PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form [here](http://bmjopen.bmj.com/site/about/resources/checklist.pdf) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

<table>
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<th>TITLE (PROVISIONAL)</th>
<th>Feasibility of Online Mindfulness-Based Interventions for Families Affected with Postpartum Depression and Anxiety: Study Protocol</th>
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<tr>
<td>AUTHORS</td>
<td>Tabi, Katarina; Bhullar, Manreet; Fantu, Lenssa; Shulman, Barbara; Dueck, Royce; Hippman, Catriona; Ryan, Deirdre; Stewart, Evelyn</td>
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VERSION 1 – REVIEW

<table>
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<tr>
<th>REVIEWER</th>
<th>Zhang, Nanhua</th>
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<td>University of Cincinnati, Pediatrics</td>
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<td>REVIEW RETURNED</td>
<td>20-Jun-2021</td>
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GENERAL COMMENTS

This manuscript presents a study protocol to examine the feasibility and acceptability of online mindfulness-based interventions (MBI) for families affected with postpartum depression and anxiety. Mothers diagnosed with postpartum depression and anxiety (PPDA) and their partners are invited to join the study. All mothers enrolled in the study will join the 8 weeks online MBI program, and their partners decide whether they want to enroll in a simultaneous 8 weeks program. The primary outcome is the feasibility of the online program, assessed from the facilitators’ and participants’ perspective. Overall, it is well-developed as a feasibility study. I have the following specific comments:

1. There is no justification of sample size. What kind of precision does the study achieve with a sample size of 30?
2. The choice to join one of the study arms itself is an outcome.
3. Related to the partners’ self-selection to join the MBI group, there is potential for selection bias. What is the plan to address this potential bias?
4. The mental health and relationship outcomes will be measured over time, and the statistical analysis of these should take into account of this feature.

<table>
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<th>REVIEWER</th>
<th>Stotts, Angela L</th>
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<td>Univ Texas Houston</td>
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<td>09-Jul-2021</td>
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GENERAL COMMENTS

This is an important line of research focusing on the postpartum period using technology-based interventions. Collecting feasibility data is an important first step in developing new intervention programs.

- Abstract is appropriate, although the participants’ perspective is included in a sentence defining the primary outcome (line 24-25) but then is listed as a secondary outcome later in the paragraph (line 29-30).
Stylistically the introduction has several 2-sentence paragraphs that could be combined, such as lines 21-30.
- Literature and rationale are needed for including partners/fathers of women with postpartum depression and anxiety in their own treatment group. Also, a rationale is needed for why mothers and fathers are receiving different mindfulness interventions. More discussion of mindfulness interventions for postpartum depression/anxiety would also be helpful to support the study.
- Should lack of access to the internet or to a wireless network be an exclusion criteria?
- This sentence makes it sound like the groups (mothers only vs. mothers and fathers both) will be compared: “Mothers from both study arms will attend the mother’s MBI group together, to increase the similarity of the main and control arm – so the only difference will be whether or not their partner also practices mindfulness.” However, this is not discussed in any other section of the paper, including the data analysis section. Further, these groups should not be compared given sample size and non-randomization and cross contamination by putting all mothers in the same group.

The specific outcomes need to be fully specified/operationalized in the outcomes section and consistent throughout. The abstract has better operationalized feasibility outcomes than the outcome section of the paper. First state the specific feasibility outcomes (e.g., frequency of technical difficulties) for both facilitators and participants (including mothers separate from fathers), and then discuss how they are measured.

In general, more details are needed in the data analysis section regarding linear regression models as well as the qualitative data analysis. What variables will be in the model? Are group comparisons implied? Also, the primary outcomes related to feasibility are not addressed here.

Consider adding a section as the end of the manuscript describing the importance of the study as well as the limitations. At minimum limitations need to be discussed.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Dr. Nanhua Zhang, University of Cincinnati
Comments to the Author:
This manuscript presents a study protocol to examine the feasibility and acceptability of online mindfulness-based interventions (MBI) for families affected with postpartum depression and anxiety. Mothers diagnosed with postpartum depression and anxiety (PPDA) and their partners are invited to join the study. All mothers enrolled in the study will join the 8 weeks online MBI program, and their partners decide whether they want to enroll in a simultaneous 8 weeks program. The primary outcome is the feasibility of the online program, assessed from the facilitators’ and participants’ perspective. Overall, it is well-developed as a feasibility study. I have the following specific comments:

Reviewer 1:
Dear Reviewer 1,
We sincerely thank you for reviewing our manuscript. We appreciate your insightful comments and suggestions that guided us to improve the quality of our paper. You will find our responses directly below each of your comments listed in point-by-point order. Following your suggestions, we added the appropriate sections into our manuscript which are highlighted in color. We have revised our statistical analysis section, including added description of how we will compare measurements of mental health and relationship outcomes at different time points.

