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Randomized trial of telehealth group intervention to reduce perinatal depressive symptoms in diverse and rural populations

Protocol Summary

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Background and Introduction

Perinatal depression occurs in 12%–15% of pregnant and postpartum women and is associated with adverse outcomes for mother, baby, and family, including preterm birth, low birth weight, and impaired cognitive development of the child (Ko, Rockhill,Tong, Morrow, & Farr, 2017; Martin, Hamilton, Osterman, Curtin, & Matthews, 2015; Bonari et al., 2004; Deave, Heron, Evans, & Emond, 2008) Early breastfeeding cessation and reduced ability to parent are also well-documented consequences (Bonari et al., 2004). Nonpharmacological therapies, such as cognitive behavioral therapy (CBT) and mindfulness-based practices (MBP), are known to be as effective as antidepressants for mild to moderate depression, and many pregnant and breastfeeding women prefer not to take antidepressants (O'Connor, Rossom, Henninger, Groom, & Burda, 2016; O'Mahen & Flynn, 2008). However, limited access to and availability of mental health professionals are common barriers to services among women living in rural and low-resource communities (Alang, 2015; Bloom, Bullock, & Parsons, 2012). Lack of consideration for cultural and ethnic variation also creates an additional barrier for many women (for example, Hispanic) (O'Mahen & Flynn, 2008; Baker-Ericzen et al., 2012; Goodman, Dimidjian, & Williams, 2013, The Health Resources and Service Administration [HRSA], 2012). Recommendations for universal screening for perinatal depression during pregnancy and postpartum have left many women and their providers searching for solutions to the current scarcity of resources available to women who screen positive. Telehealth is revolutionizing the delivery of healthcare services and is a promising platform for perinatal mental health care (HRSA, 2012). A telehealth approach will reduce barriers to access and can be tailored to deliver effective services regardless of geographic location (HRSA, 2012). Our pilot work demonstrated feasibility and acceptability of a group video conference intervention (VCI) to deliver nonpharmacological services (CBT and MBP) to women experiencing perinatal depressive symptoms (PDS) (Latendresse, Dorn, Ozawa-Kirk, & Allred, in review; Latendresse et al., in review). Our research team incorporated participant feedback into revising the VCI, including the use of a low-cost, easy-to-access Web-based platform and use of any electronic device (laptop, tablet, smartphone, or landline) to join facilitated VCI groups of six women. To build on our pilot work, we propose to evaluate the effectiveness of the VCI to reduce PDS and anxiety (a highly comorbid condition) by conducting a randomized controlled trial among women experiencing mild to moderate PDS, as measured by the Edinburgh Postnatal Depression Scale (EPDS).

Purpose and Objectives

The study will evaluate the effectiveness of a videoconference intervention (VCI) to reduce perinatal depression symptoms (PDS) and anxiety (a highly co-morbid condition) by conducting a randomized controlled trial among women experiencing mild to moderate PDS, as measured by the Edinburgh Postnatal Depression Scale (EPDS). Furthermore, we propose to evaluate differences in response to the VCI between subgroups of childbearing women; Hispanic and North European Descent populations, and rural and urban-dwelling.

Specific aims of the study include:
Aim 1: Evaluate the effectiveness of a VCI to reduce PDS and anxiety, as measured by EPDS and Generalized Anxiety Disorder-7 Item (GAD-7) scores across pregnancy and the postpartum. Methods: Pregnant women of all gestational age up to 6 months postpartum (n = 240) who screen positive for mild to moderate PDS (EPDS scores 9–20) will be randomly assigned to VCI or AC for eight weeks. Both groups will continue with standard care as directed by their primary/prenatal care providers. The EPDS and GAD-7 will be administered at three time points during pregnancy and at 2, 4, and 6 months postpartum. Hypothesis: Women participating in the VCI will have significantly lower post intervention EPDS and GAD-7 scores across pregnancy and postpartum than women in the AC group.

