Effectiveness of Therapeutic Interventions in Preventing Anxiety and Depression Disorders in Pregnant and Postpartum Women: Research Design Proposal

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Abstract

It has been estimated that nearly 400,000 babies are born in the United States each year to women who are depressed (Stanescu, Balalau, Ples, Paunica, & Balalau, 2018). Depression symptoms during the perinatal and postnatal periods for women can range in severity and often present as comorbid with anxiety (Bennett & Sylvester, 2013). There are several studies which have examined potential non-pharmacological treatments for women who suffer from or are at risk of developing postpartum depression. The results of many of these studies have been promising (Curry, 2019). There continues to be a need, however, for further and more “rigorous” testing and research in order to develop reliable interventions and preventive care for new mothers and their babies (Carter, Bastounis, Guo, & Morrell 2019; Steardo et al. 2019).

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Chapter I

Background

According to *National Vital Statistics Reports* (Martin, Hamilton, Osterman, & Driscoll, 2019) nearly 4 million women give birth each year in the United States. Among these women, as many as 1 in 7 is affected by perinatal depression, one of the more prevalent complications associated with pregnancy and the postpartum period (Curry, 2019, p. 582). During this period, it is estimated that up to 85% of women experience circumstances that are associated with affective disorders (Stanescu et al., 2018). Loughnan et al. (2018) explain that between 9 and 23% of women will experience clinical levels of anxiety either during pregnancy or the postnatal period (Loughnan et al., 2018, p. 481). Meades and Ayers (2011) suggest that in women with affective disorders the comorbidity rates between depression and anxiety during the perinatal period may be as high as 50%. It is also reported that 80% of postpartum women experience mild symptoms of depression within the first two weeks after delivery (Bennett, & Sylvester, 2013), and approximately 15% to 30% of new mothers experience persistent symptoms of depression up to 12 months following delivery (Bennett & Sylvester, 2013; Stanescu et al., 2018).

Perinatal depression and anxiety are conditions that affect new mothers as well as the babies that they carry and deliver. Authors Phipps et al. (2013) explain that developmental and cognitive delays are common among children born to untreated depressed mothers. Babies who are born to depressed mothers also display increased stress reactivity as well as lower levels of social engagement when compared with babies born to nondepressed mothers (Phipps et al., 2013). Somerville et al. (2014) explain that “antenatal anxiety can be detrimental to maternal

health during pregnancy" (p. 444). The mental health of women during the perinatal and postpartum periods is of high importance. Poor mental health in new mothers can have long-term adverse effects for them and their children, especially when untreated (Bennett & Sylvester, 2013; Loughnan et al., 2018).

Postpartum depression has been the subject of research studies and reviews (Loughnan et al., 2018). Cognitive behavioral therapy (CBT) and interpersonal therapy (IPT) have both been identified as potential treatments (Bennet & Sylvester, 2013) and preventive interventions (Curry, 2019) for PPD. It has been recommended, however, that further research be conducted to confirm the efficacy of these treatments as interventions for depression (Curry, 2019). It is also notable that perinatal anxiety has received little attention in research (Somerville et al., 2014; Loughnan et al., 2017) and remains an area of mental health that requires research regarding treatment efficacy and development (Loughnan et al, 2017).

It is the aim of this proposed research to test the effectiveness of cognitive behavioral therapy and interpersonal therapy when used as a preventive intervention for depression and anxiety levels among participants when compared to treatment as usual. The research will examine whether CBT and IPT can be effective preventive interventions for perinatal anxiety. This will open the door for further research which may indicate that these interventions are effective treatments for diagnosed anxiety disorders during the perinatal and postpartum periods. The following chapter is a review of literature covering studies related to perinatal and postpartum depression and anxiety, the problems associated with these conditions, potential interventions, and the need for further research.

