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The CALM Project: Teaching Mindfulness Meditation in Primary Care Using Computer-Based Application

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The CALM Project: Teaching Mindfulness Meditation in Primary Care Using Computer-Based Application

by

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Approval Page

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Abstract

Mindfulness-based interventions (MBI) have been studied extensively and the evidence is now credible that even brief techniques, delivered electronically using web-based applications (apps), easily accessed by smart phone, computer, or tablet, are consistently effective at anxiety reduction as well demonstrating efficacy in other commonly occurring comorbidities such as depression, stress, and panic symptoms. The purpose of this DNP project was to examine feasibility and the effect of the app, Calm.com, on anxious adult patients in primary care, using the Recovery Alliance Theory as its theoretical foundation. This pilot study was longitudinal, using a pre-test/post-test measurement of the Generalized Anxiety Disorder Seven-Item Scale (GAD-7), electronic collection of time the app was used, and qualitative measures in a group of 15 adult primary care patient volunteers. The MBI consisted of 28-sessions, varying in length from 9-18 minutes consisting of education on mindfulness and guided meditation practice. Changes in the pre/post GAD-7 scores were significant (p= 0.01), with a trend toward improvement in symptoms with more use of the app, but the changes were statistically insignificant (p= 0.20). The qualitative data confirmed participants' belief that the app was beneficial in helping them learn to relax, using short educational sessions. This project adds to the evidence that a web-based app is an evidence-based option for management of anxiety in adult primary care patients.

Keywords: mindfulness-based interventions (MBI), web-based applications (apps), smart phone, Recovery Alliance Theory, anxiety, Calm.com

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Isaiah 41:1 Fear not, for I *am* with you; be not dismayed, for I am your God. I will strengthen you, yes, I will help you. I will uphold you with my righteous right hand.

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CHAPTER I

Introduction

Anxiety disorders are the most commonly diagnosed mental disorders in Americans, affecting 18.1% of adults in any given year and posing a 28.8% lifetime risk (National Institute of Mental Health [NIMH], n.d.). However, prevalence in primary care has been shown to be higher than in the general population (Kroenke, Spitzer, Williams, Monahan, & Lowe, 2007). Patients with generalized anxiety disorder (GAD) preferentially present to their primary care providers (PCP) rather than a psychiatrist, frequently complaining of multiple, seemingly unrelated somatic symptoms at visits characterized by limited time constraints (Shear & Schulberg, 1995). Coupled with lack of familiarity with psychiatric diagnoses and a strong predisposition to rule out physical pathology first, these patients often generate costly, unnecessary, time-consuming work up with ultimate failure to appreciate or treat the actual diagnosis (Allgulander, 2006).

The economic burden to society, including both direct and indirect costs has been estimated to be on the order of $48 billion dollars annually (Shimeshan, 2014). The four anxiety disorders most often encountered in primary care are generalized anxiety disorder (GAD), panic disorder, social anxiety disorder, and posttraumatic stress disorder (PTSD), with about a third of these patients having two or more anxiety disorders (Kroenke et al., 2007). Descriptions of these disorders (World Health Organization, 2016) are given in Table 1. Of these four anxiety disorders, GAD is associated with the highest rates of comorbidity with other anxiety disorders, as well as with depressive disorders, chronic pain, unexplained physical complaints, and sleep disorders (Nutt, Argyropoulos, Hood, & Potokar, 2006). Not surprisingly, patients diagnosed with GAD generate nearly twice the annual costs in primary care when compared to patients without GAD ($2,375 versus

$1,448) and generate about $2,000 more in total health care costs yearly than patients with any other anxiety disorder (Revicki et al., 2012).

Table 1

ICD 10 Descriptions of Most Common Anxiety Disorders Encountered in Primary Care

(World Health Organization, 2016)

ICD 10 Descriptions of Most Common Anxiety Disorders Encountered in Primary Care	
Generalized Anxiety Disorder (GAD)	Anxiety that is generalized, persistent but not related to identifiable environmental circumstances. Main symptoms usually include complaints of persistent nervousness, trembling, muscular tensions, sweating, lightheadedness, palpitations, dizziness, and epigastric discomfort.
Panic Disorder	Characterized by unpredictable episodes of severe anxiety that are not related to any specific situation. Main symptoms usually include sudden onset of palpitations, chest pain, choking sensations, dizziness, and feelings of unreality (depersonalization or derealization). Also, often reported is fear of dying, losing control, or going mad.
Social Anxiety Disorder (SAD)	Fear of judgement by others resulting in avoidance of social situations. Often associated with low self-esteem, fear of criticism, and accompanied by blushing, hand tremor, nausea, or urinary urgency. Symptoms may progress to panic attacks.
Post-traumatic Stress Disorder (PTSD)	Arises after a stressful event or situation of an exceptionally threatening or catastrophic nature, which is likely to cause pervasive distress in almost anyone. Predisposing factors include personality traits of compulsivity, asthenia or prior neuroses. Main symptoms include flashbacks (reliving of traumatic event), nightmares, emotional blunting, detachment from others, unresponsiveness to surroundings, anhedonia, and avoidance of activities and situations reminiscent of the trauma, a sense of hypervigilance, an enhanced startle reaction, and insomnia. Anxiety and depression are commonly associated with these signs and symptoms, and suicidal ideation is frequent. The onset follows the trauma with a latency period that may range from a few weeks to months.

There is considerable functional impairment associated with GAD. Kroenke et al. (2007) used the Medical Outcomes Study Short Form-20 (SF-20) to measure and compare functional status in primary care patients with GAD to primary care patients with no anxiety disorder diagnosis, and found that the patients with GAD had significantly poorer scores in all domains: mental health, social function, role function, general health, bodily pain, and physical function, as well as more self-reported disability days. Insomnia and related sleep disorders plague patients with GAD, who report more difficulty falling and staying asleep, poor sleep quality, excessive daytime sleepiness and dissatisfaction with sleep in all age groups when compared to individuals without anxiety (Choueiry et al., 2016; Brenes et al., 2009). Romera et al. (2010) looked at over 7,152 patients in 87 different primary care sites and found a significantly increased prevalence of painful physical symptoms, including increased pain severity, poorer daily functional status, as well as more primary care and emergency department visits in patients with GAD versus controls at 59% versus 28.3% respectively. These researchers documented the highest incidence of painful symptoms and impairment in patients with comorbid GAD and Major Depressive Disorder (MDD), a common presentation in primary care, at 78% (Romera et al., 2010).

Treatment for GAD

Traditionally, treatment choices for GAD have included psychotropic medications, psychotherapy, or both, depending on patient preference (National Institute of Mental Health [NIMH], 2016). Response rates to psychotherapy using cognitive behavioral therapy (CBT), the most studied psychotherapeutic modality are between 47-75% and medication helps 44-81% of patients (Bandelow et al., 2013). However, in reality, patients face significant barriers either in obtaining or tolerating their particular

choice of treatment with 41% of patients surveyed reporting no current treatment (Kroenke et al., 2007).

Challenges Associated with Traditional Treatment Strategies

Adherence to pharmacologic treatment regimens involving prescription medications is poor in GAD. Patients stop taking prescribed antidepressants, the first line choice for treatment of GAD, within the first six months at rates of 50% for the newer, best-tolerated drugs and at 85% for the older, less expensive medications (Sheehan et al., 2008). Benzodiazepines, or "tranquilizers", are known to be positively associated with abuse and dependence, and are not good choices for long-term therapy (Bandelow et al., 2013). However, because they provide immediate, though temporary, relief of symptoms, these drugs are often sought out by patients, raising suspicion and concern in prescribers not wanting to cause harm or perpetuate the epidemic of benzodiazepine dependence, especially in vulnerable populations such as the elderly (Widitz & Marin, 2002). Finally, there is a subgroup of individuals that avoid treatment with psychiatric medications altogether due to the stigma of being labeled mentally ill (Boyd, Juanamarga, & Hashemi, 2015).

Adult patients of all age groups have shown an overwhelming preference for non-pharmacologic treatment for anxiety (76%) versus pharmacotherapy (13%) or for combination therapy (11%) (Mohlman, 2012). The preferred settings for psychotherapy were primary care (34%); private mental health practices (28%); university settings (20%); church, temple or synagogue (10%); or in their own homes (8%) (Mohlman, 2012). Despite overwhelming evidence that mental health diagnoses occur frequently in our population and even more frequently in patients with chronic diseases, there remains a disparity between reimbursement for physical versus psychological maladies, thereby

reducing availability and access to mental health services (Alter, 2006). One community-based cohort study of 1,642 individuals diagnosed with anxiety and depression were interviewed at baseline and again about three years later only to find that of those that were still ill, only 19% had received counseling four or more times in the past year (Young, Klap, Shoai, & Wells, 2008). Even when treatment is readily available at no cost to patients, such as in the case of the Veteran's Administration patient population, less than 30% of patients diagnosed with depression, post-traumatic stress, or anxiety disorder utilized psychotherapy services in 2010 (Mott, Hundt, Sansgiry, Mignogna, & Cully, 2014).

Mindfulness-Based Treatment for GAD

Traditional approaches help some patients somewhat, but further treatment options with demonstrated efficacy that can be offered in the primary care setting are needed. One particularly promising type of therapy is mindfulness meditation. The term mindfulness refers to "paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally" (Kabat-Zinn, 1994, p. 4).

Use of mindfulness-based interventions in US health care is not new. Its origins date back to 1979 when pioneer and father of the movement, Jon Kabat-Zinn, a molecular biologist, introduced a course in mindfulness-based stress reduction (MBSR) at the University of Massachusetts Medical School (University of Massachusetts Medical School, 2014). Kabat-Zinn designed an eight week group intervention designed to teach meditation and relaxation techniques to patients diagnosed with a wide variety of health problems, various chronic pain syndromes and medical conditions with a secondary diagnosis of anxiety and/or panic (University of Massachusetts Medical School, 2014). The content was derived from ancient Buddhist teachings, and over the years the program

has demonstrated effectiveness for enduring reduction of symptoms of a multitude of disorders, as well as for instilling self-efficacy in patients regarding the ability to enhance their own health and well-being using meditation, yoga and continued awareness of the present moment (University of Massachusetts Medical School, 2014).

