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UNIVERSITY OF CALIFORNIA,
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Evaluating the Impact of Mindfulness Meditation
to Reduce Stress and Anxiety in a Pregnant Population

DISSERTATION

Submitted in partial satisfaction of the requirements
for the degree of

DOCTOR OF PHILOSOPHY

in Nursing Science

by

Donna Balsam

Dissertation Committee:
Professor Adey M. Nyamathi, Chair
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2022

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- Outstanding Faculty Award: School of Nursing Student Valedictorian selected “Most Influential Professor” SDSU, School of Nursing, 2019

Abstract of the Dissertation

Evaluating the Impact of Mindfulness Meditation
to Reduce Stress and Anxiety in a Pregnant Population

by

Donna Balsam

Doctor of Philosophy in Nursing Science

University of California, Irvine, 2022

Professor Adey M. Nyamathi, Chair

Maternal stress and anxiety levels during pregnancy are highly prevalent and are associated with numerous poor outcomes, the most serious of which are the increased rates of infant mortality, preterm birth, and low birth weight infants. There is evidence that mindfulness training is beneficial in reducing perinatal stress and anxiety. However, traditional mindfulness training entails in-person meetings, which creates barriers, limiting accessibility.

The purpose of this study was to determine if a more accessible form of mindfulness meditation (MM) training, specifically, the Headspace app, can help reduce stress and anxiety during pregnancy. To evaluate this, a longitudinal, single-arm pilot study was implemented with 20 pregnant women, who were instructed to practice meditation twice/day during the month-long trial. Validated scales were used to measure study participant's levels of stress, anxiety, and pregnancy anxiety pre-and post-intervention. Physiological measures reflective of stress (heart rate/heart rate variability [HR/HRV] and sleep) were collected via the Oura Ring, a highly accurate sleep tracking device.

Analysis indicated statistically significant reductions in self-report levels of stress ($p=0.005$), anxiety ($p=0.011$), and pregnancy anxiety ($p=0.0001$). Analysis of physiological data

on HR/HRV and sleep, using hierarchical linear modeling, yielded a statistically significant decrease in 1 of 6 HR/HRV metrics, the low-frequency (LF) power band of the HRV; which decreased by 13% ($p=0.006$). LF is reflective of both sympathetic and parasympathetic activities, with lower values indicating relaxation/reduced mental stress. There was a trend towards statistical significance in two other metrics. The first is the ratio of the low frequency/high frequency (LF/HF) band, reflecting parasympathetic dominance/relaxed state, which decreased by 2% ($p=0.086$). The second is sleep which improved by 2% ($p=0.092$). In addition, 65% of study participants believed their sleep improved during the trial, and 95% felt that learning mindfulness helped with other aspects of their lives.

Finally, retention of participants in the study was 100%, and adherence to the intervention was very good; with 65% of participants completing about two-thirds of the intervention, and 50% completing $\geq 95\%$. This study found evidence to support that the Headspace app is an impactful mindfulness meditation intervention to aid in stress and anxiety reduction for the pregnant population.

Chapter 1: Introduction

Stress and anxiety are major health concerns in society today. There is increasing evidence that in addition to impacting emotional health, stress and anxiety have serious effects on physiological health as well. Pregnant women frequently experience and are particularly vulnerable to the negative impacts of stress and anxiety. It is estimated that 58% of all pregnant women experience prenatal stress (Stone et al., 2015), while between 20% (Dennis, Falah-Hassani, & Shiri, 2017) to 25% experience anxiety (Field, 2017). Maternal stress and anxiety levels in pregnant women have been associated with a variety of poor outcomes for the woman during pregnancy, the infant and child, and the woman's long-term health. Among the most serious associations are the increased rates of infant mortality, preterm birth, and low birth weight infants (Bussières et al., 2015; Dennis et al., 2017; Dunkel Schetter, 2011a; Dunkel Schetter & Glynn, 2011; Dunkel Schetter & Lobel, 2012; Frey & Klebanoff, 2016; Lima et al., 2018). In the U.S., approximately 11% of infants are born preterm (Schoen, Tabbah, Iams, Caughey, & Berghella, 2015), and an estimated 15 million preterm infants annually are born worldwide (Hamilton, Martin, Osterman, Curtin, & Matthews, 2015).

According to the World Health Organization (WHO), preterm birth is the leading cause of infant morbidity and mortality in children worldwide (McClure et al., 2016), leading to societal costs in the U.S. of \$26 billion each year (Frey & Klebanoff, 2016). The serious impacts of preterm birth extend to future child outcomes. Preterm infants are at increased risk of experiencing both health and developmental issues, including the increased likelihood of cognitive, motor, and socioemotional delays in childhood (Cheong et al., 2017; Oudgenoeg-Paz, Mulder, Jongmans, van der Ham, & Van der Stigchel, 2017).

In addition to impacting infant and child health outcomes, maternal stress during pregnancy affects pregnancy health and long-term maternal outcomes as well. One

example of this is the association between maternal stress levels and the increased risk of developing hypertensive disorders of pregnancy (HDP) (Morgan, Christensen, Skedros, Kim, & Schliep, 2020; Rasheed, 2019). HDP are among the most common pregnancy complications, impacting up to 10% of the pregnant population (Ying, Catov, & Ouyang, 2018). HDP are a leading cause of pregnancy-related maternal and perinatal morbidity and mortality, contributing to 10-15% of maternal deaths within the U.S. (Leffert, Clancy, Bateman, Bryant, & Kuklina, 2015).

Due to the high prevalence and negative factors associated with stress and anxiety, there is a need to find evidence-based interventions to mitigate these outcomes. In fact, a systematic review of the effects of perceived stress and anxiety during pregnancy recommends that perinatal caregivers provide appropriate support to women experiencing psychological distress in order to improve outcomes for both mothers and infants (Staneva, Bogossian, Pritchard, & Wittkowski, 2015). In addition, women who are experiencing stress and anxiety may be looking for recommendations on engaging, scalable interventions such as mobile applications (apps). This leads to the question: how do both consumers, as well as members of the healthcare team know which interventions or resources to choose? The intervention should be evidence-based and supported by a solid foundation of scientific research.

Mind-body practices like yoga, meditation, and mindfulness are becoming increasingly widespread as tools to decrease stress and anxiety. Mindfulness is the practice of observing thoughts and feelings in an objective way, with the goal to increase awareness of thoughts, feelings, and bodily sensations, while maintaining an open mind, free from distraction and judgment (Kabat-Zinn, 2009). There is evidence that mindfulness meditation (MM) training can have beneficial impacts on reducing perinatal stress and anxiety (Avalos et al., 2020; Babbar, Oyarzabal, & Oyarzabal, 2021; Beattie, Hall, Biro, East, & Lau, 2017; Braeken, Jones, Otte, Nyklíček, & Van den Bergh, 2017; Bublitz, Nillni, Livingston, Carpenter, & Salmoirago-Blotcher, 2019; Corbally & Wilkinson, 2021; Dhillon, Sparkes, & Duarte, 2017; Dimidjian et al., 2016;

Dunn, Hanieh, Roberts, & Powrie, 2012; Goodman et al., 2014; Guardino, Dunkel Schetter, Bower, Lu, & Smalley, 2014; Guo, Zhang, et al., 2021; Krusche, Dymond, Murphy, & Crane, 2018a; Lönnberg et al., 2020; Lucena et al., 2020; Matvienko-Sikar & Dockray, 2017; Matvienko-Sikar, Lee, Murphy, & Murphy, 2016; Mehdi & Fazeli, 2020; Muthukrishnan, Jain, Kohli, & Batra, 2016; Pan et al., 2019a; Shi & MacBeth, 2017; Zarenejad, Yazdkhasti, Rahimzadeh, Mehdizadeh Tourzani, & Esmaelzadeh-Saeieh, 2020; Zhang, Cui, Zhou, & Li, 2019).

The “gold standard” of mindfulness training is the Mindfulness Based Stress Reduction (MBSR) class, which is traditionally delivered over a six or eight-week period of time, requiring 30 or more hours of in-person instruction, and 45 minutes of daily homework (Avalos et al., 2020; Kabat-Zinn & Hanh, 2009). However, there are many barriers associated with the traditional MBSR course including availability, cost, and compliance for many women, limiting their accessibility (Bublitz et al., 2019; Duncan et al., 2017). This is particularly true during pregnancy, a period during which women may desire to learn MM but may not have the time required to attend the traditional course.

Internet mindfulness-based interventions (iMBIs) including computer, tablet, and app-based courses/resources appear to provide an alternative to traditional mindfulness courses, and there is evidence that MM can be effectively delivered using mobile applications (Flett, Hayne, Riordan, Thompson, & Conner, 2019; Howells, Ivtzan, & Eiroa-Orosa, 2016; Huberty et al., 2019). Interestingly, research supports that many Americans who struggle with anxiety, stress or depression prefer online mindfulness training over in-person sessions (Kubo et al., 2021; Wahbeh, Goodrich, & Oken, 2016). A review of the literature targeting the pregnant population with iMBIs yielded several studies with stress/psychological well-being, anxiety, and sleep as outcome variables (Carissoli, Gasparri, Riva, & Villani, 2021; Carissoli, Villania, Gasparria, & Rivaa, 2017; Cornsweet-Barber, Clark, Williams, & Isler, 2013; Krusche et al., 2018a; Matvienko-Sikar

& Dockray, 2017; O'Leary & Dockray, 2015; Williams, 2012; Yang et al., 2019; Yang et al., 2022). Findings revealed a decrease in stress (Krusche et al., 2018a; Matvienko-Sikar & Dockray, 2017; Williams, 2012), a trend in the direction of stress reduction (Cornsweet-Barber et al., 2013; O'Leary & Dockray, 2015), a decrease in anxiety (Yang et al., 2019; Yang et al., 2022), a trend in anxiety reduction (Cornsweet-Barber et al., 2013; Krusche et al., 2018a), and improvement in sleep (O'Leary & Dockray, 2015). However, there were various limitations to these studies, which most notably included high attrition, poor adherence, homogenous populations, and lack of objective measures of stress.

In the studies evaluated, two studies reported high attrition rates ranging from 22% (Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015) to 79% (Krusche et al., 2018a), while other studies reported poor adherence to the MM element of the intervention, with one study having a 13% adherence rate (Yang et al., 2022), another a 49% adherence rate (Yang et al., 2019), another reporting 45% (Carissoli et al., 2021), and another with a 60% intervention completion rate (Carissoli et al., 2017).

While the reviewed studies used a variety of mindfulness interventions, none of them were top-rated, which may have contributed to the poor adherence and attrition outcomes. These issues may be mitigated by using an effective, top-rated iMBI like Headspace. The Headspace (HS) mobile device application (app) is the highest scoring mindfulness app according to the Mobile Application Rating System (Mani, Kavanagh, Hides, & Stoyanov, 2015), and has been shown to reduce stress and/or anxiety in several studies (Avalos et al., 2020; Bostock, Crosswell, Prather, & Steptoe, 2018; Champion, Economides, & Chandler, 2018; Dutcher, Cole, Williams, & Creswell, 2022; Economides, Martman, Bell, & Sanderson, 2018; Fitzhugh, Michaelides, Connolly, & Daniels, 2019; Flett et al., 2019; Kirk & Axelsen, 2020; Kubo et al., 2021; Kubo et al., 2018; Quinones & Griffiths, 2019; Robinson, 2018; Rung, Oral, Berghammer, & Peters, 2020; Yang, Schamber, Meyer, & Gold, 2018). Research also supports

that HS has a beneficial impact on sleep (Kirk & Axelsen, 2020; Kubo et al., 2021; Kubo et al., 2018; Rung et al., 2020).

The majority of the studies which implemented HS as a MM intervention reported that it is an accessible and effective tool for delivering mindfulness training in various populations (Avalos et al., 2020; Bennike, Wieghorst, & Kirk, 2017; Champion et al., 2018; Economides et al., 2018; Forbes et al., 2020; Howells et al., 2016; Mistler, Ben-Zeev, Carpenter-Song, Brunette, & Friedman, 2017; Wen, Sweeney, Welton, Trockel, & Katznelson, 2017). Smartphone delivered MBIs offer a variety of benefits over other formats including providing training that is portable, scalable, personal, and low-cost (Dutcher et al., 2022; Lim, Condon, & DeSteno, 2015). There is a paucity of meditation apps designed specifically for pregnancy, and only a few general meditation apps, including HS, which have pregnancy content (Babbar et al., 2021).

One of the major limitations of the reviewed studies examining iMBIs for stress and anxiety in the pregnant population was the lack of using physiological measurements of stress, like heart rate variability (HRV) and sleep. Research supports that HRV is one of the most robust and objective measures of the stress response (Kim, Cheon, Bai, Lee, & Koo, 2018), with higher levels of stress associated with a lower HRV (Järvelin-Pasanen, Sinikallio, & Tarvainen, 2018). In contrast, higher HRV is associated with low mental stress (Taelman, Vandeput, Vlemincx, Spaepen, & Van Huffel, 2011; Teckenberg-Jansson et al., 2019), health, adaptability, resilience, well-being, and self-regulatory capacity (Kemp & Quintana, 2013; Shaffer & Ginsberg, 2017). HRV can be used as a physiological measurement of stress in pregnant women (Braeken et al., 2017; Klinkenberg et al., 2009; Neila-Vilen et al., 2021), and higher HRV has been correlated to lower levels of self-reported stress in the pregnant population (Neila-Vilen et al., 2021).

In addition to HRV, sleep quality is reflective of stress. Stress and sleep are currently understood to have a bidirectional relationship, with higher levels of stress contributing to poor sleep, and poor sleep contributing to more stress (Caruso, Palagini, Zoccoli, & Bastianini, 2019; Felder et al., 2018). Therefore, if perceived stress levels reduce, sleep should improve. The Oura Ring is a high-tech sleep and fitness tracking device, which can measure HRV in addition to metrics of sleep. Research supports that Oura Ring measurements of HRV (Cao et al., 2022; Kinnunen, Rantanen, Kenttä, & Koskimäki, 2020a) and sleep (de Zambotti, Rosas, Colrain, & Baker, 2019) are highly accurate. Including measurements of HRV and sleep contributed to the robustness of this study by providing objective physiological measurements of stress.

Current Study

For my dissertation, I conducted a longitudinal, single-arm pilot study to assess the impact of practicing MM via the HS app on reducing stress and anxiety in a pregnant population. In this study, participants were provided access and instructed to complete HS's "Basics" course, which is an introduction to the essentials of meditation and mindfulness, followed by the "Pregnancy" course. "Basics" is comprised of 3 separate 10-session courses, totaling 30 meditation sessions ranging from 3 to 20 minutes in length (for a total range of 230-450 minutes). The sessions are varied and designed to provide instruction, as well as opportunities for participants to practice guided meditation exercises, with the aim of cultivating greater mindfulness.

After completing the HS "Basics" course, study participants were instructed to complete the "Pregnancy" course, which is comprised of 3 separate 10-session courses, ranging from 10-20 minutes in length (for a total range of 300-600 minutes). For this study, participants were asked to complete 60 meditations, for a total meditation time practice range of between 530-1050 minutes, if they completed all the sessions. To my knowledge, this is the first study to be conducted utilizing this app on a pregnant population with the inclusion physiological

measurements of stress. In addition to self-report measurements reported by the women, highly accurate measurements of HRV and sleep were collected utilizing the Oura Ring.

Specific Aims

Aim 1: Evaluate the impact of practicing MM via the Headspace app on stress and anxiety among 20 pregnant women. **Ho. 1:** Participants practicing MM via the Headspace app will report decreased levels of stress and anxiety from baseline to post-intervention.

Aim 2: Evaluate the physiological effects (HRV and sleep changes over time) of practicing MM via the Headspace app among 20 pregnant women utilizing the Oura Ring. **Ho. 2:** Participants practicing MM via the Headspace app will show an increase in their HRV and an improvement in their sleep.

Aim 3: Determine if participant app usage amount is associated with differences in measured outcomes. **Ho. 3:** Study participants who use the app more frequently (number of sessions and/or total minutes used) will experience a greater reduction in their stress and anxiety than participants who use the app less frequently.

Impact Statement

Maternal stress and anxiety during pregnancy have been shown to have serious impacts on the pregnant woman, the infant, the child, and the woman's long-term health. This study utilized a brief, top-rated, mindfulness meditation intervention, in addition to including self-report as well as physiological outcome measures for stress. The results of this study may provide support for an evidence-based intervention to improve health outcomes for this vulnerable, under-studied population.

Chapter 2: Literature Review

Stress and Anxiety During Pregnancy

Stress is a multidimensional construct, which can be conceptualized and operationalized in various ways. The construct of stress refers to the relationship between a person and their environment which is perceived as taxing, or exceeding one's resources and endangering one's well-being (Folkman & Lazarus, 1984). People who are stressed often feel overwhelmed by the ongoing stressors in their lives, with a perceived/real inability to cope with those demands. Stress was defined by Hambly as a maladaptive state in which the sympathetic nervous system is overactivated, causing acute or chronic physical, psychological and behavioral impairment (Campkin, 2000). Given that stress can be acute or chronic, it has varying impacts on many of the body systems including the respiratory, cardiovascular, endocrine, gastrointestinal, nervous, and reproductive systems (Shaw, 2018). Stress can be measured with subjective self-reports, or by objective physiological measurements of stress as indicated by heart rate variability (HRV), respiratory rate, blood pressure, and the measurement of stress hormones like cortisol.

Anxiety is an emotion which is characterized by feelings of tension and worry. It is often associated with physical changes in the body, such as increases in heart rate, respiratory rate, and blood pressure, sweating, and trembling hands. Anxiety can be classified as either state or trait: state anxiety refers to a transient reaction to a specific adverse situation, whereas trait anxiety refers to a characteristic of someone's overall personality (Leal, Goes, da Silva, & Teixeira-Silva, 2017). Pregnancy anxiety is a type of state anxiety, specific to pregnancy. The leading cause of anxiety during pregnancy is fear regarding outcomes for the newborn (Deklava, Lubina, Circenis, Sudraba, & Millere, 2015). Additional causes of prenatal anxiety include unintended pregnancy, less education, low acculturation, income, and psychosocial factors like pessimism and partner tension (Field, 2017). The prevalence of perinatal generalized anxiety disorder (GAD) is 8.5%-10% during pregnancy (Misri, Abizadeh, Sanders, & Swift, 2015). A recent meta-analysis found that perinatal anxiety is highly prevalent, merits

clinical attention, and emphasizes the importance of further research into evidence-based interventions (Dennis et al., 2017).

The Stress Response

When someone perceives an event to be stressful, the body reacts in a very specific way. Sensory information is first interpreted by the amygdala in the brain, and if danger is perceived, the distress is sent to the hypothalamus. The hypothalamus regulates the autonomic nervous system (ANS), controlling body functions such as breathing, blood pressure, heartbeat, the dilation, and constriction of blood vessels, as well as the bronchioles of the lungs. The ANS is comprised of the sympathetic nervous system (SNS) as well as the parasympathetic nervous systems (PNS). The SNS regulates the “fight, flight or freeze” response, preparing the body to meet the demands of a threat, while the PNS regulates the “rest and digest” response, functioning to calm the body down, balancing the SNS and the overall ANS towards a state of equilibrium.

When triggered by a stressful event, the amygdala sends a signal to the hypothalamus to activate the SNS by triggering the adrenal glands, which release the hormone epinephrine (adrenaline) into the blood. The body responds by increasing heart rate, blood pressure, and respiratory rate, as well as releasing glucose into the bloodstream to help supply energy to the body systems. After the epinephrine subsides, the second component of the stress response system is activated by the hypothalamus, known as the hypothalamic, pituitary, adrenal (HPA) axis (La Marca-Ghaemmaghami & Ehlert, 2015). If the brain continues to perceive a threat, the hypothalamus releases corticotropin-releasing hormone (CRH) which travels to the pituitary gland, causing a release of adrenocorticotrophic hormone (ACTH), which travels to the adrenal glands, causing a release of cortisol. The presence of cortisol maintains the body in a “high alert” state until the threat passes, causing cortisol levels to fall.

A stress response serves to prepare the body for a physically or emotionally challenging situation. When it is controlled, and of limited duration, this type of stress response is called “good stress,” or allostasis, which refers to the process of maintaining homeostasis by active means (McEwen, 2007). However, when acute stress becomes chronic, it overloads allostasis, creating a state in which stress hormones and other mediators are dysregulated. Allostatic overload has many forms, including inadequate response to a stressor, prolonged response to a stressor, or lack of adaptation to the same stressor (Honkanen, 2019). In addition to being both physically and mentally exhausting, chronic stress, or “bad stress” is also a risk factor in the development of many types of diseases, such as heart disease, hypertension and diabetes (NIMH, 2021).

Pregnancy and Cortisol

During pregnancy the mother and the fetus are connected via the umbilical cord and placenta, so both are impacted by the physiology of the maternal stress response. Stress and anxiety during pregnancy cause an elevation of maternal glucocorticoids, specifically cortisol (Field, 2017; Kertes et al., 2016; La Marca-Ghaemmaghami & Ehlert, 2015; Lima et al., 2018). Elevated cortisol levels impact both the mother and fetus and are believed to be the culprit of numerous untoward effects, many of which will be detailed in the following sections.

Stress and Pregnancy

During pregnancy, stress may be experienced in a variety of different domains. Environmental stress can be caused by a variety of factors such as exposure to a natural disaster, global pandemic, and issues related to food, housing, and job insecurity. Physiological stress can be caused by discomforts related to normal or abnormal changes related to the pregnancy (i.e., irritability, fatigue, poor sleep, body discomfort). Emotional stress can be caused by worries and fears, and may be associated with memory loss, inability to concentrate and nightmares, among other effects.

There are many factors that have been found to stimulate the stress response in women during pregnancy. Among these are fear of childbirth (Rouhe et al., 2015), lack of a support system (Reid, Power, & Cheshire, 2009), a small fetal diagnosis (being told that their baby is not growing at the normal rate), (Betegón et al., 2017), the risk of preterm birth (Jallo, Thacker, Menzies, Stojanovic, & Svikis, 2017), a diagnosis of a fetal defect, a history of a previous fetal loss, preterm birth, previous neonatal intensive care unit admission, socioeconomic factors, like financial strain (Dunkel Schetter, 2011b) and job strain (Sanguanklin et al., 2014), and sociocultural factors such as gender discrimination, particularly in patriarchal societies (Waqas et al., 2015).

For many women who have been pregnant during the recent global pandemic experience of COVID-19, the stress, anxiety, and depression levels have increased (Jago, Singh, & Moretti, 2020). One study which surveyed 2740 pregnant women from 47 states during the COVID-19 pandemic in the United States found high levels of pregnancy-related anxiety, and 93% reported increased stress related to getting infected with COVID-19 (Moyer, Compton, Kaselitz, & Muzik, 2020a). Maternal stress impacts the health of the current pregnancy, the infant, the child, as well as maternal long-term health. The following sections will provide more details on the impacts of stress.

Impacts of Stress on Pregnancy Health

Stress not only impacts the emotional well-being of the pregnant woman, but additionally has serious effects on the physiological health of her pregnancy. Maternal stress during pregnancy increases the risk of developing a hypertensive disorder of pregnancy (HDP) (Barrett et al., 2018; Grobman et al., 2018; Leeners, Neumaier-Wagner, Kuse, Stiller, & Rath, 2007; Liaqat, 2019; Morgan et al., 2020). A recent study surveying over 4000 women found that higher life stress increased the risk of developing HDP by 46% (95 CI: 0.96, 2.22) after adjusting for age, race/ethnicity, BMI, education, and prior history of hypertension (Morgan et al., 2020).

As the most common pregnancy complication, impacting up to 10% of the pregnant population (Ying et al., 2018), HDP are a leading cause of pregnancy-related maternal and perinatal morbidity and mortality, contributing to 10-15% of maternal deaths within the U.S. (Leffert et al., 2015). In addition, women who are diagnosed with HDP are at increased risk for future poor health outcomes, including a 4-fold increase in future incidence of heart failure, and a 2-fold increased risk in coronary heart disease, stroke, and death (Wu et al., 2017). Women with HDP are also at increased risk of developing end-stage renal disease and diabetes. In fact, women with HDP have between 2 to 6-fold higher risk of developing end stage renal disease (Vikse, Irgens, Leivestad, Skjærven, & Iversen, 2008; Wang et al., 2013), and a 3-fold higher risk of developing diabetes mellitus (Lykke et al., 2009; Männistö et al., 2013).

There are numerous studies correlating maternal stress with increased risk of preterm labor and subsequent preterm birth (Barrett et al., 2018; Dunkel Schetter & Lobel, 2012; Morgan et al., 2020; Shapiro, Fraser, Frasch, & Séguin, 2013; Staneva et al., 2015). Preterm labor increases the risk of having a premature and low birth weight infant, in addition to being associated with increased infant morbidity and mortality. One systematic review and meta-analysis found that there were 1.42 times more premature babies born to women with prenatal stress, as compared to the non-stressed population (Lima et al., 2018).

Numerous studies have correlated increased maternal stress with increased risk of developing prenatal and postpartum depression (Brummelte & Galea, 2010), as well as having a cesarean birth (Jallo et al., 2017; Misra, Strobino, & Trabert, 2010; Moyo et al., 2015; Saunders, Lobel, Veloso, & Meyer, 2006). One recent study correlated women who had higher stress to an increased risk of premature rupture of membranes (Wang et al., 2020), which poses risks, such as infection, for both the mother and fetus/infant. Prenatal stress is also associated with an increased risk in engaging in adverse health behaviors like cigarette smoking during pregnancy, as well as early cessation of breastfeeding in the postpartum period (DiPietro, Ghera, Costigan, & Hawkins, 2004; Paul, Downs, Schaefer, Beiler, & Weisman, 2013),

decreased desire to exercise, and engage in existing support systems (Omidvar, Faramarzi, Hajian-Tilak, & Nasiri Amiri, 2018).

Impacts of Prenatal Stress on Future Maternal Stress

There is evidence that pregnant women who experience prenatal stress continue to have higher levels of stress years later. A recent observational cohort study followed over 10,000 nulliparous pregnant women through their pregnancy until seven years later (Monk et al., 2020). Stress was measured using the Perceived Stress Scale (PSS) in the first and third trimesters, and again, between 2-7 years later. Findings revealed that women with greater prenatal stress had higher levels of stress after delivery. Mean PSS scores were 12.5 (95% CI 12.3, 12.7) and 11.3 (95% CI 11.1, 11.5) in the first and third trimesters respectively. By 2–7 years later, PSS scores were 14.9 (95% CI 14.7, 15.1); an average increase of 2.4 points (95% CI 2.2, 2.6) from the start of pregnancy (Monk et al., 2020). This shows that the stress a woman experiences during pregnancy continues beyond the pregnancy, impacting the long-term well-being of the woman. This strengthens the argument for the need to find evidenced-based interventions to help pregnant women manage stress.

Impacts of Prenatal Stress on Infant and Child Outcomes

Maternal stress levels are associated with a variety of poor infant as well as child outcomes. High levels of maternal stress are associated with an increased the rate of having a low birth weight baby (OR 1.68 [95% CI 1.19, 2.38]), in addition to having a preterm birth (OR 1.42 [95%CI 1.05 to 1.91]) (Lima et al., 2018). Moderate and late preterm infants (MLPT) are born between 32 and 36 weeks' gestation, and account for approximately 80% of all premature births (Hamilton, Martin, & Osterman, 2016). Preterm infants are at increased risk for experiencing health and developmental difficulties. Compared with controls, MLPT children had worse cognitive, language, and motor development at age 2 years (Cheong et al., 2017). A recent systematic review and

meta-analysis found that prenatal stress was significantly associated with an increased risk of both autism spectrum disorder (pooled OR 1.64 [95% CI 1.15–2.34] and attention deficit hyperactivity disorder (pooled OR 1.72 [95% CI 1.27–2.34] (Manzari, Matvienko-Sikar, Baldoni, O’Keeffe, & Khashan, 2019).

In addition, there is a correlation between high maternal stress levels and the long-term health and economic outcomes of children. Elevated levels of maternal cortisol during pregnancy have been associated with negative effects on cognition of the child, number of years completed in school, and overall health (Aizer, Stroud, & Buka, 2016). In one study, children exposed to very high cortisol levels in utero had one year less schooling, five points lower verbal IQ score, and a 49% increase in the probability of having a chronic health condition when compared to their siblings who experienced lower cortisol levels (Aizer et al., 2016). This study postulates that maternal stress levels may play an important role in the intergenerational persistence of poverty (Aizer et al., 2016). Considering that 39.7 million Americans live in poverty, encompassing 12.3% of the U.S. population (Fontenot, 2018), this is a serious social and economic issue.

Impact of Anxiety on the Pregnant Woman and Offspring

There is growing evidence that maternal anxiety can also have serious negative impacts on both the antenatal and postpartum period. In fact, some researchers advocate for pregnancy-related anxiety measures to be included as part of an antenatal screening process (Blackmore, Gustafsson, Gilchrist, Wyman, & O’Connor, 2016). Pregnancy anxiety is defined as anxieties or worries that are specific to pregnancy. There is evidence that pregnancy anxiety is a unique risk factor for preterm birth (Bussières et al., 2015). A literature review of the effects of prenatal anxiety yielded 14 studies correlating maternal anxiety with lower gestational age and prematurity (Field, 2017). In a meta-analysis which included over 5.5 million people, pregnancy anxiety was more predictive of preterm birth than trait anxiety or stressful life events (Blackmore

et al., 2016; Bussi eres et al., 2015). Due to this unique correlation, a specific pregnancy anxiety measure was one of the outcome measures assessed in this dissertation study.

In addition to increasing the risk for preterm birth, maternal anxiety is also associated with a variety of poor outcomes. The cesarean section rate is higher for women with prenatal anxiety. In one study, women with state anxiety had between 20-40% higher rates of C-sections for non-medical indications (Field, 2017). Maternal antenatal anxiety is associated with an increased risk for maternal suicide (Farias et al., 2013), increased childbirth fear (Hall et al., 2009), decreased effective coping strategies (George, Luz, De Tyche, Thilly, & Spitz, 2013), higher rates of eating disorders (Micali, Simonoff, & Treasure, 2011), and increased risk of postnatal depression, which has an estimated prevalence of 13% and numerous negative consequences (Brunton, Dryer, Saliba, & Kohlhoff, 2015). In a systematic review on the relationship between prenatal anxiety and infant feeding outcomes, high levels of prenatal anxiety were associated with reduced breast-feeding intention and exclusivity (Fallon, Bennett, & Harrold, 2016).

There are many studies documenting the negative effects of antenatal maternal anxiety on infant and child development. There is evidence that prenatal anxiety leads to reduced immunity as well as increased illnesses in infants (Field, 2017). Infants exposed to maternal prenatal anxiety had more illnesses as well as antibiotic use within their first year of life (Beijers, Jansen, Riksen-Walraven, & de Weerth, 2010). Maternal anxiety during pregnancy appears to have an impact on fetal growth. Insulin-like growth factor is a major regulator in fetal growth. When researchers measured levels of insulin-like growth factor in blood extracted from the umbilical cord of newborns, they found lower levels in infants born to mothers with prenatal anxiety, in addition to lower birth weight babies (Mansell et al., 2016). In terms of future growth and development of the child, maternal anxiety in pregnancy has been associated with an increased risk of childhood attention problems (Van Batenburg-Eddes et al., 2013), behavioral problems (Rice et al.,

2010), mild cognitive impairment in educational performance (Stuart, Otterblad Olausson, & Kallen, 2011), and emotional and social difficulties (Stein et al., 2014).

