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Feasibility of Online Mindfulness-Based Interventions for Families Affected with Postpartum Depression and Anxiety: Study Protocol

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Abstract

Introduction

Postpartum depression and anxiety (PPDA) is experienced by up to 20% of families in the first year. The condition impacts not only parents but also their developing child. While Mindfulness-Based Interventions (MBI) have shown to be beneficial for this population, many parents do not have access to treatment or find it challenging to commit or complete the treatment. The COVID-19 pandemic has heightened some of the challenges that parents face. The ability to find time for needed self-care and health interventions is also affected by limited child-care support. The opportunity to attend a group online may significantly improve the accessibility to group MBI but may also bring challenges. This study aims to examine the feasibility and acceptability of online MBI groups for parents in families affected with PPDA.

Methods and analysis

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 the online groups, assessed from the facilitators' perspective, participants' perspective and the numbers flow throughout the study. The participants' perspective will involve both quantitative and qualitative data. The facilitator's 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 interactions, satisfaction and acceptability.

Ethics and dissemination

The study has received ethics approval from the University of British Columbia CW Research Ethics Board. Study results will be disseminated through peer-reviewed journals and conferences.

Trial registration number Clinicaltrials.gov (NCT04617132)

Keywords: mindfulness, postpartum depression, perinatal mental health, online, parents

Strengths and limitations of this study

- The study will be the first to examine the online delivery of Mindfulness-Based Intervention for parents in families affected by postpartum depression and anxiety
- As a feasibility study, it will have a small sample size and will not be able to determine efficacy of the intervention
- This study is limited by certain data not being collected, including other treatment interventions the participants receive, which is done with the intention to decrease the burden on participants in this feasibility study
- Insights from the study will contribute to increased accessibility to the intervention and may inform future practice within clinical and community settings

Introduction

Postpartum depression and anxiety (PPDA) is highly prevalent in parents, experienced by up to 1 in 5 families (17.7%).[1,2] In addition to impacting the parents facing distress, this condition can also have potential effects on the child.[3,4] PPDA interferes with central factors affecting the child's development: mother-infant interactions, secure attachment, the mother's responsiveness to the child's needs, and the quality of the home environment.[5] Treating maternal PPDA goes a long way towards helping the child flourish in the long-term.[3,6] Due to parents' concerns about using psychiatric medication when breastfeeding, it is crucial that effective non-pharmacological treatments become available to mothers with PPDA.[7]

The benefits of Mindfulness-Based Interventions (MBI) for the treatment of depression and anxiety in the general population are well documented.[8-12] In addition, there is a growing evidence showing the effectiveness of MBIs as a treatment option for those with PPDA.[13-16]

However, many individuals affected by PPDA do not receive any treatment or struggle to commit or complete their treatment. Some of the several factors reducing treatment commitment include challenges of limited time, commuting difficulties competing priorities faced by new parents.[17,18]

The global pandemic has contributed to heightened challenges faced by new parents. Specifically, closed child-care facilities, and social distancing measures that prevent grandparents or others who may otherwise be available to help out all contribute to a limited child-care support – an area so important especially for those facing PPDA. This can significantly limit available time for parents' self-care and health interventions that are important to manage their PPDA.

The opportunity to attend a group online may significantly improve accessibility to MBI for parents with PPDA. Related advantages may include, but are not limited to, the flexibility of attending from anywhere, including home, time saved on commute and related preparation.[19] On the other hand, some parents might find it difficult to attend sessions online, whether it may be due to technological limitations, inadequate privacy at home for disclosure of vulnerable feelings during therapeutic group, or limited ability to focus on the session when the parent is simultaneously attending to one or more children at home in case of the limited child-care support.[20-22]

The majority of the existing literature exploring the feasibility, potential, and limitations of online MBI for the perinatal population focused on mothers during pregnancy.[23-26] However, the daily routines and challenges during pregnancy differ greatly from those following the infant's birth.[27,28] These differences may include ability to commit to a regular group as well as the type of mindfulness practices that a new parent is able to incorporate into their daily routine.

From the limited amount of literature that explored online MBI in the postpartum population, the studies typically focused on non-clinical populations and postpartum parents without a current diagnosis of PPDA.[26,29,30] Gammer et al. assessed a compassion-based intervention, reporting a high attrition rate even in a non-clinical population.[29] However, the ability to commit to a regular group, as well as the level of distress and challenges experienced by parents with acute mental health issues may differ from parents within general population. Therefore, as brought to light by the COVID-19 pandemic, there is a need to explore the potential and limitations of the online delivery for parents experiencing PPDA.

The aim of this study is to examine the feasibility and acceptability of online MBI groups for parents in families affected with PPDA in the first year postpartum.

The primary objective is to determine the feasibility of the online delivery for mothers with PPDA and their partners by answering the research question: Will parents in families affected with PPDA be able to access the online MBI group and continue with the online sessions?

The secondary objectives are to capture preliminary evidence of outcomes including mental health, couple interactions, satisfaction and acceptability.

Methods and analysis

Study Design

This is a prospective, single-site study exploring the feasibility of offering mindfulness groups for the postpartum population in an online setting. The presented study is part of a larger research project exploring mindfulness for both partners in families affected by PPDA. The study will follow a non-randomized design with 2 arms, the main treatment arm representing families where both partners receive the intervention, and the control arm where only the mother with PPDA receives the intervention. This protocol has been reported using the Standard Protocol Items Recommendations for Intervention Trials checklist [31].

Participants and Recruitment

Trial site and participating centers

The study will take place at the Reproductive Mental Health Program, a tertiary mental health clinic from where the participants will be recruited. This clinic is a part of BC Children's and BC Women's Hospital and Health Centre located in British Columbia, Canada. Given that groups run online, participants will be participating from their homes or other location of their choice.

Participants

Study participants will consist of mothers referred to this clinic and their partners. Following assessment by a perinatal psychiatrist, those postpartum mothers who are diagnosed with depression and/or anxiety, and who are interested in the MBI may register for the upcoming mothers' group. Their partners will also be contacted and invited to attend the MBI partners' group. Families who meet the study criteria will be invited to participate in this study.

