Virtual Group Psychoeducational Discussions With Spanish-Speaking Mothers of Infants in Pediatric Primary Care

NCT05423093

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JHM IRB - eForm A – Protocol

- **Use the section headings to write the JHM IRB eForm A, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.**
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1. Abstract

a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

b. Postpartum depression (PPD)—depression in the first postnatal year—affects 10-20% of women and is associated with diminished functioning, impaired interpersonal relationships, decreased parenting self-efficacy and less responsive parenting (1). Immigrant Latinas living in the United States are disproportionately affected by PPD, with rates estimated between 30-42% (2). According to the 2009 US National Academies of Science review of maternal depression, "Few opportunities exist to identify the vulnerable population of children living in households with one or more parents experiencing depression or to offer prevention and treatment services that can improve the care of the depressed parent in a framework that also offers services for children" (3). The pediatric primary care setting provides a unique opportunity for the provision of such services, particularly in the current era, which promotes patient and family-centered care.

c.

d. Well-child care is often a missed opportunity to address psychosocial risk factors such as maternal depression (4). Capitalizing on this missed opportunity is critical, especially for low-income families generally and immigrant families with limited English proficiency (LEP) specifically. Latino immigrant children and families experience disparities in health care access and quality (5). Serving the rapidly growing Latino immigrant community, the Children's Medical Practice (CMP) of the Johns Hopkins Bayview Medical Center (JHBMC) is an ideal environment in which to develop and implement innovative primary care delivery models that meet identified health and psychosocial needs. We previously implemented a *group model of well-child care* at CMP for parents of infants ages 0-2 years, and noted that one benefit of group discussions amongst parents attending pediatric primary care was increased time to discuss psychosocial issues such as perinatal depression (6). However, the visits were also noted to require significant time commitment on the part of parents. In addition, with the onset of COVID-19, there were challenges converting the full visit model to a virtual format, including coordinating the scheduling of both virtual and in-person formats and provider billing (manuscript under review). Therefore, we aimed to develop a more accessible, less time-intensive virtual group discussion that could be delivered independent of primary care pediatricians and could used to augment the standard well-child care of

newborns and allow for enhanced education and discussion around topics such as perinatal depression in a group format. We hypothesize that such an intervention may be a feasible and accessible way in which to provide psychoeducation around maternal depression and increase knowledge of clinic and community supports for Spanish-speaking families of infants.

2. Objectives (include all primary and secondary objectives)

The primary objective of this proposal is to evaluate the feasibility and acceptability of a virtual group augmentation of standard individual well-child care. The virtual group session is designed to provide (1) an introduction to ancillary clinic and community services, and (2) Provide an opportunity for psychoeducation and discussion about psychosocial factors impacting parents of infants, including postpartum depression. The aims of the session are to (1) Increase participant knowledge about perinatal depression and the rationale for PPD screening in the general pediatric setting; (2) Decrease stigma about engaging in mental health treatment; and (3) Increase knowledge of available clinic and community resources related to addressing perinatal depression and social needs.

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

This project builds upon other work that we have done with the Baltimore Latino community, and specifically with perinatal Latinas. This work includes (1) Formative research to inform a depression stigma campaign in Baltimore (IRB00211051, PI: Sarah Polk) which led to the development of a website that includes (a) accessible, Spanish-language information about depression; (b) video testimonials of community members who experienced depression (https://www.fortalecebaltimore.org/historias); and (c)Information about local resources. Our team also has experience successfully implementing virtual group discussions about psychosocial topics (IRB00186999, PI: Rheanna Platt).

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

Design Overview: The current study is designed as an open/single-arm pilot of the intervention (no comparison arm for this initial/preliminary study, which is also being offered as a clinic service).

Population and recruiting: There will be two categories of study participants: (1) Spanish-speaking parents of infants (<6 months) attending Johns Hopkins Bayview Medical Center's Children's Medical Practice for pediatric primary care/infants of those parents and (2) Intervention facilitators. We aim to recruit up to 60 parent participants (with 60 corresponding infant records reviewed) and up to 10 provider/stakeholder participants

Recruitment procedures:

For parent participants, there will be three primary means of recruitment.
(1) We will post and distribute a flyer at CMP describing the visit session and providing the research team's contact information for those interested in learning more about the program.