1.1. There is no justification of sample size. What kind of precision does the study achieve with a sample size of 30?
RESPONSE:
As this was primarily a feasibility study and not designed to measure effect, a formal sample size calculation was not performed. Recruiting 30 participants will enable us to have estimates of recruitment, drop-out rates, and follow-up participation for our outcome measures, that will be informative for the design of our larger trial study. We have now included a section describing our decision to recruit a sample size for 30 patients in the statistical analysis section of our paper:

“This is primarily a feasibility study and not designed to measure efficacy, hence a formal sample size was not calculated. 30 participants will be recruited to enable estimates of recruitment, study/treatment adherence and drop-out rates, and follow-up participation for future larger trial studies.”

1.2. The choice to join one of the study arms itself is an outcome.
RESPONSE:
As described under response 2.3, we agree that this might be an important outcome for an efficacy study, and we will design the future efficacy studies to account for it. Given that for this pilot study our focus is on the feasibility of the online interventions, we selected the outcomes accordingly.

1.3. Related to the partners’ self-selection to join the MBI group, there is potential for selection bias. What is the plan to address this potential bias?
RESPONSE:
We agree that there is potential for selection bias to occur due to the partners’ self-selection to join the MBI group. For our pilot study, our focus is on the feasibility of the online interventions rather than their efficacy. In future studies where we measure the efficacy of the interventions, we will surely account for the important selection bias.

1.4. The mental health and relationship outcomes will be measured over time, and the statistical analysis of these should take into account of this feature.
RESPONSE:
We agree that the statistical analysis of the mental health outcomes and relationship outcomes should account for the fact that it will be measured over time at different time points, which will be explored using descriptive statistics for each of the measures at relevant time points. We have now included this information in the data analysis section.

“Measures that collect data over time, such as the mental health outcome measures or relationship outcome measure, will be explored using descriptive statistics for each of the measures and for each relevant time point.”

Reviewer: 2
Dr. Angela L. Stotts, Univ Texas Houston
Comments to the Author:
This is an important line of research focusing on the postpartum period using technology-based interventions. Collecting feasibility data is an important first step in developing new intervention programs.

Reviewer 2:
Dear Reviewer 2,
We thank you earnestly for reviewing our manuscript. Your input is valuable, and we are grateful for your contribution. You can find our responses below each of your comments listed in point-by-point order. After taking your comments and suggestions into consideration, we have made the corresponding changes to our manuscript which are highlighted in colour. We included sections that are dedicated to the importance and limitations of our study. We have also revised and included rationales, in both our responses and in the paper, to provide details where more clarity is needed regarding our data analysis and specifications of our feasibility outcomes in the outcome section.

2.1. Abstract is appropriate, although the participants’ perspective is included in a sentence defining the primary outcome (line 24-25) but then is listed as a secondary outcome later in the paragraph (line 29-30).
RESPONSE:
Participants’ perspective is needed for determining both the primary and secondary outcomes; however, we are assessing different outcomes of interest. Feasibility is the primary outcome, which is partially assessed through the participants’ perspective and partially through facilitators’ perspective.
Then we will also be collecting other data from the participants that will be used to measure the secondary outcomes, including mental health, couple interactions, satisfaction, and acceptability. We have revised the abstract to increase the clarity.
“In this feasibility study, participants will include mothers diagnosed with PPDA and their partners. Two online MBI groups will run simultaneously for 8 weeks: one for mothers with PPDA and another for their partners. The primary outcome will be feasibility of conducting the online groups, assessed from the facilitators’ perspective, participants’ perspective, and attrition throughout the study. The participants’ perspectives on feasibility will be assessed by questions including how difficult it was for them to make it to the sessions, specific obstacles encountered and their scheduling preferences. The facilitators’ perspective will be assessed by frequency of technical difficulties encountered, of disruptions in the online sessions, and of episodes where parents leave the screen (e.g., to calm their child). Secondary outcomes will include mental health, couple relationship, satisfaction and acceptability which will also be evaluated through participant questionnaires.”