Research reveals that pregnant women who have less social support are more likely to experience stress (Goletzke et al., 2017) and anxiety (Bayrampour, McDonald, & Tough, 2015; Bedaso, Adams, Peng, & Sibbritt, 2021), in addition to being at increased risk for developing depression, and engaging in self-harm during pregnancy (Bedaso et al., 2021). Therefore, for this study, data regarding maternal social support was collected at baseline, using the Multidimensional Scale of Perceived Social Support (MSPSS) to look for correlates between social support and stress and anxiety in this study population.

Heart Rate Variability and Stress

While study participants' self-reports of stress are valuable, of additional value are physiological measurements of stress such as cortisol and HRV. Research supports that HRV is a reliable, noninvasive marker of an individual's perception of and response to stressors (Brugnera et al., 2018; Föhr et al., 2017; Goessl, Curtiss, & Hofmann, 2017; Kim et al., 2018). A meta-analysis of stress and HRV which examined 37 publications concluded that HRV is an objective assessment of psychological health and stress (Kim et al., 2018). HRV parameters can be measured using Electrocardiogram (ECG) or Photoplethysmography (PPG). ECG monitors the electrical activity of the cardiovascular system by using electrodes attached to the skin. While it is considered the "gold standard" for HR and HRV monitoring, it has the disadvantage of limited usability for long-term monitoring. PPG, which is increasingly used in remote health monitoring systems, uses an optical method for monitoring heart activity which can be put into more convenient and portable devices, (Sarhaddi et al., 2022) like the Oura Ring.

HRV is evaluated by measuring the variation of time intervals (in milliseconds) between consecutive heart beats, or the beat-to-beat (RR) intervals (Shaffer & Ginsberg, 2017). HRV reflects vagus nerve activity, an integral part of the PNS, providing a picture into how the body

balances the ANS (Järvelin-Pasanen et al., 2018; Shaffer & Ginsberg, 2017). When people are under physical or mental stress, SNS activity increases, and PNS activity decreases. Higher variation in the time between heart beats (higher HRV) usually reflects a higher efficiency in autonomic regulation (PNS dominance), whereby the body can respond more promptly to stressors and return to a state of homeostasis (Shaffer & Ginsberg, 2017).

Certain features of HRV are reflective of the relationship between these systems. While there are approximately 70 metrics which can be derived from HRV analyses (Christodoulou, Salami, & Black, 2020), recommendations regarding which metrics to report in HRV research were initially published by the Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology (Task Force, 1996), and more recently by Laborde, et al. (2017), and include the RMSSD and high-frequency band (HF), which both represent vagal tone/PNS dominance (Christodoulou et al., 2020; Laborde et al., 2017; Shaffer & Ginsberg, 2017).

The HR/HRV metrics analyzed for this study are listed and described in Table 1, with further explanation of their significance as follows.

HR/HRV Metric	Unit	Description
<i>Time-domain metrics</i>		
HR	BPM	Heart Rate
RMSSD	ms	Root-mean square of successive RR-interval differences
SDNN	ms	Standard deviation of normal-to-normal RR-intervals
<i>Frequency-domain metrics</i>		
LF	ms ²	Power in low-frequency band (0.04 - 0.15Hz)
HF	ms ²	Power in high-frequency band (0.15 - 0.4)
LF/HF	-	The ratio of power in LF to HF band

(Teckenberg-Jansson et al., 2019)
Table 1. HRV Metric Descriptions

HRV can be analyzed by time-domain, frequency-domain, and nonlinear methods. Time domain values quantify the amount of variability in measurements of the interbeat interval, or time period between successive heartbeats (Shaffer & Ginsberg,

2017). For the purpose of this study, the time-domain metrics which were analyzed included HR (average resting), RMSSD (the root mean square of successive differences between adjacent normal heartbeats) and SDNN (the standard deviation of the interbeat intervals of normal sinus heartbeats, with “normal” referring to the removal of artifact) (Shaffer & Ginsberg, 2017, p. 3).

HR reflects a balance between sympathetic and parasympathetic systems, with lower values indicating relaxation and lower mental stress (Taelman et al., 2011). The RMSSD reflects the beat-to-beat variance in HR, is vagally mediated, and reflects parasympathetic activity in HRV (Shaffer & Ginsberg, 2017). Higher values of RMSSD reflect relaxation and lower mental stress levels (Taelman et al., 2011). The SDNN measurement estimates variability impacting HRV within a 5 minute period of time, and reflects autonomic influence on HRV (both SNS and PNS activity) (Shaffer & Ginsberg, 2017). SDNN reflects total HRV, with higher values of SDNN indicating relaxation and lower mental stress (Taelman et al., 2011).

Frequency-domain metrics are used to estimate the distribution of power within four frequency bands: ultra-low-frequency (ULF), very-low-frequency (VLF), low-frequency (LF) and high-frequency (HF) bands. Power is the signal energy which is found within a frequency band, and the total power is the sum of the energy in all four bands for a 24 hour period (Shaffer & Ginsberg, 2017).

The frequency-domain metrics which were analyzed were the power of the low-frequency (LF) and high-frequency (HF) bands, as well as the ratio of power in the LF to HF bands (LF/HF). Power in the HF band reflects parasympathetic activity (through the influence of respiration as well as input to the heart by the vagus nerve), with higher values associated with relaxation and lower mental stress (Delaney & Brodie, 2000; Shaffer & Ginsberg, 2017). The LF power band reflects both the SNS and PNS, with SNS and baroreceptor activity playing a large role in generating this frequency (Shaffer & Ginsberg, 2017). Lower levels of power in the LF band indicate relaxation and low mental stress (Delaney & Brodie, 2000). The LF/HF ratio is a commonly used index of sympatho-vagal balance, and generally increases with stress, with

lower values indicating relaxation and low mental stress (Delaney & Brodie, 2000; Taelman et al., 2011).

Normal HRV measurements can range from approximately 20-200 milliseconds, depending on an individual's age, gender, genetics, and physical fitness level (Kim et al., 2018; Oura, 2020). Short-term measurements of HRV can be impacted by a variety of factors. Short-term HRV readings which are low may be caused by the following: dehydration, alcohol consumption, illness, eating too close to bedtime, working out too close to bedtime, a hot bedroom at night, jetlag, and excessive exercise (overtraining), in addition to acute and prolonged stress (Oura, 2020). In contrast, short-term HRV levels which are high, or slightly higher than one's normal range, can be impacted by the following: a cool bedroom at night, a much-needed day of rest, participation in more mindful, low-to-moderate-intensity activities like hiking or yoga, and engagement in mindfulness meditation practice (Oura, 2020). Positioning and time of day is also an important consideration. To obtain the most accurate HRV reading, it is best to be at rest in the supine position (Herbell & Zauszniewski, 2019).

Given that short-term HRV levels are impacted by a variety of factors, many experts in the field of HRV recommend measuring HRV for longer periods of time (≥ 24 hours). Twenty-four hour (or more) HRV recordings represent the "gold standard" for clinical HRV assessment (Shaffer, McCraty, & Zerr, 2014). As such, longer-term HRV, or trends in HRV over time, provide a better picture of the body's response to a new variable, like a MM intervention. To determine meaningful changes in HRV, it is important to note that HRV varies dramatically amongst individuals, and comparisons of HRV readings are not recommended *between* individuals, but rather *within* an individual, looking at changes over time, or in relation to specific tasks.

Cardiovascular Changes During Pregnancy

There are normal physiological changes that happen during pregnancy which impact the maternal cardiovascular system. There is approximately a 50% increase in blood volume by 34 weeks' gestation. Cardiac output increases by 20% by 8 weeks' gestation and increases to around 40% by the 3rd trimester. This increase in cardiac output is predominantly achieved via an increase in stroke volume, and to a lesser extent, an increase in heart rate (Soma-Pillay et al., 2016). Traditional/current textbooks commonly state that there is a progressive rise in heart rate during pregnancy, ranging from 10 to 20 beats/min (Blackburn, 2013; Davidson, London, & Ladewig, 2012). However, in a recent systematic review and meta-analysis on heart rate in normal pregnancies among 8317 pregnant women, investigators found that the mean change in heart rate during pregnancy was an increase in 7.6 beats/min (Loerup et al., 2019); quite different than what is taught in most traditional as well as current and textbooks. A recent study which continuously monitored 58 women throughout their pregnancies and 3-months postpartum, found that HR increased significantly during the second trimester, and then decreased significantly during the third trimester; still yielding a net overall increase in HR across pregnancy, while returning to normal in the postpartum period (Sarhaddi et al., 2022).

HRV as an Outcome Variable during Pregnancy

In addition to the cardiovascular changes listed above, HRV is impacted during pregnancy. HRV values decrease during pregnancy across gestation (Carpenter, Emery, Uzun, Rassi, & Lewis, 2017; Herbell & Zauszniewski, 2019; Sarhaddi et al., 2022). A recent study which evaluated HRV changes across the three trimesters of pregnancy against a matched control found that there was reduced HRV in the pregnant groups as compared to the controls for all three trimesters, with results more marked for primiparous versus multiparous women, and an increased decline seen during second trimester (Solanki, Desai, & Desai, 2020). A more recent study found further evidence that HRV parameters decreased throughout pregnancy

(Sarhaddi et al., 2022). However, the investigators identified new trends; namely that time-domain parameters of HRV (average normal interbeat intervals [AVNN], SDNN, RMSSD, nSDNN, and nRMSSD) decreased significantly during the second trimester, but then increased significantly during the third trimester (Sarhaddi et al., 2022). Additionally, some frequency domain parameters (LF, HF, and nHF) decreased significantly during the second trimester, while HF increased significantly during the third trimester (Sarhaddi et al., 2022).

Previous studies have associated certain elements of HRV change during pregnancy with disorders like gestational hypertension (Moors et al., 2020; Walther et al., 2005), and preeclampsia (Hossen, 2013; Yang, Chao, Kuo, Yin, & Chen, 2000). HRV changes during pregnancy have also been associated with certain mental health conditions such as depression (Shea et al., 2008) and anxiety (Braeken et al., 2015; Mizuno, Tamakoshi, & Tanabe, 2017). Women with depression during pregnancy have been found to have lower 24-hour HRV parameters (Shea et al., 2008), and women with anxiety during pregnancy have been shown to have decreased HF and very-low frequency power (Mizuno et al., 2017).

Regardless of the variations in HRV during pregnancy, several studies have successfully used HRV as a physiological indicator of stress in the pregnant population (Chu et al., 2017; Hayase & Shimada, 2018; Muthukrishnan et al., 2016; Teckenberg-Jansson et al., 2019). One study evaluated the impact of a maternity yoga intervention (physical postures, breathing methods, and meditation) on the ANS, by assessing salivary amylase and HRV (Hayase & Shimada, 2018). The study found that salivary amylase levels decreased significantly in the intervention group, as compared to the control, and high frequency values of HRV were higher during the night readings for pregnant women in their 2nd and 3rd trimesters in the intervention group as compared to the control (Hayase & Shimada, 2018).

Another study was an RCT which looked at the impact of a 12-week yoga intervention (physical postures, breathing methods, and meditation) on the HRV of pregnant women with depression as compared to a control group of pregnant women who did not do the intervention. The intervention group had significant changes in HF, LF, and LF/HF, as well as a reduction in depression symptoms and perceived stress (Chu et al., 2017).

In another study evaluating the impact of live music therapy for stress reduction in pregnant women, findings revealed that music therapy increased HRV and alleviated stress and anxiety (Teckenberg-Jansson et al., 2019). Another RCT evaluated the impact of an in-person mindfulness meditation class on perceived stress scores and autonomic function tests (Muthukrishnan et al., 2016). The results showed a significant decrease in perceived stress scores, a significant decrease of blood pressure in response to cold pressor test, and a significant increase in HRV for the intervention group, who had engaged in a daily meditation practice for 5 weeks, as compared to the control (Muthukrishnan et al., 2016).

Sleep and Stress

Current research supports that the relationship between sleep and stress is bi-directional, meaning that poor sleep increases stress, and that stress, in turn, impacts sleep quality (Caruso et al., 2019; Felder et al., 2018; Scott, Webb, Martyn-St James, Rowse, & Weich, 2021). In one prospective study following 330 middle-aged women over a 9-year period, women who were characterized by high chronic stress reported lower subjective sleep quality (Hall et al., 2015). Other studies show the opposite, where women who sleep poorly have been found to have increased responses to both mild and severe stress (Wu et al., 2015). A recent systematic review and meta-analysis reviewing 95 trials and 8608 participants reported that sleep is causally related to a variety of mental health difficulties including stress and anxiety (Scott et al., 2021), and suggested that interventions to improve sleep be incorporated into mental health services.

Sleep and Pregnancy

Poor sleep quality is highly prevalent in pregnancy, impacting between 76-88% of pregnant women (Christian, Carroll, Porter, & Hall, 2019; Lucena et al., 2020; Mindell, Cook, & Nikolovski, 2015). Poor sleep quality is characterized by one or more of the following symptoms: difficulties initiating sleep (sleep latency), difficulties maintaining sleep, waking up too early, or not feeling refreshed in the morning (Van Laethem et al., 2018). Due to the relationship between stress and sleep, sleep was included as an outcome variable for this study. The study hypothesis was that if stress levels decreased, then sleep would improve. However, there are many factors specifically related to sleep during pregnancy which may impact this association. Namely, sleep problems are extremely prevalent during pregnancy, with as many as 88% of pregnant women experiencing poor global sleep quality, which is a comprehensive measure that includes latency (how quickly one falls asleep), duration, disturbance and quality (Christian et al., 2019; Felder, Baer, Rand, Jelliffe-Pawlowski, & Prather, 2017; Mindell et al., 2015).

Sleep during pregnancy can be challenging for variety of reasons. As the fetus gets larger, finding a comfortable position for sleep is difficult, particularly as women advance in gestation. This is particularly problematic for women who previously were back or stomach sleepers, as it may be difficult getting used to sleeping on one's side. Frequent nocturnal urination is common, particularly during the 1st and 3rd trimester, due to the increase in blood volume, and the pressure of the fetus on the bladder. Normal physical changes during pregnancy like increased heart rate and shortness of breath, often impact sleep. It is very common for pregnant women to experience heartburn, which is often worse at night. Pregnant women also frequently experience aches and pains, particularly in their back and legs, which may impact sleep. Vivid dreams and nightmares are common during pregnancy, and can negatively impact sleep

(Landon et al., 2020). Lastly, stress and anxiety during pregnancy may cause pregnant women to worry during the night, impacting sleep.

Poor sleep quality during pregnancy has numerous untoward effects. Poor sleep during pregnancy is a prospective risk factor for depression during both the antepartum and postpartum periods (Bacaro et al., 2020; Tomfohr, Buliga, Letourneau, Campbell, & Giesbrecht, 2015). Poor sleep during pregnancy is also associated with adverse pregnancy outcomes including intrauterine growth restriction, preterm birth, longer labor, and higher risk of cesarean birth (Bacaro et al., 2020). Due to the bidirectional relationship between sleep and stress, poor sleep is likely both an outcome as well as a predictor of increased levels of stress during pregnancy.

Mindfulness Meditation as an Intervention

Mind-body practices like yoga and meditation are becoming increasingly widespread as tools to reduce stress and anxiety. In the U.S., in 2017, the practice of meditation increased to 35.2 million practicing adults, which was a three-fold increase from 2012 (Clarke, Barnes, Black, Stussman, & Nahin, 2018). In October of 2020, guided meditation videos on YouTube were viewed 40% more than prior to the start of the pandemic (Babbar et al., 2021).

Mindfulness originated from Eastern spiritual practice, stemming from Buddhist teaching, emphasizing aspects of change, impermanence, and non-self into the moment-to-moment awareness of experience. Mindfulness emerged as an area of interest during the 1970's due to a rise in the popularity of meditation practices such as Zazen (Zen) meditation. Molecular biologist Kabat-Zinn is credited for bringing mindfulness into the mainstream of medicine and society in the 1990s, as the inventor of the Mindfulness-Based Stress Reduction (MBSR) program (Kabat-Zinn & Hanh, 2009). The MBSR program is traditionally taught over a period of six-to-eight weeks and consists of in-person sessions, and daily homework assignments, which promote mastery of the MBSR intervention. A variety of mindfulness-based programs and therapies have grown out of Kabat-Zinn's work, including mindfulness-based cognitive therapy,

mindfulness-integrated cognitive behavioral therapy, acceptance and commitment therapy, dialectical behavioral therapy, mindfulness-based childbirth and parenting, and relapse prevention for substance abuse.

Kabat-Zinn most recently defined mindfulness as “the awareness that arises through paying attention, on purpose, in the present moment, non-judgmentally, in the service of self-understanding and wisdom” (Kabat-Zinn, 2017), and has acknowledged that mindfulness can be used as an “umbrella term” for a collection of practices and personal values that enable one to live mindfully (Williams & Kabat-Zinn, 2013). The practice of mindfulness focuses on observing and accepting the present moment experience, as opposed to moving through situations on autopilot or automatically reacting to situations (Babbar et al., 2021). Mindfulness can be practiced in everyday activities such as eating, exercising, and interacting with others, and is a foundational element of a variety of meditation techniques including Mantra, Transcendental, Loving-Kindness, and Zen meditations (Babbar et al., 2021).

In contemporary psychology, mindfulness has been adopted as an approach for increasing awareness and responding skillfully to mental processes that contribute to emotional distress and maladaptive behavior (Bishop et al., 2004). Mindfulness interventions frequently conceptualize mindfulness as a *set of skills* that can be learned and practiced with the intention of reducing psychological symptoms, as well as increasing health and well-being (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006). Mindfulness practice aims to develop awareness and acceptance of one’s thoughts, emotions, and body sensations, building stress tolerance, reducing uncomfortable experiences, and reducing reactivity, which are all important for pregnant women and new mothers (Hall, Beattie, Lau, East, & Biro, 2016).

Scholars have differing approaches and research agendas regarding mindfulness. Some, including this researcher, are concerned with the acquisition of new

skills, and trials for evaluating efficacy and effectiveness. Other researchers attempt to uncover the fundamental mechanisms of action associated with mindfulness. Unsurprisingly, scholars have varying conceptualizations of mindfulness. It has been described as a one-dimensional construct i.e., “the state of being attentive to and aware of what is taking place in the present” (Brown & Ryan, 2003, p. 822), a two-dimensional construct being comprised of self-regulation of attention, and orientation to experience (Bishop et al., 2004), and a multidimensional phenomenological matrix involving a continuum of practices involving states and processes (Lutz, Jha, Dunne, & Saron, 2015).

The broader scientific research community generally refers to mindfulness as a self-regulated *attentional state* focused on present moment experiences, emphasizing curiosity, openness, and acceptance (Brandmeyer, Delorme, & Wahbeh, 2019; Dahl, Lutz, & Davidson, 2015), which fluctuates across the day (Brown & Ryan, 2003). Mindfulness can also be conceptualized as a naturally occurring quality, or *trait* which varies across people, with some having greater dispositional tendencies towards mindfulness (Lindsay & Creswell, 2017; Mesmer-Magnus, Manapragada, Viswesvaran, & Allen, 2017). This mindfulness trait is thought to be measurable in both trained and untrained subjects by scales such as the Five Facet Mindfulness Questionnaire (Baer et al., 2006; Baer et al., 2008) or the Mindfulness Attention Awareness Scale (Brown & Ryan, 2003). However, this assumption of mindfulness as a stable trait does not account for the ability to cultivate mindfulness as a skill, and it has been argued that use of such scales does not advance the understanding of the phenomenological changes which occur when individuals experience mindfulness training (Lutz et al., 2015). Other criticisms of mindfulness instruments include insufficient validity, sensitivity, and response shifts and biases (Lutz et al., 2015).

In Western, secular applications of mindfulness, it is frequently conceptualized as a *cognitive act* involving the practice of focusing attention on the body, breath, and content of thought, (Wahbeh, Goodrich, Goy, & Oken, 2016) and observing one’s own cognitive and

affective processes (Brandmeyer et al., 2019). Unfortunately, the semantic ambiguity of the term “mindfulness” makes generalizations and comparisons across research studies difficult (Anālayo, 2019; Van Dam et al., 2018). It should be noted that Kabat-Zinn’s definition of mindfulness has purposely been kept broad so as to avoid reducing mindfulness to any particular set of manualized techniques, but rather to allow participants to conceptualize it in a larger sense, or perhaps even as a way of life (Lutz et al., 2015).

A Quasi-operational Definition of Mindfulness

To better understand the lens through which this researcher conceptualizes mindfulness, a quasi-operational definition of mindfulness will be presented. It is important to note that this researcher is not presenting a full-fledged theory of mindfulness, but rather a working definition/construction intended to be a practical and instructional description of mindfulness. To do so, operationalizations/conceptions from some noted and respected mindfulness theories will be presented.

Baer et al. (2006) theorizes a five-skill model of mindfulness. This includes: observing (i.e., “noticing or attending to internal and external experiences”), describing (i.e., “labeling internal experiences with words”), acting with awareness (i.e., “attending to one’s activities of the moment”), nonjudging (i.e., “taking a nonevaluative stance toward thoughts and feelings”), and nonreactivity (i.e., “allowing thoughts and feelings to come and go, without getting caught up in or carried away by them”) (Baer et al., 2006, p. 311; Bohlmeijer, Ten Klooster, Fledderus, Veehof, & Baer, 2011). Acceptance is another fundamental tenet of mindfulness (Bishop et al., 2004; Cardaciotto, Herbert, Forman, Moitra, & Farrow, 2008; Feldman et al., 2022; Lindsay & Creswell, 2017), with acceptance meaning “experiencing events fully and without defense, as they are” (Hayes, 1994, p. 30), during which one is open to the reality of the present moment without being in a state of belief or disbelief (Cardaciotto et al., 2008; Feldman et al.,

2022; Qu, Dasborough, & Todorova, 2015; Roemer & Orsillo, 2003). Acceptance and monitoring are two features of mindfulness that are common to almost all definitions of mindfulness in the literature (Creswell, Pacilio, Lindsay, & Brown, 2014; Lindsay & Creswell, 2017). According to Lindsay & Creswell's Monitor and Acceptance Theory (MAT), attention monitoring and acceptance are the basic mechanisms underlying mindfulness, and mindfulness training effects (Lindsay & Creswell, 2017).

Another construct that is central to mindfulness is a shift in perspective, or psychological distancing which has been referred to by scholars by different names including "reperceiving" (Shapiro, Carlson, Astin, & Freedman, 2006), "decentering" (Teasdale et al., 2000), "metacognitive knowledge" (Teasdale, 1999) "de-automatization" (Deikman, 1983; Safran & Segal, 1996) and "dereification" (Wielgosz, Goldberg, Kral, Dunne, & Davidson, 2019). This is a process by which practitioners position themselves apart from the phenomena being observed (Bernstein et al., 2015), learning to view experiences more subjectively, rather than accepting them as absolute representations of reality.

Mindfulness practice teaches people to focus their attention on exploring internal experiences such as thoughts and body sensations. They are encouraged to have a shift in perspective from being immersed in their experience, by decentering (to use a word from the concepts above) from the experience (i.e., to not get caught up in it). They practice noticing what is happening, which is often focusing on the past, or projecting into the future, and they are encouraged to shift their awareness back to the present moment. This shift back to the present moment is often cued by the guide, or something that an experienced meditator learns to notice, reminding them to label their thoughts as just thoughts, encouraging them to let them go, and not get caught up in them. This redirection of focus back to the present moment experience is accomplished via a variety of techniques including refocusing on their breathing, counting, repetition of a mantra, or focusing their awareness on their body (body scan or relaxation exercise), among others.

Mindfulness Meditation and Sleep

There is evidence that MM training is beneficial for reducing sleep disturbances. One recent systematic review and meta-analysis of RCTs evaluated 18 studies with a total of 1654 participants and found moderate strength of evidence that MM interventions significantly improved sleep quality in populations with clinically significant sleep disturbance (Rusch et al., 2019). MM is theorized to target many of the same emotional and cognitive processes that impact and contribute to poor sleep quality. It has been shown to diminish emotional reactivity (Britton, Shahar, Szepsenwol, & Jacobs, 2012), ruminative thoughts (Feruglio, Matiz, Pagnoni, Fabbro, & Crescentini, 2021), and promote impartial reappraisal of salient experiences (Rahl, Lindsay, Pacilio, Brown, & Creswell, 2017), which together may facilitate sleep (Rusch et al., 2019).

Mindfulness for Stress & Anxiety Reduction in the Pregnant Population; a Review of the Literature

There is some evidence that mindfulness training can have a beneficial impact on reducing stress and anxiety in the pregnant population (Beattie et al., 2017; Beddoe & Lee, 2008; Beddoe, Yang, Kennedy, Weiss, & Lee, 2009; Bublitz et al., 2019; Dunn et al., 2012; Goodman et al., 2014; Guardino et al., 2014; Hall et al., 2016; Krusche et al., 2018a; Lönnberg et al., 2020; Matvienko-Sikar & Dockray, 2017; Mehdi & Fazeli, 2020; Muthukrishnan et al., 2016; Pan et al., 2019b; Vieten & Astin, 2008; Yazdanimehr, Omid, Sadat, & Akbari, 2016; Zhang et al., 2019; Zhang et al., 2021).

To date there have been 6 systematic reviews and/or meta-analyses evaluating the impact of mindfulness on perinatal stress and anxiety (Corbally & Wilkinson, 2021; Dhillon et al., 2017; Matvienko-Sikar et al., 2016; Shi & MacBeth, 2017; Taylor, Cavanagh, & Strauss, 2016; Yan, Wu, & Li, 2022), and one recent systematic review on mind-body interventions (Guo, Zhang, et al., 2021). The earlier systematic reviews and meta-analyses evaluated pooled results for both healthy pregnant populations, and

those who had anxiety and depression (Dhillon et al., 2017; Matvienko-Sikar et al., 2016; Taylor et al., 2016). According to the reviews, the results of the non-RCTs revealed significant decreases in anxiety, depression, and stress, but for the RCTs, though there were trends in favor of MM interventions, there was a lack of statistically significant results between intervention and control groups. The authors attributed these findings the higher risk of bias, poor study design and small sample sizes of the non-RCTs (Dhillon et al., 2017; Taylor et al., 2016).

Another systematic review found insufficient evidence of an effect for mindfulness to support perinatal mental health (Hall et al., 2016). In those reviews, stronger results were seen in women with clinically significant presentations of anxiety or depression, and reviewers suggested that future studies separate clinically and non-clinically significant study populations. As a result, another systematic review was performed which evaluated 18 studies focused on study populations with documented depression and/or anxiety (Shi & MacBeth, 2017). The results showed that women engaging in a MBI program had reductions in both perinatal anxiety and stress with moderate to large magnitude in effect sizes (Shi & MacBeth, 2017). However, when they evaluated the risk of bias, the majority of studies were rated moderate to high, with methodological issues related to selection bias, performance bias, and assessor blinding issues (Shi & MacBeth, 2017).

More recently, two additional systematic reviews have been done. The first evaluated the impact on MBIs on stress, depression, and anxiety in women without pre-existing stress, and depressive or anxiety disorders in 12 studies, 10 of which were RCTs (Corbally & Wilkinson, 2021). The researchers concluded that MBIs cause a small but clear increase in mindfulness and reductions in depression, but they did not find a significant reduction in stress. A meta-analysis on anxiety was not conducted due to the small number of and variation in reported effects (Corbally & Wilkinson, 2021).

The final and most recent paper was a systematic review and meta-analysis of MBIs evaluating 21 RCTs which included both women with or without current mental health issues. These researchers found that for women with current mental health issues, MBIs were effective in reducing stress, anxiety, and depression as well as increasing mindfulness. However, for women without mental health issues, the results indicated no difference between the mindfulness intervention groups and the control groups for stress and depression, and were unclear with regards to anxiety citing limited data to perform a sensitivity analysis (Yan et al., 2022). However, for the three studies evaluated with anxiety outcomes, there was a significant difference in the reduction of anxiety for the intervention groups as compared to the controls (Yan et al., 2022).

Another systematic review evaluated 28 RCTs with mind-body interventions to aid with stress management during pregnancy (Guo, Zhang, et al., 2021), including 13 studies which utilized a variety of mindfulness interventions. The results showed significant improvements in stress and anxiety for the intervention groups, with interventions that lasted 4-8 weeks considered to be optimum (Guo, Zhang, et al., 2021).

Headspace Mindfulness Meditation App

The widespread use of smartphones has led to a multitude of iMBIs which may improve adherence to MM interventions, as well as provide an option for those for whom in-person classes are difficult to attend. The COVID-19 pandemic has also illuminated equity and accessibility problems in healthcare, for which mobile health applications may assist. Research supports that many Americans who struggle with anxiety, stress, or depression prefer online mindfulness training over in-person sessions (Kubo et al., 2021; Wahbeh, Goodrich, & Oken, 2016). According to the Pew Research Center, 95% of Americans of reproductive age currently own smartphones (Center, 2021).

Headspace (HS) is a smartphone app-based mindfulness training program that delivers meditation sessions through audio files, accessible to users at any time. It is

available for Apple iOS or Android devices. According to a systematic review of mindfulness-based mobile apps, HS was rated as the highest scoring mindfulness app (Mani et al., 2015). The systematic review identified 700 apps, ultimately evaluating 23 which met the evaluation criteria of providing mindfulness training and education (Mani et al., 2015). The top rating was based on the Mobile Application Rating System (MARS), which is the most widely used system for rating mental health apps, providing objective and multidimensional ratings for health app quality and usability (Stoyanov et al., 2015). Headspace also received the highest possible score (5.0/5.0 for credibility, as well as a high rating for user experience) from “One Mind PsyberGuide,” a nonprofit web platform which provides and maintains an online consumer guide for digital mental health products. PsyberGuide reviews apps using four independent rating systems; PsyberGuide ratings, the MARS score, expert reviews, and transparency checklists, providing a metric of “credibility“ by analyzing the empirical research in support for the products (Neary & Schueller, 2018).

There is a substantial amount of research examining the impact of practicing MM via HS for on a variety of outcomes. The research shows that practicing MM via HS has a positive impact on the following: compassion (Lim et al., 2015), burnout and compassion fatigue (Robinson, 2018; Wylde, Mahrer, Meyer, & Gold, 2017), irritability (Economides et al., 2018), affect (Economides et al., 2018; Robinson, 2018), attention focus and mind-wandering (Bennike et al., 2017), well-being (Bostock et al., 2018; Fitzhugh et al., 2019; Howells et al., 2016; Wen et al., 2017; Yang et al., 2018), distress (Bostock et al., 2018; Kubo et al., 2018), job strain and workplace social support (Bostock et al., 2018), leadership (Nübold, Van Quaquebeke, & Hülshager, 2020), self-compassion (Wylde et al., 2017), critical thinking (Noone & Hogan, 2018), quality of life (Kubo et al., 2018; Rosen, Paniagua, Kazanis, Jones, & Potter, 2018), depression (Flett et al., 2019; Howells et al., 2016; Kubo et al., 2021; Kubo et al., 2018; Quinones & Griffiths, 2019; Rung et al., 2020), resilience (Champion et al., 2018; Fitzhugh et al., 2019; Flett et al., 2019), life satisfaction (Champion et al., 2018; Fitzhugh et al., 2019), reducing

aggression (DeSteno, Lim, Duong, & Condon, 2018), compulsive internet use (Quinones & Griffiths, 2019) and mindfulness (Flett et al., 2019; Kubo et al., 2021; Noone & Hogan, 2018; Robinson, 2018; Rosen et al., 2018; Wen et al., 2017; Wylde et al., 2017).