(2) Newborn Visits: At CMP, social work typically meets with all families of newborn as part of one of the newborn checks within the first month after birth. At this meeting, social work or pediatric providers/staff will let families know about the program (see recruitment flyer/script) and ask families whether they would be interested in being contacted by research staff for more information- and obtain permission to share family contact information from the research team so that the team may contact the family. On days when research staff are on-site at CMP, they may ask clinic staff whether they are seeing a patient that day who may qualify for the study. In this case, clinic staff will follow the procedures above (staff obtains permission from family for research staff to discuss the study with the family at the visit and/or to contact the family at a later time). For in-person interactions, staff will follow clinic/staff COVID restrictions (e.g. recommendations on masking and social distancing)

(3) Obstetric staff: Obstetric social work may identify families who have confirmed that the newborn will be receiving pediatric care at CMP and may share the recruitment flyer and ask families whether they would be interested in being contacted by research staff for more information- and obtain permission to share family contact information from the research team so that the team may contact the family.

We will obtain oral consent. Baseline measures will be collected over the phone/zoom prior to session attendance. Our team has experience obtaining oral consent and collecting measures over the phone, including those related to perinatal depression (IRB00186999, PI: Rheanna Platt)

Intervention Sessions will be offered at regular intervals, on at least a monthly basis, via Zoom. Intervention sessions are being offered as part of care at CMP. Intervention sessions will be observed by research staff.

The session, which will be observed by research staff with permission of participants, will consist of the following procedures:

Outline of Information Session Content (total 60-75 minutes)

- *Introduction and discussion of purpose of the session (5 minutes)*
- *Overview of services available at the clinic & procedures, reminder of MyChart (5 minutes total)*
- *Insurance, entitlement programs – (10-15 minutes total)*
- *Postpartum depression information, discussion of screening (30-40 minutes)*
    - *PPD information: show video and discussion afterwards*
        - *Video : (5 minutes)*
        - *Reflection/discussion about video 10 minutes*
        - *Additional core messages: 10 minutes*
            - *Prevalence and signs of of PPD*
            - *Discussion of PPD Screening procedures, rationale for screening at pediatric office*

- *Discussion of self care & social support*

- *Community resources (5 minutes, link to clinic website also sent by text)*
  - *Medical Care*
  - *Mental Health*
  - *Sources of information (clinic website)*

The video shown will be a testimonial developed by JHBMC's Centro Sol for a local mental health stigma campaign (Formative research for the campaign conducted as part of IRB00211051), video to be shown is available at https://www.fortalecebaltimore.org/historias

After the session, ideally within 2 weeks post-session, the research team will collect post-session measures and semi-structured with parent participants and conduct post-intervention interviews with participants. The post session interviews may be conducted at the same time as the surveys, or at a separate time, depending on the preference of the participant.

6 months after the session, the research team will administer questionnaires over the phone assessing feedback about the intervention, physical and mental health services utilization, and re-administering measures of stigma, depression knowledge, intention to seek PPD treatment if needed, intention to seek primary health care, and self-efficacy to manage negative emotions. A summary of measures used and timing is included in **Table 1** below.

For clinic staff/stakeholder participants:
A research assistant will clinic staff (pediatrician, social work, community outreach specialist, medical assistant, and/or nursing) via email (see recruitment email) and will subsequently obtain oral consent and obtain baseline facilitator information via phone or redcap survey, depending on the preference of the participant. After the first, 3rd and 6th session delivered by staff facilitators, brief measures of intervention feasibility and appropriateness will be obtained. In addition, up to three, 15-30 minute semi-structured interviews will be completed with facilitators/stakeholders over the course of the pilot (anticipated 1.5 years). Interviews and surveys may be conducted together/at the same time with the survey or at separate times, depending on the preference of the staff participant.
A summary of measures used and timing for staff is included in **Table 1** below.

Staff will not be recruited by their direct supervisor(s).

