Author's response to reviews

Title: The impact of a computerized decision aid on empowering pregnant women for choosing vaginal versus cesarean section delivery - Study protocol for a randomized controlled trial

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Author's response to reviews: see over
Dear Editor,

Thank you for the opportunity to resubmit our article “The impact of a computerized decision aids on vaginal versus cesarean section delivery - Study protocol for a randomized controlled trial” by Saeid Eslami, Azam Aslani, Fatemeh Tara, Leila Ghalichi, Fatemeh Erfanian, Ameen Abu-Hanna. Enclosed please find the re-submission for possible publication in Trials.

We are also grateful for the useful remarks. We have addressed all of them and changed the manuscript accordingly. Please find below our response and action to each of them. We also removed the running title from the manuscript, and we corrected the author names in the submission system. All changes are marked in the text.

We trust that the resubmitted paper meets all points made and hope that it is suitable for publication in its new form.

Sincerely,

A. Aslani, also on behalf of my co-authors.
My understanding is that the study that is currently registered is a pilot study and that the study which is reported in this manuscript is a new study with a complete modification of the randomization procedure. The inclusion of participants in this new study has not started yet. In this case, this implies to a) submit the new trial to an ethics committee and to register this new trial. This is essential to fulfil the ICMJE requirements.

We might have not been very clear in our earlier reply, but the trial that is approved, registered and described in the protocol is still valid. We only excluded the first 30 patients and the starting planned date is November 2015 (depending upon approval of the trial in your journal). We also updated the registry to reflect the sampling strategy as requested by the comments (please see below) and we will update the starting date upon acceptance of the protocol in Trials. To be on the safe side we already submitted the changes in the sampling method to the Ethical committee of Mashhad University of Medical Sciences and received their approval. We updated the manuscript accordingly.

The randomization process is still unclear. Please refer to the CONSORT 2010 statements (http://www.consort-statement.org/downloads/consort-statement) to report your manuscript particularly use the Elaboration and explanation manuscript as well as the SPRIT statements (http://www.spirit-statement.org/). Please clarify how the allocation sequence will be generated (computer or other). Further, because the study is not blinded it is important to use bloc of varying size.

Please specify: Who will generate the random allocation sequence, who will enroll participants, and who will assign participants to interventions? Please clarify whether those enrolling participants will know in which group the patient was randomized before enrolling the participants. If not there is an important risk of bias please also clarify whether participants will be informed of the treatment allocated before or after signing the consent form and if it was before, how will you handle participants randomized who will refuse to sign the consent form in the analysis...”

Thank you for your comment, we state now:

“An independent researcher will centrally perform the randomization by using the computer program on www.randomization.com. Block randomization will be applied to ensure equal group sizes within each center. Because the study is not blinded we use blocked randomization with randomly selected block sizes of 2 and 4. For each center, the independent researcher will prepare opaque, sequentially numbered, and sealed coded envelopes, with a note for either the decision aid use or not. At each center, the clinic secretary will check eligibility of each pregnant woman visiting the clinic and, if eligible, will provide her with an explanation of the aims and scope of the study and will orally invite her to participate in the study. If the invitee accepts the invitation then they will be asked to sign the informed consent form. Then the secretary writes the woman’s name and phone number on the next closed envelope. At the end of the day all envelopes, unopened yet, are collected by a research assistant. At the university, this researcher assistant opens the envelopes and allocates the participants of that day to the decision aid or control group. After group allocation, the research assistant will call the participants by phone. Those in the intervention
arm will be invited to a software educational session (consisting of 10 women in total) and invited to fill in the paper questionnaires. Those in the control arm will be invited to only fill in the questionnaires. All participants (in the intervention and control arms) will be invited to fill in the questionnaires again two weeks before the expected date of delivery. Blinding of researchers and women is not practical in this study, but the gynecologists are unaware of the patient allocations”.

The handling of missing data should be reported in the statistical analysis section. Please report a specific section for the statistical analysis (Intent to treat analysis, handling missing data, test used etc)

We agree. We added a specific section for the statistical analysis:

“The statistical analysis

Differences in the primary outcomes will be analyzed using the 'intention-to-treat' principle. The mean decisional conflict score and the mean knowledge score will be compared, using the t-test, to the respective means in the control group. In addition, the differences in the means within each group, before and after the intervention period, will be tested by the paired t-test. Comparing the actual mode of delivery in the intervention and control groups will be based on hospital maternity records and differences will be tested by the Chi square test. We will calculate the Pearson correlation coefficient between the score of decisional conflict and the mode of delivery.

We will handle missing data by a multiple imputation approach. The multiple imputation procedure replaces each missing value with a set of acceptable values that represent the uncertainty about the right value to impute. These multiply imputed data sets are then analyzed by using standard procedures for complete data and combining the results from these analyses”.

Primary outcome: please clarify that the primary outcome is mean of overall decisional conflict scores while the DCS subscales will be secondary outcomes

Thank you for your comment, we state now:

“The two primary outcomes for the study are the mean of overall decisional conflict and knowledge scores. The decisional conflict will be measured by O’Connor decisional conflict scale (DCS) [27, 32]; the DCS subscales are secondary outcomes, they will be compared between women in the two groups and between the before and after the intervention, within the two arms”.

Please make sure the study has been proofread to improve its understanding”

We checked again the entire manuscript for possible spelling and grammar errors.