Inclusion criteria

- Mother with Major Depressive Disorder (MDD), Other Specified Depressive Disorder, Unspecified Mood Disorder, Generalized Anxiety Disorder (GAD), Other Specified and/or Unspecified Anxiety Disorder as per the DSM-5 criteria; and is up to 12 months postpartum
- Mother with PPDA and partner are co-habiting

- Fluent in English

Exclusion criteria

- Age < 19
- Assessed to be at significant risk for suicide, have a psychotic disorder, and/or currently have a substance use disorder

Sample size will consist of 30 mothers with PPDA (plus 15 partners). With this sample we will be able to determine attendance and attrition rates to inform future studies. Recruitment to the study opened in September 2020 and is expected to close in September 2022. At the time of manuscript submission the study is open to recruitment.

Recruitment

Initial steps are described in Figure 1, as well as in the Participants section.
Families who meet the eligibility criteria will be invited to the study. Those who indicate interest in participating in the study will be sent an email by the research team. This email will provide them with information about the study and a copy of the consent form. They will have time to discuss it at home prior to the first online sessions of the MBI and will have the opportunity to ask questions via email. It will be made clear that their willingness to participate in the study is entirely voluntary and will not impact their potential relationship with the clinic. Participants (mothers with PPDA and their partners) can decide to participate in the intervention groups and not participate in the study. Participants will be asked to join the online room twenty minutes before their first MBI group session. Upon their arrival, they will be reminded of the study procedures and asked to sign the consent form.

Figure 1: A consort diagram highlighting the intended recruitment process for the study

Interventions

The intervention will consist of standardized 8-week MBI groups delivered online (via Zoom for healthcare settings). The groups will be facilitated in real time by trained and experienced mental health professionals. Two MBI groups will run simultaneously:

- Group for mothers diagnosed with PPDA - Mindfulness-Based Cognitive Therapy (MBCT)[32]
- Group for partners of these mothers - Mindfulness-Based Stress Reduction (MBSR)[33]

Allocation to 2 study arms:

Arm 1) Both mothers and their partners attend MBI groups (“main treatment” arm)
Arm 2) Only mothers attend an MBI group (“mother-only controls”)

Mothers whose partners are not interested or unavailable to attend the partners’ group will attend the MBI mother’s group as mother-only controls. 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.

Measures and data collection

Outcome Measures

The primary outcome is the feasibility of running online MBI groups for this population. Secondary outcomes include mental health, couple relationship, satisfaction and acceptability. Figure 2 demonstrates the outcome measures and their data collection time points.

Feasibility of the online groups will be determined by a set of assessments, including:

- Feasibility measure administered to participants – self-report questionnaire includes both quantitative and qualitative questions and will be completed by participants at week 8. This newly developed questionnaire was informed by feedback from alumni participants. See online supplemental file 1 to view this questionnaire.
- Feasibility measure administered to facilitators – aims to assess the technical difficulties and other disruptions (e.g. parent leaving the screen to calm the baby) experienced during the session. 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.

Acceptability and satisfaction

The questionnaire includes both quantitative and qualitative items, exploring what the participant is taking away from the program; recommendations for changes to the program; what impact they perceive the program had on them, their partner, their relationship; and overall satisfaction.

Demographics

Include variables on age, ethnic background, marital status, number of children and their ages, number of people in the household, and socioeconomic status.

Couple relationship

This questionnaire aims to assess couple interactions and relationship dynamics, specifically related to change over time (pre-intervention vs. post-intervention vs. 3 month follow-up). It is a self-report measure completed separately by both partners, capturing their unique perspective on their relationship. Specific areas assessed include communication and interactions within the couple (e.g. behaving in a reactive way during disagreements, blaming and criticizing the other during disagreements, attentive listening); support received (only in questionnaire for mothers with PPDA) and support provided (only in questionnaire for partners); and overall relationship satisfaction.

Mental health

- Patient Health Questionnaire-9 (PHQ-9)
  The PHQ-9 is a widely used measure assessing depression, known to have great reliability and validity.[34,35] It includes each of the 9 DSM-IV criteria and scores as “0” (not at all) to “3”

(nearly every day). Scoring includes cut-off points of 5, 10, 15 and 20, which indicate mild, moderate, moderately severe and severe depression, respectively.

- General Anxiety Disorder-7 (GAD-7)
  The GAD-7 is an efficient tool assessing anxiety, with a good validity, reliability, construct and factorial.[36] Scoring includes cut-off points of 5, 10 and 15, which indicate mild, moderate, moderately severe and severe anxiety, respectively.

Figure 2: Timeline of concurrent MBI groups and data collection time points

Statistical analysis and data management

Data is collected and managed using REDCap (Research Electronic Data Capture) hosted at BC Children's Hospital. REDCap is a secure, web-based application designed to support data capture for research studies.[37] All data entered into REDCap will be de-identified. De-identified data and outcomes will be later saved into a password-protected research computer and stored on a secure local server.

Descriptive statistics will be used to describe the study sample, including demographics, recruitment and retention rates, as well as some of the quantitative data. Exploratory analysis of the improvements in relationship and mother's mental health outcomes will be conducted using linear regression models. Qualitative data will be analyzed based on common themes and participants' answers will be quoted in discussion of this data.

Patient and public involvement

Patients and public were first involved in the development of measures, including the couple relationship questionnaire and the feasibility, acceptability, and satisfaction questionnaire. Preliminary drafts of the measures were shared with alumni participants (those who took part in the in-person MBI groups in the past), clinicians, group facilitators, and long-term mindfulness practitioners in the community. The research team conducted online interviews to consult with them and gather their opinions and suggestions for the measures. Input included an assessment of the measures' burden as well as informing the content and wording of the final versions of these measures. For example, during an interview an alumni participant suggested that the wording of a particular question may give the opposite meaning than intended to those whose first language is Mandarin. With the guidance from this alumni participant, the team reworded the question accordingly. This was very valuable feedback given that the Vancouver population and our study sample population is diverse and includes people for whom English is not their first language.