Recent advances in neuroimaging have elucidated even more important benefits of mindfulness and meditation, as it has now become clear that structural and functional changes in the brain, a concept known as neuroplasticity, occur with continuing practice. Mindfulness and meditation practices seem to serve as a type of mental exercise program that improves brain function and emotional stability. Davidson and Lutz (2008) summarized the findings of several studies using functional magnetic resonance imaging (*f*MRI) and put simply, meditators were more attentive to a flow of stimuli and less likely to become fixated and miss new stimuli, and were less reactive to emotionally-charged stimuli when compared to controls (Davidson & Lutz, 2008). A later literature review examining several types of evidence including *f*MRI reinforced these findings, again showing less emotional reactivity and increased gray matter in the regions of the brain associated with memory (Leung, Lo, & Lee, 2014). Another study compared age and educationally-matched novice and experienced practitioners of loving-kindness meditation (LKM), a specific type of meditation with a focus on wishing one's self and others well, and documented increased gray matter in brain structures associated with emotional regulation of empathy, anxiety, and mood (Leung et al., 2013).

Although evidenced-based, one obvious caveat of widespread adoption of this treatment for GAD is the impracticality of making this specialized instruction available to those without access to Kabat-Zinn's program or the few replications of the course across the US currently. However, the mainstream popularity of this ancient philosophy coupled

with current smart phone technology has made available a plethora of applications (apps) that offer basic instruction in mindfulness and meditation. A recent Pew Research Center study (Smith, 2015) found that two thirds of Americans have access to a smart phone, making it very possible to prescribe the use of certain vetted apps that provide instruction in mindfulness and meditation.

Problem Statement

GAD is a common and serious medical problem causing significant disease burden in those affected and a marked financial burden to society. Although there are effective treatment options available, there are limitations and barriers to traditional treatment of GAD that leave a significant portion of patients either untreated or undertreated.

Justification of Project

There is a need for an innovative, efficacious, cost-effective treatment strategy that could be offered to patients with GAD either as monotherapy or safely combined with pharmacotherapy and/or psychotherapy to improve outcomes. Teaching patients to practice mindfulness meditation to manage anxiety could be an efficacious addition to treatment as usual in primary care.

There are several limitations regarding anxiety treatment that this project will address. Primary care appointments are time and resource limited, so the bulk of the instruction must occur outside the parameter of the actual appointment. By far, the bulk of the evidence showing benefit for MBSR on anxiety has come from studies using lengthy interventions; however, there are examples of success with significantly abbreviated versions of the intervention (Bergen-Cico, Possemato, & Cheon, 2013; Mitchell & Heads, 2015). Although there are examples of the efficacy of smart phone

apps in social anxiety disorder and depression, there are no published studies using a smart phone app to treat GAD. However, the widespread adoption of smart phones has created the perfect opportunity to utilize this technology, by means of an app, to teach the techniques of mindfulness as well as provide reminders to patients and tracking of practice ("Calm.com," n.d.). A primary care clinician would discuss symptoms with the patient during the presentation visit and review previous and current treatments to determine if the patient is a candidate for this autonomous intervention. If there are no urgent concerns, the PCP would briefly present the evidence for mindfulness and meditation and refer a patient with a smart phone to the website to begin. A routine follow-up appointment in about two or three weeks would be recommended as well as instructions to call if there were questions, problems with the treatment or for any other reason the patient deemed necessary prior to the next visit.

Purpose

The purpose of the DNP project was to identify, implement, and evaluate an educational module to help patients diagnosed with anxiety disorders to manage symptoms, improve outcomes, and utilize the least amount of the limited resources available in the primary care environment. Also of great interest to the project administrator is experimentation with delegation of a portion of the education of patients to readily available smart phone apps rather than having to rely on human capital housed in “bricks and mortar” facilities that are expensive to build and maintain, often inaccessible, keep patients in a dependent position of having to make and keep appointments and pay for services rendered by these professionals.

Project Question/Hypothesis

This DNP project sought to answer the following questions:

1. What is the effect of the use of a mindfulness meditation app on anxiety in adult primary care patients?
2. Do patients that use the app more often or for more total time see an increased reduction in anxiety?
3. What feedback do patients provide regarding the use of a mindfulness meditation app?

Definition of Terms

For the purpose of this project, the use of mindfulness meditation will be the independent variable, with patients' anxiety levels and their qualitative reviews of the intervention defined as the dependent variables. Operational and conceptual definitions are listed below in Table 2.

Table 2

Operational and Conceptual Definitions

Operational and Conceptual Definitions	
Mindfulness Meditation	Patient education intervention delivered to primary care patients using a smart phone app aimed at development of the ability to be aware and alert in the present moment and to practice basic meditation techniques for the purpose of anxiety reduction.
Anxiety	The undesirable emotional state that is predominant in GAD and will be quantified using the tool, the GAD-7, developed to track severity of symptoms of the disorder.

Summary

Anxiety disorders are prevalent and most often present in primary care. However, these patients often complain instead of insomnia, somatic complaints, or difficulty concentrating, which not only confuses the issue, but creates increased spending on unnecessary testing. Although there are efficacious medications available to treat this disorder, side effects, cost, and negative stigma cause an overwhelming majority of patients to discontinue therapy. Counseling is overwhelming preferred by patients, but is often unavailable to them or expensive and is either never initiated or discontinued prematurely by the patient in most of the cases.

Treatment strategies that encourage patient autonomy and self-directed care must be tested as technology has made new options available. Smartphone apps are a viable option for patient education, tracking of progress, and communication. This project lends valuable information on primary care of patients with GAD as we continue to innovate to provide evidence-based care at a lower cost, utilizing technology to improve outcomes.

CHAPTER II

Research-Based Evidence

Anxiety is a commonly occurring condition and a known burden to patients, their loved ones, and to society at large. This condition causes significant disability and complicates the diagnosis and treatment of any other condition(s) the patient may have (Kroenke et al., 2007). One recent estimate of the annual direct and indirect costs of this diagnosis alone was approximately 48 billion dollars (Shimeshan, 2014).

These patients preferentially seek care from their primary care providers (PCP) (Shear & Schulberg, 1995). Commonly, patients are offered a trial of medication(s), a referral to a mental health specialist, or both. However, it is important for the PCP to have access to multiple treatment strategies to recommend a course of treatment suitable to each patient's particular preferences, as many patients decline medication and counseling (Boyd et al., 2015; Young et al., 2008).

Mindfulness meditation practice has been shown to be an efficacious intervention in anxiety (University of Massachusetts Medical School, 2014). The original program, Mindfulness-Based Stress Reduction (MBSR) was offered to patients at the University of Massachusetts Medical School in 1979 and consisted of an eight week course in which patients were taught to increase their attention to the present moment, striving for acceptance of whatever state they found themselves in, as well as to engage in daily sessions of meditation, and concentrating their attention on the breath (University of Massachusetts Medical School, 2014).

An initial broad look at the literature elucidated numerous replications of the program, as well as modified versions characterized by greatly reduced time commitments by patients and staff. Another innovation that is finding its way into mental

health treatment is use of the internet accessed by computer, smartphone, and tablet. The purpose of this DNP project was to identify, implement, and evaluate an educational module to help patients suffering with anxiety to manage symptoms and thereby improve outcomes while utilizing the least amount of the limited resources available in the primary care environment. One way to greatly reduce the cost of equipping patients with these skills would be to capitalize on the significant adoption of the internet and particularly smartphones.

Review of Literature

A review of the literature was performed with the idea of gaining insight from successful implementation of effective treatment strategies for anxiety applicable to the primary care setting. Mindfulness meditation was of particular interest due to its amenability as a complementary intervention that could be used alone or in conjunction with traditional therapies such as pharmacotherapy, with or without psychotherapy. Also appealing, mindfulness meditation, once mastered, is a practice which can be employed by a patient in an autonomous manner and is always available without cost. The main questions to be answered included: (1) what types of mindfulness meditation programs have been studied in patients with anxiety, (2) are there brief interventions that show efficacy, and (3) can technology, especially smart phones, computers, and tablets, be utilized to facilitate patient education and treatment?

A search of the literature using the databases Cumulative Index to Nursing and Allied Health Literature (CINAHL), Elton B. Stephens Company (EBSCOhost), the National Library of Medicine using PubMed, and the search engine Google Scholar from the years 2006 to 2017 was performed. The key terms searched were mindfulness meditation, smartphone apps and anxiety, mindfulness and anxiety, brief mindfulness

intervention, and primary care and anxiety disorders. The search led to an abundance of evidence to support mindfulness meditation as an efficacious choice in treatment of anxiety as well as the commonly occurring comorbidities of depression, panic symptoms, and high levels of stress.

Landmark Study

As the originator of the first formal program to teach mindfulness meditation as a medical intervention, it is important to acknowledge the landmark study conducted at the University of Massachusetts Medical Center by Jon Kabat-Zinn et al. (1992) which was designed to test the efficacy of mindfulness meditation in patients formally diagnosed with anxiety disorders using DSM-III-R criteria and to determine whether intake variables would predict outcome. At that time, there were three strategies in place aimed at self-regulation of anxiety: meditation, relaxation, and biofeedback, all with evidence of reduction of anxiety in the general population, and the latter two with variable therapeutic effects in anxious populations. Although no studies had yet formally evaluated the efficacy of mindfulness meditation in patients professionally diagnosed with anxiety disorders, participation in the mindfulness meditation program had shown reduction in both physical and psychological symptoms in patients in numerous diagnostic categories, and the maintenance of effect persisted in some groups at a four-year follow up.

