

Feasibility and Preliminary Effects of Using a Mobile App (i.e., Calm) to Decrease
Overall Stress in Middle-Aged Men and Women Who Report Elevated Stress

by

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ABSTRACT

Background: Unmanaged stress is a major contributing factor to the development of disease in both men and women. Middle-aged adults (40-64) have some of the highest stress of all age groups and the use of meditation may provide relief for conditions such as stress. A smartphone application (app) may help limit the magnitude of the perceived challenges of meditation. The purpose of this study is to determine the feasibility of a consumer-based meditation app (i.e., Calm) to reduce stress in middle-aged adults who self-report elevated stress. The preliminary effects of Calm on stress and health outcomes related to stress were explored as well as the preliminary effects of Calm on mindfulness and coping behaviors for stress were explored.

Methods: Adults were recruited to a 4-week app-based health and well-being study. Participants were randomized into either a mindfulness meditation (i.e. Calm) group or a health education (POD) control group. Participants were asked to participate at least 10 minutes per day. Assessments were conducted for stress, anxiety, depression, mindfulness, physical activity, eating habits, and coping behaviors at pre- and post-intervention and voluntary phone interviews were held post-intervention. App usage data were collected subjectively through weekly participation logs and through objective app usage data provided by Calm.

Results: Eighty-three participants were enrolled into the study and 60 completed the intervention and were analyzed. Feasibility and demand benchmarks were met with 96% of participants satisfied with the intervention and 93% found it enjoyable, appropriate, and useful. There was a 70% adherence (minutes/week) to the meditation intervention. Recruitment of men into the intervention group was 38.1% and retention of men was

81.3%. Significant changes were not observed in stress, anxiety, depression, or mindfulness, physical activity, eating habits, and coping behaviors.

Conclusion: The findings of this study support the feasibility of a 4-week, mobile app-based mindfulness meditation intervention (i.e. Calm) in middle-aged adults. These findings do not demonstrate preliminary efficacy of Calm to reduce stress, anxiety, and depression or improvement of mindfulness, physical activity, eating habits, or coping behaviors among middle-aged adults who report elevated stress. These results can be applied for improved design of future studies.

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CHAPTER 1

INTRODUCTION

The American Psychology Association (APA) and the American Institute of Stress (AIS) reported in 2018 (based on 2014 statistics) that 75% of adults experienced moderate to high stress and 33% experienced extreme stress. Stress is defined as “a process in which environmental demands tax or exceed one’s adaptive capacity, resulting in physiological changes that may place the individual at risk for disease over time (Sieverdes et al., 2017). Stress is known as a “silent killer”, in that the negative impacts of stress on the body are not initially noticed (Jaimes & Steelem 2018). Unmanaged stress is a major contributing factor to the development of cardiovascular disease, obesity, metabolic syndrome, type 2 diabetes, cancer, anxiety, depression, memory impairment, and gastrointestinal disorders (Casey, 2017).

Middle age is considered to be between 40 and 65 years of age (Hange et al., 2013, Oyama et al., 2014) and reported to have some of the highest stress of all age groups (APA, 2017). Stress symptoms, lifetime traumatic events, and chronic or daily stressors have all been associated with the decline of physical function and quality of life in this age group (De Frias & Whyne, 2015). The most common stressful life events in middle aged adults are loss of money, loss of memory, illness or death of a friend or relative, and divorce (De Frias & Whyne, 2015). Coping mechanisms for stress are commonly unhealthy in both men and women and include avoidance, overeating, smoking, excessive alcohol intake, pharmaceutical abuse, and increased sedentary behavior (Sieverdes et al., 2017, Woodhead, 2013). These coping strategies aggravate

stress-related symptoms and increase risk for disease (Sieverdes et al., 2017, Kuczmarski et al., 2017, Tamres et al., 2002). Due to the high levels of stress in middle-aged adults and the use of unhealthy coping mechanisms, there is a need for midlife adults to learn how to best manage their stress now (APA, 2017).

Gender is an important factor to consider when assessing stress. Gender influences the perceived exposure, severity, and reaction to stress as well as coping responses and health-related issues from stress (Mayor 2015, Matud 2004). Mayor reports that “gender” represents the experience of being male or female and their traditionally different social roles (Mayor, 2015). Literature suggests women determine threatening events to be more stressful than men and are found to have greater chronic stress (Matud, 2004). Women are more likely to report stress from home life, family life, and caring roles, followed by gender violence and sexist discrimination (Matud, 2004). However, significant stress is also reported in men, especially those with full-time jobs and those who are responsible for one or more family incomes (Cohen & Janicki-Deverts, 2012). Due to the increase of similarities in gender roles in modern society, the difference in stress levels between men and women are small (Mayor, 2015), but the treatment for stress between genders still remains different. Middle aged women are more likely to use complementary and alternative medicine (CAM) than men due to typically being more proactive about their health and are more concerned about their health in comparison to men (Kristoffersen et al., 2014). Women are at an increased risk for having major health conditions related to stress and seek out CAM therapies, but because men also report high

stress, they should not be overlooked when recruiting for CAM interventions focusing on the reduction or management of stress (Mayor, 2015).

Stress-management interventions have typically included cognitive-behavioral therapy (CBT) and complementary approaches. CBT interventions, as a treatment for stress, compose the majority of clinical interventions (Heber et al., 2013). The American Institute of Cognitive Therapy reports that cognitive therapy interventions involve therapeutic assistance for the patient to develop a plan to better manage their stress by focusing on one's perceptions and thoughts (Shagiwal et al., 2018) and CBT interventions are based on the psychological principles of positive psychology, mindfulness, and problem solving (Caroloan et al., 2016). Limitations to these interventions are that they are offered in person and in clinical settings (Heber et al., 2013) and geographical barriers require participants to travel, therefore, preventing participation (Fleet et al., 2018).

The top complementary and alternative medicine (CAM) treatments to reduce stress include mindfulness meditation, yoga, acupuncture, counseling, and social support programs (Creswell, 2017). Meditation has gained popularity in the United States due to its ability to improve physical and mental health outcomes (Olano, 2015) and substantial overall health benefits (Cramer et al., 2016). Meditation is a mindfulness-based practice that has been used for more than 3000 years in eastern traditions and involves the intentional self-regulation of attention to present moment experience, coupled with a non-judgmental and accepting stance toward whatever may arise (Pepping et al., 2016). Physiologic responses to meditation have been documented for decades, of which support meditation as an effective tool for decreasing stress (Williams et al., 2012). Meditation is

currently the most prevalent CAM stress reduction strategy (Sieverdes et al., 2017).

According to the Stress in America survey in 2017, the use of mindfulness meditation as a stress management strategy increased by 12%, the highest percentage since the survey was created in 2008 (APA, 2017).

Mindfulness for stress management is primarily offered through mindfulness-based stress reduction (MBSR) or mindfulness-based cognitive therapy (MBCT) interventions and both have shown to have a significant and positive effect on stress (Kabat-Zinn, 2003, Kazantzis et al., 2009, Creswell, 2017, Karaca & Sisman, 2019). Mindfulness is defined as, “the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment by moment (Kabat-Zinn, 2003).” The four components of mindfulness that help manage stress are attention regulation, body awareness, emotion regulation and sense of self (Cramer et al., 2016). De Frias and Whyne reported in 2015 that, “mindfulness reduces rumination and excessive elaborative processing of negative information in the face of emotional challenge.” Mindfulness can be a buffer between the harmful effects of stress on mental health due to its positive effects on stress that account for nearly one-third of the variance in mental health (De Frias & Whyne, 2014).

Challenges to MBSR and MBCTs are that they can be time consuming, costly, exhaustive, and not available to everyone in need (Huberty et al., 2019, Fleet et al., 2018). These interventions also have geographical barriers similar to other stress-management participation, but ultimately the most challenging limitation to the majority

of stress-management interventions are that they are only offered in person and in clinical settings, thus requiring travel time and schedule challenges (Heber et al., 2013).

Approximately 9.3 million US adults have used meditation (Cramer et al., 2016). In a 2016 review of randomized controlled trials that used mindfulness meditation to test immune system biomarkers suggested that mindfulness meditation has benefits associated with stress, mental health, and disease due to its reductions in proinflammatory processes, and the increases in cell and enzyme health (Black & Slavich, 2016). The National Health Interview Survey (NHIS) reported in 2018 that meditation is consistently one of the top five most commonly used CAM practices (Blewett et al., 2019). The use of meditation for the relief of conditions such as stress is a safe practice, unlikely to negatively interact with other treatments for health conditions (Cramer et al., 2016). Mindfulness meditation interventions have been shown to provide similar effects on health in comparison to other common approaches for treating stress (Black & Slavich, 2016). Current evidence suggests that even brief meditation interventions of 5-10 minutes, 3-4 sessions a week can buffer reactivity to stress (Creswell, 2017). However, in-person or clinic-based meditation programs have limitations including requirements for travel, time, and lack of support for the participants when daily access to the intervention is not offered or when the instructor is not available after hours (Heber et al., 2013). This lack of constant support can lead to less of an effect on stress as compared to other delivery modes (i.e., digital intervention) (Heber et al., 2013). Mental health stigma, due to societies misunderstanding and fear about mental health, is also a major barrier when deciding to practice meditation (The Lancet, 2016, Thornicroft et al., 2016).

However, the most common reported barrier to meditation is the perceived difficulty in finding time to meditate (Spears et al., 2017). There is a need to determine strategies to deliver meditation to manage stress in midlife men and women that overcomes some of the barriers to participation. Meditation requires commitment for the best results, so it is important for individuals to have easy access to meditation every day (Shaner et al., 2015). Complementary approaches such as mindfulness meditation may be an effective strategy for middle-aged adults to reduce stress if delivered online and through an avenue that is more convenient than in person or in clinical settings. A smart-phone application (app) may help limit the magnitude of the perceived challenges of meditation by providing an individual with a variety of different types of meditations, the ability to choose where the practice will take place, when, and for how long (Shaner et al., 2015).

Smartphone use is increasing and mobile health (mHealth) apps are also becoming more prevalent due to their sizeable potential to support mental health care (Neary & Schueller, 2018). The Pew Research Center stated in 2019 that 84% of men and 79% of women own a smartphone and there are more than 325,000 mHealth apps available to the consumer (Larson, 2018). Smart-phone apps have wide reach, immediate access, can be updated or upgraded at any time, and are generally low cost (Price et al. 2014, Flett et al., 2018, Duraimani, 2019). There are over 500 mindfulness-based smart phone apps available to the consumer (e.g., multiple types of meditation, breathing exercises, music/sounds, movement etc.) (Wei, 2015, Mani et al., 2015, Duraimani, 2019). A study conducted in 2019 reported the top three meditation apps on the Apple App Store were that of Calm, Aura, and Headspace. Calm was named “2017

app of the year” by Apple, is the most downloaded Health & Fitness app, and holds a review rating of 4.5 out of 5 stars (Mani et al., 2014). Calm provides daily 10-minute, guided meditations (primarily rooted in mindfulness principles). Calm teaches users the basics of mindfulness, includes components to remind users to meditate, track user activity, and allow users to share their status with others. Calm may be a resourceful (i.e., easily accessible, disseminable, low cost) strategy to reduce stress in middle aged adults.

The purpose of this study is to determine the feasibility of a consumer-based meditation app (i.e., Calm) to reduce stress in middle-aged men and women who self-report high stress. We will also explore the effect Calm on health outcomes related to stress (i.e. anxiety, depression). Finally, we will explore the effects of Calm on mindfulness and coping behaviors for stress (i.e., physical activity, overeating, and coping behaviors).

CHAPTER 2

LITERATURE REVIEW

The objectives of this literature review were to: 1) Describe adverse outcomes of unmanaged stress in middle aged adults, 2) Explore the relationship between stress and gender 3) Explore the current state of evidence-based stress reduction programs among adults 4) Explore the effectiveness of mindfulness meditation interventions to reduce stress and improve mindfulness in adults, 5) Explore consumer-based meditation application interventions to reduce stress and propose why research is needed on consumer-based meditation application to reduce stress in middle aged adults.

Adverse outcomes of unmanaged stress:

Stress can affect anyone at any age, but midlife bring particularly stressful life events that may cause chronic or high stress (APA, 2017, Casey, 2017). Stress symptoms, lifetime traumatic events, and chronic or daily stressors have all been associated with the decline of physical function, disease, and quality of life in this age group (De Frias & Whyne, 2015). Between the age of 40 and 64, common stressful life events such as memory deterioration, loss of finances, illness of a friend/relative, and divorce are reported (De Frias & Whyne, 2015, Matud, 2004). Complaints related to stress can range from mild symptoms such as a sore throat or headache to diseases that cause heart attack, cancer and even organ failure (Casey, 2017). Chronic or high stress may have a direct impact on a person's health and well-being and ultimately contribute to major health conditions such as anxiety, depression, obesity, cardiovascular disease, cancers and compromised immune systems (Casey, 2017).

When stress is unmanaged, negative coping behaviors may occur (Woodhead et al., 2013) that likely increase the risk for disease (Sieverdes et al., 2017). Negative coping behaviors include avoidance, the tendency to overeat, smoke or drink alcohol in excess, abuse prescription drugs, and be inactive (Sieverdes et al, 2017, Kuczmarski et al., 2017, Raspopow, 2013, Woodhead et al., 2013). Daily stress was found to have a positive association with an increased intake of high-fat and high-sugar foods which can lead to weight gain and obesity (Kuczmarski et al., 2017, Raspopow, 2013) and avoidance has been associated with increased alcohol consumption (Woodhead et al., 2013). Increased alcohol consumption due to avoidance coping is associated with increased stress during life events and adverse health outcomes (Tamres et al., 2002).

Woodhead and colleagues (2013) that examined the association between coping strategies in adults aging from 27-78 years old with a mean age of 44.4 at baseline and adverse outcomes thirteen years later. Results of this study indicate that avoidance coping was associated with more drinking problems and suicidal thoughts over time and reliance on this type of coping leads to the likelihood of adverse health outcomes. It is suggested that coping strategies as well as healthy individuals should not be overlooked when addressing the management of stress (Woodhead et al., 2013, Rose et al., 2012).

Due to middle-aged adults being particularly susceptible to stressful life events that can contribute to major health conditions (APA, 2017, Casey, 2017) there is a need for resources this population can use to manage their stress before negative health outcomes occur. Without an accessible and effective resource, adults may turn to negative coping behaviors to try and buffer their level of stress. However, negative

coping behaviors can increase the onset or severity of adverse health outcomes (Woodhead et al., 2013) and should be replaced with healthy stress management techniques.

The relationship between gender and stress

Research suggests there are differences in stress between men and women (Mayor, 2015, Janicki-Deverty, 2012, Mayor, 2015, Matud, 20014) due to gender having an impact on whether stress is appraised as a threat or a challenge which then ultimately plays a role in physical and mental stress (Mayor, 2015). In a survey conducted by Matud (2004) with 1566 women and 1250 men women had more daily stress with more chronic problems, conflicts, daily demands and frustrations as compared to men. The impact of life events on men and women also differed. Women reported life events to be less desirable and controllable than men and therefore resulting in higher stress levels.

Cohen and Janicki-Deverts (2012) reported on three national surveys that collected data on psychological stress administered over 20+ years 1983, 2006, and 2009. The first survey was administered to 960 male and 1,427 female US residents by telephone. The second and third survey was administered each to 2,000 US adults online. The surveys utilized the Perceived Stress Scale and assessed the association between stress and demographic characteristics. Each sample was balanced to be representative of the general population based on region, sex, age, and household income data from the 2000 U.S. Census. Stress was reported to be higher in women who were younger in age, who had less education, and less income. Although women reported higher stress-related health risks, men also reported high stress due to substantial losses of income and wealth.

A significant increase in stress was seen in white, college-educated, employed men between the ages of 45 and 64 years. This was attributed to the threat of job loss, actual job loss, or loss of retirement funds. These surveys illustrate elevated stress in both men and women in middle-aged but for different reasons.

In a study that focused on work related stress, a sample of 206 US adults (104 female, 102 males) currently employed in a professional or administrative role completed online, self-administered questionnaires regarding the relationship between sex-linked personality traits and stress (O'Connor et al., 2016). The study also reported that well-being and self-control can be protective against stress with regards to gender and although feminine individuals may be more susceptible to stress, emotional factors (e.g. well-being) may be protective against this disadvantage. Therefore, despite women typically having higher stress levels than men, their senses of well-being and self-control help mitigate this difference.