Secondary Aim 1: Explore differences in the effectiveness of the VCI to reduce PDS and anxiety across women who enroll at different stages of their pregnancy or postpartum periods.

Aim 2: Evaluate the interaction of the VCI with specific subgroups: ethnicity (Hispanic, North European descent), geographic location (rural, urban), and the outcome of PDS as measured by EPDS and GAD-7 scores across pregnancy and postpartum. We will oversample in Hispanic and rural populations to ensure sufficient representation from diverse groups. Hypothesis: Women will demonstrate differences in EPDS and GAD-7 scores across pregnancy and postpartum, dependent on their study group membership.

Secondary Aim 2: Explore an additional subgroup analysis, namely between those who are and who are not taking medication at the time of screening.

Study Population

Age of Participants: 18+

Sample Size:
At Utah: 240
All Centers:

Inclusion Criteria:
The study will include women 18 years of age and older who, at time of enrollment (1) have a viable pregnancy or have given birth within the previous 6 months, (2) have an Edinburgh Postnatal Depression Scale (EPDS) score of 9–20; (3) are English- or Spanish-speaking; and (4) are attending a collaborating prenatal or public health clinic associated with the University of Utah or Utah Department of Health.

Exclusion Criteria:
The study will exclude women who, at time of enrollment (1) have an EPDS score <9 or >20; (2) have a current diagnosis of a serious mental illness, such as psychosis,

schizophrenia, bipolar disorder, severe depression, or suicidality; or (3) have begun taking or changed dosage of any medication for a mental health condition within the past 6 weeks

Design

Randomized Trial

Study Procedures

Recruitment/Participant Identification Process:

VCI/AC Sessions

Each study clinical site has implemented a universal electronic screening for perinatal depression, which ensures that all women receiving services at all study facilities are screened during pregnancy and postpartum. In addition, staff at the collaborating sites inform women about the study by way of flyer or direct interaction. No one is involved in consenting participants or in delivering the interventions. Flyers could be handed out to potential participants or would be available at study sites (e.g., on walls with site's approval). Handing out flyers would help patients think about participating in the study for those who cannot make a decision at the study site. Screening includes the Edinburgh Postnatal Depression Scale (EPDS) and is self-completed by patients at the time of a clinical office visit. Patients complete the screening in the clinic using an electronic device (tablet, computer, or their own Smartphone) as soon as possible when they come in. Screening results are integrated into the Electronic Health Record (EHR) and/or electronic database managed by the University of Utah. Results are immediately available electronically to the patient and her healthcare provider for evaluation, management and/or referral. These electronic screening results are also available to study staff for the purposes of identifying potential study participants, i.e. positive screening results (greater than 9 on EPDS). The electronic screening process conveniently includes an item that allows patients to indicate their interest in receiving additional information and/or agreement to be contacted as a potential research participant. Those who agree will be contacted by study staff by phone or email. Alternatively, a patient can contact the study staff herself. Women who screen positive, are determined eligible to participate by study staff, and are interested in participating are contacted by study staff to discuss the study and complete the informed consent process. Informed consent is completed by telephone or video conference platform. The consent form is sent to potential participants via REDCap email or the U.S. Postal Service, if there is no email address. Eligibility is confirmed through EHR, particularly for confirming gestational age, maternal age, medication status, mental health diagnoses, etc. All potential participants are screened for suicidal and homicidal ideation, and if either are present the individual is immediately referred to a mental health professional for further evaluation, and to determine appropriateness for participating in the study.

Social media (Twitter, Instagram, and Facebook) will also be used to recruit and inform potential participants about the study. Short video clips will be played on clinic monitor screens with information about the study and small study cards will be available to take home if interested in the study. The study staff will also utilize community events to raise awareness of the study.

Radio advertisements will be used to recruit participants for the study. This will specifically be relevant for the Latina population, based on feedback from community partners.

QR code/survey link will be used to recruit participants by allowing them to take the screening on their own and give their contact information if they are interested in learning more about the study.