The study was conducted at Kabat-Zinn's clinic at the University of Massachusetts Medical Center and subjects were selected from referrals to the program during the spring and fall of 1988 that screened positive for potential anxiety disorders and agreed to participate. These individuals were then interviewed by either a psychologist or psychiatrist, trained to administer testing to formally arrive at diagnostic

criteria for generalized anxiety disorder (GAD) or panic disorder with or without agoraphobia. Those with significant other psychiatric diagnoses or current alcohol or substance abuse problems were excluded. As the study was a pilot program, the sample was intentionally kept small with 24 patients selected and 22 completing the study. A second group of patients that met criteria for participation, but were not invited to enroll were deemed non-study participants and exposed to the same mindfulness program as participants, but were not evaluated to the extent that participants were. Both study and non-study participants were assessed prior to treatment and afterwards using the Medical Symptom Checklist and the Symptom Checklist-90-Revised (SCL-90-R). Participants were also interviewed weekly by telephone from the time of recruitment to post study and then monthly for three months after program completion using the following measures: The Beck Anxiety Inventory, the Beck Depression Inventory, and ratings of frequency and severity of panic attacks. In addition to these measures, participants completed the following at recruitment, start of the program, end of the program and at the three month follow up: the Hamilton Rating Scale for Anxiety, the Hamilton Rating Scale for Depression, the Fear Survey Schedule, and the Mobility Inventory for Agoraphobia. Participants were also evaluated at recruitment to rate their expectancy to improve with treatment using a 5-point scale, use of psychotropic medication was noted and tracked, and a compliance questionnaire was completed at program's end and again at the three month follow up.

The intervention had already been in place for 10 years at the University of Massachusetts Medical Center and at that time was referred to as the stress reduction and relaxation program, an eight week course that met weekly for two hours of instruction and practice with a seven and a half hour weekend silent meditation retreat scheduled at

week six. Patients were given homework consisting of various meditation techniques that would later be discussed during class. Five classes ran concurrently and were led by one instructor each who was blinded regarding study participation or DSM-III-R diagnosis. Repeated measures analysis of variance (ANOVA) was performed to compare recruitment, pretreatment, posttreatment, and three month follow up scores and matched *t* tests were used to assess the effect of the intervention in subjects and to compare study participants with non-study participants.

The results were remarkably positive regarding reduction of anxiety symptoms in this cohort of patients meeting diagnostic criteria for anxiety and panic disorder with and without agoraphobia. Statistically significant improvement in both anxiety and depression scales occurred in the group as a whole and in 20 of the 22 individual subjects. Scores on the Fear Survey Schedule and Mobility Inventory for Agoraphobia were also significantly improved as were the number of patients experiencing panic attacks. There was no difference in scores of subjects receiving psychotropic medication when compared to those not using medication. Expectancy ratings did not predict outcome. Self-reported practice compliance did not correlate with any study outcome. No differences were noted between patients diagnosed with GAD, panic disorder with or without agoraphobia, or in those with co-morbid major depression. Study and non-study participants demonstrated equivalent significant symptom reduction on the Medical Symptom Checklist and the SCL-90-R, which would be expected given both groups received the intervention and the only difference between groups was the degree of surveillance.

This study clearly demonstrated enduring positive results on reduction of anxiety and panic using mindfulness meditation. The rate of completion was high at 92% (22/24)

and subjects continuing to practice the techniques at the three month follow up was also high at 91%, with 84% practicing three or more times a week. This study was the first to use degreed mental health professionals to diagnose participants using DSM-III-R criteria to distinguish them from the general population reporting anxiety symptoms when evaluating the effect of meditation on anxiety. However, obvious limitations were the small sample size and the fact that there was no real control group, as the only difference between the two groups was the administration of tools to measure aspects of anxiety.

Meta-Analyses of MBSR Programs

The value of meta-analyses is their broad stroke of a topic, combining findings of many studies which increases the number of study participants and when executed well, provides information on the efficacy of an intervention, the need for future research on a topic and elucidates the weaknesses of previous study designs. The disadvantage of this method includes heterogeneity in study settings, populations chosen, and research methods as well as lack of a control group in some. Therefore, meta-analyses must be critically examined and utilized for what they are intended; a generalization of findings on a topic.

Meditation programs have been widely used in medical settings as a treatment for stress and stress-related diagnoses, with little known about these programs and how they should be used to improve health outcomes. A team from John Hopkins University determined that clinicians needed to know more about these programs, the populations that may benefit from these interventions, and exactly what, in the way of results could be expected (Goyal et al., 2014).

Their objective was to use a systematic review of meditation programs to assess their effectiveness on a range of positive and negative mental states. They questioned

whether meditation demonstrated efficacy in mitigating negative mental states such as anxiety, and enhancing positive mental affect, thereby reducing the likelihood of negative health behaviors such as substance abuse.

Selection was scientifically rigorous using the *Methods Guide for Conducting Comparative Effectiveness Reviews* to select 47 trials from the group's review of 18,753 citations and 1,651 full-text articles (Agency for Healthcare Research & Quality, 2007). Only randomized controlled trials (RCT), with one or more control groups, given time and attention equivalent to the meditation intervention were selected from an impressively large number of well-known databases such as MEDLINE, PsychINFO, the Cochrane Library, and others. There were no restrictions placed on date of publication or language in which the reports were published. Only studies using adult populations with a medical diagnosis and some sort of stressor were selected. The interventions employed included a variety of meditation techniques (i.e., mindfulness based stress reduction, mindfulness based cognitive therapy, Zen, transcendental meditation, and others) that used a structured program of four or more hours of participant training and instructions to practice the technique outside of class time. Study settings were varied, but subjects resembled a general primary care population.

The review confirmed the value of meditation programs regarding the reduction of the negative aspects of stress. Mindfulness meditation showed efficacy related to study outcomes more often when compared to other meditative techniques. However, the researchers quantified the effect of mindfulness meditation as moderate, demonstrating non-inferiority rather than superiority when compared to specific controls using well-known interventions such as exercise as an example. Mindfulness meditation improved scores measuring negative affect such as anxiety, depression, pain, and stress/distress as

well as improvement of health-related quality of life. The effect on anxiety and depression was strong enough to match that of antidepressants, but, it should be noted, without the associated potential for injurious effects. Researchers found no evidence of harm to participants, though most studies failed to report on harms.

The researchers concluded that even though the literature on meditative techniques was limited, there was evidence that mindfulness meditation programs were an effective strategy for treatment of anxiety, depression, and pain. Therefore, clinicians should be prepared to discuss the benefits of these interventions with their patients.

The authors suggested that future studies should be designed to evaluate critical details needed by clinicians to effectively advise patients in the therapeutic use of meditative techniques. Despite the choice of technique, it will be important to understand the significance of instructors' level of training and expertise, time spent instructing participants, and the amount of home practice by participants to see meditation evolve to the status of evidence-based practice.

Strengths of this study included the meticulous detail in selection of studies. Two experienced investigators worked independently searching eight respected medical databases using the same subject heading terms and words found in the texts of foundational work. They reviewed the reference lists of each article to locate studies missed in the database searches. Appropriate studies in any language or date of publication were considered if inclusion criteria were met. After the list of articles was compiled, a second team of two investigators independently reviewed each full-text article and added their decision regarding inclusion. Disagreements were settled by consensus. Using only studies with controls is considered best science; these researchers went even further and did not consider individuals on a wait list or those receiving

"treatment as usual" as meeting scrutiny as control groups. Control groups for included studies were defined as individuals receiving the same time and attention as the intervention group.

The limitations of this meta-analysis are among those common to this type of research. There were studies that lacked sufficient description of study design to properly assess the potential for bias. There was a lack of standardization regarding trainers' preparation, measures, outcomes, and participant practice time that prevented analysis of effect modifiers. Sample sizes varied, but nearly half the studies enrolled less than 50 subjects. Finally, even though the researchers included only RCTs with control groups, there was often a lack of blinding of outcome assessment, high attrition rates, lack of allocation concealment with recruitment, and failure to provide intention-to-treat analysis.

Noticing the popularity of mindfulness meditation as an adjunct treatment in a wide variety of conditions, scientists from Erasmus Medical Center; Rotterdam, the Netherlands; Harvard University and Medical School, and Massachusetts General Hospital in Boston, Massachusetts, aimed to review the literature to determine more about which patient populations benefitted from these types of interventions (Gotink et al., 2015).

The ancient concept of mindfulness was first introduced to Western healthcare by Jon Kabat-Zinn as a treatment for chronic medical conditions using a standardized style of mindfulness, which he called MBSR, now widely accepted as a valid intervention for numerous diagnoses (Kabat-Zinn et al., 1992). Teasdale et al. (2000) incorporated Kabat-Zinn's mindfulness techniques into traditional cognitive psychotherapy, creating MBCT, initially aimed at reduction of recurrent depressive episodes.

Teasdale and colleagues' study was a meta-analysis of meta-analyses. The Cochrane Guidelines (Higgins, 2009) were followed as the basis for a systematic review of RCTs utilizing either MBSR or MBCT for treatment or prevention for any health outcome measure. The search for articles was conducted by two independent reviewers and utilized six medical databases using key terms. Any article selected had to be agreed upon by both researchers. A third reviewer resolved disagreements. Articles that described the use of other techniques in combination with MBSR or MBCT were only included if results were reported separately. Control groups were defined as wait list, treatment as usual, or other active treatment. Once the preliminary screening was completed, 23 reviews were selected, representing 115 unique studies and 8,683 subjects from many countries, including children and adults, patients with psychological diagnoses, medical conditions, and well individuals.

Results were categorized by diagnosis. They included 13 RCTs with 1,244 patients diagnosed with various anxiety disorders. Mindfulness interventions improved symptoms in patients with anxiety by about 50% compared to controls. Interestingly, results were significantly higher in Western populations versus others studied. There was also a definite dose-response effect, as increased time spent practicing enhanced the effect.

