

EFFICACY OF AN ELECTRONIC APPLICATION TO MODERATE SYMPTOMS OF
POSTPARTUM DEPRESSION AND IMPROVE POSTPARTUM WELL-BEING:
A PILOT STUDY

A Dissertation

by

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This dissertation meets the standards for scope and quality of
Texas A&M University-Corpus Christi and is hereby approved.

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ABSTRACT

Using a biopsychosocial framework, I examined whether an intervention of an electronic app *VeedaMom*, specifically designed to mitigate depression, is effective in reducing depression, improving well-being, and in providing a sense of social support. This study examined the mitigation of postpartum depressive symptoms and sense of well-being in two groups over three weeks. The first group (23 women) was provided an electronic app for iPhone called the *VeedaMom* app, and the second group (20 women) was provided a customized educational booklet obtained from state resources. After three weeks, the group of mothers who used the app reported a 14% decrease in symptoms of depression ($p < .05$ with a large effect size), suggesting that the app may have acted as a wellness companion. Women using the app also indicated an enhanced sense of social support on using the app, over women who used the educational booklet. In the same period, there was an increase in well-being in the group of mothers who were provided with the educational booklet. This increase in well-being was greater than the increase observed in women who used the app. Women in the group provided with the educational booklet had multiple support systems as opposed to women using the app who had fewer support systems, despite the perception of greater social support in the latter group. Thus, multiple support systems may have acted as a covariate in improving well-being. Amazon Analytics data for the app indicated a higher preference for use of some features like the meditation timer, videos, and action list. A health literacy survey showed that both the groups had similar health literacy numbers indicating that this experimental design used similar cross-sections of the population. Although this was a pilot study, the results provide evidence that the use of an electronic app like *VeedaMom* can mitigate postpartum depression

DEDICATION

I dedicate this work to my grandmother Mrs. S.N. Lalithamma who taught me the meaning of standing up for what is right and true sense of resilience.

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CHAPTER I: INTRODUCTION

This dissertation provides an overview of a study examining the efficacy of an electronic application developed to improve the well-being of new mothers by alleviating symptoms of postpartum depression (PPD). The first chapter provides an introduction to PPD, a discussion of the problem statement, and the purpose and significance of the study. Additionally, definitions of key terms and constructs used in the study are provided. In Chapter II, an overview of the theoretical framework guiding this scholarly inquiry and a review of the published literature related to the constructs will be discussed. Chapter III provides a detailed description of the methodology applied to address the research questions posed in this study, and includes a discussion of potential limitations of the study to be considered when interpreting results. Chapter IV provides a detailed information about the statistical method and analysis applied to the study. Chapter V provides discussion, limitations of the study and future directions. The appendices contain copies of IRB approval letters, instruments used, and other materials relevant to the study.

Motherhood is a time of happiness, challenges, transition, and several developmental milestones for women. The postpartum period is a time of intense transition in a woman's life, accompanied by both physical and emotional changes. These changes include adjusting to the new maternal role of being a caregiver, changes in relationships, needing to adjust schedules to make time for the baby, and new economic demands. The effects of these changes can create extreme stress, potentially leading to the onset of PPD (Schaar, 2012). The Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5; American Psychiatric Association, 2013) classifies PPD as a major depressive episode which may occur during the first four months after delivery. This type of postpartum stress is common among new mothers. While it generally takes

six weeks for mothers to adjust to their new roles, some women report longer adjustment periods or increased levels of postpartum stress (Koniak-Griffin, Anderson, Verzemnieks, & Brecht, 2000). Long periods of stress can lead to PPD, which negatively affects both maternal mental health and newborn health (Hung, 2004). In 2010, a National Institute of Mental Health report noted that 10% of women will develop PPD, and up to 25% of the 6 million pregnant women each year will develop some symptoms of PPD (Leung & Kaplan, 2009; Schaar, 2012).

PPD is diagnosable in 10% to 15% of new mothers (Ross, Murray, & Steiner, 2005). Depression in postpartum women is considered to be moderate but can be severe in a small percentage of women (Daley, MacArthur, & Winter, 2007). Moderate PPD is depression that may occur soon after delivery, or up to one year later (Jossefson, Berg, Nordin, & Sydsjö, 2001). Moderate PPD includes loss of interest in daily activities, which may have an effect on a mother's ability to care for the baby. Severe PPD, on the other hand, includes psychosis and may require hospitalization for suicidality (Lucero, Beckstrand, Callister, & Sanchez Birkhead, 2012). New mothers tend to be at highest risk for hospitalization due to depression occurring 10 to 19 days postpartum (Munk-Olsen, Laursen, Pedersen, Mors, & Mortensen, 2006). Mothers with PPD often have feelings of sadness, indifference, changes in energy or sleep, all of which carry risk to the mother and child. (Wisner, Parry, & Piontek, 2002, Tietz, Zietlow, & Reck, 2014). Additionally, mothers with PPD feel overwhelmed, tearful, angry, panicked, and may have suicidal thoughts or attempts (Centers for Disease Control [CDC], 2013).

Even with intention of seeking help, mothers may find little time for selfcare due to responsibilities of the new baby. Most new mothers and health care providers do not prefer antidepressants due to fear of medications crossing in to breastmilk (Davanzo, Copertino, De Cunto, Minen, & Amaddeo, 2011). Mothers who experience postpartum depression symptoms

benefit from interventions such as psychotherapy, which has been shown to be beneficial either by face-to-face format or via internet (Johansson & Andersson, 2012). Providing interventions such as psychotherapy via internet to help mothers better manage their time is a way of providing tools for selfcare (Krebs & Duncan, 2015). These steps can help new mothers pay attention to their well-being.

With advancement in technology and easy access to smart phones, more people are using health care apps to monitor health and well-being and to manage many health related issues. Providing tools for mothers to monitor their well-being via apps can be effective. There are various types of apps to support women's health. There are many apps that can track menstrual periods and pregnancy periods. However, there are very few apps that track postpartum related symptoms, and there are no apps that provide wellness based intervention during the postpartum period. Further, there is no published research on the effectiveness of a wellness-based electronic application (app) to manage PPD. Apps are software programs that run on mobile devices such as smartphones and tablets (Underwood, Birdsall, & Kay, 2015). Health care apps are becoming common interventions used to treat various mental health conditions such as addiction disorders, borderline personality disorders, and PTSD. Most of these apps provide support to individuals between therapeutic sessions or as personal crises arise (Carroll, Moorhead, Bond, LeBlanc, Petrella, & Fiscella, 2017). An interactive app that acts as a DBT (dialectical behavioral therapy) coach for borderline personality disorder has been found to be effective in reducing symptoms of borderline personality disorder by 30% among people who used the app on a daily basis (Rizvi, Dimeff, Skutch, Carroll, & Linehan, 2011). The current study was designed to address this gap in the PPD literature and further investigate the efficacy of utilizing emerging technology, and reduce the cost of health care, to treat a common mental health concern among new mothers.

Contemporary View of Depression Among Women During Childbirth

Over the last 40 years, the postpartum period has been characterized within the biopsychosocial model (Ross & Toner, 2004). This model of the postpartum period takes into account hormonal fluctuations, psychological well-being of the mother, and social support obtained from family and friends. Cultural differences in explaining PPD across the world were also addressed by conceptualizing the baby's birth from a biopsychosocial model (Engel, 1977). Within biopsychosocial models, childbirth is viewed as an important "life event" requiring the assumption of new social roles, skills, and behaviors for women. This significant "life event" also can be a highly stressful event, leading to feelings of uncertainty and anxiety in new mothers (Edhborg, Friberg, Lundh, & Widström, 2005). Pregnant and postpartum women require emotional support, information, and assistance to minimize these stressors and successfully transition into their new maternal role (Abrams & Curran, 2007). Support during this transition is crucial for them to assume the new role to enjoy their postpartum experience. If these forms of support are neither available nor accessible, new mothers may become more vulnerable to PPD. Untreated PPD can have negative effect on the family and create attachment issues with the new baby. These type of supports are especially important given the prevalence of PPD and its deleterious effects on the family (Sidor, Kunz, Schweyer, Eickhorst, & Cierpka, 2011).

Nationally, about 1 in 9 women experience symptoms of PPD (CDC, 2010). Estimates of the number of women affected by PPD differ by age and race/ethnicity. The CDC estimates that more women suffer from PPD and related illnesses in a given year than the total number of women with new cases of tuberculosis, leukemia, multiple sclerosis, and Parkinson's disease combined (CDC, 2008). The CDC estimates 1 in 8 women experience some form of depression in their lifetimes; motherhood can add additional stress, resulting in about 50% of women with

PPD being diagnosed with depression before or during their pregnancy (CDC, 2013). Following their first or subsequent deliveries, 10% to 15 %of women experience some form of postpartum-related symptoms (Halbreich & Karkun, 2006). Additionally, postpartum depression estimates vary by state, and can be as high as 1 in 5 women (<https://www.cdc.gov/reproductivehealth/depression/index.htm>).

Pregnancy Risk Assesement Monitoring System (PRAMS) data also shows that in 2010, 12.9% of mothers showed symptoms of postpartum derpressive symptoms (latest data available). In addition, 29.5% of women reported that there was no conversation about perinatal or postpartum depression during their visit with their health care povider ([ttps://nccd.cdc.gov/PRAMStat/rdPage.aspx?rdReport=DRH_PRAMS.Explore](https://nccd.cdc.gov/PRAMStat/rdPage.aspx?rdReport=DRH_PRAMS.Explore)). During this challenging time of transition, mobile technology may prove to be a readily available and useful tool for supporting women with PPD. An interactive app dedicated to helping women with PPD that can be downloaded on smart phones might be a novel way to provide tools for self-care which can promote lifelong wellness (Sidor et al., 2011).

Mobile devices have evolved tremendously in a short amount of time, to the point that they have begun replacing laptops in some cases. According to the Pew Research Center (2015), “85% of the young adults are incorporating their mobile devices in a host of information seeking behaviors” (p. 4). Most smart phone owners believe their phone gives them happiness, allowing them to connect socially and help take charge of their health (Boulos, Wheeler, Tavares, & Jones, 2011). Mobile phones offer sufficient computing power to perform complicated tasks such as monitoring heart-rate and adjusting medication (Boulos, Brewer, Karimkhani, Buller, & Dellavalle, 2014). Coupled with their portability, mobile phones have become a ubiquitous

accessory, and one researchers and developers have targeted as a new medium for delivering health-related services (Boulos et al., 2011).

Rationale for Development of *VeedaMom*

One of the main reasons women hesitate to seek postpartum mental health care is lack of time and/or difficulty finding child care. The postpartum period is also the time when mothers need the most support from family and friends, as this support has shown to be a protective factor against PPD (Surkan, Peterson, Hughes, & Gottlieb, 2006). Providing a mobile app is a logical choice for new mothers, as it allows them to access health related information and monitor their own mental health at their convenience (Price, Yuen, Goetter, Herbert, Forman, Acierno, & Ruggiero, 2014). Having an app to access these resources at any time of day not only allows mothers to monitor their psychological health but also provides the sense of support that is essential for well-being (Olsson, 2013).

VeedaMom is based on the biopsychosocial model as portrayed by George L. Engel. *VeedaMom* came to existence as a wellness companion, providing a way for a physician to monitor the mental status of the mother during postpartum period and empowering mothers to help themselves. The word *veeda* means life in Spanish. *Veda* or *veeda* also means knowledge, wisdom, or life in Sanskrit. The app provides knowledge and tips for improving one's emotional state by self-care, by being connected to other mothers in the *VeedaMom* social network, and by being in the present by using mindfulness techniques (Perez-Blasco, Viguer, & Rodrigo, 2013). Since the biopsychosocial model looks at PPD as a holistic phenomenon, the name *VeedaMom* is an appropriate characterization of the app. The biopsychosocial model views the client as an active participant who can positively influence their own health (Brown-Baatjies, Fouche, Watson & Povey, 2006; Engel, 1980). People respond to stress in a variety of ways. Effective

emotional management interventions can provide behavioral, cognitive, and emotional techniques to positively shift how the individual will perceive and respond to stressors (Brown-Baatjies et al., 2006; Dunkel, 2011). Therefore, an app based on the biopsychosocial framework can empower mothers to be cognizant in making decisions to use the app when there is a need to improve their ability to function better as new mothers.

VeedaMom provides a way for mothers to monitor their mood to help assess their need to contact their physician, a counselor, or a friend. This feature of finding ways to cope actively with their situation can serve as a reminder to them of self-care and is based on the Edinburgh Postnatal Depression Score (EPDS; Cox, Holden, & Sagovsky, 1987). *VeedaMom* makes self-care suggestions such as to call a friend, take a relaxing bath, listen to music, or use meditation prompts. These prompts can help mothers act to improve their current state of mind. Meditation apps can help mothers be in the present moment and accept the things that cannot be changed actively. Several types of meditation, such as body scan, mindfulness, and centering meditation are provided in the app. *VeedaMom* also provides educational videos about the postpartum period which mothers can access as a trusted source of information about what to expect during this tumultuous period in their lives.

The app also provides an option to post pictures to friends and family and enhance social connection (friends and families do not have to install the app). There is a journaling feature, with options to type or record audio (speech) to facilitate a sense of well-being. If the EPDS scores indicate a need for medical intervention, then the mobile phone GPS system will be used by the app to guide them to the nearest medical facility. If a mother responded positively to the question assessing for suicidal ideation, the app prompts them to call their doctor, their emergency contact, or a suicide hotline.

Statement of the Problem

Becoming a mother can be overwhelming and women may feel unprepared to care for a new baby. Mothers are expected to gain mastery in caring for the baby, and the arrival of baby can be exhausting given the physical, hormonal, biological, and psychological changes taking place in the mother's body. The expectations mothers place on themselves coupled with the pressures society places on them, can create additional stress, making them more vulnerable to depression (Halbreich & Karkun, 2006),

Caring for the baby leaves little time for the mother to seek help for their well-being to offset postpartum-related stresses. Technology can help mothers overcome some of the stresses they face during this postpartum period. Using apps to deliver basic medical and psychological services to mothers in the comfort of their own home and helping to connect them to services and to their friends can make mothers better manage motherhood. However, there is a lack of research regarding the overall effectiveness of services delivered by the apps and maintaining the privacy issues relating to health information (Meingast, Roosta, & Sastry, 2006). PPD has far reaching implications for healthy functioning of the mother, child, and entire family unit. Finding innovative ways to effectively prevent and treat PPD is increasingly important for health care professionals, not only to treat the mother but to raise emotionally healthy children. This study addresses the efficacy of an electronic application attempting to mediate postpartum symptoms in new mothers.

Purpose of the Study

The purpose of this study was to examine whether the mobile app, *VeedaMom*, can be effective in mitigating feelings of depression and improve psychological well-being, compared to a state-mandated postpartum resource booklet provided to mothers at the time of hospital discharge. *VeedaMom* was developed specifically to address PPD. To my knowledge, there are no apps specifically designed to enhance postpartum experience by addressing women's wellness during postpartum period. The only PPD-related app currently available collects data from women diagnosed with PPD to study their DNA and potentially predict biological factors determining PPD (Putnam et al., 2015). Although there are several mobile applications with therapy-related content, very few apps have an evidence-base supporting their usage.

This study is one of the first to empirically test the effects of the use of a mobile phone application for psychological problems versus the resource booklet that many states are required to provide mothers as they leave the hospital after the baby is born. There are no studies comparing state provided booklet to that of the effectiveness of an app. This app fills the gap that exists in the current app market. The present study further intends to establish the efficacy of *VeedaMom*, a postpartum wellness app, as a companion to new mothers to alleviate symptoms of PPD. The lack of time during the postpartum period can make it more challenging for many mothers to access face-to-face therapies. Providing an app for smart phones may be more beneficial to women because smart phones apps have become a very useful and convenient way for people to connect with one other.

One of the main risk factors for development of PPD is lack of social support, including lack of partner or spousal support (Leahy-Warren, McCarthy, & Corcoran, 2012). Support obtained from friends, family, peers, and partner or father of the baby, makes it easier for new

mothers to navigate their new role and improves psychological well-being especially during the time of stress. Women reporting little or no social support have an increased risk for developing PPD (Phipps, Raker, Ware, & Zlotnick, 2013), whereas support during this time has been shown to be a protective factor against the development of PPD (Logsdon, Birkimer, Simpson, & Looney, 2005).