We will coordinate with members of the data science service at the University of Utah to identify patients who (1) have agreed to be contacted regarding research studies and (2) meet our inclusion criteria. Members of the data science service will share a report with the research team that includes patient information, such as: name, age, sex, ethnicity, pregnancy/postpartum status, email, and mobile phone number. The research team will use this information to send study invitations via email (and printed mail, if needed) to potential participants. These emails will include information for easy-to-follow steps for opting out of the study. Individuals who elect to opt-out of the study will be removed from future communication and their information will be removed from study data. Anonymous demographic data from opt-out individuals may be retained for the purposes of describing the demographics of the total population considered for this study. Individuals who do not elect to opt-out will be contacted again (up to three times) by the research team, either via email, phone call, text, or print mail.

Focus Groups

Participants for the pre-intervention Latina focus groups will be recruited via word of mouth, community events, social media, video clips in clinics, and recruitment flyers, utilizing study staff's contacts within the Latina community. These same methods will be used to recruit participants for the main study arm.

Participants for the additional focus groups related to perceptions of mental health and recruitment will be recruited through the Community Collaboration & Engagement Team (CCET) at the University of Utah. An informational recruitment flyer will inform potential participants of the opportunity to participate. Note: American Indian populations will not be recruited without proper approval from appropriate groups

Informed Consent:

Description of location(s) where consent will be obtained:

Telephone or video conference at a time that is convenient to the woman and research team member.

Description of the consent process(es), including the timing of consent:

Women who screen positive (EPDS score of 9-20) as part of the universal perinatal depression screening program, and also indicate an interest in the study, will be contacted by study personnel by phone or email. Eligible and interested women receive a study flyer and a consent form by regular USPS mail and/or email attachment. The informed consent process is completed by telephone or videoconference at a time that is convenient to the woman and research team member. A copy of the signed consent form is then exchanged by email attachment or USPS mail.

Procedures:

Recruitment

We will coordinate with members of the data science service at the University of Utah to identify patients who (1) have agreed to be contacted regarding research studies and (2) meet our inclusion criteria. Members of the data science service will share a report with the research team that includes patient information, such as: name, age, sex, ethnicity, pregnancy/postpartum status, email, and mobile phone number. The research team will use this information to send study invitations via email (and printed mail, if needed) to potential participants. These emails will include information for easy-to-follow steps for opting out of the study. Individuals who elect to opt-out of the study will be removed from future communication and their information will be removed from study data. Anonymous demographic data from opt-out individuals may be retained for the purposes of describing the demographics of the total population considered for this study. Individuals who do not elect to opt-out will be contacted again by the research team (up to three times), either via email, phone call, text, or print mail.

Each study clinical site has implemented a universal electronic screening for perinatal depression, which ensures that all women receiving services at all study facilities are screened during pregnancy and postpartum. In addition, staff at the collaborating sites inform women about the study by way of flyer or direct interaction. No one is involved in consenting participants or in delivering the interventions. Flyers could be handed out to potential participants or would be available at study sites (e.g., on walls with site's approval). Handing out flyers would help patients think about participating in the study for those who cannot make a decision at the study site. Alternatively, a patient can contact the study staff herself.

Social media (Twitter, Instagram, and Facebook) will also be used to recruit and inform potential participants about the study. Short video clips will be played on clinic monitor screens with information about the study and small study cards will be available to take home if interested in the study. The study staff will also utilize community events to raise awareness of the study.

Radio advertisements will be used to recruit participants for the study. This will specifically be relevant for the Latina population, based on feedback from community partners.

Enrollment

Women who have indicated an interest in participating in the study will be contacted by a study team member by text, telephone and/or email to discuss the study and complete the

informed consent process. During that time, eligibility is confirmed through EHR (please see the #4b recruitment/participant identification process), particularly for confirming gestational age, maternal age, medication status, mental health diagnoses, etc. All potential participants are screened for suicidal and homicidal ideation, and if either are present the individual is immediately referred to a mental health professional for further evaluation, and to determine appropriateness for participating in the study.