Even though many primary care clinicians are skeptical regarding MBSR and MBCT, the fact is that they show significant improvement in depression, anxiety, stress, and quality of life in patients with mental disorders. Perhaps the greatest value of mindfulness interventions in primary care is in adding them to the usual treatment of common diagnoses such as cancer, cardiovascular disease, chronic pain, and chronic somatic conditions. As well as primary prevention of mental disorders.

These techniques are relatively easy to implement and empower patients to take a more active role in their treatment. Mindfulness interventions have been found to present no significant harm to patients and are cost effective, as one instructor can impact large numbers of patients who engage in most of the therapy at home without the involvement of clinical staff.

This study represents the largest analysis of mindfulness-based interventions to date and evaluated the intervention effect on numerous diagnoses commonly presenting in primary care. The authors suggest that the variety in populations and settings across the globe increases the ability for clinicians to generalize findings. The researchers were careful to control for duplication of results given the high probability that published meta-analyses often included some of the same studies in their work.

Any meta-analysis is inherently limited as included studies differ regarding populations, settings, measures, and many other characteristics. This study presented an enormous problem of heterogeneity. The authors created a category designated as mixed populations, but admit that interpretation of effect in this group would be problematic. Due to the nature of the interventions, double blinding was not an option, thereby skewing results.

However, since the interventions require active participation by subjects to achieve the therapeutic benefit, any randomization that placed disinterested individuals in the intervention group would minimize the positive effect of the intervention. Meanwhile, interested subjects in the control group could either become worse, out of frustration of not being chosen for the intervention or simply start the practice on their own, both responses skewing results. Bias exists inherently in these types of studies.

Brief Programs

Jon Kabat-Zinn's MBSR program is an eight-week program during which participants attend a structured two-hour class each week, a day-long meditation retreat off-site, and are asked to practice at home 45 minutes daily (Kabat-Zinn et al., 1992). This represents quite a time commitment; approximately 24 hours of instructor time and about 60 hours for participants. To overcome this perceived barrier, there have been many adaptations of the program that lessen the time commitment for both instructors and participants.

The advantages of a briefer program are appealing, but only if efficacy is not comprised. Sponsoring institutions could decrease the cost of any program that used less staff time and classroom space. Potential participants would likely be more interested in shorter time commitments. The following three articles are recent examples of the research of brief programs.

Anxiety is very prevalent among college students. The American College Health Association reported in its most recent survey of the nation's colleges and universities that 59% of undergraduate students reported feelings of overwhelming anxiety within the previous 12 months, and only 17% of them reported receiving any mental health services (American College Health Association, 2016). This high incidence of anxiety, coupled with low rates of seeking counseling, led to development of a MBSR program which was incorporated into an elective academic undergraduate course on addictive behaviors (Bergen-Cico et al., 2013). The aim of the study was to learn whether participation in a five week MBSR would lead to improvement in self-compassion, mindfulness skills, and trait anxiety among a group of non-clinical university undergraduates. A secondary aim was to determine the feasibility of modifying higher education curricula to incorporate a

brief MBSR component with potential of positive psychological benefit to students, without compromising the academic mission of institutions of higher learning. The authors hypothesized that the intervention would yield benefit.

The project took place on a college campus between January 2010 and May 2012. Participants were a group of 119 undergraduates, with 72 students in the treatment group and 47 in the control group. The treatment group met during five consecutive classes for two hours, or just 10 hours, engaging in sitting and breath work, guided body scan, and movement such as yoga or walking, led by their professor who was trained in MBSR through the University of Massachusetts Center for Mindfulness in Medicine, Health Care, and Society. The control group participants were simultaneously enrolled in the same class, but a different section, taught by the same professor at a different time. Both groups completed "baseline" surveys at week one and a "follow up" survey at week six. The survey consisted of four measures; the Kentucky Inventory of Mindfulness Skills (KIMS) and the Philadelphia Mindfulness Scale (PHLM), which measure mindfulness skills; the Self-Compassion Scale (SCS), which measures one's self-forgiveness mindset, and the Spielberger State-Trait Anxiety Inventory-Trait Form Y-2 (STAI-T) for measurement of anxiety.

After participation in a five-week MBSR, students in the intervention group improved mindfulness skills as demonstrated by significant pre-and-post scores on the KIMS and the PHLM ($p \leq .001$). Self-compassion increased significantly ($p \leq .001$) as measured by the SCS. There were no changes in the control group's scores of the KIMS, PHLM, or the SCS. The treatment group showed non-significant improvement in the STAI-T, whereas the control group scores demonstrated increased anxiety.

College undergraduates participating in the brief MBSR received psychological benefits compared to controls. The gains centered around increased mindfulness and self-compassion. Although the MBSR group showed only slight reduction in anxiety, it must be noted that the control group's anxiety scores increased. The authors surmise that the trait for anxiety may be more resistant to change and may require longer MBSR programs. Also mentioned was the possibility that another measure, with increased sensitivity to the construct anxiety, may have captured changes missed on the STAI-T.

A significant contribution to the literature, this study demonstrated positive changes in an authentic student population as compared to study designs that may not be applicable to this high-risk group. Incorporation of MBSR into typical curricula reduced barriers of time and travel to attend a program, thereby impacting a much greater number of students. The utilization of a formally-trained facilitator, a graduate of the program originated by Jon Kabat-Zin, increased validity of the intervention and the study as a whole.

There were a few weaknesses of the study. This study used convenience samples rather than including a wider selection of students and lacked randomization. The authors admited that the timing of post-intervention survey administration may have been affected by the fact that students were in the midst of preparing for mid-term exams, which likely captured exceptionally high levels of stress for both populations. Finally, a follow up survey, several weeks or months after the MBSR-infused class, would have elucidated whether the changes were enduring.

Another high-risk group for stress-related symptoms is health care workers. To address this issue, a Washington state community hospital implemented a brief mindfulness-based program for physicians, using a combination of in-person class time,

video modules on mindfulness, and teleconferences (Pflugeisen, Drummond, Ebersole, Mundell, & Chen, 2016). The aim of the program was to assist physicians in high-stress roles to develop mindfulness skills to reduce stress and improve well-being. The application of video modules to convey most of the content as opposed to face-to-face class time was intended to increase ease of participation by staff and decrease institutional costs.

Researchers introduced the program to their physician staff as part of a wellness initiative on a first-come, first-served basis. A total of 23 physicians enrolled and 19 completed the program. Baseline, end of program, and 16-week follow up surveys were administered, designed to measure stress using the Perceived Stress Scale (PSS), burnout using Maslach Burnout Inventory (MBI), and mindfulness skills using the Kentucky Inventory of Mindfulness Skills (KIMS). Significance was set at a p value of 0.05. The intervention consisted of three 90-minute live sessions (weeks 1, 4, and 8), eight online videos of five to seven minutes in length, and weekly one-hour teleconference coaching calls scheduled at a time to accommodate the majority of participants. An audio library of resources was made available to participants and they were sent a brief daily email related to the week's lesson. Participants self-reported their use of the program materials each week.

The program proved to be very effective, with significant changes in seven of the eight outcomes from baseline and end-of program, post-intervention or both. A significant reduction in stress from baseline to program end were striking ($p \leq .0005$) and even improved at the post-test ($p \leq .00001$). Other significant changes persisting at the follow-up survey were: increase in sense of personal accomplishment and use of mindfulness skills.

At study's end, it was concluded that a brief version of MBSR using video-modules was an effective and practical means for meeting the needs of busy physicians needing flexibility regarding educational programs. Most importantly, after the modules were produced, they can be used over and over as a very cost-effective means of reaching many more employees. Program graduates could even be used to facilitate the in-person classes and teleconferences, creating self-sustainability.

The strength of this pilot study was in its design with goals of providing economically feasible and flexible education to solve institutional problems. As a pilot program, it served its purpose, however, the weaknesses included a very small sample size, the lack of randomization and utilization of a control group.

Very brief mindfulness programs, beginning to show efficacy, attracted interest as they could be used widely due to low cost and the ability to target large numbers of people. Researchers from Wake Forest University School of Medicine and the Department of Psychology at the University of North Carolina at Charlotte, NC designed a very brief (60 minutes) mindfulness intervention to test its effect on psychologic distress, anxiety, heart rate, and blood pressure on well undergraduates (Zeidan, Johnson, Gordon, & Goolkasian, 2010). They also included a sham meditation group to tease out any differences between the actual practice of meditation and an intervention of deep breathing and relaxation that would be introduced as meditation training as a deceptive technique. A third group, another control group, also met for 60 minutes, but received no actual intervention. There was no expectation that such a brief exposure to MBSR would discern changes in depression, fatigue, or vigor, but they did hypothesize that both groups would exhibit a decrease in anxiety levels.

The study took place in the psychology department of one of the universities after 88 subjects were selected from a pool of student volunteers who had expressed a desire to learn to meditate, but had no prior experience with meditation. Six students did not complete the program, leaving a final group of 82 subjects. There were three arms of the study: a meditation group (n = 29), a sham meditation group (n = 27), and a control group (n = 26). The experiment took place over three consecutive days for 20 minutes each. The subjects, 5-8 per session, met in the same room at about the same time each day.

The meditation group was led by an instructor with eight years of training in mindfulness meditation interventions. The subjects were not asked to practice outside of class, unlike most MBSR programs. During class, they were instructed to sit in a chair, close their eyes and relax. Then, they were taught to focus on the flow of their breath and to just let go of any thoughts that occurred and then return their focus and attention back to their breath. The 20-minute sessions included brief instructions and then seven minutes of silence in which to practice the technique. At the end of each session, all subjects answered "yes" when asked individually if they felt like they were truly meditating.