Researchers suggest that some Internet-based psychotherapy services are equivalent to face-to-face interventions (Johansson & Andersson, 2012). Offering some type of psychological intervention for PPD via Internet has been tested in Canada, where women in the treatment group showed more than 30% improvement in depression symptoms compared with the control group (Pugh, Hadjistavropoulos, & Fuchs, 2014). Current empirical research available are very limited on Internet-based psychotherapy treatments comparing them with wait-list control groups (Johansson & Andersson, 2012; O'mahen, Richards, Woodford, Wilkinson, McGinl, Taylor, & Warren, 2014). The present study will contribute to the body of research on the efficacy of electronic applications for health interventions and identify possible benefits for women to reduce some of the psychological risk factors that occur during the postpartum period.

Research Questions

1. Is there a difference in depressive symptom reduction between postpartum women using the *VeedaMom* app and those using the state-provided resource booklet over time?
2. Is there a difference in perceived psychological well-being between postpartum women using the *VeedaMom* app and those using the state-provided resource booklet over time?
3. Is there a difference between the perceived social support between postpartum women using the *VeedaMom* App and those using the state provided resource booklet over time?

4. Is there a statistically significant difference in health literacy scores between the group using *VeedaMom* app and those using the state provided resource booklet?
5. Is there a significant difference among the usage of certain of features provided in the app that can be examined using Amazon Analytics data?

Significance of the Study

The Coastal Bend of Texas is the curved region of the Gulf Coast in which the largest city is Corpus Christi. A Coastal Bend Health Needs Assessment reported that 12% of women in this area are of childbearing age, with 40 % of them claiming that poor physical and mental health kept them from their usual activities (Meyer, Araiza, Jorgensen, Brown, Huang, & Brittany-Stoker-Garcia, 2016). The same assessment found that 56% of emergency room visitors were women between the ages of 17 and 64. The use of emergency room was for their physical and mental health, and their children's health conditions. Women in general were reported as using an emergency room 15% more than the state average. The Coastal Bend area has a disproportionately low percentage of mental health providers compared to the state average. The report also identified a need for general health education and awareness about child rearing and maternal nutrition.

Coastal Bend area mothers can greatly benefit from using an app because they do not need to leave home to seek support. Mothers with signs of PPD can benefit from psycho-education programs about prenatal and postnatal depression as there is a shortage of mental health workers in rural areas of Texas and a need for health education to improve health behaviors in general. Creating awareness about maternal mental health following delivery will help cut costs of treating women for PPD-related complications in the future and will also benefit the child's health as the child matures.

Using technology to provide therapy has gained a lot of support among people and more research is being conducted to provide better ways of delivering different therapies. Many European countries are successfully using the internet to provide health and psychological support to their population. There is also an interest in treating PPD by providing some form of psychological therapy via internet (Pugh, Hadjistavropoulos, & Fuchs, 2014). This mode of delivering therapy is easily accessible to others and there is also less stigma associated with it because it can be anonymous and private. The downside of delivering therapy via internet is that attrition rates can be high. The high attrition rate is generally associated with lack of time or interest in the therapy especially if the therapy is provided in modules (Pugh et al., 2014). With the advent of new technology, women can access some form of health care support in the comfort of their own home via electronic applications that can be downloaded to a smartphone or tablet device. Women of child bearing age are more comfortable with technology having grown up in the age of smart phones and tablets (Tripp, Hainey, Liu, Poulton, Peek, Kim, & Nanan, 2014).

Mobile health apps have proven to be beneficial accessories to help people manage their own health and wellness, promote healthy living, and gain access to useful information when and where they need it. Medical and supportive services are now being offered online for a variety of conditions (Neubeck, Lowres, Benjamin, Freedman, Coorey, & Redfern, 2015). Numerous mobile health applications have made point of contact with patients much easier and have provided access to health care in remote regions and hard to reach populations who typically lack access to healthcare (Ventola, 2014). With the challenge of having to care for a newborn and balancing a demanding schedule, the use of such applications could have great appeal to mothers experiencing symptoms of PPD.

Definition of Key Terms

Postpartum period: The first six weeks following birth of the baby. It is also the period of hormonal and physical changes in a woman's body (Wisner, Parry, & Piontek, 2002).

Postpartum depression (PPD): A mood disorder that can affect women after childbirth. Mothers with postpartum depression experience feelings of extreme sadness, anxiety and exhaustion that may make it difficult for them to complete daily care activities for themselves or for others. It lasts longer than baby blues (Wisner, Parry, & Piontek, 2002).

Well-being: Well-being generally includes global judgments of life satisfaction and feelings ranging from depression to joy (Diener & Seligman, 2004). A positive outcome that is meaningful for people and for many domains of the society and it is a measure of how people perceive that their lives are in homeostasis. However, many indicators that measure living conditions fail to measure what people think and feel about their lives, such as the quality of their relationships, their positive emotions and resilience, the realization of their potential, or their overall satisfaction with life i.e., their well-being.

Social Support: Social support is how one is connected to friends and family, and other areas from which they can draw support. Social support is defined as the interpersonal resources accessed and mobilized when individuals attempt to deal with the everyday stresses and strains of life. Social support includes both the availability of support and perceptions of social support. Social support includes availability of support from family, partner, friends and community. Perceived social support can be knowing that support is available if needed within their social network (Gottlieb & Bergen, 2009; Reid & Taylor, 2015). Social support in any form acts as a buffer that protects an individual from the

potentially adverse effects of stressful events, thus enhancing coping ability and health outcomes (Ugarriza, Douchand Brown, & Chang-Martinez, 2007).

Electronic app: Software programs that run on smartphones and other mobile devices. Mobile health apps can help people manage their own health and wellness, promote healthy living and gain access to useful information when and where they need it (Underwood Birdsall, & Kay, 2015)

iPhone: Wireless communication device manufactured by Apple, Inc.

Health Literacy: Health literacy (HL), or literacy within the context of the health care system, includes information or communication processing skills that gives the capacity to patients beyond functional reading abilities (Nutbeam, 2008). Low health literacy may influence the participatory capacities of the patient and health care provider relationship. Low health literacy can also affect patient decision-making and involvement of care. Providing education about caring for the newborn and finding time for self-care during postpartum period can enhance postpartum experience.

Remaining Chapters

Chapter Two provides a literature review regarding postpartum depression, including definition, prevalence, and screening. Also discussed is postpartum depression in the context of biopsychosocial phenomenon. The literature review also addresses the use of app technology in mental health care. Chapter Three provides a description of the study's participants and settings, a rationale for the use of, and an explanation of data analysis procedures. The results are presented in chapter Four. Chapter Five includes a discussion of the results, implications for mental health professionals, social change for women and recommendations for future research.

CHAPTER II: REVIEW OF THE LITERATURE

Introduction

Postpartum health has most often been contextualized from the medical perspective (Hendrick, Altshuler, & Suri, 1998). There has been a more recent increase in public awareness of the emotional, social, and physical changes occurring during the postpartum period (Ross, Sellers, Evans, & Romach, 2004; Razurel, Bruchon-Schweitzer, Dupanloup, Irion, & Epiney, 2011). This review of the literature explores how social, emotional, and physical changes can influence a new mother's ability to cope with this exciting yet potentially stressful time in their lives. The review also examines how technology can enable women to take control of their health, along with medical help when needed.

This review of the literature was conducted using the key words such as counseling interventions, postpartum depression, biopsychosocial models of health, holistic health-based interventions, and electronic-based interventions through the Internet or as smart phone application-based treatments. Literature was obtained through MEDLINE, National Institute of Mental health, and Centers for Disease Control, PubMed, the Mental Measurements Yearbook and Academy of Obstetrics and Gynecology.

Framework for the Study

George Engel, a psychiatrist, proposed the biopsychosocial model in 1977 to account for the biological, psychological, and sociological inter-connectedness spectrum among systems of the body (Engel, 1980; Engel, 2012). This model takes diseases such as PPD, depression, and many mood disorders out of the purview of the medical model and examines them from a social and psychological context (Adler, 2009). Prior to Engel, models viewed the mind and body as separate entities (Gatchel, 2004). Treating the body alone did not address many diseases, and

mental health was not given enough attention. To address this deficiency, the biopsychosocial model was conceptualized as a multidimensional model emphasizing a holistic approach to the critical care of a patient (Engel, 1977). The biopsychosocial model is based upon the principles of general systems theory (Ross & Toner, 2004; Saxbe, 2017). General systems theory conceptualizes every being as comprised of component parts, which are grouped into larger components, beginning with sub-atomic particles, atoms, which are further organized into molecules and ultimately organized into the "whole" person. Engel also proposed that there are further hierarchies of which the person is a component, including family, community, society, and the biosphere (Engel, 1980).

The biopsychosocial model was selected as the guiding framework for this study because it provides a more holistic, wellness-based approach to understanding the causes of postpartum depression as well as effective prevention efforts (Engel, 1980). This chapter will explore current approaches to coping with PPD using a biopsychosocial approach while providing a detailed discussion of PPD from a biopsychosocial perspective. The biopsychosocial model emphasizes self-care, psychological support and emotional support in mitigating symptoms of PPD (Ross & Toner, 2004). As stated earlier, postpartum-related depression can negatively influence the care a mother is able to give to her child unless she is able to find resources to counter balance her stresses. This model goes well with the resources *VeedaMom* can provide for mothers, which includes sense of control in ways they can combat PPD, social isolation and information about baby rearing that is readily available. This model also supports the fact that the app provides a sense of well-being to new mothers, allowing them to mitigate the effects of PPD. The proposed research compares efficacy of *VeedaMom* versus the state required booklet.

Conceptualization of Variables

Postpartum Depression

The postpartum period, also referred to as puerperium, can be an exciting time that can be challenging and potentially stressful for a new mother and her family (Misri, Reebye, Milis, & Shah, 2006). This period begins one hour after delivery and continues for about six weeks. Physicians consider a woman to be postpartum for up to 12 months after delivery of a baby (Misri et al., 2006). This duration is established to accommodate the complete physical and emotional recovery time of pregnancy and childbirth. During the postpartum period, the new mother must cope with new expectations of herself, dramatic emotional and physical changes, and new expectations from others, all the while adjusting to her new maternal role (Josefson, Berg, Nordin, & Sydsjö, 2001). In addition to these adjustments, a woman may also experience dynamic changes in her relationships, new responsibilities, constraints, and economic demands (Surkan et al, 2006). These profound changes can lead to postpartum stress, depression, and anxiety.

PPD affects 20% of new mothers and is one of the most common complications after childbirth in the United States (Surkan et al., 2006). PPD is a mood disorder ranging in severity from postpartum baby blues to severe psychosis (Lucero, Beckstrand, Callister, & Sanchez Birkhead, 2012). Postpartum blues, baby blues, and maternity blues refer to the initial shift in emotions, hormonal changes, and physical changes that follow immediately after birth. Researchers have shown that between 70-75% of women experience postpartum blues (Dennis & Ross, 2006). Symptoms of postpartum blues include mood swings, tearfulness and feelings of sadness which can PPD can turn in to depression which can linger on. PPD greatly affects the health and well-being of a new mother, her family, and the child (Baker et al., 2005; Dennis et

al., 2004; Hanna, Jarman, & Savage, 2004). Additionally, it is a condition that begins peripartum and continues postpartum, affecting women with or without a previous history of depression, and regardless of culture (Hanna, Jarman, & Savage, 2004).

Literature on the onset of symptoms has been mixed. According to some researchers, symptoms may develop within the first six weeks postpartum (Moraes, Lorenzo, Pontes, Montenegro, & Cantilino, 2017), whereas other researchers have found that the onset could begin within the first 12 weeks postpartum (Phipps, Raker, Ware, & Zlotnick, 2013). Symptoms of PPD could manifest anytime up to a year postpartum (Yawn, Bertram, Kurland, & Wollan, 2015). If the condition was not treated, PPD lasted about 12 months (Ross, Murray, & Steiner, 2005). Most mothers have an increased risk of incident hospital admission with any PPD within first three months, with the highest risk from 10 to 19 days after childbirth (Munk-Olsen, Laursen, Pedersen, Mors, & Mortensen, 2006). PPD is characterized by disabling symptoms that include feelings of inadequacy as a new parent, insomnia, guilt, loss of interest in food, tearfulness, anger, lack of concentration, irrational thinking, loneliness, a sense of loss, and lack of interest in self-care (Tripp, Hainey, Liu, Poulton, Peek, Kim, & Nanan, 2014). Women often suffer in silence, which makes this a condition that largely goes undetected by medical professionals (Tripp et al., 2014). Early detection and effective screening can prevent PPD from becoming a more serious mental illness (Howell et al, 2015, p. 61).

Well-being

Well-being generally includes global judgments of life satisfaction and feelings ranging from depression to joy (Diener & Seligman, 2004). Well-being is a positive outcome that is meaningful for people and for many domains of society and is a measure of how people perceive their lives to be in a state of homeostasis. However, many indicators measuring living conditions

fail to measure what people think and feel about their lives, such as the quality of their relationships, their positive emotions, resilience, and realization of their potential, or their overall satisfaction with life which can have a profound effect on their psychological well-being.

Psychological well-being is one of the important reserve capacities which can make a difference in how one values his or her life. There are many definitions of psychological well-being, and each definition differs slightly from study to study (Diener 2006; Olsson, Hagnelius, Olsson, & Nilsson, 2013). Psychological well-being generally involves the individual's subjective evaluation of various aspects of his or her life such as physical and mental issues, and life circumstances. Psychological well-being consists of three basic elements: the individual's affect, which means positive or negative emotional states; the ability to possess adaptive capacity or coping skills; and perception of satisfaction and purpose (Olsson, Hagnelius, Olsson, & Nilsson, 2013). Psychological well-being, as used in this study, is closely related to the concept of positive functioning which entails aspects of life satisfaction (Olsson, et al., 2013).

Psychological well-being in postpartum mothers is a complex variable that may be influenced by both personal and social factors such as health status, and functional status. Individuals with more satisfaction in personal and social factors may report a higher level of well-being. Well-being leads to better coping with life events (Diener, 2006; Razurel, Kaiser, Sellenet, & Epiney, 2013). Higher level of psychological well-being improves the ability to bounce back from life's stresses, while decreasing symptoms of chronic pain (Pressman & Cohen, 2005).

Social Support

Social support has consistently been reported as a form of protection against postpartum stress and depression (Haslam, Pakenham, & Smith, 2006). It is thought to enhance a mother's

adjustment to her new role and responsibilities by strengthening her sense of self-efficacy (Haslam et al., 2006). Self-efficacy defined social support as "interpersonal transactions that provide individuals with self-esteem, stress-related aid, and emotional assistance" (p. 278). Social support refers to social resources that one perceives are available to them within their social network. Social support also refers to support provided to them (Gottlieb & Bergen, 2009).

Increased levels of social support have been a protective factor against PPD (Leahy & Warren, McCarthy, & Corcoran, 2012). Social support reflects the affective aspects of relationship and the belief that mothers can count on them when they need support and help. Social support also includes people around whom mothers can feel secure, safe and with whom they can be totally themselves. Such a place can provide better emotional support for mothers in their new role.

Social support also plays a positive role in healthy pregnancy and a better postpartum experience. Finding social support appears to reduce pregnancy related stress and anxieties. Knowing that support systems are available also helps mothers to prepare for postpartum period. Multiple social support includes support from various sources such as family friends and significant others and these support systems are known to decrease effects of negative life events (Agostini, Neri, Salvatori, Dellabartola, Bozicevic, & Monti, 2015).

Health Literacy

Health literacy in postpartum depression is the knowledge and beliefs about mental disorders which aid their recognition, management and possible prevention. Providing information about PPD and ways to combat has proven to be beneficial. Providing information about self-care and ways to seek help has proven to reduce number of severe postpartum depression among mothers (Thorsteinsson, Loi, & Moulynox, 2014). An individual with good

mental health literacy would be able to identify some symptoms and be able to seek help when needed. High level of mental health literacy can increase the possibility that mothers will be able to seek help and find meaningful interventions. Misconceptions surrounding the diagnosis of postpartum depression as “baby blues” shows lack of literacy about postpartum depression. Providing information can enable mothers to seek source of information for interventions.

Technology-Supported Health Care

The Internet is one of the newest modalities being used increasingly as a clinical tool for psychological treatment (Johansson, & Andersson, 2012). Ninety-five million adults, or 80% of Internet users, search the web to find health information in the U.S (Fox, 2011; Carroll, 2017). Sixty-six percent of adult users search the internet for information on a specific medical problem and 23% of adults who use the Internet search for information on stress, depression, anxiety, and other mental health concerns Internet has increased the ability for consumers to gain access to what was formerly exclusive information only available to experts within a field (Harris, 2013). Technology can be beneficial in terms of getting information regarding health conditions, information about medicines and even obtaining some form of psychological therapy.