According to Mayor (2015), under similar conditions there are no differences in stress based on gender with regards to stress hormone release, heart rate, and experience of stress (Mayor, 2015). Additionally, gender differences in coping behaviors have been decreasing over the past two decades (Matud, 2004) due to the blending of gender traits and that masculinity and femininity both seek social support and positive thinking (Mayor, 2015). Mayor (2015) also reported that when sociodemographic factors are controlled for, gender differences in disease and health disappear because most of the non-physiological differences between men and women are created socially rather than

determined biologically. This article provides justification that both men and women are impacted by stress and both are in need for interventions to manage stress.

Although research suggests there are differences between genders with regards to stress, cultural changes over the years have lessened the impact of these differences. Feminine genders are still reported to be more susceptible to stress, but personality traits such as well-being and self-control may help buffer the impact of stress. However, when sociodemographic factors are controlled for, gender differences in stress are lessened, suggesting both men and women need stress reduction interventions.

Evidence-based stress reduction programs in adults

Cognitive-Behavioral-Therapy Interventions

Cognitive-behavioral-therapy (CBT) interventions, as a treatment for stress, have composed the majority of clinical interventions (Heber et al., 2013). CBT is based on the psychological principles of positive psychology, mindfulness and problem solving (Caroloan et al., 2016). CBT interventions that have shown an effect include organizational, multimodal, or alternative with cognitive-behavioral programs (Richardson & Rothstein, 2008).

In a study by Rose and colleagues (2013), high stress graduate students (N=66), with a mean age of 27, in a computer-based randomized controlled trial were randomized into a SMART-OP stress management training program (SMT) group or an attention control (AC) group. The SMT consisted of six, 30-45-minute weekly sessions of computer-based cognitive behavioral therapy (CBT) approaches such as self-guided, multimedia, stress management and resilience training. This SMART-OP was considered

brief as other SMT trainings typically last 9-11 hours. The attention control (AC) group was also asked to attend 6, 30-45-minute weekly sessions that entailed watching videos and reading material on stress and stress management. Measures included the PSS and the Stress and Perception of Control Scale (SPOCS) at pre- and post-intervention. Results indicated the intervention group had significantly less stress and more perceived control over stress than the AC group following intervention. Shorter sessions were well liked and sufficient for improving stress as 59 out of 66 participants completed all stress management training sessions and the pre- and post-assessments. This study was the first study to use a “brief” self-guided, multimedia intervention and its findings promote the efficacy of *online* stress management techniques for high stress individuals who may not seek help due to stigma, cost, or access to care but future research with a population that includes middle-aged adults is needed.

In a more recent study individuals (N=137) with a mean age of 45 and clinical work-related stress were recruited for a randomized controlled trial of a CBT stress management intervention (Glasscock et al., 2018). The intervention group was asked to complete six, 1-hour, in person sessions of individual CBT for a maximum of 4 months and offered a psychologist in a meeting between the individual and the employer. Individual sessions focused on how the participant was interpreting and coping with stressful situations and homework was given between sessions. The control group received no treatment but were free to seek care elsewhere. Outcomes were that of stress and mental health measured using the PSS-10 and the General Health Questionnaire (GHQ-30). Measures were taken at baseline, 4 months, and at 10 months. Significant

effects for both perceived stress and mental health were seen at both 4 months and 10 months. However, there were no longer any differences between groups after 6 months and it could not be determined what component of the intervention (i.e. psychological counseling, the workplace intervention, or their combination) was effective. At 4 months, only 2 out of 57 participants dropped out of the intervention group, but 15 out of 79 had dropout out from the control group. At 10 months follow up, a total of 7 in the intervention group did not complete all the surveys and a total of 17 in the control group did not complete all the surveys. Dropout rates in the intervention group could have been due to the time intensive sessions as participants had to complete six, 1-hour, in person sessions over 4 months. The intervention may also have been weakened due to the participants being encouraged to discuss stressful matters with their management. However, a larger drop-out rate was observed in the control group. There is a need to explore interventions that are less time intensive and specific to middle-aged adults.

Although there is research to support that CBT interventions can reduce stress in different populations, there is a lack of research specific to middle-aged adults (Richardson & Rothstein, 2008, Glasscock et al., 2018, Rose et al., 2013). These interventions are also often time consuming and only offered to those that have access in person. Additionally, it is unclear what components of CBTs are actually driving the effects observed. There are greater and clearer effects seen in the potential benefits of mindfulness-based therapies for the reduction of stress (De Frias & Whyne, 2015, Cherkin et al., 2016) and mindfulness-based therapies targeting high stress, middle-aged adults are needed.

Mindfulness-Based Therapy Interventions

Mindfulness-based interventions are also a popular strategy to reduce stress. Mindfulness may be effective for stress reduction by reducing rumination and excessive elaborative processing of negative information (De Frias & Whyne, 2015). The top mindfulness interventions in the literature are that of Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT) (Gu et al., 2015). MBCT utilizes both MBSR and Cognitive Behavioral Therapy (Alsubaie et al., 2017). Both MBSR and MBCT incorporate formal mindfulness practices for training acceptance, attentional control and non-judgmental attitudinal dimensions of mindfulness (Alsubaie et al., 2017, Crane et al., 2017). MBSR and MBCT interventions have shown to have a significant and positive effect on stress (Kabat-Zinn, 2003, Kazantzis et al., 2009, Creswell, 2017, Karaca & Sisman, 2019) through the four components of mindfulness: attention regulation, body awareness, emotion regulation, and sense of self (Cramer et al., 2016).

Short MBSR programs may have a significant positive effect on teachers with high stress. In a pilot, randomized controlled trial Flook (2013) randomized 18 public elementary school teachers with a mean age of 43 into an intervention group (n=10) that received MBSR training and the remaining teachers (n=8) were assigned to a waitlist control group. The MBSR training lasted 8 weeks, 2.5 hour/week, followed by a 6-hour silent practice. In addition to the MBSR training in person, the intervention group were asked to practice between 15-45 minutes per day for 6 days/week with guided recordings. Measures of psychological distress, mindfulness and self-compassion, burnout, teacher

classroom behavior, cortisol, neuropsychological and attentional tasks and mindfulness practice compliance were taken at pre and postintervention. Daily minutes of informal practice was 21.7 on average and the daily minutes of formal practice was that of 7.5 minutes on average. These results suggest that more than 7.5 minutes on average may be sufficient to see a reduction in stress and that these effects may generalize to the middle-aged population. There is a need to determine the dose that will elicit the most significant changes in stress as well as if this dose will be effective in middle-aged adults.

In an even shorter MBSR program De Vibe and colleagues (2013) randomized 288 students with a mean age of 24 into an intervention or control group. The intervention group was originally asked to complete the MBSR program that included 8-weekly sessions of 2.5 hours each, 30 minutes of daily practice at home, followed by a 7-hour session at week six and seven. After a focus group interview before the intervention began, the intervention was reduced to six weekly sessions of 1.5 hours each, 30 minutes of daily home practice, followed by a 6-hour session in week 7. The control group received no intervention. The General Health Questionnaire, Maslach Burnout Inventory Student version, the Perceived Medical School Stress, Subjective Well-being, and the Five Facet Mindfulness Questionnaire were administered at both pre and postintervention. Stress was significantly reduced following the MBSR intervention as well as an increase in mindfulness. The researchers report that after the change to the requirements of the program, the intervention was still equivalent to the original MBSR program. However, even after the program was reduced the average attendance rate for the sessions was 5.3 out of 7 sessions and there were still six participants who did not

show up and for the intervention and eleven that were lost to follow up for unknown reasons. Although MBSR programs are reported to be successful in reducing stress, they require continuous person participation and intensive commitment. Research should explore what the most feasible time point is to elicit positive effects on stress outcomes. Additionally, this study lacked a comparable control group, struggled with the recruitment of men, and did not include middle-aged adults. Studies are warranted that include a control group but also are able to recruit men equal to that of women.

Similar findings were observed in a low-dose MBSR (MBSR-ld) program in a working adult sample with a mean age of 45 (Klatt et al., 2008). Participants were randomized into either the 6-week intervention group (n=22) or a wait-list control (n=20). The intervention consisted of 60-minute sessions, once a week, on campus. Self-reported measures of perceived stress, sleep quality, and mindfulness were measured at week zero and week six of the intervention as well as salivary cortisol assessed weekly. These outcomes were measured using the Perceived Stress Scale, the Pittsburgh Sleep Quality Index, the Mindful Attention Awareness Scale, and the Assessment of Salivary Cortisol. There was a significant reduction in perceived stress and an increase in mindfulness in the MBSR-ld group. The shortened MBSR program reduced the daily time commitment of a traditional MBSR program and still produced significant decreases in perceived stress increases in daily mindfulness for healthy working adults. Adherence to the MBSR protocol was 85% with only one participant in the intervention group that did not complete at least 80% of the study. This study supports the use of smaller doses of mindfulness to be effective for individuals limited by time and potentially for those

considered middle-aged. Future studies could explore mindfulness programs with smaller doses.

MBSR for the treatment of stress is consistently supported by the literature in multiple populations including students, professionals, and middle-aged women as well as in varying doses (De Vibe et al., 2013, Flook et al., 2013, Park et al., 2016, Karaca & Sisman, 2019). However, the lack of active control group, sample size, study attendance, and recruitment of men continue to be highlighted. Additionally, although middle-aged adults are observed to be included in these studies, they are not a priority. Greater sample sizes, attendance, and recruitment could all possibly be remedied with a lower dose of daily and weekly mindfulness practice (Flook et al., 2013, De Vibe et al., 2013, Klatt et al., 2008) in conjunction with a more easily accessible avenue for individuals to have access to mindfulness-based programs for the management of stress (Klatt et al., 2008) as well as

Web-based mindfulness therapy interventions

New, limited research is emerging delivering web-based mindfulness therapies (Lloyd et al., 2018). Drozd and colleagues (2013), in a randomized study in master's students to determine the effects of a web-based intervention for stress reduction. Students (N=259) (18 years or older) were randomized into either a stress intervention or a control group. The intervention group consisted of 13, 10-minute sessions over one month and the control group received the intervention after the final data collection. The intervention included education on stress, how to build awareness of the source of stress, and prevent or manage prolonged or high levels of stress. Measurements of stress,

mindfulness, and procrastination were collected at week zero and one, two, and six months following the intervention. A total of 34 (27%) of the participants dropped out of the intervention group. Most participants did not provide reasons why they discontinued but of those who did, most reported a lack of time or the program to be too extensive. Future research should consider a less extensive intervention for greater potential adherence. The results of this study indicated that a web-based intervention for stress reduction can increase mindfulness and decrease procrastination and therefore lower stress levels in a sample that included middle-aged adults. However, the researchers report that the effect of the stress intervention was independent of the participant's gender, age or education and recommend that future interventions should include more men, investigate psychological moderators of treatment effects.

Krusche (2013) conducted a web-based mindfulness course (based on principles from MBSR and MBCT interventions) for stress, anxiety, and depression in 273 participants with a mean age of 48. All self-recruited individuals paid \$90 dollars to participate and were asked to practice one formal meditation and one informal practice each day of the week (as much as they could) or at least 10 interactive sessions (minimum of 4 weeks) of guided meditation videos and automated emails consisting of MBSR and MBCT components. The specific dose of each meditation was not reported but it was reported that each practice may have varied in time. Outcomes of stress, anxiety, and depression were measured using the Perceived Stress Scale, the Generalized Anxiety Disorder Assessment-7, and the Patient Health Questionnaire-9. Surveys were administered at preintervention, postintervention and at 1-month follow up. The

participants were instructed to complete the program in less than four weeks and the mode completion time was 4 weeks. Dropout rates were not reported by the researchers however, 86% of participants completed all 12 questionnaires. The results of this study show a significant decrease of stress, anxiety, and depression at postintervention and at follow up. These findings were comparable to cognitive behavioral interventions, in person interventions, and other online mindfulness courses. This study suggests that a 4-week, online mindfulness interventions that utilizes MBSR and MBCT components are acceptable and accessible for the reduction of stress and secondary outcomes in a sample that includes middle-aged adults. However, this study is limited due to the lack of control group, controlled dose, time commitment, and cost to participate. Home-based or web-based mindfulness intervention research is still in its infancy and exploring the efficacy and effectiveness of these interventions in middle-aged adults is needed.

Mindfulness Meditation

Meditation as a complementary approach to stress-reduction has gained popularity in the US (Cramer et al., 2016) however, outside of MBSR, mindfulness meditation as a practice on its own is limited (Ratanasiripong et al., 2015). Meditation is a mindfulness-based practice that has been practiced for thousands of years in eastern traditions and involves the intentional self-regulation of attention to present moment experience, coupled with a non-judgmental and accepting stance toward whatever may arise (Pepping et al., 2016). Research suggests that mindfulness meditation can improve self-reported measures of disease symptoms by representing a mental training framework for cultivating the state of mindful awareness in daily life, but how it effects biological

mechanisms and disease is less clear (Black & Slavich, 2016). There are few studies that have been conducted in middle-aged men and women with high perceived stress. Below we review a few studies in other populations.

In a 4-week, randomized study conducted by Ratanasiripong (2015) nursing students (N=89) with a mean age of 19, in Thailand were assigned to one of three groups, biofeedback group, mindfulness meditation group, or a control group and completed pre- and postintervention surveys. Both intervention groups received two trainings and asked to use their new skill independently 3x per day for four weeks and the control group received no intervention. Outcomes of stress and anxiety were measured using the Perceived Stress Scale and the State-Trait Anxiety Inventory Scale. Attendance or dropout rates were not reported by the researchers, but it was stated that a sample size of at least 66 (22 in each group) was needed for power. Results of this study indicated that both the biofeedback group and the mindfulness meditation group had significantly reduced anxiety, however, the biofeedback group only maintained stress levels while the mindfulness meditation group had significantly lower stress levels, suggesting meditation may be more beneficial for the long-term management of stress. However, the study did not have a control group, targeted a young sample, did not include men, and findings are not generalizable due to the population in Thailand.

Similar findings were also found in a sample of physical therapy (PT) students with a mean age of 26.5. Chambers and colleagues (2016) assessed the effects of meditation on stress levels in an 8-week quasi-experimental study. Twenty-four PT students in either their first or second year of their doctoral program were taught and

asked to practice meditation independently for 20 minutes, 2x a day for 8-weeks, before breakfast and before dinner. Outcome measures of stress, blood pressure, and salivary cortisol levels were measured using 3 stress questionnaires (Perceived Stress Scale, General Anxiety Disorder-7, Stress Visual Analog Scale). All measures were taken at pre- and postintervention and salivary cortisol was measured in the morning and evening. All participants completed the study with a mean compliance of 91.6%. Results of this study indicate that an 8-week meditation program significantly reduced perceived stress and reduced blood pressure. All participants finished the 8-week study, and all meditated at least once per day. These findings are promising when considering the intervention consisted of shorter bouts of meditation. More research is needed on shorter bouts of meditation in a middle-aged population sample.

Munoz and colleagues (2016) conducted a randomized control trial of a mindfulness meditation intervention to reduce stress in 46 adults, ages 18-65 with a mean age of 44. Participants participated in either a mindfulness meditation class or the comparison group (no intervention). The meditation group consisted of seven, 2-hour sessions for 6 weeks with one, 4-hour class during one weekend morning. Outcomes of stress and hope were measured using the Perceived Stress Scale and the Adult Hope Scale administered as pre- and postintervention. The results of this study indicated that the meditation group had significant increases in hope and significant decreases in stress compared to the comparison group. These findings may be generalizable to the middle-aged population, but future research is needed. Not all participants attended every session and 11 out of 41 participants did not complete the study but six-weeks was reported to be

enough of an intervention to have decreases in stress. Unfortunately, daily meditation was not monitored. Future studies need to assess the number of minutes that are attended. Additionally, randomization of participants recruited from a more diverse population sample outside of just one organization is warranted.