Chapter II

Problems Associated with Postpartum Depression and Anxiety

Depression and anxiety are the two most common mental health disorders among women in the perinatal period. Somerville et al. (2014) state that “co-morbid depression and anxiety may be more common in pregnant women than independent diagnoses of depression and anxiety” (p. 451). According to Steardo et al. (2019) a “significant number of women experience comorbid anxiety, obsessive compulsive symptoms and post-traumatic disorders” (p. 2). Postpartum depression (PPD) rates are higher among adolescent mothers (Phipps, Raker, Ware, & Zlotnick, 2013) and approach nearly 90% for women with a history of PPD (Stanescu et al., 2018). Studies suggest that 30-40% of pregnant women with histories of major depression will experience a relapse of depressive symptoms during the perinatal period (Dimidjian et al., 2015).

In the United States there are an estimated 520,000 women suffering annually with postpartum depression (PPD) (Loudon, Nentin, & Silverman, 2016). The symptoms of PPD can be present prior to delivery, however most researchers classify the condition as a depression occurring within the first six months after delivery (Phipps, Raker, Ware, & Zlotnick, 2013). Perinatal depression is a condition that has a direct impact on the new mother, her baby, and on those within the household, especially the baby’s father (Stanescu, Balalau, Ples, Paunica, & Balalau, 2018). Women who experience clinical levels of anxiety during pregnancy and remain untreated are considered to be three times more likely to develop postnatal depression (Loughnan et al., 2018; Meades & Ayers, 2011; Somerville et al., 2014). Antenatal anxiety has been linked to low birthweight in infants, labor complications, low Apgar (Appearance, Pulse, Grimace, Activity, and Respiration) scores for baby, and long-term negative effects in children (Meades & Ayers, 2011).

Symptoms for postpartum and perinatal depression include worry, irritability, anhedonia, anxiety, low mood, sleep disturbance, inability to cope, excessive concern for baby's care, suicidal thoughts, guilt, negative self-image, and appetite changes (Bennett & Sylvester, 2013; Stanescu et al., 2018). In the case of postpartum psychosis, a condition that affects approximately 1 in 500 new mothers, symptoms can include hallucinations, delusions, cognitive confusion, paranoia, and hostility (Bennett & Sylvester, 2013). New mothers diagnosed with generalized anxiety disorder (GAD) are described as "less responsive and less engaged" when interacting with their newborn infant (Somerville et al., 2014, p. 444).

Bennett and Sylvester (2013) identify that, in many cases, women suffering from postpartum mental illness who are accurately diagnosed can "generally expect to recover within 6 months" (p. 4) when they receive appropriate treatment. However, symptom detection is often a barrier to proper diagnosis. Studies have shown that screening for postpartum depression is not a standard clinical practice and suggest that as many as 50% of mothers afflicted with PPD go unidentified (Loudon, Nentin, & Silverman, 2016). For this reason, prevalence rates related to PPD and other maternal mental illnesses should be reviewed with prudence (Stanescu et al., 2018; Steardo et al., 2019).

New fathers are shown to be at risk for developing PPD as well. This risk increases when the mother is diagnosed with the disorder (Stanescu et al., 2018). For the women who do not receive treatment, postpartum depression can also pose problems for her and baby. Left untreated, PPD can cause mothers to have a difficult time bonding and developing secure attachments with baby and to prematurely discontinue breastfeeding (Bennett & Sylvester, 2013; Stanescu et al., 2018). In more severe cases, PPD can precipitate a "nonaccidental injury to the infant" (Bennett & Sylvester, 2013, p. 5).

For adolescent mothers, PPD is associated with discontinued education, suicide, and substance abuse (Phipps, Raker, Ware, & Zlotnick, 2013). A new mother's mental condition also has an impact on her child's development and behaviors. Long-term depression and anxiety during the perinatal period can lead to growth and developmental complications for baby (Carter, Bastounis, Guo, & Morrell 2019), and are associated with complications for the mother and developmentally poor outcomes for the child (Loughnan et al., 2018). It has also been reported that babies born to untreated depressed mothers exhibit perceptible negative interactions, decreased levels of social engagement, and increased stress reactivity by comparison to infants born to nondepressed mothers (Phipps et al., 2013).