Globally, health care services are constantly changing due to evolving technology. Great strides have been made in ways people are being treated. Robot assisted surgeries are cutting down time for patients to recover. Technology is helping doctors and health care workers provide care to consumers in self-managing many aspects of diseases such as heart disease, medication management and diabetes. Tele-health care technology is allowing doctors to reach areas of the world that were not possible previously.

An important function of technology in health care services is to encourage and support healthcare consumers to use technology to adopt healthy behaviors and to be able to self-manage

many chronic conditions. Technology can connect patients with their health care practitioners so that patients can be monitored if they need medical intervention. This type of intervention is done with diabetes patients, patients undergoing kidney dialysis and asthma patients (Boulos, Brewer, Karimkhani, Buller, & Dellavalle, 2014).

Technology has also impacted health care field in many ways by providing support in the form of tele-health. For example, tele-health has facilitated addressing heart conditions remotely by allowing doctors to monitor their patient's heart and provide needed care. Chronic diseases such as arthritis, kidney problems can be treated remotely with the help of technology. Technology also enables community health care workers to provide care to people living in remote areas of the world.

Similarly, mobile health (*mHealth*) care has rapidly grown in the last few years with a series of deployments worldwide, providing early evidence of the potential for mobile and wireless technologies (Modi, Gopalan, Shah, Venkatraman, Desai, Desai, & Shah, 2015; Galloway, 2017). The technology can provide the kind of support needed for smoking cessation, anxiety reduction, and anger management (Christofferson, Hertzberg, Beckham, Dennis, & Hamlett-Berry, 2016). *mHealth* is being applied in maternal and child health (Modi, et al.2015), and programs reducing the burden of the diseases linked with poverty, including HIV/AIDS, malaria, and tuberculosis (Galloway, 2017). *mHealth* applications are being tested in such diverse scenarios as improving timely access to emergency and general health services and information (Okuboyejo & Eyesan, 2014) managing patient care, reducing drug shortages at health clinics enhancing clinical diagnosis and treatment adherence (Lund, Nielsen, Hemed, Boas, Said, Said, & Rasch, 2014) among others. For example, *mHealth* applications has helped reduce clinical prescribing errors by 14% in critical care environments (Ventola, 2014).

Use of Smart Phone Applications

Mobile technology is a rapidly expanding field and there are more than 300 million mobile phone users and 64% of them use smart phones (Carroll et al., 2017). Americans between the ages of 18 and 49 own 85% of smart phones in the United States (Hwang, Chan-Olmsted, Nam, & Chang, 2016). One in three smart phone owners use their phones to look up health care information on a regular basis. Given the high use of smart phones, there are limitless possibilities of using them to improve clinical practice in the immediate future (Hilty, Snowdy, Shoemaker, Gutierrez, & Carli, 2016). A major advantage of mobile phones is that they are with people at almost all times, and so there is immediate access to information. This contrasts with laptops, most tablets, and desktop computers. Further, due to the increasing computing power on mobile phones, they also have very high capacity to perform a myriad of functions which can be utilized for improving health care. Finally, smartphone apps are generally available in Android platform as well as Apple platforms and there are many health care apps that are helping women use phones for tracking their reproductive health.

Rationale for the App

According to Pew Research Center (2015), “currently 85% of the young adults are incorporating their mobile devices in to a host of information seeking behaviors” (p. 4). When it comes to emotions, most smart phone owners believe their phone allows them to connect socially and helps them take charge of their health. Additionally, 58% of people who use their smart phone had at least one fitness tracker app on their phones (Krebs & Duncan, 2015). Women use apps to monitor ovulation period, keep track of premenstrual symptoms among other conditions. Smart phones and apps are a good way to induce positive health behaviors (Carroll et

al., 2017). Thus, mobile phone apps can be used for monitoring and reporting information on personal health and physiology.

One of the main reasons women hesitate to seek postpartum mental health care is lack of time or difficulty finding a baby sitter. New mothers find that time is a major constraint to visiting a health care provider. Women are required to follow up with their physicians 6 weeks after their delivery. During the six weeks checkups physicians can assess the physical and mental health of the new mother. Many women skip their first six weeks checkup due to transportation issues or difficulty finding reliable babysitting (Sukran et al., 2006) especially if they are feeling better physically. The opportunity to receive mental health care is lost if new mothers miss their appointments.

Providing an app seems like a logical choice for mothers so they can access health related information and use the app to help monitor their mental health (Price, Yuen, Goetter, Herbert, Forman, Acierno, & Ruggiero, 2014). Postpartum time is a hectic time for the new mothers and having a mobile app that can be with them to access at any time of the day not only empowers the mothers but also provides a sense of support that is essential for well-being.

The app *VeedaMom* was created by the PI and another doctoral student based on the biopsychosocial framework. *VeedaMom* came to existence as a wellness companion and a way for the physician to monitor the mental status of the mother during postpartum period. The model looks at postpartum as a holistic phenomenon. The biopsychosocial model views the clients as active participants who can take charge and influence their own health (Brown-Baatjies et al., 2006; Engel, 1980). Effective emotional management interventions can provide behavioral, cognitive, and emotional techniques to positively shift the individual's perception and response to stressors (Brown-Baatjies et al., 2006). An app based on the biopsychosocial model will enable

mothers to cognitively make decisions to use the app, when there is a need to improve their ability to function better as new mothers.

The app provides a way to monitor the mother's mood to assess whether they need to contact their physician, a counselor, or a friend. This feature of finding ways to cope actively with their situation can be empowering to the new mother. Based on the score, the app makes suggestions to use one of the many actions provided in the action list. Some of them include calling a friend, take a relaxed bath, perform simple yoga poses, or listen to music. Meditation prompts with a timer is also provided in the app, prompting mothers to act to improve their mood. Meditation apps can help them be in the present moment and accept the things that cannot be changed actively. Several types of meditations such as body scan, centering, acceptance of pain is provided in the app including mindfulness routine for pain and discomfort. In addition, there are educational videos on the postpartum period which mothers can access as a trusted source. There is provision to post pictures to their friends and family which will create ways of connecting that can enhance social support. A journaling feature, either by typing or audio-recording, is provided to facilitate a sense of well-being. Based on an EPDS score, GPS based functions in the app can guide a mother to the nearest medical facility if there is a need for medical intervention. This is particularly important if a mother responded to the question assessing suicidal ideation. The app prompts them to call their doctor, their emergency contact, or a suicide hotline.

The *VeedaMom* app was developed as a wellness companion for postpartum mothers to alleviate symptoms of depression and strengthen psychological well-being. As discussed earlier, it is based on biopsychosocial model. The app not only validates the stresses that a woman faces

as a new mother but connects her with friends and family, thereby facilitating support seeking, while linking her EPDS score to her physician for care.

In summary, a wellness approach to reduce the symptoms of PPD can be effective in helping mothers cope with all the stresses that come with their new role. However, due to the paucity of data, there is a need for research to examine the relationship between wellness-based apps and PPD. Moreover, counseling journals have limited articles on PPD and in the efficacy of counseling in reducing the symptoms of depression in post-partum mothers. Counselors currently use evidence-based research from the nursing and psychology journals to work with clients. Using the American Counseling Association (ACA) advocacy competencies, the counselor can empower their clients to make the most informed decisions to get appropriate treatment if she is showing symptoms of PPD. Counselors can also advocate at the state level to create better policies to offer treatment for their clients who may be having postpartum symptoms (Choate & Gintner, 2011).

Summary

This chapter provided an in-depth review of the existing research related to depression during postpartum, prevalence, screening, and treatment interventions in biopsychosocial context. It also provided a review of literature on the use of technology in mental health care, and in specific how the apps are changing the way wellness can be attained the use of apps in relation to postpartum depression.

CHAPTER III: METHODOLOGY

The purpose of this study is to test the efficacy of an electronic application, *Veedomom*, in mitigating PPD and improving overall well-being compared to a state-required resource booklet given when women leave the hospital after delivery. There is insufficient research and data on mothers who experience post-partum symptoms and who obtain treatment with an application accessed through a smart phone. This study evaluates the efficacy of a wellness application designed specifically for post-partum mothers experiencing symptoms of depression.

Research Questions

This study is novel as it determines whether use of the app *VeedaMom* can alleviate postpartum related symptoms such as depression and improve psychological well-being, thereby enhancing a positive postpartum experience. The research questions for this study are as follows:

1. Is there a statistically significant difference in reducing depressive symptoms between postpartum women using the *VeedaMom* app and those using the state-provided resource booklet pre- and post- intervention??
2. Is there a statistically significant difference in perceived psychological well-being between postpartum women using the *VeedaMom* app and those using the state-provided resource booklet pre- and post- intervention?
3. Is there a statistically significant difference in perceived social support between postpartum women using the *VeedaMom* App and those using the state provided resource booklet post intervention?
4. Is there a statistically significant difference in health literacy scores between the group using *VeedaMom* app and those using the state provided resource booklet?

5. Is there a significant difference among the usage of certain of features provided in the app that can be examined using Amazon Analytics data?

Research Design

To evaluate the efficacy of the *VeedaMom* app in mitigating PPD, the study was employed using allocation design by providing one group with the app on a day of the week and the other group with the state provided booklet (SPB) on another day of the week. The group receiving the *VeedaMom* app was designated as the Experimental Condition (EC) while the group receiving the SPB was designated as the women's health education (WHE) group. Participants downloaded the app and got instructions during the last week of their pregnancy, so they have time to sign in to the app and download it on their phones. Mothers get busy once the baby is born and they may not have the time to download the app, sign in, and use it. They were requested to use the app within the first few days after their baby's birth. The treatment period is for a duration of three weeks of app usage use following delivery. They were asked to use the app at least once a day. Then they completed follow up instruments at the end of three weeks. The SPB was given at the time of recruitment to WHE group and they were encouraged to use the resources and information provided in the booklet after the baby's arrival. They were asked to complete the same instruments as the EC group at the end of three weeks. The state resource was downloaded and compiled from a resource guide specifically for the mothers in the study. The resource guide is a thirty-page document from which information was extracted to create a three-page customized handbook which we call the SPB. The resource guide is an extensive document including links to websites. It provides information about postpartum care and postpartum depression found in pages 12-15, in the section titled Maternal and Child Health (MCH) - Information for Parents of Newborn Children. Pages 12-13 provide information on

planning after the delivery and provide tips about seeking support as a new mother, self-care, information about breast feeding, paying attention to emotions and spending time with the baby. Information on pages 14 and 15 include postpartum mood disorders, and perinatal depression references. There is information that describes perinatal depression, postpartum anxiety, psychosis, and associated symptoms, with a checklist of symptoms to watch for. The information suggests that if there is perinatal depression then the mother should ask for support and focus on wellness among other things. Condensing these pages into a concise SPB made it easier to transmit the information to mothers in the WHE group.

A mixed method analysis of variance (mixed ANOVA) was used to compare the mean differences between the EC and WHE groups in reducing depressive symptoms and improving psychological well-being over the course of a three-week treatment period. The EC group was comprised of women receiving the app and the WHE group was comprised of women using the state-required resource booklet. The dependent variables, depression and psychological well-being, were assessed for all participants over pre-and post- time points. The primary purpose of this design was to understand whether an interaction between the within-subjects and between-subjects factors influence the dependent variables. In addition, two questions provided along with the post-treatment questionnaire examined whether the app and the SPB can provide an improved perception of social support to postpartum mothers.

In this study, the intervention is the *VeedaMom* app and its efficacy in reducing depressive symptoms and improving well-being and perceived social support were tested. The following steps implemented this design: (a) dependent variable was operationally defined, (b) an operational definition of the intervention was provided, (c) baseline data were collected at the time the app was downloaded, (d) analytics data were collected in a HIPAA complaint server

during the intervention phase, and (e) post data was collected at the end of the intervention period which lasted three weeks - the most vulnerable time in terms of PPD is from 10 days to 19 days (Munk-Olsen, Laursen, Pedersen, Mors, & Mortensen, 2006). Data produced will aid in the evaluation of the electronic app's support to postpartum mothers in reducing symptoms of postpartum-related depression, improving well-being, and enhancing the postpartum experience.

The participants in both groups were asked to fill out two instruments before the intervention begins. The instruments are (Appendix 4): (a) the EPDS measuring overall depression (Cox, Holden, & Sagovsky, 1987), and (b) the WHOQOL-BREF measuring psychological well-being (Webster, Nicholas, Velacott, Cridland, & Fawcett, 2010), but only using the psychological section of the scale. After three weeks of intervention, the instruments were administered for a second time (to both groups) to measure the effect of intervention. Along with completing the post intervention instruments participants also addressed two questions about social support. The two questions were administered to understand if either *VeedaMom* or the SPB facilitated a sense of social support in any way. In addition to these instruments, the frequency with which the app was used by participant, and the amount of time spent using each feature of the app was tracked to analyze the use of features of the app. This data will provide an overview of the frequency with which particular features of the app are used. Since this is a pilot study, the app can be modified based on information about which features of the apps were used the most.

Study Participants

Data was collected from women with babies from one day post-delivery to three weeks into their postpartum period. Mothers were recruited from local physicians' offices for the study. Recruitment efforts included notifying physicians, perinatal nurses, and the public using posters,

information cards, and word of mouth. All data collection was completed in December 2017.

The nurses performed an initial intake assessment of mothers and informed them of my intention to speak with them about participating in the current research study. I then spoke to mothers and gave them details about the study, the voluntary nature of their participation, and asked if they were willing to participate. I obtained informed consent from the mothers who were willing to take part in the study. After obtaining informed consent, participants' demographic information was collected. The recruitment for the app took place two days a week and recruitment for the state provided resource took place on two different days to avoid cross conversation between mothers. Mothers downloaded the app (Appendix A) from the iTunes App store and were given instructions about using the app. For the WHE group, participants were encouraged to use the SPB provided to them (Appendix H).

Inclusion criteria for the *VeedaMom* participants included: (a) 18 years of age or older, (b) self-reported access to and comfort using an app on the iPhone, (c) a score of 10 or higher on the EPDS, (d) not receiving other psychotherapy, and (e) if taking medication, doing so at a stable dose for at least one month. Participants not meeting the above criteria were considered ineligible for reasons including: (a) if they did not meet PPD symptom inclusion criteria, (b) they declined to participate, (c) they recently had a change in their medication, or (d) were not able to use the app in English. Although there is no report whether primiparas (first time) mothers experience PPD more or less than subsequent pregnancies (Pugh, Hadjistavropoulos, & Fuchs, 2014), only mothers who have had their first or second child were asked to take part in this study. Having many children at home may add to the mother's stresses and complicate data analysis. A score of 10 or higher was required because scores between 10 and 13 can indicate borderline risk for PPD (Salvatore, Simpkins, Hunter, & Khandelwal, 2016)

Measurement of Constructs

The primary focus of this study is to understand if *VeedaMom* can effectively mitigate PPD and improve postpartum well-being. All the instruments are described below.

Depression

The Edinburg Postnatal Depression Scale (EPDS; Cox, Holden, & Sagovsky, 1987) consists of 10 short statements of common depressive symptoms, with four possible responses for each symptom (Appendix E). Each statement is about depressive symptoms participants are experiencing or have noticed in the past seven days and is rated on a scale of 0 to 3. The Scale has a maximum score of 30, with no subscales. After the responses are obtained the scores are totaled. Scores between 10 and 13 are borderline risk for PPD (Knights, Salvatore, Simpkins, Hunter, & Khandelwal, 2016). A score of 13 or more is at a level where there is a need to follow-up, and if question number 10 receives a score of 1, 2 or 3 an assessment of suicidal symptoms is flagged. Higher scores indicate a greater need for intervention.

The EPDS has demonstrated psychometric properties with a good reliability and validity in a similar study (Cox et al., 1987). A validation study was carried out on 84 mothers using the Research Diagnostic Criteria for depressive illness based on Goldberg's Standardized Psychiatric Interview (Goldberg, Cooper, Eastwood, Kedward, & Shepherd, 1970). The EPDS was found to have good sensitivity and specificity and is sensitive to change in the severity of depression over time. In a recent study, the EPDS was administered to new mothers in the one week to three-month postpartum period and its test retest validity and alpha coefficient was found to be .85, indicating good specificity to change in the severity of depression over time (Morales, Lorenzo, Pontes, Montenegro, & Cantilino, 2017).