Research continues to support meditation as an effective tool for decreasing stress (Williams et al., 2012) and it is currently the most prevalent home-based or web-based, CAM (complementary and alternative medicine) stress reduction strategy in the literature (Sieverdes et al., 2017). However, majority of studies do not focus their stress reduction strategies in middle-aged adult populations or their assessments on coping behaviors. They also either lack a control group completely or lack a comparable control group. This unfortunately decreases the strength of the supported research and future studies should consider the importance of focusing on midlife adults and include a comparable control group when testing these findings. The length of a meditation intervention and number of required in person session should also be considered for participation adherence and short bouts of daily meditation is suggested for success. Additionally, not everyone has access to quality mindfulness/meditation taught by professionals. The explosion of smartphone-based mindfulness programs provides a potential mindfulness meditation intervention with an advantage of a low cost, portable, professional, educational, likeable mode of delivery that provides access for any populations with access to the internet (Creswell, 2017).

Mindfulness-based mobile consumer apps

There is a high prevalence of smartphone ownership and use of consumer-based mobile application (app) programs with more than 325,000 mobile health apps available

to the consumer (Larson, 2018). Specifically, there are over 500 mindfulness-based smart phone apps available to the consumer (Wei, 2015). There is growing evidence to support the positive impact of mindfulness but there is little information known on the quality of mobile health apps (Mani et al., 2015). Only 4% of mindfulness-based apps offer training and education and the lack of evidence for the effectiveness of these apps needs to be addressed (Mani et al., 2015). Despite the increasing number of mindfulness apps, there is a lack of research conducted on the effectiveness of them (Duraimani et al., 2019).

Both meditators and non-meditators (18-64 years of age) were assessed by Duraimani (2019) in a cross-sectional and longitudinal study of the effects of a mindfulness meditation mobile application platform on reducing stress and anxiety. The cross-sectional study assessed meditators (n=111) and non-meditators (n=111) who used a meditation app for 90 days. App usage dose or meditation dose was not reported. Outcomes of stress, anxiety, and depression were measured using the Depression, Anxiety, Stress Scale (DASS) at pre- and post-intervention. Results of this study showed the meditation app substantially reduced the participants stress and anxiety and although this study did not focus their sample on middle-aged adults, they were included. The second study followed 67 individuals who used a meditation app alone for 21 days to affirm the reported substantial reduction in stress and anxiety in its users. App usage dose or meditation dose was also not reported. Adherence rates to the study were not reported. Researchers suggested that time commitment and cost of participating in mindfulness meditation programs can be significant and using a mobile app could be easier, cost-

effective, and have greater significant positive effects similar to in person interventions. However, randomization with a comparable control group is recommended to support these findings.

Undergraduate students (N=208) between the age of 18 and 49 years who were recruited to evaluate two mindfulness meditation apps for mental health (Flett et al, 2018). Each participant was randomly assigned to use Headspace, Smiling Mind, or an attention control app (control). Participants completed a 10-day trial where they were asked to complete a 10-minute session on their assigned app each day. Outcomes of depression symptoms, anxiety, stress, resilience, flourishing, college adjustment, mindfulness, expectation and perceptions of app use, and app adherence were measured with self-reported surveys at baseline, daily, and postintervention. App use adherence was high and consistent during the 10-day period and those who used the app more frequently had greater effects. Significant improvements were seen in depressive symptoms, college adjustment, resilience (Smiling Mind only), anxiety, mindfulness (Headspace only) in comparison to the control group. The study suggest that brief meditation sessions can have improvements of mental health in short term and when used regularly but an appropriate and effective app must be used to achieve these benefits. Future research should collect app usage data objectively in addition to self-reported data for more reliable findings as well as investigate mindfulness-based apps independently against an active app-based control.

College students with a mean age of 20 were examined in a randomized controlled trial assessing the efficacy of the mindfulness meditation mobile app “calm” to

reduce stress by Huberty and colleagues (2019). College students (N=109) were randomly assigned to either the intervention group or a waitlist control group. The intervention group was asked to meditate using Calm at least 10 minutes per day for 8-weeks. Measures of stress, mindfulness, and self-compassion were taken at baseline, postintervention, and at follow up (week 12). Primary outcomes were that of stress, mindfulness, and self-compassion. Stress was measured using the Perceived Stress Scale, mindfulness was measured using the Five Factor Mindfulness Questionnaire, and self-compassion was measured using the Self-Compassion Survey Short-Form. Secondary outcomes were that of sleep quality, alcohol consumption, physical activity, and fruit consumption. Sleep quality was measured using the Patient-Reported Outcomes Measurement Information System. Binge drinking, physical activity participation, and healthy eating were measured using the Youth Risk Behavior Surveillance survey. Feasibility of the Calm app were also measured including acceptability and demand. Results of this study indicate the efficacy of the Calm app to reduce stress and improve mindfulness and self-compassion in college students but future research with Calm specific to midlife adults is needed. Out of the 109 participants enrolled in the study, 18 did not complete the postsurvey, 2 did not set up Calm, and 1 did not meditate totaling an 80.7% adherence rate. Huberty (2019) reported that the use of a smartphone-based mindfulness app may be similar to in-person stress-reduction interventions. Participants also reported high satisfaction with the use of Calm to reduce stress and the researchers suggest Calm is a cost-effective, convenient, easy to access, and enjoyable way to manage stress. Research is needed in the exploration of the effectiveness and

acceptability of mobile applications like Calm for the delivery of mindfulness meditation for positive health outcomes.

To date there has not been a mobile application that has been formally tested for its effectiveness in improving mindfulness in middle aged adult. No intervention has assessed using a mindfulness-based mobile app to reduce stress, anxiety, depression, and improve coping behaviors in middle aged adults. There is only one intervention by Huberty and colleagues (2019) that tests the efficacy of Calm to reduce stress in a college student population with full randomization (mentioned above). The results of this study report the efficacy of the Calm app to reduce stress and improve mindfulness as well as high satisfaction with the app. However, a comparable or equivalent control group is still needed for more reliable findings.

Calm is a consumer-based mindfulness meditation application based upon mindfulness meditation principles such as attention regulation, body awareness, emotion regulation, and sense of self without judgement. Calm is universal and non-denominational and offers both guided and unguided meditation options, as well as meditation “Masterclass” taught by mindfulness experts. Calm does not offer yoga but does offer mindfulness movement and gentle stretching. Music, relaxing nature scenes and sounds are also offered with music ranging from 3 minutes to an hour. Sleep stories, in addition to meditation, are also a main component of Calm with stories ranging from 12-45 minutes. The meditations range from two minutes to one hour and also include foundation courses. “How to Meditate” offers simple and easy to follow meditations and education for everyone and “7 Days of Calm” teaches the basics of mindfulness

meditation in a series. In addition to the foundation courses, Calm offers an abundance of meditations with a variety of intentions (e.g. “Anxiety Release”, “Easing Depression”, “7 days of Calming Anxiety”, “Mindful Eating Series”, etc.). Calm’s meditations and their progression of meditations closely resemble the structure of MBSR practices.

CHAPTER 3

STUDY PURPOSE & HYPOTHESES

As demonstrated in the literature review, there is only one study providing preliminary support for the mindfulness-based app Calm for the reduction of stress, and that is in a much younger age category (college age students). There is a strong need for future research examining the effects of Calm in middle aged adults. The purpose of this study was to determine the feasibility and preliminary effects of using a mobile app (i.e., Calm) to decrease overall stress in middle-aged (i.e., 40-64 years) men and women who report elevated stress (>15 on PSS). This study also tested the feasibility and preliminary effects of a health education podcast control app.

Specific aim 1: Determine the feasibility (acceptability, demand) of using CALM app ≥ 10 min/day to reduce stress in middle-aged men and women who report elevated stress (score ≥ 15 on Perceived Stress Scale [PSS]).

Benchmarks for feasibility: (acceptability) Recruitment $>40\%$ men; $>75\%$ satisfied with intervention; $>75\%$ perceive daily meditation and app components as appropriate and useful; (demand) Retention of men $>75\%$; $>70\%$ adherence (minutes/week) to the meditation intervention.

Specific aim 2: Explore the preliminary effect of meditation using Calm on overall perceived stress as compared to the health education group.

Hypothesis 1: There will be a significant reduction in overall perceived stress using Calm as compared to the health education group.

Specific aim 3: Explore the preliminary effect of meditation using Calm on anxiety and depression.

Hypothesis 2: There will be a significant reduction in anxiety in the Calm group as compared to the health education group.

Hypothesis 3: There will be a significant reduction in depression in the Calm group as compared to the health education group.

Specific aim 4: Explore the preliminary effects of meditation using Calm on mindfulness, physical activity, eating habits, and coping behaviors.

Hypothesis 4: There will be a significant improvement in mindfulness in the Calm group as compared to the health education group.

Hypothesis 5: There will be a significant improvement in physical activity, eating habits, and coping behaviors in the Calm group as compared to the health education group.

CHAPTER 4

METHODS

This study was approved by the Institutional Review Board at Arizona State University. All study participants completed an informed consent prior to participating.

Study Participants:

Participants for the study included men and women who met the following criteria: 1) 40-64 years of age, 2) reported a score of 15 or higher on the Perceived Stress Scale (PSS), 3) had access to a smartphone on a daily basis, 4) were willing to download the Calm app, 5) and able to read and understand English. Potential participants were excluded if they: 1) had practiced mindfulness meditation for more than 60 minutes per month for at least one month within the last 12 months, 2) were currently using the Calm app or another meditation app, 3) were currently prescribed antidepressants, 4) or were currently residing outside the United States. Table 1 describes the inclusion/exclusion criteria.

Table 1. Inclusion/Exclusion Criteria	
Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none">- men or woman- age 40-64- report a score of 15 or higher on the Perceived Stress Scale (PSS)- have access to a smartphone on a daily basis- willing to download the Calm app- willing to be randomized to a meditation group or a health education podcast control group	<ul style="list-style-type: none">- have practiced mindfulness for >60 min/month in the last 6 months- currently using the Calm app or another meditation app- currently prescribed mood medication(s)- currently reside outside the United States

Recruitment

Middle aged adults were recruited nationally from February 6th to April 20th utilizing internet-based strategies, including social media (i.e. Facebook, Instagram, Twitter), social networking sites, and researchmatch.org. Recreation and community centers (e.g. YMCA) were contacted and attended in person and asked to advertise the study by posting the provided recruitment material (i.e. flyers, blurbs) to their bulletin boards, website, or social media site. The study was also advertised by passing out recruitment flyers at community events and stores. To address the feasibility benchmark of the recruitment of men, it was made clear on recruitment flyers and in online (researchmatch.org) and social media blurbs that men were encouraged to participate. Potential participants were directed to an eligibility survey administered via REDCap (Vanderbilt University).

Research Design

The study was a randomized controlled trial, feasibility study design. One hundred middle-aged men and women were randomized, after consenting, to either an app-based meditation group (n=50) (Calm) or an app-based health education control group (n=50) (POD). Participants randomized to Calm were asked to complete 4 weeks of at least 10 min/day of app-based meditation, through Calm, a consumer-based app. Those randomized to POD were asked to complete 4 weeks of at least 10 min/day of app-based health education videos and podcasts. The following sections describe the study-related procedures for the meditation group and the health education control group,

respectively. Because the study began recruitment at the same time as the COVID-19 pandemic, we added a COVID-19 perception survey.

Intervention

Meditation Group (Calm)

The meditation prescription was for 4-weeks and include approximately 10-minute, app-based meditations 7x a week to achieve 70 minutes of meditation participation each week. Participants were asked to complete the 30 day, “How to Meditate” meditation series to familiarize themselves with the principles of meditation and to standardize the meditation and teaching content. For each 10-minute session, an educational component on a principle of mindfulness meditation was explained and discussed. Following the discussion, a related meditation was guided (e.g., body scan, breath focus, and loving kindness). Additionally, participants were reminded each week in a weekly email to participate in at least 70 minutes of meditation (10 min/day).

Calm participants were asked to complete weekly self-report logs (i.e. participation (meditation) logs) through a REDCap survey delivered via email that records the amount of time spent participating in meditation. Meditation participation were assessed by Calm and shared with the research team. This includes type of meditation, day and time of meditation and total time spent. Questionnaires were administered at two time points throughout the study, including baseline (week 0), and post-intervention (week 4). These questionnaires included questions pertaining to participant demographics, the severity of reported perceived stress, secondary outcomes of stress (i.e. anxiety and depression), and mediators to stress (i.e. mindfulness, physical

activity, eating, and coping behaviors). Finally, Calm participants were asked to complete a satisfaction survey following the intervention.

Control Group (POD)

The control prescription was for 4-weeks and include approximately 10-minute, app-based education podcasts, 7x a week to achieve 70 minutes of podcast participation each week. The podcasts were chosen to be related to general health and well-being from publicly available audio. The podcasts did not include content related to mindfulness, stress, or sleep to be sure there was a distinct difference in content in comparison to the Calm app. Only those enrolled in the study had access to the podcasts and only for the duration of the study (non-commercial use). POD participants were asked to complete the same assessments as the Calm intervention group at baseline (week 0), and post-intervention (week 4).

Participant Incentive

Calm participants had access to Calm for free (valued at 13.00 per month). Additionally, all participants received a \$10 gift card (i.e., Amazon) for completing the post-intervention questionnaires, and all participants received an additional \$5 gift card (i.e., Amazon) for completing the follow-up phone interview (week 5).

Independent/Dependent Variables

The study's independent variable is that of meditation. The dependent variables are that of self-reported stress, outcomes of stress (i.e. anxiety and depression), and behaviors related to stress (i.e. mindfulness, physical activity, eating, and coping behaviors). The meditation intervention was delivered over 4-weeks, app-based, and

streamed online. Feasibility benchmarks measures included acceptability and demand. Recruitment benchmarks were measured using a demographic survey (week 0). Acceptability was measured with a satisfaction survey post-intervention (week 4). Demand was measured using adherence (minutes/week) to the meditation intervention. Adherence to meditation was recorded in weekly reports from the Calm informatics team. Reports included the date and time of each meditation participated in, the title of the meditation, and the duration of participation (i.e., the time spent viewing the meditation) for each participant.

To answer the proposed hypotheses, overall perceived stress was measured with the Perceived Stress Scale (PSS). Anxiety and depression were measured using the *Hospital Anxiety and Depression Scale (HADS)*. Mindfulness was measured using the Mindful Attention Awareness Scale (MAAS). Physical activity was assessed using the International Physical Activity Questionnaire- Short Form (IPAQ-SF), eating was assessed using the Salzburg Stress Eating Scale (SSES), and coping was assessed using the Brief COPE inventory. Self-reported scores were used for all measures and administered at baseline (week 0) and post-intervention (week 4). The feasibility of the Calm app and the overall study satisfaction were assessed through satisfaction survey created by the researcher as well as the weekly participation logs and the app usage data provided by Calm. Satisfaction phone interviews were conducted by the researcher after the intervention had closed (week 5). An additional survey regarding COVID-19 perceptions was administered only at post-intervention to better understand how the pandemic may have impacted participant stress during the study. The participants were

provided the details and information about the study prior to their start date. Participants were told to contact the researchers via email or phone any time with questions or concerns.

Instruments

Stress

Perceived Stress Scale (PSS)

The PSS is used to measure the degree of self-appraised stress in one's life using a 10-item self-report measure that asks participants to rate the extent to which they have felt their life to be stressful within the past month (Khalili et al., 2017). The PSS is reported to be a reliable and valid measure ($\alpha=.84$). The questionnaire utilizes a five-point Likert scale ranging from 1 (never) to 5 (very often). Higher scores indicate higher levels of perceived stress. A sample question is, "In the last month, how often have you been upset because of something that happened unexpectedly?"

Anxiety and Depression

Hospital Anxiety and Depression Scale (HADS)

The HADS includes seven anxiety and seven depression questions and are scored separately (Bjelland et al., 2002). The questionnaire utilizes a four-point Likert scale ranging from 0 to 3. A score of 8-10 indicated a mild case, 11-14 is moderate, and 15-21 is a severe case. HADS is known for its simplicity and speed of use. The combination of anxiety and depression being tested together allows for signs of depression to be seen earlier, as anxiety often proceeds depression in response to stress. The HADS is reported to be a reliable and valid measure ($\alpha=.60-.80$). A sample question for anxiety is, "I feel

tense or ‘wound up’.” A sample question for depression is, “I still enjoy the things I use to enjoy.”