Further, during the study (at week 8 of the data collection), participants will be surveyed about a variety of items, which will inform and refine the study intervention prior to conducting future clinical trials. Specifically, this will include timing and scheduling of the intervention sessions, technical challenges they faced with the online delivery, non-technical challenges they faced while attending or trying to make themselves available to attend the session, and their overall experiences with the intervention.

Ethics and dissemination

Ethics approval

Ethics approval for this study and all its instruments was obtained from UBC Children's and Women's Research Ethics Board (number H20-01884).

Consent

Written consent from potential trial participants (see supplemental file 3) will be obtained by the research team via REDCap platform, signed in real time during a Zoom videoconference call prior to the first session. The potential participants will be sent a copy of the consent form a week before the session to read and discuss beforehand. They will have opportunity to ask any questions about the study or the consent form both over email and orally during the videoconference call.
It is not expected that participating in this study will pose any additional risk to the participants compared to receiving clinical care without the research component. In case any participants feel distressed at any point during the study, they will have a list of emergency resources they can use to contact on-call psychiatrists, emergency departments or other crisis services.

Data storage and privacy

Participants will be given unique study codes that will be stored separately and only known to the research team. Personal information and de-identified data will be saved in two separate folders on a research computer that will be password-protected and stored on a secure server. No data will be shared with any outside agencies without the consent of the subjects. Selected research team members will have access to the final trial dataset while other team members will only have access to de-identified data when needed.

Dissemination

Results from this study will be disseminated in peer-reviewed journals, at national and/or international conferences and oral presentations. Study findings will be shared via clinical rounds, webinars and symposia with clinicians, policy and community partners.

Supplementary materials

- Supplementary File 1: Feasibility and Acceptability Questionnaire Administered to Participants
- Supplementary File 2: Feasibility Survey Administered to Facilitators
- Supplementary File 3: Consent Form Signed by Participants.

Footnotes

Author Contributions

KT, SES, MB, and LF designed the study and prepared the ethics application. BS and RD contributed to developing the measures, and BS, RD, and DR contributed to the study design with clinical insights. KT and MB drafted the manuscript. SES and LF edited the first drafts of the manuscript. All authors read and approved the final manuscript.

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Competing interests

None declared.

Patient consent for publication

Not required.

Provenance and peer review

Not commissioned; externally peer reviewed.

Trial registration

Clinicaltrials.gov (NCT04617132)

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Figure Legends

Figure 1: A consort diagram highlighting the intended recruitment process for the study

Figure 2: Timeline of concurrent MBI groups and data collection time points

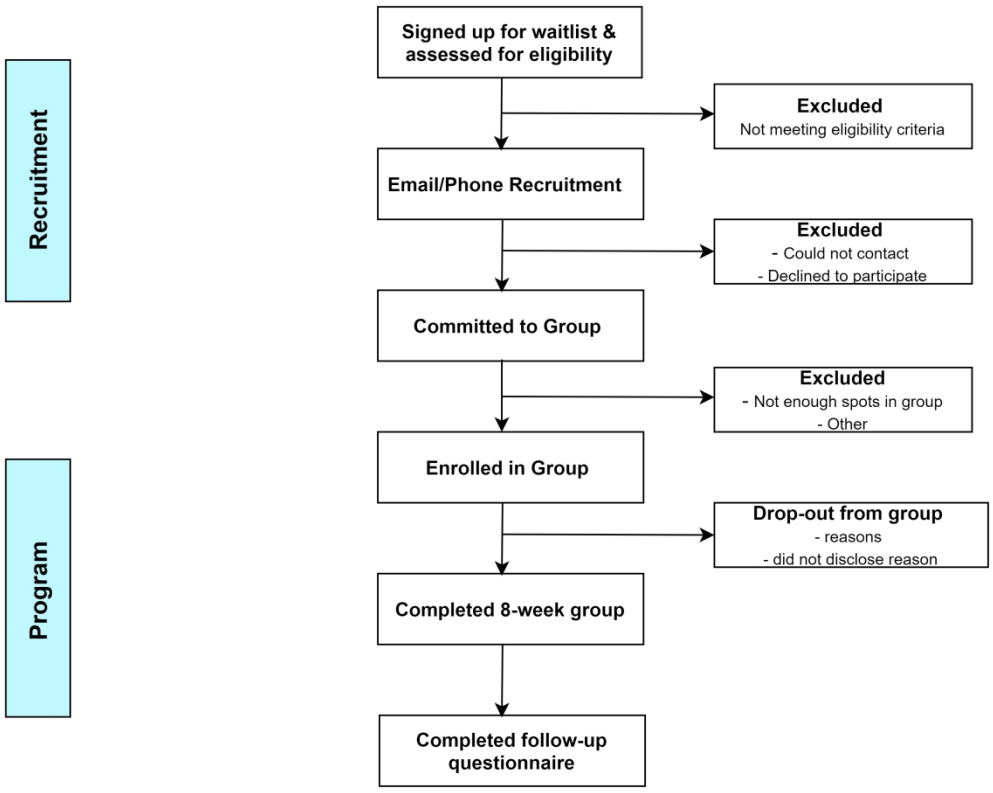

Figure 1: A consort diagram highlighting the intended recruitment process for the study