Psychological Well-being

The World Health Organization Quality of Life Assessment BREF (WHOQOL-BREF) is a 26-item measure assessing quality of life in the following four domains: physical health (e.g., sleep, pain); psychological health (e.g., self-esteem, concentration), social relationships (e.g., support, personal Relationships), and environment (e.g., physical safety, financial resources) (Webster, Nicholas, Velacott, Cridland, & Fawcett, 2010). Participants respond on a 5-point Likert scale ranging from 1 (not at all) to 5 (an extreme amount). The psychological well-being part of the scale has a maximum score of 17, with higher scores indicating healthy coping skills and resilience. The computerized version of the WHOQOL-BREF has demonstrated good psychometric properties with Cronbach alpha coefficient 0.81 when the measure was used with women diagnosed with and without PPD (Webster, et al.,2010).

The WHOQOL-BREF was developed in 1988 by the World Health Organization Quality of Life Group across 15 international field centers. The self-report style questionnaire contains 26 items, each representing one facet or aspect of life. The facets are defined as those aspects of life considered to have contributed to a person's overall health. Eight questions account for social relationship, three questions account for environment, six questions account for psychological health, two questions about general health and seven questions account for physical health. This questionnaire has been used in many settings across the world for various conditions including PPD. For this study, only the psychological well-being part of the test was used. Thus, psychological well-being serves as a dependent variable.

Perceived Social Support

Social support has been described as a two-dimensional construct consisting of emotional support (concern, comfort, and encouragement); instrumental support (money, time,

and tangible assistance); and informational support where advice, education, and knowledge sharing takes place (Evans, Donelle, & Hume-Loveland, 2012; Leahy-Warren, McCarthy, & Corcoran, 2012). Lack of social support has been associated with the development of PPD (Ugarriza, 2007). Mothers with good social support network tend to have lower levels of PPD (Corrigan, Kwasky, & Groh, 2015).

To understand whether the app or state provided booklet enhanced the perception of social support in new mothers, we asked the following two survey questions post intervention with specific reference to the use of the app or the state provided booklet. These two categorical “yes” or “no” questions were asked to further gain a better understanding of network of social support during the postpartum period.

1) As a mother of a newborn, do you feel supported by your family and friends?

and

2) As a mother of a newborn, do you feel a sense of connectedness with your circle of friends and family?

Health Literacy

Institute of Medicine and National Library of Medicine defines health literacy as “the degree to which individuals have the capacity to obtain, process and understand the basic health information and services needed to make appropriate decisions” (Institute of Medicine, 2004).

Approximately 80 million Americans have low health literacy and it is associated with poor health outcomes (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011). This is, however, a crisis of proper understanding of medical information more than a problem of access to information. Patients and families who find it hard to understand health information have a difficult time following medical recommendations and are at greater risk for health problems.

These problems in turn can have a negative effect on health outcomes and the entire health care system.

Sometimes the terminology can have a detrimental effect on the understanding of health literacy. Regardless of the terms and measures used, there is an association between health literacy skills and health outcomes (Guy, Sterling, Walker, & Harrison, 2014; Thorsteinsson, Loi, & Moulynox, 2014). Lower adult literacy may lead to infrequent use of preventive services, poor understanding of one's medical conditions including mental health.

Health literacy was measured using a questionnaire from a study conducted by Thorsteinsson et al., (2014). A participant is more literate or is aware of PPD if she answers "yes" questions. A score of "no" was indicated as 0 and a score of "yes" was counted as 1. The scale goes from a minimum of 0 (all "no") to 17 (all "yes"), with each choice weighted equally.

Implementation of *VeedaMom*

Information about the study and about the *VeedaMom* app was provided to mothers before they signed the consent form. The consent form was signed only after learning about the study. The participants were made aware that their participation was voluntary and they could decide to withdraw from the study any time and still get to keep *VeedaMom* for use. *VeedaMom* was downloaded by participating mothers on their iPhone. After reading and signing the consent form, study participants were asked to participate in completing the EPDS to see their present psychological status. Based on EPDS scores, study participants were guided to either contact their physicians, contact a therapist, or contact a friend for support. For example, if the score was between 20 and 30 then they were asked to contact their health care provider and were told that the app is not a right choice. If the scores were between 10 and 20, they were recruited for the

study. The mothers were given information about an emergency plan that includes information on the nearest health care facility, health care provider's number, and suicide hot line.

Intervention

Participants were asked to download the app and get the instructions on how to use the app during the last week of their pregnancy so that they had the time to sign in to the app and download it on their phones. New mothers were able to start using this app anytime during the first few days after the birth of the baby. In *VeedaMom*, specific features are grouped into two categories to enhance psychological well-being and to mitigate feelings of depression.

VeedaMom allows the mothers to enter frequently used telephone numbers such as those of their friends, family, and health care providers. Based on the EPDS score, the app automatically provides suggestions to call specific people.

There are prompts to assess and track emotional well-being by answering the 10-item EPDS. Based on the EPDS score, the app encourages users to practice self-care. The app offers mindfulness and meditation exercises. Mindfulness refers to being present in the moment fully. The practice of mindfulness awareness and social connectivity has been shown to alleviate and prevent symptoms of depression and anxiety (Muthukrishnan, Jain, Kohli, & Batra, 2016; Vieten & Astin, 2008). The videos in the app provide psycho education based on Acceptance Commitment Therapy (ACT), Dialectical Behavioral Therapy (DBT) for mild forms of discomfort, and feelings of anxiety or depression. The timer helps customize the length of the meditation. Different genre of music in the app can be used as a relaxation medium. Mothers can post pictures to social media sites and invite their circle of contacts to see them. There also is an in-app journal where mothers can type or record voice messages to express how they are feeling or what they are experiencing in the moment. Journaling and expressing feelings have been

shown to be beneficial to emotional well-being in new mothers (McDaniel, Coyne, & Holmes, 2012). The app also includes suggestions as a form of psychological intervention that may help prevent and manage symptoms of depression via mindfulness exercises. More details on the *VeedaMom* app are provided in Appendix A.

Procedure

The study was presented to the Texas A&M University-Corpus Christi Institutional Review Board (IRB) and the IRB from Driscoll Hospital shown as Appendix J and Appendix I, respectively. Upon approval of the study, mothers in their thirty sixth week of pregnancy were recruited from local fetal and maternal clinics. PI met expectant mothers and informed them about the study. They were asked to sign the consent form and complete demographic questionnaires. Mothers were recruited on two different days of the week. One group on a particular day was offered the app. On another day, mothers were offered SPB. The WHE group was offered SPB required by the state about PPD. The SPB includes information regarding PPD and some helpful websites and phone numbers (Appendix H). The EC group, downloaded *VeedaMom* app to their iPhones. Participants in the WHE group were placed on a wait-list for three weeks before being offered a chance to download the app. The WHE group were encouraged to use SPB as a resource.

Both groups were measured for depression using the EPDS using a paper and pencil assessment before the intervention started (pre-measurement), and three weeks after pre-measurement (post measurement). EC group was asked to complete the EPDS every week in the app. Mothers were requested to use the app at least once a day at their convenience. Amazon Analytics recorded number of times the app was accessed each day. The app could be accessed as many times as needed. In order to understand if the app is of benefit to mothers, mothers were

encouraged to use the app at the least once a day so they can fully utilize the features of the app. Mothers were also encouraged to use the journaling feature as many times as possible.

Data Collection

I used a questionnaire to collect demographic information from study participants at the beginning of the study during the initial meeting with the study participant (Appendix 3). Mothers were also administered the EPDS and WHOQOL-BREF instruments after informed consent documents were signed and before the app was downloaded. All the information collected in the app will be kept confidential. The app uses a secure HIPAA (Health Insurance Portability and Accountability Act) compliant server to transmit and maintain the data. Amazon Analytics was used to record the number of times the app is accessed by study participants to use any of the features. Each feature in the app was totaled for the user, and frequency of use was calculated. At the end of three weeks, the EPDS and WHOQOL-BREF instruments was re-administered. Also, the two social support questions were administered and recorded.

Data Analysis

A mixed ANOVA design was used to compare the mean differences between groups that have been split on two factors also known as independent variables. In this study, the variables are depression and well-being. Data analysis will be able to show if there is a statistically significant difference between the depression scores and well-being scores over time in the two groups and whether the app made any noticeable differences in mitigating depression as well as improve well-being over the SPB.

App Utilization Data

Utilization metrics data included the number of users and number of times each feature was used. Each feature when used was recorded under the participant's assumed name. Only I

(and the participant) knew the real name. For example, journaling feature, which allowed the user to type or audiotape a journal entry, was checked to determine how many entries were recorded, and the entries were checked against the assumed name of the participant. Amazon Analytics provides data on the most used features of the app. Frequency data will help us fine-tune the features to improve the app.

Summary

This chapter covers the study protocol, research questions, the study's methodological design including the rationale, instrumentation (including *VeedaMom* app used as intervention), and the methods utilized for data collection and analysis.

CHAPTER IV: RESULTS

This pilot study investigated the effectiveness of an electronic application to mitigate symptoms of PPD and improve well-being (EC group) versus the effectiveness of resource material provided by the state (WHE group). The instruments used to study PPD were: (a) EPDS administered as pre- and post-interventions to depression within first week of birth and three weeks postpartum; and (b) WHOQOL administered pre- and post- to measure psychological well-being. To measure whether the app provided any type of social support, the post-questionnaire included two questions which required wither a yes or a no to both EC and WHE groups.

Data Screening and Cleaning

Raw data was organized according to participants' ID numbers and transferred to an SPSS data spreadsheet. Data entry was checked against any errors and for missing values. There were two outliers: one in the depression data and one in well-being data. They were included in the analysis since the studentized residuals was under 3 (Miller, 1991). Amazon Analytics data was downloaded to a Microsoft Excel spreadsheet to examine the features of the app that were most used.

Chi square analyses were performed on the demographic data to examine if the groups were equivalent pre-intervention. As shown in Table 1 the groups are equivalent and not different with respect to the demographic variables, namely race ($p = 0.15$), marital status ($p = 0.19$), job status ($p = 0.49$), and support system ($p = 0.14$).

Descriptive Data

This section contains a descriptive summary of the sample characteristics and demographics of the participants in the study. The potential population of the study consisted of

62 women from one fetal maternal clinic in the coastal bend area of Texas and two additional primary care clinics in South Texas. This is a pilot study with a sample size of 43 participants: 23 women who downloaded the app and completed the study by providing pre-and post-survey. These women are designated as the EC group. The remaining 20 women used the state provided resource and completed both the pre- and- post surveys. Table 2 shows descriptive statistics of the variables used in the study. These women are designated as the WHE group. In addition, both groups were also asked to submit their answers to two “yes” or “no” questions to understand if the app or the state resource helped them to improve their perception of social support.

Appendix G provides the process flowchart for the study. The flowchart shows the steps that lead to the selection of the final sample used for data analysis (Schulz, Altman, & Moher, 2010). The recruitment took place on different days for both groups. The summary of participant demographics presented below details the characteristics of the app group (EC) and the state provided resource group (WHE).

Demographics for EC and WHE

Participant Recruitment

The sample represents the clinical population in coastal bend city of Texas (see Appendix G) and two clinics in a South Texas city. Participants were solicited on different days of the week for EC and WHE. Mothers in EC group were given an opportunity to download the app during the last week of their pregnancy and were asked to start using the app few days after the birth of the baby. Mothers in the WHE group were also given the SPB during their last week of pregnancy and asked to refer to the book as a resource after the birth of the baby.

Table 1*Demographics*

| Variable | Group 1 | | Group 2 | | Total sample | | χ^2 | <i>p</i> |
|-----------------------------|--------------|-------|---------------|----|--------------|------|-----------------|----------|
| | EC n = 23 | | WHE n = 20 | | 43 | | | |
| | n | % | n | % | n | % | | |
| Mean age | 29.10 | | 27.75 | | | | | |
| Range (years) | (18-41) | | (19-43) | | | | | |
| Marital status | | | | | | | | |
| Married/partner | 10 | 43.45 | 5 | 25 | 15 | 34.8 | $\chi^2 = 1.68$ | |
| Single | 5 | 21.73 | 7 | 35 | 12 | 27.5 | $p = 0.194$ | |
| Job status | | | | | | | | |
| Fulltime | 9 | 39.13 | 4 | 20 | 13 | 30.2 | | |
| Student | 3 | 13.04 | 3 | 15 | 6 | 13.9 | $\chi^2 = 2.39$ | |
| Part-time | 4 | 17.39 | 3 | 15 | 7 | 16.2 | $p = 0.494$ | |
| None | 7 | 30.43 | 10 | 50 | 17 | 39.2 | | |
| Race | | | | | | | | |
| Hispanics | 6 | 26.08 | 7 | 35 | 13 | 23.2 | | |
| Asian | 7 | 30.04 | 1 | 5 | 8 | 18 | $\chi^2 = 5.39$ | |
| White | 9 | 39.13 | 9 | 45 | 18 | 41 | $p = 0.145$ | |
| Other | 1 | 4.34 | 3 | 15 | 3 | 6.9 | | |
| Support system | | | | | | | | |
| Spouse/partner or mother | 12 | 52 | 9 | 39 | 21 | 91 | $\chi^2 = 3.88$ | |
| Spouse & mother | 8 | 35 | 11 | 55 | 19 | 90 | $p = 0.143$ | |
| Spouse, mother&family | 5 | 21 | 14 | 70 | 19 | 91 | | |

Participants were between 18–43 years of age and had never participated in a postpartum support intervention prior to the current study. The demographics of the participants are provided in Table 1. There were 23 participants in the EC group (users of the app) and 20 participants in WHE group who completed the study. These participants also completed pre- and post-intervention surveys and answered the questions about social support. The mean age of the participants in EC group was 29.1 years with a *SD* of 4.72. The youngest participant was 18 and the oldest was 41 years old. The mean age of the participants in WHE group was 27.75 with *SD* of 7.35. The youngest participant was 19 and the oldest was 43 years of age. These participants completed both pre-and post-intervention surveys and answered questions about social support.

Data Analysis

The descriptive statistics of the variables (depression and well-being) are summarized in Table 2. The statistical analysis of each of these variables will be presented separately, and in detail, below. I will first describe depression and then well-being.

Table 2

Descriptive Statistics of the variables in the study

| Variable | | Mean | SD | Range |
|------------|----------|-------|------|-------------|
| Depression | EC post | 12.17 | 2.32 | 11.16-13.18 |
| | EC pre | 14.17 | 2.72 | 12.99-15.35 |
| | WHE post | 13.05 | 2.72 | 11.77-14.32 |
| | WHE pre | 13.55 | 2.98 | 12.15-14.94 |
| Well-being | EC post | 18.13 | 1.75 | 17.38-18.88 |
| | EC pre | 17.87 | 1.74 | 17.12-18.62 |
| | WHE post | 17.90 | 1.71 | 17.10-18.70 |
| | WHE pre | 16.41 | 2.64 | 15.16-17.74 |

Depression

The EPDS was administered when the app was first given to mothers in their last two weeks of pregnancy. This score was considered as the first-time point, pre-intervention. They were asked to start using the app and all its features for three weeks, beginning a few days after delivery. Subsequent to the three-week period the second questionnaire was administered.

Research Question 1:

Is there a statistically significant difference in depressing symptom reduction between postpartum women using the *VeedaMom* app and those using the state-provided resource booklet pre- and post- intervention?

Before applying the ANOVA model, data was scanned for outliers using Box-and-whisker plots. There was one outlier. It was included in the analysis because the studentized residual standard deviation was 2.32 which is less than 3 (Miller, 1991). The assumption of normality was met for the depression scores collected at pre- and at post-intervention. The Shapiro-Wilk's test was run for all combinations of between-subjects factor (group) and within-subjects factor (time). The dependent variable (depression) is normally distributed as assessed visually from the Normal Q-Q plot, and from Shapiro-Wilk's test (at $p > 0.05$) with $p = 0.16$ and $p = 0.58$ (pre- and post-intervention, respectively, for EC group), and $p = 0.05$ and $p = 0.11$ (pre- and post-intervention, respectively, for WHE group). To assess the equality of variance for depression for the two groups, Levene's test of homogeneity of variance was used. Variance for the groups were not statistically different ($p > 0.05$) with $p = 0.75$ and $p = 0.25$ for pre- and post-intervention, respectively. To test equality of the two covariance matrices (EC and WHE), Box's M test was used. Covariance matrices were found to be not statistically different with $p = 0.57$.