Barriers to Treatment/Intervention

There are many factors and barriers that contribute to women not receiving appropriate mental health care during the perinatal and postpartum period. Loudon, Nentin, and Silverman (2016) refer to postpartum depression as a "two-stepped problem" (p. 504). The first step is identification followed by the second step, which is treatment. The same authors point out that identification can be problematic as a standardized method to screen for PPD does not exist, and patients often downplay or deny symptoms.

Loudon et al. (2016) also note that women (especially those who are experiencing symptoms of severe depression) are not always consistent with the follow-up care recommended after delivery. Often, the women who are at higher risk for developing PPD are also those who are less likely to appear for postnatal follow-up care due to low social support, financial difficulties and lack of childcare. Those who do participate in follow-up care are not always properly screened for mood changes (Louden et al., 2016).

The second step to the PPD problem, as suggested by Louden et al. (2016), is providing treatment or intervention. There are complications to the process of providing treatment because universal services are currently considered unaffordable in most situations (Bennett & Sylvester, 2013). However, according to Louden et al. (2016), “without concurrent systems enhancements that provide access to treatment, universal PPD screening programs are unethical and unjustified and may result in exposing the clinician to significant litigation” (p. 504).

Research and Potential Solutions

Research has been conducted in attempts to uncover solutions to the problems presented by postpartum depression. The following includes information regarding different demographics, risk factors, screening methods, and effective therapeutic interventions.

Concerning Adolescent Mothers

Phipps, Raker, Ware, and Zlotnick (2013) conducted a randomized controlled trial to determine whether prenatal intervention would be feasible with adolescent mothers. The intervention being tested was an interpersonal therapy-based program. The program was administered to adolescent women during pregnancy. The treatment was administered starting prior to 25 weeks gestation and continued beyond delivery (including assessments at follow up sessions up to 6 months postpartum). According to Phipps et al. (2013), the trial showed an “overwhelmingly positive trend in support of the interpersonal therapy-based intervention program” (p. 192.e5). The control group used during the study had a 25% rate of PPD versus the 12.5% rate within the group receiving the interpersonal therapy-based intervention (Phipps, Raker, Ware, & Zlotnick, 2013). The authors admit, however, that the study was considered a pilot study and as such the sample size was small.

Concerning Biological Contributions

There are biological and psychological risk factors associated with PPD including personal history of depression, family history of psychopathology, previous diagnosis of bipolar affective disorder, anxiety or depression during pregnancy, low social support, socioeconomic status, recent negative life events, or partner violence (Bennett & Sylvester, 2013; Stanescu et al., 2018). Studies have found possible risk factors to include perceived expectations about how a new mother should be having a “wonderful” time, should be fulfilled, or should intuitively exhibit “mothering behaviors” (Bennett & Sylvester, 2013). There is, however, no conclusive association between PPD and obstetrical factors according to Stanescu et al. (2018).

Roussos-Ross (2019) explains that women are at an increased risk of developing depression during times when there is “noted fluctuation in hormone levels” (p. 25). She also explains that research shows that “hormone fluctuations, and not specific levels of estrogen and progesterone, may be related to onset or exacerbation of [depressive] symptoms” (p. 25). There are hormonal changes that occur within 48 hours following delivery, including a sudden drop in estrogen, progesterone, and cortisol concentrations leaving women at an increased risk of developing symptoms of depression at that time (Stanescu et al., 2018).

Recent studies also indicate that depression may be associated with immunity. Stanescu et al. (2018) describe a study of 51 women that was conducted during pregnancy and postpartum periods to assess mood, anxiety, and cytokine levels. The study found that “an increase in pro-inflammatory markers occurs during the peripartum period in patients with depressive or anxious symptoms”. These results suggest that in women who are experiencing mental illness there is a greater immune response during the end of pregnancy (Stanescu et al., 2018).