The same facilitator led the sham group and began the sessions with an introduction of mindfulness meditation; however, the emphasis was on breathing exercises while they were being given just the notion that they were meditating. As with the meditation group, the last seven minutes were held in silence for practice of the breathing technique. The critical missing piece of this group's training was the lack of guided instruction to focus on the flow of the breath, which is the very basis of mindfulness meditation. Everyone in this group also responded "yes" when asked if they felt like they were truly meditating.

The control group was a test of non-manipulation. This group of students was also told that they were registered for a mindfulness intervention, but were only told to sit still in their chairs for the 20-minute session. They could speak, but were not allowed to do homework or sleep.

The measures chosen were all credible and found elsewhere in the literature. The Profile of Mood States (POMS) was chosen to measure psychologic distress using six domains: tension, depression, confusion, fatigue, anger, and vigor. Anxiety was measured using The State/Trait Anxiety Inventory (STAI). The cardiovascular measures were blood pressure (BP) and heart rate (HR) measured by an automatic device, the Dinamap 5000. All measures were administered just prior to the first session and afterwards BP and HR were checked and the STAI was re-administered. The STAI was administered before and after the second session. Participants completed the STAI and had their BP and HR measured prior to the third session and all the measures were administered afterwards.

After the data were analyzed, a significant decline in negative mood, demonstrated by reduced scores of the POMS, was seen in each group, but the meditation group demonstrated a significant reduction in total pre-and-post total scores as well as the sub-scales when compared to the other groups. STAI scores demonstrated significant pre-and-post session decreases in anxiety by the meditation and sham groups, but did not differ significantly with pre-and-post study results. The control group did not show any significant changes. Each group demonstrated pre-and-post session reductions in HR, but only the mindfulness group showed a significant total pre-and-post study decrease in heart rate. Systolic BP decreased in each group measured before and after each session, but there was no significant intergroup effect. Diastolic BP was a little lower in each

group before and after the sessions, but not significantly so and there was no intergroup effect.

This study showed that a very brief meditation intervention significantly improves overall mood; specifically, depression, tension, fatigue, confusion, and anxiety. Brief meditation also reduced heart rate when compared to sham meditation and a control group. There were no significant changes of systolic or diastolic BP, but it is noteworthy that this young population began each session with normal blood pressure readings; therefore, it may not be realistic to expect significant reductions. The authors proposed that perhaps the reduced blood pressure effect would occur if the population was subjected to high level stressors.

The strengths of this study centered on its inclusion of a sham meditation group, a reasonably designed control group, and randomization of an acceptable number of subjects. However, because the study population included only young, well college students, generalization of findings to any other population would be inappropriate. The authors, themselves, mentioned the fact that the same instructor led both the meditation and sham groups, therefore creating the possibility of bias. A longitudinal study measuring subjects again after some time had passed, would answer the question of whether the effect of such a brief intervention was enduring. Overall, this study contributed greatly to the state of the science as there is a need for brief interventions and this mere 60-minute intervention demonstrated significant improvement of several important health variables.

Internet-Based Interventions (smart phones, tablets, and computers)

Meta-analyses. The wide-spread use of smart phones capable of downloading applications (apps) for various uses has led to development of numerous products aimed

at improvement of mental health symptoms such as depression, anxiety, stress, insomnia, substance abuse, and eating disorders. It has not gone without notice that use of this portable technology could provide services to many more people than currently served by traditional means. Research is just beginning to test the efficacy of these apps delivered via smart phones and other devices.

Little quality research regarding the efficacy of mental health apps had been done while the use of such apps was proliferating; therefore, Donker et al. (2013) performed a literature search, using seven widely accepted databases to identify reports published in English from January 1, 2008 (release of the first app) to May 30, 2013. To be included in the review, studies had to use a mental health app that was downloadable to both the Android and iPhone from their respective app store. The study had to use a pre-post design with a control group defined as individuals on a wait list, receiving treatment-as-usual, or receiving some other treatment. Eight studies representing 227 participants using five unique apps were selected. The population included community-residing adults, patients from an outpatient clinic, adults from their workplace, adolescents from a general medical practice, and female university students.

The quality of the studies was judged to be generally low according to the authors, mainly due to missing information such as methods of randomization, dropout rates, details of blinding, or lack of description of statistical analyses. The scales used to assess depression and anxiety were PHQ-9, GAD-7, STAI, Quick Inventory of Depression Symptoms-Clinician Rated (IDS-C), Depression and Anxiety Scale (DASS), and the Beck Depression Inventory (BDI-II).

The results were inconsistent. Out of the four studies that measured depression, two studies showed significant improvement from baseline to the end of the study, but

the other two failed to demonstrate benefit. The latter two studies' population was adolescents from a general practice. However, there was very little difference between the intervention group and the control group. Both received the same therapy, but the intervention group used their smart phones to utilize Ecological Momentary Assessment (EMA), a method of data collection that allows participants to report their symptoms, mood, or behavior in real time or close to their experiences of interest to researcher(s).

Three trials measured anxiety and stress. Each showed statistically significant positive changes in anxiety and stress. One study also demonstrated significant improvement in coping skills in studies using oncology nurses and female college students.

Although the use of this technology is relatively new and many of the trials lack quality, there is potential to use smart phone apps to increase access to mental health care at low cost. However, there is a need for large, scientifically sound studies of the apps themselves as well as acceptance and use of smart phones by the public to improve mental health symptoms.

This was a difficult meta-analysis due to the heterogeneity of almost every element of interest in the trials selected, but this is the way information about innovations is introduced. The main strength of this study was that the researchers used what was available to them from just a few trials to report on this new technology to the scientific community. Limitations of the studies themselves included lack of long-term follow up, small sample sizes, and lack of evidence that the apps were designed around evidence-based practice.

Again, observing the proliferation of on-line mindfulness-based interventions (MBI) for a wide variety of psychological diagnoses or symptoms, Spijkerman, Pots, and

Bohlmeijer (2016) set as their aim to estimate the effect of these interventions on mental health. After an extensive review of the literature (any published study up to March 23, 2015), they selected 15 trials that met their criteria. Only on-line RCTs of MBIs using validated measures for effect on depression, anxiety, stress, or well-being in adults (18 years or older) were chosen.

The total population of included studies was comprised of 2,360 participants, 1,211 in the intervention groups and 1,149 in the control groups. The majority of the samples were comprised of more female subjects than male, and all subjects were adults ranging in age from 18-58 years. There were five studies using subjects with somatic complaints, three studies of patients with psychological conditions, and the remaining seven studies used populations of students, employees or other non-clinical subjects.

Their findings showed that on-line MBIs were more effective on psychological versus somatic variables. Stress and mindfulness showed the highest pre-and-post improvements ($p<.001$), depression and well-being were improved ($p<.01$) as was anxiety ($p<.05$). Adherence rates, defined as the percentage of the population that completed 100% of the program, were 39.5-92%. The effect of therapists' input as part of the program or if there was a dose response could not be determined due to under powering. Their conclusion was that MBIs appear to be effective at improvement of mental states, but much more investigation is warranted.

The authors were limited as to the number of studies that could be included due to poor design, thereby decreasing the generalizability of the findings. There were also limitations regarding sub-group analysis because the studies were underpowered. Heterogeneity of study characteristics had a limiting effect regarding generalization. The authors faced all the above issues and yet provided another early look at the use of MBIs

in healthcare. Their suggestions for future research will prove helpful regarding study design (more longitudinal studies, less use of non-clinical populations, and exploration of characteristics of study drop outs).

As trends suggesting the efficacy of using computer-based mindfulness meditation interventions to treat mental health problems grew, interest in the efficacy of use of apps alone also grew. Fish, Brimson, and Lynch (2016) conducted a review of studies using mindfulness techniques delivered electronically without facilitator involvement to measure the effect on stress, depression, and anxiety in a variety of populations. The impetus of their investigation was to determine if technology alone, a very cost-effective treatment modality, would produce results equivalent to those reported by face-to-face interactions with health care providers.

They began their work by searching three electronic databases, Ovid Medline, PsychINFO, and Embase, using key words, titles, and medical subject headings (MeSH) derived from "mindfulness" and "technology". Ten studies met their inclusion criteria: mindfulness courses delivered by technology only, inclusion of clinical outcomes in study reports, interventions without direct facilitation, and access to the full paper published in English.

Population characteristics of selected studies represented a range of 15 to 273 subjects, all adults from 25 to 56 years of age. A distinct gender bias was noted with 71-98% female participants, but this finding is similar to face-to-face intervention statistics. Study participants consisted of students, individuals diagnosed with cancer, or fibromyalgia.

The interventions were all web-based except one which used audio compact discs (CD's). Four of the ten studies measured changes in anxiety using widely-accepted tools,

including the Hospital Anxiety and Depression Scale (HADS), GAD-7, Responses to Stress Questionnaire (RSQ), and the Beck Anxiety Inventory (BAI). The courses varied in duration from one to three months. Two studies used patient reminders and two did not, but all required homework which varied widely (30 minutes a day to almost two hours daily) and was not always measured. Only one of the four studies used a control group, which was described as a discussion group.

Each study demonstrated positive results on anxiety, however only two of the four studies tested the significance of subjects' pre-and-post scores. A reduction in rumination was observed in one study, but no meaningful statistics were provided. The one study that used a control group found considerable improvements in patients in the intervention group ($p<0.01$).

Although the use of web-based technology as a means for care delivery is in its infancy, it appears to be a viable alternative to costly one-on-one therapies. Most studies showed positive effects, but study design must also evolve to match the standards that health care professionals have come to expect before adopting a change in practice.

The fact that the authors did not try to meet the standards required for a formal meta-analysis is a strength, considering the quality of the available studies, and termed their project a review with report of findings. The main issues continue to be: large drop-out rates, lack of control groups, lack of follow up to document endurance of effect, poor measurement of participants' usage of the intervention, lack of documentation of expertise and qualifications of course designers, and an observed population bias with high numbers of women and students which make any results non-generalizable.