There have been 14 studies utilizing HS as an intervention for stress, anxiety or sleep as outcome variables (Avalos et al., 2020; Bostock et al., 2018; Champion et al., 2018; Dutcher et al., 2022; Economides et al., 2018; Fitzhugh et al., 2019; Flett et al., 2019; Kirk & Axelsen, 2020; Kubo et al., 2021; Kubo et al., 2018; Quinones & Griffiths, 2019; Robinson, 2018; Rung et al., 2020; Yang et al., 2018). In these studies, HS has been shown to reduce stress in the general population (Bostock et al., 2018; Champion et al., 2018; Economides et al., 2018; Kirk & Axelsen, 2020), with medical students (Yang et al., 2018), among college students, (Flett et al., 2019), community support workers, (Robinson, 2018), highly stressed customer service workers (Dutcher et al., 2022), cancer patients and caregivers (Kubo et al., 2018), pregnant women with moderate to severe depression in their first or second trimester (Kubo et al., 2021), and postpartum women with depression (Avalos et al., 2020). HS has also been shown to have a beneficial impact on sleep for a variety of populations including pregnant women with moderate to severe depression in their first or second trimester (Kubo et al., 2021), postpartum women with depression (Avalos et al., 2020), a community sample of women in southern Louisiana, (Rung et al., 2020), the general population (Kirk & Axelsen, 2020), and among cancer patients who received chemotherapy and their informal caregivers (Kubo et al., 2018).

For this dissertation research study, participants were instructed to complete HS's 30-day introductory MM course, the "Basics," which is comprised of three subsequent courses of 10 sessions each, for which participants have the ability to choose varying lengths of time. Sessions from Basics 1 can be set for 3, 5 or 10 minutes. Sessions from Basics 2 can be set for 10 or 15 minutes. Sessions from Basics 3 can be set for 10, 15 or 20 minutes. The app

designers cleverly made the course times variable, as it provides a variety of options for the users to choose from, depending on their mood and schedule.

After completing the “Basics,” participants were instructed to complete the “Pregnancy” pack, totaling 30 sessions, ranging in time from 10-20 minutes each. In all, study participants were asked to complete 60 guided meditations, with 100% completion of the intervention time ranging from 530-1050 minutes.

The meditations are guided by an experienced teacher, former Buddhist monk, Andy Puddicombe, although for many of the meditations, users have the ability to choose a variety of other guides, including women, if preferred (the content is the same). During the guided meditations, the teacher focuses on three different elements: the approach, the practice, and the integration. During the approach, the guide explains the dynamics of the mind, and how it commonly behaves during mediation. During the practice, meditation techniques are reinforced to cultivate clarity and a sense of calm, often using an object of focus, such as the breath, or a visualization. Finally, with the integration element, the teacher explains how to take the techniques learned and apply them to everyday life (Headspace). The techniques emphasize both awareness of the present moment, as well as compassion for the self and others. The content is designed to build as users complete each course, reinforcing knowledge and expanding on techniques (Headspace). There are many advantages of learning/practicing mindfulness meditation through an iMBI. These include: standardized content, efficiency, accessibility, and low cost (Zhang, Xue, & Huang, 2020), in addition to convenience, and personal choice regarding practice times.

Mediation and HRV

HRV is understood to overlap with neurobiological mechanisms associated with mindfulness training, specifically the regions in the brain involved with self-regulation (Christodoulou et al., 2020). As a result of this association, HRV is increasingly being utilized as a biomarker in mindfulness-based intervention research. HRV is understood to be a cardiac

index of the self-regulatory capacity to utilize the executive functioning skills necessary to manage feelings, thoughts, and goal-directed behavior (Christodoulou et al., 2020; Thayer, Åhs, Fredrikson, Sollers III, & Wager, 2012).

To date, there have been 1 scoping review, 3 meta-analyses, and 1 systematic review examining the impact of meditation on HRV. According to one scoping review of 17 mindfulness-based intervention (MBI) studies, the reviewers found that there was an increase in HRV reactivity following implementation of an MBI among non-clinical samples (Christodoulou et al., 2020). However, the review did not include any quantitative assessment. The authors described the results as challenging to integrate for a variety of reasons including the following: variability in HRV assessment and analysis including reported HRV metrics, duration of HRV recording, variation in exclusion criteria which is impactful to HRV (like caffeine, nicotine, medications), lack of controlling for impactful covariates (such as age), as well as variety in MBI program type and delivery metrics (Christodoulou et al., 2020).

To obtain accurate HRV time-domain measurements, current best practice recommendations denote a minimum of a recording duration of 5 minutes (Task Force, 1996). In total, 9 out of the 17 studies in this review, were in compliance with this recommendation, and 4 studies did not report the duration of their HRV recordings. The authors noted that MBIs had a greater impact on study participants who were engaging in stressful tasks (e.g. performing math, public speaking), but overall, concluded that more research was necessary to address the high variability of methodology across the studies (Christodoulou et al., 2020).

In the first meta-analysis conducted on HRV changes associated with MBI participation (Rådmark, Sidorchuk, Osika, & Niemi, 2019), investigators found no association between changes in HRV and MBI participation (Rådmark et al., 2019), and suggested a need for larger and more rigorously conducted RCTs to be conducted. A

more recent meta-analysis focused on the effects of mindfulness and meditation on specific elements of HRV (RMSSD and HF), which are vagally mediated, and thought to better reflect PNS downregulation of the heart (Brown et al., 2021). This meta-analysis evaluated 19 RCTs, and found insufficient evidence to indicate that MBIs lead to vagally mediated HRV in comparison to control conditions, and called for well-designed RCTs with low risk of methodological bias to be implemented in the future (Brown et al., 2021). The third a meta-analysis, evaluating 21 studies about HRV and meditation, found that short-term changes in HRV indices were observed during meditation, but that there was limited evidence for significant long-term effects (Bin Waleed et al., 2022). A recent systematic review which analyzed 10 controlled studies examining MBIs on HRV had mixed results, and indicated inconsistencies across the literature highlighting uncertainties regarding how MBIs impact HRV (Backlund, 2022).

The Oura Ring

The Oura Ring and other devices like the Fitbit, and Apple Watch utilize relatively new technology, and are referred to as *multisensory wearables* (Roberts, Schade, Mathew, Gartenberg, & Buxton, 2020). The Oura Ring and smartphone application (app) use sensors to collect information from the body including resting heart rate, HRV, body temperature, respiratory rate, movement, and sleep patterns. The sensors include a photoplethysmogram (PPG) for heart rate and respiration assessment, a 3D accelerometer for movement, and a negative temperature coefficient (NTC) monitor for body temperature. The Oura Ring utilizes actigraphy, which is a validated method of objectively measuring sleep parameters and average motor activity utilizing an accelerometer (Smith et al., 2018). Research supports that Oura Ring measurements of HRV (Cao et al., 2022; Kinnunen et al., 2020a) and sleep (de Zambotti et al., 2019) are highly accurate.

The Oura Ring uses the sensor data, physiological signals, sleep and activity patterns to report on three main metrics; sleep, activity, and a readiness score (Kinnunen et al., 2018). The

readiness score is a measure showing how the body responds to and recovers from the demands of daily life. The sleep information includes data on sleep quality and duration, including length, quality (REM, deep, and light), disruptions in sleep, movement during sleep, awake times, sleep latency, time in bed, and sleep efficiency, ultimately yielding a sleep score (Oura, 2020). The activity score combines profile information (age, weight, height, and gender) with measurements of physical activity, which is used to estimate movement and activity. Oura calculates signals into units of energy expended (calories) and equivalent activity measures (steps or miles) including goal progress (calories burned based on readiness level), total burn (total daily energy expenditure; total daily calories), walking equivalency (in miles) and total steps (Oura, 2020). For the purpose of this study, the Oura Ring was chosen for its ability to track HRV and sleep data.

Internet Mindfulness-Based Interventions in Pregnancy; A Review of the Literature

Internet mindfulness-based interventions (iMBIs), including computer, tablet, smart phone, and app-based courses/resources, provide an alternative to traditional mindfulness courses. Rather than being required to attend a six to eight-session in-person course, people can experience mindfulness training via the convenience of their own device, and on their own timeframe. Compared to in-person training, digital mediums are more affordable, demand less time, are wider-reaching, and may be more engaging (Spijkerman, Pots, & Bohlmeijer, 2016). As such, iMBIs provide an alternative to the time-consuming, in-person course. If shown to be an effective method of reducing stress and anxiety during pregnancy, use of evidence-based iMBIs can be recommended by providers at a large scale. A variety of iMBIs exist, and some have been tested specifically with the pregnant population.

To examine the impact of iMBIs on stress and anxiety during pregnancy, a literature review was done, initially finding 30 articles. Upon closer examination, 21 were excluded. For example, programs which delivered mindfulness interventions via

alternate modalities, including phone-delivered (Bublitz et al., 2019) were excluded, as were others that were delivered in real time via telemedicine consultations (Latendresse et al., 2021; Singla et al., 2021). One was eliminated as it delivered the live MBSR class online via the Zoom platform for women diagnosed with COVID-19 (Güney, Cengizhan, Okyay, Bal, & Uçar, 2022). Many other publications which showed up in the literature search were excluded because they were proposals (Chen et al., 2022; Finlay-Jones et al., 2020; Hulsbosch et al., 2020; Lenz et al., 2018; Müller et al., 2020). One study examined pregnant women's use of a popular app (Calm), and it was excluded because it was a survey, and did not include stress/anxiety as outcome variables (Green, Neher, Puzia, Laird, & Huberty, 2022). Another study using the same app was excluded as it included both pregnant women and non-pregnant gynecological patients in the same study population, not differentiating between them (Smith et al., 2021). Another study was eliminated as it was a psychoeducational positive psychology intervention with a minimal mindfulness intervention (Corno et al., 2018).

As this study was focused on a healthy population, studies that targeted pregnant women with specific comorbidities, other than anxiety, were excluded, including one focused on pregnancy loss (Jensen et al., 2021), two others focusing on maternal perinatal depression (Kubo et al., 2021; Sun et al., 2021), three which focused on the postpartum timeframe, rather than during pregnancy (Avalos et al., 2020; King, 2009; O'Mahen et al., 2013), and another because it targeted hospitalized, high-risk women (Goetz et al., 2020). Two were excluded because the sample population had preterm labor, and the interventions did not specifically focus on mindfulness meditation (Jallo et al., 2017; Scherer et al., 2014).

The remaining nine studies utilized iMBIs specifically targeted toward the pregnant population, with stress/psychological well-being, anxiety, or sleep as outcome variables (Carissoli et al., 2021; Carissoli et al., 2017; Cornsweet-Barber et al., 2013; Krusche et al., 2018a; Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015; Williams, 2012; Yang et al., 2019; Yang et al., 2022). Five were RCTs (Krusche et al., 2018a; Matvienko-Sikar & Dockray,

2017; O'Leary & Dockray, 2015; Yang et al., 2019; Yang et al., 2022), two were quasi-experimental studies with no control group (Cornsweet-Barber et al., 2013; Williams, 2012), and two studies were quasi-experimental randomized studies which had control groups (Carissoli et al., 2021; Carissoli et al., 2017).

Four of the studies measured stress as a primary outcome measure (Cornsweet-Barber et al., 2013; Krusche et al., 2018a; Matvienko-Sikar & Dockray, 2017; Williams, 2012), while two Italian studies focused on psychological well-being (Carissoli et al., 2021; Carissoli et al., 2017). Two of the studies measured anxiety as an outcome variable (Yang et al., 2019; Yang et al., 2022), and one measured sleep (O'Leary & Dockray, 2015). It should be noted that the reviewed studies included additional outcome measures like depression and mindfulness, but as these are not outcomes measured in this study, those results will not be discussed.

Three studies used the same stress assessment tool, the Perceived Stress Scale (PSS) (Cornsweet-Barber et al., 2013; Krusche et al., 2018a; Williams, 2012), while two others used the Prenatal Distress Questionnaire (PDQ), a stress assessment specific to pregnancy, in addition to salivary cortisol as an objective measure of stress (Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015). To measure anxiety, two studies used the State-Trait Anxiety Inventory (STAI) (Cornsweet-Barber et al., 2013; Williams, 2012), and three used the General Anxiety Disorder-7 (GAD-7) (Krusche et al., 2018a; Yang et al., 2019; Yang et al., 2022). Two of the studies measured psychological wellbeing with the Italian version of the Psychological Wellbeing Questionnaire (Carissoli et al., 2021; Carissoli et al., 2017). Only one study in the literature review measured sleep as an outcome variable, and they used the Jenkins Sleep Quality Questionnaire (O'Leary & Dockray, 2015).

The interventions had varying lengths of time; one study lasted eight weeks (Yang et al., 2019), four studies lasted four weeks (Carissoli et al., 2021; Carissoli et al.,

2017; Krusche et al., 2018a; Yang et al., 2022), two studies lasted three weeks (Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015), and two studies used a self-paced schedule to complete the intervention (Cornsweet-Barber et al., 2013; Williams, 2012).

A variety of MM interventions were employed by the studies in the literature review. Two used variations of similar interventions; pregnancy-specific, pre-recorded MBSR classes presented on an online platform called WeChat (Yang et al., 2019; Yang et al., 2022). The earlier iteration was an RCT, comparing MM training with an emphasis on attention monitoring and acceptance training with a control group (Yang et al., 2019). The later variation was 3-arm RCT in which one of the arms was the control group, one arm focused on mindfulness with monitoring training, and the third arm emphasized mindfulness with monitoring and the addition of acceptance training (Yang et al., 2022). The interventions for both studies consisted of four, 1-1.5 hour-long classes, in addition to instructions for study participants to practice 20 minutes of daily unguided MM.

Two other studies used a single audiophile-delivered mindfulness intervention to be practiced twelve times throughout the trial, one lasting six minutes, the other lasting nine minutes (Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015). Two other studies used the same intervention, the "BenEssere Mamma" app, which included psychoeducation on various topics, and instructions to complete 20 guided MM sessions throughout the study period (Carissoli et al., 2021; Carissoli et al., 2017). Two other studies used the same intervention, a computer-based mindfulness and biofeedback class called "Healing Rhythms," which consisted of psychoeducation and meditation training in structured classes. These classes included 15 guided meditations which were practiced concurrently with a biofeedback element consisting of heart rate variability (HRV) monitoring and galvanic skin response (GSR) (Cornsweet-Barber et al., 2013; Williams, 2012). The remaining study utilized the intervention "Be Mindful Online," a 10-session variation of the eight-week MBSR course, containing psychoeducation as well as formal and informal mindfulness instruction (Krusche et al., 2018a). Six studies used

interventions developed specifically for pregnancy (Carissoli et al., 2021; Carissoli et al., 2017; Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015; Yang et al., 2019; Yang et al., 2022), while the remainder of the studies utilized generic mindfulness content not specifically geared toward pregnancy (Cornsweet-Barber et al., 2013; Krusche et al., 2018a; Williams, 2012).

Several of the studies had multiple components as part of the intervention. Two of the studies had dual component interventions, combining MM practice and gratitude journaling (Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015). For the two studies which used the "Healing Rhythms" intervention, in addition to psychoeducation and mindfulness practice, there was biofeedback involving HRV and GSR (Cornsweet-Barber et al., 2013; Williams, 2012). In addition to the mindfulness content, two studies had interventions which included peer group support elements, and check-in contact with providers (Yang et al., 2019; Yang et al., 2022). Two of the studies used an app called "BenEssere Mamma," which, in addition to guided MM practice, contained educational content about various topics including stress, emotional awareness, and nutrition, in addition to a mood diary journal (Carissoli et al., 2021; Carissoli et al., 2017).

Results of Studies in Literature Review

For the majority of the studies, the results showed that the MM interventions had a positive impact on reducing stress and anxiety, as well as improving psychological wellbeing and sleep. Three studies showed a decrease in stress after the intervention (Krusche et al., 2018a; Matvienko-Sikar & Dockray, 2017; Williams, 2012), while two studies trended in the direction of stress reduction (Cornsweet-Barber et al., 2013; O'Leary & Dockray, 2015). Of the two studies which used salivary cortisol as a measure of stress, one resulted in a significant decrease in salivary cortisol for the intervention group (Matvienko-Sikar & Dockray, 2017), while the other had no significant decrease

(O'Leary & Dockray, 2015). Two studies had significant decreases in anxiety (Yang et al., 2019; Yang et al., 2022), and two others trended in the direction of anxiety reduction (Cornsweet-Barber et al., 2013; Krusche et al., 2018a). For the Italian studies which utilized psychological wellbeing as the outcome measure, significant improvements were found for the intervention groups in the area of autonomy (Carissoli et al., 2021; Carissoli et al., 2017), and greater self-acceptance after childbirth (Carissoli et al., 2021). For the study which measured sleep as an outcome variable, there were significant improvements in sleep quality (O'Leary & Dockray, 2015).

Two of the studies showed greater post-intervention improvement in stress for study participants who had a higher initial baseline level of stress (Cornsweet-Barber et al., 2013; Matvienko-Sikar & Dockray, 2017). Similarly, two studies specifically recruited women with mild to moderate anxiety symptoms and found significant post-intervention reductions in anxiety (Yang et al., 2019; Yang et al., 2022). These results aligned with the findings of a systematic review which showed that significantly larger effect sizes were found for studies that recruited pregnant subjects with elevated symptoms of stress and anxiety as compared to those without elevated stress and anxiety levels (Taylor et al., 2016).

Limitations of iMBIs for Pregnant Population

Aside from the limited number of studies, there were various limitations to the studies as follows: small sample size, high attrition, low adherence, problematic study design, risk of bias, homogeneity, confounders, and lack of objective measurements of stress. Only two studies had objective measures of stress, such as salivary cortisol levels (Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015). Four of the studies had small sample sizes, ranging from 9 to 46 participants (Cornsweet-Barber et al., 2013; Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015; Williams, 2012).

Study Limitations: High Attrition and Lack of Adherence. For many of the studies, there were issues related to high attrition rates and lack of adherence to the intervention. Three

studies had high attrition rates, one with a 79% attrition rate (Krusche et al., 2018a), and two others studies with 22% attrition rates (Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015). Several studies showed poor adherence to the intervention, with one study reporting 45% of the expected exercises completed (Carissoli et al., 2021) and another reporting 60% (Carissoli et al., 2017).

Interestingly, studies reported adherence in unique (biased) ways, which were not necessarily reflective of adherence to the MM portion of the studies. Two of the studies reported adherence as the number of psychoeducational and guided MM sessions completed (out of four total), not fully addressing compliance with the daily suggested MM practice part of the intervention. As such, they both reported good adherence, with one study reporting that 74% of the participants completed three out of the four sessions (Yang et al., 2022), and the other reported a completion rate of 83.9% (Yang et al., 2019). However, in addition to attending the class, a component of the intervention was an expectation that participants practice MM for 20 minutes daily. For both of these studies, the adherence to the MM practice was low, as was briefly acknowledged by one of the studies (“adherence to daily mindfulness practice was fairly low”) (Yang et al., 2019, p. 72), and yet, they did not include many more details, or calculations about it. In one of these studies, a self-guided daily practice of 20 minutes for the eight-week study period was part of the intervention. The investigators reported that the mean number of MM practice sessions was 3.25 times per week with an average of 21.23 minutes per meditation. This means that study participants completed an average of 551.98 out of the recommended 1120 minutes, which amounts to 49% adherence of the MM part of the intervention (Yang et al., 2019).

In another study by the same authors which had the same problem, the suggested MM practice time was 20 minutes daily for the 4-week duration, totaling 560 minutes. The investigators reported the average number of MM practices was 3.41 times

for an average of 21.53 minutes per session, which amounts to a 13.1% adherence rate to the MM part of the intervention (Yang et al., 2022).

In one of the studies, only 21% of the participants randomized into the intervention group completed the intervention (Krusche et al., 2018a). The authors of the study attributed the high attrition rate to poor usability and acceptability of the intervention. In one study which utilized “BenEssere Mamma” app, study participants completed an average of 12 of the suggested 20 exercises, for a 60% adherence rate (Carissoli et al., 2017). In a later study using the same intervention, participants completed an average of 9 out of the suggested 20 exercises, for a 45% adherence rate (Carissoli et al., 2021), potentially implying an issue with the usability and acceptability of the app.

Another study considered a practice session complete if the participant completed both the MM and the gratitude journaling session. Those study participants averaged 63% adherence rate (O’Leary & Dockray, 2015). None of the studies provided any cash or gift card incentives, which may have contributed to attrition and adherence issues.

Study Limitations: Problematic Study Design. There were several studies with problematic study designs. Two of the studies measured MM time by study participant self-report (Yang et al., 2019; Yang et al., 2022), which potentially calls to question the validity of the data. Another study had a similar problem, as they reported adherence to the intervention as the number of gratitude journal diary entries completed, but did not keep track of the amount of time study participants spent practicing MM (Matvienko-Sikar & Dockray, 2017). In this study, participants completed an average of 8 out of the 12 required gratitude journal entries for a 66% adherence rate (Matvienko-Sikar & Dockray, 2017). The frequency and total time spent practicing MM was not mentioned, if measured at all in this study.

Another issue related to study design had to do with the potential problem of requiring/assigning novice meditators to engage in self-led practice, as opposed to having guided MM sessions, as was the case in two of the studies (Yang et al., 2019; Yang et al.,

2022). It is possible that novice meditators lack the training, knowledge, and discipline to effectively practice MM by themselves.

Several studies had problematic study design related to the intervention being comprised of multiple components other than MM, leading to potentially confounding study results. Two studies had dual component interventions, coupling gratitude journaling with MM practice (Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015). A gratitude journal intervention is different than a MM intervention; yet in the study, the researchers did not contain separate analyses for the different interventions (Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015). Due to this problematic study design, it is impossible to differentiate whether the study effects occurred as a result of the gratitude journaling or the MM elements of the study.

Two other studies had similar issues regarding study design. These studies used "Healing Rhythms," a multi-modal program including psychoeducation and guided MM practice, in addition to a biofeedback element which included HRV monitoring and galvanic skin response, a measure of psychological arousal (Cornsweet-Barber et al., 2013; Williams, 2012). When interventions have multiple components, it is impossible to determine which element of the intervention contributed to the largest effect size to the study results.

Two other studies had similarly problematic study design issues. For these of the studies, in addition to the online mindfulness courses, and suggested daily MM practice, the intervention included peer group support, and regularly scheduled check-in contact with health care support staff and/or providers (Yang et al., 2019; Yang et al., 2022). These additional elements are potential confounders of the study results, as it is impossible to determine if the effect of the study outcomes was due to the MM part of the intervention, or if it was influenced by the other elements of the intervention.

Another potentially problematic study design was offering the same MM audio file for participants to listen for the entire study period, as was the case in two studies (Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015). Listening to the same meditation may have been repetitive and boring, which could have contributed to lack of compliance.

All of the studies in the literature review took place outside the United States: two in New Zealand, two in China, two in Italy, two in Ireland, and one in England. Many of the studies had issues related to homogeneity of the study population. Most of the studies had participants who were well educated (Carissoli et al., 2021; Carissoli et al., 2017; Cornsweet-Barber et al., 2013; O'Leary & Dockray, 2015; Yang et al., 2022). Several studies did not include demographic information on ethnicity (Cornsweet-Barber et al., 2013; Williams, 2012; Yang et al., 2019; Yang et al., 2022), and the remainder of the studies in the literature review cited a lack of diversity in their study population (Carissoli et al., 2021; Carissoli et al., 2017; Krusche, Dymond, Murphy, & Crane, 2018b; Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015). This is problematic as it impacts the generalizability of the results to the general public.

The Gaps

This review of the literature indicated that there were various gaps in current knowledge, presenting many areas for future research. To fill these gaps, future research studying the impact of iMBIs on stress and anxiety for the pregnant population ideally would entail rigorously designed, adequately powered RCTs, specifically attending to issues of bias, inclusive of participants representing diverse populations, and utilizing physiologic measures of stress.

This pilot dissertation study took into consideration the problematic issues illuminated in the literature review, with plans for the results of this study to inform a future RCT. Engagement and usability/acceptability was an issue for the majority of the studies in the literature review (Carissoli et al., 2021; Carissoli et al., 2017; Krusche et al., 2018a; Matvienko-Sikar & Dockray, 2017; Yang et al., 2019; Yang et al., 2022). This may have been because the MM interventions

were not sufficiently engaging, were self-led, or may have been too long to maintain interest in a self-driven digital format.

One of the reasons that HS was selected as the MM intervention for this proposed study was to potentially address the engagement and adherence challenges portrayed in the reviewed studies. Some features that the HS app has which may assist with this include content variety, content length, choice of teachers, and programmable reminders. HS offers meditations which have content centered around a variety of themes (e.g.: anxiety, sleep, anger, growth, etc.), as well as varying lengths of time which may be chosen by the participant. Additionally, HS offers the ability for the user to choose a variety of teachers to deliver the standardized content, providing more control for participants, as well as choices which might be more appealing. HS is programmable to set alerts for user smartphones to remind them to do the intervention. The participants in this dissertation study were provided with written instruction as well as verbal encouragement to do this. An important feature of HS is that it is able to track study participant usage data, so adherence can be objectively measured, contributing to study validity.

Only two studies in the literature review included a physiologic measure of stress as an outcome (Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015), and only one included sleep (O'Leary & Dockray, 2015). The addition of HRV and sleep as physiologic measures for stress created a stronger study design. None of the studies in the literature review gave incentives for the participants to be involved. This study included a nominal financial incentive which was distributed twice throughout the trial. In addition, the investigator's personal email and cell phone number were given, so that study participants had 24-hour access if assistance was required.

In designing a rigorous study, an important consideration is to minimize confounding factors. As such, specific inclusion and exclusion criteria were delineated,

which made study design improvements based upon the limitations of studies in the literature review. A healthy pregnant population was chosen to eliminate the risk of additional stressors & anxiety related to a medical diagnosis, medications, potential hospitalizations, and other such issues.

The women in the proposed study could not be in concurrent psychotherapy, or on psychoactive medications to minimize the risk of confounding factors related to other treatment. People undergoing psychotherapy may be taught mindfulness and stress reduction strategies, which would be considered a confounder. If people were on, or started psychoactive medications during the study course, that confounds the impact of the intervention alone, as they may be feeling better due to the medications, as opposed to because of the intervention.

Another potential confounder was yoga practice. There is evidence that practicing yoga (three times per week) during pregnancy can reduce stress (Kusaka, Matsuzaki, Shiraishi, & Haruna, 2016). As such, a regular yoga practice is a confounder, and part of exclusion criteria. In addition to yoga practice, practicing other forms of complementary mindful practices (tai chi, meditation, body scan and reiki) were also exclusion criteria for the study, as it was important to exclude participants who currently already had a mindful-type practice.

In contrast to several of the studies in the literature review, the proposed study design contained a singular intervention, MM with the HS app. This was not the case with several of the studies in the review, which contained interventions that had multiple elements including additional teaching about stress, teaching about nutrition, gratitude interventions, journaling elements, peer group support, biofeedback, and interactions with healthcare personnel. When interventions contain multiple elements, the various elements are confounders, and it is difficult ascertain which element of the intervention was responsible for the effect on the outcome variables. This study examined the impact of a single intervention, MM with the HS app, and evaluated whether use of it assisted pregnant women to reduce their stress and anxiety levels.

Chapter 3: Theoretical Framework

Theory is the main foundational component of scholarly disciplines, helping members within the discipline identify and articulate their focuses (Meleis, 2012).

Theories are developed to answer specific scientific questions in addition to identifying the relationships between concepts, in order to clarify and explain phenomena.

Theoretical frameworks are the basic structures developed to organize the concepts, which are focused on a scientific question. The objective of a theory is to formulate a minimum set of generalizations which allow someone to understand and explain the explicitly defined observable relationships among the variables (Meleis, 2012). The theory identifies, defines, and labels concepts, and defines relationships between those concepts. The theory then is able to provide insights into the practice discipline, as well as to guide research within that field.

Greeson's conceptual model (Figure 1), Mechanisms of Mindfulness: Effects on Sleep Quality & Stress Physiology (Greeson et al., 2018), shows the hypothesized mechanisms of mindfulness that represents the conceptual framework for this study, with the replacement of the MBSR intervention with the Headspace (HS) intervention (Figure 2). The adapted model proposes that mindfulness practice via the HS app causes an increase in mindfulness for study participants. This in turn impacts both cognitive (thinking) as well as emotional (feeling) processes. Specifically, this conceptual framework proposes that practicing mindfulness meditation (MM) via HS leads to an increase in mindfulness, which leads to a decrease in cognitive perseveration (i.e. negative, repetitive, intrusive thoughts), and an increase in emotion regulation. These changes, in turn, lead to an improvement in sleep quality, and a reduction in stress symptoms and stress physiology (e.g., irritability, restlessness, headaches, stomach aches, nausea, fatigue, sweating, etc.). More details regarding these relationships will be discussed in the paragraphs below.

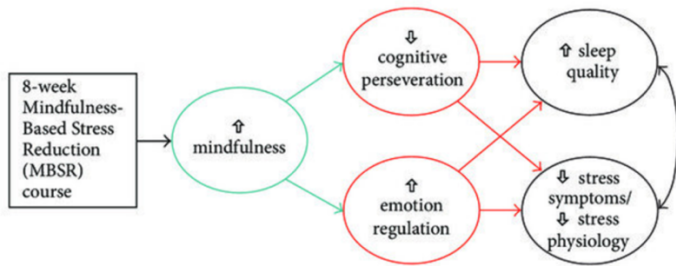


Figure 1. Greeson's Model: Mechanisms of Mindfulness: Effects on Sleep Quality & Stress Physiology

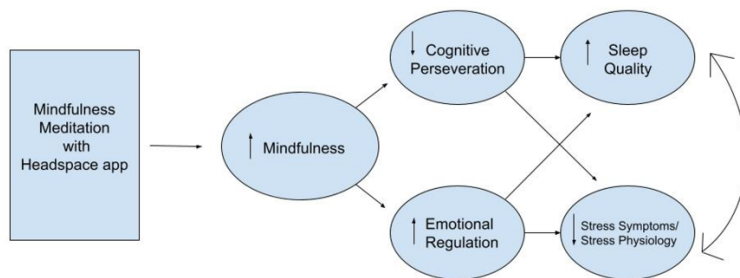


Figure 2. Adapted Greeson Model: Mechanisms of Mindfulness: Effects on Sleep Quality & Stress Physiology

Mindfulness

According to the adapted Greeson model, practicing MM with the HS app leads to an improvement in mindfulness. Details of mindfulness were outlined in a previous section, but to review, mindfulness is the awareness that arises through paying attention, on purpose, in the present moment, non-judgmentally (Kabat-Zinn & Hanh, 2009). According to this model, increased mindfulness leads to a reduction in cognitive perseverations and an improvement in emotional regulation. These changes then lead to a buffering the stress response, decreasing stress symptoms/physiology as well as improving sleep.

Cognitive Perseveration

According to the model, an increase in mindfulness leads to a decrease in cognitive perseveration. Cognitive perseveration is a term used in psychology defined as “repeated or

chronic activation of the cognitive representation of one or more psychological stressors” (Brosschot, Gerin, & Thayer, 2006, p. 114). Cognitive perseveration is characterized by self-focused negative, repetitive, intrusive thoughts, rumination, worry, and mind wandering about negative topics (Greeson et al., 2018). The perseverative cognition hypothesis asserts that cognitive perseveration is associated with prolonged physiological responses to emotional stress (Brosschot et al., 2006; Greeson et al., 2018), including physiological effects like increased heart rate, blood pressure, and cortisol levels (Ottaviani et al., 2016). Improved mindfulness helps decrease cognitive perseveration by utilizing focused attention to increase awareness of the negative thought patterns, and promoting acceptance, nonreactivity and nonjudgment, anchored in present moment experience. According to the model, this decrease in cognitive perseveration then results in improvements in stress symptoms/stress physiology, and sleep quality.