Regarding Assessments and Interventions

Early screening and detection of symptoms leading to early diagnosis is considered optimal as it can lead to higher success rates for treatment (Bennett & Sylvester, 2013; Stanescu et al., 2018). Stanescu et al. (2018) make the statement that “antepartum and postpartum screening, an early diagnosis, and a tailored approach to depression are essential for better results and prognosis related to both mother and child” (p. 163). The most common screening tools used in relation to perinatal depression are the Physicians Health Questionnaire 2 (PHQ-2), and the Physicians Health Questionnaire 9 (PHQ-9). The Edinburgh Postpartum Depression Schedule (EPDS) is the most frequently used assessment tool with women whose PHQ results exhibit a likelihood of PPD (Bennett & Sylvester, 2013). There are other assessment tools available that appear to be less commonly used by physicians assessing women during pregnancy. These assessments include the Hamilton Anxiety Rating Scale, the Hamilton Depression Rating Scale, The Global Assessment of Functioning, and the Family Coping Questionnaire (Steardo et al., 2019).

Survey research indicates that women prefer non-pharmacological approaches to treatment during pregnancy and while breastfeeding (Dimidjian et al., 2015; Bennett & Sylvester, 2013). Once a diagnosis of PPD is established, there are a few options for non-pharmacological therapeutic intervention. According to S.J. Curry (2019), the US Preventive Services Task Force found persuasive evidence indicating that cognitive behavioral therapy (CBT) and interpersonal therapy are effective in the prevention of perinatal depression. CBT has been shown to decrease symptoms for women diagnosed with PPD in as little as one session (Stanescu et al., 2018). Another study has shown that Mindfulness-Based Cognitive Therapy can be adapted for perinatal depression (MBCT-PD). This approach may be a workable option for

preventing depressive relapse during pregnancy among women with a history of depression (Dimidjian et al., 2015).

Future Research

Progress is being made in finding therapeutic interventions and preventive methods for women diagnosed with and at risk of developing PPD. There is, however, more that needs to be examined. Steardo et al. (2019) express that despite many associations and several task forces having "highlighted the importance of developing screening and treating programs for [perinatal depression], there are still many unsolved issues, such as efficacy and the availability of those programs whose efficacy has been demonstrated by [Randomized Controlled Trials]" (p. 8).

Carter et al. (2019) bring attention to the fact that little research has assessed the magnitude of anxiety symptoms in pregnant and postnatal women exhibiting depressive symptoms. It is their contention that research designed to test the efficacy of treatments for postnatal anxiety is generally absent. Loughnan et al. (2018) also bring attention to the need for research evaluating the efficacy of treatments and interventions for perinatal anxiety. There also appears to be little research focusing on PPD interventions for single mothers (Bennett & Sylvester, 2013) and pregnant adolescents (Phipps et al., 2013).

Discussion

The effects of postpartum depression go beyond what the new mother experiences. Persistent depression for a new mother has a direct impact on her health and the well-being of her infant (Phipps et al., 2013). Unfortunately, many women go without being diagnosed and as a result do not receive proper treatment. Some of the common barriers preventing women from receiving the care that they require are poor screening practices in clinical settings and missed appointments for follow up care (Loudon et al., 2016). It has been suggested that

psychoeducation during pregnancy may work to modify a mother's negative expectations about caring for baby therefore decreasing anxiety levels and lessening the risk for developing depression (Bennett & Sylvester).

For the women who are properly diagnosed, there are therapeutic interventions that have shown promise in decreasing symptoms and offering relief. Steardo et al. (2019) state that there are several interventions that have been established in order to prevent the development of perinatal depression and that "although several of these interventions have been made available in clinical practice, research is needed in order to confirm their efficacy" (p. 2). In other words, progress has been made in working toward solutions and interventions for treating women with postpartum depression and anxiety, however, further research is required.

Chapter III

Proposed Research

The purpose to this proposed study is to measure the effect of CBT and IPT on depression and anxiety levels of perinatal women when compared to a control group of perinatal women who receive treatment as usual. It is expected that the posttest scores of women who receive either cognitive behavioral therapy or interpersonal therapy as preventive treatment for perinatal depression and anxiety will be similar between groups and lower than the posttest scores of women receiving treatment as usual. In the past, research has suggested that CBT and IPT are effective treatments for women with postpartum depression. Past studies, however, did not look at preventive measures for perinatal anxiety or consider the comorbidity rates of depression and anxiety among perinatal women.

