Author’s response to reviews

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

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Author’s response to reviews: see over
Revision of the study protocol “Does a decision aid improve informed choice in mammography screening? Study protocol for a randomized controlled trial”

Dear Dr. O’Donovan:

Thank you very much for allowing us to submit a revised version of our paper. The feedback of the reviewers was very helpful. Having incorporated many of the suggestions and amended the manuscript to take these comments into account, we believe that our manuscript has now substantially improved. Below, we provide detailed information on how we have dealt with each of the suggestions made by the reviewers. For reasons of clarity, we first quote the corresponding passages from each reviewer’s report (in italics) and then outline the modifications we have made in response to each suggestion.

We would like to express our thanks to both you and the reviewers for the time and effort that you have invested in the reviewing process. We hope that the paper now meets the requirements for publication in the Journal “BMC Women’s Health”.

Please do not hesitate to contact me for further questions.

Sincerely,

Maren Reder
Minor essential revisions:

The paper reports a protocol for testing a German decision aid for women invited for first-time mammography screening. I do not believe that this protocol breaks significant new ground in methodology of evaluating the impact of decision aids, but the protocol could be used to provide a reasonable evaluation of this decision aid. My main critique of this protocol and the authors’ discussion of it is that it does not delve deeply enough into the challenging question of how to evaluate the impact of a decision aid. However, I support publication, given the standards of this journal.

For randomized trials that compare a decision aid to usual care (as in the current study) or ones that compare two decision aids, the key question is whether patients in one group make overall better decisions or have improved health outcomes. Many guidelines focus on decision quality rather than health outcomes, for good reason. For instance, as the International Patient Decision Aids Standards (IPDAS) consortium emphasizes, decision aids are appropriate when the decision is “preference sensitive,” i.e. where there is more than one medically acceptable choice and where the “best choice” for one person may differ from that for another, based on their goals and preferences. (Elwyn, O’Connor et al. 2006, Stacey, Legare et al. 2014) As the authors say, in such situations, a decision should be informed, where the patient has “good knowledge of the situation,” and “an attitude congruent with the choice.” In this setting, finding that one of the groups has improved health outcomes does not matter as much, as long as the individuals made improved decisions for themselves.

We agree that the important outcome is decision quality and not health outcomes. More information on the preference sensitivity of the decision has been added (ll. 55-58).

The challenge is deciding what counts as “good knowledge” and how to measure congruence between the attitude and the choice. The challenge of determining what counts as “good knowledge” can be seen in the question of whether decision aids should disclose specific quantitative information, including perhaps absolute risk and risk reduction framed in multiple ways, and whether patients should be expected to remember that information. IPDAS requires disclosure of large amounts of quantitative information though does not comment on how much of this information should be retained by patients, and at what times, for decisions to count as informed. (Elwyn, O’Connor et al. 2006, Trevena, Zikmund-Fisher et al. 2012) In addition, some commentators (including myself) have argued that there are good reasons to question whether such data should be disclosed to all patients, and whether it will improve decisions. (McDonald, Charles et al. 2011, Schwartz 2011, Zikmund-Fisher 2013) These questions are motivated by the existence of widespread limitations in patient numeracy and irrational responses to quantitative risk information, due to heuristics, biases, and gist based reasoning.
Thank you for this helpful advice. A discussion about disclosure of quantitative information in the decision aid has been added (ll. 70-76).

In addition, reviews have recognized important problems with measuring whether patients have “an attitude congruent with the choice” that they have made. (Sepucha and Ozanne 2010, Sepucha and Fowler Jr 2013)

Thank you for this comment. A discussion about measuring congruence between attitude and decision has been added (ll. 77-83).

The authors of the current protocol provide little comment or analysis of these important problems with two essential components of evaluating whether patients have made informed choices – measuring knowledge and congruence between attitude and choice. Instead, for example, they accept without comment the claim that patients should be informed about the “probability of positive and negative outcomes,” (MS p. 3) and they say that the decision aid “will include the probabilities of a positive and negative screening result.” (p. 6) Finally, in the evaluation of knowledge, patients will be asked the “frequency of positive screening results.” (p. 8) For each of these decisions that the authors made regarding the design of the decision aid and its evaluation, much more could be said about their choice of disclosing and then measuring the retention of the relevant quantitative information. Leaving such discussion out of this paper raises questions about the eventual evaluation of the decision aid.