Emotion Regulation

Emotion regulation refers to both an increased awareness of emotions, and a greater understanding of emotional responses. Mindful emotion regulation is characterized by a way of attending to and responding to negative emotions marked by focused attention, open awareness, acceptance/nonjudgment, compassion, curiosity, as well as the ability to act consciously versus automatically reacting to stress (Feldman et al., 2022; Greeson et al., 2018). In Greeson’s model, increased mindfulness leads to improved emotional regulation, which then causes a decrease in stress symptoms/stress physiology, and an improvement in sleep. A more detailed description of these constructs, and how they are influenced by mindfulness will be described in the following paragraphs.

Emotion Regulation: Top-Down and Bottom-Up

Two different pathways exist in the brain to process stress and regulate emotions, the “top-down” and the “bottom-up” pathway. The top-down pathway refers to

the topmost part of the brain, the prefrontal cortex, which is associated with thinking, logic, cognitive flexibility, impulse inhibition, and higher-order emotion awareness. In the top-down approach to emotion regulation, emotions are conscious responses to how one thinks about their circumstances. In other words, people feel something based on their thoughts regarding a particular stimulus. As an example, a student has a test the following day for which they have not prepared and thinking about the test causes an emotional reaction (stress, anxiety).

The bottom-up pathway involves the lower parts of the brain which include the brain stem and limbic system. The brain stem is the oldest part of the brain, often called the “reptilian brain,” and is responsible for vital respiratory and cardiac functioning. The limbic system includes the hippocampus, the amygdala, and the hypothalamus. The hippocampus is responsible for learning, memory, and spatial reasoning. The amygdala processes emotions and attaches emotional meaning to memory. The hypothalamus is a gland in the brain which plays a crucial role in many functions including hormone release, controlling appetite, body temperature, sexual behavior and regulating emotional responses.

The lower parts of the brain are home to the sympathetic nervous system (SNS) and the hypothalamus pituitary adrenal (HPA) axis, which are responsible for the fight, flight or freeze responses. When a threat is perceived, the SNS is activated, causing several physiological responses (increased heart rate and respiratory rate, etc.), designed to ready the body for brief vigorous action to enhance survival in the face of a threat. If the threat persists, the HPA axis initiates the second component of the stress response system, continuing to augment the SNS, in addition to initiating a hormone cascade resulting in the release of cortisol, which functions to keep the body in a high alert state for a longer period of time.

In contrast, when the parasympathetic nervous system (PNS) is initiated, it reduces heart and breathing rates, and helps restore the body to a state of rest and recovery. This settling response from the PNS tempers activation of the SNS, allowing the autonomic nervous

system (ANS) to return to a baseline level of equilibrium (Brody, Scherer, Turner, Annett, & Dalen, 2018).

In the bottom-up approach to emotion regulation, an emotion is sparked in response to a stimulus. In other words, a person first becomes aware of body sensations or feelings, and then thoughts follow. As an example, a honking car horn (stimulus), stimulates physiological sensations associated with SNS activation (increased heart rate, increased respiratory rate, etc.), as well as associated emotions (fear, stress, anxiety, aggression, anger), followed by a thought (“Ahh, this car is tailgating me and nearly ran me off the road! What an *#@*!”). Interestingly, the body does not always differentiate between high stress situations and actual survival threats. In fact, many individuals have physiological responses to minor daily stressors in the same way they would to an actual threat to their survival (Parker, Nelson, Epel, & Siegel, 2015). This is common in people with a trauma history, like those with PTSD (Wahbeh, Goodrich, Goy, et al., 2016).

Mindfulness and Emotion Regulation: Mechanisms of Action

Research supports that MM improves emotion regulation (Britton et al., 2012; Hill & Updegraff, 2012; Huang et al., 2019; Jazaieri et al., 2014; Prakash, Hussain, & Schirda, 2015). This is proposed to occur by facilitating neuroplasticity and connectivity in regions of the brain specifically related to emotion regulation (Brandmeyer et al., 2019). Improved mindfulness increases the brain’s ability to appraise and respond to stress threats along both the top-down and bottom-up pathways (Brandmeyer et al., 2019; Brody et al., 2018). Mindfulness supports stimulation of the part of the brain responsible for higher order emotional awareness (prefrontal cortex), augmenting its connections with the area of the brain responsible for emotional processing (amygdala) (Brody et al., 2018; Kral et al., 2018). Strengthening the neuronal connections between the prefrontal cortex and the amygdala theoretically provides *more time* for cognitive

processes to activate, enhancing the potential for thoughtful responses to emotionally charged situations (Carmody, 2015). Utilizing the top-down pathway promotes *acting* versus *reacting* to a situation. In other words, with improved mindfulness, people learn to disengage from automatic emotional responding (Carmody, 2015), gaining an increased potential to make conscious decisions regarding their behavioral responses by learning to stop and think before acting (Coatsworth et al., 2015; Martínez, Martínez-Pampliega, & Ramos, 2020; McEvoy, Graville, Hayes, Kane, & Foster, 2017).

Another proposed mechanism is via the bottom-up pathway. Mindfulness facilitates this by buffering the bottom-up fight, flight, freeze response either by reducing SNS arousal, or by improving PNS settling (Brody et al., 2018; Creswell & Lindsay, 2014; Tang, Hölzel, & Posner, 2015). MM practice typically begins with drawing one's attention to the breath, with participants being cued to actively focus on their breath, breathing a little slower and deeper than usual. This activates the PNS, reducing breathing rate, heart rate, and blood pressure, producing sense of calm and increased safety (Wahbeh, Goodrich, Goy, et al., 2016; Zaccaro et al., 2018). By a similar mechanism, focusing on the breath may also reduce SNS arousal. According to the model, improved mindfulness enhances emotion regulation by increasing the brain's ability to appraise and respond to stress threats via both the top-down cognitive and bottom-up physiological pathways. When stress symptoms/stress physiology are improved, sleep quality is enhanced as well.

Stress and Sleep

The relationship between stress and sleep has previously been discussed in this dissertation, but to review, as shown in the Greeson model, it is a bidirectional relationship. According to this model, improved sleep quality causes a reduction in stress symptoms/stress physiology, and the reverse is true as well. When people have lower stress symptoms and stress physiology, their sleep quality improves. Greeson's model explains the relationship between mindfulness meditation and the main outcome variables in this study, stress, and

sleep. According to the model, meditation with the HS intervention causes an improvement in mindfulness. With improved mindfulness, people learn to improve their emotion regulation and decrease cognitive perseveration, leading to the subsequent reduction in both stress symptoms/stress physiology, as well as an improvement in sleep quality.

Chapter 4: Methodology

The methods section contains the following sections: overview of study design, study population with inclusion and exclusion criteria, study setting, procedures, measures, statistical analysis plan, and potential problems.

Overview of Study Design

The goal of this pilot research study was to evaluate the impact of a mindfulness meditation app, Headspace, on outcomes of stress and anxiety levels among pregnant women. The two main branches of research are quantitative and qualitative research. Quantitative studies use data which can be analyzed utilizing conventional statistical methods, while qualitative studies focus more on methods used to gain insight related to behavior or attitudes (Peat, 2001). While there are many ways to go about answering potential research questions, experimental studies are the best way to test the impact of a treatment or intervention. The study designs, which would best answer the current research question, are quantitative, experimental, interventional research designs.

The study design chosen for this proposal was a prospective, longitudinal, single-arm trial (SAT). In this type of study design, subjects are examined over time to observe for any changes that may occur. This study design is a form of an “open trial” in which both the study participants and the researchers are aware of the treatment/intervention the research subject receives. These types of studies are traditionally appropriate in the initial clinical investigation of a new treatment/intervention (Phase 1 studies), or with a novel population, and the data gathered is intended to inform a future, larger, more methodologically rigorous study, like an RCT.

The intervention for this study included two of Headspace’s learning “packs”; the “Basics,” and the “Pregnancy” pack. “The Basics,” contains 30 meditations to introduce the basics of meditation. Participants were asked to do two meditations per day, ranging from 5-20 minutes, to be completed during the first 14 days of the trial. Following this, participants were

asked to complete the 30 meditations contained in Pregnancy pack, which ranged in time from 10-20 minutes, twice daily.

Prior to the start of the intervention, participant self-reports of stress and anxiety were assessed via a structured questionnaire. The questionnaire assessment for the anxiety measures were repeated once at the midpoint of the study (two-week mark), and again at study completion. The questionnaire for stress was only repeated at study completion, due to the stress measure (PSS) guideline of evaluating stress over a month-long period. As this study duration is approximately a month long, it would have been inappropriate to use this measure at the study midpoint. During the study, the participants were instructed to wear the Oura Ring, which tracks their HRV and sleep metrics. At study completion, the self-report stress and anxiety data were analyzed (Aim 1), and the HRV and sleep data were analyzed by evaluating trends throughout the study period to determine any changes (Aim 2).

At study completion, app usage data was collected from HS. The app usage amount was analyzed to determine if study participants who used the app more frequently experienced greater reductions in their stress and anxiety levels as compared to participants who used the app less frequently. To quantify this, the total number of sessions, as well as the total number of minutes utilized were collected and analyzed (Aim 3).

Study Population

The study sample consisted of 20 study participants, which could achieve between 78.2% and 93.4% power, with a large effect size (0.35) with an alpha (error probability) of 0.05. Inclusion criteria included: 1) pregnant women residing in San Diego County; 2) between the ages of 18 and 35; 3) low risk pregnancy, estimated to be between 10 and 32 weeks of pregnancy gestation; 4) ability to read and understand English; 5) access to a smartphone, Wi-Fi, email, and the ability to download apps.

For this pilot study, low-risk, pregnant women were chosen to minimize the risk of confounding variables due to patient preexisting or pregnancy-related illness. The age range of 18-35 years was chosen as below 18 and over 35 are considered higher risk pregnancies, and have issues related to adolescence and advanced maternal age, which increase the health risks associated with the pregnancy. The participants needed to be able to read and understand English, as the investigator was involved in the screening process and is an English speaker. The study period took approximately 1 month +/- 2 weeks. Excluding women past 32 weeks' gestation allowed for more time to complete the study prior to birth.

Exclusion criteria included: 1) women who currently regularly practiced mindfulness or regularly engage in any other mindful-like complementary practice such as yoga, tai chi, body scan or reiki ($\geq 3X/week$); 2) current enrollment in a mindfulness/meditation class; 3) hearing impairment which limits their ability to hear the app; 4) cognitive impairment which limits participation in the study; 5) women with a chronic health or pregnancy induced medical condition which would qualify the current pregnancy as "high risk" (hypertensive disorders of pregnancy, diabetes, multiple fetus, growth restriction, placental problems, etc.); 6) women currently in psychotherapy; 7) women currently taking psychoactive medications, and 8) women who have severe depression or anxiety.

Women with regular meditation, yoga, or complimentary mindfulness practices were excluded from the study as they were already engaging in meditation and or other meditation-like practice. This study is focused on how an intervention, which would be *new to them*, may help with their stress/anxiety levels. Women currently in psychotherapy were excluded because of the possibility that they might be receiving mindfulness training from their therapists. Women who had severe depression or anxiety would need a more in-depth intervention/treatment plan of care than what this study could have provided.

Selection bias refers to when individuals in a study differ from the population of interest. Measures were taken to recruit eligible candidates, which were representative of as many

diverse ethnicities and ages as possible. The more diverse the study population, the more it positively impacts the external validity, or generalizability, of the study results.

Study Site

Study participants were recruited from three sites, the Linda Vista Health Care Center (LVHCC), Best Start Birth Center (BSBC), and West Coast OB/GYN; all of which are located in San Diego, California. According to the U.S. Census, the race/ethnicity demographics of San Diego County are as follows: Caucasian 45%; Hispanic/Latino 34.1%; Asian 12.6%; and Black 5.5% (United States Census Bureau, 2019).

The Linda Vista Health Care Center is a Federally Qualified Health Center (FQHC), serving a large, underserved community, including members of the Hispanic and Asian/Vietnamese populations. The clinic has three part-time providers in the prenatal program, two OB-GYN physicians, and a certified nurse midwife. At the clinic, providers see approximately 40 new pregnant patients per month, of whom 20% are teens and 20% are advanced maternal age. The providers see a total of about 120 pregnant clients each month. They serve an economically and ethnically diverse population, with approximate demographics as follows: Caucasian 45%; Hispanic/Latino 34.1%; Asian 12.6%; and Black 5.5%.

BSBC is the first Nationally Accredited and licensed birth center in California (Best Start Birth Center, 2020). They have insurance contract agreements with Medi-Cal, TriCare (military), and most private insurance companies. They serve an economically and ethnically diverse population, with approximate demographics as follows: Caucasian 45%; Hispanic/Latino 34.1%; Asian 12.6%; and Black 5.5%. Approximately half of their patients receive Medi-Cal benefits. They have two full-time and three part-time certified nurse midwives. The providers see between 20-40 new patients per month, and average about 30 births/month. About half of their new patients are primigravid (experiencing their first pregnancy) (Shari Stone-Ulrich, 2020).

West Coast OB/GYN (WC OB/GYN) has three sites in San Diego County including North, Central and East County, where eleven providers provide patient care. They serve an economically and ethnically diverse population, with approximate demographics as follows: Caucasian 45%; Hispanic/Latino 34.1%; Asian 12.6%; and Black 5.5%.

Program Delivery Procedures

Recruitment

After IRB approval for the study was obtained by UCI, potential participants were recruited via IRB-approved flyers which were placed in the waiting rooms of LVHCC, BSBC and WC OB/GYN. The flyer briefly described the study and provided investigator contact information (phone and email) for interested potential participants. In addition, BSBC included it in the welcome packets for all new clients. The midwives, social worker and childbirth educator who work there were aware and supportive of the study.

Once contacted, the investigator sent the potential participant a recruitment email (Appendix 1) which contained further details about the study, including eligibility criteria. The participant was instructed to review the email and contact the investigator if they met the eligibility criteria listed in the email and were still interested. If there was no contact within one week's time, a follow-up email was sent by the investigator. Once contacted, if potential participants indicated that they were still interested, a phone conversation was scheduled to further assess eligibility, explain study details, and answer any questions.

During the ensuing phone call, potential participants were asked to give their verbal consent for the investigator to further assess their eligibility for the study via the inclusion and exclusion criteria (Appendix 2), in addition to screening them for severe anxiety and depression. This was done by means of a screening algorithm built into REDCap (see below) and entered into the computer by the investigator while on the phone with the potential participant. Participants were assured that the screening interview was done in a private, confidential location, and that their data would be securely stored.

Potential study participants were screened for depression using the Edinburgh Postnatal Depression Scale (EPDS) (Cox, Holden, & Sagovsky, 1987). If potential participants scored ≥ 19 , which is the cutoff for severe depression on this scale, they were ineligible for participation in the study. Potential study participants were screened for severe anxiety using the Generalized Anxiety Disorder Scale (Spitzer, Kroenke, Williams, & Löwe, 2006). If potential participants scored ≥ 15 , which is the cutoff for severe anxiety on this scale, they were they were ineligible for participation in the study.

If screening measures indicated either severe depression or severe anxiety, women were then counseled to seek treatment for their mental health through their primary or perinatal care provider, as well as calling “211,” and/or accessing <https://211sandiego.org/resources/> online to be connected with free and reduced rate mental health resources in San Diego County. None of the study participants which were screened had severe depression or severe anxiety. If the potential participant met the study criteria, interested and eligible women were informed about the consent process.

Recruitment and screening began immediately after IRB approval, which was obtained in October of 2021. Study participants were enrolled between October of 2021 through May of 2022, and the study enrollment was completed in June of 2022. The final HS app usage data report was received in July of 2022, with data analysis to follow. It took 8 months to recruit 20 eligible study participants. 33 people expressed interest and were screened, but twelve people were ineligible due to either advanced maternal age (8) or being beyond the cut-off of 34 weeks’ gestation (4) (Figure 3). One woman was scheduled to be consented but canceled at the last minute due to a family crisis.

Meeting With Study Participant

Depending on where the participant lived, a meeting place was arranged at a mutually agreed upon convenient meeting spot, like a local park or coffee shop (keeping in mind distancing guidelines for COVID-19). The approved Informed Consent document

was read and discussed, as well as the Research Data Privacy Acknowledgment document required by Headspace. An opportunity was provided for potential participants to ask questions. After all questions were answered, and if the woman continued to show interest, the potential participants were asked to sign the document. The participants were informed that their personal information would be kept confidential, that the study was voluntary, and that they could terminate participation at any point. At that time, the participant was considered enrolled.

REDCap

In addition to the consent forms, the investigator accessed the various baseline measures on REDCap for the participants to complete on a tablet, while being available for questions. REDCap is a highly secure, HIPAA-compliant web-based application developed to manage data for clinical research. All surveys utilized during the study were accessed and distributed via REDCap.

Assistance with Oura Ring and App

The investigator assisted each study participant to create an Oura Ring account, which included a username, password, and a random ID to ensure confidentiality. The study participants were loaned an Oura Ring to wear nightly during the study period, with the option to wear it during the day. To obtain a baseline value for study participant's HRV and sleep, participants were instructed to wear the ring for four nights prior to the start of the HS intervention. This four-night baseline included two weekend nights and two weeknights, to attempt to capture a range of typical stress in an average week. The investigator provided instructions to the study participant regarding use and care of the Oura Ring, (Appendix 5) and time was allotted to answer questions. The investigator confirmed the study participants' ability to utilize the Oura Ring app by return demonstration.

The participants' user information was stored on a server and dashboard, which communicated with the Oura server to download the participants' data. The app can store about one weeks' worth of data. In order for the data to be transferred to the server, the participant

needed to open the app on their device. The study participants were instructed to open the app every day or so, to check the charge of the ring, and enable the necessary transfer of data. The dashboard was monitored on a weekly basis to ensure the participant's adherence to wearing the ring per study protocol. If it was observed that the participants were not wearing the ring as instructed, the investigator contacted the study participant to provide any necessary support and reinforcement of study guidelines.

On a handful of occasions, when monitoring of the server indicated that there were gaps in data retrieval, study participants were contacted to remedy the situation. One participant misunderstood, and thought the ring was only to be worn for the first 4 nights. Others needed to be reminded to either open the app more frequently, or to update the app. After the app was opened and updated, the data was relayed to the server.

Assistance with Headspace App

Headspace (HS) provided user codes to the investigator which were utilized to assist the participants to create accounts. The investigator provided instructions to the study participant regarding HS (Appendix 5), and time was allotted to answer questions. The investigator confirmed the study participants ability to utilize the HS app by return demonstration. The investigator encouraged the study participant to set daily reminders, at a time of their choosing, on the Headspace app. If desired, the investigator assisted with this.

Incentive

As a study incentive, participants each received a 6-month subscription to the Headspace app, as well as \$50. The participants were instructed that at the mid-study point, REDCap would automatically send them surveys to complete, and that once those were completed, they would receive their first \$15 gift card incentive by email.

Participants were informed that at study completion, there would be additional surveys

for them to complete, which would again be automatically sent to them by REDCap. They were informed that once those surveys were completed, they would be contacted by the investigator to arrange a meeting time/place to return their Oura Ring and charger and receive their remaining financial incentive (\$35 gift card).

Of the 20 women enrolled, all of them completed the baseline, midpoint, and end of study assessments, except for two participants. While one study participant completed the baseline Pregnancy-Related Anxiety Scale (PRAS), there was an issue saving it, so the results did not capture in REDCap. Another study participant did not complete the 2 midpoint assessments. One hundred percent of the enrolled study participants completed the study and were included in the analysis. The only missing data was the aforementioned baseline PRAS for one study participant, and the midpoint GAD-7 and PRAS assessments for the other participant.

Locator Guide

A locator guide was requested from the study participants (see Appendix 3). This included the study participants' email and cell phone numbers, and other personal information to aid in contacting the participant, should a problem arise. The investigator also provided personal email and cell phone numbers, in the event that the participants required assistance or had any questions.

Measures

The measures section includes the description and rationalization for using each specific measure, as well as evidence of validity and reliability, and previous studies which demonstrate the accuracy of the chosen measures. It is important to include detailed descriptions of how the researchers operationalize the key concepts/variables, including the outcome, exposure, and potential confounding variables. The screening measures were administered by the investigator, and all the remaining self-report measures were completed by the study participants on

REDCap. Table 2 depicts which self-report measures were utilized at the various time points in the study:

Screening Measures	Baseline Measures	T2 (2 weeks)	End of Study Measures
	Socio-demographic Measure		Post-Assessment Questionnaire
Depression: Edinburgh Depression Scale	Social Support: MSPSS		
Anxiety: GAD-7	Anxiety: GAD-7	Anxiety: GAD-7	Anxiety: GAD-7
	Pregnancy Anxiety: PRAS	Pregnancy Anxiety: PRAS	Pregnancy Anxiety: PRAS
	Stress: PSS		Stress: PSS

Table 2. Measures Timeline

Screening Measures: Depression and Anxiety

Depression. The Edinburgh Postnatal Depression Scale (EPDS) (Cox et al., 1987) is the most commonly used tool to screen for depression in the perinatal period (Levis, Negeri, Sun, Benedetti, & Thombs, 2020). The EPDS is a 10-item scale which screens for depression for both pregnant as well as postpartum women. Scores range from 0-30, with higher scores indicating presence of depressive symptoms. A recent systematic review and meta-analysis recommended a cut-off value of 11 or higher for a sensitivity of 81% and a specificity of 88% (Levis et al., 2020). The EPDS has also been validated against both the DSM-5 (for major depression) and the ICD-10 (for mild, moderate or severe depression) diagnostic criteria for depression, with high sensitivity and specificity (Smith-Nielsen, Matthey, Lange, & Væver, 2018). The study findings confirmed a EPDS score of 11 or more as the optimal cutoff for depression according to both the DSM-5 and ICD-10 (Smith-Nielsen et al., 2018). Based on this measure,

women who score ≥ 19 have severe depression (McCabe-Beane, Segre, Perkhounkova, Stuart, & O'Hara, 2016).

Anxiety. The GAD-7 assesses the most prominent diagnostic features from the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) (Association, 2013) for generalized anxiety disorder: nervousness, inability to stop worrying, excessive worry, restlessness, difficulty in relaxing, easy irritation, and fear of something awful happening. In the United Kingdom, the first two questions of the GAD-7 (GAD-2) have recently been recommended by the National Institute for Health and Care Excellence (NICE) as a brief screening measure for anxiety in perinatal women (Sinesi, Maxwell, O'Carroll, & Cheyne, 2019).

Respondents were asked to rate how often they had experienced the survey anxiety symptoms within the last two weeks. Scores of 0, 1, 2, and 3 correspond to "not at all," "several days," "more than half the days," and "nearly every day." Scores range from 0-21. Scores of 5, 10, and 15 are cut-off points for mild, moderate, and severe anxiety respectively (Spitzer et al., 2006). Further evaluation is recommended when the score is 10 or greater. With the threshold score of 10, the GAD-7 has a sensitivity of 89% and a specificity of 82% for GAD. In addition, it is moderately good at screening for three other common anxiety disorders; panic disorder (sensitivity 74%, specificity 81%), social anxiety disorder (sensitivity 72%, specificity 80%), and post-traumatic stress disorder (sensitivity 66%, specificity 81%) (Spitzer et al., 2006).

The GAD-7 has demonstrated good reliability (Cronbach's $\alpha=0.89$) and validity in the pregnant population (Zhong et al., 2015) with a broad range of educational levels. The GAD-7 has been validated in a diverse group of ethnicities including: German (Hinz et al., 2017), Chinese (Tong, An, McGonigal, Park, & Zhou, 2016), Portuguese (Sousa et al., 2015), Finnish adolescents (Tiirikainen, Haravuori, Ranta, Kaltiala-Heino, & Marttunen, 2019), as well as across diverse socio-economic status (Hinz et al., 2017). This measure was additionally used in the study at three different timepoints: baseline, mid-study (2 weeks), and at study completion (4 weeks).

Sociodemographic Characteristics

Information regarding the following sociodemographic measures/participant characteristics were collected:

- Age (years; continuous variable)
- Race/ethnicity (Caucasian, African American, Asian/PI, Hispanic, Other; categorical variable)
- Relationship status (married, divorced, separated, cohabitating, partner deployed, single/alone; categorical variable)
- Current employment status (full-time, part-time, unemployed; categorical variable)
- Education level (years completed; continuous variable)
- Weeks' gestation at start of study; continuous variable
- Children in the home (number, continuous variable)
- Ages of children in the home (continuous variable)

Social Support (Baseline Measure)

Social support was assessed utilizing the Multidimensional Scale of Perceived Social Support (MSPSS) (Zimet, Dahlem, Zimet, & Farley, 1988), one of the most validated and extensively translated social support outcome measures (Dambi et al., 2018). The MSPSS consists of 12 questions using a 7-item Likert's scale for the participant to rate responses from "very strongly disagree" (1), to "very strongly agree" (7). The total score is the sum of all 12 items divided by 12, with higher numbers indicating higher levels of social support. The measure evaluates perceived adequacy of support from three sources: family, friends, and significant others. Example statements include: "I get the emotional help and support I need from my family," and "my friends really try to help me."

The MSPSS has shown good to excellent internal reliability with a Cronbach's alpha of 0.81 to 0.98, and test-retest reliability of 0.92-0.94 (Dahlem, Zimet, & Walker, 1991; Zimet et al., 1988; Zimet, Powell, Farley, Werkman, & Berkoff, 1990). Good internal reliability has been demonstrated with pregnant women, for whom this measure has been utilized in various studies (Grobman et al., 2018; Razurel, Kaiser, Sellenet, &

Epiney, 2013; Zimet et al., 1988). The measure has been utilized for studies in multicultural settings with diverse populations (Laksmi, Chung, Liao, & Chang, 2020) and diverse socioeconomic backgrounds (Trejos-Herrera, Bahamón, Alarcón-Vásquez, Vélez, & Vinaccia, 2018). In addition to English, psychometric properties have been demonstrated in Turkish-language, Urdu translations (South Asian), Thai, and Polish versions (Hardan-Khalil & Mayo, 2015) (Akhtar et al., 2010). The psychometric properties have been tested and validated among a variety of populations, including psychiatric outpatients, adolescents, and older adults, in addition to clinical and non-clinical populations (Hardan-Khalil & Mayo, 2015). This measure was assessed at baseline only.

Outcome Measures

Physiologic Measurement: Heart Rate and Heart Rate Variability (HR/HRV).

HR/HRV data was collected by the Oura Ring. The Oura Ring has wireless capability to sync the data with the Oura app, which wirelessly transferred data to the server for future analysis of the participants' HR/HRV & sleep data. Research supports that Oura Ring measurements of HR/HRV are highly accurate (Cao et al., 2022; Kinnunen et al., 2020a). Recent research comparing nocturnal HR and HRV values obtained with the Oura Ring as compared to the “gold standard” ECG measurement indicated high validity of the Oura Ring for these measures among a healthy adult population (Kinnunen et al., 2020a). Researchers found “close to perfect agreement between the Oura ring estimates and the ECG measurements in nocturnal average HR and beat-to-beat HRV” (Kinnunen, Rantanen, Kenttä, & Koskimäki, 2020b, p. 4).

Photoplethysmography (PPG) is the optical measurement method which was used for heart rate monitoring and analysis purposes. PPG technology uses a light source and a photodetector at the surface of skin to measure the volumetric variations of blood circulation (Castaneda, Esparza, Ghamari, Soltanpur, & Nazeran, 2018). PPG is a commonly used signal in wearable technology designed for stress measurement (Honkanen, 2019). HR and HRV

computed from a PPG signal have been validated by the Apple Watch (Hernando, Roca, Sancho, Alesanco, & Bailón, 2018) as well as the Oura Ring (Honkanen, 2019).

To extract HR and HRV, the PPG signal needs to be preprocessed using proper digital signal processing (DSP) techniques (e.g., a moving average filter). Then, using a wavelet peak detection algorithm, the HR and HRV were calculated. *Time-domain and frequency-domain HRV variables* were extracted. The time-domain variables extracted through statistical analysis were the HR, RMSSD, and SDNN. For the frequency domain analysis, Fast Furrier Transform and Power Spectral Density algorithms were used to extract LF and HF bands, and the LF/HF ratio (Kim et al., 2018; Shaffer & Ginsberg, 2017). As a member of the investigator's committee, Dr. Rahmani delegated Salar Hashemitaheri, a computer science graduate student working in his lab, to analyze the HR/HRV and sleep data from the Oura Ring.

Physiologic Measurement: Sleep. The Oura Ring utilizes actigraphy, which is a validated method of objectively measuring sleep parameters and average motor activity utilizing an accelerometer (Smith et al., 2018). Oura collects the following sleep data: sleep duration (length), sleep quality (REM, deep, and light), disruptions in sleep, movement during sleep, awake times, sleep latency, time in bed, and sleep efficiency (Oura, 2020). This data is analyzed, ultimately yielding a sleep score, which ranges from 0-100, with higher scores indicating better sleep. Research supports that Oura Ring measurements of sleep are highly accurate (de Zambotti et al., 2019).

Self-report Measures

Anxiety (GAD-7 and PRAS). The anxiety measures (GAD-7 [see above] and PRAS) were assessed at baseline, mid-study (2 weeks), and at study completion.

PRAS. Anxiety was also measured using the Pregnancy-Related Anxiety Scale (PRAS) (Rini, Dunkel-Schetter, Wadhwa, & Sandman, 1999). As there is a distinction between pregnancy-related anxiety and other types of anxiety, this measure was

included in order to assess feelings and concerns specific to pregnancy and childbirth. This measure evaluates pregnant women's worries related to her health and the baby's health, in addition to anxiety about the birth and caring for her child.

This 10-item instrument uses a Likert scale, where participants answer questions with options ranging from "never or not at all" (1) to "a lot of the time or very much" (4). Sample statements include: "I am confident of having a normal childbirth," "I have a lot of fear regarding the health of my baby," and "I am concerned/worried about losing the baby." Scores range from 0 to 30, with higher scores indicating greater participant anxiety.

This scale has good internal reliability in both English and Spanish, with a Cronbach's alpha = 0.78 and 0.80, respectively (Rini et al., 1999), and has been utilized among pregnant women with a wide range of socioeconomic and demographic backgrounds (Moyer, Compton, Kaselitz, & Muzik, 2020b). In addition, pregnancy anxiety scores have been shown to be fairly stable throughout the course of pregnancy (Kane, Schetter, Glynn, Hobel, & Sandman, 2014).

Stress (PSS). The outcome variable, stress, was measured using the Perceived Stress Scale (PSS) (Cohen, Kamarck, & Mermelstein, 1983). This measure is time specific and asks participants to reflect their feelings during the past month. As such, for this study, the measure was only able to be utilized at two time points: at baseline, and again at the end of the month-long intervention.

The PSS is a self-report questionnaire which was designed to measure how unpredictable, uncontrollable, and overloaded participants perceive their lives to be (Cohen et al., 1983). The PSS-10 is a 10-item, 5-point Likert scale ("0" indicating 'never' experienced, through to "4" indicating 'very often' experienced), which asks participants to respond to the questions based on their thoughts or feelings over the previous month. A sample question is: "How often have you felt that you were unable to control the important things in your life?" Scores range from 0 to 40, with higher scores relating to higher levels of perceived stress.