Latina Focus Groups

Those enrolled in the pre-intervention focus groups will participate in a 1-hour focus group. Participants will give feedback on how to tailor the intervention and control group content to best serve Latina participants. There will be a total of 2 Latina groups with up to 10 participants per group.

Perceptions of Mental Health and Recruitment Focus Groups

Those enrolled will participate in a 2-hour virtual focus group. These women will fill out a short demographic survey online. Participants will give feedback about experiences of participating in research about and treatment of maternal mental health via telehealth. There will be three focus groups with up to 15 participants each, the first focused on rural Hispanic/Latina women, the second focused on the general rural population, and the third on the rural American Indian/Alaska Native population. These women will receive a $75 gift card to Amazon or a local grocery store electronically or by mail. Note: American Indian populations will not be recruited or enrolled without proper approval from appropriate groups

Stratified Randomization Into Study Groups

After consenting to participate, women will be assigned by computer-generated randomization by two different stratifications (Hispanic/NED and Urban/Rural) to one of two study groups: Videoconference intervention (VCI) or Attention Control. Both groups will continue with standard of care as directed by their prenatal care provider. After randomization, the participant will receive study information pertinent to her specific study group, by mailed hard copy and/or emailed electronic document. Enrollment and randomization will continue until the following enrollment goals are met.

VCI Participants

A study team member will contact the participant by telephone and/or email to determine which group start date works best for her and to schedule a time for technology testing and instruction.

All Participants: Technology Literacy

Prior to the start date of the first VCI or AC session, each participant will meet with study staff for the purpose of (1) assessing the participant's technology literacy, (2) testing the participant's Internet connection and chosen electronic device, and (3) providing instruction and demonstration for connecting to the videoconference platform (Acano). More than one meeting may be required and will include meeting via Acano and troubleshooting directly

with the participant. After this is completed to the satisfaction of the participant and study staff, the next step will be to schedule the participant to meet with the VCI group facilitator via Acano.

Individual Participant Acano Meeting with VCI or AC Group Facilitator

Prior to the first VCI or AC group session, participants will be scheduled for a 30-minute Acano or phone meeting with the individual who will be facilitating the participant's assigned group. The purpose of the meeting is for the facilitator to (1) establish a one-on-one connection with the participant prior to the start of the group, (2) repeat the technology check with the participant, and (3) identify any concerns that would disqualify the woman from study participation (e.g., serious mental health conditions, including severe depression or suicidal ideation that may need immediate referral for more intensive therapy and/or pharmacotherapy).

Group VCI Sessions

Using the UTN-supported Acano platform, women will attend weekly, 1-hour videoconference sessions with 4–5 other participants (maximum $n = 6$), for a total of 10 sessions: one initial session for getting acquainted with one another and the program, eight sessions for engagement in the VCI intervention, and a follow-up "reunion" 6–8 weeks after the last session. Members of the Latina community will be enrolled in study groups that will include 15 minutes of extra mental health content, based on recommendations from the focus groups done in the community and their needs (actual intervention content will not be altered, just additional mental health background will be included). Participants will attend each session using their own Internet connection and electronic device (computer, laptop, electronic tablet, smart phone) to connect to Acano. Alternatively, participants can connect via the Internet without video, or as a last resort can simply call in by telephone landline or basic mobile phone. The intervention is a standardized and manualized program called UPLIFT (Using Practice and Learning to Increase Favorable Thoughts), developed and evaluated by Dr. Thompson. UPLIFT is an 8-week group intervention based on CBT and MBP, therapies with demonstrated effectiveness in the prevention and treatment of depression. Originally developed as an online and telephone-based approach, we have adapted and piloted the program for videoconference use in a pregnant population.12,13 Our revised telehealth approach has several advantages over conventional in-person therapies, including (1) improved accessibility to therapy among working, low-income, and rural-dwelling mothers, and those with time, childcare, and transportation barriers; (2) the ability to develop a supportive community among other mothers of similar risk status and life circumstances; (3) the ability for women to build an effective skill set for the prevention and treatment of depression that can last a lifetime; (4) the addition of nonverbal communication between group participants and the facilitator when videoconferencing is used; and (5) sufficient time to acquire and practice Mindfulness-Based Cognitive Behavioral Therapy skills early in pregnancy, prior to baby's arrival and the postpartum period, when the risk of depression is highest. After the 8-week intervention, a cohort "reunion" will be held approximately 6–8 weeks after the last session. The approach just described was developed based on the strong recommendations of participants in our pilot studies, including the initial pre-UPLIFT meeting