Mindfulness

Mindful Attention Awareness Scale (MAAS)

The MAAS includes 15-items designed to measure the core components of mindfulness distributed across cognitive, emotional, physical, interpersonal, and general domains and measures the extent to which individuals are able to maintain awareness of present-moment experience (Brown & Ryan, 2003). The MAAS is reported to be a valid and reliable measure with good internal consistency ($\alpha=.80-.87$). The MAAS utilizes a six-point Likert scale ranging from 1 (almost always) to 6 (almost never) with higher scores reflecting higher levels of mindfulness. A sample question is, “I find it difficult to stay focused on what’s happening in the present.”

Coping Behaviors

International Physical Activity Questionnaire- Short Form (IPAQ-S)

The IPAQ-S includes 7-items assessing the types of, and intensity of daily physical activity and sitting time recalled from the last seven days and calculated to provide total metabolic equivalent (MET) minutes per week (Birfitte et al., 2017, Wang et al., 2013). The IPAQ-S is reported to be a valid and reliable measure with good internal consistency ($\alpha=.80$). A sample question is, “During the last 7 days, on how many days did you walk for at least 10 minutes at a time?”

Salzburg Stress Eating Scale (SSES)

The Salzburg Stress Eating Scale includes 10-items designed to measure general stress eating tendencies (Meule et al., 2018, Blechert et al, 2018).. The SSES is reported to be a valid and reliable measure with good internal consistency ($\alpha=.88$). The SSES utilizes a five-point Likert scale ranging from 1 (I eat much less than usual) to 5 (I eat much more than usual). A sample question is, “During periods of great stress,…”

Brief COPE

The Brief COPE inventory is a 28-item multidimensional measure of strategies used for coping or regulating cognitions in response to stressors (Cooper et al., 2008, SOBC, 2019). This scale is an abbreviated version of the COPE Inventory. The Brief COPE is reported to be a valid and reliable measure ($\alpha=.83$) with fair internal consistency. The Brief COPE utilizes a four-point Likert scale ranging from 1 (I haven’t been doing this at all) to 4 (I’ve been doing this a lot). The scale is broken down into subscales assessing self-distraction, active coping, denial, substance abuse, use of emotional support, use of instrumental support, behavioral disengagement, venting, positive reframing, planning, humor, acceptance, religion, and self-blame. A sample question is, “I’ve been using alcohol or other drugs to make myself feel better.”

Study Satisfaction Survey

It is important to test the feasibility of an intervention to provide preliminary data for future interventions (Bowen et al., 2009). Bowen suggest potential feasibility areas of focus and outcomes of interest. The study satisfaction survey was a 10-item questionnaire created by the research and modeled after Bowen’s suggestions. Areas of focus were on acceptability and demand of Calm as a result of the mindfulness meditation intervention

in a middle-aged adult sample as well as the acceptability and demand of the POD app. Acceptability measures allowed for the collection of participant satisfaction, intent to continue use, perceived appropriateness, and other reactions to the intervention. Demand measures allowed for the collection of actual use of the intervention, participants demand for the intervention, or other intentions of use. The 10 questions are included in Appendix A.

Study Satisfaction Interview

The study satisfaction interview questions were created by the researchers and modeled after Bowen's feasibility recommendations similar to the satisfaction survey (Bowen et al., 2009). Participant from both groups were asked to volunteer to assess participant experience with the study and with using their assigned app. The questionnaire included eleven questions and are included in Appendix B.

COVID-19 Survey

The COVID-19 survey was created by the researchers and modeled after behavioral research questions created by the Center for Disease Control and Prevention (CDC) (Vartti et al., 2019) to assess perceptions of and experiences with the virus. The survey asked questions regarding risk perceptions, worry, precautionary behaviors, information sources, stress, mental health, and physical health. Questions are included in Appendix C.

Statistical Analysis

To examine the influence of the intervention effect, the primary outcome measure was perceived general stress (as measured by the Perceived Stress Scale) and secondary

outcome measures was anxiety and depression. The data were first examined through the evaluation of descriptive statistics (e.g., mean and frequencies). Frequency distributions were examined for each variable at each time-point. Significance was determined based on a two-tailed alpha level of .05. All statistical procedures were performed using IBM SPSS version 26 and Statistical Analysis Systems (SAS) Software, version 9.4.

To examine the intervention effect, the general linear model (GLM) was used to conduct a series of two-way mixed ANOVAs exploring within-group changes in perceived stress, anxiety, depression, mindfulness, and coping across pre- and post-intervention, for the intervention and control group. In addition, pairwise tests adjusted for multiple comparisons with planned contrasts were used. The hypothesized planned contrasts were that stress, anxiety, and depression would decrease. We also hypothesized that mindfulness will increase, and coping scores would improve (i.e. more physical activity, better eating, and better coping behaviors).

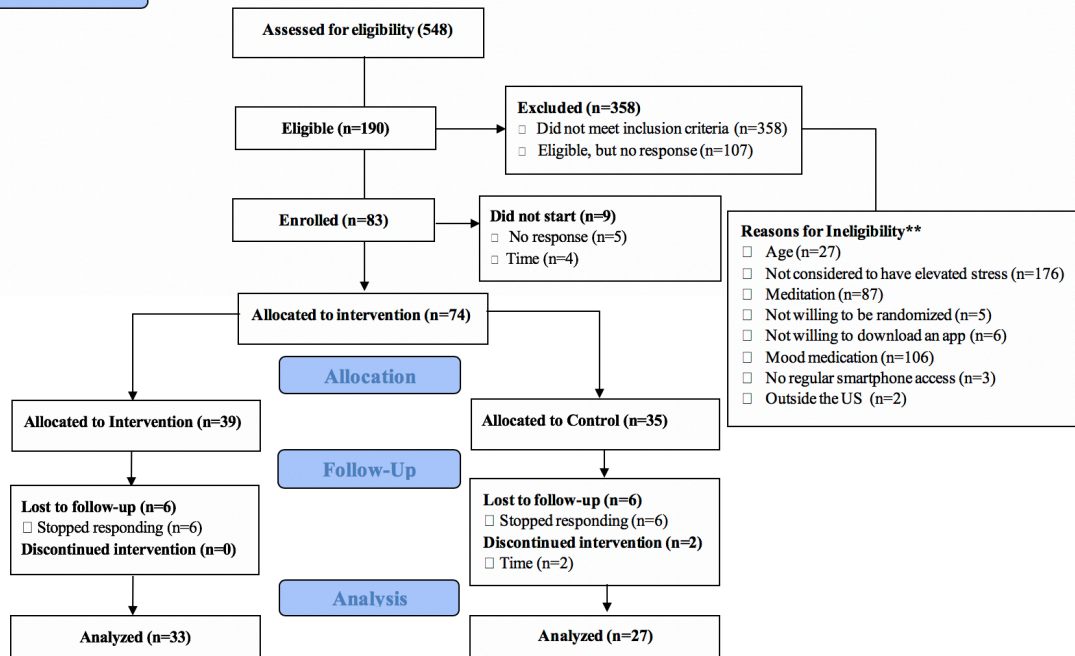
CHAPTER 5

RESULTS

Participant Enrollment

A total of 548 interested adults completed the eligibility questionnaire. Of those who completed eligibility, 35% (n=190) were eligible and 65% (n=358) were ineligible. The reasons for ineligibility were 1) Not considered to have elevated stress (49.2%; n=176), 2) Currently prescribed mood medication (29.6%; n=106), 3) Participated in meditation for more than 60 minutes per month in the past 3 months (24.3%; n=87), 4) Not between the ages of 40 and 64 (7.5%; n=27), 5) Not willing to download an app (1.7%; n=6), 6) Not willing to be randomized (1.4%; n=5), 7) No regular access to a smartphone (0.8%; n=3), and 7) Reside outside the US (0.6%; n=2). Eligible participants (N=190) were sent an intake video link via email to review the study details. Almost half of those eligible (43.7%; n=83) completed the intake video and signed the informed consent. Forty-three participants were randomized to the intervention group and forty to the control group. After removing participants who did not complete the post-surveys (16.9%; n=14) or did not start the intervention (10.8%; n=9), a total of 60 participants, ages 40-64 years, were included in the analysis. Figure 1 describes participant enrollment.

Figure 2. Enrollment



Participant Demographics

Calm group

Table 2 presents the baseline characteristics of the intervention participants (N=32). The mean age of the sample was 52.1 (SD=7.1) years of age. The majority of participants were female (62.5%; n=20), Caucasian (84.4%; n=27), non-Hispanic (90.6%; n=29), married (71.9%; n=23), awarded a bachelor's degree or higher (68.7%; n=22), obtain an annual household income of more than \$61,000 per year (68.8%; n=22), have no history of PTSD (78.1%; n=25), have no history of depression (75.0%; n=24), and are considered to be in good health (53.2%; n=17).

Control group (POD)

Table 2 also presents the baseline characteristics of the POD participants (N=26). The mean age of the sample was 50.8 (SD=6.1). The majority of participants were female

(69.2%; n=18), Caucasian (73.1%; n=19), non-Hispanic (96.2%; n=25), married (50.0%; n=13), awarded a bachelor's degree or higher (76.9%; n=20), obtain an annual household income of more than \$61,000 per year (61.5%; n=16), have no history of PTSD (84.6%; n=22), have no history of depression (80.8%; n=21), and are considered to be in good health (46.2%; n=12).

Table 2. Baseline Demographics			
	Calm Group (n=32)	POD Group (n=26)	
	n(%)	n(%)	P
Age, years (M)	52.1	50.8	0.18
Gender			0.59
Male	12 (37.5)	8 (30.8)	
Female	20 (62.5)	18 (69.2)	
Education			0.67
Bachelor's degree or higher	22 (68.7)	20 (76.9)	
Ethnicity			0.41
Hispanic	3 (9.4)	1 (3.8)	
Non-Hispanic	29 (90.6)	25 (96.2)	
Race			0.27
White/Caucasian	27 (84.4)	19 (73.1)	
Asian/Asian American	1 (3.1)	0 (0.0)	
Black/African American	4 (12.5)	7 (26.9)	
Income			0.57
\$61,000 or above	22 (68.8)	16 (61.5)	
\$60,000 or less	10 (31.2)	10 (38.5)	
Marital Status			0.41
Married	23 (71.9)	13 (50.0)	
Single	5 (15.6)	6 (23.1)	
Divorced	2 (6.3)	2 (7.7)	
Partnered	2 (6.3)	4 (15.4)	
Separated	0 (0.0)	1 (3.8)	
History of PTSD			0.53
Yes	7 (21.9)	4 (15.4)	
No	25 (78.1)	22 (84.6)	

History of Depression			0.60
Yes	8 (25.0)	5 (19.2)	
No	24 (75.0)	21 (80.8)	
Health Status			0.11
Excellent	3 (9.4)	2 (7.7)	
Very good	6 (18.8)	11 (42.3)	
Good	14 (43.8)	10 (38.5)	
Fair	8 (25.0)	1 (3.8)	
Poor	1 (3.1)	2 (7.7)	

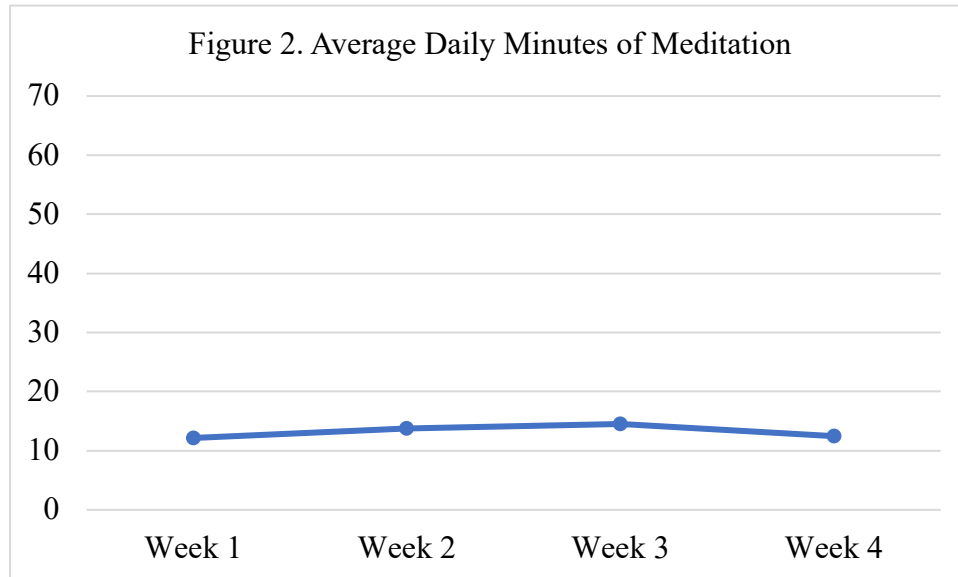
Feasibility

Acceptability of Calm (Satisfaction, Enjoyment, Intent to Continue Use)

Acceptability was assessed using a satisfaction survey at post-intervention (week 4). Table 3 presents the satisfaction survey results for the Calm group. Approximately 57.1% (16/28) of the adults indicated that Calm helped reduce their perceived stress in the short term and 82.1% (23/28) said that Calm increased their awareness of the importance of addressing stress. Almost all of the participants 96.4% (27/28) reported they were satisfied with the “How to Meditate” meditation series, 92.9% (26/28) found it enjoyable, and 64.3% (18/28) would continue to use Calm in the future. *Demand of Calm (Adherence, Recruitment of Men, and Retention of Men)*

Figure 2 describes average weekly minutes of meditation. Participants in the intervention group (n=24) engaged in an average of 10.7 minutes of meditation per day and an average of 74.6 minutes of meditation per week over the course of the study. The majority of participants in the Calm group 79.2% (19/24) completed at least 30 minutes per week using the Calm app and 62.5% (15/24) of participants meditated more than 70 minutes per week. Recruitment of men into the intervention group was 38.1% (16/24)

and retention of men was 81.3% (13/16). On average there was a 70.8% adherence rate to the meditation intervention.



POD Control App

Table 3 also presents the results from the POD satisfaction survey. The majority of the sample 52.6% (10/19) was satisfied with the intervention and 63.2% (12/19) did not report a reduction in their stress in the short term. However, the majority of the sample 52.6% (10/19) reported the POD app may help reduce stress in the long term and 63.2% (12/19) reported an increase in their awareness of the importance of addressing stress. Additionally, on average, there was a 62.2% adherence rate to the control condition.

Table 3. Satisfaction Survey Results		
	Calm Group (n=28)	POD Group (n=19)
Questions	n(%)	n(%)
Reduced stress in short term	16(57.1)	7(36.8)
Will help reduce stress in long term	19(67.9)	10(52.6)
Increased awareness of the importance of addressing stress	23(82.1)	12(63.2)
Will help reduce stress in the future	17(60.7)	4(21.1)
Overall satisfaction with study	27(96.4)	10(52.6)
Participation in the app was enjoyable	26(92.9)	8(42.1)
Would continue to use the app	18(64.3)	6(31.6)
Likely to recommend the app to others	22(78.5)	8(42.1)

Primary Outcomes (Stress, Anxiety, and Depression)

Table 4 describes changes in the primary outcome measures within the intervention group (n=33). There were no significant changes in participants' scores when measured using the PSS or HADS scales at baseline and post-intervention (week 4). The results did not indicate a significant time effect for stress ($d=0.005$), anxiety ($d=0.037$) or depression ($d=0.109$). Thus, there is not significant evidence to reject the null hypothesis.

Secondary Outcomes (Mindfulness, Physical Activity, Eating Habits, and Coping Behaviors)

Table 4 also describes changes in the secondary outcome measures within the intervention group (n=33). There were no significant changes in participants' scores when measured using the MAAS, IPAQ, SSES, or the Brief COPE scales at baseline and

post-intervention. The results did not indicate a significant time effect for mindfulness ($d=0.067$), physical activity ($d=0.018$), eating habits ($d=0.032$), or coping behaviors ($d=0.054$). Thus, there is not significant evidence to reject the null hypothesis.