The PSS was chosen due to its good psychometric qualities, which have been previously demonstrated (Cohen et al., 1983; Lee, 2012; Roberti, Harrington, & Storch, 2006). An analysis and comparative study (Roberti et al., 2006) found that the measure had good internal consistency, with Cronbach's alpha of 0.85 for perceived helplessness and 0.82 for perceived self-efficacy, with a reported Cronbach's alpha of 0.89 for the total score. The PSS-10 is "a reliable and valid self-report measure of perceived stress" (p. 143) in a non-clinical population of predominantly female participants. The measure has been validated in a variety of diverse ethnicities including Vietnamese (Dao-Tran, Anderson, & Seib, 2017), Arab (Roof, James-Hawkins, Rahim, & Yount, 2019), Caribbean (Campbell, Gromer, Maynard, & Emmanuel, 2019), Chinese (Sun, Gao, Kan, & Shi, 2019), Malaysian (Siang, Baharuddin, Rahman, Shah, & Noor, 2016), and Hispanic Americans (Baik et al., 2019). It has also been validated for people of diverse socio-economic status (Siang et al., 2016). The measure has been used in pregnant samples (Beattie et al., 2017; Guardino et al., 2014; Krusche et al., 2018a; Pan et al., 2019a; Vieten & Astin, 2008; Woolhouse, Mercuri, Judd, & Brown, 2014) and maternal samples (Hunter et al., 2019) with a broad range of educational levels.

Statistical Analysis Plan

A traditional statistical analysis plan includes the following: description of the hypothesis for the research question, identification of primary exposure variable(s), identification of outcome variable(s), identification of other independent variables (covariates), types of models used for the plan, measures of association, and description of how specific variables will be chosen to be included in the model. The statistical analysis section also includes a descriptive analysis, primary analysis, secondary analysis (if appropriate), plans for handling of missing data, and a sample size estimation. An important reason to be transparent is to prevent a "fishing expedition," or analysis of data in multiple ways until results are achieved.

In the statistical analysis, the outcome variables determine which model type to use, as well as the measure of association. If the outcome variable is dichotomous (binary), the models used are either logistic regression or log-binomial and Poisson, and the measures of association are the odds ratio and the risk ratio (and prevalence ratio), respectively. If the outcome variables are continuous, the model type used is a linear regression (ordinary least squares), and the measure of association is the mean difference. Other measures of association are hazard and rate ratios (which will not be discussed here, as they are not applicable to the study) (Shin, 2019).

Handling of missing data needs to be addressed. Approaches to handling missing data include complete case analysis (excludes missing observations), last observation carried forward, and multiple imputation (what is known from non-missing data is used to impute values to the missing observations). For this study, we will perform complete-case analysis.

The effect size needs to be addressed. Effect size refers to the strength of the association, or the magnitude of the observed difference between the groups. The larger the effect size, the stronger the relationship between two variables. For quantitative measures, it is described in terms of either the difference in means, or Cohen's *d* (the standardized difference in means/standard deviation) (McLeod, 2019).

Descriptive Analysis

The statistical analysis section includes a descriptive statistical analysis of the study population's demographic and clinical characteristics. Frequencies and proportions were calculated for categorical variables; mean, median, standard deviation, and interquartile range were calculated for continuous variables. Continuous variables were assessed for normal distribution by visual inspection of histograms and the kurtosis statistic. Graphical displays were produced. R studio (RStudio, 2020) was used for all analyses, and statistical testing was performed using a one-tailed alpha-level of 0.05. In addition, relationships were assessed between the major variables in the study.

To determine the relationship between sociodemographic variables and social support on stress, anxiety, and pregnancy anxiety, univariate analysis was done to determine if there were correlations. For continuous variables, if the measures were normally distributed, univariate analysis was done using Pearson Moment Correlations. If they were not normally distributed, Spearman Rho Correlations were done. For the categorical variables, point-biserial correlation was done if the variables were naturally dichotomized, and biserial correlation, if the variables required artificial dichotomization.

Study Goal and Hypothesis

The goal of this study was to determine if use of the MM intervention HS by pregnant women improved their stress and anxiety by means of self-report as well as physiological measures. In addition, frequency of app usage data was analyzed to determine impacts on outcome measures.

Aim 1. Evaluate the impact of the Headspace app on stress and anxiety among 20 pregnant women. **Ho. 1:** Participants practicing meditation exercises via the Headspace app will report decreased levels of stress and anxiety from baseline to post-intervention.

Aim 2. Evaluate the physiological effects (HRV and sleep changes over time) of the Headspace app among 20 pregnant women utilizing the Oura Ring. **Ho. 2:** Participants practicing meditation exercises via the Headspace app will show an increase in their HRV, and an improvement in their sleep score.

Aim 3. Determine if participant app usage amount is associated with differences in measured outcomes. **Ho:3.** Study participants who use the app more frequently (number of sessions, and/or total minutes used) will experience a greater reduction in their stress and anxiety than participants who use the app less frequently.

Analysis

Aim 1. Evaluate the impact of the Headspace app on stress and anxiety among 20 pregnant women. **Ho. 1:** Participants practicing meditation exercises via the Headspace app will report decreased levels of stress and anxiety.

The self-report measurements of stress and anxiety were measured twice, once at baseline, once at study completion. Paired t-tests were done to compare the before-and-after observations on the same subjects for the various measures (PSS, GAD-7, PRAS). The null hypothesis for the paired t-test is that the average difference between the before/after sample measures is zero. The alternative hypothesis for the paired t-test is that there is a significant difference between the two (before/after) sample measures.

Statistical significance was determined by observing the p-value, which gives the probability of obtaining a p-value as, or more extreme, than what was observed under the null hypothesis. If the p-value was <0.05 , there is strong evidence to reject the null hypothesis. This corresponds to a 5% chance of obtaining a result like the one that was observed, or more extreme if the null hypothesis was true. After, a 95% confidence interval was calculated for the true mean difference.

Aim 2. Evaluate the physiological effects (HRV and sleep changes over time) of the Headspace app among 20 pregnant women utilizing the Oura Ring. **Ho. 2:** Participants practicing meditation exercises via the Headspace app will show an increase in their HRV, and an improvement in their sleep score.

Aim 2 Primary Analysis: HLM Modeling. To analyze the data, hierarchical linear modeling (HLM, also known as multi-level, or mixed effects modeling) was done. HLM is the preferred statistical method to be used as it accounts for observations being clustered among the study participants over time. The HLM for the HR/HRV components and sleep score were modeled by Salar Hashemitaheri. The dependent variables of the model were Oura Ring

HR/HRV metrics and sleep score. The fixed effect was the measurement of time (30 days total) to get an estimate of if the HR/HRV metrics and sleep scores changed over the study period.

Independent variable.

- All study participants were instructed to use the intervention

Dependent/outcome variables.

- HR (heart rate; resting); continuous variable
- SDNN (standard deviation of the interbeat interval of normal sinus beat); continuous variable
- RMSSD (root mean square of successive differences between normal heartbeats); continuous variable
- HF (high frequency power band); continuous variable
- LF (high frequency power band); continuous variable
- LF/HF (the ratio of LF to HF power bands); continuous variable
- Oura Ring sleep score; continuous variable

Aim 2 Secondary Analysis: HRV. In addition to HLM, HRV was analyzed with a paired t-test. RMSSD was the HRV metric selected for this analysis, as it is the HRV metric most commonly associated with HRV. To determine the RMSSD scores for each study participant, the RMSSD values from the first 4 days (baseline RMSSD) and last 4 days (end of study RMSSD score) were obtained. As the Oura app records HRV values every 5 minutes, the average RMSSD scores were calculated after data was cleaned by using only the RMSSD values during the study participant's sleep time (between 10 pm and 7 am). One study participant worked the night shift, so for her, the hours of sleep were calculated between 8 am and 2 pm.

The null hypothesis for this paired t-test was that the average difference in mean RMSSD scores was zero; that would be no significant difference in the average RMSSD score before the intervention as compared to the average RMSSD score at study completion. The alternative hypothesis is that there would be a difference in the RMSSD score from pre-intervention to study completion. Statistical significance was determined by observing the p-value, which gives the probability of obtaining a p-value as, or more

extreme, than what was observed under the null hypothesis. If the p-value was <0.05 , there is strong evidence to reject the null hypothesis. This corresponds to a 5% chance of obtaining a result like the one that was observed, or more extreme if the null hypothesis was true. After, a 95% confidence interval was calculated for the true mean difference.

Aim 2 Secondary Analysis: Sleep. In addition to HLM, sleep was analyzed with a paired t-test. A baseline sleep score was calculated from an average of the first four days and was compared to an average sleep score calculated from the final four days of the study. These values were compared by a paired t-test to observe if any significant changes occurred during the study period. The null hypothesis for this paired t-test was that the average difference in mean sleep scores was zero; that there would be no significant difference in the average sleep score before the intervention as compared to the average sleep score at study completion. The alternative hypothesis was that there would be difference in the sleep score from pre-intervention to study completion. Statistical significance was determined by observing the p-value, which gives the probability of obtaining a p-value as, or more extreme, than what was observed under the null hypothesis. If the p-value was <0.05 , there is strong evidence to reject the null hypothesis. This corresponds to a 5% chance of obtaining a result like the one that was observed, or more extreme if the null hypothesis was true. After, a 95% confidence interval was calculated for the true mean difference.

Aim 2 Secondary Analysis: Subjective Sleep. In addition, a subjective measure of sleep was evaluated by the following Likert's scale question asked at study completion: "My sleep improved during this trial," with the following 5-point Likert response options: 1 = strongly disagree, 2 = disagree, 3 = neither agree or disagree, 4 = agree, and 5 = strongly agree, as part of the post-intervention questionnaire.

Aim 3. Determine if participant app usage amount is associated with differences in measured outcomes. $H_0:3$. Study participants who use the app more frequently (number of

sessions, and/or total minutes used) will experience a greater reduction in their stress and anxiety than participants who use the app less frequently.

Aim 3 Analysis. To calculate if there was a relationship between study participant app usage, and the stress and anxiety outcome variables, app usage amount was first categorized into “low” versus “high” users. Low users were defined as those who completed <75% of the intervention, either in terms of the minutes used or the sessions completed. High users were defined as those who completed $\geq 75\%$ of the intervention. Next, a change score was calculated for the outcome variables (stress, anxiety, pregnancy anxiety, sleep and HRV) by subtracting the baseline score from the end-of-study score. For the HRV and sleep variables, these scores were calculated from values obtained in the Aim 2 secondary analysis.

Paired t-tests were done to compare if the change scores for high users was greater than those of low app users. The null hypothesis is that there would be no difference between the mean of the change scores for high app and low app users. The alternative hypothesis is that the difference for mean change scores would be greater for high app users than for low app users. Statistical significance was determined by observing the p-value, which gives the probability of obtaining a p-value as, or more extreme, than what was observed under the null hypothesis. If the p-value was <0.05 , there is strong evidence to reject the null hypothesis. This corresponds to a 5% chance of obtaining a result like the one that was observed, or more extreme if the null hypothesis was true.

Chapter 5: Results

The purpose of this study was to evaluate if practicing mindfulness meditation with the HS app is impactful at reducing stress and anxiety during pregnancy. Study results are detailed in the following sections.

Descriptive Statistics

Thirty-three people expressed interest in the study and were screened for eligibility. Twelve people were ineligible due to either advanced maternal age or being beyond the cut-off of 34 weeks' gestation. One woman was scheduled to be consented but canceled at the last minute due to a family crisis. 100% of the enrolled study participants completed the study and were included in the analysis (Figure 3).

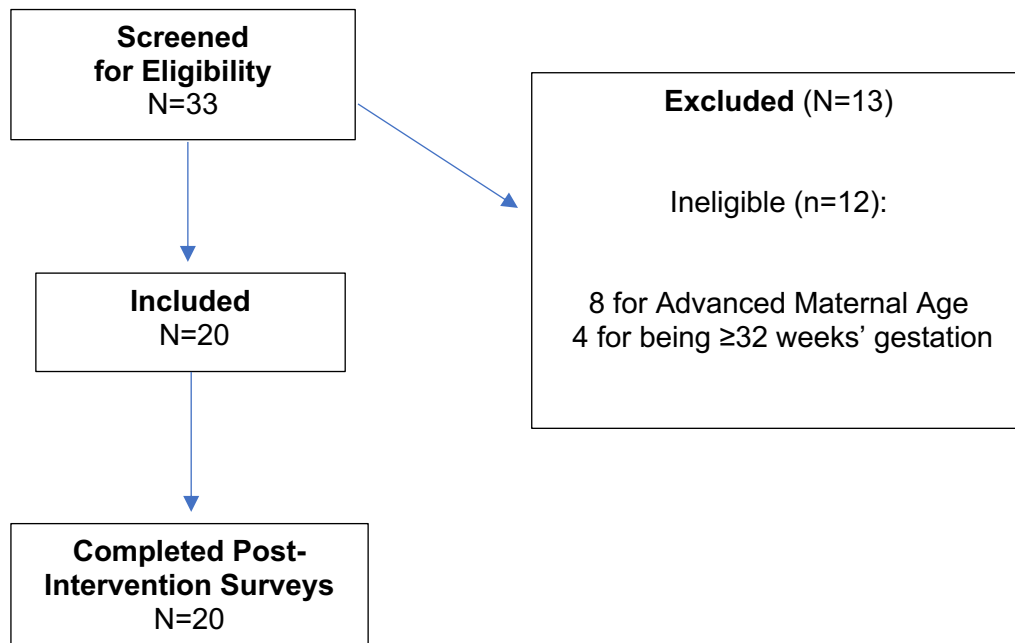


Figure 3. Study Flow Chart

Everyone who was enrolled in the study completed all the baseline, midpoint, and end-of-study assessments, except for two participants. While one study participant completed the baseline PRAS, there was an issue saving it, so the results didn't capture in REDCap. Another

study participant did not complete the two midpoint assessments. Other than those three missing assessments, all other measures were completed by the study participants.

Demographic and Baseline Data

Demographic and other relevant baseline data are presented in Table 3.

Characteristics	N	%
Age [M (SD)]	29.45 (3.27)	
Race/Ethnicity %		
White/European American	16	69.6
Hispanic or Latino	4	17.4
Asian/Pacific Islander	2	8.7
Black/African American	0	0
Other	1	4.3
Parity		
Primiparous	12	60
Multiparous	8	40
Trimester of Gestation		
1 st trimester	6	30
2 nd trimester	11	55
3 rd trimester	3	15
Education		
Completed master's degree or higher	6	30
Completed bachelor's degree	8	40
Completed associate degree	4	20
Completed high school or equivalent	2	10
Relationship Type		
Married	15	75
Cohabiting	3	15
Single	2	10
Employment Status		
Full time	14	70
Part time	3	15
Unemployed	3	15
Exercise		
Regular exercise	10	50
No regular exercise	10	50
Denied alcohol, recreational drugs, or vaping	20	100
Caffeine		
Denied caffeine use	7	35
Drank 1-2 cups of caffeinated drinks/day	13	65
Regular stress-management activities		
Yes	12	60
No	8	40
Social Support [M (SD)]	6.14 (0.73)	
High social support	18	90
Moderate social support	2	10
Low social support	0	

Table 3. Demographic and Baseline Data

Age

The pregnant women ranged in age from 25 to 35 years, and the average study participant's age was 29.45 (Table 3). Eleven women were between 25-30 years old, and 9 women who were between 31-35 years old.

Race/Ethnicity

Most study participants (69.6%) were White/European American, with 17.4% Hispanic/Latino, and 8.7% Asian American (Figure 4).

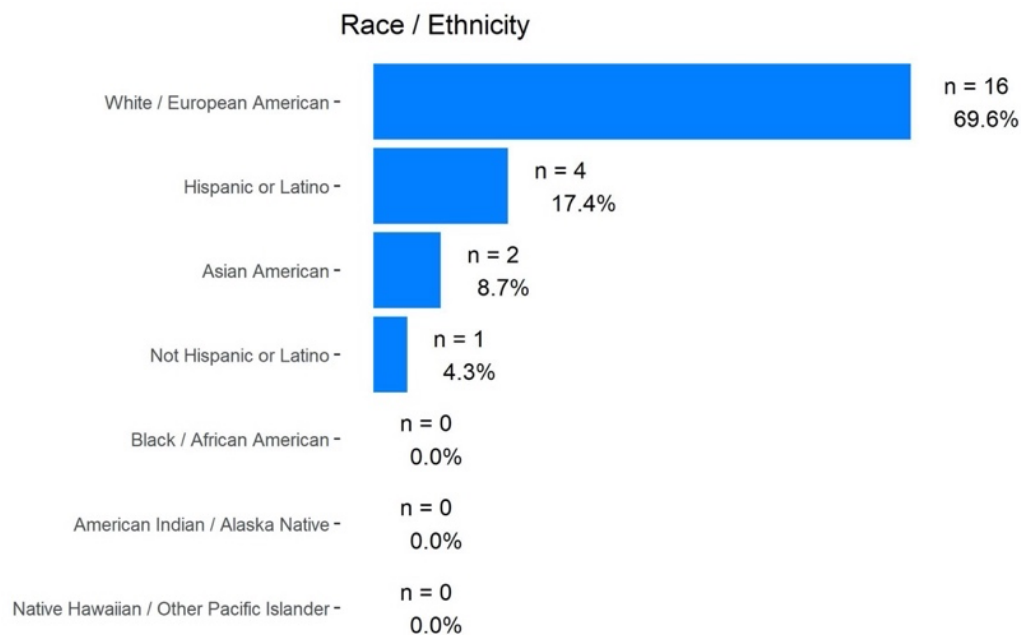


Figure 4. Baseline Characteristics: Race/Ethnicity

Parity

The majority of the study participants (60%) were primiparous (pregnant for the first time), while the remainder were multiparous (Table 3). As a recent study reported that HRV changes are more marked for primiparous versus multiparous women (Solanki et al., 2020), it was important to collect data on parity.

Trimester Gestation

At the start of the study, 6 participants (30%) were in their first trimester, 11 (55%) were in their second trimester, and 3 (15%) were in their third trimester. During the month-long trial, all of the study participants stayed in their original trimester (within a 1-week range) with the exception of three who changed; one from 1st to 2nd, and two from their 2nd to their 3rd trimester. So, at study completion, 5 (25%) were in their first trimester, 10 (50%) were in their second trimester, and 5 (25%) were in their third trimester (Table 4). A recent study which identified trends in HRV metrics during pregnancy found that certain HRV parameters had significant changes during specific trimesters of gestation (Sarhaddi et al., 2022). Therefore, it was important to collect and present data on gestational trimester of participants.

<i>Study ID</i>	<i>Primiparous (P) or Multiparous (M)</i>	<i>Gestational age; Study Start</i>	<i>*Trimester: Study Start</i>	<i>Gestational age: Study End</i>	<i>Trimester: Study End</i>
1	M	23	2 nd	27	2 nd
2	M	19	2 nd	23	2 nd
3	M	25	2 nd	29	2 nd
4**	M	28	2 nd	32	3 rd
5	P	32	3 rd	36	3 rd
6**	P	28	2 nd	32	3 rd
7	P	30	3 rd	34	3 rd
8	P	10	1 st	14	1 st
9	P	20	2 nd	24	2 nd
10	M	14	2 nd	18	2 nd
11	P	10	1 st	14	1 st
12	P	24	2 nd	28	2 nd
13	M	30	3 rd	34	3 rd
14**	P	11	1 st	15	2 nd
15	M	15	2 nd	19	2 nd
16	M	23	2 nd	27	2 nd
17	P	10	1 st	14	1 st
18	P	10	1 st	14	1 st
19	P	10	1 st	14	1 st
20	P	21	2 nd	25	2 nd

Table 4. Study Participant's Parity and Trimester

**Indicates a change in trimester

* Where 1st Trimester = 0-13 weeks; 2nd Trimester=14-28 weeks; 3rd Trimester=29-42 weeks

Education

Most of the study participants were highly educated, with 60% who completed a college degree (20% associates, 40% bachelors) and 30% who completed a master's degree or higher (Figure 5).

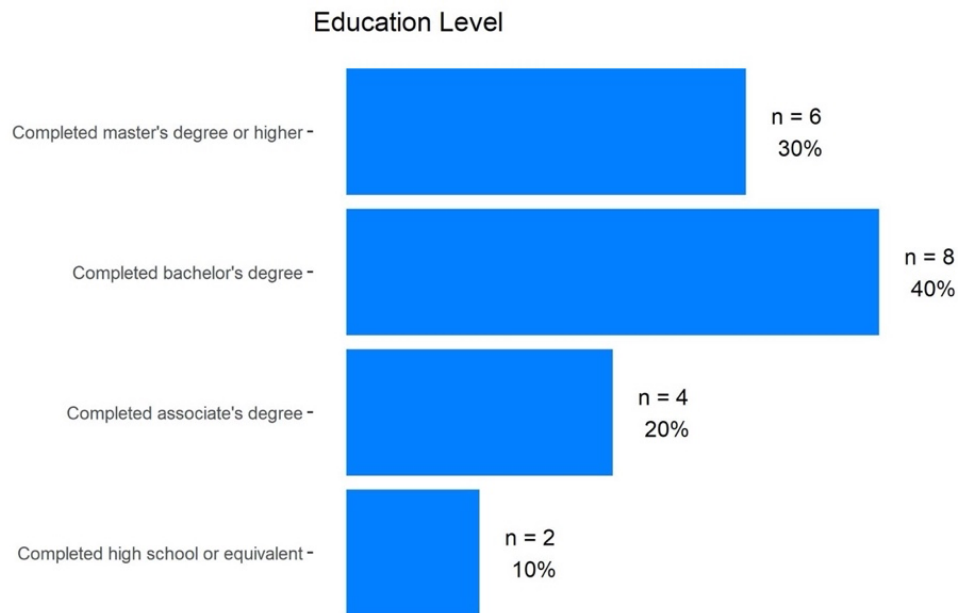


Figure 5. Baseline Characteristics: Education Level

Relationship Type

Most of the participants were married (75%), while 15% were cohabitating, and 10% were single (Figure 6).

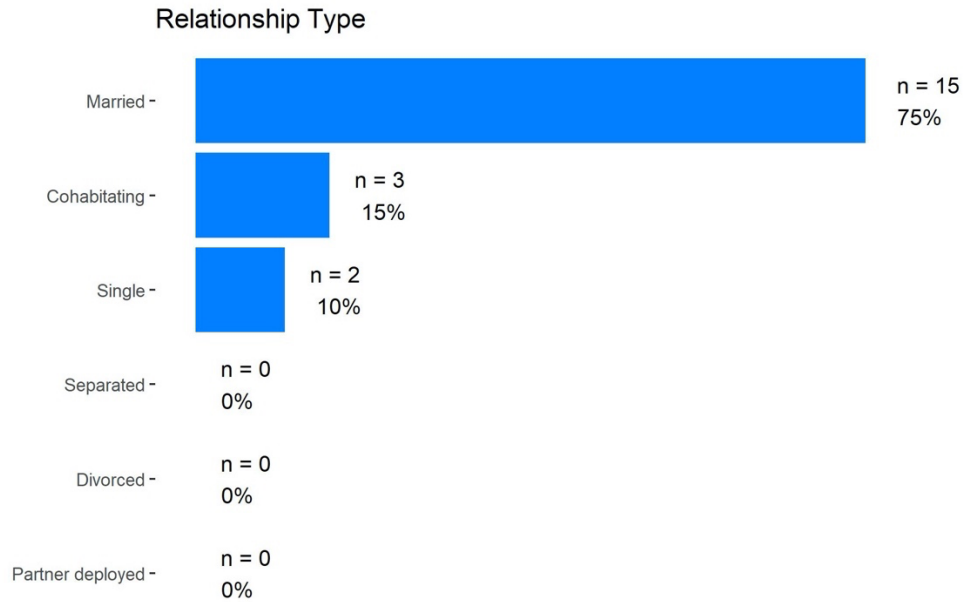


Figure 6. Baseline Characteristics: Relationship Type

Employment

The majority of the sample worked, with 70% of participants working full-time, 15% working part-time, and 15% unemployed (Figure 7).

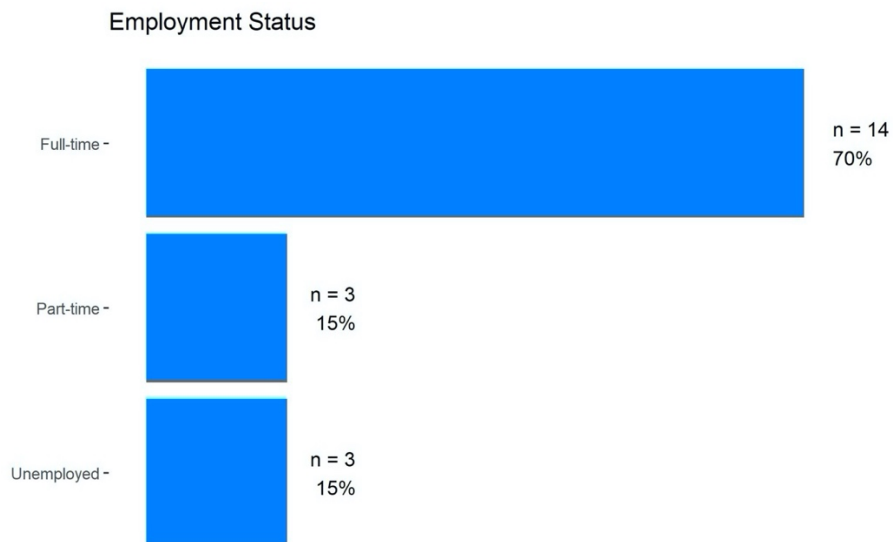


Figure 7. Baseline Characteristics: Employment Status

Baseline Exercise

Data on exercise was collected as an increase in exercise level during the trial could be a potential confounder. Exercise data was also collected as part of the post-intervention survey to determine if there was an increase in exercise during the trial. The following is the baseline exercise data: 50% of the women stated that they regularly exercised, and 50% said they did not. For those who did exercise, the majority engaged in moderate exercise for approximately 2-3 days/week, while 3 participants engaged in more high intensity workouts, more frequently (5-7 days/week) (Figure 8).



Figure 8. Baseline Characteristics: Exercise Status

Drugs, Alcohol, Tobacco, and Caffeine

Use of certain prescribed and over the counter medications, alcohol, tobacco, recreational drugs, and excessive caffeine can impact HRV, so baseline data on participant usage was collected. None of the study participants were taking prescribed, or over the counter, medications which are known to impact HRV. 100% of the participants denied using alcohol, recreational drugs, or tobacco, including vaping. This eliminates these substances as potential confounders of the study results. All study participants surveyed in the trial indicated that they consumed low to no caffeine (less than or equal to 1-2 cups) (Figure 9). Because none of the

study participants had excessive caffeine intake, caffeine can be eliminated as a potential confounder of these outcome variables.

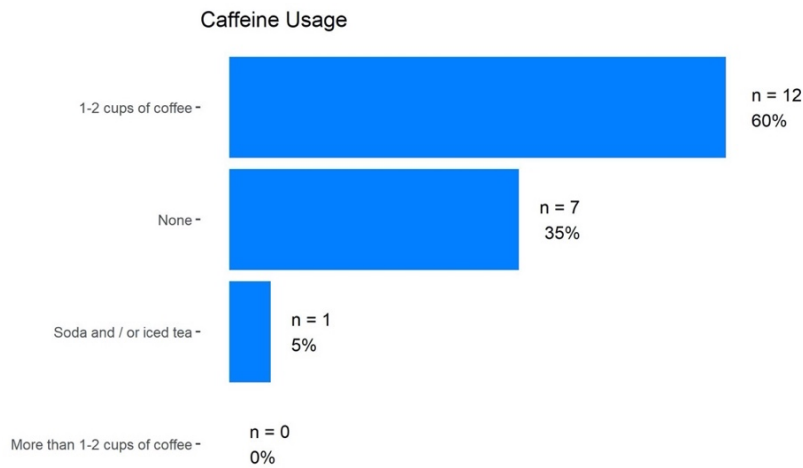


Figure 9. Baseline Characteristics: Caffeine Usage

Regular stress/anxiety management activities

On the baseline survey, participants were asked this question; "Are there any stress/anxiety management activities you do on a regular basis?" 40% of the participants said "no." The remaining 60% said "yes," with a variety of answers including the following: "prayer, alone time, exercise/working out, social support from friends and family, taking a bath, massage and applying lotion with focus." (Figure 10)

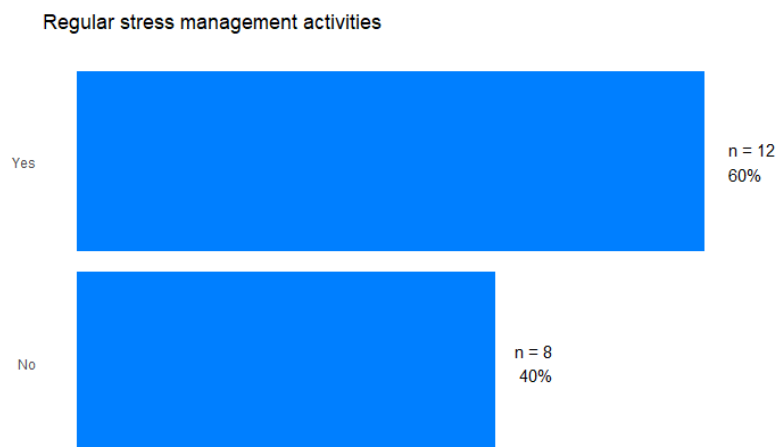


Figure 10. Baseline Characteristics: regular stress/anxiety management

Social Support

Baseline social support was assessed by the Multidimensional Scale of Perceived Social Support (MSPSS). The MSPSS is a 12-item scale with answer choices ranging from 1-7, with higher numbers indicating higher levels of social support (Zimet et al., 1988). Scores ranging from 1 to 2.9 could be considered low support; a score of 3 to 5 could be considered moderate support, and a score from 5.1 to 7 could be considered high support (Zimet et al., 1988). The median score for the MSPSS for the study participants was 6.29, with a range of 4.58-7 (Table 5). The majority of the study participants (90%) had high social support (Figure 11). The social support scale for study participants can be further broken down as follows: 2 participants (10%) had moderate social support, and zero participants had low social support (Figure 11).

Baseline Social Support: MSPSS								
Total Count (N)	Missing	Mean	Standard Deviation	Percentile				
				Min	0.25	0.50 (median)	0.75	Max
20	0 (0.0%)	6.14	0.730	4.58	5.71	6.29	6.67	7

Table 5. Baseline Social Support

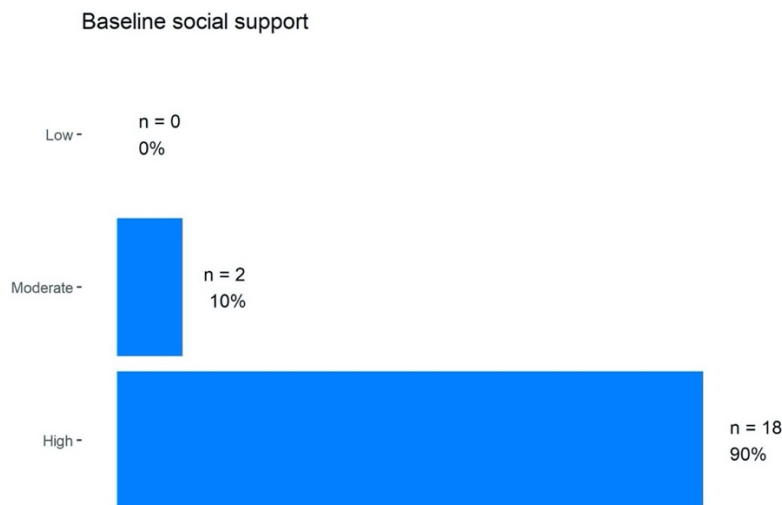


Figure 11. Baseline Social Support

Relationship Between Sociodemographic Variables, Baseline Characteristics, and Social Support on Stress and Anxiety

To determine if there was a relationship between baseline characteristics, sociodemographic variables, and social support on stress, anxiety and pregnancy anxiety, univariate analysis was done. Age and social support were normally distributed continuous variables, so analysis was done using Pearson Moment Correlations. The remainder of the variables were categorical. Point-biserial correlation was done if the variables were naturally dichotomized, and biserial correlation, if the variables required artificial dichotomization. Results are presented in Table 6.