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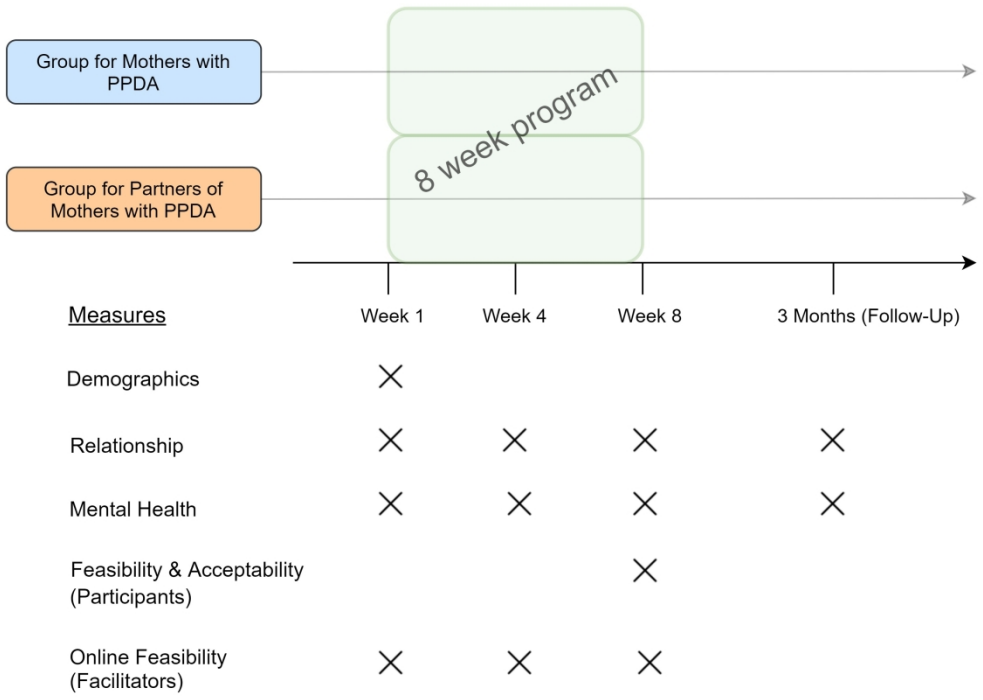

Figure 2: Timeline of concurrent MBI groups and data collection time points

1109x804mm (72 x 72 DPI)

Supplementary File 1. The feasibility questionnaire completed by participants at week 8, after completion of the intervention.

Feasibility and Acceptability Questionnaire Administered to Participants

1. Overall, how satisfied are you with the program?

1. Quite dissatisfied
2. Indifferent or mildly satisfied
3. Mostly satisfied
4. Very satisfied

2. Did you find a positive impact/helpfulness of the program on:

- Yourself

1. Not at all helpful
2. A little bit helpful
3. Mostly helpful
4. Very helpful

- Your partner

1. Not at all helpful
2. A little bit helpful
3. Mostly helpful
4. Very helpful

- Relationships and interactions between you and your partner

1. Not at all helpful
2. A little bit helpful
3. Mostly helpful
4. Very helpful

3. What are you taking away from this program? What do you perceive as the benefits of participating?

4. What were the main challenges you encountered during the program? What would you recommend that changes for future programs?

5. How easy/difficult was it to make it to the online sessions and follow the program?

1. Very easy
2. Mostly easy
3. Neutral
4. Some difficulties
5. Very difficult

6. What were some of the obstacles? (Select all that apply)

1. Lack of time
2. My mood/health/energy level
3. Group scheduled at wrong time/day of the week
4. Pandemic related obstacles
5. Child-related needs
6. Other:
7. Not applicable

7. Scheduling: Were there certain days of the week or times (e.g. mornings, afternoons, evenings; certain hours) that would have made it easier to attend the sessions?

8. How often did you experience technical difficulties during the online sessions (e.g. video or sound not working immediately, other technical functions needed to participate in the group not working)?

1. Not at all
2. Minority of sessions
3. Once every session
4. More than once per session

9. How often did you experience any non-technical interruptions during the online sessions (e.g. child or other family members needing your attention; other reasons)?

1. Not at all
2. Minority of sessions
3. Once every session
4. More than once per session

Supplementary File 2. The survey is completed by facilitators on a weekly basis.

Feasibility Survey Administered to Facilitators

Week ____

1. **Were there any technical difficulties during this session?**

____ Yes ____ No

2. **Were there any situations when participants were not present during this session? (Select all that apply)**

- ☐ Nothing at all
- ☐ People turning off their video cameras
- ☐ Disruptions & temporarily not being present during the session (e.g. left the screen to calm or attend to the baby)
- ☐ Early sign-off
- ☐ Late sign-in
- ☐ Other: _____

3. This space is for any additional comments/explanations you would like to include.

Supplementary File 3. Consent form signed by participants.

Participant Consent and Signature

Taking part in this study is entirely your choice. You have the right to refuse to participate in this study. If you decide to participate, you may choose to end the study at any given time without providing a reason and without any impact on your access to services from this clinic.

Signature on this consent form means:

- I have read and understood the information on this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have the satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.

_____ _____

Participant Signature Date

_____

Printed Name

Supplementary File 4. SPIRIT checklist.

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	
Funding	#4	Sources and types of financial, material, and other support	11
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1,10
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	1
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a

Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3,4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	4
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7,8
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	5
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document	n/a

		that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8,9
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values).	8,10

		Reference to where details of data management procedures can be found, if not in the protocol	
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	8,9
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n/a
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			

Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2,10
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	11
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	10
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	11
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a

Appendices

Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	SM3
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

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Feasibility of Online Mindfulness-Based Interventions for Families Affected with Postpartum Depression and Anxiety: Study Protocol

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Feasibility of Online Mindfulness-Based Interventions for Families Affected with Postpartum Depression and Anxiety: Study Protocol

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Abstract

Introduction

Postpartum depression and anxiety (PPDA) is experienced by up to 20% of families in the first year. The condition impacts not only parents but also their developing child. While Mindfulness-Based Interventions (MBI) have shown to be beneficial for this population, many parents do not have access to treatment or find it challenging to commit or complete the treatment. The COVID-19 pandemic has heightened some of the challenges that parents face. The ability to find time for needed self-care and health interventions is also affected by limited child-care support. The opportunity to attend a group online may significantly improve the accessibility to group MBI but may also bring challenges. This study aims to examine the feasibility and acceptability of online MBI groups for parents in families affected with PPDA.

Methods and analysis

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.

Ethics and dissemination

The study has received ethics approval from the University of British Columbia CW Research Ethics Board. Study results will be disseminated through peer-reviewed journals and conferences.

