Reviewer's report

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.

Version: 2 Date: 20 January 2014

Reviewer: Sarah Damery

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This protocol outlines an interesting study which has the potential to improve communication of hereditary or familial cancer risk between patients receiving counselling and their relatives, and potentially to improve the uptake of screening and preventive services on the part of relatives who may have elevated cancer risk.

The study is well designed and in the main fairly clearly described. However, there are a few points that are not clear and which would benefit from changes to enhance the reader’s understanding of what is being described:

Major compulsory revisions

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.

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.

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.
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.

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

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.

Minor issues not for publication

1. 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. Although the study is currently underway, the protocol should describe things that haven’t happened yet, so the tense should always say things like ‘patients will be randomised’ or ‘questionnaires will be administered’ etc.

2. 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.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

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