Table 1- Instruments used and timing of assessments		
Maternal Assessments		
Pre-session	Post Session (1-2 weeks)	6 months post-session
-Demographic information -Stigma Concerns Mental Health Care (SCMHC) -Adapted Personal Stigma Scale -Adapted Depression	**Post-measures** -SCMHC -Adapted Personal Stigma Scale -Adapted Depression Knowledge Measure	-6 month follow-up survey -SCMHC -Adapted Personal Stigma Scale -Adapted Depression Knowledge Measure

Knowledge Measure (Rapid Risk Factor Surveillance) -Perceived Social Support -History of Mental Health Treatment -PPD knowledge (Rapid Risk Factor Surveillance) -Intention/Willingness to seek tx if developed PPD -PROMIS self-efficacy to manage negative emotions	-Intention/Willingness to seek PPD tx if needed -Intention to engage in own primary care -PROMIS self-efficacy to manage negative emotions **Satisfaction questions** -Single Session Intervention Satisfaction Questionnaire -Intervention Acceptability Measure **Qualitative Interview**	-Intention/Willingness to seek PPD tx if needed -Intention to engage in own primary care -PROMIS self-efficacy to manage negative emotions
Clinic Staff Assessments		
Baseline	**After 1st, 3rd, 6th session delivery**	
Background/Baseline Questionnaire	**Quantitative** -Intervention Appropriateness Measure -Feasibility of Intervention Measure **Qualitative Interview**	

Research staff will review electronic medical records (EMR) for children of participants from Bayview Medical Center Children's Medical Practice (CMP) to examine healthcare utilization and related health outcomes. We will look at the child's medical record at infant age 12 months.

Participant/Infant data collected using EPIC will include:

- Patient demographics (age, gender, race/ethnicity, language, insurance coverage)
- Up-to-date with age-appropriate, on-time well-child visits
- Chief complaint/reason for episodic visits
- Number of ED or urgent care visit reports in chart and reason for visits
- Visit Diagnoses and Problem List diagnoses
- Number of documented visits with the clinic family support services and primary reason for the visit
- BMI or weight-for-length percentile
- My Chart enrollment
- # of My Chart encounters documented
- Completion and results of recommended psychosocial screening (maternal depression, social needs)
- Parent participation in clinic psychosocial programming offered by the clinic (e.g. support groups, parenting and stress management interventions)

b. If your study involves data/biospecimens from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies. Please note: Certificate of Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016. If this situation applies, Section 36, question 6 in the application will need to be answered "Yes" and "Hopkins Faculty" should be selected in question 7. No other documents are required. **N/A**

c. Study duration and number of study visits required of research participants.

For Parents, there will be 4 contact points with research staff over approximately 6-8 months, as detailed below

(1) At the time of consent, complete a questionnaire prior to participation in group session this will be completed over the phone or via zoom, as we have successfully done in other studies providing intervention or preventive intervention about maternal depression (IRB00186999)

(2) Attendance at the virtual group information session (60-75 minutes, sessions will be offered monthly at the clinic), prior to infant age 6 months

(3) Complete post- intervention questionnaire and interview (scheduled by phone/zoom after the session) approximately 1-2 weeks post-session

(4) Complete brief questionnaire at 6 months post-session (scheduled by phone).

Infant medical record review will occur through the 12-month (or equivalent visit-allowing 18 months for delayed well-child visits)

For clinic staff, the study duration will be a total of up to 1.5 years. In addition to having video group sessions observed by research staff, there will be up to 4 contact points with research staff. Associated visits include:
(1) At the time of consent, complete baseline questionnaire
(2) Completion of feasibility and appropriateness measures after delivery of 1st, 3rd and 6th sessions.
(3) Completion of up to 3 semi-structured interviews (after delivery of first session and up to 2 more times over a 1.5 year period). We will attempt to conduct interviews at the same time as the feasibility measures but will schedule as per the preference and availability of staff.

The content and modality of assessments are shown in Table 1 above; specific measures are attached to the IRB protocol.

d. Blinding, including justification for blinding or not blinding the trial, if applicable.