Trial registration number Clinicaltrials.gov (NCT04617132)

Keywords: mindfulness, postpartum depression, perinatal mental health, online, parents

Strengths and limitations of this study

- The study will be the first to examine the online delivery of Mindfulness-Based Intervention for parents in families affected by postpartum depression and anxiety
- As a feasibility study, it will have a small sample size and will not be able to determine efficacy of the intervention
- This study is limited by certain data not being collected, including other treatment interventions the participants receive, which is done with the intention to decrease the burden on participants in this feasibility study

- Insights from the study will contribute to increased accessibility to the intervention and may inform future practice within clinical and community settings

Introduction

Postpartum depression and anxiety (PPDA) is highly prevalent in parents, experienced by up to 1 in 5 families (17.7%).[1,2] In addition to impacting the parents facing distress, this condition can also have potential effects on the child.[3,4] PPDA interferes with central factors affecting the child's development: parent-infant interactions, secure attachment, the parent's responsiveness to the child's needs, and the quality of the home environment.[5] Treating PPDA helps parents as well as it goes a long way towards helping the child flourish in the long-term.[3,6] Due to mothers' concerns about using psychiatric medication when breastfeeding, it is crucial that effective non-pharmacological treatments become available to mothers with PPDA.[7]

The benefits of Mindfulness-Based Interventions (MBI) for the treatment of depression and anxiety in the general population are well documented.[8-12] In addition, there is a growing evidence showing the effectiveness of MBIs as a treatment option for those with PPDA.[13-17]

However, many individuals affected by PPDA do not receive any treatment or struggle to commit or complete their treatment. Some of the several factors reducing treatment commitment include challenges of limited time, commuting difficulties, and competing priorities faced by new parents.[18,19] The global pandemic has contributed to heightened challenges faced by new parents. Specifically, closed child-care facilities, and social distancing measures that prevent grandparents or others who may otherwise be available to help out all contribute to a limited child-care support – an area so important especially for those facing PPDA. This can significantly limit available time for parents' self-care and health interventions that are important to manage their PPDA.

The opportunity to attend a group online may significantly improve accessibility to MBI for parents with PPDA. Related advantages may include, but are not limited to, the flexibility of attending from anywhere, including home, time saved on commute and related preparation.[20] On the other hand, some parents might find it difficult to attend sessions online, whether it may be due to technological limitations, inadequate privacy at home for disclosure of vulnerable feelings during a therapeutic group, or limited ability to focus on the session when the parent is simultaneously attending to one or more children at home in case of the limited child-care support.[21-23]

The majority of the existing literature exploring the feasibility, potential, and limitations of online MBI for the perinatal population focused on mothers during pregnancy.[24-27] However, the daily routines and challenges during pregnancy differ greatly from those following the infant's birth.[28,29] These differences may include ability to commit to a regular group as well as the type of mindfulness practices that a new parent is able to incorporate into their daily routine.

From the limited amount of literature that explored online MBI in the postpartum population, the studies typically focused on non-clinical populations and postpartum parents without a current diagnosis of PPDA.[27,30,31] Gammer et al. assessed a compassion-based intervention, reporting a high attrition rate even in a non-clinical population.[30] However, the ability to commit to a regular group, as

well as the level of distress and challenges experienced by parents with acute mental health issues may differ from parents within the general population. Therefore, as brought to light by the COVID-19 pandemic, there is a need to explore the potential and limitations of online delivery for parents experiencing PPDA.

The aim of this study is to examine the feasibility and acceptability of online MBI groups for parents in families affected with PPDA in the first year postpartum. The primary objective is to determine the feasibility of the online delivery for mothers with PPDA and their partners by answering the research question: Will parents in families affected with PPDA be able to commit to the online MBI group and continue with the online sessions? The secondary objectives are to capture preliminary evidence of outcomes including mental health, couple relationship, satisfaction and acceptability.

Methods and analysis

Study Design

This is a prospective, single-site study exploring the feasibility of conducting mindfulness groups for the postpartum population in an online setting. The presented study is part of a larger research project exploring mindfulness for both partners in families affected by PPDA. The study will follow a non-randomized design with 2 arms, the main treatment arm representing families where both partners receive the intervention, and the control arm where only the mother with PPDA receives the intervention. This protocol has been reported using the Standard Protocol Items Recommendations for Intervention Trials checklist.[32]

Participants and Recruitment

Trial site and participating centers

The study will take place at the Reproductive Mental Health Program, a tertiary mental health clinic from where the participants will be recruited. This clinic is a part of BC Children's and BC Women's Hospital and Health Centre located in British Columbia, Canada. Given that groups run online, participants will be participating from their homes or other location of their choice.

Participants

Study participants will consist of mothers referred to this clinic and their partners. Following assessment by a perinatal psychiatrist, those postpartum mothers who are diagnosed with depression and/or anxiety, and who are interested in the MBI may register for the upcoming mothers' group. Their partners will also be contacted and invited to attend the MBI partners' group. Families who meet the study criteria will be invited to participate in this study.

Inclusion criteria

- Mother is up to 12 months postpartum

- Mother with Major Depressive Disorder (MDD), Other Specified Depressive Disorder, Unspecified Mood Disorder, Generalized Anxiety Disorder (GAD), Other Specified and/or Unspecified Anxiety Disorder as per the DSM-5 criteria;
- Mother with PPDA and partner are co-habiting
- Fluent in English

Exclusion criteria

- Mother of age < 19
- Mother assessed to be at significant risk for suicide, have a psychotic disorder, and/or currently have a substance use disorder
- Lack of access to the internet or a wireless network

Sample size will consist of 30 mothers with PPDA (plus 15 partners). With this sample we will be able to determine attendance and attrition rates to inform future studies. Recruitment to the study opened in September 2020 and is expected to close in September 2022. At the time of manuscript submission the study is open to recruitment.

Recruitment

Initial steps are described in Figure 1, as well as in the Participants section.
Families who meet the eligibility criteria will be invited to the study. Those who indicate interest in participating in the study will be sent an email by the research team. This email will provide them with information about the study and a copy of the consent form. They will have time to discuss it at home prior to the first online sessions of the MBI and will have the opportunity to ask questions via email. It will be made clear that their willingness to participate in the study is entirely voluntary and will not impact their potential relationship with the clinic. Participants (mothers with PPDA and their partners) can decide to participate in the intervention groups and not participate in the study. Participants will be asked to join the online room twenty minutes before their first MBI group session. Upon their arrival, they will be reminded of the study procedures and asked to sign the consent form.