Comparison of Outcomes Between Groups

Table 4 also describes the changes in participant scores between the Calm group ($N=33$) and the control group ($N=26$) when measured at baseline and post-intervention (week 4). Follow-up comparisons indicated that each pairwise difference was not significant, $p < .01$. There were no significant differences in stress ($d=0.001$), anxiety ($d=0.020$), depression ($d=0.009$), or mindfulness ($d=0.006$), physical activity ($d=0.036$), eating habits ($d=0.035$), or coping behaviors ($d=0.000$) over the 4 weeks, suggesting that the participation in the intervention did not decrease levels of stress, anxiety, or depression, and did not improve outcomes of health or coping behaviors. Thus, there is not significant evidence to reject the null hypothesis.

Comparison of Outcomes Between Genders

Table 5 describes the changes in participant scores for each outcome measure between genders in both the Calm (male $n=13$, female $n=20$) and POD (male $n=8$, female $n=18$) groups as well as between groups. Although this was not a specific aim of this study, it is important to note that comparisons indicated that each pairwise difference was also not significant ($< .01$) and that mean changes within and between groups did not differ significantly between genders.

Table 4. Mean Changes for Outcome Measures							
Variable	Calm Group			POD Group			F,p
	n	Mean (SD)	t,p	n	Mean (SD)	t,p	
Stress (PSS)							
pre	33	19.2(7.3)	t=1.8,p=0.582	27	18.8(8.0)	t=-0.2,p=0.821	F=0.3,p=0.859
post	33	19.9(8.1)		27	19.1(6.4)		
Anxiety (HADS)							
pre	33	8.8(4.3)	t=-0.3,p=0.769	27	7.2(2.8)	t=-1.7,p=0.099	F=2.2,p=0.278
post	33	8.9(4.4)		27	8.2(3.5)		
Depression (HADS)							
pre	33	5.8(3.4)	t=-0.6,p=0.582	27	4.5(3.4)	t=-2.1,p=0.044	F=7.1,p=0.469
post	33	6.5(3.5)		27	5.7(3.9)		
Mindfulness (MAAS)							
pre	33	56.6(14.0)	t=1.9,p=0.066	27	59.9(10.3)	t=1.0,p=0.321	F=4.1,p=0.554
post	33	53.7(13.6)		27	58.3(10.3)		
Physical Activity (IPAQ)							
pre	33	706.9(383.1)	t=1.5,p=0.132	26	753.9(335.6)	t=-0.6,p=0.560	F=1.1,p=0.435
post	33	637.2(315.6)		26	766.4(396.4)		
Eating Habits (SSES)							
pre	33	28.8(9.6)	t=-1.9,p=0.066	27	29.7(8.5)	t=0.1,p=0.953	F=1.9,p=0.151
post	33	31.6(10.7)		27	29.6(8.8)		
Coping (Brief COPE)							
pre	33	64.8(9.2)	t=1.2,p=0.233	26	64.8(9.3)	t=1.5,p=0.158	F=3.3,p=0.981
post	33	62.8(12.1)		26	62.7(8.9)		

Table 5. Mean Changes for Outcome Measures by Gender														
Variable	Calm Group						Control Group						Between Groups	
	Male			Female			Male			Female				
	n	Mean (SD)	t, p	n	Mean (SD)	t, p	n	Mean (SD)	t, p	n	Mean (SD)	t, p		F, p
Stress (PSS)	pre	13	21.8(7.1)	t=-	20	17.5(7.2)	t=-	8	16.9(6.8)	t=-0.7, p=0.482	18	19.6(8.5)	t=-0.3, p=0.745	F=0.2, p=0.076
	post	13	21.4(6.3)	0.3, p=0.772	20	18.9(9.1)	0.8, p=0.424	8	19.3(6.9)		18	19.1(6.4)		
Anxiety (HADS)	pre	13	10.3(4.8)	t=1.3, p=0.212	20	7.8(3.7)	t=-	8	7.1(1.7)	t=0.7, p=0.483	18	7.3(3.1)	t=-	F=1.4, p=0.210
	post	13	9.2(4.1)		20	8.75(4.7)	1.8, p=0.091	8	6.4(3.1)		18	9.0(3.4)	2.6, p=0.017	
Depression (HADS)	pre	13	7.1(4.0)	t=-	20	5(2.8)	t=-	8	4.4(3.1)	t=-0.2, p=0.826	18	4.5(3.6)	t=-	F=0.3, p=0.087
	post	13	7.2(3.5)	0.1, p=0.904	20	6.1(3.6)	1.8, p=0.090	8	4.6(4.3)		18	6.2(3.8)	2.4, p=0.027	
Mindfulness (MAAS)	pre	13	51.3(14.6)	t=0.9, p=0.370	20	60(12.9)	t=1.7, p=0.109	8	58.0(9.4)	t=-0.5, p=0.617	18	60.7(10.8)	t=2.1, p=0.054	F=0.0, p=0.050
	post	13	48.8(14.0)		20	56.8(12.7)		8	60.0(13.9)		18	57.6(8.7)		
Physical Activity (IPAQ)	pre	13	785.8(502.3)	t=1.5, p=0.171	20	655.6(284.2)	t=0.7, p=0.472	8	937.5(302.7)	t=-0.2, p=0.840	18	676.7(325.2)	t=-	F=3.1, p=0.402
	post	13	670.3(348.9)		20	615.7(299.4)		8	948.5(387.0)		18	689.7(384.3)	0.4, p=0.696	
Eating Habits (SSES)	pre	13	26.8(9.5)	t=-	20	30(9.7)	t=-	8	30.4(6.5)	t=1.2, p=0.276	18	29.4(9.4)	t=-	F=0.2, p=0.070
	post	13	28.3(6.7)	0.7, p=0.488	20	33.7(12.3)	1.8, p=0.089	8	26.9(6.2)		18	30.8(9.6)	1.2, p=0.257	
Coping (Brief COPE)	pre	13	60.2(10.1)	t=0.1, p=0.938	20	67.9(7.3)	t=1.6, p=0.133	8	65.1(11.6)	t=-0.6, p=0.591	18	64.6(8.6)	t=1.4, p=0.175	F=0.1, p=0.053
	post	13	60.0(12.8)		20	64.6(11.6)		8	63.3(13.0)		18	62.4(7.0)		

Study Satisfaction Interview

At the end of the intervention (week 5) we conducted interviews to assess how individuals felt about the intervention. Six participants volunteered to be interviewed, all reported being satisfied with the intervention, would recommend the intervention to others, and observed and experienced the benefits of an app-based and digitally delivered intervention. All participants enjoyed the meditations and the voice of the guide of the meditations, did not encounter any barriers to using the app, wanted to continue to use the app, and saw positive changes in their mental health, physical activity, and stress in the short term. Almost all 83% (5/6) reported positive changes in their sleep. Qualitative feasibility in addition to the satisfaction survey provided supplemental insight to the experiences and needs of our participants.

COVID-19 Survey

Table 6 presents the results of the COVID-19 survey and Appendix C presents the complete COVID-19 survey questions. The majority of participants in the intervention group 93% (26/28) reported COVID-19 affected their stress, mental health 82% (23/28), and physical health 61% (17/28).

Worry

The majority of intervention participants 79% (22/28) reported feeling worried about personally getting COVID-19, 93% (26/28) about a family member getting COVID-19, and 86% (24/28) about the spread of COVID-19 in their area.

Risk perceptions

Only 18% (5/28) of the intervention group reported their personal risk of getting COVID-19 to be high and 14% (4/28) expressed their personal risk of getting COVID-19 to be higher compared to others in the United States. Only 7% (2/28) reported to have/potentially have COVID-19, 39% (11/28) reported personally knowing someone who has/may have COVID-19, and 21% (6/28) said they know someone who personally knows someone who has/may have COVID-19. Some expressed their ability to prevent getting COVID-19 to be high 39% (11/28), less 32% (9/28) expressed their ability to prevent getting COVID-19 in comparison to others to be high, and only 18% (5/28) believed their ability to prevent COVID-19 to be higher compared to infectious disease in general.

Precautionary behaviors

Almost half 43% (12/28) of the intervention group avoided eating in restaurants or food courts, washed their hands more, avoided physical contact with others, and maintained physical distance from others when they saw them. Less 40% (11/28) reported they avoided traveling to infected areas, travel on airplanes, travel via public transit, and avoided public events/large gatherings and moderate-sized gatherings. Some 36% (10/28) reported wearing a mask and avoiding public spaces for leisure, recreation, or non-essential outings 32% (9/28), and adapted their schedule to avoid crowds 32% (9/28). Some reported 29% (8/28) taking extra care of cleanliness and using disinfectants with others reported that they increased their exercise 32% (9/28), payed more attention to sleep 21% (6/28), and their eating habits 18% (5/28). Only 14% (4/28) reported avoiding routine errands and taking supplements 7% (2/28).

Table 6. COVID-19 Survey Results		
	Calm Group (n=28)	POD Group (n=23)
Question	n(%)	n(%)
Perception of personal risk to be high	5(17.9)	3(13.0)
Perception of personal risk to be high compared to others in the US	4(14.3)	3(13.0)
Ability to prevent contracting to be high	11(39.3)	11(47.8)
Ability to prevent contracting is high compared to others in the US	9(32.1)	12(52.2)
Ability to prevent is higher compared to infectious diseases	5(17.9)	7(30.4)
Personally worried about getting COVID-19	22(78.6)	20(86.9)
Worried about a family member getting COVID-19	26(92.9)	22(95.7)
Worried about the spread	24(85.7)	22(95.7)
Changes made to decrease risk of getting COVID-19		
washed hands more frequently	12(42.9)	18(78.3)
avoided eating in restaurants or food courts	12(42.9)	16(69.6)
avoided physical contact with others	12(42.9)	18(78.3)
maintained physical distance from others when you see them	12(42.9)	18(78.3)
avoided traveling to infected areas	11(39.3)	15(65.2)
avoided travel on airplanes	11(39.3)	17(73.9)
avoided travel via public transit	11(39.3)	17(73.9)
avoided public events/large gatherings	11(39.3)	18(78.3)
avoided moderate-sized gatherings	11(39.3)	18(78.3)
wore a mask	10(35.7)	16(69.6)
avoided public spaces for leisure, recreation, or non-essential outings	9(32.1)	12(52.2)
adapted schedule to avoid crowds	9(32.1)	13(56.5)
took extra care of cleanliness	8(28.6)	17(73.9)
used disinfectants	8(28.6)	17(73.9)
increased exercise	7(25.0)	11(47.8)
payed more attention to getting enough sleep	6(21.4)	9(39.1)
payed more attention to eating habits	5(17.9)	9(39.1)
avoided routine errands	4(14.3)	8(34.8)
took herbal supplements	2(7.1)	7(30.4)
other	1(3.6)	2(8.7)
Payed attention to information about changes and updates	26(92.9)	23(100.0)
Information about COVID-19		
health officials	10(35.7)	15(65.2)
televised news	9(32.1)	11(47.8)
friends and family	8(28.6)	7(30.4)
newspapers	7(25.0)	5(21.7)
doctors/medical professionals	6(21.4)	5(21.7)

social media	5(17.9)	6(26.1)
other online sources	4(14.3)	7(30.4)
magazines	1(3.6)	3(13.0)
other	4(14.3)	4(17.4)
Confidence in sources	26(92.9)	23(100.0)
Had/potentially had COVID-19	2(7.1)	1(4.3)
Personally know someone who had/may have had COVID-19	11(39.3)	8(34.8)
Know someone who personally knows someone who had/may have had COVID-19	6(21.4)	9(39.1)
Pandemic has affected stress	26(92.9)	22(95.7)
Pandemic has affected mental health	23(82.1)	20(87.0)
Pandemic has affected physical health	17(60.7)	17(73.9)

CHAPTER 6

DISCUSSION

Principal Findings

The purpose of the study was to test the feasibility and preliminary efficacy of a 4-week mindfulness meditation intervention delivered using a consumer-based mobile app (i.e. Calm) to reduce stress in middle-aged adults. This is one of the first studies to test an app-based mindfulness meditation app in midlife adults between the ages of 40 and 64. It was hypothesized that Calm would be feasible (i.e., accepted and demanded) as a result of the intervention, stress, anxiety, and depression would be reduced and mindfulness, physical activity, eating habits, and coping behaviors would be improved. Calm was perceived as feasible. Participants expressed that the app was enjoyable, easy to use, and were likely to continue using the app. There were insignificant between-group and within-group differences on all main outcome variables including perceived stress, anxiety, and depression, mindfulness, physical activity, eating habits, and coping behaviors. Findings suggest that Calm is well liked among middle-aged adults and further research with the app is warranted to determine if the app can improve outcomes of health and well-being in this population.

Feasibility

Acceptability of Calm

Participants in this study were satisfied with the Calm app, found it enjoyable, appropriate, and useful. These findings are similar to other app-based mindfulness meditation interventions such as a 10-day trial conducted in college students using

Headspace and Smiling Mind (Flett et al., 2019), a 30-day intervention in healthy adults using Headspace (Champion et al., 2018), and a feasibility study conducted in adult women (age was not reported) using the Headspace app for 30 days (Rung et al., 2020). Similar to our study, all of these studies asked their participants to participate for at least 10 minutes per day inside the app. All studies participants found the apps to be enjoyable, appropriate, and useful. However, it is difficult to compare feasibility of other mobile apps to Calm due to the various components such as application interfaces, usability, and length of programs not being identical (Huberty et al., 2019).

A study in cancer patients supports the feasibility of using Calm for 10 minutes per day for 8 weeks as compared to the 10% Happier app (Huberty et al., 2019,) and another in college students during an 8-week intervention (Huberty et al., 2019). Our feasibility findings are important because in order to test the efficacy of app-based mindfulness meditation to improve health outcomes research suggests apps to be easy to use and enjoyable so that participants continue to use the app and are able to achieve health benefits (Laurie & Blandford, 2016, Bowen et al., 2009).

Demand of Calm

Our benchmark of 70% adherence to the meditation prescription was met as we had 70% adhere to the 4-week meditation prescription, higher than many 4-week randomized controlled trials (Flett et al., 2019, Champion et al., 2018, Rung et al., 2020). In a recent 4-week study testing the feasibility and acceptability of a mobile mindfulness meditation (Headspace) intervention among women, only 13.5% (43/318) of their participants participated in the program (logged in to the Headspace app at least once)

(Rung et al., 2020). A randomized controlled trial testing the effect of two popular apps on mental health reported that app usage was high during the beginning 10-day period (8/10 days), but low during the following 30-days (extended use period) as less than 20% used the app two or more times a week (Flett et al., 2019). It is important to note that these studies measured adherence to the intervention using self-reported data. In a 30-day mobile app meditation study (Champion et al., 2018) only 20% of the participants (6/29) used the app for 25 or more of the 30 sessions and that collection of this data was also self-reported. Not only did we have better demand than other feasibility or pilot intervention using a mindfulness mobile app (Flett et al., 2019, Rung et al., 2020, Champion et al., 2018) we assessed adherence using app usage data provided by Calm. There are inherent limitations to self-reported data and future studies should consider using more objective measures for determining participation in meditation.

We did not meet our benchmark to recruit more than 75% men. Despite this, the percentage of men in this study was greater than other mindfulness meditation interventions (Huberty et al., 2019, Howells et al, 2016, Krushe et al., 2013, Cavanagh et al., 2013, Torous et al., 2018, Hwang & Jo, 2019). Krushe conducted a web-based mindfulness intervention requiring 10 sessions in a minimum of 4 weeks and only about 22% of the participants were male (Krushe et al., 2013). Hwang conducted a 4-week randomized controlled trail evaluating the effectiveness of a mobile app-based stress-management program and only 5% of the participants were male (Hwang & Jo, 2019). Many recent studies involving app-based meditation do not even include men at all (Coelhoso et al., 2019, Rung et al., 2020, Jones et al., 2019). Although the majority of

participants recruited for most mindfulness meditation studies are female, unlike this study, many researchers do not report focusing their recruitment efforts on the inclusion of men or report this as a limitation to their studies (Krushe et al., 2013, Torous et al., 2018, Hwang, 2019). Future interventions should continue to focus on the recruitment and retention of men to meditation interventions, especially because men are considered to be less likely to seek out stress management strategies, but similar to women, are still at risk for chronic diseases related to stress (Cohen and Janicki-Deverts, 2012, Mayor et al., 2015).

The findings suggest that an app-based, 4-week, 10 minutes per day mindfulness meditation intervention with Calm is feasible (accepted and demanded) in middle-aged adults. Participants expressed unanimous satisfaction and enjoyment with the intervention and felt it was appropriate and useful.