N/A

e. Justification of why participants will not receive routine care or will have current therapy stopped.
N/A, this is offered as a clinic service in addition to routine care

f. Justification for inclusion of a placebo or non-treatment group.
N/A, being conducted as a single arm pilot

g. Definition of treatment failure or participant removal criteria.
Participant removal criteria include: development of parent condition that would preclude participation in group discussions clinically inadvisable; or parent preference to discontinue/exit group discussion prior to its conclusion. Staff will be removed from the study if they prefer to discontinue participation or if they no longer facilitate sessions.

h. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.
As this is a single session intervention delivered as an adjunct to routine well-child care, no additional actions are taken/required to be taken

i. If biological materials are involved, please describe all the experimental procedures and analyses in which they will be used.
N/A

5. Inclusion/Exclusion Criteria

Parent inclusion criteria
-Parent of infant <6 months attending JHBMC CMP for pediatric primary care
-Parent Identifies Spanish as preferred healthcare language (as sessions will be offered in Spanish)
-Felt not to have a contraindication to participation (e.g., condition in the parent that would preclude the ability to reasonably participate in a virtual group session) at the initial social work assessment
-For the purposes of the study, mothers are considered the study participants and fathers are not considered study participants. However, fathers may participate in the video information sessions

Infant inclusion criteria:
infant <6 months attending JHBMC CMP for pediatric primary care

Staff Inclusion criteria
Co-facilitating or participating in delivery of virtual information session

6. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used.
N/A

b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.
N/A

c. Justification and safety information if non-FDA approved drugs without an IND will be administered.
N/A

7. Study Statistics

a. Primary outcome variable.

Feasibility of virtual group augmentation will be assessed by:
-Reach (number approached who attend)
-Provider/stakeholder survey (Feasibility of Intervention Measure) (7)
-Provider/Stakeholder and parent semi-structured interview
Acceptability of virtual group augmentation will be assessed by
-Acceptability of Intervention Measure (completed by parents) (7)
-Intervention Appropriateness Measure (completed by staff/stakeholders) (7)
-Satisfaction survey (See supplemental study documents)
-Semi-structured interviews with parents and providers/stakeholders (see supplemental study documents)

b. Secondary outcome variables.

Parent-completed
-Stigma Concerns About Mental Health Care (8)
-PPD Knowledge Measure (adapted from Rapid Risk Factor Surveillance Scale) (9)
-(Adapted) Personal Stigma Scale (8)
-Intention/Willingness to seek PPD tx if needed (see supplemental study documents)
-Intention to engage in own primary care (see supplemental study documents)
-Mental health and primary care services utilization (from National Latino and Asian American Study) (10)
-Self-reported use of clinic website and/or services
-Self-reported mental health and primary care service utilization

c. Statistical plan including sample size justification and interim data analysis.
Summary statistics will be used to describe participant characteristics, intervention implementation metrics, and outcome measures. We will assess mean changes in selected parent measures (Stigma Concerns about Mental Health Care, Depression Knowledge, Intention/willingness to seek PPD treatment if needed). This is a pilot study designed to assess feasibility and acceptability of the intervention and is not powered to detect differences in outcome measures.

For qualitative data, the interviews will be digitally-recorded and then transcribed and translated (if applicable). Prior to analysis names and other identifying factors in the interview will be removed or assigned a pseudonym. We will explicitly ask for permission to record interviews, and will not audio record interviews if any participant does not feel comfortable with doing so. After completing an interview or visit, the digital file will be downloaded to a Safe Desktop site. Files will not contain identifying information but will be labelled with the participant unique identifying code. Audio recordings will be deleted from digital recorders as soon as successful downloading of the file has been confirmed. Fidelity checklists and observation notes will also be included in the qualitative data collection and analysis.

During analysis of qualitative study data, the study team will develop preliminary themes iteratively and through consensus. At least two investigators will independently code each text segment and then generate analytic conclusions with other study team members.

d. Early stopping rules.
As we are not using any drugs or medical devices we do not anticipate the need for early stopping except when desired by the participant.