2.2. Stylistically the introduction has several 2-sentence paragraphs that could be combined, such as lines 21-30.
RESPONSE:
Thank you for your input regarding the stylistics of the introduction. We agree that some of the paragraphs could be combined and have done as such.

2.3. Literature and rationale are needed for including partners/fathers of women with postpartum depression and anxiety in their own treatment group. Also, a rationale is needed for why mothers and fathers are receiving different mindfulness interventions. More discussion of mindfulness interventions for postpartum depression/anxiety would also be helpful to support the study.
RESPONSE:
Thank you for your queries about the mindfulness interventions. We have now revised the manuscript to include our rationale for why mothers and partners are receiving different mindfulness interventions.
“The CANMAT guidelines recommend MBCT for adults with depression as a first-line maintenance treatment and as a second-line adjunctive treatment for acute depression.[11] The mothers are patients at our clinic with a formal diagnosis of postpartum depression and/or anxiety, thus they are...
offered the MBCT. Their partners, who are not formal patients at our mental health clinic, receive MBSR which has been shown to help with stress management and coping with adversity in both those with a medical diagnosis and the non-clinical population. [34]

As suggested, we have added more discussion of mindfulness interventions for postpartum depression/anxiety, including a supporting literature. “This is the first study to explore the feasibility and acceptability of online MBIs for families affected with PPDA. MBIs are beneficial for people with depression in the general population and are recommended in clinical guidelines internationally. [15, 41, 42] A growing number of studies suggest that MBIs are also effective for depression and anxiety in the postpartum period. [13-17] Preliminary literature shows that MBIs improve symptoms of anxiety and psychological distress in new mothers. [14, 15] While exact mechanisms of MBIs in the perinatal population are yet to be examined, Dimidjian et al described potential domains of involvement. [43] They observed that rumination, decentralization and self-compassion have been shown in the general population to be significantly improved following MBIs. [43, 44, 45] The same processes of rumination and self-critical attitudes also play a contributory role in perinatal depression. [43, 46-48] Moreover, a study by Perez-Blasco showed that MBIs support postpartum individuals in cultivating self-compassion, parental self-efficacy, and various dimensions of mindfulness including observing, acting with awareness, non-judging and non-reactivity. [14, 15] However, many new parents do not have access to treatment or find it challenging to commit to or complete the treatment.”

2.4. Should lack of access to the internet or to a wireless network be an exclusion criteria?
RESPONSE:
We agree that a lack of access to internet or a wireless network would be an exclusion criteria as internet connection is required to be able to attend the online intervention sessions. We have added that to our exclusion criteria in the methods section.

“Exclusion criteria:

• Lack of access to the internet or a wireless network”

2.5. This sentence makes it sound like the groups (mothers only vs. mothers and fathers both) will be compared: “Mothers from both study arms will attend the mother’s MBI group together, to increase the similarity of the main and control arm – so the only difference will be whether or not their partner also practices mindfulness.” However, this is not discussed in any other section of the paper, including the data analysis section. Further, these groups should not be compared given sample size and non-randomization and cross contamination by putting all mothers in the same group.
RESPONSE:
We have deleted this sentence, to avoid misleading the readers.
In fact, we plan to compare these two arms in the future studies, that will be efficacy focused and will have much larger sample size, will be randomized and will have other methodological features important for efficacy studies that support this comparison. In this pilot study, focused on feasibility of the online solution, this won’t be the case and therefore we have revised the paper so it does not include the sentence.

2.6. The specific outcomes need to be fully specified/operationalized in the outcomes section and consistent throughout. The abstract has better operationalized feasibility outcomes than the outcome section of the paper. First state the specific feasibility outcomes (e.g., frequency of technical difficulties) for both facilitators and participants (including mothers separate from fathers), and then discuss how they are measured.
RESPONSE:
Thank you for your response on the matter. We apologize for any unclarity you perceived based on the way we phrased our outcomes section. In addition to revising our written explanation in the
outcomes section, we have included a figure that fully operationalizes each outcome and how it will be measured. We hope that this will bring more clarity and consistency to our paper.

