Author's response to reviews

Title: Interventions to reduce postpartum stress in first-time mothers: A Randomized-Controlled Trial

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Author's response to reviews: see over
Dear Editorial Team,

Thank you for the reviews and for your willingness to consider our revised manuscript. Please find our point-by-point response to the comments of the reviewers below.

**Reviewer #1 (Karen Erte):**

1. Please provide a more thorough discussion and explanation of the PSS-10, including its use in the postpartum.

   We added the following statement: “PSS-10 has been used to assess perceived stress in a number of different populations including university students, the elderly as well as pregnant and postpartum women.” P6 L12

2. Response bias due to social desirability on the part of the mothers seems like a real threat in this study, but it was not mentioned. Related, what did the mothers know about the aims of the study?

   We added the following statement: “Given that the study participants were informed at enrollment that the aim of the study was to reduce stress in the postpartum, this may have also biased their responses to the PSS-10 questions as they may have wanted to appear to respond to the intervention to please the assessors.” P12 L 14

3. The authors note that the assessors may have known the subject’s intervention allocation. Please discuss in further detail.

   Blinding the assessors would not have been possible since we expected women to discuss the intervention they had received during the assessment visit. It would not have been realistic to expect them to avoid doing so even if we had asked them to. We clarified this on P12 L 8 as follows: “In addition, although recruiters were blinded to the intervention allocation of participants, the assessors could not be blinded since it would have been impossible to insure that participants did not mention that intervention they had received at the time of assessment.”

4. Is there a way to put the approx 3-point difference in context? It would be particularly useful if it could be put into the context of predicting depression. If that is not possible, perhaps compare based on sociodemographic differences, or any other relevant characteristics or interventions (previously published) that show an approx 3-point difference?

   PSS is a 10-item Likert scale (0-4). Any drop of 4 points would be significant as it could imply: 1. One of the stress items that was occurring very often disappeared or 4 items dropped by one point or other. In the literature, a 2 point drop was found to be statistically significant and women with lower scores are less stressed.
5. Page 10, lines 9 & 18-19 refer to differences that were not statistically significant. Please be clear that these were not stat sig.

Done.

6. Table 1 - what are the numbers in parenths?

In parentheses are those who refused/missing. We have noted this in the title. Since these are confusing we removed them.

7. Table 3 - what are the numbers in parenths? Please indicate that numbers are %.

Same as previous table. Numbers in parentheses were removed and we modified the title to indicate that numbers are percentages.

8. Table 4 - ditto

Done.

9. Figure needs title, y-axis description, a description or key, and the lines need to be larger for comprehension.

Done.

Minor questions/comments:
10. The sample is from women delivering in hospitals. Is that the norm in Beirut? What % of deliveries occur in hospitals?

It is estimated that 90% of all deliveries in Lebanon occur in the hospital setting. We added this statement on P4 L7.

11. Pg 5, line 8, the parenthetical phrase seems like a note to a co-author. Perhaps revise or rephrase.

We removed the statement and kept the reference.

Reviewer #2: (Zoltan Kozinsky)

In the ‘Abstract’ section the first sentence is too general and repetition of the main result.

We are not sure what sentence this is referring to exactly. We would be happy to change whatever is general or repetitive.

The authors do not mention, but I hope that all participants with other psychiatric disorders were also excluded from the study.
All women were competent and history of psychiatric disorders was obtained in the initial intake and elaborated on in the follow up assessment.

Did the postpartum film involve information regarding the education of the newborns (page: 5, line: 12)? The description of the postpartum support film is too short and would be better if the authors provide more information and does not only cite a PhD thesis.

This was added to the paragraph related to the film for further clarification: “Although the film included some health related information (e.g. signs that indicate the infant is receiving adequate amounts of breast milk), the main intent was to reassure mothers that the stressors they are experiencing are common and transient. Actors representing first-time mothers were included to provide humor about the stressors.” P5 L 17

It is a little bit pity that the rates of lost to follow up are relatively high in the study and in majority that is due to wrong addresses. Was the control group statistically similar to all of the intervention arms?

This is related to several factors. 1. Addressed in Lebanon are difficult. Houses are not numbered and many streets have no clear names or multiple names that change over time. 2. A woman can move between several homes - especially immediately after a delivery. She can live in her own home, stay with her parents or her in-laws, or move between her urban home and village home. The issue with the wrong address was not surprising to us and this loss to follow up was not unexpected to us.

The results section is quite short. It would be very interesting whether the authors analyze the stress-lowering effect with multiple linear regression analyses in order to characterize the sociodemographic background and obstetric characteristics of the alterations in the PSS scores.

The main aim of the RCT was to test whether the intervention reduces stress. The final results showed that the stress scores of those who received the film had the lowest score. The means used in the final results (Figure 1) are adjusted for all socio demographic and health related variables as there were no differences among the groups (Table 3 and 4). Therefore, there is no need to do a multiple regression. To investigate the stress lowering effect is an interesting topic that would require different analyses and variables and that are not within the scope of this paper.

It reduces the importance of the results that only 62% watched the film and only 30% used the telephone service. Is there any explanation why are the rates so low and could the authors explain in the ‘Discussion’ that there are tricks in the data interpretation due to not all participants who were allocated in an intervention arms performed the project. This is a high rate of protocol violation.
This is not unusual in an RCT. This is actually what happens in real life when a health practitioner advises his/her patients on a treatment. Compliance is never 100%. The use of the hotline is within the figures reported in the literature.

The authors concluded that the ‘impact of the film was stronger’, whereas in the Results they interpret their data as not significantly different from each other.

This was already clarified. There was a tendency for the film to be stronger but this was not statistically significant.

The methods are appropriate and well described, but it might be beneficial to complete both the statistical analyses and add some information to the study design as I indicated in my comments.

This point was responded to above.

Thank you again and we look forward to your response.

Best regards,
Hibah Osman, MD, MPH