	PSS	GAD-7	PRAS
Age	0.045	0.120	0.285
Parity	-0.004	-0.168	-0.289
Race/Ethnicity	0.059	-0.134	-0.091
Education	0.353	0.238	0.381
Employment	-0.184	0.272	0.404
Relationship Status	0.183	-0.027	-0.042
Social Support	-0.390	-0.097	-0.021
Trimester: 1st vs. 2nd & 3rd	-0.104	0.003	0.044
Stress-management activities: yes/no	0.248	0.122	-0.016

Table 6. Relationship between sociodemographic variables and baseline stress and anxiety

The values of the strength of association for the absolute value of “r,” the correlation coefficient, are generally defined as follows: 0-0.1 is regarded as “negligible correlation,” 0.1-0.39 as “weak,” 0.40-0.69 as “moderate,” 0.7-0.89 as “strong” and 0.9-1 as “very strong” correlation (Schober, Boer, & Schwarte, 2018). A positive correlation indicates if one variable goes up, the other goes up as well. A negative correlation indicates if one variable goes up, the other goes down.

None of the sociodemographic variables and baseline characteristics had “strong” or “very strong” correlations with the baseline self-report outcome variable scores (stress, anxiety, or pregnancy anxiety). The majority of the sociodemographic

variables and baseline characteristics had a “negligible” or “very weak” correlations with the exception of the relationship between employment and pregnancy anxiety, which had a “moderate positive” correlation ($r=0.404$) This indicated that participants who were employed full-time had higher levels of pregnancy anxiety.

Several variables had “weak positive” correlations. Regular stress-management activities and stress had a “weak positive” correlation ($r=0.248$), indicating that study participants who engaged in regular stress management activities were more likely to be stressed. Education and general anxiety ($r=0.238$), as well as education and pregnancy anxiety ($r=0.381$) had “weak positive” correlations, indicating that people with higher education (bachelor’s or master’s degrees) had both higher anxiety, and higher pregnancy-specific anxiety. Employment and general anxiety had a “weak positive” correlation ($r=0.272$), indicating that participants who worked full-time had higher general anxiety. Age and pregnancy anxiety had a “weak positive” correlation ($r=0.285$), indicating that study participants who were older had higher pregnancy anxiety.

Two variables were found to have “weak negative” relationships. Social support and stress had weak negative correlation (-0.390), indicating that participants with higher social support had lower stress. Parity and pregnancy anxiety also had a weak negative correlation (-0.289), indicating that women who were multiparous had less pregnancy anxiety.

Results of the Specific Aims

Aim 1: Evaluate the impact of practicing MM via the Headspace app on stress and anxiety among 20 pregnant women. **Ho. 1:** Participants practicing MM via the Headspace app will report decreased levels of stress and anxiety from baseline to post-intervention.

The Aim 1 hypothesis was fully supported. Study participants who practiced MM via the Headspace app reported decreased levels of stress and anxiety from baseline to post-intervention.

Paired t-tests were utilized to compare study participant pre-and post-intervention scores for stress, anxiety, and pregnancy anxiety. Participants reported statistically significant reductions in levels of stress ($p=0.005$), anxiety ($p=0.011$), and pregnancy anxiety ($p=0.0001$) from baseline to post-intervention (Table 7). These results provide support for the hypothesis that the study participants practicing MM via the Headspace app will report decreased levels of stress and anxiety from baseline to post-intervention.

Measure	Pre-Intervention		Post-Intervention		P-value
	Mean	SD	Mean	SD	
PSS	14.4	5.83	10.25	5.4	0.005*
GAD-7	4.65	3.25	2.6	2.93	0.011*
PRAS	10.84	5.2	5.9	3.99	0.0001*

Table 7. Aim 1 Pre-and Post-Intervention Mean Comparisons

*P-value <0.5

Details of Aim 1 Analysis

Self-report Stress. Pre-and-post intervention comparisons for the stress variable (PSS) are depicted in Figure 12.

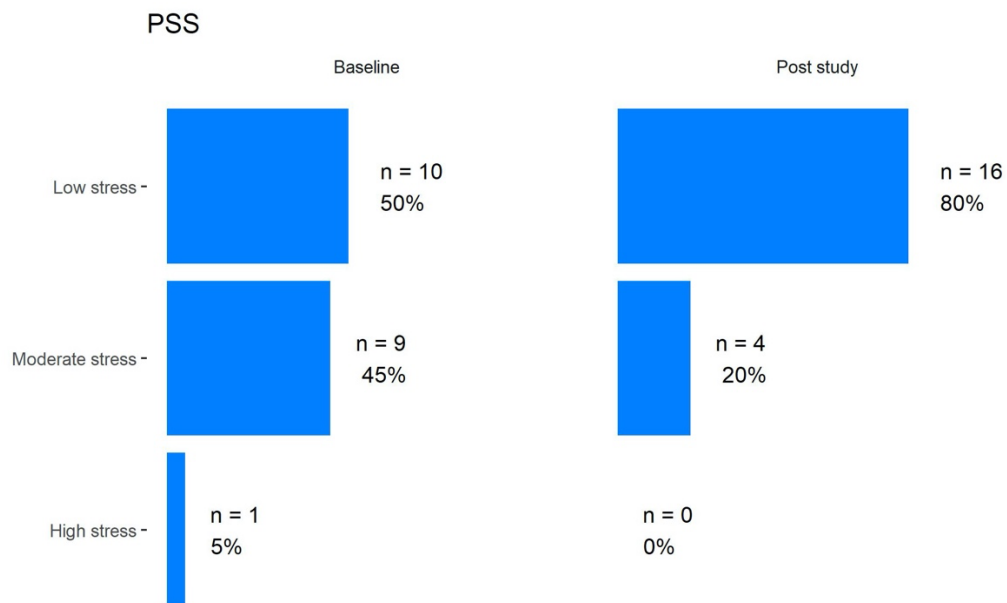


Figure 12. Stress (PSS) Baseline & Study-End Comparison

Stress Analysis (PSS)

The goal of Aim1 was to evaluate the impact of the HS app on stress and anxiety among 20 pregnant women, with the hypothesis being that participants would report decreased levels of stress and anxiety from baseline to post-intervention. The null hypothesis was that there would not be a decrease in stress and anxiety. Stress was evaluated at baseline and post-intervention by the PSS via a paired t-test, and there were no violations for normality assumptions. Statistical significance was determined by observing the p-value, which gave the probability of obtaining a p-value as or more extreme than was observed under the null hypothesis. A p-value of <0.05 would indicate that there was strong evidence to reject the null hypothesis that there was not a decrease in the PSS values from pre to post intervention. The obtained p-value was 0.005 (Table 7). This is strong evidence that we can reject the null and accept the alternative hypothesis to conclude that there was a difference in baseline and post-intervention PSS scores. Further, the difference was directional, indicating that study participants who practiced MM via the HS app experienced a reduction in stress, as evidenced by the reduction in their PSS scores. Additional details regarding baseline and post-intervention stress data for study participants are presented as follows.

Baseline Stress (PSS). Baseline stress was assessed with the PSS. According to the PSS, scores of 0-13 are considered low stress; 14-26 are considered moderate stress, and 27-40 are considered high perceived stress (Cohen, 1988; Cohen et al., 1983). The baseline median PSS score for the study participants was 13.5, which is at the top end of the low stress range (Table 8). Baseline PSS scores for study participants were as follows: 10 participants (50%) had low stress, 9 participants (45%) had moderate stress, and 1 participant (5%) had high stress (Figure 12).

Baseline Stress: PSS								
Total Count (N)	Missing	Mean	Standard Deviation	Percentile				
				Min	0.25	0.50 (Median)	0.75	Max
20	0 (0.0%)	14.40	5.83	3	10.50	13.50	18.25	27

Table 8. Baseline Stress (PSS)

Post-Intervention Stress (PSS). The mean post-intervention score for the PSS was 10.25 with standard deviation of 5.4 (Table 9). This was a decrease from the baseline mean score of 14.4 (Table 8). Further study participant PSS post-intervention score breakdown was as follows: 16 participants (80%) had mild stress, 4 participants (20%) had moderate stress, and none of the participants had high stress (Figure 12). For the post-intervention PSS as compared to the baseline PSS study participant changes were as follows: 4 people moved into the “low stress” category; there were 5 fewer people in the “moderate stress” category, and there was no one in the “high stress” category (Figure 12).

Post-Intervention Stress: PSS								
Total Count (N)	Missing	Mean	Standard Deviation	Percentile				
				Min	0.25	0.50 (Median)	0.75	Max
20	0 (0.0%)	10.25	5.40	1	7	10	13	21

Table 9. Post-intervention Stress (PSS)

Anxiety Analysis (GAD-7)

Pre-and-post intervention comparisons for the anxiety variable (GAD-7) are depicted in Figure 13.

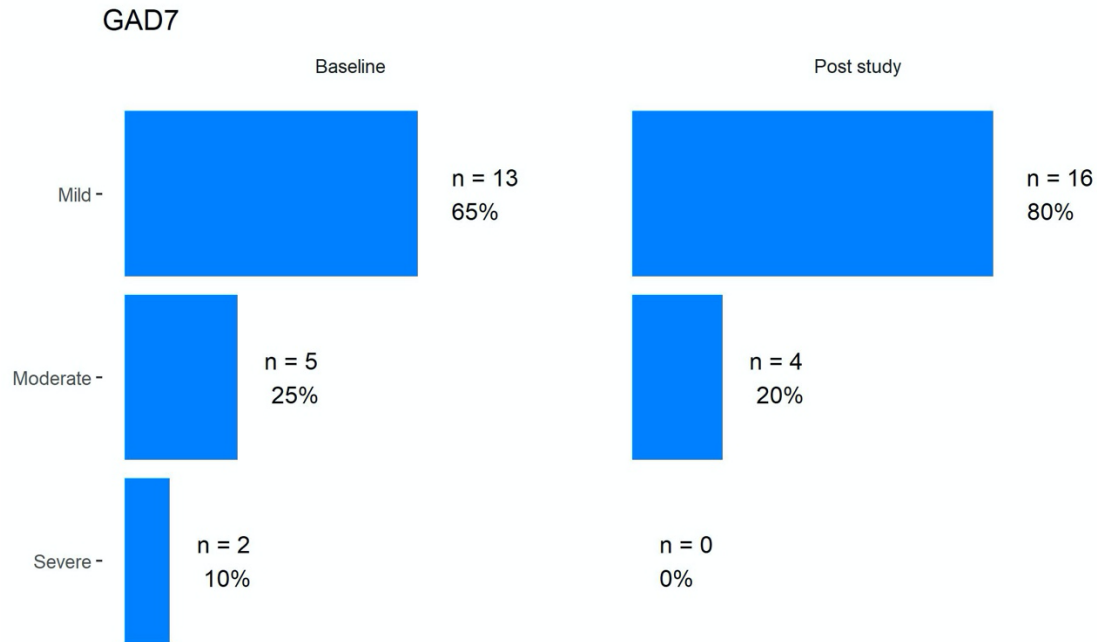


Figure 13. Anxiety (GAD-7) Baseline & Study-End Comparison

One of the goals of Aim1 was to evaluate the impact of the HS app on anxiety, with the hypothesis being that participants would report decreased levels of anxiety from baseline to post-intervention. Anxiety was evaluated at baseline and post-intervention by the GAD-7 via a paired t-test. The GAD-7 sample violated normality assumptions, so the proposed statistical analysis method from Aim 1 was not appropriate. Rather, the Wilcoxon signed-rank test with continuity correction was performed, which is the non-parametric alternative to the t-test. Statistical significance was determined by observing the p-value, which gives the probability of obtaining a p-value as, or more extreme, than what was observed under the null hypothesis. If the p-value was <0.05 , there was strong evidence to reject the null hypothesis. The p-value was 0.011 (Table 7). This is strong evidence to reject the null hypothesis and accept the alternative hypothesis that study participants who practiced MM via the HS app experienced a reduction in their anxiety levels. Additional details regarding baseline and post-intervention anxiety data for study participants are presented as follows.

Baseline Anxiety (GAD-7). Baseline anxiety was assessed by the GAD-7. The GAD-7 is scored out of 21 points, with cutoffs of 5, 10, and 15 interpreted as representing mild, moderate, and severe levels of anxiety (Spitzer et al., 2006). The median GAD-7 score for the sample at baseline was 3.5, with a range of between 0-13 (Table 10). A median of 3.5 means that the majority of the sample had mild anxiety at baseline. Further, at baseline the breakdown of anxiety for the study participants was as follows: 13 participants (65%) had mild anxiety, 5 people (25%) had moderate anxiety, and 2 people (10%) had scores indicating severe anxiety (Figure 13).

Baseline Anxiety: GAD-7									
Total Count (N)	Missing	Mean	Standard Deviation	Sum	Percentile				
					Min	0.25	0.50 (Median)	0.75	Max
20	0 (0.0%)	4.65	3.25	93	0	2.75	3.50	6	13

Table 10. Baseline Anxiety (GAD-7)

Post-Intervention Anxiety (GAD-7). The mean post-intervention score for the GAD-7 was 2.6, with a standard deviation of 2.93 (Table 11). At the end of the study, the majority of study participants (80%) had mild anxiety (Figure 13). The GAD-7 post-intervention score breakdown was as follows: 4 participants (20%) had moderate anxiety, and none of the participants had severe anxiety (Figure 13). When comparing post-intervention GAD-7 as compared to the baseline GAD-7 (Figure 13), study participant changes were as follows: 3 people moved into the “low anxiety” category; there was 1 less person in the “moderate anxiety” category, and there was no one in the “high anxiety” category.

Post-Intervention Anxiety: GAD-7									
Total Count (N)	Missing	Mean	Standard Deviation	Percentile					
				Min	0.25	0.50 (Median)	0.75	Max	
20	0 (0.0%)	2.60	2.93	0	0	1	4.25	9	

Table 11. Post-Intervention Anxiety (GAD-7)

Pregnancy Anxiety Analysis

One of the goals of Aim1 was to evaluate the impact of the HS app on pregnancy-specific anxiety, with the hypothesis being that participants would report decreased levels of pregnancy-specific anxiety from baseline to post-intervention. Pregnancy-specific anxiety was assessed using the PRAS, and statistically analyzed with a paired-t test to observe if there were differences in baseline and post-intervention values. Statistical significance was determined by observing the p-value, which gives the probability of obtaining a p-value as, or more extreme, than what was observed under the null hypothesis. If the p-value was <0.05, there was strong evidence to reject the null hypothesis, that there was no difference in the pre/post PRAS values for study participants. The p-value for the PRAS was 0.0001 (Table 7), which is strong evidence to reject the null hypothesis, and conclude that there was a difference in baseline and post-intervention PRAS scores. Further, the difference was directional, indicating that study participants who practiced MM via the HS app experienced a significant reduction in pregnancy specific anxiety, as evidenced by the reduction in their PRAS scores from baseline to post-intervention. Additional details regarding baseline and post-intervention pregnancy-specific anxiety data for study participants are presented as follows.

Baseline Pregnancy Anxiety. Pregnancy-specific anxiety was also evaluated using the PRAS. For the PRAS, scores range from 0 to 30, with higher scores indicating greater participant anxiety. The baseline median PRAS score was 10.0, with a range of between 2-22 (Table 12). Unlike the PSS and GAD-7, the PRAS does not provide categories for “mild, moderate and severe” pregnancy anxiety. Details about individual study participant’s baseline pregnancy anxiety scores are shown in Figure 14.

Baseline Pregnancy Anxiety: PRAS								
Total Count (N)	Missing	Mean	Standard Deviation	Percentile				
				Min	0.25	0.50 (Median)	0.75	Max
19	1 (5%)	10.84	5.20	2	7.50	10	14.50	22

Table 12. Baseline Pregnancy Anxiety (PRAS)

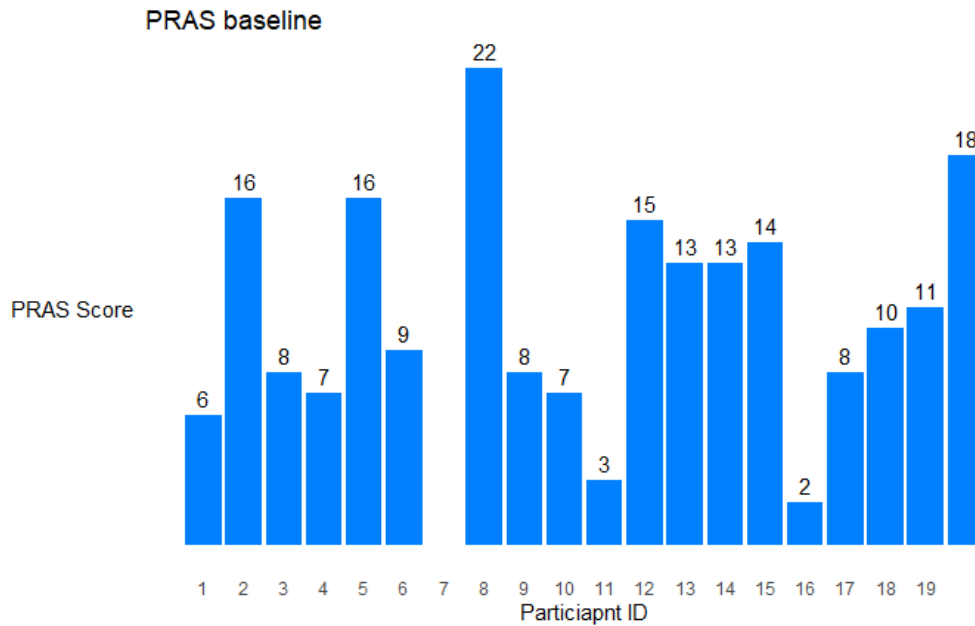


Figure 14. Baseline Pregnancy Anxiety (PRAS)

Post-Intervention Pregnancy Anxiety (PRAS). The mean post-intervention score for the PRAS was 5.9, with a standard deviation of 3.99 (Table 13). This was a decrease from the baseline mean PRAS score of 10.84 (Table 12). Details about individual study participant’s post-intervention pregnancy anxiety scores are shown in Figure 15.

Post-Intervention Pregnancy Anxiety: PRAS								
Total Count (N)	Missing	Mean	Standard Deviation	Percentile				
				Min	0.25	0.50 (Median)	0.75	Max
20	0 (0.0%)	5.90	3.99	0	2.75	5.50	9.25	14

Table 13. Post-Intervention Pregnancy Anxiety (PRAS)

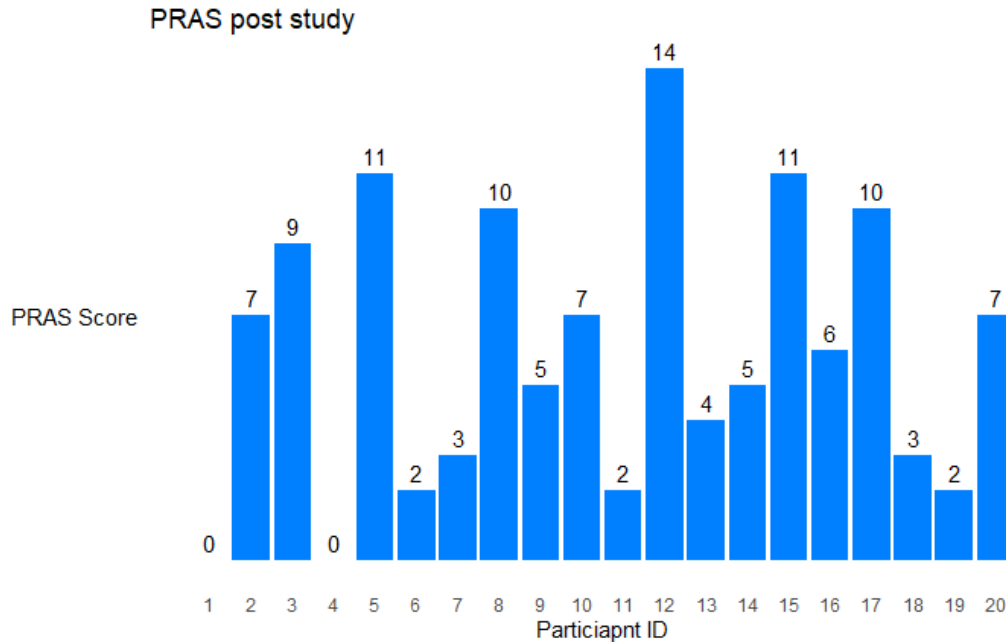


Figure 15. Post-Intervention Pregnancy Anxiety (PRAS)

Aim 2. Evaluate the physiological effects (HRV and sleep changes over time) of practicing MM via the Headspace app among 20 pregnant women utilizing the Oura Ring. Ho. 2: Participants practicing MM via the Headspace app will show an increase in their HRV and an improvement in their sleep.

Aim 2: Primary Analysis; Hierarchical Linear Modeling (HLM) of HR/HRV Metrics

The Aim 2 primary analysis hypothesis was partially supported. Study participants who practiced MM via the Headspace app showed a change in one of six HR/HRV components associated with stress reduction.

The outcome variables in Aim 2 were analyzed via hierarchical linear modeling (HLM) by Salar Hashemitaheeri, a computer science graduate student who was working in Dr. Rahmani’s lab (Table 14).

Monitoring Parameter	% Change in 4 Weeks	P-value
<i>HR/HRV Parameter</i>		
Min HR (resting)	increased by 2.3%*	0.007*

RMSSD	decreased by 9%*	0.007*
SDNN	decreased by 7%	0.086
HF	decreased by 11%	0.070
LF	decreased by 13%*	0.006*
LF/HF ratio	decreased by 2%	0.086
<i>Sleep Parameter</i>		
Sleep Score	Increased by 2%	0.092

Table 14. Aim 2 Primary Analysis Results: HRV Metrics and Sleep

*P-value <0.05

Various HR/HRV metrics can be extracted and analyzed, with each metric correlating with a physiological representation of stress, depending on if their values are lower or higher. To evaluate the impact of an intervention on these metrics, we can observe if the values increase or decrease. Table 15 provides details regarding the expected direction that HR/HRV metrics move as a result of reduced stress.

HR/HRV Metrics Stress Physiology Associations			
Metric	Reflects	Indication of Low Stress/Relaxation	Reference
HR	Relative balance between SNS and PNS	Lower values	Taelman et al., 2011
RMSSD	PNS activity	Higher values	Taelman et al., 2011; Shaffer & Ginsberg, 2017
SDNN	Both sympathetic & parasympathetic activity	Higher values	Taelman et al., 2011; Shaffer & Ginsberg, 2017
LF	Both sympathetic & parasympathetic activity	Lower values	Delaney & Brodie, 2000; Shaffer & Ginsberg, 2017
HF	Parasympathetic activity	Higher values	Delaney & Brodie, 2000; Shaffer & Ginsberg, 2017
LF/HF	Sympatho-vagal balance	Lower values	Delaney & Brodie, 2000; Taelman et al., 2011

(Teckenberg-Jansson et al., 2019)

Table 15. HR/HRV Metrics Stress Physiology Associations

One of six HR/HRV parameters, the low frequency power band (LF), significantly changed in the hypothesized direction. Findings revealed that participants had a statistically significant reduction in LF of 13% ($p=0.006$). The LF band primarily reflects baroreceptor activity while at rest, indicating a balance of both sympathetic and parasympathetic activation. Lower values indicate relaxation/lower mental stress. The statistically significant reduction of LF provides evidence to support the Aim 2 hypothesis that study participants practicing MM had an improvement in their physiological stress measure (HRV).

While it appears that there are statistically significant results in two additional HR/HRV parameters, HR and RMSSD, further explanation is warranted. Although these values changed significantly, they moved in the opposite direction of what was hypothesized. Minimum/resting HR increased by 2.3% ($p=0.007$), but it was hypothesized that this value would decrease. However, an increase in HR is consistent with the normal changes which occur during pregnancy. Similarly, RMSSD decreased by 9% ($p=0.007$), but RMSSD is reflective of parasympathetic activation, with higher values indicating relaxation/lower mental stress. It was hypothesized that RMSSD would increase as a result of the intervention. Further details of the remaining HRV metrics which were analyzed are as follows.

SDNN. SDNN is the standard deviation of the interbeat interval of normal sinus beat and is reflective of overall HRV. Higher SDNN values indicate relaxation/lower mental stress. The HLM modeling indicated that the SDNN values decreased by 7% (p -value 0.086), which is the opposite of what was hypothesized. However, the p -value indicates that these results were not significant.

HF. The HF component of HRV represents parasympathetic input to the heart by the vagus nerve, with higher values indicating relaxation/lower mental stress. The HLM modeling indicated that the HF values decreased by 11% and were not statistically significant (p -value 0.070). This was the opposite of what was hypothesized.

LF/HF. The ratio of the LF to HF power bands of the HRV signal is called the LF/HF ratio, and it is used to evaluate sympatho-vagal balance, where a lower value indicates relaxation/lower mental stress. The HLM modeling indicated that while there was a 2% decrease over the study period, the p-value was not statistically significant (0.086).

Aim 2 Primary Analysis: Hierarchical Linear Modeling (HLM) of Sleep Metric

The Aim 2 primary analysis hypothesis regarding the sleep variable was unsupported. According to the HLM modeling, study participants who practiced MM via the Headspace app did not show a significant improvement in their sleep. However, the sleep score increased by 2% (p=0.092), which is trending in the direction of statistically significantly improved sleep.

Aim 2 Secondary Analysis: Paired t-test

The Aim 2 secondary analysis hypothesis was not supported. In addition to HLM modeling, paired t-tests were utilized to assess if there were changes in individual participants' sleep and HRV (RMSSD) scores from baseline to study completion (Table 16). The analysis did not indicate an increase in participant's HRV (p=0.241), or an improvement in sleep (p=0.572).

Measure	Pre		Post		p-value
	M	SD	M	SD	
HRV (RMSSD)	38.20	18.98	37.03	17.651	0.241
Sleep Score	77.24	6.44	77.49	5.522	0.572

Table 16. Aim 2 Pre-and Post-Intervention Mean Comparisons of HRV and Sleep Scores

When the scientific community refers to HRV, they are generally referring an a single HRV metric, the RMSSD (root mean square of successive differences between normal heartbeats). When the Oura Ring app reports the HRV value, it is actually the RMSSD. In addition to the HLM analysis, a secondary analysis was done via paired t-test comparing HRV changes from baseline to post-intervention. The HRV metric used for this analysis was RMSSD.

The study participants were instructed to wear the Oura Ring for 4 days prior to the start of the intervention to obtain an average baseline sleep and average baseline HRV scores. The Oura app calculates HRV values every 5 minutes. As HRV data is more accurate during participant's sleep hours, the data was cleaned to average only the nighttime HRV from the hours between 10 pm and 7 am. One study participant worked the night shift, so her HRV was averaged during her sleep hours (8 am and 2 pm). Average baseline and study-end sleep HRV scores were calculated from the first four (baseline) and final 4 days of the study (Table 17).

Study ID	Baseline Sleep Score	Study-End Sleep Score	Baseline HRV (RMSSD)	Study-End HRV (RMSSD)
1	82	80.25	39.35	45.38
2	82.5	78.75	35.15	23.95
3	75.75	69.75	18.92	19.26
4	80.25	80.75	36.53	38.42
5	81.5	77	45.04	41.36
6	66.5	79.25	24.39	21.47
7	82.25	74.75	14.14	15.60
8	75.75	82	28.11	45.54
9	88	88.5	40.49	30.12
10	79.5	84.75	32.625	36.72
11	76.5	75.75	31.91	41.24
12	70	79.5	30.90	29.1
13	74.5	68	24.75	18.04
14	67	69.25	32.02	24.57
15	76.25	72	83.72	77.21
16	89.75	83.75	35.32	42.62
17	69	71.25	51.39	46.38
18	70.5	81	89.87	81.75
19	77.25	78.75	45.84	38.52
20	80	74.75	23.60	23.26

Table 17. Comparison of Baseline and Study-End Sleep and HRV Scores

The baseline sleep and HRV scores were compared to the study-end sleep and HRV scores by a paired-t-test analysis. The mean change in sleep score for the study participants was -0.185, however the p-value (0.572) indicates that this change was not significant. The mean change in HRV for the study participants was -0.718, however the p-value (0.241) indicates that this change was not significant. Therefore, there was insufficient evidence to support the study hypothesis that study participants would have an increase in their HRV and sleep scores.

Parameter	Ho**	Balajewicz-Nowak, 2016	Kolovetsiou-Kreiner, 2018	Solanki, 2020	Garg, 2020	Sarhaddi, 2022	Balsam, 2022
# of pregnant participants		36	18	24: 1 st 37: 2 nd 30 control	66	58	20
RMSSD	↑	N/A	-10.7%*	-8.8%	N/A	-3.5%*	-9%* (p=0.007)
SDNN	↑	N/A	-5.5%	-8.6%	-8.3%*	-3.9%*	-7% (p=0.086)
LF	↓	-1.3%*	-1.7%	+0.6%*	-16%*	-10%*	-13%* (p=0.006)
HF	↑	-4.6%*	-4.4%*	-1%*	-23%*	-7.1%*	-11% (p=0.070)
LF/HF	↓	+11.3%*	+77%*	+11%*	+24%*	0%	-2% (p=0.086)
Samples over time per subject		9	6	3	12	196 (9,826)	28 (3,024)

Table 18. Slope Comparison

**Ho = hypothesis = predicted direction of change with a stress-reducing intervention

* P value <0.05

Aim 2 Slope Comparison of Pregnancy HRV Parameters

A review of 5 articles which examined trends in HRV during pregnancy yielded the results in Table 18 (Bałajewicz-Nowak et al., 2016; Garg et al., 2020; Kolovetsiou-Kreiner et al., 2018; Sarhaddi et al., 2022; Solanki et al., 2020). From these articles, data was extracted to calculate the slope of the HRV parameters as a function of time, normalizing the percent change over a 4-week period to be consistent with this dissertation study's 4-week time frame. In

addition, data was selected from the 1st and 2nd trimesters of pregnancy, as that time frame best aligned with the gestational age of the participants in this dissertation study.

In the table, the first column is the expected direction of change predicted in the HRV parameters as a result of a stress-reducing intervention (Teckenberg-Jansson et al., 2019). As HRV parameters (RMSSD, SDNN, LF, and HF) are known to decrease across pregnancy (Herbell & Zauszniewski, 2019; Sarhaddi et al., 2022), the question was whether the HS intervention in this dissertation study would cause “less” of a decrease. The bold entries in Table 18 indicate studies where our hypothesis compared favorably.

Aim 3: Determine if participant app usage amount is associated with differences in measured outcomes. **Ho:3.** Study participants who use the app more frequently (number of sessions, and/or total minutes used) will experience a greater reduction in their stress and anxiety than participants who use the app less frequently.