The estimates of the mean for the variable depression (Table 2) show effect of time. For EC group, there is a reduction in mean EPDS scores from pre- treatment score of 14.17 to post-treatment score of 12.17 (n = 23). Note that a reduction in EPDS score indicates a reduction in post-partum depression. For WHE group, there is a reduction in mean EPDS scores from pre-intervention score of 13.55 to post intervention score of 13.05 (n = 20). Figure 1A depicts the mean values for depression scores across groups and time.

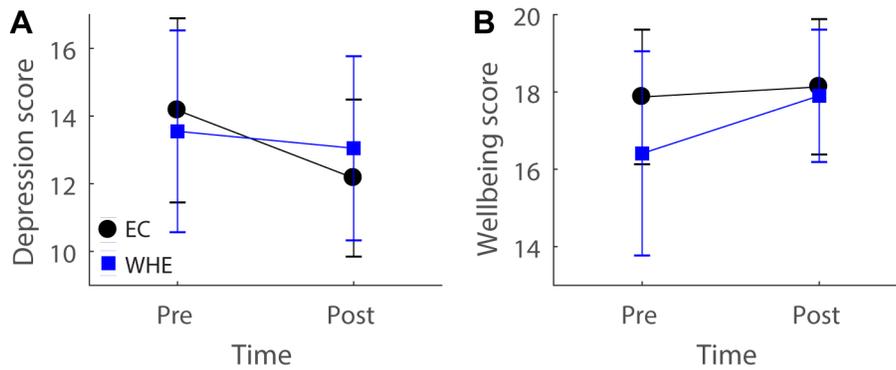


Figure 1 Marginal means for EC group (app users, filled black circles) and WHOQOL group (state provided resource users, filled blue squares): A) depression, pre- and post-intervention (abscissa), EPDS score (ordinate), and B) well-being, pre- and post-intervention (abscissa), WHOQOL score (ordinate). Error bars are one standard deviation.

Table 3

Tests of Within-Subjects Effects

Measure: Depression

| Source | time | Type III Sum of Squares | df | Mean Square | F | Sig. |
|--------------|--------|-------------------------------|----|-------------|--------|------|
| time | Linear | 33.430 | 1 | 33.430 | 20.306 | .000 |
| time * group | Linear | 12.035 | 1 | 12.035 | 7.310 | .010 |
| Error(time) | Linear | 67.500 | 41 | 1.646 | | |

In a test of within-subjects contrast (Table 3, row marked as "time"), there is a statistically significant difference ($p < .05$) in the depression scores at pre-and post-intervention times ($F(1, 41) = 20.31$, with $p < 0.05$). In other words, with time, the intervention was beneficial for both groups.

Table 4

Tests of Between-Subjects Effects

Measure: Depression

Transformed variable: Average

| Source | Type III Sum of Squares | df | Mean Square | F | Sig. |
|-----------|-------------------------|----|-------------|---------|------|
| Intercept | 14995.31 | 1 | 14995.31 | 1171.04 | .000 |
| group | .340 | 1 | .340 | .027 | .871 |
| Error | 525.00 | 41 | 12.805 | | |

There is no statistically significant between-subjects difference, i.e., between the EC and WHE groups (Table 4, row marked "group") $F(1, 41) = 0.027$, $p = 0.87$.

The marginal means of scores for depression (Table 2, and Figure 1A) support the idea that there is a main effect of time (as shown in Table 3) although there is no main effect of group (Table 4).

There was a statistically significant interaction between the intervention and time (time*group) on EPDS depression score $F(1, 41) = 7.31$, $p = 0.01$; Table 3, row marked time*group). This indicates that although there is no main effect of group, there are different effects of the interventions EC and WHE on mean depression scores over time. Since there was a

two-way interaction effect, to investigate the significant interaction, four follow-up tests were conducted, and a Bonferroni correction was applied with $p < 0.05$ to avoid the risk of inflating the Type 2 error. A paired sample t-test was performed to compare the means between pre- and post-intervention depression scores. An independent t -test comparing the means between EC and WHE group showed that there was no significant difference between EC and WHE groups for pre-intervention ($t(41) = 0.72, p = 0.47$, two-tailed), or post-intervention ($t(41) = 1.13, p = 0.26$, two-tailed). There was a significant difference between pre- and post-intervention depression scores for EC group ($t(22) = 4.74, p < 0.05$, two-tailed), but no significant difference for the WHE group ($t(19) = 1.45, p = 0.16$, two-tailed).

Thus, there is a main effect of time with a reduction in depression scores for both groups, and there is a significant effect in the difference between treatments or interaction between intervention time and treatment. Further, an analysis of interactions showed that depression scores for EC improved significantly over time whereas scores for WHE did not.

Well-being

The second variable in the research was psychological well-being. The effectiveness of *VeedaMom* app on psychological well-being (EC group) as measured by the scores of WHOQOL instrument was compared with that of SPB (WHE group). The initial WHOQOL was administered during the signing up of the app and the same instrument was administered three weeks after the intervention. The goal is to check if there is any difference between the pre-and post-intervention scores on well-being among women who used the app versus those who used SPB.

Research Question 2:

Is there a statistically significant difference in perceived psychological well-being between postpartum women using the *VeedaMom* app and those using the state-provided resource booklet pre- and post- intervention?

Before applying the ANOVA model, data was scanned for outliers using Box-and-whisker plots. There was one outlier. It was included in the analysis because the studentized residual standard deviation was 2.52 which is less than 3 (Miller, 1991). The assumption of normality was met for the well-being scores collected at pre- and at post-intervention. The Shapiro-Wilk's test was run for all combinations of between-subjects factor (group) and within-subjects factor (time). The dependent variable (well-being) is normally distributed as assessed visually from the Normal Q-Q plot, and from Shapiro-Wilk's test (at $p > 0.05$) with $p = 0.14$ and $p = 0.17$ (pre- and post-intervention, respectively, for EC group), and $p = 0.27$ and $p = 0.7$ (pre- and post-intervention, respectively, for WHE group). To assess the equality of variance for depression for the two groups, Levene's test of homogeneity of variance was used. Variance for the groups were not statistically different ($p > 0.05$) with $p = 0.23$ and $p = 0.88$ for pre- and post-intervention, respectively. To test equality of the two covariance matrices (EC and WHE), Box's test was used. Covariance matrices were found to be not statistically different with $p = 0.18$.

The estimates of the mean for the variable well-being (Table 2) show effect of time. For EC group, there is an increase in mean WHOQOL scores from pre- treatment score of 17.87 to post-treatment score of 18.13 ($n = 23$). Note that an increase in the WHOQOL score is an improvement in the sense of well-being. For WHE group, there is an increase in mean WHOQOL scores from pre-intervention score of 16.41 to post-intervention score of 17.9 ($n = 20$). Figure 1B depicts the mean values for WHOQOL scores across groups and time.

Table 5*Tests of Within-Subjects Effects*

Measure: well-being

| Source | time | Type III Sum of Squares | df | Mean Square | F | Sig. |
|--------------|--------|-------------------------------|----|-------------|-------|------|
| time | | 16.585 | 1 | 16.585 | 9.224 | .004 |
| time * Group | Linear | 8.213 | 1 | 8.213 | 4.568 | .039 |
| Error(time) | Linear | 73.717 | 41 | 1.798 | | |

In a test of within-subjects contrast (Table 5, row marked “time”) there is a statistically significant difference in the well-being scores at pre-and post-intervention times, ($F(1, 41) = 9.22$, with $p < 0.05$). In other words, with time the intervention was beneficial for both groups.

Table 6*Tests of Between-Subjects Effects*

Measure: well-being

Transformed Variable: Average

| Source | Type III Sum of Squares | df | Mean Square | F | Sig. |
|-----------|----------------------------|----|-------------|----------|------|
| Intercept | 26434.435 | 1 | 26434.435 | 4368.448 | .000 |
| Group | 15.458 | 1 | 15.458 | 2.555 | .118 |
| Error | 248.100 | 41 | 6.051 | | |

There is no statistically significant between-subjects difference, i.e., between the EC and WHE groups (Table 6, row marked “group”) ($F(1, 41) = 2.55$, $p = 0.12$).

The marginal means of scores for well-being (Table 2, and Figure 1B) support the idea that there is a main effect of time (as shown in Table 5) although there is no main effect of group (Table 6). When the interaction between time and group was examined (Table 5), there was a statistically significant interaction (time*group) on WHOQOL well-being score ($F(1, 41) =$

4.57, $p = 0.04$). These results suggest that although there is no main effect of group, there are different effects of the interventions EC and WHE on mean well-being scores over time. As with the analysis of depression scores, we further analyzed the two-way interaction effect on well-being. Four follow-up tests were conducted and a Bonferroni correction was applied with $p < 0.013$ to avoid the risk of inflating the Type 2 error. A paired-sample t-test was performed to compare the means between pre- and post-intervention well-being scores. There was no significant difference between EC and WHE groups for pre-intervention ($t(41) = 2.11, p = 0.04$), or post-intervention ($t(41) = 0.43, p = 0.66$). There was a significant difference between pre- and post-intervention well-being scores for WHE group ($t(19) = 3.57, p < 0.05$ two-tailed), but no significant difference for the EC group ($t(22) = 0.65, p = 0.52$).

Thus, there is a main effect of time with an increase in well-being scores for both groups, and there was a significant effect in the difference between treatments or interaction between intervention time and treatment. Further, an analysis of interactions showed that well-being scores for WHE improved significantly over time whereas scores for EC did not.

Effect Size for Depression and Well-being

Effect size tells us how much one group differs from another. It quantifies the size of associations or the size of differences between the groups. This information is not available from the p -value of tests of significance. Therefore, what is needed is not just a system of hypothesis testing but also a system for telling us precisely how large the effects we see in our data really are. Hedges g is a good measure of effect size when the sample size is below 50 and not equal between groups. Hedge's g is also used to measure an outcome associated with an intervention (Watson, Lenz, Schmit, & Schmit, 2016) and is interpreted with a recommended cut-off for

small effect size as 0.2, medium effect size as 0.5 and large effect size as 0.8. Hedges g effect size are shown below.

Table 7

Hedge’s g Effect Size and Confidence Interval

| Variable | | Mean scores | Confidence Interval | Hedges g | Effect Size |
|------------|-----|-------------|---------------------|----------|-------------|
| Depression | EC | 12.17 | 0.047-1.508 | 0.8 | Large |
| | WHE | 14.17 | -0.0712-1.056 | 0.17 | Small |
| Well-being | EC | 18.13 | -.0646 - 0.349 | 0.15 | Small |
| | WHE | 17.87 | -1.35 - 0.031 | 0.66 | Medium |

Perceived Social Support

Research Question 3:

Is there a statistically significant difference in perceived social support between postpartum women using the *VeedaMom* App and those using the state provided resource booklet post intervention?

Figure 2 shows the data in response to the two post-survey questions on their perception of social support on using either the app (EC group) or the state provided booklet (WHE group). These questions were posed verbally, and participants responded with a single “yes” or “no” to both questions or did not respond (N/R). In the EC group 12 (out of 23) participants answered “yes” (52%), 4 answered “no” (17%), and 7 did not respond (31%). In the WHE group 2 (out of 20) answered “yes” (10%), 9 answered “no” (45%), and 9 did not respond (45%). Thus, only 10% of the women who used the state resource felt that it gave them an enhanced sense of social support, whereas 52% of the EC group felt that the app enhanced their perception of social

support. Forty five percent of WHE group felt that the state provided booklet did not help in their perception of social support, whereas only 17% of EC group felt that the same when using the app.

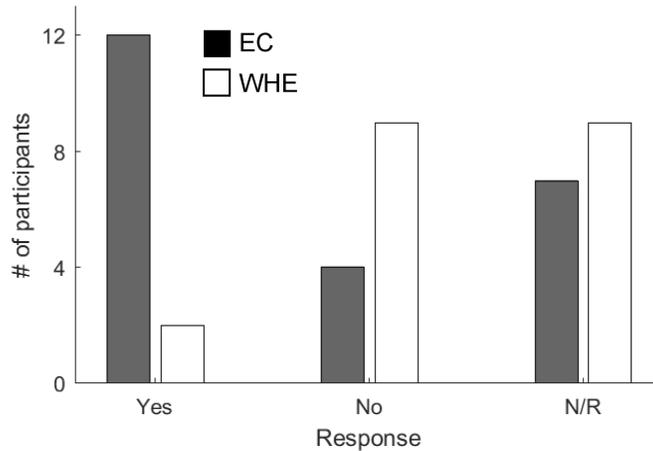


Figure 2 Perceived social support. Participant's responses to post-intervention survey. Participants of the EC group (users of app, black bars) were asked about their perception of social support or social connectedness. Similarly, with participants from the WHE group (users of state provided resources, white bars). Questions were "yes" or "no". Some users did not respond (N/R). Ordinate is the number of users for each group (EC, n = 23; WHE, n = 20).

Health Literacy

Research Question 4:

Is there a significant difference in mean scores for Health literacy between the group using *VeedaMom* app and those using the state provided resource booklet?

Health literacy was tested in both groups EC and WHE by asking questions related to postpartum depression. A questionnaire was used from a study conducted by Thorsteinsson et al., (2014) among 520 women in a community setting in Australia. A participant is more literate or is aware of PPD if she answers "yes" questions. A score of "no" was indicated as 0 and a score of "yes"

was counted as 1. The scale goes from a minimum of 0 (all “no”) to 17 (all “yes”), with each choice weighted equally.

The number of times a participant answered “yes” was counted and a frequency histogram was constructed separately for each group. Figure 3 depicts the frequency histograms for the two groups (WHE: left panel, EC: right panel). The means number of “yes” responses are 5.69 (WHE) and 5.75 (EC).

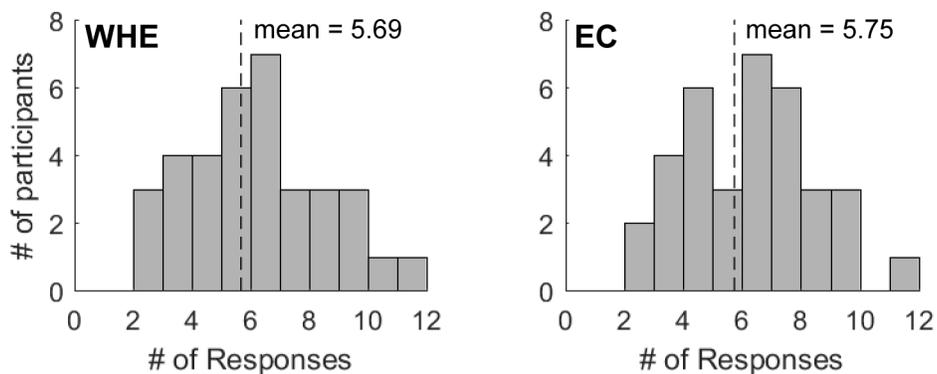


Figure 3 Health literacy survey. Histogram of "yes" responses to questions about PPD for WHE group (left panel) and EC group (right panel). Total number of questions was 17. Number of "yes" (abscissa) and frequency of participants (ordinate). The distributions had similar means (WHE: 5.69 and EC: 5.75 "yes" responses, respectively).

Amazon Analytics

Research Question 5:

Is there a significant difference among the usage of certain of features provided in the app that can be examined in the Analytics data?

Amazon Analytics was used to track the number of users over a period of 14 weeks. Although the study design was only for a period of three weeks mothers were using the app past the study period. All the app users (EC group) had to sign in to download the app from the

iTunes store, and the Amazon server keeps track of how many signed in and their sign-in names. Analytics also keeps track of how many different features of the app are used. Even though only 23 participants were recruited for the EC group, over 70 women used the app over a period of 14 weeks since the Analytics were implemented. For this larger group, on average there were 22.18 daily users with a SD of 2.54. Every week 4.5 new users signed-up, with maximum of 10 new users. The data shows an average of 2.47 accesses (use/day) with SD of 1.6 per day. On some days usage was high (as many as 8 accesses per day across all users) and on some it was low (1 access per day across all users). Unfortunately, the server that collected the data had a glitch and stopped functioning after 14 weeks, preventing data collection in the final few weeks of this study. The app has some features that proved popular. For instance, participants were encouraged to take the EPDS test every week. They received scores between 0 and 30. If they received scores between 0 and 10 they were encouraged to keep doing whatever they were doing. If their score was between 11 and 20 the app pops-up an action list which provides suggestions or prompts for alleviating the mood. These include calling a friend, listening to music, reading a book, performing simple yoga poses, meditation, etc. Participants used the action list on average 18.3 times per week. Another popular feature was a timer feature which allowed a participant to time meditation, or any other relaxing activity. This meditation timer was used on average 7.8 times per week

Summary

In this chapter, statistical analysis was conducted on the dependent variables depression and well-being. Data about social support, Amazon Analytics, and health literacy are shown in graph format. The next chapter discusses the results obtained and how they are interpreted in the

context of the app, implications for practice, the ways in which app can promote social change and recommendations for future research.