and post-UPLIFT "reunion." Women will begin VCI sessions no later than 20-weeks gestational age, with completion no later than 36 weeks gestational age.

UPLIFT Manualized Program

All sessions will be facilitated by a credentialed mental health professional specifically trained in the UPLIFT program. Each 1-hour session will include a check-in, instruction, skill building, and discussion. Latina participants will have 15 minutes extra content to discuss mental health more in depth as part of the intervention group, based on feedback we received, which will not alter the actual intervention content itself.The facilitator will use an UPLIFT manual as the outline for each specific session of the 8-week series. Each participant will also receive the UPLIFT manual (print and/or electronic document), which contains details and resources for each session. Sessions will focus on increasing knowledge about depression and pregnancy, CBT, and MBP. Participants will learn and practice skills related to CBT and mindfulness, and engage in discussions and group exercises for each session's main topic. Topics include thought monitoring, identifying distortions in thoughts, self-esteem, identification of problems, goal setting, and achieving support. Exercises include relaxation; body scan; progressive muscle relaxation; attention to breath, sights, and sounds; and meditation. Each week, participants will be provided with recommendations for between-session practices, which will be discussed at the beginning of the next class.

Attention Control (AC) Group

Women who are randomized into the AC will participate in an 10-week education program delivered by group videoconference platform supported by UTN. The education program is manualized and designed to enhance participant knowledge related to pregnancy, childbirth, newborn care, and feeding, or parenting young babies. All participants in the AC group will receive a mailed hard copy and/or emailed electronic packet (participant's choice) that includes topical education, which includes information about perinatal depression and mood disorders (e.g., anxiety and obsessive-compulsive disorder, postpartum psychosis), interpretation of EPDS scores, common therapies for PD, local resources for obtaining therapies, and encouragement to discuss their EPDS scores with their prenatal care provider. This approach provides a control group that reduces bias as much as possible, and most closely reflects an optimal care level that includes screening and patient education for all pregnant and postpartum women.

Data Collection

Data collected for this study will come from the following sources: Clinical universal screening records (the EPDS in the electronic health record [EHR]), participant-completed study questionnaires, audio-recorded VCI sessions, and participant focus groups. EPDS is a validated survey.

Clinical Screening Records

Screening that is completed in the clinical setting as part of their routine clinical care is immediately communicated to and addressed by clinical providers at the time of the prenatal or postpartum visit. EPDS and GAD-7 measurements completed periodically and

electronically by enrolled participants as part of the study (not as part of their routine clinical care) are evaluated and addressed by study personnel within 24-48 hours of completion. Participants are contacted directly by study personnel for scores >20 on the EPDS, or if the participant indicates thoughts of harm to self. Furthermore, the EPDS and GAD-7 are electronically scored, interpreted, and communicated to the participant immediately. At that same time, participants also receive electronic resources, including crisis and suicide prevention hot line phone numbers, website links, and study personnel contact information.