Figure 1: A consort diagram highlighting the intended recruitment process for the study

Interventions

The intervention will consist of standardized 8-week MBI groups delivered online (via Zoom for healthcare settings) and will be adapted to the needs of parents during the postpartum period. The groups will be facilitated in real time by trained and experienced mental health professionals. Two MBI groups will run simultaneously:

- Group for mothers diagnosed with PPDA - Mindfulness-Based Cognitive Therapy (MBCT)[33]
- Group for partners of these mothers - Mindfulness-Based Stress Reduction (MBSR)[34]

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]

Allocation to 2 study arms:

Arm 1) Both mothers and their partners attend MBI groups ("main treatment" arm)

Arm 2) Only mothers attend an MBI group ("mother-only controls")

Mothers whose partners are not interested or unavailable to attend the partners' group will attend the MBI mother's group as mother-only controls.

Measures and data collection

Outcome Measures

The primary outcome is the feasibility of running online MBI groups for this population (Figure 2). Secondary outcomes include mental health, couple relationship, satisfaction and acceptability. Figure 3 demonstrates the outcome measures and their data collection time points.

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: Feasibility of conducting the online MBI groups measured in a variety of ways, aiming to decrease the workload and burden on participants

Acceptability and satisfaction

This questionnaire includes both quantitative and qualitative items, exploring what the participant is taking away from the program; recommendations for changes to the program; what impact they perceive the program had on them, their partner, their relationship; and overall satisfaction.

Demographics

Includes variables on age, ethnic background, marital status, number of children and their ages, number of people in the household, and socioeconomic status.

Couple relationship

This questionnaire aims to assess couple interactions and relationship dynamics, specifically related to change over time (pre-intervention vs. post-intervention vs. 3-month follow-up). It is a self-report measure completed separately by both partners, capturing their unique perspectives on their relationship. Specific areas assessed include communication and interactions within the couple (e.g. behaving in a reactive way during disagreements, blaming and criticizing the other during disagreements, attentive listening); support received (only in questionnaire for mothers with PPDA) and support provided (only in questionnaire for partners); and overall relationship satisfaction.

Mental health

- Patient Health Questionnaire-9 (PHQ-9)
  The PHQ-9 is a widely used measure assessing depression, known to have great reliability and validity.[35,36] It includes each of the 9 DSM-IV criteria and scores as “0” (not at all) to “3” (nearly every day). Scoring includes cut-off points of 5, 10, 15 and 20, which indicate mild, moderate, moderately severe and severe depression, respectively.
- General Anxiety Disorder-7 (GAD-7)
  The GAD-7 is an efficient tool assessing anxiety, with a good reliability and validity (construct and factorial).[37] Scoring includes cut-off points of 5, 10 and 15, which indicate mild, moderate, moderately severe and severe anxiety, respectively.

Figure 3: Timeline of concurrent MBI groups and data collection time points

Statistical analysis and data management

Data is collected and managed using REDCap (Research Electronic Data Capture) hosted at BC Children's Hospital. REDCap is a secure, web-based application designed to support data capture for research studies.[38] All data entered into REDCap will be de-identified. De-identified data and outcomes will later be saved into a password-protected research computer and stored on a secure local server.

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]

Patient and public involvement

Patients and public were first involved in the development of measures, including the couple relationship questionnaire and the feasibility, acceptability, and satisfaction questionnaire. Preliminary drafts of the measures were shared with alumni participants (those who took part in the in-person MBI groups in the past), clinicians, group facilitators, and long-term mindfulness practitioners in the community. The research team conducted online interviews to consult with them and gather their opinions and suggestions for the measures. Input included an assessment of the measures' burden as well as informing the content and wording of the final versions of these measures. For example, during an interview an alumni participant suggested that the wording of a particular question may give the opposite meaning than intended to those whose first language is Mandarin. With the guidance from this alumni participant, the team reworded the question accordingly. This was very valuable feedback given that the Vancouver population and our study sample population is diverse and includes people for whom English is not their first language.

Further, during the study (at week 8 of the data collection), participants will be surveyed about a variety of items, which will inform and refine the study intervention prior to conducting future clinical trials. Specifically, this will include timing and scheduling of the intervention sessions, technical challenges they faced with the online delivery, non-technical challenges they faced while attending or trying to make themselves available to attend the session, and their overall experiences with the intervention.

Ethics and dissemination

Ethics approval

Ethics approval for this study and all its instruments was obtained from UBC Children's and Women's Research Ethics Board (number H20-01884).

Consent

Written consent from potential trial participants will be obtained by the research team via the REDCap platform, signed in real time during a Zoom videoconference call prior to the first session. The potential participants will be sent a copy of the consent form a week before the session to read and discuss beforehand. They will have the opportunity to ask any questions about the study or the consent form both over email and orally during the videoconference call.
It is not expected that participating in this study will pose any additional risks to the participants compared to receiving clinical care without the research component. In case any participants feel distressed at any point during the study, they will have a list of emergency resources they can use to contact on-call psychiatrists, emergency departments or other crisis services.
See supplemental file 3 to view the consent form.

Data storage and privacy

Participants will be given unique study codes that will be stored separately and only known to the research team. Personal information and de-identified data will be saved in two separate folders on a research computer that will be password-protected and stored on a secure server. No data will be shared with any outside agencies without the consent of the subjects. Selected research team members will have access to the final trial dataset while other team members will only have access to de-identified data when needed.

Dissemination

Results from this study will be disseminated in peer-reviewed journals, at national and/or international conferences and oral presentations. Study findings will be shared via clinical rounds, webinars and symposia with clinicians, policy and community partners.

Discussion

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.

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.