CHAPTER V: DISCUSSION

The purpose of this study was to examine, based on the psychosocial model, the reduction in PPD of 43 women who were given either the *VeedaMom* app or state resource for use over three weeks, post-partum. The other research question was to study if either the app or the state provided resource have any effect on a mother's psychological well-being during the postpartum period. In addition, the research also wanted to gain insight into the extent of social support available to the participants. All the questions were based on the biopsychosocial framework. To my knowledge, this study is the first attempt to examine if there is a difference between a state provided resource to combat PPD and a phone app (*VeedaMom*, a wellness application) that is specialized toward mitigating PPD.

Currently 12 states, including the state of Texas, provide some form of information about peripartum wellness during the first trimester checkup (at six weeks of pregnancy). Women in the state of Texas are also required to be provided with a resource list about access to maternal health care, postpartum health issues including postpartum depression, and caring for the newborn, before being discharged from the hospital after delivery. The state of Texas also provides useful information about maternal health care through its health website as "Maternal & Child Health (MCH) - Information for Parents of Newborn Children" (n.d.). However, 86% of the participants and over 90% of women who were screened for eligibility for the study were not aware of the information that was provided to them. This information becomes critical for mothers who may be experiencing symptoms of PPD. I adapted the information contained in the resource list and the state of Texas website to create a customized resource list which I call the "state provided booklet" or SPB. The intention of providing SPB was to help women access the resource whenever they needed it, rather than going through the state of Texas health website.

The SPB was provided to a group of expectant mothers who form the participant group called WHE.

The growth of internet technologies, including eHealth (electronic health) and *mHealth* (mobile health), holds the promise of health care delivery that is both speedy and cost-effective. National Institute of Women's health website provides information about postpartum related mental health issues "postpartum depression" (n.d.). However, there are few mobile apps that are available for use during peripartum and one for postpartum period (Mehralizade et al., 2017). The postpartum app that is available is created as part of consortium to find biological reasons for postpartum depression "PPDACT" (n.d.) by collecting saliva from postpartum women. In addition, the app directs mothers to health care providers in the area. Websites provide useful information although they cannot be individualized as with a phone app. This is particularly important for obtaining social support from family, friends, and caregivers, on an immediate basis. To fill this important gap, I and another student created a mobile application that functions as a "wellness companion", specifically providing information and resources (through app features) for alleviating postpartum depression. This app is called *VeedaMom* and was provided to a group of expectant mothers who form the participant group called EC.

This study provides some promising data on treating PPD and well-being using a mobile phone application. The data also gives some insight in to the usefulness of the app and statistical information on its efficacy. PPD is addressed in Research Question 1 where I showed that both groups EC and WHE benefitted from intervention over time, but the EC group showed a larger effect size (Hedges g , 0.8) than the WHE group (Hedges g , 0.17). The mixed ANOVA test showed that there is an interaction between group and time (time*group) indicating that not only is intervention better in mitigating depression but also the modality that is used. That is, the

VeedaMom app results in greater reduction in EPDS depression scores in comparison with the reduction achieved by use of the state provided resource.

The SPB is a useful resource because it compiles state provided information in one place (as a 3-page booklet) and can be readily referred to. Thus, there is a reduction in depression scores even though the effect size is small. One disadvantage of the SPB is that the information is "static", i.e., it is not interactive like a mobile app, and this may reduce the motivation needed to go through the material when needed. On the other hand, women who had the app were able to select and access features of the app that they considered beneficial any time they felt like using them. Some features such as the use of the timer, viewing videos, and action list were particularly popular. Although I cannot show direct correlation between how each participant used some features of the app and their decrease in EPDS scores, app usage data from Amazon Analytics (Chapter 3) provides the relative daily usage (number of times some feature of the app was used per day) and provides some broad statistics on the use of app. The interactivity of the app, the ability to use it to connect with friends and family (from within the app) and select features that are useful, most likely makes it preferable to more conventional printed material. We also paid special emphasis to the overall look and appeal of the user interface so that new mothers are encouraged to try it out and hence explore the features that may be useful to them. In this sense, it is highly personalized and targeted to the individual. Preliminary feedback suggests that the user interface was particularly appealing to pregnant women.

Well-being in EC and WHE groups was addressed in Research Question 2. The definition of well-being varies from scale to scale. The scale that was used here was taken from the World Health Organization (WHOQOL, Appendix D). Only the psychological domain of this scale was used. This addresses many questions about body image, meaning of life, and enjoyment of life.

In general, it addresses participants understanding of quality of life and is culturally sensitive. This scale has been validated in many countries and is hence well-established. I examined the well-being scores obtained from the WHOQOL survey. Both EC and WHE groups show a statistically significant improvement in well-being over time (from pre-intervention to post-intervention), with WHE group demonstrating medium effect size (Hedges $g = 0.66$) and the EC group showing smaller effect size (0.14). That is, use of the SPB resource provides greater improvement in well-being scores than use of the mobile app. There could be many reasons for this result (the opposite was observed with depression scores). The demographics of the participants (Table 1) provides information about the participant's support system. Some mothers have only a single support system, either mother or spouse/partner (9% of WHE participants and 12% of EC participants). Some mothers indicated multiple levels of support from mother, family, spouse/partner and extended family (70% of WHE participants and 21% of EC participants). Overall, the WHE group had access to multiple levels of support over the EC group. Thus, the support system may have acted as a confounding variable in increasing the perception of well-being and contributed to an enhanced sense of well-being. The results also support Engel's biopsychosocial model by affirming postpartum as a biopsychosocial phenomenon.

Both social support and social networks are known to increase postpartum experience by reducing depression (Surkan et al., 2006). However, despite multiple levels of support the WHE group did not demonstrate as large a reduction in depression scores as the EC group. There are two possible explanations for these results: (a) while social support is important, it is not the only contributor to a reduction in depression scores, and (b) it is likely that the app (more than SPB) contributes to greater reduction in depression scores even though most participants in the group did not have access to multiple levels of support like the WHE group.

The role of perceived social support on WHE and EC groups was examined in Research Question 3. Here I examined the perception of social support after using the app versus using SPB. The two questions related to this question were sent along with post intervention instruments. Figure 2 shows that many participants in both groups did not respond (45% of WHE and 30% of EC participants). As expected, most from the WHE group said they found no benefit from the SPB. The SPB has suggestions for improving social support but it does not help in facilitating social support. It is up to the mothers to act on those suggestions. Our results show that the WHE had multiple levels of support accounting for better well-being scores. Thus, it is expected that the WHE group did not see the SPB as a direct contributor to an enhanced feeling of social support (10% of WHE participants had a better feeling of social support post-intervention). On the other hand, the app provides greater social connectivity and hence, an increased sense of social support (52% of EC participants had a better feeling of social support post-intervention). The relative lack of multiple levels of support for the EC group (over the WHE group) may have acted as a confounder. EC group may have relied more on the app for social support and hence reported enhanced perception of social support. Another confound is that the EC group is self-selected for app users (i.e., people who rely on the phone for social connectivity). These participants may be more connected socially using social media. Hence, an app that increases social connectivity may lead to the perception of enhanced social support among participants of the EC group.

The app also facilitates many forms of connectivity. The app suggests entering names of friends and families to reach out if needed. It also provides an action list if the weekly EPDS score is between 10 and 20. A few of the activities suggested in the action list include calling a friend and planning some activity such as a walk. The goal of the action list is to provide some

suggestions and to have quick access to some mood elevating activities. Perceived social support is known to alleviate loneliness and increase a sense of community (Cheng, Huang, Chien, Cheng, & Chen, 2016). Thus, these features allow mothers to take charge of self-care based on guided suggestions.

Data from Amazon Analytics showed that 70 women signed up to use the app and used some features regularly even though only 23 women were part of the study. When considering the larger group of 70 app users we noticed that on average nearly one-third (about 22 users) used the app on a given day ($SD = 2.54$). Over the 14 weeks that we collected analytics there was wide variation in the usage by EC participants, with average daily usage ranging from 1 to 8 uses per day. On average about 2.47 accesses were made per day ($SD = 1.6$) for the 23 participants in this study. Of relevance here is that the analytics suggests that the most frequently used features were videos, timer for meditation, and action list. Such data (on which features are used most frequently or infrequently or not at all) allow for modification of the app, keeping it relevant to maternal care and new mothers. The availability of analytics makes an app attractive to counselors as it can allow remote monitoring of self-care, compliance, etc. It can also provide counselors with valuable information daily about the mental health status of the user. Given the tremendous burden on our health care system, an app can extend care outside a clinical setting while allowing for close monitoring through usage analytics. With word of mouth and referrals more women will make use of the app. Making the app available to health care providers can make the app more accessible to postpartum mothers and benefit more women. The *VeedaMom* app has promise outside of a clinical setting. It allows a clinician to access a wealth of data remotely, at low cost, and use the information for alleviating PPD. We have barely scratched the surface with this app, and more work remains to be done in terms of features and analytics.

Limitations of the Study

There were many limitations of the study. This is a pilot study with a sample size of 23 women (EC group, users of *VeedaMom* app) and 20 women (WHE group, users of state provided resource or SPB). Follow up studies are needed with a larger sample size. The goal of the *VeedaMom* app is to be a wellness companion and help mothers cope with depression and increase their sense of well-being. As mentioned earlier, it is a wellness companion not intended to replace medical intervention. This study had only two-time points and the app intervention is based on EPDS and WHOQOL scores. Thus, in order to draw stronger conclusions, we must have a larger sample size, there should be more time points, we must use different postpartum instruments to test the validity of the scores, and finally we must include post-intervention follow up. Further, the development of the app must be guided by addressing the needs of the mother and yet make available the appropriate analytics to a counselor for appropriate intervention as and when needed. Admittedly more needs to be done but as a pilot program, this study this gives ideas for future development.

One of the main concerns about the study was attrition. More mothers have used the app, but many have not reported their EPDS scores. Due to a glitch in the software Amazon Analytics did not notify the researchers when participants did not submit their weekly EPDS (the feature was included in the app algorithm but failed to function). We have only 23 mothers who reported pre-and post-data. Numerous factors may contribute to the attrition and the participant's inability to report. Participants may be using *VeedaMom* for a few days, but the app may not be their priority given their new situation as they are busy with the baby or they may lack interest in using the app. Participants may also have lacked motivation to meet again to fill out the instruments as their new responsibilities make their schedule more unpredictable or the time is

not available. A combination of behavioral and psychological changes can prevent participants from completing the study even though the app is readily accessible. Future work should design the study around these challenges.

Currently *VeedaMom* is only available on the Apple iPhone platform. There were two problems in using this platform. First, I was not able to include women who owned Android smart phones. Second, only participants who have iPhone with a data plan can use the app. Many women who wanted to participate in the study did not have iPhones and the ones who had iPhone had very limited data allocation to download the app. This may indicate a low socioeconomic status of patient population as the iPhone and a data plan can be expensive. Finally, many potential participants had old phones that cannot run the app, or had phones with limited data space, or were on a monthly contract and were not able to pay for data usage. This is a pilot study, so these limitations will help refine the model for use across several mobile platforms and thereby cover a larger population. Finally, *VeedaMom* is not equipped to measure any biological factors including the role of hormonal changes in PPD. Future apps may be able to incorporate some way of linking the data from medical facilities to measure their cortisol, estrogen and progesterone levels thereby closing the loop between patient, physician, and counselor.

One of the disadvantages of using an app is that there is no face-to-face contact nor any direct therapeutic relationship. However, this is a problem that almost all *mHealth* applications encounter. Perhaps more research and development will lead to some enhancement in face-to-face contact with the counselor. There is also no control on the amount of time that mother's use the app. Usage may be too little, or sufficient but not lead to improvements in well-being. For example, mothers can develop familiarity with the app and not actually take care of themselves

by excessively socializing with people. Educational background, culture and social economic status can all make a difference if the results are to be generalized to a larger population. The present study is a pilot study in a few cities across Texas which may represent a small population with a specific cultural and socioeconomic status.

Delivery of support through electronic application to mothers who are in their postpartum phase is still being tested. It is also beneficial to study the usage of these apps in different cultures especially if women feel stigmatized by PPD. Future research will need to use different centers to duplicate the current study and be applied to other groups in the general population. More research will also be needed to determine which groups within a population are comfortable with using the app.

Theoretical Implications

According to Engel (2012), the biopsychosocial model theory includes evaluating the biological, psychological, and social factors that are involved in postpartum wellness (Engel, 2012). The study's outcome shows that the model was significant for understanding PPD reduction, in terms of EPDS scores. Engel's biopsychosocial model provided an approach that clarifies the influence of having an app to support postpartum wellness. In this study, the app *VeedaMom* was able to provide support to mitigate depression, increase well-being moderately and provide a sense of social support. As mentioned above multiple support system among WHE group has contributed to a higher score on well-being. Although, the sample size for the app group was only 23, more people have used the app (70 as shown by Amazon Analytics). Along with the depression, well-being and perceived social support data the outcomes can be broadly seen as supporting Engel's model.

Practical Implications

The present study has practical implications for the use of application-based interventions to mitigate depression, increase well-being, and foster a sense of social support to enhance postpartum experience. Empirical evidence was provided for the efficacy of this kind of intervention in decreasing depression scores as measured by the EPDS. Further empirical support on improvements in wellness and interest in the app, provides additional motivation for mental health practitioners to provide access to these types of *mHealth* interventions as part of wellness support for mothers.

The study also has policy implications for health departments. It can be used to provide support for insurance coverage for app-based intervention in maternal depression. States not only have to find better ways of disseminating information to mothers before they leave the hospitals, but also support *mHealth* technology to reduce the long-term costs of treatment for other mental health issues in mothers and children that may result from untreated PPD. This will save costs in the long run.

Implications for Counselor Educators

There is a big gap in the counseling literature about treating postpartum depression. Counselors need training to develop skills necessary to provide effective counseling among pregnant and postpartum women. A search for articles in counseling journals, covering the last 10 years, provided one article about best practice guidelines for diagnosis and treatment for prenatal depression (Choate & Gintner, 2011). Not only training is necessary but also advocacy on behalf of the client if a mother prefers counseling as a first resource rather than only medication. This is important because there are still concerns about medications crossing the placenta or breastmilk. The use of serotonergic antidepressant agents and other drugs during pregnancy and breastfeeding can change brain development, and where the behavioral

consequences may depend on the stage of development: i.e., prenatal, or early and late postnatal. (Reebye, Ng, Misri, & Stikarovska, 2012). Pregnant women clients need support during postpartum period especially if they were seeking counseling. PPD diagnosis is more difficult because clients may not find time to come to seek help or may assume it is just "postpartum blues" which usually goes away. In those cases, EPDS screening can be used as tool to identify depression. Counselor educators can teach masters level students about looking for any signs of depression among their pregnant and postpartum clients. Counselor educators can encourage counselors to advocate for mental health screening and teach skills to make sure they are aware of signs of depression among women of child bearing years if they have recently delivered.

Also adding a module about women and their mental well-being in family therapy classes including information about peri and postpartum depression can be very beneficial for counselors in training. There is not enough literature about differentiating between post-partum blues, postpartum depression and psychosis. Providing research funding and opportunities in women's mental health during child rearing years can not only help mothers but children as well. Counselors in training will be able to provide enough support by following best practice guidelines for diagnosis and treatment (Choate & Gintner, 2011).

Implications for Social Change

PPD is an important public health interest that has the possibility to result in negative consequences for women and family (McNeill, Lynn, & Alderdice, 2012) Besides the 10% to 13% of women identified having PPD, many women who experience symptoms of depression during pregnancy and during the postpartum period are embarrassed by their feelings or uninformed that their symptoms may be associated to PPD. Therefore, these women may not be properly diagnosed (Pugh et al., 2014).