Individual studies. There is a greater demand for mental health services than supply in most parts of the US (Alter, 2006). As this is also the case in the United

Kingdom (UK), a group of researchers tested a web-based MBSR/MBCT intervention to determine its feasibility to provide services to individuals with increased stress, anxiety, and depression (Krusche, Cyhlarova, and Williams, 2013). They hypothesized the following: that perceived stress, anxiety and depression would be improved after completion of the web-based course; the improvements would be maintained at the one-month follow up; that participants that practiced more would see more improvement in symptoms; and the efficacy would be comparable to other types of mental health interventions.

The course was a collaboration between the Mental Health Foundation, Wellmind Media and leading UK mindfulness instructors. Participants self-selected the online course and paid about $90 (US) for its use. A total of 5,094 people signed up for the course and 1,497 completed the course and the one-month follow up questionnaire (29%). The sample was mostly female (78%), with an average age of 47.7 years.

The course consisted of 10 instructional videos led by two instructors, one male and one female. Formal meditation skills were taught (body scan, mindful movement, sitting meditation, and focus on breathing) as well as incorporating mindfulness into daily life, such as mindful eating. There were assignments to complete and motivational emails. Participants were also asked to practice at least one formal meditation using one of the video resources and one informal practice daily and at least one extra practice or task. Prompts to self-report program activity and homework were strategically included.

Measures were carefully selected to measure outcomes. The Perceived Stress Scale (PSS) measures perception of events as uncontrollable and overwhelming. Anxiety was measured using the Generalized Anxiety Disorder Assessment (GAD-7) and

depression was measured with the Patient Heath Questionnaire (PHQ-9). Participants completed surveys pre-and-post intervention and at one month after course completion.

Baseline scores on all the measures were significantly higher than the general population. The average PSS score confirmed that participants were “highly stressed”, the GAD-7 showed an average of at least “moderate anxiety”, and the PHQ-9 scores were consistent with “moderate depression”. After course completion, PSS scores were significantly reduced and there was significant reduction from course completion to the one-month follow up testing. The same pattern was demonstrated with the GAD-7 and PHQ-9. Patients with higher baseline test scores were found to practice less, and to see less improvement. However, when controlling for baseline symptom severity, more practice was associated with greater change in pre-and-post intervention scores.

It can be concluded from the results that use of an online mindfulness course produced significant change in stress levels, anxiety, and depression. A dose response was positively associated with improvement. Interestingly, a phenomenon of less participation was observed in participants with the highest baseline scores, suggesting that severe symptoms may be responsible for a degree of disability preventing participation in self-help programs. These individuals may require a different type of therapy to meet their specific needs.

There were many strengths to this study. The population was large and because subjects self-selected they likely represent a section of society that would be seen in primary care offices. The intervention appeared to be of high quality due to the collaborative efforts of very credible experts. The fact that there was a cost to use the website, would seem to represent buy-in from subjects, but the attrition in this trial was 71%. It would have been interesting if the researchers had attempted to understand the

differences between enrollees that dropped out and those that completed the intervention. One must also wonder if cost was a barrier for some potential subjects. Other weaknesses include self-reported participation and the lack of a control group.

The standard therapies for SAD are CBT and pharmacotherapy, both of which miss certain segments of the population. Many affected individuals decline seeing a therapist at all, or for less than the recommended number of treatments. Others shun pharmacotherapy due to frequent side effects, cost, and not wanting to depend on daily medications for this or any disorder. Both treatment modalities are charged with stigma. Therapy delivered by smart phone or other devices via the internet overcome many of patients' objections.

Two different treatment methodologies, cognitive behavior therapy (CBT) and interpersonal psychotherapy (IPT) were formatted to be delivered via smartphone as well as computer and tablet to test their effect on patients diagnosed with social anxiety disorder (SAD) (Dagoo et al., 2014). CBT is characterized by changing non-productive thoughts and patterns of reaction to stressors by teaching patients to challenge negative thoughts and patterns, thereby significantly controlling the symptoms of anxiety. IPT's focus is on improvement of problematic interpersonal relationships, which then lower patients' psychological distress.

In this study, the CBT group was the main intervention group and the IPT group served as an alternate treatment group. It was hypothesized that CBT delivered by a smartphone app would show a significant decrease in symptoms of SAD, but no hypothesis was formulated regarding the IPT group as this therapy was a much less-studied treatment for this disorder.

This randomized controlled study was advertised nationally in the Swedish press which directed interested parties to the study's website. Inclusion criteria were designed to identify the diagnosis of SAD in adults (18 year or older), while eliminating individuals with co-morbidities of suicidal ideation, alcohol abuse or dependence, psychosis, or bipolar disorder. Potential candidates would not currently be engaged in any form of psychotherapy, nor would they have received CBT within the last four years, and if on psychotropic medication, the patient would be stable and the dose unchanged for at least the last three months.

A total of 235 applied to participate in the study, but after the thorough screening, only 52 were selected to participate. The population was about equally split between males and females (48.1% and 51.9% respectively) and ranged in age from 20-65 years. Half the group had completed high school and 46.2% had attended a university for an average of 2.3 years. This population represented a typical segment of Swedish society.

Participants were randomized to one of the two arms of the study using an electronic randomizer. Each group was exposed to a nine-week program consisting of nine modules and weekly homework. Access to the material required use of a secure password. Only the IPT group received weekly contact with a therapist limited to 15 minutes; however, there was no description of this contact regarding method of delivery. The primary outcome was improvement in the Liebowitz Social Anxiety Scale-Self Report (LSAS-SR), a tool used to measure avoidance and fear in social situations.

At the end of nine weeks, 30 participants (57.7%) had completed the treatment modules, 63% of the CBT group and 52% of the IPT group. Since participants could access the material using smart phone, computer, or tablet, the researchers noted that usage was 42.8%, 50.05%, and 7.14% respectively. Both groups showed significant

improvement using pre-and-post LSAS-SR scores using $p<.05$ as significance level, but the CBT group changes reached a significance level of $p<.001$ whereas the IBT group changes showed a significance level of $p<.01$. When participants were assessed for significant improvement individually, the CBT group had a 55.6% rate of response compared to an 8% in the IBT group. Both groups demonstrated stability of change at a three-month follow up analysis.

The results lead to the conclusion that patients are willing to utilize electronic devices as a treatment modality for anxiety, although in this case, the smart phone was used a little less often to access the treatment modules when compared to the computer. There were technical difficulties encountered with the smart phone platform that may have impacted the results. Future studies could limit access to just a smart phone app to get more precise data regarding its real acceptance by patients; however, patients may prefer having options regarding access.

Study limitations are basically the same ones that plague this emerging science and its research. There was not a control group, though at least a new therapy was compared to one that has demonstrated success when delivered in one-on-one sessions, group therapy, and even a few instances of success using a smart phone app. The sample sizes were small and the attrition rates high, which resulted in a study that was not powered to fairly compare the treatment groups. Another issue is that the population was gleaned of patients with most of the commonly-occurring co-morbidities, and even though this group looked like a typical segment of the population, they were likely not the group one would encounter in a treatment setting, therefore limiting generalizability of results

Researchers from Oregon Health and Science University (OHSU) were interested in whether mindfulness training could make a difference in stress and cognitive decline in seniors, but wanted to test feasibility of a web-based care delivery system since the benefits of reduced cost and wider access are known to be advantages associated with this technology (Wahbeh, Goodrich, & Oken, 2016). A randomized, controlled trial, in the form of a pilot study, using the Internet Mindfulness Meditation Intervention (IMMI), developed by the research team, was compared to a control group given a generic health and wellness education program. Once screening was completed, participants were enrolled in the study. The two groups were evenly matched, varying in age from 65-90 years of age, 88% Caucasian, and 50% female. The drop-out rate was rather low at 24% and when questioned as to the reason for not completing the study, they consistently reported a problem of lack of time to participate fully.

Pre-and-post study data was collected in participant's homes by a research assistant blinded as to randomized group assignment and an unblinded research assistant visited to instruct participants in use of the technology. Study modules were initially accessed using the iPad tablet, but many participants had difficulty with this device, so they were allowed to use their home computers if they chose. The interventions consisted of six weekly modules, an hour long, with homework assignments of 30 minutes daily. Program use was collected electronically.

Acceptability was found to be high, based on client satisfaction questionnaires. There were no differences in stress or cognition scores or program usage, as researchers expected due to the short study period and small sample size.

The study was well designed. It included a control group and made data collection easy for participants. Care was taken to give one-on-one instruction in use of technology

as this age group varies in adoption of and expertise regarding use of electronic devices. Although the sample size was small, the groups were well balanced regarding age, gender, education, marital status, and cognition. As there was difficulty noted with use of the iPad, seniors' comfort with technology may have been underestimated. Another problem identified in this pilot study was the length of time participants took to type in narrative responses to homework questions. Revisions have been made for the follow up study requiring selection of multiple-choice check boxes. The authors admitted that it was likely that only a segment of the senior population are candidates for this type of care delivery system due to difficulty with novel technology.

Neuroplasticity and Mindfulness Meditation

It is now a well-known fact that the human brain is capable of changes in volume, activity levels, blood flow, and hard wiring of neural pathways and connections, an attribute known as neuroplasticity. The following articles represent examples of research demonstrating positive changes in the brain in response to mindfulness meditation techniques.

A multi-disciplinary team of researchers wanted to learn more about the mechanism(s) of improvement in the brain's white matter in response to a mindfulness meditation training program, Integrative Body-Mind Training (IBMT) compared to a control group using relaxation training (RT) (Tang, Lu, Fan, Yang, & Posner, 2012). They hypothesized that the positive effects of IBMT were due to a change in brain structure, or neuroplasticity, rather than a training effect of an existing neural network.