Participants

Participants for this study will include pregnant women ages 18 years and older who are currently in the first or second trimester of their pregnancy (< 27 weeks gestation). To recruit participants, informational fliers (see Appendix A) will be distributed at WakeMed North Family Health & Women's Hospital located in Raleigh, North Carolina and through a network of obstetricians' offices that use WakeMed Hospital for delivery. Office staff at these locations will be asked to distribute fliers to pregnant women who visit their offices. 300 women will be included in the research study and randomly divided into one of three test groups.

Once selected, participants will be asked to sign an informed consent form and a HIPAA authorization form (see Appendices B and C). The HIPAA authorization will enable researchers to collect background information, mental health and medical history. Women with intellectual disability, history of affect disorder or anxiety disorders, prior symptoms of depression or anxiety

that exceed the “cutoff” levels on applicable scales of depression or anxiety (>39 for STAI, >26 for PASS, >8 for EPDS), and those previously diagnosed with other significant mental disorders (i.e., schizophrenia, schizophrenia spectrum or other psychotic disorders, delusional disorders, dissociative identity disorder) will be excluded from the study. Potential participants whose pretest scores exceed the cutoff for depression or anxiety (suggesting potential diagnosable condition of depression or anxiety) will be recommended for further evaluation and treatment from a mental health professional and will not be included in this study. Women who qualify, are selected, and agree to participate in the study will not be compensated (financially or otherwise) for their participation.

Research Design

The research conducted for this study will employ a quantitative experimental between-groups (pretest-posttest control group) design. Participants will be randomly assigned to one of three groups: a cognitive behavioral therapy (CBT) group, an interpersonal therapy (IPT) group, or a treatment as usual (TAU) control group. The design will test the effect that the independent variable (treatment) has on the dependent variables (depression and anxiety).

Measures

The measures used to determine levels of depression and anxiety throughout the course of the experiment will be the Perinatal Anxiety Screening Scale (PASS), the State-Trait Anxiety Inventory (STAI), and the Edinburgh Postpartum Depression Scale (EPDS).

The PASS is a 31-item anxiety scale specifically designed to assess anxiety levels in women during the perinatal period. It is made to assess four categories of anxiety disorders: (1) acute anxiety and adjustment, (2) general worry and specific fears, (3) perfectionism, control and trauma, and (4) social anxiety (Somerville et al., 2014, p. 443). After preliminary study and

validation of the scale, Somerville et al. (2014) state that “the PASS is an acceptable, valid and useful screening tool for the identification of risk of significant anxiety in women in the perinatal period” (p. 443).

The STAI is a 40 item self-report measure consisting of two subscales (Spielberger, 1977). Each subscale (one related to state anxiety and the other related to trait anxiety) contains 20 items (Meades & Ayers, 2011). Participants will be asked to respond to statements such as *I feel at ease* or *I lack self-confidence* by rating them on a 4-point scale ranging from “not at all” to “very much so” (Spielberger, 1977). Certain scores on the STAI have been used to “indicate risk of problematic anxiety in perinatal samples” (Somerville et al., 2014, p. 446). The STAI has been shown to have “criterion, discriminant and predictive validity and may be most useful for research purposes as a specific measure” (Meades & Ayers, 2011, Abstract para. 3).

The EPDS is a 10-item self-report questionnaire. Somerville et al. (2014) state that it has “high reliability (0.87) and sensitivity as a screen for depression” (p. 445). During pregnancy and postpartum periods, Tendais, Costa, Conde, and Figueiredo (2014) state that “the EPDS has demonstrated a high level of diagnostic ability in distinguishing between depressed and non-depressed women” (p. 4).