"Feasibility of conducting the online groups will be determined by a set of assessments (see Figure 2), including:

- Feasibility measure administered to participants – self-report questionnaire includes both quantitative and qualitative questions, such as frequency of technical and non-technical interruptions, how easy/difficult it was to make it to the sessions and follow the program, specific obstacles encountered (e.g. time, mood, child’s needs), and participants’ scheduling preferences. This newly-developed questionnaire was informed by feedback from alumni participants. It will be completed by participants at week 8. See online supplemental file 1 to view this questionnaire.
- Feasibility measure administered to facilitators – aims to assess the frequency of technical difficulties and frequency as well as the type of non-technical interruptions (e.g., parent leaving the screen to calm the baby, turning off the camera, early sign-off, late sign-in). This short survey will be completed by group facilitators after each session. See online supplemental file 2 to view this survey.
- Numbers tracked along the study, including recruitment, attendance and drop-out rates. See Figure 1 for details.
- Inquiry exploring reasons for drop-outs"

Figure:

2.7. In general, more details are needed in the data analysis section regarding linear regression models as well as the qualitative data analysis. What variables will be in the model? Are group comparisons implied? Also, the primary outcomes related to feasibility are not addressed here.

RESPONSE:

Thank you for your queries related to the data analysis. We have revised the data analysis section to include this information.

“Descriptive statistics will be used to describe the study sample, including demographics, recruitment and retention rates, as well as some of the quantitative data. Feasibility outcomes will be assessed by looking at attendance, dropout and retention rates, descriptive statistics of quantitative data and through inductive content analysis [39] of qualitative data in the facilitator survey as well as the participant survey to find common themes surrounding the factors that affected feasibility of the program on either end. Measures that collect data over time, such as the mental health outcome measures or relationship outcome measure, will be explored using descriptive statistics for each of the measures and for each relevant time point. Exploratory analysis of the improvements in relationship and mother’s mental health outcomes will be conducted using linear regression models, which will be used to model an association between relationship outcomes and each measure of mothers’ mental health outcomes. Inductive content analysis [39] of responses to open-ended questions will be used for qualitative data to find common themes and participants’ answers will be quoted in discussion of this data. This is primarily a feasibility study and not designed to measure efficacy, hence a formal sample size was not calculated. 30 participants will be recruited to enable estimates of recruitment, treatment adherence, drop-out rates, and follow-up participation for future larger trials [40].”

2.8. Consider adding a section as the end of the manuscript describing the importance of the study as well as the limitations. At minimum limitations need to be discussed.

RESPONSE:

Thank you for your response. We agree that a section about the importance of the study as well as the limitations would be important to add, and we have now done so.

“Importance

The online delivery of evidence-based interventions is promising as it may significantly improve the accessibility to care for this population. Even in urban communities, perinatal mental health services
are only available in limited locations where most families need to commute long ways to access them on a regular basis when they finally make it off the waitlist to access this care. These challenges are further exacerbated for new parents living in rural areas where specialized care is not available, who would need to travel long distances to access this care, which may not be feasible on a regular basis. Further, the online groups are available also during times of crisis, including a pandemic, when in-person interventions are limited or paused. An online option ensures continued care even during circumstances where in-person options are unavailable.

Additionally, there are many other challenges faced by parents that may reduce their ability to commit to in-person treatment including limited child-care support, competing priorities during limited available time, and related limited time for self-care and health routines. Offering online groups that can be attended from home and eliminating commute times, can give parents extended time to attend to more of their needs that day. For all these reasons, the option to attend the group online may empower families to more easily access treatment and commit to the entirety of the intervention.

Limitations
Several limitations arise due to the feasibility nature of the study, including a smaller sample size, non-randomization of study arms, and potential for selection bias, thus limiting the generalizability of the secondary outcomes. Limited self-report data is being collected to decrease the burden on participants and focus on feasibility outcomes. Specifically, short-form versions of questionnaires are being used and not all data of interest is being collected, which also limits the efficacy conclusions. For example, data regarding other treatments received by participants in parallel with the MBIs are not being collected to ease the participant workload. Further, the study’s inclusion and exclusion criteria limit the generalizability of this study’s results, such that findings may not apply to teenage mothers; mothers with severe depression, a psychotic disorder, or a substance use disorder; mothers facing barriers in terms of housing or related amenities (without access to internet connectivity and/or a private place to participate in the group); or birthing individuals who do not identify as mothers.

**VERSION 2 – REVIEW**

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Zhang, Nanhua</th>
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