In this study, 68 Chinese undergraduates were randomly and evenly assigned to one of the two groups, both of which were four weeks in length consisting of ten hours of training and practice, with no other details of the interventions reported. Diffusion tensor

imaging (DTI), a type of Magnetic Resonance Imaging (MRI), capable of providing detail of white matter fibers, was administered at pre-test, week two, and week four of the study. Significant improvements were noted in the structure and size of white matter fibers and an increase in myelin, the outer insulating layer of nerve fibers, in the IBMT group only. The changes were noted most in the anterior cingulate cortex, a region of the brain known to regulate decision making, impulse control and emotions.

These findings are important because the minute structural changes in the white matter fibers elucidate the structural changes that took place in response to a four-week practice of IBMT, thereby further supporting the concept of favorable neuroplastic changes with this mindfulness practice. The study report was written documenting the specifics of the imaging techniques, which is important for future research. Limitations would include a relatively small sample size.

A group of Chinese researchers were interested to learn of any unique structural or functional differences in practitioners of Loving-Kindness Meditation (LKM) and if there were differences between experts and novices (Leung et al., 2013). Because LKM is based on the practice of consciously wishing wellness, happiness, peacefulness, and safety for one's self and others (Fronsdal, 2008), the researchers hypothesized that they would find more gray matter in areas of the brain associated with social cognition and emotional processing.

The population was composed of 25 healthy Chinese men, 10 of which had long term experience with LKM and were considered experts. There were 15 others who expressed interest in LKM, but had only seven hours of basic training and self-practice. All subjects were right-handed, and had no history of traumatic brain injury, medical

problems or mental health disorders that could possibly affect brain structure. Each underwent brain imaging using high-resolution MRI.

The LKM group demonstrated increased gray matter volume in the right angular and posterior parahippocampal gyri, regions important in emotional regulation such as empathy, anxiety, and mood. There are known psychological diagnoses associated with low volume gray matter or impaired connectivity in these two regions such as depression (Gilbert et al., 2010), bipolar disorder (Chen, Suckling, Lennox, Ooi, & Bullmore, 2011), and schizophrenia (Gradin et al., 2011). This is an important finding as the logical conclusion would be the potential of non-pharmacological treatment for these common disorders.

Again, the weaknesses lie in small sample size and lack of longitudinal follow up. It is also worth mentioning that the entire population was male, making the generalization to the findings in females scientifically invalid.

There are certain EEG patterns of the frontal lobes of the brain that have been associated with positive mood, particularly an asymmetry favoring more activity in the left frontal region. Therefore, a team of researchers hypothesized that this pattern could be duplicated using single photon emission computed tomography (SPECT) scanning in subjects trained in IBMT when compared to a control group using simple relaxation techniques (RT) (Tang, Lu, Feng, Tang, & Posner, 2015).

Forty right-handed Chinese undergraduates were randomly assigned to IBMT or relaxation group with 20 subjects in each group. All subjects were screened to ensure that they had no prior meditation training and no history of psychiatric or neurological conditions which would skew results. Their mood was evaluated with a brief self-report mood scale, similar to the short form of Positive and Negative Affect Schedule

(PANAS). Participants received 30 minutes of IBMT or relaxation training for a total of 2.5 hours over a five-day period. IBMT involves relaxation, mental imagery, and mindfulness training, guided by a coach, and reinforced using a compact disk. The RT group was trained in an ordered progressive relaxation of muscle groups. Both groups underwent SPECT scanning of the brain, pre-and-post intervention, after a 10 minute preparation period of relaxing in a dark room with eyes closed.

The IBMT group showed significantly better post-intervention scores in mood in comparison to the RT group and the IBMT group alone showed significant post versus pre-intervention mood scores. (all $p < 0.05$). The IBMT group, but not the RT group, demonstrated a significant cerebral blood flow (CBF) increase in subgenual/adjacent ventral anterior cingulate cortex, the medial prefrontal cortex, and insula after training (all $p < 0.05$).

This study, using the finding of frontal lobe asymmetry, showing more blood flow to the left frontal lobe, suggests that a few hours of training produces this effect in both groups, but IBMT's increase was greater than RT. Therefore, there may be potential in the use of IMBT to improve mood by increasing blood flow to a region of the brain associated with attention and self-regulation. Very importantly SPECT scanning of subjects demonstrated a physiological mechanism for improvement in mood using a meditative technique. Increasingly, evidence is coming forward to suggest that the use of meditation could be a valid intervention for mood disorders and other mental and physical malfunctions in the brain.

A large multidisciplinary team of scientists associated with universities in Spain and Germany set about to determine the effect of a mindfulness meditation intervention on the functional connections or linkages between different parts of the brain associated

with mood regulation using *f*MRI technology (Yang et al., 2016). They hypothesized that the intervention would show positive results in all areas measured.

The subjects selected were 13 university students (three males and ten females) recruited by university advertisement to participate in a 40-day mindfulness meditation course. They were screened and found to have no psychiatric or neurological disorders and no prior exposure to meditation. All subjects were right handed with a mean age of 24.53 years.

The intervention was a blend of MBSR and acceptance and commitment therapy. The course consisted of eight 1.5-hour classes and an expectation to practice on their own 45 minutes a day. The actual amount of time spent was self-reported. Three measures were administered pre-and-post intervention; the POMS (assessment of six domains of mood), the STAI (measures anxiety state and trait, or likelihood to respond to stimuli with increased anxiety), and the Center for Epidemiologic Studies Depression Scale [(CES-D), (a measure of degree of depression)]. They also underwent a resting *f*MRI prior to the intervention and again after the mindfulness meditation course. The post-intervention imaging consisted of both a resting and an active meditation scan.

The subjects demonstrated changes in connectivity between several regions of the brain both in the pre-test/post-test imaging during rest and between the resting versus meditation images acquired after eight weeks of mindfulness meditation training. The neural connections were essentially re-wired in a way that favored self-regulation and less anxiety and depression. All three measures showed significant changes; the CES-D dramatically so, with scores dropping from 16.23 ($\pm$ 9.54) to 9 ($\pm$6.20) and trait anxiety from 21.30 ($\pm$8.6) to 16.84 ($\pm$9.56), as well as the tension domain of the POMS from 8.00 ($\pm$3.36) to 5.38 ($\pm$5.18).

Again, the use of meditation for eight weeks improved scores on standard measures and demonstrated favorable neuroplasticity. Previous studies reported on the changes in the volume and characteristics of gray and white matter, but this was the first study to investigate functional connectivity between several regions of the brain. Not only do these findings represent an opportunity to treat mood disorders with meditation, but may even begin to explain the physiological hardwiring needing readjustment in serious psychological diagnoses such as autism, schizophrenia, bipolar disorder and others, which are very difficult to treat with currently available therapies.

The study of neuroplasticity is in its beginning stages and the work requires complex and expensive testing which explains the small sample sizes. Although there were important changes associated with the meditation intervention, there was no control group in this experiment. The authors point out that the mean pre-intervention scores on the CES-D were positive for depression, as a score of 16 is the point at which depression is diagnosed. This likely represented mild, sub-clinical depression in several subjects, but contend that sub-clinical depression is very common in society and accurately represents a segment of the population that presents in the primary care setting regularly. It would have been interesting to test the subjects again at a much later date since mindfulness meditation is a skill set that appears to improve over time.

Cost-Effectiveness of MBSR Interventions

A group of Canadian researchers, concerned about the increasing demands and decreasing resources in healthcare, performed a prospective study of 1,730 patients who had attended a MBSR program associated with their healthcare system, St. Joseph's Health Centre in Toronto, Canada (Knight, Bean, Wilton, & Lin, 2015). They were especially interested in whether patients' attendance of a MBSR program, known to

decrease stress, had an impact on health care consumption. Stress and its related comorbidities, anxiety and depression, have been shown to be a risk factor for approximately twice the health care consumption when compared to low-stress groups, and these researchers wanted to shift at least partial responsibility to patients (Revicki et al., 2012).

The study's intervention group had attended a 10 week course consisting of a screening conducted the first week to determine if there was sufficient interest and ability to take part in the course. The next nine weeks involved a formal weekly class, three hours in length as well as daily homework. The group also attended a one-time seven-hour class. Of the 1,770 participants who had attended the course from May 2002 to April 2007, 1,730 gave permission for their data to be used in the study (97.7%).

The initial computation was the pre-and-post healthcare consumption of the MBSR group after all unique identifiers were removed. Comparison groups (or control groups) were formed, matching three similar individuals to each MBSR patient using five different databases. Variables considered were demographic information (age, gender, neighborhood and neighborhood average income, rural versus urban areas, acuity level, and number of insurance claims).

The comparison of healthcare consumption of the MBSR group with the controls showed that the MBSR group consumed more than twice as much in healthcare dollars before the intervention. When the MBSR group was measured pre-and-one-year-post intervention, there was a decrease in cost of services of $244-$279 per participant, representing an average of $375,000 for each 1,500 participants ($250). This effect was no longer detected at a two-year comparison.

Therefore, it may be concluded that even though the savings seem small, it would cover the small cost of the MBSR program and add to that the increased satisfaction by patients to feel better and spend less time in health care clinics. A very important finding in the study was the fact that the effect only lasted about a year. This needs to be explored so mindfulness can become a lasting trait, thus providing a more lasting or even increased effect.

It is important that the actual cost savings of the intervention were calculated just to reassure healthcare administrators that at least MBSR was not a loss leader and may likely be honed over the years to become more efficient and long-lasting as more knowledge is obtained regarding the specifics of program design and how to capture the best results. Prospective studies have an innate weakness of demonstrating association rather than cause and effect, but much attention was given to removing bias with three well-matched controls for each MBSR participant. Another issue is that the prospective studies have limitations such as the ability to examine if and for how long, participants in the MBSR program continued the practices learned. It is very likely that the loss of savings in the second year was due to lack of continued practice, but there was no way of knowing. Another limitation was that any out-of-pocket expenses for healthcare were not accounted for.