Procedure

Each participant will complete the self-report scales for depression and anxiety that will serve as pretest scores for the study. The measures used will include the Perinatal Anxiety Screening Scale (PASS) alongside the State-Trait Anxiety Inventory (STAI) to measure levels of anxiety, and the Edinburgh Postpartum Depression Scale (EPDS) to measure levels of depression. After participants have been recruited and selected for the research study, they will each be assigned a number. Researchers will then use the randomization tool found on

randomizer.org to randomly assign participant numbers in blocks of three to equally distribute participants among the three treatment test groups (CBT, IPT, or TAU).

Participants who are assigned to cognitive behavioral therapy will be asked to attend weekly one-hour therapy sessions. The first session will take place during the second trimester of their pregnancy (approximately 23 to 26 weeks gestation) and will continue once a week for eight weeks resulting in eight therapeutic sessions. Therapy sessions will be conducted by a counselor who is familiar with perinatal mental health and trained in cognitive behavioral therapy. Sessions will be held in an office located in the WakeMed North Family Health and Women's Hospital in Raleigh, North Carolina. CBT will be used to educate participants regarding pregnancy, postpartum depression, and perinatal anxiety. Participants will evaluate negative cognitions and beliefs they hold concerning themselves and their future. Counselors will use CBT techniques to work with participants through worries and anxiety-provoking or depressive thought patterns. At the conclusion of the eight sessions, participants in the CBT group will complete the EPDS, STAI, and the PASS. This will take place in person with a counselor present. Participants will complete the same surveys again at two weeks postpartum, six weeks postpartum, and six months postpartum. Each of the postpartum surveys will be completed via telephone to reduce the potential for participants leaving the study due to an inability to make an appointment.

Participants allocated to the interpersonal therapy group will attend eight weekly counseling sessions beginning during the second trimester. The sessions will be conducted by a counselor who is familiar with the perinatal period for women and trained in interpersonal therapy that has been adapted for perinatal therapy. The IPT adaptation is an eight-session structure of therapy for antenatal depression and addresses anxieties that are often faced by

women during the antenatal period (O'Hara, n.d.). The counseling sessions will take place in person at the WakeMed Women's Hospital location. Each of the participants in the IPT therapy group will complete the PASS, the STAI, and the EPDS at the conclusion of the eight sessions of therapy. This second assessment (the first was the pretest) will be conducted in person with a counselor present. Participants will complete the assessments again at two weeks postpartum, six weeks postpartum, and a final time at six months postpartum. The postpartum assessments will be done via telephone.

The participants who are assigned to the "treatment as usual" group will not be attending regular sessions. They will continue all prenatal obstetrical visits and any other healthcare treatments as recommended by their physician(s). Participants will be asked to complete the PASS, STAI, and EPDS surveys at approximately 35 weeks gestation (a comparable time frame to those who will have completed the eight weeks of therapeutic sessions). The surveys will be conducted in person with a counselor present. The participants will complete the same surveys at two weeks, six weeks, and six months postpartum (each of these will be conducted over the telephone).

Results

It is expected that participants within the two groups receiving preventive treatment in the form of CBT or IPT will have lower scores on each of assessment scales used in the study (indicating lower rates of depression and anxiety) than participants receiving "treatment as usual". Variance of scores between participants in the CBT treatment group and the IPT treatment group are not expected to be significant.

The independent variable in this study is categorical and the dependent variables are quantitative. There are three test groups and more than one outcome variable. A multivariate

analysis of variance (MANOVA) will be the statistical method used to do a comparison of means.

Discussion

This study presents an opportunity for researchers to confirm what others have claimed regarding the efficacy of CBT and IPT for treating perinatal and postpartum women for depression. The aim of this study is to work toward finding interventions that effectively reduce postpartum depression and anxiety rates through prevention. Another goal for this research is to offer information to the study of anxiety rates during the perinatal period. Perinatal anxiety has been overshadowed by postpartum depression throughout research (Loughnan et al., 2018). This is true despite the fact that depression and anxiety are often comorbid during the perinatal and postpartum periods (Somerville et al., 2014). By measuring both depression and anxiety levels of research participants, information for comorbid rates among TAU participants will be available for future use.