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

i. Risks associated with completing measures and interviews: Completing measures about sensitive topics (eg depression), or participating in interviews may be stressful for the participants.

ii. Risks associated with participation in group discussions
-Symptom/situation disclosure: it is possible that parent participants will disclose psychosocial circumstances warranting concern and evaluation and that the provider may have difficulty managing multiple disclosures.
-Group dynamics: it is possible that parents will feel uncomfortable participating in group discussions
-There are risks that other group members may discuss what happened in the group outside of that setting

iii. Risks associated with Observation process
Reactivity and Observer Bias – We are mindful of the reactivity effect (i.e. study participants' behavior being influenced by the presence of observers). We note that several staff typically are present in other group interventions in the clinic as well as in the obstetric clinic (facilitator, co-facilitator, MA/Nursing staff), which we believe may "normalize" the presence of additional staff to

some degree. We will utilize unobtrusive observation and note-taking techniques to minimize this effect. Finally, we will regularly reinforce with group facilitators that the observation process will not affect job performance/evaluation.

iv. Risks to confidentiality- Virtual discussion Risks associated with virtual group discussion, there is risk that discussion via Zoom groups may be "hacked"- this risk will be minimize by use of JHU professional accounts with password protection (a separate password for each group discussion). Virtual groups are conducted as part of routine clinical care at CMP (e.g. parent support groups) and research studies (, thus we do not anticipate additional risk related to research.

b. Steps taken to minimize the risks.

Completing research measures or interviews: The PI or the trained research assistant will be available at all times while the participant is filling out questionnaires or participating in interviews. Participants will be reminded that they do not have to answer any questions with which they feel uncomfortable. Should a participant become distressed, the study staff member can provide reassurance, evaluate his/her concerns, and remind participant that he/she may stop at any time. The participant will also be asked if he/she would like to discuss concerns with on-site clinic social work or mental health staff or with the Principal Investigator, Dr. Platt, a bilingual psychiatrist.

Risks associated with participation in group discussions

1.. Group discussion facilitators have been trained in Facilitative Leadership through the Centering Healthcare Institute prior to conducting any groups. We plan to have the CMP clinic social worker, who is experienced in managing group psychotherapy and support groups (including parenting groups, general support groups, and groups focused on domestic violence in the Latino community), co-facilitate the discussions to minimize these risks.

2.We have developed a proactive management plan for disclosures which will include participation of relevant on-site staff (i.e.; embedded mental health providers and clinic social work staff). During the study/group visits we will have a plan for availability of this staff to the provider (as well as the PI, who is a bilingual psychiatrist) for additional support to group visit facilitators. JHBMC-CMP has two embedded social workers who are available for "curbside" consultations and evaluation of risk, including suicidality. We will also review and follow clinic protocols for management of positive maternal depression screens prior to study initiation (including further on-site evaluation and treatment, and referral sources). Clinic psychiatric emergency procedures will be

reviewed and detailed with both sites prior to the study. The PI will also be available to providers and study staff at all times for assistance and consultation and communication of concerns. Required reporting procedures (e.g. child protective agency reporting or other reporting) will be followed and these reporting requirements will be described in the participant consent script

3. Ground Rules" for the group, which include not discussing issues brought up in the group with individuals outside of the group, will be reviewed at the start of each session

Risks associated with observation process:

We will utilize unobtrusive observation and note-taking techniques to minimize this effect. Finally, we will regularly reinforce with group facilitators that the observation process will not affect job performance/evaluation. *If participants do not wish to have visits observed, we will have providers complete the fidelity checklist after the visits*

Risks associated with participating in group sessions via Zoom

-We will require a meeting password for all Zoom sessions. This password will only be shared with participants and the study team.
-Participants will be asked to join the sessions from a private space, if possible.
-When we go over "ground rules" at the beginning of each session, we will remind participants to be careful about what they share since everyone in the group is joining from their home and there is a risk that something they say could be heard by someone not in the group such as a child, spouse or other family member

c. Plan for reporting unanticipated problems or study deviations.