As already stated above, a discussion about disclosure of quantitative information in the decision aid has been added (ll. 70-76). This includes the evaluation aspect of knowledge, which has been expanded in the methods section (ll. 257-261).

Similarly, much more could be said about the authors’ claim that “uninformed compliance is a major public health problem in the German MSP.” (p. 3) Guidelines issued by leading organizations including the United States Preventive Services Task Force and American Cancer Society recommend that women ages 50-75 with average risk for breast cancer get screened with mammograms. (Smith, Cokkinides et al. 2009, USPSTF 2009) This means that these organizations have concluded that getting screened carries more benefits than risks for women in these groups, overall. Therefore, while of course it is essential for individual women to make informed decisions about being screened, there is also good reason to count increased uptake of screening as a good thing. It’s not just that such screening saves lives overall, it’s that fair minded individuals who are charged with evaluating the benefits and risks have concluded that overall the benefits outweigh the risks for most people. From this perspective, while it is reasonable to consider screening to be an “efficient” choice, not simply a preference-sensitive one. And these considerations also raise questions for the authors assertion that “uninformed compliance is a major health a major public health problem in the German MSP.” (MS p.3)
Thank you for this helpful advice. The point on “uninformed compliance” has been elaborated and a discussion of the preference sensitivity of this choice has been added (ll. 55-58). The authors agree that it is essential for women to make informed choices but disagree with the statement that increased uptake of screening is a good thing per se. The Cochrane review indicates that mammography screening does not have an effect on overall mortality (Gøtzsche & Jørgensen, 2013). Therefore the authors conclude that it is reasonable to treat the decision about participation in the German mammography screening programme solely as a preference sensitive one.

So the main upshot of this review is to recommend that the authors discuss the issues raised in this Summary. I would consider this a minor essential revision, rather than a major compulsory revision.

Review 1475513332148447

Major compulsory revisions

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.

   Thank you for this helpful advice. The decision aid was developed as part of this study. More information on the development and piloting process has been added. The tense of this section has been changed to past (ll. 160-173).

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?

   Thank you for this comment. Information on the feasibility of presenting both questionnaires and decision aid online has been added to the information about the pilot study (ll. 165-173). The expected drop-out rate has been specified in the “Sample size” section (ll. 319-320). Telephone contact was not possible with the personal data we could obtain from population registries, as this information was not included in the personal data of the registries; this is therefore not further discussed in the protocol.

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?

While writing the manuscript we also tried to convey this information in a table, but adequate description of the outcomes warranted more detail than could be included in a table alone. We therefore decided to use text and an overview table. Most outcome measures differ in their response format, so that it seemed most fit to describe each response format separately.

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.

Thank you for this advice. The estimated extend of non-response and drop-out has been described in more detail (ll. 319-320).

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

This section has been rewritten to be clearer (ll. 329-340).

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

As described in the text, women aged 50 will be eligible for this study. No other age groups are included. Information on previous mammograms has been added (ll. 141-142).

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?

Sorry for being not clear in this respect. This part has been rewritten to make it clear that the women themselves assign the information items to their category. Steps 1 and 2 allow the women to reflect on what different effects of the screening mean to them personally and what weight these have in the decision (ll. 205-209).

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?

Thank you for this helpful advice. The women know whether they receive an online decision aid or just usual care, so blinding was not possible. This information has been added (ll. 111-113).

9. Line 112: please clarify the text around ability to link individual patients data to their earlier assess-
ments. 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.

Sorry for being not clear in this respect. This part has been rewritten to make it clear that the code consists of the same elements at each assessment and should therefore be the same (ll. 131-134).

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.

Thank you for this helpful advice. This sentence has been changed to all-cause mortality benefits (ll. 42).

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”)

Thank you for this comment. This has been clarified (ll. 46-50).

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

Thank you for this comment. This sentence has been changed as suggested (ll. 59).

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

The words „of a decision“ have been added to further explain which implementation we are referring to (l. 66).

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.

Thank you for this helpful advice. The results of the pilot study were summarized (ll. 165-173).

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

Thank you for this comment. The text has been deleted (ll. 100).
16. Add “Randomised Controlled Trial” as a key word.

Thank you for this comment. We added the key word as suggested (l. 33).

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

The discussion has been structured into more paragraphs (ll. 349-362).

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

The manuscript had already been submitted to EDANZ prior to our initial submission. All changes suggested by EDANZ were carefully followed.