In summary, this study will address the question of whether online groups are indeed feasible for postpartum parents affected with PPDA. Also, this protocol paper outlines a practical design of an online feasibility trial aiming to minimize participant burden, that may inform the design of future studies exploring other online health intervention.

Supplementary materials

- Supplementary File 1: Feasibility and Acceptability Questionnaire Administered to Participants
- Supplementary File 2: Feasibility Survey Administered to Facilitators
- Supplementary File 3: Consent Form Signed by Participants

Footnotes

Author Contributions

KT, SES, MB, and LF designed the study and prepared the ethics application. BS and RD contributed to developing the measures, and BS, RD, and DR contributed to the study design with clinical insights. KT and MB drafted the manuscript and designed the figures. SES and LF edited the first drafts of the manuscript. CLH contributed to the qualitative analysis plan, discussion section, and language polishing. LF formatted the final manuscript and the references. All authors read and approved the final manuscript.

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Competing interests

None declared.

Patient consent for publication

Not required.

Provenance and peer review

Not commissioned; externally peer reviewed.

Trial registration

Clinicaltrials.gov (NCT04617132)

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Figure Legends

Figure 1: A consort diagram highlighting the intended recruitment process for the study

Figure 2: Feasibility of conducting the online MBI groups measured in a variety of ways, aiming to decrease the workload and burden on participants

Figure 3: Timeline of concurrent MBI groups and data collection time points

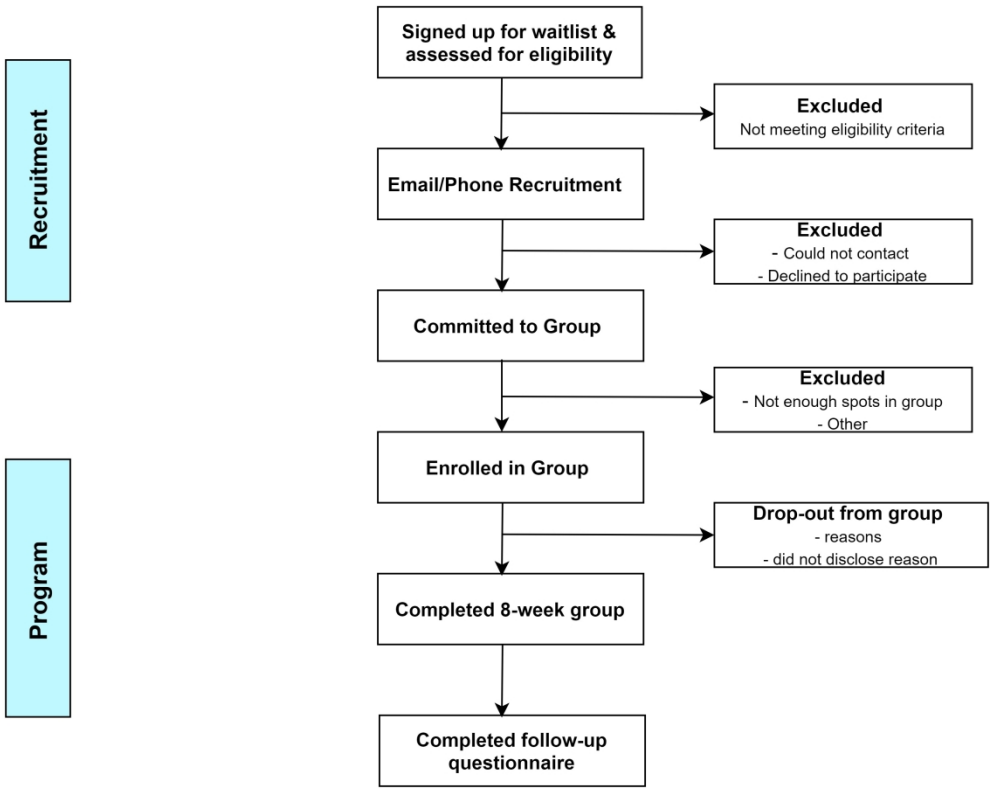

Figure 1: A consort diagram highlighting the intended recruitment process for the study

1095x873mm (72 x 72 DPI)

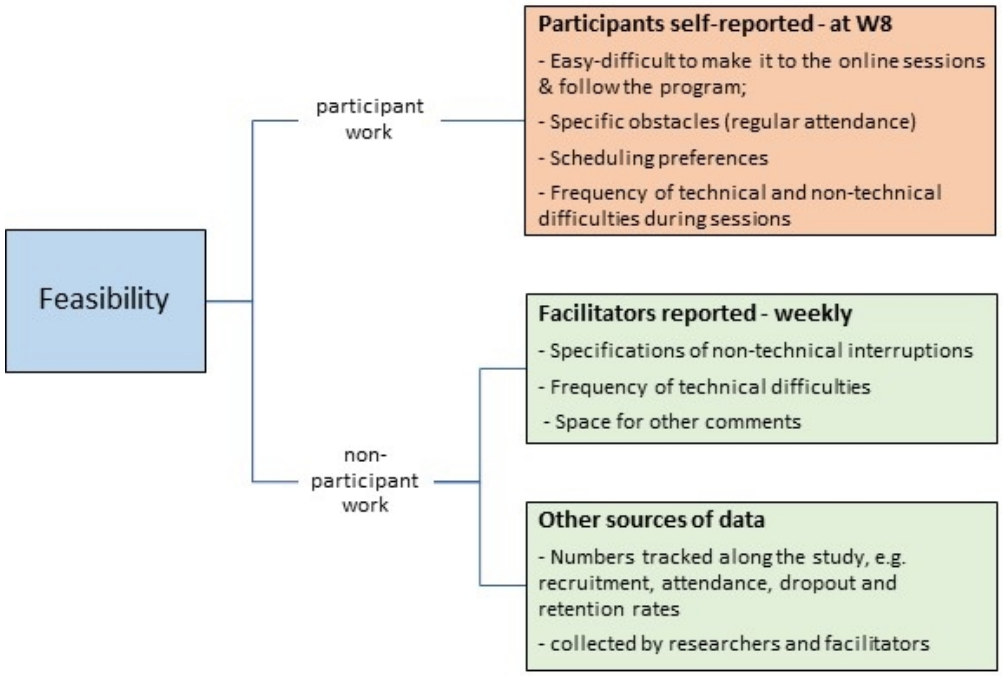

Figure 2: Feasibility of conducting the online MBI groups measured in a variety of ways, aiming to decrease the workload and burden on participants