Pretest scores may be used to reduce potential attrition bias should participants leave the study prior to completion (Heppner et al., 2016). However, this may be insufficient as some studies suggest that postpartum depression and anxiety may be what precludes missed follow up appointments for postnatal women (Tendais et al., 2014, p.7). Follow up (postpartum) assessments for this study will be done via telephone or e-mail to reduce this potential error.

There may be confounding constructs with levels with the proposed design because participating counselors will be trained in the specific therapies that will be employed. Outcomes may vary using counselors who are only generally trained or are less familiar with perinatal treatments and concerns.

Meades and Ayers (2011) discuss several studies that test outcomes of test-retest reliability of the STAI anxiety scale among perinatal samples of women. The studies reviewed by Meades and Ayers (2011) show that trait scores are lower for women after birth than during pregnancy. The authors also reveal that, in more than one study, trait scores were significantly decreased when scores were taken 2-3 days after delivery and again months later. This study will administer the first postpartum assessment scales two weeks postpartum. It has been noted that a majority of women experience “baby blues” during the first two weeks after delivery (Bennet & Sylvester, 2013). A diagnosis of postpartum depressive disorder has a general onset of two weeks to one year postpartum (Bennet & Sylvester, 2013).

According to the United States Census Bureau (www.census.gov) Raleigh, North Carolina is a city with a population just under 500,000. This number does not include the greater metropolitan area surrounding the city. Raleigh contains a diverse population and WakeMed North Hospital is the only women’s hospital in Wake County. Working through WakeMed hospital will create the opportunity to find a participation sample that reflects the community as well as a more generalizable population of pregnant women.

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Appendices

Appendix A

We are looking for women who are currently in their first or second trimester of pregnancy to participate in a research study.

Participants will be part of ongoing efforts to make pregnancy a better, healthier experience for every new mother.

Contact Us
cummingsa@nyack.edu
212.625.0500

Be a part of a healthier, happier tomorrow!

***must be 18 or older to participate**

Appendix B

ALLIANCE GRADUATE SCHOOL OF COUNSELING
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Enhancing Mental Wellness for Women during pregnancy and postpartum

Principal Investigator: Ann Cummings, MHC Graduate Student, Alliance Graduate School of Counseling (AGSC)
Faculty Advisor: Dr. Julio Orozco, Ed.D., AGSC

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

1.1 Key Information

Things you should know:

- The purpose of the study is to learn more about the emotional and mental health needs of women during pregnancy and within the weeks following delivery
- If you choose to participate, you will be asked to answer 81 survey questions related to your emotional state and levels of stress. The surveys will be conducted once at the start of the study and on four additional occasions (the last set of surveys will be conducted six months *after* your child is born).
- You will be asked to attend a total of eight weekly one-on-one sessions with a clinician.
- Subjects such as pregnancy, infertility, and previous miscarriages may be come up during weekly sessions.

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

The purpose to this study is to test the effectiveness of certain therapeutic methods provided during pregnancy as a method of preventing perinatal mental health issues in new mothers.

3. WHO CAN PARTICIPATE IN THE STUDY

3. Who can take part in this study?

Pregnant women in their first trimester or early second trimester of pregnancy (less than 26 weeks gestation) aged 18 years and older

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

- Assessments may be conducted over the phone or in person at an office in the WakeMed North Family Health & Women's Hospital located in Raleigh, NC.
- All one-on-one sessions will be conducted at an office located in the WakeMed North Family Health & Women's Hospital in Raleigh, NC.
- You can expect to answer a total of five survey questionnaires over the course of the study related to your emotional state and/or feelings of stress. These surveys may be conducted in person or via telephone.
- You will be asked to attend eight one-on-one sessions with a counseling professional who is trained in therapeutic techniques relative to this study. The first session will take place during the second trimester of your pregnancy and will continue weekly until all eight sessions have been completed.
- Individuals may be assigned to a control group. Such individuals will not be attending the eight weekly one-on-one sessions. If you are selected to participate in this way, you will be asked to complete the survey questionnaires at five different times during your pregnancy and after (the last survey will be completed six months after your baby is born).
- Participants will be randomly assigned to one of three different groups. The first two groups will be attending one-on-one sessions, each with a differing style of intervention. The third group will not be attending weekly sessions. Each group will answer the survey questionnaires described above.
- Information from this study will be collected in conjunction with some background medical information from each participant. Background information will include family mental health history, your mental health history, and information that directly relates to current and previous pregnancies.

