Author's response to reviews

Title: Values Clarification in a decision aid about fertility preservation: does it add to information provision? Two randomized experiments with healthy participants

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Author's response to reviews: see over
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Dear Dr Dolan,

We would like to thank the editor for the kind opportunity to revise and resubmit our manuscript "Values Clarification in a decision aid about fertility preservation: does it add to information provision? Two randomized experiments with healthy participants (MS: 1848265293117094)"). Herewith we resubmit a third revision of our manuscript for review to BMC Medical Informatics and Decision Making.

In the following we will describe point by point how we have responded to the comments of the reviewer. All comments were taken into account. For the purpose of clarification, we have indicated in the revised paper where changes have been made, and we have keyed these to the reviewers’ comments below. Attached you will find the revised manuscript.

We thank you and the reviewer for your very constructive comments that have helped to further improve our manuscript. We hope the manuscript in its present form will be found acceptable for publication in BMC Medical Informatics and Decision Making.

Yours sincerely, on behalf of my co-authors,
Mirjam Garvelink

Reviewer’s comments

Major compulsory revisions

1. The results are presented in a confusing manner.

Currently the results are presented for a mixture of a priori and post hoc groups of study participants. As a result, it is difficult for readers to interpret what the results mean in the overall context of the study. Since both experiments being reported were randomized trials, I think the best approach would be to follow the usual rules and conduct an intention to treat analysis using the original groups as the primary study outcome. The sub-group analyses based on actual usage of the VCE can still be presented but as secondary analyses that were not part of the original experimental plan. Presentation of the results of these two sets of analyses should be presented separately and the differences clearly noted.

As suggested by the reviewer we have now made the difference between primary (intention to treat) and secondary analyses more clear. In experiment 1 we already made a division between primary and secondary analyses in the methods section and results, so we have only added the terms “primary analyses” and “secondary analyses” between brackets to the applicable paragraphs in the results section, and we have added to the methods section: “Analyses were subdivided in primary (intention to treat) and secondary analyses (based on actual use of the DA and VCE)”. In table 1 we have made separate columns for both types of analyses and if applicable the post hoc data.

In experiment 2 we have also added the following sentence to the methods section: “Analyses were subdivided in primary (intention to treat) and secondary analyses (based on actual use of the DA and VCE).” Additionally we have subdivided the results section in primary and secondary analyses and relocated the text accordingly. In table 2 we have made separate columns for both types of analyses and if applicable the post hoc data.

2. The conclusion that the difference in DC between women who used the VCE is due to selection bias is not supported by the data.

From the data presented it is not possible to determine if the improvement in DC
seen in the women who used the VCE is a true effect of using the VCE or not and I think the results should be interpreted accordingly. This is one instance of a post-hoc sub-group analysis I alluded to in my first comment. As such the results should be interpreted very carefully.

Reviewer 1 is correct in mentioning that the conclusion that ‘the difference in DC between women who did or did not use the VCE is due to selection bias’ is not supported by the data. This statement was merely meant as a suggestion, a possible explanation for our strange finding and thereby a starting point for further research, and not a conclusion of the experiment. As suggested by the reviewer we have checked our interpretations carefully and rephrased the last sentence of the conclusion of experiment 1 to: “However, since there was no difference between the VCE-users and the women who received a DA with information only (without VCE) this might be an effect of VCE-use in a self-selected group (for example related to personality characteristics), and is not likely an effect of the VCE per se.” Additionally we have moved it to the introduction of Experiment 2 so that it is more clear for the reader that it is merely meant as hypothesis, and not based on the data.

3. The data reported regarding the 2nd experiment DC results appear to be different in the text and Table 2. The text reports that there were no significant differences in DCS or any subscales but the Table suggests otherwise.

Reviewer one is correct to state that Table 2 suggested that there was a significant difference in DCS subscales while the text stated otherwise. The difference that was mentioned in the table was a difference between women who did or did not use the VCE within the group of women who received the DA+VCE, with referral to the VC (groups E and F). This data should not have been mentioned in the table since it is not a primary or secondary analysis. We have removed the data and the post hoc comparison from the table.

4. The results reported in Tables 1 and 2 need to be identified more clearly. Currently it is difficult to discern which group comparisons were done and if all comparisons are being reported. I think this is the result of the mixture of primary and secondary analyses that I described in my first comment.

(see comment number 1)

Discretionary revisions
1. It would be helpful to include a sentence summarizing the implications of the study findings in the abstract.
As was suggested by the reviewer, we have added a sentence about the implications of our research to the abstract: “More research is needed to be able to make clear recommendations regarding the need for tailoring of information provision to of personality characteristics, and to assess the effect of VCE use in actual patients”.

2. On page 5, the sentence that starts on line 7: “One scenario based study…” could be revised to state that prior studies have found mixed results more effectively.
As was suggested by the reviewer we have rephrased the sentence on line 7, page 5 to: “Prior studies with healthy participants have found mixed results”.

3. On page 6, the last sentence starting with “Based on considerations…” is quite long and complex and should be revised.
As was suggested by the reviewer we have revised the long sentence on page 6, to: “ Patients indicated on two VAS scales a) whether the statement is considered to be an advantage or disadvantage to the FP option, and b) the importance of the statement [9] (figure 1)”.

4. The effects on experiment one of the significant difference in desire for future children between the intervention and the control group should be discussed.
As suggested by the reviewer we have added discussion of the finding of a significant difference in desire for children in the randomization groups in experiment one. Since actual desire for children could have influenced decision making about fertility preservation, all analyses were repeated while controlling for whether or not women had a desire for children. As the results of these analyses were very comparable to the results reported
here, we may conclude that the results of experiment one are not critically dependent on baseline levels of desire for children.

We have added to the results section: “Since there was a significant difference in desire for children between the groups, we have repeated all the analyses correcting for desire for children. Results of the additional analyses were similar to the above mentioned results.”

We have added to the limitations section of the discussion: “Despite randomization, there was a significant difference in desire for future children between women who received a DA with VCE and those who received information only in experiment 1. Although all respondents had to imagine that they had a “hypothetical desire for children” for the future as part of the hypothetical script, their actual desire for children could have influenced decision making about fertility preservation. Therefore, all analyses were repeated while controlling for whether or not women had a desire for children. As the results of these analyses were very comparable to the results reported here, we may conclude that the results of experiment one are not critically dependent on baseline levels of desired children.”

5. It would be easier to interpret the time data if it were converted to minutes (as reported in the text).
As suggested by the reviewer we have converted the time data in both tables to minutes, instead of seconds.