152x140mm (96 x 96 DPI)

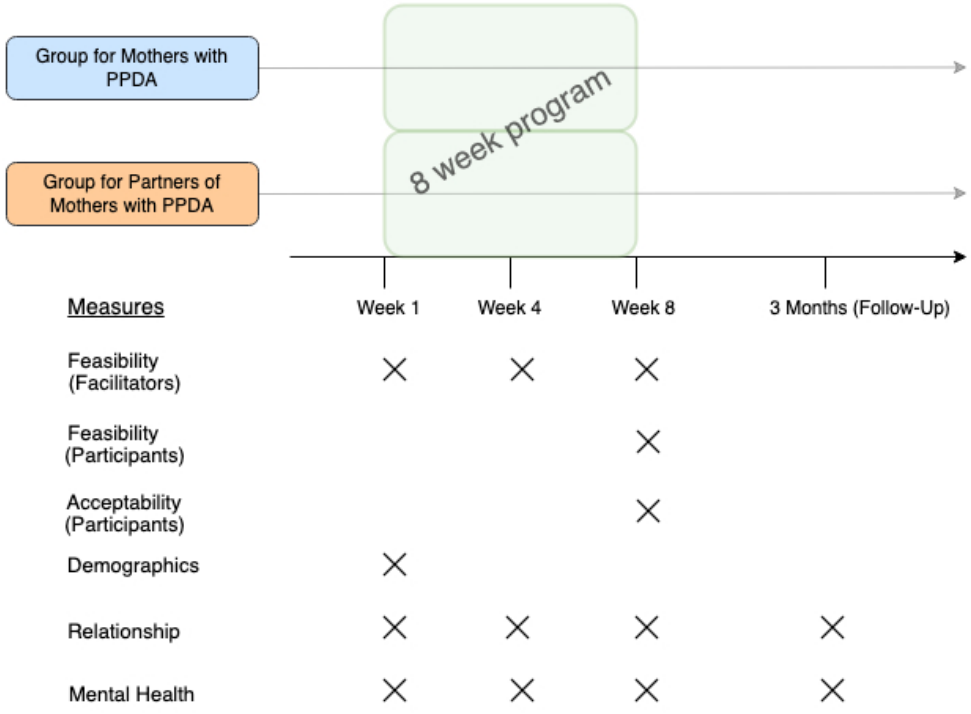

Figure 3: Timeline of concurrent MBI groups and data collection time points

224x169mm (72 x 72 DPI)

Supplementary File 1. The feasibility questionnaire completed by participants at week 8, after completion of the intervention.

Feasibility and Acceptability Questionnaire Administered to Participants

1. Overall, how satisfied are you with the program?

1. Quite dissatisfied
2. Indifferent or mildly satisfied
3. Mostly satisfied
4. Very satisfied

2. Did you find a positive impact/helpfulness of the program on:

- Yourself

1. Not at all helpful
2. A little bit helpful
3. Mostly helpful
4. Very helpful

- Your partner

1. Not at all helpful
2. A little bit helpful
3. Mostly helpful
4. Very helpful

- Relationships and interactions between you and your partner

1. Not at all helpful
2. A little bit helpful
3. Mostly helpful
4. Very helpful

3. What are you taking away from this program? What do you perceive as the benefits of participating?

4. What were the main challenges you encountered during the program? What would you recommend that changes for future programs?

5. How easy/difficult was it to make it to the online sessions and follow the program?

1. Very easy
2. Mostly easy
3. Neutral
4. Some difficulties
5. Very difficult

6. What were some of the obstacles? (Select all that apply)

1. Lack of time
2. My mood/health/energy level
3. Group scheduled at wrong time/day of the week
4. Pandemic related obstacles
5. Child-related needs
6. Other:
7. Not applicable

7. Scheduling: Were there certain days of the week or times (e.g. mornings, afternoons, evenings; certain hours) that would have made it easier to attend the sessions?

8. How often did you experience technical difficulties during the online sessions (e.g. video or sound not working immediately, other technical functions needed to participate in the group not working)?

1. Not at all
2. Minority of sessions
3. Once every session
4. More than once per session

9. How often did you experience any non-technical interruptions during the online sessions (e.g. child or other family members needing your attention; other reasons)?

1. Not at all
2. Minority of sessions
3. Once every session
4. More than once per session

Supplementary File 2. The survey is completed by facilitators on a weekly basis.

Feasibility Survey Administered to Facilitators

Week ____

1. **Were there any technical difficulties during this session?**

____ Yes ____ No

2. **Were there any situations when participants were not present during this session? (Select all that apply)**

- ☐ Nothing at all
- ☐ People turning off their video cameras
- ☐ Disruptions & temporarily not being present during the session (e.g. left the screen to calm or attend to the baby)
- ☐ Early sign-off
- ☐ Late sign-in
- ☐ Other: _____

3. This space is for any additional comments/explanations you would like to include.

Supplementary File 3. Consent form signed by participants.

Participant Consent and Signature

Taking part in this study is entirely your choice. You have the right to refuse to participate in this study. If you decide to participate, you may choose to end the study at any given time without providing a reason and without any impact on your access to services from this clinic.

Signature on this consent form means:

- I have read and understood the information on this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have the satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.

_____ _____

Participant Signature Date

_____

Printed Name

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	#3	Date and version identifier	
Funding	#4	Sources and types of financial, material, and other support	11
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1,10
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	1
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and	n/a

		other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3,4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	6
Objectives	#7	Specific objectives or hypotheses	4
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	n/a

Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	n/a
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7,8
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	5
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a

Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	n/a
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	n/a
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n/a
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8,9
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	8,10

Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	8,9
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	n/a
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2,10

Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	11
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	10
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	11
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a

Appendices

Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	SM3
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a