POD Control App

This is one of the first studies to test an active and comparable (i.e., time and attention) control app against a mindfulness meditation app. Future research testing comparable control apps should consider the structure and content of the app thoughtfully to avoid any outcome measure (e.g., stress) mitigating or aggravating effect. Future app-based, meditation interventions that focus on stress reduction should consider utilizing a comparable control app to test against their intervention and support their findings.

Primary Outcomes (Perceived Stress, anxiety, and depression)

This study was one of the first to examine the stress-reducing preliminary effects of mindfulness meditation using the mobile app Calm in middle-aged adults. There were

no reductions in stress, anxiety, or depression nor were there any trends in the right direction. In another 30-day, pilot, randomized controlled trial, Champion and colleagues tested the efficacy of an app-based mindfulness (Headspace) on psychosocial outcomes in healthy adults (N=74) compared to a waitlist control (Champion et al., 2018). Self-reported measures were collected at 10 and 30 days. The researchers saw a large improvement in stress at 10 days but less at 30 days in comparison to the control group. The main purpose of our study was feasibility. Feasibility studies are used to test an intervention in a limited way (Bowen et al., 2009), thus only four weeks in duration was necessary, similar to the duration of other feasibility studies (Chittaro & Vianello, 2016, Rung et al., 2020). It is likely that we did not see improvements in stress, anxiety, or depression in our study because of the duration (Huberty et al., 2019, Bostock et al., 2019) and it has been reported that it takes at least 4-weeks to see measurable changes in stress (Baer et al., 2012). Longer mindfulness meditation interventions are supported in an 8-week study targeting midlife adults, Bostock tested forty-five, 10-20 minutes app-based mindfulness sessions for 8-weeks compared to a waitlist control group (Bostock et al., 2019). Although adherence to the intervention was poor (an average 36% of the total sessions were completed), the researchers reported improved well-being and decreased distress at the end of the intervention. Improvements in perceived stress, mindfulness, and self-compassion were also reported in an 8-week study testing the efficacy of Calm to reduce stress in college students (N=72) compared to a waitlist control (Huberty et al., 2019). More research is warranted to determine the duration of time before changes in mental health are realized by participants. It is possible that with a longer intervention

(greater than 4-weeks) or follow up data collection, our study could have seen significant changes in stress, anxiety, and depression symptoms in a middle-aged population.

Secondary Outcomes (Mindfulness and Health Behaviors)

Mindfulness

Improvements in overall mindfulness from baseline to post-intervention (week 4) were not observed. This is consistent with a 4-week (28-day), app-based, randomized controlled trial testing mindfulness-based training against self-compassion training, and cognitive behaviors psychoeducation on mental health (Torous et al., 2018). Participants in the mindfulness-based program (n=703) were asked to complete 10-15-minute sessions daily and complete self-reported measures at baseline, post-intervention, and at a 3-month follow up. Significant improvements in mindfulness were not observed at post-intervention or follow-up and the researchers suggested longer mindfulness practice compared against a placebo control to see an effect. However, other 4-week (3-day) interventions have seen improvements in mindfulness (Bennike et al., 2017, Chittario & Vianello, 2016). In a 30-day, online, randomized control trial assessing mind wandering using the same mindfulness measure (MAAS) used in our intervention (Bennike et al., 2017), intervention participants (n=54) received online mindfulness training and the control group (n=41) received online brain training. Significant increases in mindfulness were observed in the intervention group when compared to the control. Additionally, in a 4-week, app-based study (Chittario & Vianello, 2016), participants downloaded the mindfulness app (AEON) and answered a mindfulness questionnaire at three time points over the four weeks. Results indicated that inexperienced meditators significantly

increased their mindfulness in 4-weeks after participating inside the app (Cittaro & Vianello, 2016). Objective usage data was collected to support these findings, but it was not compared against a control group. It is still unclear why some interventions show a positive effect of mindfulness after only 4 weeks and some take longer. The Calm group even had a slight negative trend at post-intervention, and this may have been due to the study being conducted during a pandemic. Additionally, participants in this study were asked to complete a 30-day “How to Meditate” series where each meditation focused on a different aspect of mindfulness. For each day (10-minute session), an educational component on a principle of mindfulness meditation was explained and discussed with a guided meditation following the discussion. It is possible that with longer time spent in guided meditation (at least 10 minutes or more) or a longer intervention duration (greater than 4 weeks), participants could have had more opportunities to apply what they learned in and outside of their meditation practice. It is also possible that with a focus on specific mindfulness meditation components participants could have had more time to improve on specific aspects of mindfulness meditation instead of being briefly exposed to many components. Cavanagh suggests that mindfulness meditation interventions may be more effective in the short-term when mindfulness training focuses on improving perseverative thinking (i.e. rumination) and future interventions may see similar effects as longer interventions by reducing perseverative thinking (Cavannagh et al., 2018). Future research is warranted on the appropriate meditation dose, intervention duration and timing, and what components of mindfulness are most effective at improving mindfulness in the short term.

Coping Behaviors

Insignificant changes in physical activity, eating habits, and coping behaviors were observed when measured from baseline to post-intervention (week 4). However, a slight negative impact on eating habits was observed. This is not surprising as stay-at-home orders were put into place as a result of a pandemic during this intervention. There is a lack of studies focusing on the effects of app-based mindfulness meditation on coping behaviors. Specifically, there is a lack of research on the effect mindfulness meditation on physical activity and eating behaviors as coping mechanisms for stress (Strowger et al., 2018). Many studies focus on physical activity and eating habits for the improvement of weight, weight loss, or other aspects of health (Ruffault et al., 2017, Schneider et al., 2019) but not for the purpose of coping with stress.

In a recent 4-week, 10 minutes per day, app-based (Headspace) mindfulness meditation intervention in a sample of adult women, insignificant changes in physical activity levels were reported (Rung et al., 2020) and no control group was used to support these findings. These findings are also consistent with the longer 8-week, mindfulness meditation intervention using Calm in college students (N=72). Changes were not observed in physical activity or eating habits (i.e., fruit and vegetable consumption) as a result of the intervention (Huberty et al., 2019). More research is warranted to assess the effects of app-based mindfulness meditation and the appropriate, dose, intervention duration, and mindfulness component(s) focus that is needed to see an impact on physical activity.

Although there is a lack of studies testing mindfulness meditation and its effects on coping behaviors, a recent study in students (N=71) received in person mindfulness meditation training followed by one-week of at home practice and self-reported coping flexibility over the next 3 weeks compared to a waitlist control group (Jones et al., 2019). Results from this study indicate that mindfulness meditation can increase coping flexibility and that greater meditation practice is correlated with better coping (Jones et al., 2019). The researchers suggested mindfulness meditation could increase one's ability to monitor and modify coping behaviors during times of stress (Jones et al., 2019). It is possible that greater effects could be observed when focusing mindfulness meditation training on a specific outcome (i.e. coping behaviors). Future research is needed to test the effects of app-based mindfulness meditation on coping behaviors related to stress.

Study Satisfaction Interview

Only a portion of the intervention participants volunteered for the post-intervention interview (19%) however, the interviews did provide further justification for future efficacy testing of Calm in middle-aged adults. Despite the lack of preliminary effects in the outcomes, all participants that were interviewed reported satisfaction with the intervention and would recommend it to someone else. Unanimous positive changes in mental health, physical health, and stress in the short term were reported and the majority reported positive changes in their sleep. This is consistent with a qualitative study that assessed adult cancer patients' and survivors' perceptions of the Calm app (Huberty et al., 2020). The survey included responses that were open-ended, but they did not utilize open communication (interview). Little conducted twelve, semi-structured (i.e.

script) interviewed to understand the extent to which mobile apps supported participant motivation, attitudes, and behaviors about meditation followed by an online survey (Little, 2016). Similar to this study, Little reported positive responses regarding app-based meditation usage with a small sample size (N=10) and expressed that it is hard to recruit for qualitative research. Qualitative research, specifically interviews, are an important tool to test the results observed in the qualitative data (Little, 2016). Future research should include post-intervention interviews to test the validity of its findings.

COVID-19 Survey

Although this study was not aimed at addressing outcomes related to perceptions of COVID-19, we collected this information because the study was aimed at preliminary effects on stress. COVID-19 has been strongly linked to changes in the way we live and work (Behan, 2020). These changes have led to overwhelming worry, fear, and negative coping behaviors that increase levels of stress (Behan, 2020) and may have impacted the findings of this study. The majority of participants reported feeling negatively impacted by the COVID-19 pandemic during the time of this intervention and (94%) reported an increase in stress and a deterioration of their mental and physical health. Participants were worried about contracting the virus, a loved one contracting the virus, and for the spread of the virus in their community. Although not many reported feeling personally at risk for contracting the virus, participants did report staying attentive to information regarding COVID-19 and adjusting their lifestyles to avoid contracting the virus. Unfortunately, three participants (6%) reported they had or potentially had been exposed to the virus and more reported personally knowing someone who did, and the majority of

participants reported knowing someone who personally knew someone who contracted the virus.

It is possible that meditation helped those in the intervention group maintain levels of stress, anxiety, and depression (as opposed to having heightened levels) due to COVID-19 over the 4 weeks even though the control group also did not see an increase in these outcomes. The general health education content of the control app may have also helped mitigate the impact of COVID-19. Future research is warranted on the impact of COVID-19 on stress and health outcomes related to stress and how a meditation app may buffer that impact.

Limitations

This study is not without its limitations. First, the majority of the sample was both white and female adults and therefore the generalizability of the findings may be limited. However, we were able to recruit 35% men which contributes to what is known about using a mobile app to deliver meditation to men (Fett et al., 2019, Duraimani et al., 2019). Future research should aim to recruit a more diverse sample (e.g., gender, race/ethnicity, and education level). Second, this intervention was only 4-weeks in length and did not include a follow-up. A longer intervention or follow up could provide more insight to the potential effect of app-based meditation and the ability for the Calm app to influence new users to continue use. Thirdly, all health outcome measures were self-reported and can lead to response bias when trying to recall past emotions or behaviors (Althubaiti, 2016). Additionally, the sample size of 60 was not large enough to have adequate power to analyze gender as a moderator to stress or health behaviors as a

mediator to stress to detect an effect. Future interventions should consider a greater sample size to analyze potential mediators or moderators to stress. Most importantly, due to the unforeseen and unfortunate timing of the COVID-19 pandemic in the United States, its negative impacts (e.g., fear of death of self or loved ones, restriction of human contact, restriction of social gatherings, restriction of large religious or spiritual activities, closers of gyms, loss of work, etc.) on society could have had an important impact on the findings of this study. We conducted a survey about COVID-19 perceptions to learn more about how COVID-19 might have impacted stress during the study. Meditation delivered via a mobile app may have helped participants to manage stress as we did not see an increase in stress, anxiety, or depression levels during this time.

Suggestions for future research

Research investigating the use of mobile applications to deliver mindfulness meditation to middle-aged adults to improve their health and well-being is in its infancy. However, due to the insignificant findings of this study, there is a need for further research to explore how app-based meditation can improve stress and other factors related to stress (i.e., anxiety and depressive symptoms, mindfulness, and health behaviors) in midlife adults. Future researchers should 1) Implement interventions that are longer than 4-weeks, 2) Examine the effects of Calm on health and well-being outcomes in a larger sample size, 3) Examine the effects of Calm on health and well-being in a more diverse sample of middle-aged adults, 4) Collect follow up data, 5) Conduct post-intervention interviews, 6) Consider objective measures of stress (e.g.

salivary cortisol levels), 7) Utilize a comparable (i.e. time and attention) control app as the control group, and 8) Consider outside influences on stress and timing of intervention.

CHAPTER 7

CONCLUSION

The findings of this study support the feasibility of a 4-week, mobile app-based mindfulness meditation intervention (i.e. Calm) in middle aged adults. These finding do not demonstrate the preliminary efficacy of Calm to reduce stress, anxiety, and depression or the improvement of mindfulness, physical activity, eating habits, or coping behaviors among middle-aged adults who report elevated stress. These finding are not consistent with other recent app-based interventions focusing on stress reduction. However, a 4-week app-based mindfulness meditation intervention with a comparable app-based control group may be feasible and less burdensome (i.e., components, time) way to deliver mindfulness meditation to midlife adults. These results may not have had a powerful implication for the general population of middle-aged adults but can be applied for improved design of future studies. Future research in middle-aged adults is warranted.

REFERENCES

- Alsubaie, M., Abbott, R., Dunn, B., Dickens, C., Keil, T. F., Henley, W., & Kuyken, W. (2017). Mechanisms of action in mindfulness-based cognitive therapy (MBCT) and mindfulness-based stress reduction (MBSR) in people with physical and/or psychological conditions: A systematic review. *Clinical Psychology Review, 55*, 74-91. doi:10.1016/j.cpr.2017.04.008
- APA Reports Results of Its Stress in America Survey. (2018). *Professional Services Close-Up*.
- Baer, R. A., Carmody, J., & Hunsinger, M. (2012). Weekly Change in Mindfulness and Perceived Stress in a Mindfulness-Based Stress Reduction Program. *Journal of Clinical Psychology, 68*(7), 755-765. doi:10.1002/jclp.21865
- Bale, T. L., & Epperson, C. N. (2015). Sex differences and stress across the lifespan. *Nature neuroscience, 18*(10), 1413-1420. doi:10.1038/nn.4112
- Behan, C. (2020). The benefits of Meditation and Mindfulness practices during times of crisis such as Covid-19. *Irish journal of psychological medicine, 1*-8. doi:10.1017/ipm.2020.38
- Birkner, C. (2017). Moment of Zen: meditation apps are helping consumers find peace in a hyper-connected world.(CHILL OUT). *ADWEEK, 58*(5), 10.
- Bjelland, I., Dahl, A. A., Haug, T. T., & Neckelmann, D. (2002). The validity of the Hospital Anxiety and Depression Scale: An updated literature review. In (Vol. 52, pp. 69-77).
- Black, D. S., & Slavich, G. M. (2016). Mindfulness meditation and the immune system: a systematic review of randomized controlled trials. *Annals of the New York Academy of Sciences, 1373*(1), 13-24. doi:10.1111/nyas.12998
- Blechert, J., Reichenberger, J., & Meule, A. (2018). Stress eating and emotional eating: new scales and new findings. *Appetite, 123*, 461-461. doi:10.1016/j.appet.2017.11.054
- Blewett, L., Rivera Drew, J., King, M., & Williams, K. (2019). IPUMS Health Surveys: National Health Interview Survey. In (6.4 ed.). Minneapolis, MN: IPUMS.
- Bostock, S., Crosswell, A. D., Prather, A. A., & Steptoe, A. (2019). Mindfulness On-The-Go: Effects of a Mindfulness Meditation App on Work Stress and Well-

- Being. *Journal of Occupational Health Psychology*, 24(1), 127-138.
doi:10.1037/ocp0000118
- Casey, G. (2017). Stress and disease. *Kai Tiaki : Nursing New Zealand*, 23(6), 20-24.
- Cavanagh, K., Churchard, A., O'Hanlon, P., Mundy, T., Votolato, P., Jones, F., . . . Strauss, C. (2018). A Randomised Controlled Trial of a Brief Online Mindfulness-Based Intervention in a Non-clinical Population: Replication and Extension. *Mindfulness*, 9(4), 1191-1205. doi:10.1007/s12671-017-0856-1
- Chambers, J., Phillips, B., Burr, M., & Xiao, D. (2016). Effects of Meditation on Stress Levels of Physical Therapist Students. *Journal of Physical Therapy Education*, 30(3), 33-39. doi:10.1097/00001416-201630030-00007
- Cherkin, D. C., Sherman, K. J., Balderson, B. H., Cook, A. J., Anderson, M. L., Hawkes, R. J., . . . Turner, J. A. (2016). Effect of Mindfulness-Based Stress Reduction vs Cognitive Behavioral Therapy or Usual Care on Back Pain and Functional Limitations in Adults With Chronic Low Back Pain: A Randomized Clinical Trial. *JAMA*, 315(12), 1240-1249. doi:10.1001/jama.2016.2323
- Coelhoso, C. C., Tobo, P. R., Lacerda, S. S., Lima, A. H., Barrichello, C. R. C., Amaro, E., & Kozasa, E. H. (2019). A new mental health mobile app for well-being and stress reduction in working women: Randomized controlled trial. *Journal of Medical Internet Research*, 21(11). doi:10.2196/14269
- Cohen, S., & Janicki-Deverts, D. (2012). Who's Stressed? Distributions of Psychological Stress in the United States in Probability Samples from 1983, 2006, and 2009. *Journal of Applied Social Psychology*, 42(6), 1320-1334. doi:10.1111/j.1559-1816.2012.00900.x
- Cooper, C., Katona, C., & Livingston, G. (2008). Validity and Reliability of the Brief COPE in Carers of People With Dementia: The LASER-AD Study. *Journal of Nervous and Mental Disease*, 838.
- Coulon, S. M., Monroe, C. M., & West, D. S. (2016). A Systematic, Multi-domain Review of Mobile Smartphone Apps for Evidence-Based Stress Management. *American Journal of Preventive Medicine*, 51(1), 95-105. doi:10.1016/j.amepre.2016.01.026
- Cramer, H., Hall, H., Leach, M., Frawley, J., Zhang, Y., Leung, B., . . . Lauche, R. (2016). Prevalence, patterns, and predictors of meditation use among US adults: A nationally representative survey. *Scientific Reports*, 6(1). doi:10.1038/srep36760