Recognizing the factors that are helpful to moderate PPD could reduce attachment issues with children and help women raise well-adjusted children (Raskin, Easterbrooks, Lamoreau, Kotake, & Goldberg, 2016). In this sense the EPDS is a powerful tool. The utilization of the EPDS is important because it can assist in monitoring the symptoms of depression. Implementing the EPDS will help in identifying depressive symptoms early and therefore can assist in reducing the incidence of postpartum depression. A mobile app such as *VeedaMom* incorporates the EPDS test and can be a useful tool in assessing and monitoring PPD.

The app appears to have promoted some healthy behaviors as seen by Amazon Analytics. More people have used the timer and videos. So, it appears that women are paying more attention to self-care. Since we know that more women have downloaded the app than those who took part in the study it must signify that other mothers must have obtained information from friends and family or through third-persons. This type of conversation can lead to social changes and connectivity. In the words of Harvard Medical School faculty, Dr. Gottlieb, (personal communication, Dec 17th, 2017). “Prenatal/post-partum period can be used as an opportunity for women to establish new habits of self-care and self-awareness that can promote their own well-being and that of their children and families. Having an app – something always available and developing the habit of checking in on one’s mental health – can then become a life-time habit!” Just knowing that another mother needs this type of support or a conversation can lead to lessening of the stigma attached to postpartum depression in general.

Directions for Future Work

The current study was initially designed to assess efficacy of the app on reducing postpartum depression by increasing psychological well-being across the first three months but was limited to three weeks due to time factor and small sample size. With a larger sample size,

future studies should conduct comparisons between women with app on both Apple and Android platforms and state provided resource. They should measure depression, well-being and social support by using the biopsychosocial framework. Also having a group with no intervention as a control group and taking a third-time point will provide better data to measure the efficacy of the app.

Using the app in other states, across cultures, and across socio-economic strata, can give data about how health care technologies can be used to mitigate not just symptoms of postpartum depression but how they can work as a health promotion tool. Making use of technologies that are available to improve maternal mental health by providing easy access to self-care can be very empowering to mothers especially in places where there is a lack of access to mental health facilities.

Conclusions

There are very few studies that are available comparing efficacy of a well-being companion app to mitigate postpartum depression to that of conventional resources (such as the state provided resource). This study found that there is a difference between two groups - one group using a well-being app and another using only state provided resources - over time. While both groups experienced reduction in depression and improvement in well-being, the app provided greater improvement in mitigating depression than the state provided resource. On the other hand, the state provided resource participants experienced greater improvement in well-being than app users which I partly attribute to the greater social support available to these mothers. More studies are needed with a control group to compare the efficacies of these and other interventions in providing support during the postpartum period.

Although this is a pilot study, findings from this study do provide insight into the usefulness of electronic apps to mitigate postpartum depression among new mothers. There are thousands of applications but very few apps have been tested in some experimental conditions. This app is built to remind women about self-care, so mothers can provide better care for their families. Finally, any intervention that enhances the health and well-being of mother can also enhance the health and well-being of her child.

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APPENDIX A

Description of the App:

VeedaMom is a mobile application (app) designed to be used as a companion tool to help you prevent and/or manage postpartum depression. Postpartum depression refers to feelings of sadness or anxiety experienced after your pregnancy. New mothers will be able to start using this app from their 1st week after they have the baby as a wellness companion. You will be prompted to assess and track your emotional well-being answering the 10-item Edinburgh Postnatal Depression Scale. The app will offer you suggestions depending on the results. The app will offer you mindfulness and meditation exercises and tools, such as a mindfulness timer and music. Mindfulness refers to being in the present in the now to your fullest extent. The practice of mindfulness and social connectivity has been shown to alleviate and prevent symptoms of depression and anxiety. You will be able to post pictures to social media sites. There is also an in-app journal where you can type or record voice messages to express how you are feeling or what you are experiencing in the moment. What is unique about our app is the fact that it includes psychological interventions that may help you prevent and manage symptoms of depression via mindfulness exercises and psycho-educational videos based on validated and evidence-based approaches.

Description of the study:

The present is a randomized study to learn about the experiences of using the app. No information that might identify you will be used when publishing results and findings from this study. Some of you will receive the app right away and some of you will get the resource guide. But at the end of the study every will have the app for their continued use. If you chose to participate, your responses to the in-app journal may be analyzed for common themes. At the beginning of the survey you will be given 2 instruments to complete and at the end of 3 weeks you will complete another set of the same 2 instruments. You can withdraw from participating in the study at any time, with no consequences and continue to use the app. You will find more detailed information about the study in the Informed Consent form. You will be asked to choose a username when you register for the app. Please use a username that does not clearly identify you. You will use the same username as a pseudonym throughout the study.

APPENDIX B

Informed Consent Form to Participate

Use of a Mobile Application (App) *VeedaMom* as a Companion during Postpartum period

Introduction

The purpose of this form is to provide you information that may affect your decision as to whether or not to participate in this research study. If you decide to participate in this study, this form will also be used to record your consent. Research studies include only participants who choose to take part. You are being asked to take part in this study because you are a new mother. Please take your time to make your decision. Be sure to ask any questions that you may have.

Purpose

You have been asked to participate in a research project studying the use of a mobile application (App) for the screening, prevention, and management of postnatal (postpartum) depression. The purpose of this study is to investigate your well-being using a mobile application (App) during your postpartum. You were selected to be a possible participant because you are a new mother and receive medical services from one of the clinics supporting this research study.

Who is the doing the study?

This study is being conducted by Veena Prasad under the supervision of Dr. Joshua Watson. I am a doctoral student in the Department of Counseling and Educational Psychology at Texas A&M University Corpus Christi.

What will I be asked to do?

If you agree to participate in this study, you will be asked to download a mobile application, register as a user, and provide demographic information that includes a username, password, age, ethnic background, and number of times you have been pregnant. You will also fill out 3 instruments, so we can assess if you are benefiting by using the app. Each week, the app will remind you to answer 10 questions that will help determine if you are at risk of experiencing postpartum depression. You must answer all questions each week. The app will provide you with psycho-educational videos related to your feelings during pregnancy. It will also provide you

with mindfulness exercises. I request that you watch all videos and practice the exercises during the length of the study. You will also have access to other information and functions of the app. You will be able to post your pictures to social media sites and use one of the predesigned frames to keep your friends and family informed if you chose to do so. You are not required to post pictures or join social media sites for this study. You will be asked to record your experiences, thoughts, and feelings in a journal provided through the app. You can type your input or record a voice message. At the end of the study you will be asked to fill out the instruments.

What are the risks involved in this study?

The risks associated in this study are minimal and are not greater than risks ordinarily encountered in daily life. Nevertheless, occasionally remembering or writing about unpleasant events, feelings, or thoughts can result in your experiencing discomfort or strong feelings that could be stressful. As with all research, there is a chance that confidentiality could be compromised; however, I am taking steps to reduce confidentiality breach.

What are the possible benefits of this study?

The interventions delivered through the app are designed to alleviate signs of psychological distress and/or depression and promote mothers' well-being. The use of the app might encourage you to engage in healthier behaviors during postpartum and to help you experience your emotions in a healthier manner. Through participation in this study, you might help advance research and develop more adequate interventions for postpartum depression and other health issues. Most of all, you can access the information at any time of the day.

Do I have to participate?

No. Your participation is voluntary. You may decide not to participate or to withdraw at any time without your current or future relations with Texas A&M University-Corpus Christi or your healthcare provider being affected.

Who will know about my participation in this research study?

This study is confidential. No identifiers linking you to this study will be included in any sort of report that might be published. Research records will be stored securely and only Veena Prasad will have access to the records.

If you choose to participate in this study, you will be asked to fill out instruments before we start the study and after the study is complete. After we analyze the data, all data will be encrypted and saved for three years.

Whom do I contact with questions about the research?

If you have questions regarding this study, you may contact Veena Prasad at (210)478-6285, or veena.prasad@tamucc.edu

Whom do I contact about my rights as a research participant?

The Research Compliance Office and/or the Institutional Review Board at Texas A&M University-Corpus Christi have reviewed this research study. For research-related problems or questions regarding your rights as a research participant, you can contact the University's Research Compliance Officer, at (361) 825-2497.

Signature

Please be sure you have read the above information, asked any questions you might have, and received answers to your satisfaction. You will be given a copy of the consent form for your records. By signing this document, you consent to participate in this study. You also certify that you are 18 years of age or older by signing this form.

Signature of Participant: _____ **Date:** _____

Printed Name: _____

APPENDIX C

Demographic Questionnaire

Demographic Questionnaire

Name: _____ Username: _____

Phone Number: _____

Email address: _____

Age: What is your age?

-----Marital Status:

- Single Married or domestic partnership
 Widowed Divorced
 Separated

Origin Race/Ethnicity:

- White
 Black or African American
 American Indian and Alaska Native
 Asian
 Native Hawaiian or Other Pacific Islander
 Other/Two or more (Please specify: _____)
 Hispanic or Latino
 would rather not disclose

Is this your first baby? Yes _____ No _____

If not, please specify:

- 2nd baby
 3rd baby
 4th baby or more

How old is the baby?

1-4 weeks old

4-8 weeks old

8-12 weeks

12 weeks and beyond

Do you have support from your:

partner/spouse

mom

other family members

family members

APPENDIX D

(Instruments) WHOQOL-BREF World Health Organization Quality of Life:

World Health Organization. (1996). WHOQOL-BREF: introduction, administration, scoring and generic version of the assessment: field trial version, December 1996.

The following questions ask how you feel about your quality of life. I will read out each question to you, along with the response options. Please choose the answer that appears most appropriate. If you are unsure about which response to give to a question, the first response you think of is often the best one (The numbers after responses indicates the scores of the responses).

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life in the last four weeks (The overall quality of life and general health facet).

1. How much do you enjoy life?

- Not at all: 5
- A little: 4
- A moderate amount: 3
- Very much: 2
- An extreme amount: 1

2. To what extent do you feel your life to be meaningful?

- Not at all: 5
- A little: 4
- A moderate amount: 3
- Very much: 2
- An extreme amount: 1

3. How well are you able to concentrate?

- Not at all: 1
- A little: 2
- A moderate amount: 3
- Very much: 4
- Extremely: 5

4. Are you able to accept your bodily appearance?

- Not at all: 1
- A little: 2
- Moderately: 3
- Mostly: 4
- Completely: 5

5. How satisfied are you with yourself?

- Very dissatisfied: 1

Dissatisfied: 2
Neither satisfied nor dissatisfied: 3
Satisfied: 4
Very satisfied: 5

6. How often do you have negative feelings such as blue mood, despair, anxiety, depression?

Never: 5
Seldom: 4
Quite often: 3
Very often: 2
Always: 1

Webster, J., Nicholas, C., Velacott, C., Cridland, N., & Fawcett, L. (2010). Validation of the WHOQOL-BREF among women following childbirth. *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 50(2), 132-137.

APPENDIX E

EDINBURG POSTNATAL DEPRESSION SCALE (EPDS)

NAME: _____

Address: _____

Baby's Age: _____

As you have recently had a baby, we would like to know how you are feeling. Please UNDERLINE which comes closest to how you have felt IN THE PAST 7 DAYS, not just how you feel today.

Here is an example, already completed.
I have felt happy:

- Yes, all the time.
- Yes, most of the time.
- No, not very often.
- No, not at all.

This would mean, "I have felt happy most of the time" during the past week. Please complete the other questions in the same way.

In the Past 7 Days:

1. I have been able to laugh and see the funny side of things as much as I always could.

- 0 – As much as I always could
- 1 – Not quite so much now.
- 2 – Definitely not so much now
- 3 – Not at all

2. I have looked forward with enjoyment to things.

- 0 – As much as I ever did
- 1 – Rather less than I used to
- 2 – Definitely less than I used to
- 3 – Hardly at all

3. I have blamed myself unnecessarily when things went wrong.

- 3- Yes, most of the time.

- 2 - Yes, some of the time
 - 1 - Not very often
 - 0 - No, never
4. I have been anxious or worried for no good reasons
- 0- No, not at all.
 - 1- Hardly, ever
 - 2- Yes, sometimes
 - 3- Yes, very often
5. I have felt scared or panicky for no very good reason.
- 3- Yes, quite a lot
 - 2 - Yes, sometimes
 - 1 - No, not much
 - 0 - No, not at all
6. Things have been getting on top of me.
- 3 Yes, most of the time I haven't been able to cope at all
 - 2 Yes, sometimes I haven't been coping as well as usual
 - 1 - No, most of the time I have coped quite well
 - 0 - No, I have been coping as well as ever
7. I have been so unhappy that I have had difficulty sleeping
- 3- Yes, most of the time
 - 2 - Yes, sometimes
 - 1 - Not very often
 - 0 - No, not at all
8. I have felt sad or miserable
- 3 - Yes, most of the time.
 - 2 - Yes, some of the time
 - 1 - Not very often
 - 0 - No, never
9. I have been so unhappy that I have been crying
- 3-Yes, most of the times,
 - 2-. quite often
 - 1- Only occasionally
 - 0 -No, not at all
10. The thought of harming myself has occurred to me.
- 3-Yes, quite often
 - 2-Sometimes
 - 1-Hardly ever
 - 0-Never

Edinburgh Postnatal Depression Scale (EPDS) [Cox, Holden & Sagovsky 1987]

The EPDS is a self-rated questionnaire that has been used in Europe and Australia for over 10 years to screen women for PPD. It asks women to rate how they have been feeling in the last 7 days and consists of 10 short statements of common depressive symptoms with 4 choices per statement. Each statement is rated on a scale of 0 – 3 with possible total scores ranging from 0 – 30.

To administer the test, you give the woman a pen and the questionnaire and ask her to answer the questions in relation to the past 7 days. The questionnaire should only take a few minutes to complete.

APPENDIX F

Flyer soliciting participation in the study



Research study at Driscoll Maternal Fetal Medicine

Veeda Mom

What is it?

This study plans to study the experiences of postpartum women(women who have had babies during last 6 months) using an app to promote maternal wellness and mental health by screening and managing depressive symptoms.

Who is eligible?

- Pregnant women 34 weeks and up
- New mothers with babies up to 6 months
- 18 years and up.
- Must be i-phone users in English .

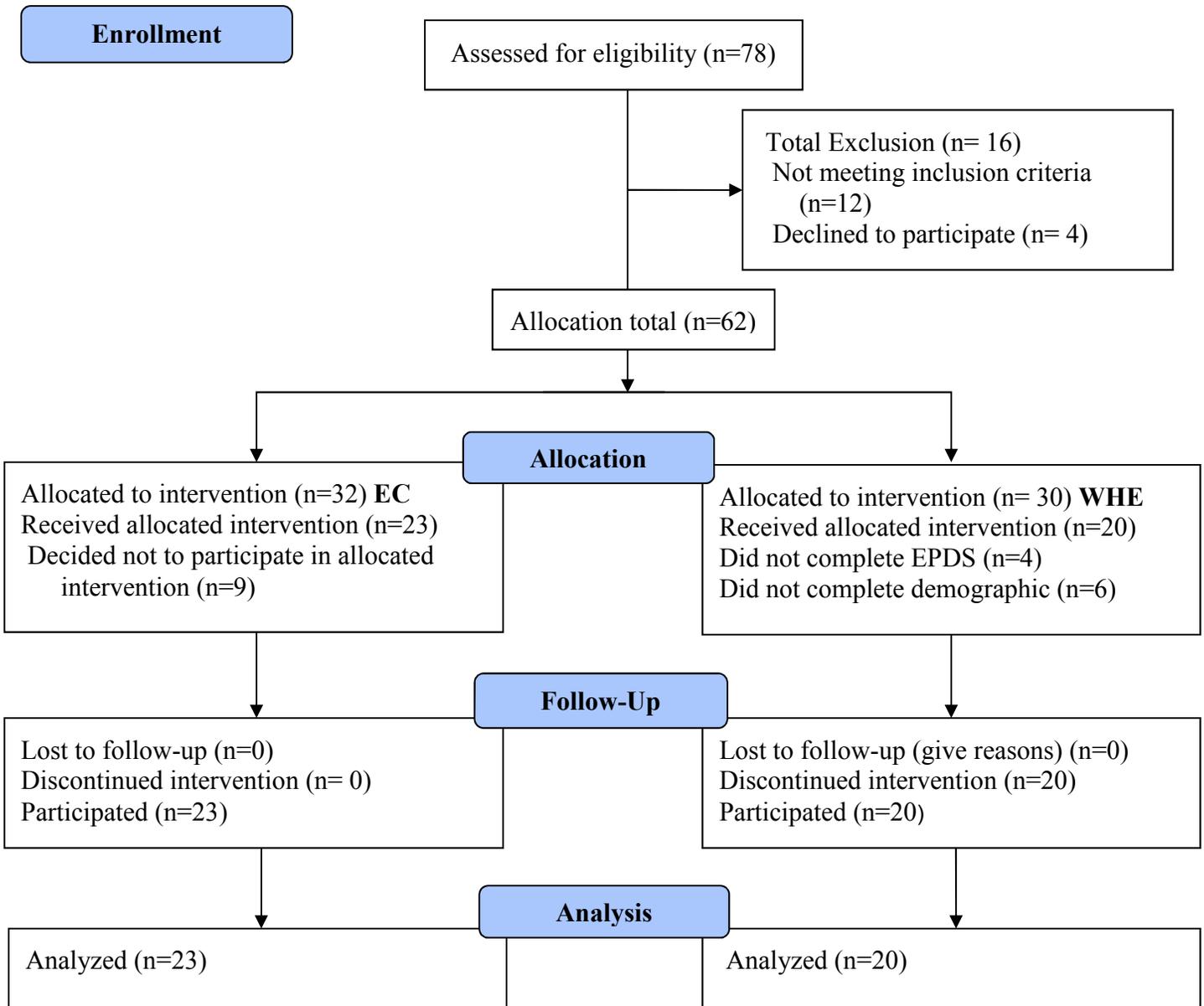
How do I refer a patient?