The research staff and involved providers will be trained and instructed on the need to report to the investigator any indication that an adverse event has occurred. When the PI learns of an adverse event, she will investigate until they understand as many details of the adverse event as possible. Staff will make an excel sheet to summarize any adverse event by type of adverse event and by study condition, stored on secure internal drive (e.g. onedrive). The investigator will review this excel sheet periodically. We will follow JHU's IRB's definition for an adverse event and will report any adverse events to both the Johns Hopkins University School of Medicine IRB B promptly (within 5 working days).

d. Legal risks such as the risks that would be associated with breach of confidentiality.
Risks to Confidentiality- research material: There are risks that the confidentiality of participants could be violated and the participant's involvement in the study could be revealed to people not involved in the study such as friends, family members, or colleagues (for a description of data confidentiality procedures see protection against risks below). This could have a negative impact on the participant if they wished to keep their involvement in the study private.

Confidentiality Risks of Data and Materials: Although all notes/data will be stored in a secure and confidential manner, and we will code all stored data and store it separate from any direct participant identifiers, accidental breaches of confidentiality are technically possible.

Steps taken to address risk include:
-Precautions against loss of or breach of collected data will include making sure that no data forms or data files ever contain identifying information and that any files identifying participants are protected and destroyed as soon as possible. Identifiable data will never be stored on portable devices unless this is for the purpose of locking those devices in secure physical storage. Appropriate firewalls, encryption, and password protection will be used for network-connected devices used to store or manipulate data.
-Parent participant name and contact information will be securely and separately stored in a locked location during the duration of the pilot so study team members can contact participants to provide information to connecting to the session, or for follow up with consent from the participant. After the pilot has ended, all contact information will be destroyed unless families wish to have it retained for contact in future studies. Confidentiality of data will be assured using subject identification numbers for all data collection and analyses. Parents will receive a unique ID number. Audio recorded data will be identifiable only by a group ID number and originals will be stored in a locked cabinet; no names or individual ID#s will be attached to these recordings. Questionnaires will be completed over the phone, directly entered by research staff, or will be sent via RedCap, as per participant preference
-Survey Data will then be housed in a secure database (i.e.; REDCAP) and accessed on secure workstations connected to servers that are accessible by study members who hold authenticated logins and passwords, and data will be backed up by the candidate and the research staff regularly.

-Interview data will be collected by staff in a secure private area or over the phone and audio recorded using a device that is passcode protected and that automatically encrypts files. The interviews will be digitally-recorded and then transcribed and translated (where applicable) by an approved transcription/translation service with experience with confidential research data. Prior to analysis, names and other identifying factors in the interview will be removed or assigned a pseudonym/ID number. All material will be collected specifically for the proposed research project.
-To protect confidentiality all research participants will be identified by a unique identifier of the participant's initials and a sequentially assigned participant number for forms and data files, and not the participant's name. All research data will be stored in a locked area that is only accessible to research staff and will not be left unattended. Any documents with confidential information will be shredded before being discarded. Confidential information will not be given to anyone outside of the research study, unless there is concern about risk to self or others. All staff will be trained in these procedures. All data files and analyses will be performed on research computers using only code numbers to identify participants. Audio will be recorded on a device that is passcode-protected and encrypted. Only summaries of group data will be

reported in any publications or presentations, with no identification of individuals.

Confidentiality- EMR data: Failure to maintain confidentiality of data collected on caregiver-patient dyads would be associated with breach of confidentiality. We will keep the child's name and date-of-birth in a separate, secure file within the REDCap database used to manage survey and collected EMR data. We will maintain a separate file with a link to study ID with personal health information for each participant (child name, date of birth, MRN, phone number, parent name, address) which will also have the participant ID. This file will be encrypted and password protected and will be accessed only by trained study staff. Once study participation and EMR review concludes, all PHI for that participant will be removed and their data will only be available by participant ID in REDCap. REDCap is a well-respected established platform for securely storing research data. Once the electronic medical record has been located and reviewed, these child identifiers will be removed from the database. For participants who consent to be contacted for future research their contact information will be kept in a separate, encrypted file.

e. Financial risks to the participants.

-Risks associated with participation include charges on the cell phone bill associated with participation in consenting, completing measures, and participating in the group sessions via video conferencing, which will require either internet access or use of smartphones with data plans. Participants will be provided with remuneration that is expected to cover potential cell phone charges for completing measures. We will assess technology access and for individuals without internet access or unlimited data plans, will allow participation/call-in via phone
-As the clinic plans to offer these information sessions as part of the menu of services available within the clinic and has budgeted staff time appropriately, there will not be loss of income to staff facilitating the intervention

9. Benefits

a. Description of the probable benefits for the participant and for society.