- Crane, R. S., Brewer, J., Feldman, C., Kabat-Zinn, J., Santorelli, S., Williams, J. M. G., & Kuyken, W. (2017). What defines mindfulness-based programs? The warp and the weft. In (Vol. 47, pp. 990-999).
- Creswell, J. D. (2017). Mindfulness Interventions. *Annu. Rev. Psychol.*, 68(1), 491-516. doi:10.1146/annurev-psych-042716-051139
- de Frias, C. M., & Whyne, E. (2015). Stress on health-related quality of life in older adults: the protective nature of mindfulness. *Aging & Mental Health*, 19(3), 201-206. doi:10.1080/13607863.2014.924090
- de Vibe, M., Solhaug, I., Tyssen, R., Friborg, O., Rosenvinge, J., Sørli, T., & Bjørndal, A. (2013). Mindfulness training for stress management: a randomised controlled study of medical and psychology students. *BMC Medical Education*, 13(1), 107. doi:10.1186/1472-6920-13-107
- Drozd, F., Raeder, S., Kraft, P., & Bjørkli, C. A. (2013). Multilevel growth curve analyses of treatment effects of a Web-based intervention for stress reduction: randomized controlled trial. *Journal of medical Internet research*, 15(4), e84. doi:10.2196/jmir.2570
- Duraimani, S. (2019). A Cross-sectional and longitudinal study of the effects of a mindfulness meditation mobile application platform on reducing stress and anxiety. *International Journal of Yoga*, 12(3), 226-232. doi:10.4103/ijoy.IJOY_56_18
- Eysenbach, G., Zhang, Y., Morrison, L., van Harten, W., Subnis, U., Jacob, C., . . . Mesa, R. (2019). Smartphone-Based Meditation for Myeloproliferative Neoplasm Patients: Feasibility Study to Inform Future Trials. *JMIR Formative Research*, 3(2). doi:10.2196/12662
- Flett, J., Hayne, H., Riordan, B., Thompson, L., & Conner, T. (2019). Mobile Mindfulness Meditation: a Randomised Controlled Trial of the Effect of Two Popular Apps on Mental Health. *Mindfulness*, 10(5), 863-876. doi:10.1007/s12671-018-1050-9
- Flook, L., Goldberg, S. B., Pinger, L., Bonus, K., & Davidson, R. J. (2013). Mindfulness for Teachers: A Pilot Study to Assess Effects on Stress, Burnout, and Teaching Efficacy. *Mind, Brain, and Education*, 7(3), 182-195. doi:10.1111/mbe.12026
- Glasscock, D., Carstensen, O., & Dalgaard, V. (2018). Recovery from work-related stress: a randomized controlled trial of a stress management intervention in a clinical sample. *International Archives of Occupational and Environmental Health*, 91(6), 675-687. doi:10.1007/s00420-018-1314-7

- Goyal, M., Singh, S., Sibinga, E. M. S., Gould, N. F., Rowland-Seymour, A., Sharma, R., . . . Haythornthwaite, J. A. (2014). Meditation Programs for Psychological Stress and Well-being: A Systematic Review and Meta-analysis. *JAMA Internal Medicine, 174*(3), 357-368. doi:10.1001/jamainternmed.2013.13018
- Gu, J., Strauss, C., Bond, R., & Cavanagh, K. (2015). How do mindfulness-based cognitive therapy and mindfulness-based stress reduction improve mental health and wellbeing? A systematic review and meta-analysis of mediation studies. *Clinical Psychology Review, 37*, 1-12. doi:10.1016/j.cpr.2015.01.006
- Heber, E., Ebert, D. D., Lehr, D., Nobis, S., Berking, M., & Riper, H. (2013). Efficacy and cost-effectiveness of a web-based and mobile stress-management intervention for employees: design of a randomized controlled trial. *BMC Public Health, 13*, urn:issn:1471-2458.
- Howells, A., Ivtzan, I., & Eiroa-Orosa, F. (2016). Putting the 'app' in Happiness: A Randomised Controlled Trial of a Smartphone-Based Mindfulness Intervention to Enhance Wellbeing. *Journal of Happiness Studies, 17*(1), 163-185. doi:10.1007/s10902-014-9589-1
- Huberty, J., Green, J., Glissmann, C., Larkey, L., Puzia, M., & Lee, C. (2019). Efficacy of the Mindfulness Meditation Mobile App "Calm" to Reduce Stress Among College Students: Randomized Controlled Trial. *JMIR mHealth and uHealth, 7*(6), e14273-e14273. doi:10.2196/14273
- Hwang, W. J., & Jo, H. H. (2019). Evaluation of the Effectiveness of Mobile App-Based Stress-Management Program: A Randomized Controlled Trial. *International journal of environmental research and public health, 16*(21). doi:10.3390/ijerph16214270
- Jones, D. R., Lehman, B. J., Noriega, A., & Dinnel, D. L. (2019). The effects of a short-term mindfulness meditation intervention on coping flexibility. *Anxiety Stress Coping, 32*(4), 347-361. doi:10.1080/10615806.2019.1596672
- Josefsson, T., Lindwall, M., & Broberg, A. (2014). The Effects of a Short-term Mindfulness Based Intervention on Self-reported Mindfulness, Decentering, Executive Attention, Psychological Health, and Coping Style: Examining Unique Mindfulness Effects and Mediators. *Mindfulness, 5*(1), 18-35. doi:10.1007/s12671-012-0142-1
- Kabat-Zinn, J. (2003). Mindfulness-Based Interventions in Context: Past, Present, and Future. *Clinical Psychology: Science and Practice, 10*(2), 144. doi:10.1093/clipsy/bpg016

- Karaca, A., & Şişman, N. (2019). Effects of a Stress Management Training Program With Mindfulness-Based Stress Reduction. *Journal of Nursing Education, 58*(5), 273-280. doi:10.3928/01484834-20190422-05
- Khalili, R., Sirati Nir, M., Ebadi, A., Tavallai, A., & Habibi, M. (2017). Validity and reliability of the Cohen 10-item Perceived Stress Scale in patients with chronic headache: Persian version. *Asian Journal of Psychiatry, 26*, 136-140. doi:10.1016/j.ajp.2017.01.010
- Klatt, M. D., Buckworth, J., & Malarkey, W. B. (2009). Effects of Low-Dose Mindfulness-Based Stress Reduction (MBSR-ld) on Working Adults. *Health Education & Behavior, 36*(3), 601-614. doi:10.1177/1090198108317627
- Kristoffersen, A. E., Stub, T., Salamonsen, A., Musial, F., & Hamberg, K. (2014). Gender differences in prevalence and associations for use of CAM in a large population study. *BMC complementary and alternative medicine, 14*(1), 463. doi:10.1186/1472-6882-14-463
- Krusche, A., Cyhlarova, E., King, S., & Williams, J. M. G. (2012). Mindfulness online: a preliminary evaluation of the feasibility of a web-based mindfulness course and the impact on stress. *BMJ Open, 2*(3). doi:10.1136/bmjopen-2011-000803
- Krusche, A., Cyhlarova, E., & Williams, J. M. G. (2013). Mindfulness online: an evaluation of the feasibility of a web-based mindfulness course for stress, anxiety and depression. *BMJ Open, 3*(11). doi:10.1136/bmjopen-2013-003498
- Larson, R. S. (2018). A Path to Better-Quality mHealth Apps. *JMIR mHealth and uHealth, 6*(7), e10414-e10414. doi:10.2196/10414
- Little, D. (2016). Supporting or inhibiting motivations to meditate? A semi- structured interview study of the user experience of mobile mindfulness apps. In. University College London.
- Lloyd, A., White, R., Eames, C., & Crane, R. (2018). The Utility of Home-Practice in Mindfulness-Based Group Interventions: A Systematic Review. *Mindfulness, 9*(3), 673-692. doi:10.1007/s12671-017-0813-z
- Louise, C., Marcos, E., & Chris, C. (2018). The efficacy of a brief app-based mindfulness intervention on psychosocial outcomes in healthy adults: A pilot randomised controlled trial. *PloS one, 13*(12), e0209482. doi:10.1371/journal.pone.0209482

- Luis, G. J., & Robert, S. (2018). Mobile Stress Interventions: Mechanisms and Implications. *EAI Endorsed Transactions on Pervasive Health and Technology*, 4(13), 1-14. doi:10.4108/eai.28-2-2018.154343
- Mak, W. W., Tong, A. C., Yip, S. Y., Lui, W. W., Chio, F. H., Chan, A. T., & Wong, C. C. (2018). Efficacy and Moderation of Mobile App-Based Programs for Mindfulness-Based Training, Self-Compassion Training, and Cognitive Behavioral Psychoeducation on Mental Health: Randomized Controlled Noninferiority Trial. *JMIR mental health*, 5(4), e60-e60. doi:10.2196/mental.8597
- Mani, M., Kavanagh, D. J., Hides, L., & Stoyanov, S. R. (2015). Review and Evaluation of Mindfulness-Based iPhone Apps. *JMIR mHealth and uHealth*, 3(3), e82. doi:10.2196/mhealth.4328
- Matud, M. P. (2004). Gender differences in stress and coping styles. *Personality and Individual Differences*, 37(7), 1401-1415. doi:10.1016/j.paid.2004.01.010
- Mayor, E. (2015). Gender roles and traits in stress and health. *Frontiers in psychology*, 6, 779-779. doi:10.3389/fpsyg.2015.00779
- Meule, A., Reichenberger, J., & Blechert, J. (2018). Development and preliminary validation of the Salzburg Stress Eating Scale. *Appetite*, 120, 442-448. doi:10.1016/j.appet.2017.10.003
- Michie, S. (2002). CAUSES AND MANAGEMENT OF STRESS AT WORK. *Occupational and Environmental Medicine*, 59(1), 67. doi:10.1136/oem.59.1.67
- Munoz, R. T., Hoppes, S., Hellman, C. M., Brunk, K. L., Bragg, J. E., & Cummins, C. (2018). The Effects of Mindfulness Meditation on Hope and Stress. *Research on Social Work Practice*, 28(6), 696-707. doi:10.1177/1049731516674319
- Neary, M., & Schueller, S. M. (2018). State of the Field of Mental Health Apps. *Cognitive and Behavioral Practice*, 25(4), 531-537. doi:10.1016/j.cbpra.2018.01.002
- O'Cathain, A., Hoddinott, P., Lewin, S., Thomas, K. J., Young, B., Adamson, J., . . . Donovan, J. L. (2015). Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. *Pilot Feasibility Stud*, 1, 32. doi:10.1186/s40814-015-0026-y
- O'Connor, P. J., & Brown, C. M. (2016). Sex-linked personality traits and stress: Emotional skills protect feminine women from stress but not feminine

- men. *Personality and Individual Differences*, 99, 28-32.
doi:10.1016/j.paid.2016.04.075
- Olano, H. A., Kachan, D., Tannenbaum, S. L., Mehta, A., Annane, D., & Lee, D. J. (2015). Engagement in Mindfulness Practices by U.S. Adults: Sociodemographic Barriers. *The Journal of Alternative and Complementary Medicine*, 21(2), 1-102.
doi:10.1089/acm.2014.0269
- Oyama, H., & Sakashita, T. (2014). Differences in specific depressive symptoms among community-dwelling middle-aged Japanese adults before and after a universal screening intervention. *Soc Psychiatry Psychiatr Epidemiol*, 49(2), 251-258.
doi:10.1007/s00127-013-0735-6
- O'Brien, L., Mathieson, K., Leafman, J., & Rice-Spearman, L. (2012). Level of Stress and Common Coping Strategies Among Physician Assistant Students. *The Journal of Physician Assistant Education*, 23(4), 25-29. doi:10.1097/01367895-201223040-00006
- Pepping, C., Walters, B., Davis, P., & O'Donovan, A. (2016). Why Do People Practice Mindfulness? An Investigation into Reasons for Practicing Mindfulness Meditation. *Mindfulness*, 7(2), 542-547. doi:10.1007/s12671-016-0490-3
- Price, M., Yuen, E. K., Goetter, E. M., Herbert, J. D., Forman, E. M., Acierno, R., & Ruggiero, K. J. (2014). mHealth: A Mechanism to Deliver More Accessible, More Effective Mental Health Care. *Clinical Psychology & Psychotherapy*, 21(5), 427-436. doi:10.1002/cpp.1855
- Rao, M. S. (2016). Innovative tools and techniques to manage your stress to ensure work-life balance. *Industrial and Commercial Training*, 48(6), 320-324.
doi:10.1108/ICT-05-2015-0035
- Raspopow, K., Matheson, K., Abizaid, A., & Anisman, H. (2013). Unsupportive social interactions influence emotional eating behaviors. The role of coping styles as mediators. *Appetite*, 62, 143-149. doi:10.1016/j.appet.2012.11.031
- Ratanasiripong, P., Park, J. F., Ratanasiripong, N., & Kathalae, D. (2015). Stress and Anxiety Management in Nursing Students: Biofeedback and Mindfulness Meditation. *The Journal of nursing education*, 54(9), 520-524.
doi:10.3928/01484834-20150814-07
- Richardson, K. M., & Rothstein, H. R. (2008). Effects of Occupational Stress Management Intervention Programs: A Meta-Analysis. *Journal of Occupational Health Psychology*, 13(1), 69-93. doi:10.1037/1076-8998.13.1.69

- Rose, R. D., Buckey, J. C., Zbozinek, T. D., Motivala, S. J., Glenn, D. E., Cartreine, J. A., & Craske, M. G. (2013). A randomized controlled trial of a self-guided, multimedia, stress management and resilience training program. *Behaviour Research and Therapy*, *51*(2), 106-112. doi:10.1016/j.brat.2012.11.003
- Ruffault, A., Czernichow, S., Hagger, M. S., Ferrand, M., Erichot, N., Carette, C., . . . Flahault, C. (2017). The effects of mindfulness training on weight-loss and health-related behaviours in adults with overweight and obesity: A systematic review and meta-analysis. *Obesity Research & Clinical Practice*, *11*(5), 90-111. doi:10.1016/j.orcp.2016.09.002
- Rung, A. L., Oral, E., Berghammer, L., & Peters, E. S. (2020). Feasibility and Acceptability of a Mobile Mindfulness Meditation Intervention Among Women: Intervention Study. *JMIR mHealth and uHealth*, *8*(6), e15943. doi:10.2196/15943
- Salleh, M. R. (2008). Life event, stress and illness. *The Malaysian journal of medical sciences : MJMS*, *15*(4), 9-18.
- Sanda, B., Vistad, I., Haakstad, L. A. H., Berntsen, S., Sagedal, L. R., Lohne-Seiler, H., & Torstveit, M. K. (2017). Reliability and concurrent validity of the International Physical Activity Questionnaire short form among pregnant women. *BMC sports science, medicine & rehabilitation*, *9*(1), 7. doi:10.1186/s13102-017-0070-4
- Schneider, J., Malinowski, P., Watson, P. M., & Lattimore, P. (2019). The role of mindfulness in physical activity: a systematic review. *Obesity reviews : an official journal of the International Association for the Study of Obesity*, *20*(3), 448. doi:10.1111/obr.12795
- Shaner, L., Kelly, L., Rockwell, D., & Curtis, D. (2017). Calm Abiding: The Lived Experience of the Practice of Long-Term Meditation. *Journal of Humanistic Psychology*, *57*(1), 98-121. doi:10.1177/0022167815594556
- Sieverdes, J. C., Adams, Z. W., Nemeth, L., Brunner-Jackson, B., Mueller, M., Anderson, A., . . . Treiber, F. A. (2017). Formative evaluation on cultural tailoring breathing awareness meditation smartphone apps to reduce stress and blood pressure. *mHealth*, *3*, 44-44. doi:10.21037/mhealth.2017.09.04
- Spears, C., Houchins, S., Bamatter, W., Barrueco, S., Hoover, D., & Perskaudas, R. (2017). Perceptions of Mindfulness in a Low-Income, Primarily African American Treatment-Seeking Sample. *Mindfulness*, *8*(6), 1532-1543. doi:10.1007/s12671-017-0720-3