Participant-Completed Questionnaires

Questionnaires will be completed by participants via a secure, Web-based data management system (REDCap). Women in all study groups will receive an emailed link to the questionnaire. Study questionnaires are to be completed at six time points: T1 = enrollment; T2 = after group session 9; T3 = 2 months post session 9 T4 = 4 months post session 9; T5=6 months post session 9; T6= 8 months post session 9. In addition to participant demographics, questionnaires will include the EPDS as a measure of the primary outcome of interest: depressive symptoms, as well as the GAD-7 as a measure of comorbid anxiety (GAD-7 is a validated survey). To document the standard of care that all participants receive during study participation, the questionnaire at all six-time points also asks participants to report whether they (1) received a diagnosis of depression, anxiety, or other mental health condition; (2) were prescribed or initiated any medication for depression or anxiety; (3) were referred to and/or engaged in mental health services; and/or (4) have engaged in any type of nonpharmacological therapies for depression/anxiety during the study. If a participant does not have an email address, study staff will assist her to establish and access a free email address. All participants will receive instruction on how to access and complete the study questionnaires. The entire questionnaire takes approximately 15 minutes to complete. Participants receive $20 for each questionnaire completed.

Focus Groups

Participants will be invited to attend one focus group interview with 6-8 other participants, again using the UTN-supported videoconference platform, and within 8 weeks of completing the last group session (VCI or AC). The purpose of the focus group is to collect data directly from participants regarding satisfaction with the program, e.g. program content, videoconference platform, development of community, support, suggestions for improvement, etc. Participants receive $20 for attending the focus group.

Digital Recording of Sessions and Focus Groups

To document and evaluate intervention and attention control group fidelity and standardization, and for future qualitative data analysis, we will record all focus groups, and a random selection of sessions. The Acano platform has recording capability built into the Web-based program, and is managed by UTN. The recording is unobtrusive and runs seamlessly in the background, unnoticed by facilitators or participants. Acano is a secure, HIPAA-compliant program. All participants are informed that sessions may be recorded, and this is also part of the informed consent process and consent document. The digital recordings are stored securely in a shared, password-protected file system, backed up continuously, and protected

by the UTN and U of U firewalls. Recordings are transcribed by a professional transcriptionist, de-identified, and uploaded to a secure, shared file on the U of U protected electronic environment.

Data Analysis

We will use multilevel generalized mixed modeling under an intent-to-treat approach to compare the outcome measures of EPDS and GAD-7 between group 1 (VCI) and Group 2 (AC) at six-time points during pregnancy and postpartum. This is an appropriate statistical approach for the described RCT protocol. Sensitivity analysis was conducted with G-Power 3.1. We used RMANOVA with 6 total measures as a conservative power analysis for our mixed-effects model. The sample is powered for the fixed effect of Intervention X Time. For study aim 1: Using RMANOVA with alpha = 0.5, 6 total measures, 0.3 for correlation between repeated measures, and a sample size of 192 total participants gives greater than 90 percent power to detect an effect size of 0.1, which is a net decrease in EPDS and GAD-7 of roughly 1 point decrease per time point, assuming a standard deviation of 5. For study aim 2: For the stratified samples of urban/rural or Hispanic/NED, we have greater than 80 percent power to detect the same Intervention X Time effect size of 0.1.

Dissemination Plan

Sharing of data generated by this project is an essential part of our proposed activities and will be carried out in several different ways. We are interested in our results being available to the community of scientists interested in maternal-fetal medicine, health communication, and ethical and social implications of population-level genetic screening. We will register this project with clinicaltrials.gov upon notification of award, in accordance with NIH policy. The Project Administrator will be expected to update the clinicaltrials.gov listing every 6 months, or as needed during recruitment.

We also plan to present our findings at conferences and publish the findings.

Procedures performed for research purposes only:

Group Videoconference Intervention Sessions (UPLIFT Manualized Program): All sessio will be facilitated by a credentialed mental health professional specifically trained in the UPLIFT program. Each 1-hour session will include a check-in, instruction, skill building, discussion. The facilitator will use an UPLIFT manual as the outline for each specific sess of the 8-week series. Each participant will also receive the UPLIFT manual (print and/or electronic document), which contains details and resources for each session. Sessions will focus on increasing knowledge about depression and pregnancy, CBT, and MBP. Particip will learn and practice skills related to CBT and mindfulness, and engage in discussions a group exercises for each session's main topic. Topics include thought monitoring, identify distortions in thoughts, self-esteem, identification of problems, goal setting, and achieving support. Exercises include relaxation; body scan; progressive muscle relaxation; attention breath, sights, and sounds; and meditation. Each week, participants will be provided with

recommendations for between-session practices, which will be discussed at the beginning of the next class.