4.2 How much of my time will be needed to take part in this study?

If you are selected to participate in the weekly sessions, you will be asked to commit to eight one-hour sessions with a counselor. You will also be asked to complete three surveys (a total of 81 questions) on five separate occasions. The first set of surveys will be conducted prior to the start of the study and the final set will be conducted six months after the birth of your child.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

This study involves surveys that will ask personal questions about your emotions and stress levels. This may cause discomfort for some.

Individuals involved in weekly one-one-one sessions may experience emotional responses to their sessions. Subjects surrounding pregnancy, infertility, and previous miscarriages may be approached during weekly sessions. If weekly sessions uncover mental health concerns, we will connect you with the appropriate mental health professional.

You are not required to answer any questions that you are uncomfortable answering.

Because this study collects information about you, a risk of this research is a loss of confidentiality. We will work to maintain security in relation to your personal information.

5.2 How could I benefit if I take part in this study? How could others benefit?

This study will provide therapeutic sessions that may provide you with new skills and insight for coping with your pregnancy and new motherhood. This study will also provide information that may help others in the prevention of mental health disorders related to pregnancy and the postpartum period following delivery.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9 “Contact Information”. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study?

You will not be paid to participate in this study.

7.2 Will I need to pay anything to be part of the study?

You will not be required to pay for your part in this study. Transportation costs to and from the offices will not be provided or reimbursed.

7.3 Who could profit or financially benefit from the study results?

No one involved in the research of this study will benefit financially from the study results.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

Your information will be protected according to HIPAA guidelines. We will take every precaution to keep your information confidential.

8.2 What will happen to the information collected in this study once the study is over?

We will keep the information we collect about you during the research.
We will not keep your name or other information that can identify you directly.
The results of this study could be published in an article or presentation but will not include any information that would let others know who you are.

8.3 Will my information be used for future research or shared with others?

We may use or share your research information for future studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. Future research may be similar to this study or completely different. We will not ask for additional informed consent for any future studies using the information collected during this study.

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished

Principal Investigator: Ann Cummings
Email: cummingsa@nyack.edu
Phone: 321.277.4305

Faculty Advisor: Julio Orozco
Email: julio.orozco@nyack.edu
Phone: 240.731.2820

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

Nyack College
Alliance Graduate School of Counseling
2 Washington St
New York, NY 10004
Telephone: 212.625.0500

10. YOUR CONSENT

Consent/Assent to Participate in the Research Study

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records and we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what this study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Appendix C

HIPAA Authorization

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to [name or other identification of specific health care provider(s) or description of classes of persons, e.g., all doctors, all health care providers] at [name of covered entity or entities] to use or disclose (release) your health information that identifies you for this research study.

The health information to be used for this research includes: Medical history related to pregnancy (current and previous pregnancies), family medical history, mental health history, family history of mental disorders

The health information listed above may be used by and/or disclosed (released) to:

Ann Cummings

[Name of covered entity] is required by law to protect your health information. By signing this document, you authorize [name of covered entity] to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

You may change your mind and revoke (take back) this Authorization at any time, except to the extent that [name of covered entity (ies)] has already acted based on this Authorization. To revoke this Authorization, you must write to [name of the covered entity(ies) and contact information].

This Authorization does not have an expiration date

_____	_____
Signature of participant or participant's personal representative	Date
_____	_____
Printed name of participant or participant's personal representative	If applicable, a description of the personal representative's authority to sign for the participant