- Strowger, M., Kiken, L. G., & Ramcharran, K. (2018). Mindfulness Meditation and Physical Activity: Evidence From 2012 National Health Interview Survey. *Health Psychology, 37*(10), 924-928. doi:10.1037/hea0000656
- The, L. (2016). The health crisis of mental health stigma. *The Lancet, 387*(10023), 1027-1027. doi:10.1016/S0140-6736(16)00687-5
- Thornicroft, G., Mehta, N., Clement, S., Evans-Lacko, S., Doherty, M., Rose, D., . . . Henderson, C. (2016). Evidence for effective interventions to reduce mental-health-related stigma and discrimination. *The Lancet, 387*(10023), 1123-1132. doi:10.1016/S0140-6736(15)00298-6
- Torous, J., Lo, H. M. H., Boettcher, J., Boeldt, D., Mak, W. W. S., Tong, A. C. Y., . . . Wong, C. C. Y. (2018). Efficacy and Moderation of Mobile App-Based Programs for Mindfulness-Based Training, Self-Compassion Training, and Cognitive Behavioral Psychoeducation on Mental Health: Randomized Controlled Noninferiority Trial. *JMIR Mental Health, 5*(4). doi:10.2196/mental.8597
- van Emmerik, A. A. P., Berings, F., & Lancee, J. (2018). Efficacy of a Mindfulness-Based Mobile Application: a Randomized Waiting-List Controlled Trial. *Mindfulness, 9*(1), 187-198. doi:10.1007/s12671-017-0761-7
- Varti, A. M., Oenema, A., Schreck, M., Uutela, A., Zwart, O., Brug, J., & Aro, A. (2009). SARS Knowledge, Perceptions, and Behaviors: a Comparison between Finns and the Dutch during the SARS Outbreak in 2003. *International Journal of Behavioral Medicine, 16*(1), 41-48. doi:10.1007/s12529-008-9004-6
- Wang, C., Chen, P., & Zhuang, J. (2013). Validity and Reliability of International Physical Activity Questionnaire-Short Form in Chinese Youth. *Research Quarterly for Exercise and Sport, 84*(S2), S80-S86. doi:10.1080/02701367.2013.850991
- Williams, V. A.-L., Ness, V. P., Dixon, V. J., & McCorkle, V. R. (2012). Barriers to Meditation by Gender and Age Among Cancer Family Caregivers. *Nursing Research, 61*(1), 22-27. doi:10.1097/NNR.0b013e3182337f4d
- Woodhead, E. L., Cronkite, R. C., Moos, R. H., & Timko, C. (2014). Coping Strategies Predictive of Adverse Outcomes among Community Adults. *Journal of Clinical Psychology, 70*(12), 1183-1195. doi:10.1002/jclp.21924
- Yusoff, M. S. B. (2011). The validity of the Malay Brief COPE in identifying coping strategies among adolescents in secondary school. *International Medical Journal, 18*(1), 29-33.

Zhang, H. (2018). New Media, Part Six: “Patient-Centered” Mobile Apps for Meditation and Stress Reduction. *Journal of Palliative Medicine*, 21(10), 1537-1538.
doi:10.1089/jpm.2018.0434

APPENDIX A
SATISFACTION SURVEY

1. On a scale from 1-5, (i.e., 1- not at all helpful, 5- very helpful) How helpful was Calm in reducing your stress in the short-term?
2. On a scale from 1-5, how helpful do you feel Calm will be in reducing your stress in the long-term?
3. Did Calm help to increase awareness of the importance of addressing stress?
 - a. Yes, please explain
 - b. No, please explain
4. Would you use Calm to help reduce your stress in the future? Provide reasoning.
 - a. Yes
 - b. Maybe
 - c. No
5. Provide your reasoning for selecting the answer you did.
6. How would you rate your overall satisfaction with participating in the 30 day, “How to Meditate” meditation series (i.e. content, or pleased)?
 - a. Very much satisfied
 - b. Somewhat satisfied
 - c. Neither satisfied nor dissatisfied
 - d. Somewhat dissatisfied
 - e. Very much dissatisfied
7. Participating in the 30 day, “How to Meditate” meditation series was enjoyable (i.e. engaging, or pleasurable).
 - a. Very much enjoyable
 - b. Somewhat enjoyable
 - c. Neither enjoyable nor unenjoyable
 - d. Somewhat unenjoyable
 - e. Very much unenjoyable
8. How likely are you to continue using the Calm app?
 - a. Extremely likely
 - b. Likely
 - c. Neutral
 - d. Unlikely
 - e. Extremely unlikely
9. If you are likely, why are you likely to continue to use Calm?
10. If you answered unlikely, why are you unlikely to continue to use Calm?
11. How likely are you to recommend the Calm app to other adults (e.g., friends, colleagues, family)?
 - a. Extremely likely
 - b. Likely
 - c. Neutral
 - d. Unlikely
 - e. Extremely unlikely
12. If you are likely, why are you likely to continue to use Calm?
13. If you answered unlikely, why are you unlikely to continue to use Calm?
14. What meditation(s) did you find the most enjoyable? _____

15. What meditation(s) did you not find enjoyable? _____

APPENDIX B
INTERVIEW QUESTIONS

1. Have you noticed any changes in your sleep while participating in this study?
 - a. If yes, what has changed?
 - b. If yes, what do you think has contributed to these changes?
2. Do you feel that your physical health has changed at all while participating in this study?
 - a. Fatigue levels? Overall health?
 - b. If yes, what has changed?
 - c. If yes, what do you think has contributed to these changes?
3. Do you feel that your mental health has changed at all while participating in this study?
 - a. Self-esteem? Mental/emotional well-being?
 - b. If yes, what has changed?
 - c. If yes, what do you think has contributed to these changes?
4. Has meditation using the Calm app impacted your life in any other ways?
5. What did you like or dislike about the podcast content?
6. What are your intentions about continuing meditation using the Calm app?
 - a. Do you intend to continue meditating?
 - b. Do you intend to try out another meditation app or in-person group meditation?
 - c. Are there any other complementary approaches that you are interested in trying? (Tai Chi? Qi Gong? Massage? etc.)
7. What were some of the barriers you encountered while meditating using a smartphone app?
8. What were some of the benefits of meditating while using a smartphone app?
 - a. Ease of access? Lack of distractions from group atmosphere? Etc.
9. If someone asked you what you thought about them participating in smartphone-based intervention, what advice would you give them?
10. What did you like most about using the Calm/Podcast application?
11. What did you like least about using the Calm/Podcast application?

APPENDIX C
COVID-19 SURVEY

Risk perceptions

How would you describe your personal risk of getting COVID-19?

(1= very low, 2=low, 3=moderate, 4=high, 5= very high)

Compared to other women in the United States, how would you describe your personal risk of getting COVID-19?

(1=much lower, 2=lower, 3=about the same, 4=higher, 5=much higher)

How would you describe your ability to prevent getting COVID-19?

(1= very low, 2=low, 3=moderate, 4=high, 5= very high)

Compared to other women in the United States, how would you describe your ability to prevent getting COVID-19?

(1=much lower, 2=lower, 3=about the same, 4=higher, 5=much higher)

Compared to infectious diseases in general, how would you describe your ability to prevent getting COVID-19?

(1=much lower, 2=lower, 3=about the same, 4=higher, 5=much higher)

Worry

How worried are you about...

... personally getting COVID-19?

... a family member getting COVID-19?

... the spread of COVID-19 in in your area?

(1=not at all worried, 2=a little worried, 3=somewhat worried, 4=a good bit worried, 5=very worried)

Precautionary behaviors

What, if any, changes have you made to decrease your risk of getting COVID-19

- avoiding traveling to affected areas
- avoiding eating in restaurants or food courts
- avoiding physical contact with others (e.g., shaking hands)
- maintaining physical distance from others when you see them
- avoiding travel on airplanes
- avoiding travel via other modes of public transit (e.g., taxis, trains, subways)
- avoiding public events/large gatherings
- avoiding moderate-sized gatherings (e.g., with groups of friends or family members)
- avoiding public spaces for leisure, recreation, or other non-essential outings (e.g., parks, gyms, etc.)
- avoiding routine errands (e.g., grocery store, pharmacy)
- adapting your schedule to avoid crowds
- wearing a mask
- washing hands more frequently
- taking extra care of cleanliness
- using disinfectants
- paying more attention to eating habits (e.g., eating a balanced diet)
- increasing exercise
- taking herbal supplements

- paying more attention to getting enough sleep
- other? describe

Information sources

How would you rate your attentiveness to information about ongoing changes and updates regarding the COVID-19?

(1=not at all paying attention to, 5=very much paying attention to)

Where do you receive information about the COVID-19?

- Newspapers
- Televised news
- Magazines
- Social media
- Other online sources (not including online newspapers, television news networks, or magazines)
- Health officials (e.g., CDC, WHO, state health officials)
- Doctors/medical professionals
- Friends and family
- Other (please describe)

[For endorsed sources] How much confidence do you place in the information you receive from these sources (e.g., accuracy)
(1=none/very little, 5=very much)

Do you have/potentially have COVID-19?

Do you personally know someone who has/may have COVID-19?

Do you know someone who personally knows someone who has/may have COVID-19?

To what extent do you feel the COVID-19 pandemic has affected your stress?

Not at all	A little bit	Neutral	Quite a bit	A lot
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To what extent do you feel the COVID-19 pandemic has affected your mental health?

Not at all	A little bit	Neutral	Quite a bit	A lot
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To what extent do you feel the COVID-19 pandemic has affected your physical health?

Not at all	A little bit	Neutral	Quite a bit	A lot
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APPENDIX D
IRB APPROVAL LETTER



APPROVAL: EXPEDITED REVIEW

[Jennifer Huberty](#)
[Exercise Science and Health Promotion](#)

-
 Jennifer.Huberty@asu.edu

Dear [Jennifer Huberty](#):

On 1/1/2020 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Feasibility of using a mobile app (i.e., Calm) to decrease overall stress in middle-aged (i.e., 40-64 years) men and women who report high stress (>15 on PSS).
Investigator:	Jennifer Huberty
IRB ID:	STUDY00011219
Category of review:	
Funding:	Name: Arizona State University (ASU)
Grant Title:	
Grant ID:	
Documents Reviewed:	<ul style="list-style-type: none"> • Baseline Questionnaires, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Diane Ehlers CITI Cert, Category: Other; • Eligibility Survey, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Exempt Wizard Pilot Completion, Category: Other; • Funding, Category: Sponsor Attachment; • Informed Consent, Category: Consent Form; • Intervention Questionnaires, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Interview Questions, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);

	<ul style="list-style-type: none"> • Participant Scripts, Category: Participant materials (specific directions for them); • Post-Intervention Questionnaires, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Protocol, Category: IRB Protocol; • Recruitment Blurbs, Category: Recruitment Materials; • Recruitment Flier, Category: Recruitment Materials;
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The IRB approved the protocol from 1/1/2020 to 12/31/2020 inclusive. Three weeks before 12/31/2020 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 12/31/2020 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Breanne Laird
Holly O'Rourke
Breanne Laird
Diane Ehlers
Linda Larkey

APPENDIX E
RESEARCH GRANT AWARD NOTICE

ASU Graduate & Professional Student Association
Research Grant Program (2019-2020)
sent by: Sierra Ferguson

February 10th, 2020

Dear Breanne-

Thank you for submitting an application to the GPSA and ASU Graduate College Graduate Research and Support Program (GRSP). We appreciate your passion for graduate research and your commitment to academics at ASU.

Congratulations! We are pleased to inform you that your project titled Breanne Laird has been selected for funding in the amount of \$2,000. The reviewer committee is confident your outstanding project demonstrates the high caliber of graduate student research that we have come to expect at Arizona State University.

The Graduate Research Support program is administered by the GPSA and the Graduate College. Over the next week, we will be preparing the paperwork for your grant, during which time we will transfer your information to the Graduate College who will administer your grant funds.

A copy of your itemized budget will be on file with the Graduate College. You can either save all your receipts and invoices for your requested funds and request a reimbursement every 30 days or work directly with the Graduate College Business Office to make purchases. More information regarding the purchasing and reimbursement process can be found in the attached PowerPoint.

REIMBURSEMENT

You may request reimbursement for expenses beginning January 1st, 2020 through May 1st, 2020. Although you have been selected for funding, reimbursement is contingent upon Graduate College approval of eligible expenses. Any questions about allowable expenses should be emailed to the Graduate College staff at (grad-gpsa@asu.edu) for approval prior to purchasing. Please include a copy of your award letter when requesting funds. Final reimbursement decisions are made by Graduate College. The Graduate Research Support Program will NOT reimburse the following:

1. Equipment purchase (no laptops, no camera, etc.)
2. Any single transaction greater than or equal to \$1,000
3. Tuition or remuneration of time spent on project
4. Conference travel (although travel for data collection is allowed)
5. Terminal publication charges (e.g., binding/printing of thesis or dissertation)
6. Dissertation expenses (i.e., printing, editing, translation of dissertation, etc.)
7. Salaries and wages for research assistants, ASU affiliates or employees

IMPORTANT: HOW TO ACCEPT YOUR AWARD

In order to access the funds you have been awarded, you must email gpsa.research@gmail.com and state that you 1) Accept the award and 2) Agree to the awardee responsibilities listed below. Failure to do so will result in forfeiture of your award.

AWARDEE'S RESPONSIBILITIES

Funded grant recipients will:

1. Be responsible for bringing the project to completion within the stated time period.
2. Ensure appropriate expenditure of funds.

PLEASE NOTE: Expenses need to be turned in to Graduate College within 30 days of expenditure. You do not need to spend all of the award at once. But for each purchase, you need to turn in your receipt and appropriate paperwork within thirty days.

3. Acknowledge in any public presentation and publication of the results, the support provided by GPSA and the Graduate College.

PROGRESS REPORT

As a condition of the Graduate Research Support Program award, all grant recipients are required to submit an electronic copy of a progress report which is due no later than April 24th, 2020. This report should not be a copy of the thesis or dissertation, but rather, a summary of the research that clearly states the justifications and significance of the project's outcome or progress. The copy of this final report must be three (3) pages and turned in electronically to gpsa.research@gmail.com.

AWARD RECOGNITION

We will be honoring you at the Graduate Student Symposium before the Change the World event on April 2nd, 2020. We will email you with more details in the coming months. You are also invited to present the results of your research as a part of the GPSA section at Change the World.

OTHER AWARD INFORMATION

Please review the attached PowerPoint for more detailed information about your award. The PowerPoint includes information on allowable expenses, processes for purchasing different items, and the reimbursement process. The reimbursement form is also attached.

PLEASE NOTE: It is YOUR responsibility to review the funding rules, processes, and reimbursement requirements. Failure to follow Graduate College, Graduate & Professional Student Association, and Arizona State University policies could result in failure to receive any funds/reimbursement. To ensure that you understand the rules and processes associated with this award, please carefully review the attached PowerPoint AND attend Office Hours with Graduate College (see details below).

FUNDING QUESTIONS?

Please contact the graduate college (grad-gpsa@asu.edu), if you have questions about the funding process, or to verify the eligibility of any imminent purchases.

We look forward to seeing the results of your research.

Sincerely,

Sierra Ferguson
Vice President of Internal Affairs
Graduate and Professional Student Association (GPSA)