Aim 3 Results Summary Analysis

The Aim 3 hypothesis is not supported. Study participants who used the app more frequently did not show a greater reduction in their stress and anxiety than those who used the app less frequently (Table 19).

Measure	Mean Change Score	P-Value
PSS	-0.210	0.418
GAD-7	-0.576	0.287
PRAS	-0.968	0.174
Sleep	0.229	0.411
HRV	0.914	0.191

Table 19. Aim 3 Analysis

Headspace Usage

Participants were asked to complete sixty meditations during the study period, which is amounts to two meditations per day. As participants could choose the length of time to meditate, completion of the intervention was a range of time between 530-1050 minutes. Table 20

indicates the total number of minutes each participant meditated with HS, the number of sessions completed, and percentages related to each category.

Headspace App Usage Data				
Study ID	Number of HS minutes used	% Minutes	Number of Sessions Completed	% Sessions Completed
1	952	100	58	96.7
2	344	65	45	75
3	565	100	58	96.7
4	460	86.8	40	66.6
5	184	34.7	22	36.7
6	165	31.1	18	30
7	345	65.1	37	61.7
8	579	100	48	80
9	678	100	60	100
10	49	9.2	9	15
11	622	100	60	100
12	316	59.6	34	57
13	182	34.3	19	31.7
14	457	86.2	59	98
15	505	95	50	83.3
16	38	7.2	5	8.3
17	52	9.8	26	43.3
18	544	100	53	88.3
19	637	100	62	100
20	558	100	54	90

Table 20. Headspace app Usage Data

To calculate if there was a relationship between study participant app usage, and the stress and anxiety outcome variables, paired t-tests were done to compare if the

pre/post study change scores for the outcome variables were different between low-and high-app usage users. The paired samples t-test was performed to compare stress (PSS) for low app users and high app users. The difference in the mean of the change scores between low and high app users was -0.210, which was not significant ($p=0.418$). The paired samples t-test was performed to compare anxiety (GAD-7) for low app users and high app users. The difference in the mean of the change scores between low and high app users was -0.576, which was not significant ($p=0.287$). The paired samples t-test was performed to compare pregnancy anxiety (PRAS) for low app users and high app users. The difference in the mean of the change scores between low and high app users was -0.968, which was not significant ($p=0.174$). The paired samples t-test was performed to compare sleep (sleep score) for low app users and high app users. The difference in mean change scores between low and high app users was 0.229, which was not significant ($p=0.411$). The paired samples t-test was performed to compare HRV (RMSSD) for low app users and high app users. The difference in mean change scores between low and high app users was 0.914, which was not significant ($p=0.191$).

Further details regarding HS app usage data are as follows. Eight study participants completed 100% the intervention, either completing all 60 meditations, or a minimum of 530 minutes of meditation. Eight participants completed between 531-952 minutes. Ten participants (50%) completed 95% or more of the intervention. Thirteen participants (65%) completed at least 65% of the intervention, and twelve participants (60%) completed at least 75% of the intervention. Five participants (25%) did not appear to engage with the app much, completing <35% of the intervention. However, most of the study participants (14 participants; 70%) completed 50% or more of the intervention, which speaks positively regarding study participant adherence to the HS intervention.

Additional Self-Report Assessment Questions

Self-report Sleep

In addition to the physiological measures of sleep measured by the Oura Ring, subjective (self-report) sleep was assessed in the pre-intervention assessment, asking the participants to comment on the following statement: "I typically sleep well," with the following answer choices: strongly disagree; disagree; neither agree nor disagree; agree; or strongly agree. In the pre-intervention survey, 25% of participants claimed they did not sleep well, 30% were neutral, and 45% said they typically slept well (Figure 16).

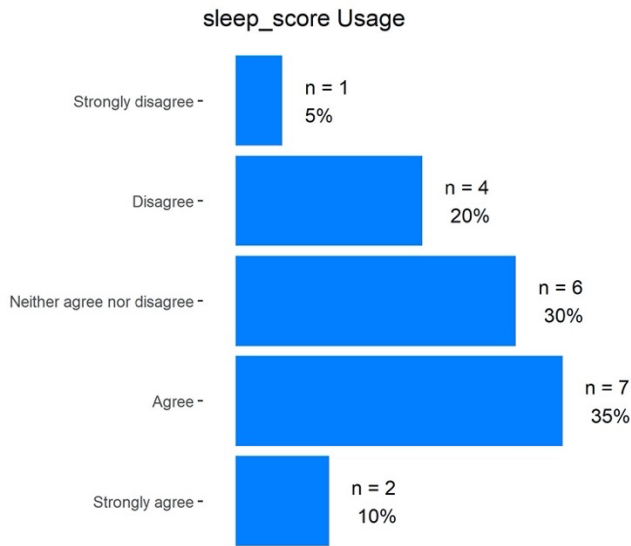


Figure 16. Baseline Characteristics: Self-report Sleep

As part of the post-intervention assessment questionnaire, participants were asked if they believed their sleep improved during the trial. 65% of the participants indicated that they believed their sleep improved (Figure 17).

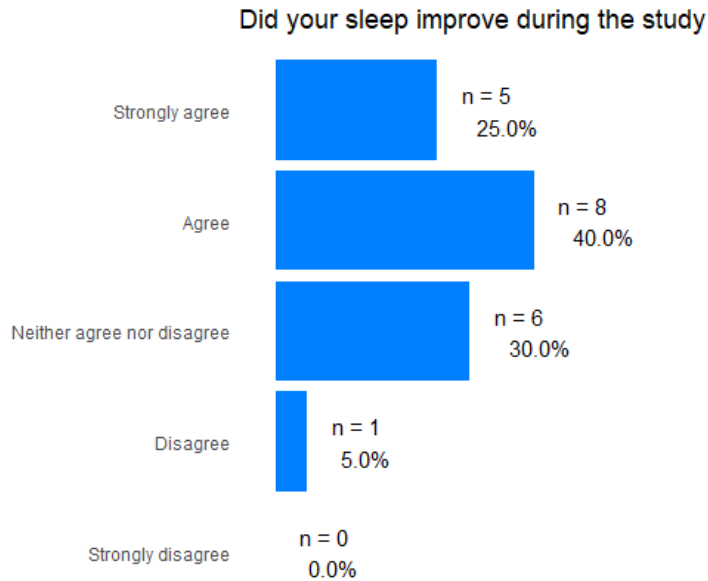


Figure 17. Post-Assessment Questionnaire Subjective Sleep

Exercise

Exercise is known to improve sleep quality (Banno et al., 2018), and regular exercise is associated with a reduction in both stress (Guo, Kehoe, et al., 2021) and anxiety (Aylett, Small, & Bower, 2018). Therefore, if a study participant’s exercise level increased during the trial, it could have impacted the measured outcome variables. Study participants were asked to comment on the following statement: “My exercise level increased during this trial,” with the following answers: strongly disagree; disagree; neither agree nor disagree; agree; or strongly agree. Eleven participants selected either disagree or neither agree nor disagree, indicating that for 55% of the participants, their exercise level did not change during the trial. Nine participants selected either agree or strongly agree, indicating that 45% of the participants had an increased level of exercise during the trial (Figure 18). Further analysis revealed that 5 study participants who stated that they did not regularly exercise before the trial indicated that their exercise levels increased during the trial. For these 5 participants, improvements in self-report stress, anxiety,

pregnancy anxiety, and sleep could have resulted due to their increased exercise levels during the trial.

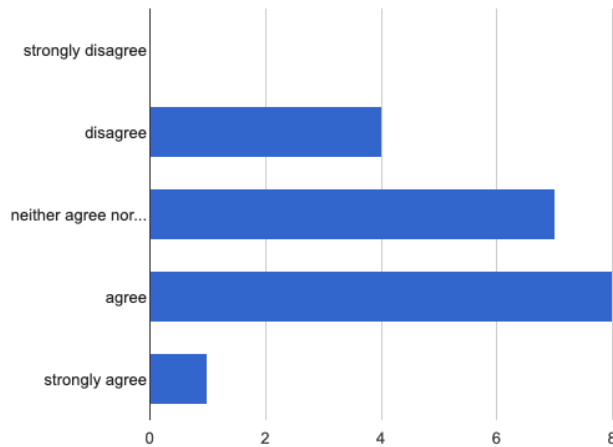


Figure 18. Post-Assessment Questionnaire: Exercise

Stressors During the Study Period

On the post-intervention assessment, participants were asked the following question: Was there something new that happened to you during the study period that was particularly stressful (e.g., an illness, a COVID-19 scare/diagnosis, etc.)? If so, what was it and when did it happen? Three participants (15%) stated no, or nothing particularly. The remaining 85% said yes. Answers are provided in Table 21.

Study ID	Response (quoted)
1	No
2	I was told by my OB that I would need to schedule a cesarean under general anesthesia because of a spinal issue. Also in the last few weeks work has been stressful (although I also had a lovely week off).
3	Nothing particularly. Sleep habits interrupted by a teething toddler.
4	Extremely busy holiday season and family demands. Parents got Covid, maternity care transferred, and job threatened to fire me.
5	Just going to the east coast to see family, my grandpa cancer came back and he's not wanting to do anything and just getting prepared for the baby
6	No there was not.
7	possible issues with the placenta
8	My mom had a heart attack and I had to spend the weekend in the hospital with her!
9	Yes, about half way through I found out many Of my hours for my social work licensure won't count and I am going to obtain licensure later than anticipated.
10	We moved houses and my husband's workload and hours increased.

11	We got a leak and half our kitchen got removed. I've been without a kitchen for about 3 weeks now. It's rather hard to eat healthy for the baby while mainly eating out...
12	I had to be tested a second time for gestational diabetes. I was concerned i would put myself or my baby in an unhealthy position. The results came back that I did not have it.
13	We moved houses during the first week
14	Applying for jobs was stressful, can't remember time of month. But probably toward beginning of study.
15	My husband left for several days at a time due to being active duty military
16	Family stress 5/16 -current
17	severe morning sickness all day
18	I had finals at school during the beginning of the study.
19	Had a day where now to find out it can be a completely normal symptom of pregnancy really scared me and I went to the doctors.
20	5/27-5/30: Travel caused sleep patterns to be irregular

Table 21. Stressors During Study Period

Utility of Mindfulness

In the post-intervention assessment, participants were asked “Did learning/practicing mindfulness meditation help with other aspects of your life?” Nineteen participants (95%) answered yes, while one participant answered no (Figure 19).

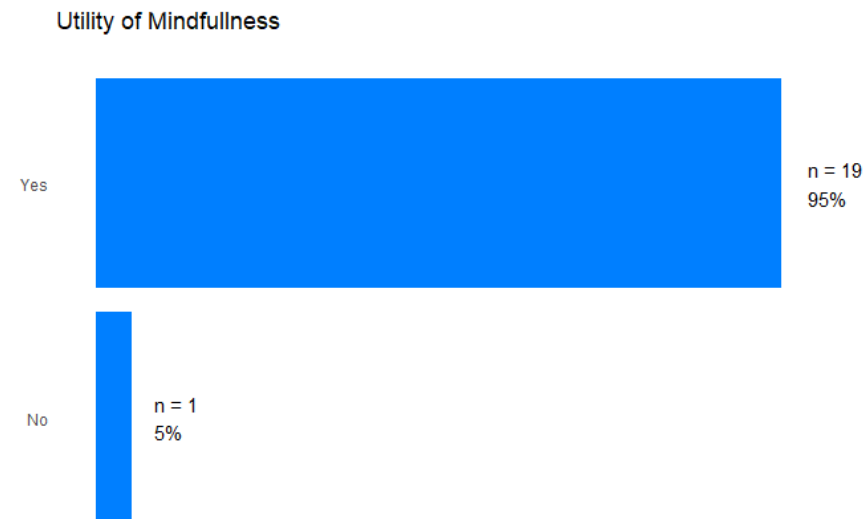


Figure 19. Post-Assessment Questionnaire: Utility of Mindfulness

As a follow-up to the previous question, on the post-intervention assessment, study participants were asked “If you answered, ‘yes’ to the previous question, please provide some more details about which ways meditation helped with other aspects of your life.” Three

participants did not answer, and seventeen participants (85%) answered, with details of their responses provided in Table 21.

Study ID	Response (quoted)
1	Stopping to listen and scan my body has been very helpful. I now can quiet myself and focus on my breathing easily.
2	Meditation helped me tremendously in falling asleep quickly at night and staying asleep. That has been a major benefit. I've also noticed I'm more patient when driving in traffic or at other unstructured times when normally my mind would wander. Overall it's helped a lot with "free thinking" time- but I'm still very stressed by typical life stressors like work.
3	I felt like I was getting a little time to myself and making myself a priority which is something I struggle with.
4	I feel like my relationships drastically improved by taking time to stop and reflect and have some mindfulness before overthinking and arguing. My husband noticed an improvement in my maturity in handling conflict.
5	It has definitely taught me to take a step back and think about an event and how I should respond
6	In stressful moments at work, at home, or with family I was able to take a step back and take a few deep breaths. Allowing me to rethink the situation and not be so reactive.
7	improved stress response, more relaxed. improved breathing exercises. new tools to help with falling back to sleep. improved energy. less nausea.
8	I was able to remain calm during this extra stressful time - especially with other factors including my father not being the most helpful during times of high stress. I was able to quickly act, be there for my mom AND communicate effectively with all of my family who was worried while remaining calm for my mom.
9	Supported my sense of relaxation and ease. It was nice to begin and end my days with a new, calming ritual.
10	I was able to immediately bring my focus to my breathing to center myself first before figuring out a way to resolve any issue. I also am able to exercise more at the new house by having the space and energy to chase my toddler around.
11	unanswered
12	Meditation has helped me take a moment to calm my mind from everyday stresses.
13	myself taking a minute or two to think through some of the mindfulness/meditation and it helped tremendously. I truly felt like a more patient mother and wife
14	Work
15	Meditation taught me to slow down from the stresses of everyday life and take a few minutes to focus on me and my pregnancy.
16	unanswered
17	unanswered
18	I felt more patient with my husband and my dog. I felt more motivated to take a moment before responding to stressors. This made me react with thoughtfulness instead of emotion more often.
19	Just trying to be more mindful of how I feel, view things, and talk to my husband. I've been emotional at times, so it's helped with that.
20	Meditation helped me start each day with a better, more at-ease perspective, instead of diving head first into a long to-do list upon waking.

Table 22. Post-Assessment Questionnaire: Utility of Mindfulness

Chapter 6: Discussion

Introduction

Stress and anxiety during pregnancy have many untoward effects on the health and well-being of the woman's pregnancy, the developing fetus, and the mother and child's future health outcomes. There is a need to find evidence-based interventions to assist with this problem. While there is evidence that learning mindfulness meditation (MM) in traditional, in-person mindfulness-based stress reduction courses is effective in reducing stress and anxiety during pregnancy (Babbar et al., 2021), the popularity of internet mindfulness-based interventions (iMBIs) offers the advantage of scalability and convenience. However, in addition to the scarcity of research in this area, the literature review showed various study limitations including problematic study design and methodology (Cornsweet-Barber et al., 2013; Matvienko-Sikar & Dockray, 2017; O'Leary & Dockray, 2015; Yang et al., 2019; Yang et al., 2022), poor adherence to the interventions (Carissoli et al., 2017; Krusche et al., 2018a; Matvienko-Sikar & Dockray, 2017; Yang et al., 2019; Yang et al., 2022), and lack of physiologic measures of stress (Carissoli et al., 2017; Cornsweet-Barber et al., 2013; Krusche et al., 2018a; Williams, 2012; Yang et al., 2019; Yang et al., 2022).

This dissertation research was conducted to address these limitations by implementing a well-designed study utilizing popular and cutting-edge technology. Headspace (HS), a top-rated, highly effective app, was chosen to deliver the MM content and as well as to assist with adherence to the intervention. The Oura Ring was utilized to collect physiological measurements of stress to strengthen the validity of the study. Our findings revealed Aim 1 self-report hypothesis was fully supported; study participants who practiced MM via the HS app experienced a significant reduction in their self-report stress levels from pre-to post-intervention. In Aim 2, one of six HR/HRV physiological measures of stress, the low frequency band of the HRV (LF), improved during the study. The following sections provide detailed discussion

regarding the stress, anxiety, and sleep findings, review this dissertation study's strengths and limitations, and propose areas of future research.

Aim 1 Self-Report Outcomes: Stress and Anxiety

Stress

The Aim 1 stress self-report hypothesis was fully supported; study participants who practiced MM via the HS app experienced a significant reduction in their self-report stress levels from pre-to post-intervention ($p=0.005$).

Anxiety

The Aim 1 anxiety self-report hypothesis was fully supported; study participants who practiced MM via the HS app experienced a significant reduction in both general anxiety ($p=0.011$), and pregnancy-specific anxiety ($p=0.0001$).

Stress and Anxiety in the Literature. Systematic reviews and meta-analyses of the literature indicate that studies on mindfulness interventions have larger effect sizes on pregnant participants with higher baseline stress and anxiety levels as compared with samples with lower stress and anxiety levels (Hall et al., 2016; Shi & MacBeth, 2017; Taylor et al., 2016; Yan et al., 2022). In a systematic review and meta-analysis of 12 studies examining the effects of MM interventions on pregnant women without pre-existing stress or anxiety disorders, Corbally and Wilkinson (2021) found insufficient evidence of a reduction in stress. Further, a meta-analysis was not performed on the anxiety variable due to a small number of and large variation in reported effects on general anxiety (Corbally & Wilkinson, 2021).

For the population in this dissertation study, the baseline assessment of stress indicated that 50% of participants had low stress, 45% of participants had moderate stress, and 5% had high stress. The study results indicated that the intervention was powerful in significantly reducing stress, even for a population with low-to-moderate stress at baseline. In terms of anxiety, with the majority (65%) of our study population assessed

as experiencing mild general anxiety, our intervention resulted in a statistically significant reduction in general anxiety. For the pregnancy-specific anxiety measure, the developers of the scale did not provide cutoff points to delineate mild, moderate, or severe anxiety. As the scale has a range of 0-30, with higher numbers associated with increased pregnancy anxiety, with a mean baseline PRAS score of 10.84 (SD 5.2), this was interpreted as mild to moderate pregnancy anxiety. The results of this dissertation study indicated that there was a significant reduction in pregnancy anxiety for study participants, even for a population who had mild to moderate pregnancy anxiety at baseline.

Aim 2 Physiological Outcomes: HR/HRV & Sleep

HR/HRV

For the Aim 2 physiological hypothesis of stress, the results were partially supported. The dissertation study results for this population indicated that the low frequency band (LF), one of six HR/HRV parameters evaluated in this study, decreased by 13% ($p= 0.006$). This provides some physiological evidence of reduced stress, as the findings and direction of change are consistent with the literature.

A variety of HRV metrics have been studied and referenced in the literature, and in this relatively new field of scholarship, there have been methodological concerns as well as inconsistencies in the choice of the HRV parameters in many studies which utilize HRV as an outcome variable. In a recent systematic review on reducing psychological stress in peripartum women with HRV biofeedback (Herbell & Zauszniewski, 2019), of the two articles included in the review, the authors noted that one study used only one parameter (RMSSD) (Siepmann et al., 2014), while another used a variety of parameters (HF, LF, SDNN) (Kudo, Shinohara, & Kodama, 2014).

In four additional studies which utilized HR/HRV as outcome variables in mind-body stress-reducing interventions (excluding biofeedback) for pregnant women, a variety of HR/HRV

parameters were used. These included HR, LF, HF, LF/HF, SDNN, RMSSD, and SD2 (Chu et al., 2017; Hayase & Shimada, 2018; Muthukrishnan et al., 2016; Teckenberg-Jansson et al., 2019), all of which were utilized in this dissertation study except for SD2. In two of these papers, if one of the HRV metrics changed in the expected direction, the findings were reported as evidence that the intervention was effective (Hayase & Shimada, 2018; Muthukrishnan et al., 2016). The third study reported evidence that the intervention was effective with a change in 2 (of 12) HR/HRV parameters (Teckenberg-Jansson et al., 2019). The fourth study assessed efficacy of the intervention with a change in 3 of 4 HRV parameters (Chu et al., 2017). In this dissertation study, reporting a change in one of the HR/HRV parameters which moved in the direction of stress reduction as evidence of potential efficacy of this intervention follows current reporting trends in the literature.

While there were statistically significant results in the self-report stress findings of this study, as well as one of the physiologic measures, the lack of statistically significant changes in the remaining HR/HRV measures could be due to pregnancy physiology. According to the literature, while HRV can be used as an objective measure of stress in the pregnant population, interpreting HRV in this population is challenging, (Neila-Vilen et al., 2021) as cardiovascular and hormonal changes of pregnancy impact HRV. Normal cardiovascular changes which occur as a result of pregnancy, including an increase in blood volume, stroke volume, cardiac output, and heart rate, all influence HRV (Herbell & Zauszniewski, 2019), resulting in HRV being greatly diminished across gestation (Carpenter et al., 2017; Herbell & Zauszniewski, 2019; Sarhaddi et al., 2022). The higher cortisol levels and blunted HPA-axis response to glucocorticoids during pregnancy (Soma-Pillay et al., 2016) may also affect the stress response (van der Zwan, Huizink, Lehrer, Koot, & de Vente, 2019), and contribute to the diminished HRV seen during pregnancy.

The Aim 2 hypothesis for this dissertation study was that the intervention would cause a decrease in stress, as physiologically evidenced by an increase in HRV (higher

RMSSD). The study results for this population indicated that the RMSSD levels decreased by 9% ($p= 0.007$), which was the opposite to our hypothesis. However, this decrease in RMSSD is consistent with the literature as well as expected changes in pregnancy physiology. In three of the studies in the literature review which utilized mind/body stress-reducing interventions for pregnancy, none had statistically significant changes in RMSSD (Hayase & Shimada, 2018; Muthukrishnan et al., 2016; Teckenberg-Jansson et al., 2019), and the fourth did not evaluate RMSSD (Chu et al., 2017).

The remaining HRV findings in this dissertation study are also consistent with the normal expected changes in pregnancy physiology. A recent study which evaluated the HRV changes across three trimesters of pregnancy for 89 women compared to 30 age-matched controls, found that there was reduced HRV in all three trimesters. Additionally, results were more marked for primiparous versus multiparous women (Solanki et al., 2020). The majority of the women in this dissertation study were primiparous (60%), which may have contributed to the study findings.

Another recent study found further evidence of diminishing HRV parameters throughout pregnancy; however they identified trends in HRV which correlated to specific trimesters (Sarhaddi et al., 2022). The investigators noted that SDNN and RMSSD decreased significantly during the second trimester, but then increased significantly during the third trimester, and that LF and HF decreased significantly during the second trimester, while HF increased significantly during the third trimester (Sarhaddi et al., 2022).

During the trial, of the six study participants who started in their first trimester, one progressed to her second trimester. Of the 11 who started in their second trimester, one progressed to her third trimester. Over the study period, 10 women in the trial (50%) were in their 2nd trimester. According to the literature, SDNN, RMSSD, LF and HF HRV parameters decrease significantly during the second trimester (Sarhaddi et al., 2022). In this dissertation study, SDNN levels decreased by 7% ($p=0.086$), RMSSD decreased by 9% ($p=0.007$), and HF

decreased by 11% ($p=0.07$). These results are consistent with what current research documents as the expected trend of HRV parameters during pregnancy.

The changes in study participants' HR as analyzed in this dissertation study were interesting. The HLM results of this study indicated that participant's resting HR increased by 2.3% (p -value 0.007). For the general population, we would have expected a stress-reducing intervention to cause a decrease in HR. However, in pregnancy, there is an expected increase in HR due to the normal physiological changes which occur. A recent meta-analysis evaluating trends in HR among 8,317 pregnant women found that on average, the HR during pregnancy increased by 10% (7.6 beats/min) (Loerup et al., 2019). As the increase in HR for this dissertation study population was 2.3% (p -value 0.007), it is possible that the intervention impacted participants HR, potentially causing a smaller increase than would have been expected without a stress-reducing intervention. It could be that the impact was less pronounced due to the normal physiological pregnancy changes which impact HR.

Slope Comparison of Pregnancy HRV Parameters

Table 18 depicts details constructed from a review of 5 articles which examined trends in HRV metrics during pregnancy without a stress-reducing intervention (Bałajewicz-Nowak et al., 2016; Garg et al., 2020; Kolovetsiou-Kreiner et al., 2018; Sarhaddi et al., 2022; Solanki et al., 2020). It is well established that HRV decreases across pregnancy (Herbell & Zauszniewski, 2019; Sarhaddi et al., 2022). To compare the results of normal pregnancy HRV trends matched by trimester to the results of this dissertation study, slope trends per individual HRV parameter were calculated. The purpose of this was to answer whether the HS intervention in this dissertation study would cause "less" of a decrease in the HRV parameters. The bold entries in Table 18 indicate studies where our hypothesis compared favorably. For instance, in row 3 of the table, the measure of RMSSD, as reported in Kolovetsiou-Kreiner et al. (2018), was found to decrease by 10.7% over a 4-week period. Our findings of a decrease of 9% are thus higher and

may reflect a positive outcome from the intervention. However, as also seen in the table, the data from Solanki et al. (2020) and Sarhaddi et al. (2022), decreases in RMSSD of 8.8% (not statistically significant) and 3.5%, respectively, contradict our hypothesis. It is difficult to extrapolate trends when results of the various studies are so varied. Nonetheless, the statistically significant findings in the LF metric appears to confirm our hypothesis, as our reported LF value decreased more than the values in 4 out of the 5 comparison studies.

Our LF/HF parameter decreased by 2%, moving in a direction that was consistent with our hypothesis, and with a p-value which was trending towards significance (0.086). As seen in the table for the other studies, the LF/HF values vary greatly, as is common when dividing by small numbers. Our value was the only one that moved in the negative direction, which was an interesting comparative finding, and one that could be further investigated in the future.

Sleep

In addition to stress and anxiety, sleep was the third outcome variable evaluated in this dissertation study. A recent narrative review which included 13 studies evaluating mindfulness interventions during pregnancy noted that none of the studies evaluated sleep quality and asserted that it is imperative to evaluate sleep in this population (Lucena et al., 2020). In this dissertation study, sleep data was collected in two different ways; self-report data was collected by survey and physiological data was collected by the Oura Ring. It was hypothesized that participants who practiced MM via the HS app would show an improvement in their sleep. The results of the sleep outcome variable were mixed. The self-report survey data indicated that the majority of the study participants (65%) felt that their sleep improved during the trial, and the Oura Ring physiological sleep data showed that the sleep score increased (improved) by 2% ($p=0.092$), which is trending in the direction of significance.

There are three factors to consider in understanding the sleep data results. The first relates to pregnancy, and the prevalence of poor sleep for women during this time. A recent study which collected subjective sleep data during each trimester of pregnancy for 133 women

found that 88% reported poor overall sleep quality at some time during pregnancy (Christian et al., 2019). It is possible that the study participants did not have a statistically significant improvement in their physiological measure of sleep because they were pregnant. However, in this dissertation study, 65% of participants reported that their sleep improved during the trial. It may be that their sleep was worse prior to the intervention (because of pregnancy), but that the intervention had a positive impact on their sleep, which could explain the trend towards sleep improvement documented by the Oura Ring, as well as the self-report results.

The second factor to consider regarding the sleep data results is the potential bias of the reporting tool. The survey consisted of pre/post Likert-style questions developed by the investigator, which lacked the validity of a standardized sleep assessment. This is further discussed in the “Study Limitations” section.

The third relates to the accuracy of the Oura Ring for pregnancy. While the Oura Ring sleep assessment technology may be highly accurate for the general population, it may not be as accurate for the pregnant population. The Oura Ring does not have specific settings or calibrations for pregnancy, and Oura’s metrics which constitute a “good” sleep score in the general population may not translate to the pregnant population. A recent study comparing sleep quality between 65 pregnant and 67 non-pregnant women matched controls found that most of the pregnant women in the study had reduced quality of sleep, citing the following contributing factors: sleep position/discomfort, night calf cramps, awakening to use the restroom, and awakening due to dreams (Kasperczyk, Joško-Ochojska, Bodzek, & Janosz, 2019). It may be that the frequent movement experienced by most pregnant women during sleep may have negatively impacted the “restfulness” Oura metric, a factor in the calculation of overall sleep score, thus negatively impacting the overall sleep score.

Aim 3 Discussion: App Usage

Aim 3 hypothesized that study participants who used the app more frequently would experience a greater reduction in their stress and anxiety than participants who used the app less frequently. The Aim 3 hypothesis was not supported. The app usage amount was categorized into “low” versus “high” users, with low users defined as those who completed <75% of the intervention, either in terms of the minutes used or the sessions completed. High users defined as those who completed $\geq 75\%$ of the intervention. Statistical analysis determined that there was no difference in measured outcomes for participants in the low user group versus the high user group. One explanation for this is that the study participants achieved stress and anxiety reduction when they completed whatever level of use was needed by them; possibly a lower “dose” was sufficient for those individuals. Other possible explanations include small sample size, insufficient time, and bias resulting from study design. This type of study design, the SAT (single arm trial) as compared to the randomized controlled trial (RCT), is more susceptible to bias. It is possible that the results were over-optimistic resulting from bias due to expectation of benefit from the intervention.

Utility of Mindfulness

Perhaps some of the most compelling data from this dissertation study came from the post-intervention assessment questions regarding the utility of mindfulness. When asked “Did learning/practicing mindfulness meditation help with other aspects of your life?” 95% participants answered “yes.” This question affirms that in addition to assisting with stress and anxiety levels (as the data show), study participants overwhelmingly expressed that learning mindfulness helped them in other aspects of their life. Participants were further asked to expand on this question, and their answers were fascinating (Table 21). Thematic assessment revealed that learning/practicing MM helped study participants with the following: improved patience, improved perspective, improved focus, and improved conflict management, as well as a reduction in emotional reactivity, and a greater focus on self-care. However, as the

investigator was the sole interpreter of these results, they could be biased, and future studies should include a qualitative aspect, with multiple reviewers to perform a proper qualitative thematic analysis.

Study Strengths

Methodology

This dissertation study was designed with methodology which contributed to its overall strength. The use of technology via the Oura Ring and the HS app enabled the collection of specific, objective data like HRV, sleep, and intervention-time usage, which contributed to the validity of the data. This study was designed with consideration to best-practices related to HRV collection which included ≥ 24 -hour HRV monitoring (Shaffer et al., 2014), and the inclusion of the HRV metrics (RMSSD and HF), initially recommended by the Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology (Task Force, 1996), and more recently by Laborde, et al (2017). Data was also collected on potential confounders which could have impacted the outcome variables (use of medications, alcohol, nicotine, substances, caffeine, and exercise).

Low Attrition and Good Retention

This study attended to issues of attrition which was problematic in previous studies found in the literature. Measures to combat attrition were the following: providing financial incentives at two different time points, selecting a top-rated, popular intervention (HS), selecting engaging tech (the Oura Ring and app), and utilizing REDCap for the collection of measures. A total of 100% of the participants in this study completed their post-intervention assessments, and received their financial incentive, as well as returned the Oura Rings and chargers, indicating a 100% retention rate. There was no attrition; none of the participants dropped out.

