Author’s response to reviews

Title: An implementation-effectiveness hybrid trial of video-based family therapy for peripartum depression in home visited mothers: A protocol for a pilot trial

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Author’s response to reviews:

My co-authors and I would like to thank the Reviewers for their thoughtful contributions, which have greatly improved our manuscript. We have revised the manuscript to reflect the changes suggested by the Reviewers. Below, we include the Reviewers’ comments followed by a short response with the location of the edits in the manuscript. The revised manuscript also includes the tracked changes. We revised the References to match the revisions. Please email me if you have any questions or need additional information.

Thank you.
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1. Given that participant behavioral outcomes will be assessed, the study meets NIH criteria for clinical trial registration: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html. Authors are advised to provide the clinical trial registration information to accompany this protocol.

Thank you for this helpful suggestion. The study has been registered as a clinical trial. We included the required trial registration information below the Abstract on page 2.

Introduction:

2. However, authors need to make a stronger argument for their choice of intervention ("systemic treatment model informed by family-oriented Dialectical Behavior Therapy skills for adolescents"). What is the current evidence for this family treatment model with or without technological enhancements?

We provided more details on the selection of the intervention in the first paragraph on page 5. We also corrected an error in the frequency of the treatment sessions in the second sentence in the “Intervention” section on page 12.

3. On page 3, authors write “Untreated maternal depression leads to poor outcomes in home visited families.” Please explicate for the reader specific outcomes these are and the significance of addressing them.

We described examples of poor home visiting outcomes in the last three sentences in the first paragraph on page 3.

4. On page 4, authors write ‘This is not surprising given the limited research on video-based family therapy.’ Authors are advised to briefly summarize the other contexts video based family therapy has been used and relevant findings.
We highlighted findings from studies of technology-based, family-oriented interventions in the last sentence in the second paragraph on page 4.

5. On page 6, authors state ‘Furthermore, we conducted a preliminary research study that produced findings that suggested a need for integrating the video-based, family oriented treatment into the two Federal HV Program sites.’ This preliminary study should be discussed further in the introduction: What was the study purpose, methodology, and specific findings?

The second and third paragraphs on page 7 include the details of our preliminary study.

Methods:

6. On page 6, Authors indicate that this study is an implementation-effectiveness hybrid trial. It would be helpful to reference the Curran et al (2012) paper [Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact Medical Care, 50(3), 217-226] and which hybrid type (1, 2, or 3). However, given that this study is not an RCT, this study is more likely characterized as quasi-experimental trial. Authors should indicate which features of the current protocol align and differ from the Curran et al. (2012) typology.

Thank you for recommending the inclusion of the Curran et al. (2012) article. We specified the features of our protocol that align with and differ from the Curran et al. (2012) typology in the second paragraph on page 8.

7. On page 7, authors indicate that “This study includes a historical comparison comprised of 12 depressed adolescent mothers who were previously enrolled in home visiting and have similar characteristics to those who will be recruited for the study.” More detail is requested regarding how the historical comparison group will be chosen: What were the matching mechanisms? How were they recruited and how was their recruitment different from the 12 adolescent mothers receiving the intervention?
We further defined the matching criteria in the second paragraph on page 9.

8. On pages 7-8, authors provide an extensive list of exclusionary criteria for adolescent mothers in the study. Given these exclusions, how might the proposed sample of adolescents receiving the intervention differ from the population authors wish to generalize too? This issue should be addressed in the limitations, if generalization of findings is likely to be impeded by the exclusion criteria. Additionally, how will these exclusionary characteristics be identified and by whom?

We increased the age limit for eligible adolescent mothers to 25 years old and increased the length of time in the postpartum period from 12 months to 18 months as these characteristics are present in many home visited depressed mothers in New England. These two changes are noted in the first sentence in the last paragraph on page 4. We also decreased the cut point from 10 to 8 on the EPDS since the study intervention is preventive, and this change is noted in the first sentence in the last paragraph on page 4. We further specified how the exclusionary characteristics will be identified, and by whom, in the second paragraph on page 10. We also included a “Limitations” section on page 17, which highlights the issues with generalizability.

9. On page 11, authors make reference to the use of focus groups but do not identify which participant type will be involved in the focus group (home visitors, mothers, other staff, etc.). Table 1 indicates that the respondents will be home visitors, but it would be helpful to put in narrative form who will complete which assessments in the methods text.

We clarified that only home visitors will participate in the focus groups in the third sentence in the first paragraph on page 14.

10. The sample size (n = 24) substantially limits the ability for authors to determine any statistically significant differences between sample groups. More detail is requested in how authors will determine there a sufficient difference between the intervention and comparison groups on key outcomes. If no significant differences are detected, how will the results inform whether authors should pursue a larger scale trial? What other pieces of information could be gathered that would provide important information regarding how to power a larger scale trial?
We specified how the results could be used to inform our decision to move forward with a larger study in the first paragraph on page 17. We specified the sample size limitation in the “Limitations” section on page 17.