Reviewer’s report

Title: Does a decision aid improve informed choice in mammography screening?
Study protocol for a randomized controlled trial

Version: 2  Date: 3 November 2014

Reviewer: Haryana Dhillon

Reviewer’s report:

Thank you for the opportunity to review this manuscript reporting the background, rational, and design of a randomised controlled trial of decision aid for use in mammography screening. This is a timely study addressing the important issue of informed choice in mammography screening.

As this is the protocol for a RCT the major compulsory revision related to the methodology as proposed:

1. Page 6, has the Decision Aid already been developed? If so, briefly describing the development and pilot process may give this section more structure, at the moment it is a little difficult to interpret. The paper currently reads as those this is work still to be done.

2. How did the authors determine if an entirely online intervention and data collection procedure would be suitable for this study? Please clarify what your estimates of participant drop-out rate is. Could compliance with the study assessments and intervention be improved through telephone contact?

3. The outcome measures are comprehensive, perhaps it would be preferable to detail the measures and the relevant response categories and the scoring in a table. It is somewhat confusing to read the brief descriptions and then the response categories as they are. Is there a simpler way of presenting this information, for example are most of the responses actually 3-point Likert scales?

4. The sample size calculations and assumptions are well described and suitable to meet the aims of the study. Although attrition or drop-out of subject has not been addressed – this should be included.

5. Statistical analysis: as detailed covers the main points. This could be more clearly expressed.

6. Line 118: please clarify the age of the proposed sample, is it just women who are 50 years of age? Are you including an age range? What about women who have had a previous mammogram for some reason – will they be excluded or included

7. Interactive part: Please clarify who will assign the information its category? Is that the system, or the patient? Is this really a values clarification exercise?
8. Why is the study unblinded? Could you please include some discussion about how you considered if blinding was possible and why you decided to go with an unblinded design?

9. Line 112: please clarify the text around ability to link individual patients data to their earlier assessments. As it currently reads I interpret this to mean that the participant will generate a unique code for each assessment time point, if that is the case I’m unclear as to how the data could be linked.

Discretionary Revisions

10. Paragraph 1. Recommend reconsidering the statement “despite lack of evidence for the overall benefits of mammography screening”. Mammography screening is a controversial area, it would be sensible to think extremely carefully about statements such as this to ensure your message is not misconstrued, nor your well planned work obscured by criticism of your perception of screening. Perhaps if you mean there is no evidence for the overall mortality benefits of mammography screening this would be clearer.

11. Similarly, please clarify what is meant by ‘scientific uncertainty’ later in the small paragraph (“This decision is made in the context of scientific uncertainty”)

12. Paragraph 2: suggest add word “women” so it reads “the proportion of women making informed choices,”

13. Line 60: implementation of what is more likely?

14. Line 78-80: the authors refer to a pilot study conducted during 2014 – but no further discussion of the results of the pilot are included.

15. Line 81: the text “for the first time” are not necessary I’d recommend deleting them.

16. Add “Randomised Controlled Trial” as a key word.

17. The discussion needs to be better structured, with more paragraphs to break up the ideas discussed.

Level of interest: An article of importance in its field

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

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare I have no competing interests