Adherence to the Intervention

One of the reasons that HS was chosen as the intervention for this study was due to the hypothesis that the quality of this app, and the various features it has, would ensure sufficient delivery of the content as well as aid in study participants' adherence. In the literature, participant adherence to MM interventions has historically been a study limitation, which I proposed could be due to the boring, repetitive, or otherwise unengaging nature of the intervention. In this dissertation study, 13 of 20 participants completed $\geq 65\%$ of the intervention, and, in fact, 10 of these participants completed $\geq 95\%$ of the intervention. Considering that app completion was gauged by either completing 60 meditations, or by completing 530-1050 minutes of meditation, the study participants practiced an impressive amount of MM. Overall, the adherence to the intervention in this study was very good.

Large Data Set

The utilization of technology which enabled continuous HR/HRV monitoring of the study participants during sleep hours was a strength of this study, particularly as compared to a number of studies in the literature, which collected data intermittently during trials (Table 22). For example, Garg et al. (2020) collected study participants HRV data during three different trimesters of pregnancy, at 5-minute intervals for 20 minutes (12 readings); Solanki et al. (2020) collected data similarly, but for 5-minutes in total (3 readings); Kolovetsiou-Kreiner et al. (2018) collected for 5-minutes, 6 times throughout pregnancy (6 readings); and Bałajewicz-Nowak et al. (2016) collected data for 3 separate tests during 3 different times throughout pregnancy, for unspecified lengths of time (9 readings). In contrast, Sarhaddi et al. (2022) utilized technology to enable continuous monitoring of participants from the end of the first trimester, and throughout pregnancy until 3 months postpartum, yielding a very large data set. Similarly, this dissertation study utilized continuous HR/HRV monitoring during study participants sleep hours (9 hours average/night), which, over a 4-week period yielded approximately 3000 data points per individual. This large number of data points reduces the standard error in the results, contributing to the overall strength of the study.

Inclusion of Sleep and Exercise

The addition of sleep data collected by the Oura Ring, as well as self-report sleep, was a strength in this study. Additionally, none of the other studies in the literature review collected data on exercise, so the addition of this data in this dissertation research study was a study strength.

Study Limitations

A limitation of this study was the single-arm trial (SAT) study design. In comparison to RCTs, SATs lack a comparator arm, so they cannot definitively address issues related to efficacy of an intervention. Results of SATs cannot confidently be attributed to the intervention itself; rather than an independent attenuation of symptoms over time, or to other events in the participants' lives, including their usual perinatal healthcare (Taylor et al., 2016). Additionally, study results from open trials often produce results that are over-optimistic due to bias in a positive direction as a result of expectation of benefit (Aggarwal & Ranganathan, 2019). Other limitations of SATs lie in the fact that they are susceptible to bias due to secular trends, learning effect, and regression to the mean (Shin, 2019).

However, the RCT study design may not a panacea for human subject research, as RCTs come with their own limitations. There is evidence that study participants in control conditions are often motivated to make their own improvements (McBride, 2018). In addition, some studies find that participants in control groups end up having unexpected significant improvements in outcomes as a result of social support, discussions among groups, and a desire to improve their own health (Kinser & Robins, 2013).

The results of this dissertation study are consistent with those of similar study designs found in the literature. Two meta-analyses which evaluated mindfulness interventions during pregnancy found that non-RCTs showed significant decreases in stress and anxiety, but for the

RCTs, there were no differences for the intervention groups compared to controls (Dhillon et al., 2017; Taylor et al., 2016). The authors postulated that these results may have been due to the limited number of studies, small sample size, and confounders (Dhillon et al., 2017; Taylor et al., 2016). The majority of the RCTs reviewed were either pilot or feasibility studies, often having small sample sizes, which contributed to the lack of adequate power to demonstrate efficacy of the MBI (Dhillon et al., 2017). Regarding confounders, most of the RCTs included in the meta-analysis had treatment as usual comparison groups, and the control group participants often engaged in potentially confounding activities like attending pregnancy classes/support groups and prenatal yoga classes (Guardino et al., 2014; Taylor et al., 2016).

Another limiting factor in this study was the sample size. Sample size calculation is generally used in experiments with a control group versus SATs, and the sample size calculation for this study was originally calculated to require 28 participants to achieve 85% power with a large effect size (0.35) and an alpha (error probability/significance level/p-value) of 0.05. However, that original calculation was determined based upon pre/post t-tests, and not considering the multiple data points collected with HRV as an outcome variable. The sample size was re-calculated with support of a statistician, and a new sample size of 20 study participants was estimated to achieve between 78.2% and 93.4% power, with a large effect size (0.35), and an alpha of 0.05. However, the study may have been underpowered due to the sample size to achieve significant findings in the remaining HRV metrics.

Time may have been another limiting factor in this study. It may have required more time to manifest study participant changes in some of the other HRV metrics. One of the meta-analyses postulated insufficient time as possible explanation of the lack of significant differences in between-group differences in measures of stress and anxiety for study participants practicing MBIs (Taylor et al., 2016).

An additional limitation was that the sample population was homogenous, consisting of predominantly white, highly educated women. This is not representative of the San Diego

community and impacts the generalizability of study results. The pandemic greatly impacted recruitment. I had difficulty getting past security and gaining entrance to many clinics, which I would have access to, but for COVID-19. Another possible solution is to intensify recruitment strategies at clinics which serve more diverse communities.

Another limitation may be that the Oura Ring sleep metrics are not calibrated for the pregnant population. More research needs to be done comparing self-reported data from validated sleep scales, qualitative data, and Oura Ring data for this population to better understand if the Oura Ring accurately measures sleep during pregnancy.

Another potential limitation of this study was not using a validated sleep assessment like the Pittsburgh Sleep Quality Index (PSQI). The PSQI measure has good validity and internal consistency (Cronbach's $\alpha = 0.7-0.83$) (Mollayeva et al., 2016), and has been widely used to evaluate sleep during pregnancy (Mindell et al., 2015; Sedov, Anderson, Dhillon, & Tomfohr-Madsen, 2021; Smyka, Kosińska-Kaczyńska, Sochacki-Wojcicka, Zgliczyńska, & Wielgoś, 2021). Using a validated scale is a stronger study design than making up one's own Likert-style questions.

Finally, another potential limitation of this study was that it took place during the COVID-19 global pandemic, which likely added to the study participants' stress levels. In an ideal experiment, conditions would remain consistent while implementing an intervention, so changes in outcome variables can be attributed solely to the intervention. This study was designed to test an intervention to assist with the reduction of stress and anxiety. However, the reality is that we cannot hold people's life conditions in neutral, and if participants experienced unexpected stressors during the trial, those stressors could potentially confound study results. Therefore, as part of the post-intervention questionnaire, a question was asked evaluating participant stressors during the study period. Eighty-five percent of study participants indicated that something stressful happened during the study period, which could have potentially impacted study outcomes.

Potential Confounders as Further Limitations

Data was collected on potential confounders in the study. None of the study participants were on any medications or used substances, including caffeine in excessive amounts, which could have impacted their HRV results. However, exercise may have been a confounder, as exercise is associated with improved sleep and the reduction of stress and anxiety. Nine of 20 study participants (45%) indicated that their level of exercise increased during the study period. Additionally, 13 of 20 study participants (65%) also reported that their sleep improved and 6 of the study participants (46%) who had improved sleep also had increased exercise during the trial. As such, there is a question as to whether the improvement in their stress, anxiety and sleep could have been related to the increase in exercise, and not necessarily the MM intervention. This raises further questions regarding the relationships between these variables and the pathway of the theoretical model. For example, does sleep mediate the relationship between MM and stress? Where does exercise fit in? Did they have more energy to exercise as a result of their improved sleep? More research needs to be done to better understand the relationship between these variables.

Another limitation of this study is regarding the possible confounding nature of the Oura Ring and app. The Oura Ring tracks participants' activity level and sleep, and the app gives participants daily scores for each metric, along with recommendations for improvement. As study participants were encouraged to open the app daily so the data could be transferred to the server, they likely saw their daily scores and may have been influenced by them. For example, if someone got a poor sleep score one day, the Oura Ring prompts them with notifications to go to bed earlier. Additionally, if someone's activity score was poor one day, they may be influenced to be more active moving forward. The app itself could have confounded study results by encouraging study participants to change their behavior.

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conditions would remain consistent while implementing an intervention, so changes in outcome variables can be attributed solely to the intervention. This study was designed to test an intervention to assist with the reduction of stress and anxiety. However, the reality is that we cannot hold people's life conditions in neutral, and if participants experienced unexpected stressors during the trial, those stressors could potentially confound study results. Therefore, as part of the post-intervention questionnaire, a question was asked evaluating participant stressors during the study period. 85% of study participants indicated that something stressful happened during the study period, which could have potentially impacted study outcomes.

Plans for Future Research

Researching pregnant women with HRV as an outcome variable is complicated. Further research needs to be done to add to the body of knowledge regarding trends in HRV for pregnant women in various populations. In the future, there are a number of strategies that could be implemented to strengthen this study. These include the following:

First, to choose a stronger design, such an RCT with a mixed-methods component. It would be important for the RCT to have controls which are matched by parity and gestational age, among other potential factors like maternal age and race/ethnicity, which also impact HRV.

Second, not make the age of 35 a hard cut-off for participation in this study, as this contributed to the exclusion of many potential study participants. In future studies like this, it would be important to consider age on a case-by-case basis, and allow participation if the pregnancy is low risk, and all other eligibility criteria are met.

Third, reword study Aim 2 to reflect an "improvement in HR/HRV" as opposed to an "increase in HRV." HR was combined with HRV, which is not technically correct. HR is a different outcome measure than the HRV parameters that can be extracted, and best to separate in future studies. Also, an "increase in HRV" not technically correct. An

“increase” is not the expected direction of change resulting from a stress-reducing intervention for three of the HRV metrics (HR, LF, and LF/HF), where the opposite is true.

Fourth, the study should have a large enough sample size to evaluate potential mediators in the pathway of the theoretical model, as well as to independently analyze HR/HRV trends per trimester.

Fifth, I would use a validated sleep assessment like the Pittsburgh Sleep Quality Index to strengthen the study design instead of a survey I invented.

Sixth, future study design could potentially involve collecting HR/HRV data from study participants over a longer period (≥ 2 months).

Seventh, future study design utilizing the Oura Ring would entail collecting and analyzing data on exercise to better assess this potential confounder.

Eighth, the theoretical framework/model can be modified to include the following: self-report anxiety as an outcome variable; pathways and constructs to better reflect pregnancy-specific issues (hormonal changes; HR/HRV) and exploring the possibility of mediators along the pathway.

Conclusion

As stress and anxiety during pregnancy are highly prevalent, and have numerous poor physiological and mental health outcomes, it is important to find effective, evidenced-based interventions for this population. There is some evidence that IMBIs are a good alternative to in-person MM courses, but the literature review showed limitations in the studies including problematic study design, poor engagement with the interventions, and a lack of objective physiological measures of stress to support the validity of the interventions. This dissertation study was designed to mitigate these issues by choosing HS, a top-rated app to deliver the mindfulness intervention, utilizing the Oura Ring to collect data on the physiological measures, and implementing a well-designed study.

This dissertation study evaluated the impact of MM to reduce stress and anxiety in a pregnant population. The hypothesis regarding the delivery of the MM intervention via the HS app was supported; the pregnant women in this study who used the HS app to practice MM reported statistically significantly decreased levels of stress, anxiety, and pregnancy-specific anxiety. Additionally, the choice of this app proved effective at mitigating the attrition and adherence issues prevalent in the literature review. The qualitative report indicated that the study participants found MM benefited them in a variety of additionally impactful ways.

The utilization of the Oura Ring and app enabled the evaluation of physiological measures of stress which improved the strength of the study design and provided physiological evidence of reduced stress as shown by the statistically significant change in the LF band of the HRV. While the Oura Ring data did not show an improvement in sleep, the majority of study participants surveyed indicated that sleep improved during the trial. The addition of physiological outcome measures and the sleep variable was innovative. This study added to the body of scientific knowledge supporting MM as an intervention to aid in stress and anxiety for the pregnant population. While future research needs to be done, this pilot study showed promising initial results.

Protection of Human Subjects

As this study was a human clinical trial, every effort was made to protect the study participants involved. There were minimal physical risks to the participants, as the intervention consisted of meditation via their own electronic device. The main risk involved a breach of confidentiality/privacy. The private, identifiable information obtained from the subjects were the eligibility screening questionnaire, sociodemographic survey, the pre-post stress and anxiety assessments, retrieved electronic data from Oura, and app usage data obtained from Headspace.

To ensure confidentiality, study participants were assigned a unique code that was used in all electronic and paper documents, including individual

surveys/questionnaires used for the study. All electronic and paper data were maintained in password-protected computers. All discussion with sponsors was done using the participants' coded names. All telephone correspondence was conducted in private spaces. No identity information appeared on the data collection forms, and the participants' names were not used to report study findings.

There is minimal risk involved in wearing the Oura Ring. The ring was evaluated by the candidate and research subject to ensure proper fit. In the event that the participants' fingers swelled, participants were instructed to contact the investigator to discuss options. This did not occur with any of the study participants in the trial.

The researcher did not have any conflicts of interest and did not experience any ethical violations.

Appendix

Appendix 1: Recruitment Email

SUBJECT LINE: MINDFULNESS FOR PREGNANCY STUDY

Dear xxx,

Lead Researcher Donna Balsam, and researchers from the Sue & Bill Gross School of Nursing at the University of California, Irvine are recruiting participants for a research study on mindfulness meditation for stress and anxiety during pregnancy. This study may help us to better understand if learning and practicing mindfulness meditation via the Headspace app can help pregnant women reduce their stress and anxiety levels.

Eligibility Criteria: You are eligible to participate in this study if you:

- live in San Diego County
- are between 18 to 35 years old
- are between 10 and 32 weeks' gestation with a low risk pregnancy (you don't have any health problems like high blood pressure, preterm labor, etc.)
- you are able to read and understand English
- you are new to meditation practice
- you have access to a smartphone, Wi-Fi, email, and the ability to download apps.

Exclusion Criteria: You are ineligible for this study if you:

- regularly practice mindfulness or regularly engage in any other mindful-like complementary practice such as yoga or tai chi (≥3X/week)
- are currently enrolled in a mindfulness/mediation class
- have a hearing impairment which limits your ability to hear the app
- have a cognitive impairment which limits participation in this study
- have a chronic health or pregnancy induced medical condition which would qualify your current pregnancy as "high risk" (examples: chronic hypertension, preeclampsia, placental problems, etc.)
- are currently in psychotherapy or taking psychoactive drugs or medications (e.g., cannabis (marijuana), antidepressants (e.g. Prozac, Zoloft, etc.)
- have severe depression or anxiety, for which we will do a brief screening test to determine eligibility.

The study will take place in your home, or wherever you decide to practice meditation. At the start of the study, we will assist you to access a brief survey which should take approximately 10 -15 minutes. A similar survey will be emailed to you two more times: at the mid-study point (2 weeks) and again at study completion (4 weeks). The research team will instruct you on how to download and use the Headspace app, and the Oura Ring app. The Oura Ring is a fitness and sleep tracking device in the form of a ring you wear on your finger. During the study period, we

will ask you to wear a the Oura Ring while you sleep at night to monitor your stress and sleep. The study requires you to practice meditation with the Headspace app two times per day for the 30 day study period (between 5-20 min/session).

Researchers will use your information to conduct this study. All data containing your identifiable information will be stored on an encrypted web-based system maintained by UCI Health Information services.

You will be compensated for your participation in this research as follows: \$15 gift card after you complete the mid-study questionnaires, and a \$35 gift card at study completion and after you complete the post-study questionnaires and return the Oura Ring and charger.

If you are interested in participating in this study, please contact Donna Balsam at dbalsam@uci.edu, or call her at (619) 828-3522.

Thank you very much for your time.

Sincerely,

Donna Balsam

Appendix 2: Eligibility Screening

	Yes	No
Do you live in SD county?		
Are you between the ages of 18 and 35?		
Can you understand and read English?		
Do you have access to a smartphone, wi-fi, email, and can you download apps?		
Is your pregnancy considered low risk? (single baby pregnancy, no health problems)		
Do you have any chronic health conditions? <ul style="list-style-type: none"> If so, please list: 		
Do you have any pregnancy-related health conditions? (example: hypertensive disorders of pregnancy, diabetes, growth restriction, placental problems) <ul style="list-style-type: none"> List: 		
Do you have a mental health condition for which you are receiving treatment?		
Are you currently in psychotherapy?		
Other than vitamins, antacids or allergy medications, are you currently taking any medications? <ul style="list-style-type: none"> List: 		
Do you regularly (at least once per week) engage in any other mindful-like practices such as yoga, tai chi, meditation, mindfulness, body scan, reiki or any similar mindfulness practice?		
If you answered "YES," in the past 7 days, how many times did you practice any of the above mindful-like practices? _____		
Do you practice yoga on a regular basis (≥3X/week)?		
Are you currently enrolled in a mindfulness meditation class?		
Do you have any hearing impairment which would limit your ability to hear the app?		
Eligible?		

Appendix 3: Locator Guide

<p>On this form we collect information that will help us reach you during the study, and at study completion to collect the loaned Oura Ring & charger, and to complete the post-study questionnaires. The information you give us will be kept in a separate place from your answers on the interview. It will be used only to locate you for your follow-up, and it will not be given to anyone else. We will not tell any contact anything except that you have been asked to take part in a health study. Please also select one person from this form who you feel is the best person for the staff to contact in the event they cannot reach you for your follow up.</p>
<p>Is it okay if we contact you to check on your progress & provide support for any questions you may have?</p> <p>Circle/highlight: YES NO</p>
<p>Which is your preferred way to be contacted?</p> <p>Circle/highlight: EMAIL PHONE</p>
<p>What is your e-mail address:</p>
<p>What is your cellphone #:</p>
<p>What is your preferred meeting place to receive study instructions & supplies? (Ex. your home, prenatal clinic, local park)</p>
<p>Would you prefer study information in paper or electronic form?</p> <p>Circle/highlight: PAPER ELECTRONIC (EMAILED)</p>
<p>Full legal name:</p>
<p>What first name do you want us to use?</p>
<p>Preferred pronouns:</p>
<p>Date of Birth:</p>
<p>Home address:</p>
<p>Spouse/partner's name (if applicable):</p>
<p>Emergency contact name (person/friend or family member who knows how to reach you):</p>
<p>Emergency contact cell phone:</p>
<p>Emergency contact address:</p>

Appendix 4: Demographic & Pre-Assessment Survey

Age, years	
Race/ethnicity: <ul style="list-style-type: none"> Caucasian, African American, Asian/PI, Hispanic, Other 	
Relationship status: <ul style="list-style-type: none"> married, divorced, separated, cohabitating, partner deployed, single/alone 	
Current employment status: <ul style="list-style-type: none"> full-time, part-time, unemployed 	
Education: # of years in school: (ex. 8= through 8 th grade; 12=graduated high school; 14=2 year associate's degree; 16=bachelor's degree; 18=master's degree)	
Weeks' gestation at start of study (current date)	
Children in the home?	
Ages of children in the home	
Do you currently exercise? If so: frequency/duration/intensity	
Do you regularly drink alcohol? # of drinks/week; type; oz.	
Do you regularly use any recreational drugs? Type; frequency	
Do you smoke or vape tobacco? Amount:	
On a typical day, indicate how much caffeine you consume: Coffee X 8 oz cups; tea x oz; caffeine containing soft drinks; x oz espresso; x oz iced coffee or iced tea drinks	
I typically sleep well Strongly disagree/Disagree/Neither agree nor disagree/Agree/Strongly Agree	
Are there any stress/anxiety management activities you do on a regular basis? Ex. massage, aromatherapy, prayer, etc? If so, what?	

Appendix 5: Instructions and Product Information

Headspace App:

- Basic directions:
 - While practicing the mindfulness meditation exercises, your focus should be on the guide is teaching you. For example, you should not have it on in the background while cooking or driving.
 - Give yourself the allotted time to do the meditation exercises, which range from 5 to 20 minutes, based on your selection.
 - Consider making a goal to do it at about the same time each day, with a recommendation to do it first thing in the morning. However, the time of day you choose isn't as important as the consistency of doing it every day.
 - Consider setting a daily reminder on your smart phone.
 - Find a space to sit, either on a cushion or chair, as long as you're comfortable.
 - The place should be relatively quiet, free from distractions.
 - You may listen with headphones.
 - Straighten your back to sit comfortably without slouching.
 - Bring your awareness to your breath, and follow the prompts of your guide.
- Watch "Getting Started" on the app.
- To set up Reminders on the app, follow these steps:
 - Tap the "Profile" icon on the top left corner of the app
 - Tap on the Settings gear next to your name at top left
 - Select "Notifications" and then "Reminders"
 - Slide the "Remind me" switch to on
 - Slide the "Put it on my calendar" switch to on and tap "Allow" for notifications if you want the reminders added to your calendar
 - Set the time and frequency you want to be notified and your settings will be saved

Oura Ring & Smartphone App:

- The Oura Ring and Smartphone Application (App) collects physiological measures like heart rate variability, heart and respiratory rate, activities, and sleep quality.
- The Oura Ring App can report:
 - Sleep quality and duration: length, quality (REM, Deep, and Light), disruptions in sleep, movement during sleep, awake times, sleep latency, time in bed, sleep efficiency, sleep score.
 - Readiness score: a measure showing how the body responds to and recovers from the demands of daily life; generated using all of the sensor data, physiological signals, sleep and activity patterns that are monitored by the ring.
- For the purpose of this study, the Oura Ring will collect objective data on stress, which is heart rate variability (HRV).
- The app is free to download from both the App Store (IOS) or Google Play Store (Android).
- After the ring is set up with the app, you can open the app each morning to retrieve sleep and recovery data.
- Please open the app every 1-2 days to facilitate the transfer of HRV data to our server.
- **For this study, wear the ring at night, during sleep hours**
 - Suggestion: put it on at night when brushing your teeth, take it off in the morning when brushing your teeth, and place it in the charger unit. Please store carefully as it is valuable (\$300).
- You may wear the ring 24/7 if you choose.

- Ensure sensors are on the palm side of the finger, with the flat part of the ring away from your palm.
- The ring is water (and hand sanitizer) resistant, so it can get wet.
- You may shower with it on, but please remove if engaging in water sport activities like swimming.

Charging

- Battery life is 5-7 days.
- The light on the charger will pulse and turn solid when ring is fully charged.
- When connected to Bluetooth, you can see the ring's battery level by tapping the circle in the top right corner of the Oura app.
- The app will also remind the wearer to charge when battery gets low.
- Charging is quick: takes <1 hour.

For this study:

- The Oura Ring will be worn for the study period, during the hours of sleep.
- Please ensure you sleep with the ring on for 4 nights (2 weekend, 2 weekday) prior to starting the Headspace meditation intervention (this will allow us to obtain a baseline HRV).
- The investigator will give participants an overview of the Oura Ring and Smartphone Application at the baseline visit.
- The investigator will meet with the participants at baseline to distribute the Oura Ring, and one month later, to retrieve the Oura Ring and charger.

Appendix 6: Edinburgh Postnatal Depression SCALE (EPDS)

(Cox et al., 1987)

We would like to know how you have been feeling in the past week. Please indicate which of the following comes closest to how you have been feeling over the past seven days, not just how you feel today. Please tick one circle for each question that comes closest to how you have felt in the **last seven days**.

Here is an example already completed.

I have felt happy:

- Yes, all of 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.

1. I have been able to laugh and see the funny side of things

- As much as I always could
- Not quite so much now
- Definitely not so much now
- Not at all

2. I have looked forward with enjoyment to things

- As much as I ever did
- Rather less than I used to
- Definitely less than I used to
- Hardly at all

3. I have blamed myself unnecessarily when things went wrong

- Yes, most of the time
- Yes, some of the time
- Not very often
- No, never

4. I have been anxious or worried for no good reason

- No, not at all
- Hardly ever
- Yes, sometimes
- Yes, very often

5. I have felt scared or panicky for no very good reason

- Yes, quite a lot
- Yes, sometimes
- No, not much
- No, not at all

6. Things have been getting on top of me

- Yes, most of the time I haven't been able to cope at all
- Yes, sometimes I haven't been coping as well as usual
- No, most of the time I have coped quite well
- No, I have been coping as well as ever

7. I have been so unhappy that I have had difficulty sleeping

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

8. I have felt sad or miserable

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

9. I have been so unhappy that I have been crying

- Yes, most of the time
- Yes, quite often
- Only occasionally
- No, never

10. The thought of harming myself has occurred to me

- Yes, quite often
- Sometimes
- Hardly ever
- Never

Appendix 7: General Anxiety Disorder 7-item Scale

(Spitzer et al., 2006)

Generalized Anxiety Disorder 7-item (GAD-7) scale

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all sure	Several days	Over half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
<i>Add the score for each column</i>	+	+	+	
Total Score (<i>add your column scores</i>) =				

If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all _____
 Somewhat difficult _____
 Very difficult _____
 Extremely difficult _____

Scoring

Scores of 5, 10, and 15 are taken as the cut-off points for mild, moderate and severe anxiety, respectively. When used as a screening tool, further evaluation is recommended when the score is 10 or greater.

Using the threshold score of 10, the GAD-7 has a sensitivity of 89% and a specificity of 82% for GAD. It is moderately good at screening three other common anxiety disorders - panic disorder (sensitivity 74%, specificity 81%), social anxiety disorder (sensitivity 72%, specificity 80%) and post-traumatic stress disorder (sensitivity 66%, specificity 81%).

Source: Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. *Arch Intern Med.* 2006;166:1092-1097.

Appendix 8: Perceived Stress Scale

(Cohen et al., 1983)

Perceived Stress Scale

A more precise measure of personal stress can be determined by using a variety of instruments that have been designed to help measure individual stress levels. The first of these is called the **Perceived Stress Scale**.

The Perceived Stress Scale (PSS) is a classic stress assessment instrument. The tool, while originally developed in 1983, remains a popular choice for helping us understand how different situations affect our feelings and our perceived stress. The questions in this scale ask about your feelings and thoughts during the last month. In each case, you will be asked to indicate how often you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer fairly quickly. That is, don't try to count up the number of times you felt a particular way; rather indicate the alternative that seems like a reasonable estimate.

For each question choose from the following alternatives:

0 - never 1 - almost never 2 - sometimes 3 - fairly often 4 - very often

- _____ 1. In the last month, how often have you been upset because of something that happened unexpectedly?
- _____ 2. In the last month, how often have you felt that you were unable to control the important things in your life?
- _____ 3. In the last month, how often have you felt nervous and stressed?
- _____ 4. In the last month, how often have you felt confident about your ability to handle your personal problems?
- _____ 5. In the last month, how often have you felt that things were going your way?
- _____ 6. In the last month, how often have you found that you could not cope with all the things that you had to do?
- _____ 7. In the last month, how often have you been able to control irritations in your life?
- _____ 8. In the last month, how often have you felt that you were on top of things?
- _____ 9. In the last month, how often have you been angered because of things that happened that were outside of your control?
- _____ 10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

Appendix 9: Pregnancy-Related Anxiety Scale 10-item Instrument

(Rini et al., 1999)

PREGNANCY ANXIETY 10-item Instrument (Rini et al. 1999) English and Spanish versions (Info from dunkel@psych.ucla.edu)

English Version

The next set of questions is about your feelings and expectations about the birth and your baby.

Please indicate your own feelings about each statement by indicating how well it describes you or how true it is for you.

CARD E FOR RESPONSES

**NOT AT ALL
SOMEWHAT
MODERATELY
VERY MUCH**

1. I am confident of having a normal childbirth.
2. I think my labor and delivery will go normally.
3. I have a lot of fear regarding the health of my baby.
4. I am worried that the baby could be abnormal.
5. I am afraid that I will be harmed during delivery.

Now I want to read a list of things about pregnancy and new babies that might concern you. Using the responses on this card (**HAND CARD F FOR RESPONSES**), please tell me whether these things never concern you, concern you some of the time, most of the time, or a lot of the time.

**NEVER
SOMETIMES
MOST OF THE TIME
A LOT OF THE TIME**

6. I am concerned (worried) about how the baby is growing and developing inside me.
7. I am concerned (worried) about losing the baby.
8. I am concerned (worried) about having a hard/difficult labor and delivery.
9. I am concerned (worried) about taking care of a new baby
10. I am concerned (worried) about developing medical problems during the pregnancy.

Spanish Version

Las siguientes preguntas son acerca de lo que usted siente y espera con respecto al parto y a su bebé.

Por favor indique lo que siente sobre cada afirmación, indicando qué tan bien esa afirmación la describe a usted o describe qué tan cierto eso es para usted. **CARD E FOR RESPONSES**

**PARA NADA
UN POCO
MODERADAMENTE
MUCHO**

1. Confío en que tendré un parto normal.
2. Creo que el parto y el nacimiento se desarrollarán normalmente.
3. Siento mucho miedo con respecto a la salud de mi bebé.
4. Me preocupa que el bebé podría no ser normal.
5. Tengo miedo de que el parto me haga daño.

Ahora quiero leerle una lista de cosas con respecto al embarazo y a los bebés recién nacidos que tal vez la preocupen. Usando las respuestas en esta tarjeta (**HAND CARD F FOR RESPONSES**), por favor dígame si estas cosas nunca la preocupan, la preocupan algunas veces, la preocupan la mayor parte del tiempo o la preocupan casi todo el tiempo.

**NUNCA
ALGUNAS VECES
LA MAYOR PARTE DEL TIEMPO
CASI TODO EL TIEMPO**

6. Me preocupa cómo está creciendo y desarrollándose el bebé adentro mío.
7. Me preocupa perder el bebé.
8. Me preocupa que el parto y el nacimiento sean difíciles.
9. Me preocupa ocuparme de un bebé recién nacido.
10. Me preocupa tener problemas médicos durante el embarazo.

Appendix 10: Multidimensional Scale of Perceived Social Support

(Zimet et al., 1988)



Multidimensional Scale of Perceived Social Support (MSPSS)

We are interested in how you feel about the following statements. Read each statement carefully. Indicate how you feel about each statement.

		Very Strongly Disagree	Strongly Disagree	Mildly Disagree	Neutral	Mildly Agree	Strongly Agree	Very Strongly Agree
1.	There is a special person who is around when I am in need.	1	2	3	4	5	6	7
2.	There is a special person with whom I can share joys and sorrows.	1	2	3	4	5	6	7
3.	My family really tries to help me.	1	2	3	4	5	6	7
4.	I get the emotional help & support I need from my family.	1	2	3	4	5	6	7
5.	I have a special person who is a real source of comfort to me.	1	2	3	4	5	6	7
6.	My friends really try to help me.	1	2	3	4	5	6	7
7.	I can count on my friends when things go wrong.	1	2	3	4	5	6	7
8.	I can talk about my problems with my family.	1	2	3	4	5	6	7
9.	I have friends with whom I can share my joys and sorrows.	1	2	3	4	5	6	7
10.	There is a special person in my life who cares about my feelings.	1	2	3	4	5	6	7
11.	My family is willing to help me make decisions.	1	2	3	4	5	6	7
12.	I can talk about my problems with my friends.	1	2	3	4	5	6	7

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Zimet GD, Dahlem NW, Zimet SG, Farley GK. The Multidimensional Scale of Perceived Social Support. *Journal of Personality Assessment* 1988;52:30-41.

Appendix 11: Post-Assessment Questionnaire

Directions: For the following statements, please circle the number which best indicates your feelings about each statement

		Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1	My exercise level increased during this trial	1	2	3	4	5
2	My sleep improved during this trial period	1	2	3	4	5

Open ended questions:

- Was there something new that happened to you during the study period that was particularly stressful? (e.g. an illness, a Covid scare/diagnosis, etc) If so, what was it and when did it happen?

- Did learning/practicing mindfulness meditation help with other aspects of your life? If so, which?

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