Specialists associated with the Driscoll Maternal Fetal Medicine department may refer a patient that meets criteria for the study. To refer please contact: Veena.Prasad@tamucc.edu



APPENDIX G

VeedaMom recruitment flowchart



APPENDIX H

Texas Department of State Health Services:

(http://dshs.texas.gov/mch/parents_of_newborn.shtm?terms=postpartumpercent20depression)

Planning for After Delivery

You will have lots of feelings before and after your baby is born. Some of these feelings include joy, excitement, nervousness, and stress. All of these feelings are normal. Below are some things you plan for after your baby is born.

- **Be realistic about being a new parent:** There is so much to learn about your baby and about your role as a parent. Be patient with yourself. You may not always feel like having visitors or you might be too tired to dress up for a dinner party. It takes time to get used to your baby's eating and sleeping schedule.
- **Ask for support:** You can ask friends and family to help you with chores at home. You can ask co-workers or friends to bring you easy-to-heat meals so you don't have to cook. Ask grandparents, family and friends to plan their visits at different times so that you are not overwhelmed with visitors.
- **Keep your body healthy:** Include a variety of foods in your diet, like fruits, vegetables, whole grains, protein and dairy. Eating well will help your body recover from childbirth and will help you to stay healthy and feel your best. Try to get at least 30 minutes of physical activity a day. Exercise is a great way to get rid of stress and keep your mind and body healthy. The benefits of daily exercise include: stronger heart, muscles and bones, less stress, better sleep, more energy, healthier weight, and fewer illnesses. You can build exercise in your day by using the stairs or parking at the far end of a parking lot and walking the extra distance to the entrance of your destination. Avoid using tobacco, alcohol and any other mood-altering drugs that are not prescribed to you for a medical condition. Be sure to follow up with your provider for a postpartum visit at about six weeks after delivery. This is time to make sure your body is healing well and to start talking about birth control, going back to work, and any health conditions or concerns you may have. Even though you'll be busy, this appointment is not one to skip. If you have problems with breastfeeding, medical symptoms like fever, heavy bleeding, persistent pain, problems urinating, or other health concerns, or if you think you may be depressed, do not wait for your scheduled postpartum visit—ask for help.
- **Stay connected:** There are lots of emotional and physical changes that happen after having a baby. Because of that, it is important to have people in your life you can talk to. This could mean having a cup of coffee with a friend, attending a parenting class or a new mom's support group, or connecting with other families in your neighborhood to share ideas about parenting. Look for yoga classes or walking groups for new moms. Exercise is a great way to stay healthy.

- **Pay attention to your emotions:** You can do this by talking with your health care provider or a counselor. You can also try writing in a diary or talking with a friend or partner. If you feel very sad before, during, or after pregnancy, it is important to get help.
- **Learn about breastfeeding:** Postpartum depression rates have been found to be lower in breastfeeding moms. Breastfeeding provides your baby with complete nutrition and protects both mothers and babies against illness. Breastfed babies have fewer common childhood illnesses like ear infections and diarrhea and are at lower risk for more serious problems like asthma, diabetes, obesity, and sudden infant death syndrome (SIDS). Mothers who breastfeed are at lower risk for developing health conditions such as heart disease, breast or ovarian cancer, rheumatoid arthritis, and type 2 diabetes. Breastfeeding costs less than bottle feeding, and helps you bond with your baby. Breastfeeding doesn't always come naturally, but there are things that you can do to get off to a good start. Learn about breastfeeding during your pregnancy by taking a class and reading. The Department of State Health Services' website. www.BreastmilkCounts.com is a one-stop resource for breastfeeding information. Once your baby is born, ask for help in the hospital with positioning and latching your baby. If breastfeeding hurts, if you feel frustrated or you are unsure about anything, ask for help. Breastfeeding support may be available to you from your hospital, health care provider, through your health plan, or through programs like the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). Information and referrals to breastfeeding support resources are available at no cost from the Texas Statewide Lactation Support Hotline: 1(800) 550- 6667.
- **Spend quality time with your baby.** Holding and smiling at your baby makes your baby feel loved. Spending time in skin-to-skin contact with your baby has been shown to reduce stress and anxiety. It's good for your baby too! Reading, singing, talking, playing, and interacting with your baby helps stimulate your baby's brain. Getting outside and taking your baby for walks helps you stay healthy and gives your baby some new things to look at and learn about. Your interactions matter.

Postpartum Mood Disorders

Perinatal Depression

Perinatal depression is depression that happens during or after pregnancy. It is not the same thing as the "baby blues," which go away within a week or two of birth. It can occur during pregnancy or within a year after the end of your pregnancy. Without treatment, symptoms may last a few weeks, months, or even years. In rare cases, the symptoms are severe and can be potentially dangerous to the mother and baby.

Use the checklist below to decide if you have symptoms of perinatal depression. If you check more than one box, talk with a trained health care provider or mental health professional who can help you find out if you are suffering from perinatal depression and talk to you about treatment options.

During the past week or two –

- I have been unable to laugh and see the funny side of things.
- I have not looked forward to things I usually enjoy.
- I have blamed myself unnecessarily when things went wrong.
- I have been anxious or worried for no good reason.

- I have felt scared or panicky for no good reason.
- Things have been getting the best of me.
- I have been so unhappy that I have had difficulty sleeping.
- I have felt sad or miserable.
- I have been so unhappy that I have been crying.
- the thought of harming myself, my baby, or others has occurred to me.

If I Have Perinatal Depression, What Can I Do?

You may find it hard to talk about it if you are feeling depressed. Know that you are not alone. Perinatal depression affects thousands of women and can be treated successfully. It is possible to feel better. Here are some things that can help.

- **1. Lean on Family and Friends:** Ask for help with a few hours of weekly child care so that you can take a break. Get help cleaning the house or running errands. Share your feelings openly with friends and family. Let them help and support you when you need it.
- **2. Talk to a Health Care Provider:** An easy way to raise the subject is to bring the above checklist with you to your next appointment. Show the items you checked and talk about them. If you feel that your provider does not understand what you are going through, please do not give up. There are many providers who do understand, who are ready to listen to you, and who can help you.
- **3. Find a Support Group:** Find other women in your community experiencing perinatal depression. This can give you a chance to learn from others and to share your own feelings. Ask your health care provider how to find and join a support group.
- **4. Talk to a Mental Health Care Professional:** Many mental health professionals have special training to help women with perinatal depression. They give you a safe place to express your feelings and help you manage and even get rid of your symptoms. If you can, choose counselors who have experience in treating perinatal depression.
- **5. Focus on Wellness:** An important step toward treating perinatal depression is taking care of your body. A healthy diet combined with exercise can help you gain your lost energy and feel strong. Eat breakfast in the morning to start your day right. Eat two servings of fruit and three servings of vegetables each day, choose healthy snacks and avoid alcohol. Also, fit exercise into your day. It will make you feel good and can even reduce your stress level.
- **6. Take Medication as Recommended by Your Health Care Provider:** Sometimes, medications are needed to treat depression. You should talk to your health care provider about which medication, if any, may be best for you. Ask questions about your treatment options; be active in deciding how you will get better. Make sure to tell your provider if you are taking any other medicines.

Postpartum anxiety and psychosis

A very small number of women suffer from a severe form of perinatal depression called postpartum psychosis.

Women who have a bipolar disorder or other psychiatric problems may have more of a risk for postpartum psychosis. Symptoms may include:

- Extreme confusion
- Hopelessness
- Cannot sleep (even when exhausted)
- Refusing to eat
- Distrusting other people
- Seeing things or hearing voices that are not there
- Thoughts of hurting yourself, your baby, or others

If you or someone you know fits this description, please seek medical help immediately. This is a medical emergency requiring URGENT care.

Perinatal Depression References and Resources:

1. **2-1-1 Texas.** <http://www.211texas.org/>. This service helps you to find state and local resources. Dial 2-1-1 from your phone or, from your cell phone, by dialing 1-877-541-7905.
2. Maternal & Child Health Bureau. *Depression During and After Pregnancy: A Resource for Women, Their Families, & Friends:* <http://mchb.hrsa.gov/pregnancyandbeyond/depression/index.html>
3. **Postpartum Support International (PSI):** <http://www.postpartum.net>. This service provides information and resources and referrals related to mental health during pregnancy and postpartum. Help Line: 800-944-4773.
4. **Substance Abuse and Mental Health Services Administration National Helpline** also known as, the Treatment Referral Routing Service. This Helpline provides 24-hour free and confidential treatment referral and information about mental and/or substance use disorders, prevention, and recovery in English and Spanish. www.samhsa.gov/find-help/national-helpline or National Helpline: 1-800-662-HELP (4357).
5. **National Suicide Prevention Lifeline.** If you or someone you know is contemplating suicide, please call 1-800-273-TALK (8255). If you are faced with a medical emergency, call 9-1-1.
6. The **Office on Women's Health's National Women's Health Information Center** is a website with information and resources about women's health, including depression during and after pregnancy. <http://www.womenshealth.gov>

APPENDIX I

Driscoll Children's Hospital Institutional Review Board Approval Letter



May 2, 2017

Veena Prasad, MA
Doctoral Candidate
Department of Counseling and Educational Psychology
Texas A&M
Corpus Christi, Texas

Ryan Loftin, M.D., FACOG
Maternal Fetal Medicine Services
Driscoll Children's Hospital
3533 S. Alameda
Corpus Christi, TX, 78411

RE: New study application IRB number 17.011: Randomized Controlled Pilot Study of An Electronic Application to Mitigate Postpartum Depression, Improve Postpartum Well-being

Dear Investigators:

Your request for approval of the new study referenced above was reviewed and granted approval on May 2, 2017. The expedited review was conducted in accordance with the Federally-defined categories of expedited review stated in 45 CFR 46.110 and 21 CFR 56.110, research no more than minimal risk.

You are granted permission to post DCH IRB approved study flyer, identify and recruit participants at DCH Maternal Fetal Medicine Services Department.

The study is subject to continuing review (submit continuing review application and progress report) on or before **May 1, 2018** unless closed before that date.

If approval of the study expires without an approval to continue, research must stop. No research activities should occur after the expiration of approval.

Please note that any changes to the study as approved must be promptly reported and approved. Some changes may be approved by expedited review; others require full board review.



Please note that any changes to the study as approved must be promptly reported and approved. Some changes may be approved by expedited review; others require full board review.

Please follow guidelines for research information use, storage and retention.

Should you have any questions or concerns regarding this review, please contact the IRB office at 361-694-4619 or email: Juleros.Nazareno@dchstx.org.

Thank you for keeping the board informed of your activities.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Kevin Schooler'.

Kevin P. Schooler, MD
IRB Chairman

APPENDIX J

Texas A&M University – Corpus Christi Institutional Review Board Approval Letter



OFFICE OF RESEARCH COMPLIANCE
Division of Research, Commercialization and Outreach

6300 OCEAN DRIVE, UNIT 5844
CORPUS CHRISTI, TEXAS 78412
O 361.825.2497 • F 361.825.2755

| | |
|-----------------------------------|----------------------------|
| Human Subjects Protection Program | Institutional Review Board |
|-----------------------------------|----------------------------|

APPROVAL DATE: June 15, 2017
TO: Veena Prasad
CC: Dr. Joshua Watson
FROM: Office of Research
Compliance Institutional
Review Board
SUBJECT: Initial Approval

| | | |
|------------------|--|---------------|
| Protocol Number: | | HSRP #81-17 |
| Title: | “Efficacy of an Electronic Application to mitigate symptoms of postpartum depression and improve postpartum well-being: A pilot study” | |
| Review Category: | | Expedited 7 |
| Expiration Date: | | June 15, 2018 |

Approval determination was based on the following Code of Federal Regulations:

Eligible for Expedited Approval (45 CFR 46.110): Identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will NOT reasonably place them at risk of criminal or civil liability or be damaging to the their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Criteria for Approval has been met (45 CFR 46.111) - The criteria for approval listed in 45 CFR 46.111 have been met (or if previously met, have not changed).

-
- (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Provisions:

Comments: The TAMUCC Human Subjects Protections Program has implemented a post-approval monitoring program. All protocols are subject to selection for post-approval monitoring.

This research project has been approved. As principal investigator, you assume the following responsibilities:

1. Informed Consent: Information must be presented to enable persons to voluntarily decide whether or not to participate in the research project unless otherwise waived.
2. Amendments: Changes to the protocol must be requested by submitting an Amendment Application to the Research Compliance Office for review. The Amendment must be approved by the IRB before being implemented.
3. Continuing Review: The protocol must be renewed each year in order to continue with the research project. A Continuing Review Application, along with required documents must be submitted 45 days before the end of the approval period, to the Research Compliance Office. Failure to do so may result in processing delays and/or non-renewal.
4. Completion Report: Upon completion of the research project (including data analysis and final written papers), a Completion Report must be submitted to the Research Compliance Office.
5. Records Retention: All research related records must be retained for three years beyond the completion date of the study in a secure location. At a minimum these documents include: the research protocol, all questionnaires, survey instruments, interview questions and/or data collection instruments associated with this research protocol, recruiting or advertising materials, any consent forms or information sheets given to participants, all correspondence to or from the IRB or Office of Research Compliance, and any other pertinent documents.
6. Adverse Events: Adverse events must be reported to the Research Compliance Office immediately.
7. Post-approval monitoring: Requested materials for post-approval monitoring must be provided by dates requested.
8. Continuing Review: The protocol must be renewed each year in order to continue with the research project. A Continuing Review Application, along with required documents must be submitted 45 days before the end of the approval period, to the Research Compliance Office. Failure to do so may result in processing delays and/or non-renewal.
9. Completion Report: Upon completion of the research project (including data analysis and final written papers), a Completion Report must be submitted to the Research Compliance Office.
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11. Adverse Events: Adverse events must be reported to the Research Compliance Office immediately.
12. Post-approval monitoring: Requested materials for post-approval monitoring must be provided by dates requested.



Human Subjects Protection Program

Institutional Review Board

APPROVAL DATE: August 18, 2017
TO: Veena Prasad
CC: Dr. Joshua Watson
FROM: Office of Research
Compliance Institutional
Review Board
SUBJECT: Amendment Approval

Protocol Number: HSRP #81-17
Amendment #: 1
Title: Efficacy of an Electronic Application to mitigate symptoms of postpartum depression and improve postpartum well-being: A pilot study
Review Category: Expedited (7)
Expiration Date: August 18, 2017

Approval determination was based on the following Code of Federal Regulations:

Eligible for Expedited Approval (45 CFR 46.110): Identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will NOT reasonably place them at risk of criminal or civil liability or be damaging to the their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Criteria for Approval has been met (45 CFR 46.111) - The criteria for approval listed in 45 CFR 46.111 have been met (or if previously met, have not changed).

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Approved Amendments: 1. Some additional Survey questions. 2. Add new Site for study. 3. Add small gift card incentive.

Provisions:

Comments: The TAMUCC Human Subjects Protections Program has implemented a post-approval monitoring program. All protocols are subject to selection for post-approval monitoring.

This research project has been approved. As principal investigator, you assume the following responsibilities:

1. Informed Consent: Information must be presented to enable persons to voluntarily decide whether or not to participate in the research project unless otherwise waived.
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