Attention Control Group (delivered by group videoconference platform):The education program for women >=32 weeks gestation is manualized and designed to enhance participant knowledge related to pregnancy, childbirth, newborn care, and feeding. The education program for women >32 weeks gestation is designed to enhance knowledge related to parenting and young babies. All participants in the AC groups will receive a mailed hard copy and/or emailed electronic packet (participant's choice) that includes topical education, which will also include information about perinatal depression and mood disorders (e.g., anxiety and obsessive-compulsive disorder, postpartum psychosis), interpretation of EPDS scores, common therapies for PD, local resources for obtaining therapies, and encouragement to discuss their EPDS scores with their prenatal care provider.

Participant-Completed Questionnaires. Questionnaires will be completed by participants via a secure, Web-based data management system (REDCap). Women in all study groups will receive an emailed link to the questionnaire. Study questionnaires are to be completed at six time points: T1 = enrollment; T2 = post intervention ; T3 = 2 months post intervention GA; T4 = 4 months post intervention; T5= 6 months post intervention; T6= 8 months post intervention. In addition to participant demographics, questionnaires will include the EPDS as a measure of the primary outcome of interest: depressive symptoms, as well as the GAD-7 as a measure of comorbid anxiety. To document the standard of care that all participants receive during study participation, the questionnaire at all six-time points also asks participants to report whether they (1) received a diagnosis of depression, anxiety, or other mental health condition; (2) were prescribed or initiated any medication for depression or anxiety; (3) were referred to and/or engaged in mental health services; and/or (4) have engaged in any type of nonpharmacological therapies for depression/anxiety during the study. If a participant does not have an email address, study staff will assist her to establish and access a free email address. All participants will receive instruction on how to access and complete the study questionnaires. The entire questionnaire takes approximately 15 minutes to complete. Participants receive $20 for each questionnaire completed.

Focus Groups

Participants will be invited to attend one focus group interview with 6-8 other participants, again using the UTN-supported videoconference platform, and within 8 weeks of completing the last group session (VCI or AC). The purpose of the focus group is to collect data directly from participants regarding satisfaction with the program, e.g. program content, videoconference platform, development of community, support, suggestions for improvement, etc. Participants receive $20 for attending the focus group. A questionnaire with the same questions asked in the two randomized groups will be completed by participants via a secure, web-based data management system (REDCap) upon completion of the focus group or completed on a paper document kept in a secure locked cabinet in the College of Nursing until data can be entered into REDCap..

Statistical Methods, Data Analysis and Interpretation

Enrollment and randomization will continue until the following enrollment goals are met: Urban Latinas = 60 (n = 30 VCI; 30 AC); Rural Latinas = 60 (n = 30 VCI; 30 AC); Urban, North European-descent (NED) = 60 (n = 30 VCI; 30 AC); Rural NED = 60 (n = 30 VCI; 30 AC), for a total of 240 participants.

Data Analysis:

We will compare demographics, partum group, and medications between groups ($\chi 2$) to document the results of our randomization process. We will further document and test for differences in frequency and means in groups related to additional study-related variables. Examples include dose of participation and birth complications or pre-term deliveries. We will explore the addition of these variables in our analytical models.

We will utilize multilevel generalized mixed modeling (via SPSS and R) under an intent-to-treat (ITT) approach to compare the outcome measures of EPDS and GAD-7 between Group 1 (VCI) and Group 2 (AC) at up to six time points. To assess whether we will need to nest participants within clusters (Level 3, group-level) given that the intervention/control are administered in groups, we will conduct an analysis that adds an additional level (nesting participants within clusters) to our proposed model and calculate the model's ICC.As an exploratory analysis, for both aims, we will add the fixed effect of baby's sex to final models and report results.