say “decline participation” instead.*

We appreciate this helpful suggestion by the reviewer, and have amended this (page 8, 3\textsuperscript{rd} paragraph; page 9, 2\textsuperscript{nd} paragraph).