-For the parents participating in the pilot, there is no guarantee of benefits to any of the participants. However, benefits to participation may include an increase in knowledge about postpartum depression as well as about clinic and community resources, and improvements in engagement in well-child care, and social support through participating in the intervention.

-There are no direct benefits to stakeholders participating in the pilot. However, it is possible that delivery of information in groups may decrease the need for time spent delivering information to individual parents

We believe that this project can serve as a replicable and accessible model for care delivery Spanish-speaking population in Baltimore, and to health care systems more generally through a) identifying an intervention method that is acceptable and feasible in a non-clinical as well as a

clinical setting and b) developing mechanisms for increasing access to Latino mental health services.

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

-Participants will be compensated for time spent completing research measures. Participants will receive $20 for completing the baseline survey measures, $20 for completing follow-up survey measures, and $20 for completing 6-month survey measures
-Stakeholders/clinic staff will be compensated for time spent completing research measures. Staff will receive $5 for completing appropriateness and feasibility measures
-Participants and staff will receive $40 for each interview completed

- Compensation will either be mailed or electronically delivered to intervention participants, depending on their preference.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

The potential costs to the participants include time spent in visits and study activities. Remuneration for the study is designed to partially offset this potential loss of income. Additionally, there may be cellular phone charges to participants for any phone communication or use of data plan to connect virtually to the group sessions during the study. There is no cost to the participants for the surveys for any source of data collection.

There is no associated cost of the study procedures, as the clinic staff anticipate that delivery of the program will be part of the regular menu of services offered by the clinic, within the scope of current clinic/personnel responsibilities

12. Transfer of Materials

Transfer of biospecimens from Johns Hopkins to another organization for research purposes and receipt of biospecimens from an outside organization for your research must adhere to JHU policies for material transfer (https://ventures.jhu.edu/faculty-inventors/forms-policies/) and biospecimen transfer (https://hpo.johnshopkins.edu/enterprise/policies/176/39187/policy_39187.pdf?_=0.622324232879).

N/A

Please complete this section if your research involves transfer or receipt of biospecimens.-
NOT APPLICABLE

a. Will you **receive** biospecimens from an external entity for this research? [Yes/**No**].
If "Yes", please confirm you will secure an MTA/research agreement from the appropriate office (JHTV/ORA) prior to transfer.
See: https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/ .

b. Will you **transfer** biospecimens to an external entity as part of this research? [Yes/**No**]
If "Yes", please address each of the following:
1) Describe the nature of the research collaboration with the external entity and the rationale for the transfer. (Include an explanation of your intellectual contribution to the design of the research study, resulting data and sharing, and participation in the planned publications.)

2) Please confirm you will secure an MTA through the appropriate office (JHTV or ORA) prior to transfer.
(See: https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/.)

3) If the biospecimens you intend to transfer were obtained through clinical or research procedures at Johns Hopkins and "Other" is selected in Item 4, Section 23, please submit the following items in that Section:

a. A pdf version of a completed JHTV Online "Material Transfer Agreement Request Form for Outbound Material" https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/ **OR** a copy of the COEUS PD (Proposal Development Summary).
b. A completed Biospecimen Transfer Information Sheet https://www.hopkinsmedicine.org/institutional_review_board/forms/.
c. A signed and dated "De-identified Human Subject Certification" https://www.hopkinsmedicine.org/institutional_review_board/forms/
d. Approval documents from recipient site, if applicable.
e. Copies of the consent forms associated with the IRB protocols under which the biospecimens were collected, with language appropriate to this transfer highlighted.
f. The name of the specialist you are working with in ORA to complete a contract/MTA.

Please see the following website for more information about transferring human biospecimens to outside entities:
https://www.hopkinsmedicine.org/institutional_review_board/news/announcement_transfer_human_biospecimens_outside_entities.html/ .

REFERENCES

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