Gaps in the Literature

Since MBSR has been utilized in the medical setting since 1979, there is a great deal of literature available on the topic. However, use of MBSR and similar mindfulness meditation techniques delivered by internet-connected devices, not closely managed by clinicians, represents the most neglected area of research. Due to the ability to greatly reduce the cost of treating patients with anxiety symptoms using electronic technology,

augmenting the available evidence-based therapies (CBT and pharmacologic agents), and giving patients some autonomy and responsibility for their care, clearly this is the area where more exploration is needed. This gap further strengthens the argument that this DNP project is justified.

Strengths and Limitations in the Literature

Although the strengths and limitations in the literature were addressed with the reporting of each study, a concise review will clarify this important aspect of the literature review. Table 3 details this information.

Table 3

Strengths and Limitations in the Literature

Strengths and Limitations in the Literature	
Strengths	• Documentation of an emerging therapy despite poor study design early on. • The practicality of the studies regarding motivation to vet a new therapy, decrease the cost of healthcare services, and utilize technology to both explore and deliver MBSR and similar therapies to symptomatic patients. • Many of the studies were well-designed, adhering to standards that today make MBSR an evidence-based intervention for use in patients suffering with anxiety. • Good progression from surveys to eventual detailed anatomical and physiological documentation of benefit of mindfulness meditation interventions
Limitations	• Early studies lacked the rigor necessary to support mindfulness meditation as an evidence-based therapy for anxiety. ▪ Small samples sizes ▪ Convenience samples versus clinical samples from which generalizable results could be applied ▪ No or poorly designed control groups ▪ Poor reporting of results using appropriate statistical methods ▪ Lack of longitudinal studies to determine endurance of effect of intervention ▪ Incomplete reporting of important aspects of the study

Theoretical Framework

This DNP project was motivated by and built around the Recovery Alliance Theory of Mental Health Nursing (RAT), a mid-range nursing theory, originally proposed for application in mental health nursing settings (Shanley & Jubb-Shanley, 2007). Even its name reflects the power of relationship between patient and nurse to effect recovery. Below is a diagrammatic view of the RAT in Figure 1. The theory is characterized by six outer constructs (humanistic philosophy, common humanity, empowerment, strengths focus, partnership relation, and recovery) which underpin the theory and are described in Table 4. There are three concepts that describe the way the constructs are translated into nursing practice, a working alliance, coping, and self-responsibility/control and are summarized in Table 5.

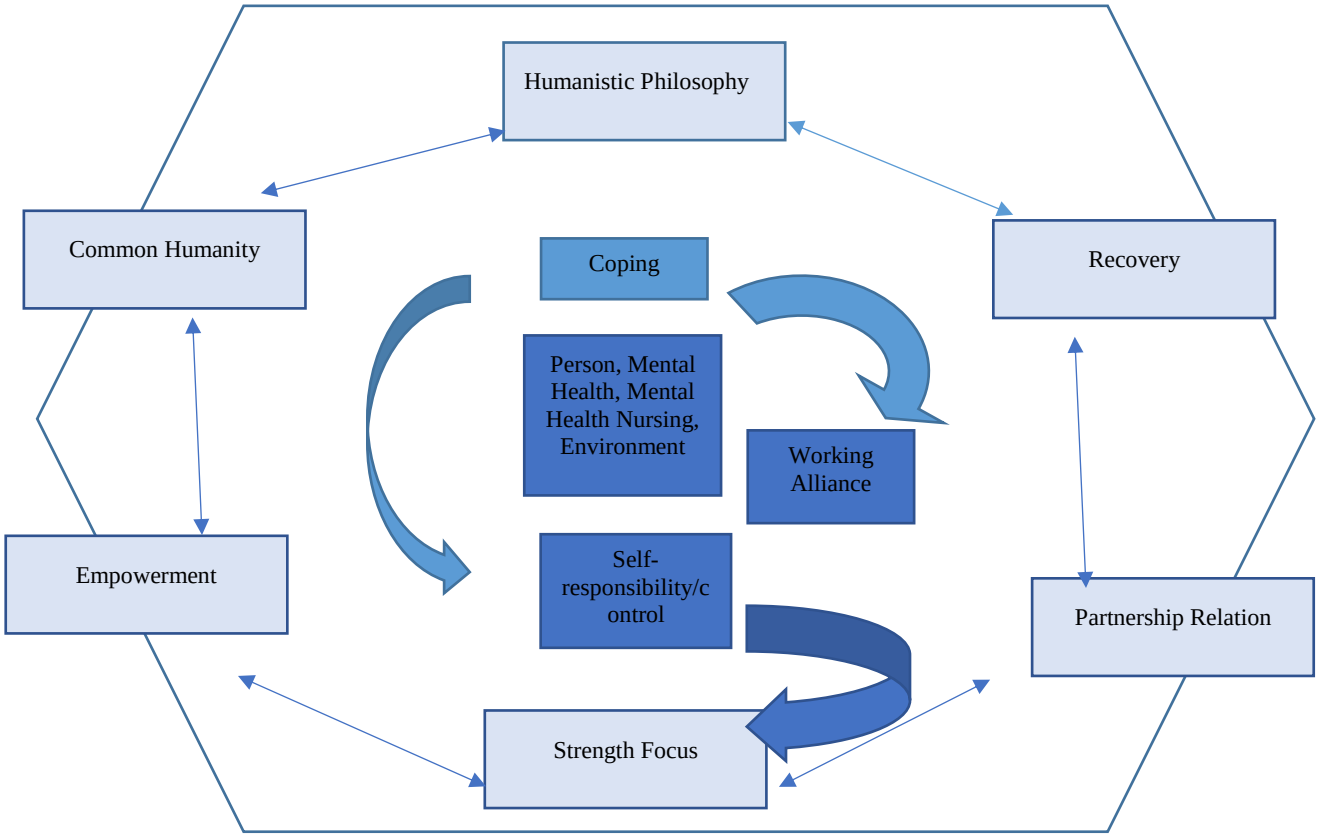


Figure 1. Diagram of Recovery Alliance Theory (Shanley & Jubb-Shanley, 2007)

Table 4

The Constructs of the Recovery Alliance Theory (Shanley & Jubb-Shanley, 2007)

Constructs	Definition
Humanistic Philosophy	Reflective of a move away from the medical model to humanistic philosophy: ▪ Individuals are social animals and share a common humanity. ▪ Individuals have the potential for growth through awareness of and interaction with self and others. ▪ The individual's growth is enhanced by a respectful approach in validating the person's ability to deal competently with his or her own life experiences. ▪ Individuals have the ability to make choices and to exercise control in decisions affecting their lives. ▪ Individuals cannot be categorized in that they are composed of many different facets of which none stands alone.
Recovery	Nurses participate in helping patients believe they are more than a diagnosis. Together they explore problems, understand the power of a willingness to change, and optimistically use their strengths to address problems. Each small step is celebrated, building optimism for recovery in the patient.
Partnership Relation	The nurse and patient enter an equal partnership, characterized by everyday speech, free-flowing dialogue, and a holistic approach to care. Patients are seen as possessing the skills, or the ability to learn them, that will lead them to cope with mental illness successfully. In the end, the power to accept or reject nursing advice lies with the patient alone, and that is respected.
Strengths Focus	There is concentration on patients' strengths rather than a medical diagnosis, which offers recovery as a real option.
Empowerment	Focus on a medical diagnosis is not helpful to patients. Instead, the patients' own understanding of their mental health concerns is the starting point, and from there active participation and decision-making is facilitated by the nurse.
Common Humanity	There is an emphasis on the fact that nurses and patients stand on equal ground, that of being human, with the potential to understand the other's perspective, concentrating more on how we are alike rather than how we are different.

Table 5

The Concepts of the Recovery Alliance Theory (Shanley & Jubb-Shanley, 2007)

The Concepts of the Recovery Alliance Theory	
Concept	Definition
Working Alliance	▪ Everyday speech, avoiding professional jargon, enhances approachability, and reinforces a common humanity with patients. ▪ Variable context and times of interactions, which may not always occur at a healthcare facility. A home visit or meeting at a public location may increase the nurse's insights regarding the patient. ▪ Self-disclosure refers to the ability to interact in a non-judgmental manner with patients, even sharing some individual information, to help a patient feel understood. ▪ Unscripted dialogue is used as appropriate to address irregularities in patient behaviors or location of patient interactions as an opportunity to effect change. ▪ Holistic perspective refers to being open to the patient as a human being without limiting interactions to a narrow definition of providing nursing care. More information about a patient leads to a sense of common humanity.
Coping	Individuals adopt strategies to cope with stress. They may manage, alter, or regulate their emotional responses.
Self-Responsibility/Control	Opposite of the medical model which views mental illness as occurring as a result of some sort of pathology (external locus of control), patients are encouraged to accept responsibility for their own well-being (internal locus of control).

Studies Using the Recovery Alliance Theory of Mental Health Nursing

Treatment of mental illness has changed over the years, but perhaps one of the most refreshing changes is a move from the medical model of treatment of a disease, which focuses on a diagnosis, to treatment of the patient holistically. Gandi and Wai (2010) designed a three-month intervention, Partnership-in-Coping, to address mental health needs in a group of patients being treated at the Federal Neuro-Psychiatric Hospital in Kaduna, Nigeria.

The participants, 56 of 230 in-patients and out-patients, were randomized to receive either the Partnership-in-Coping intervention or to receive treatment as usual. The groups consisted of 29 males and 27 females with schizophrenia, depression, mania, anxiety disorders, and drug-induced psychosis, all equally distributed between the two groups. Participants' ages ranged roughly from 16-60 and were evenly split between inpatients and outpatients.

Ten research assistants provided most of the care rendered to the intervention group. Interestingly, these ten individuals were selected from among the multidisciplinary facility staff after scores on the Professional Quality of Life (ProQOL R-IV) demonstrated a "willing attitude and a teachable disposition" (Gandi & Wai, 2010, p. 325). Study participants were measured once, at the end of the study using the well-validated Mental Health Recovery Measure (MHRM), a self-evaluation tool that quantifies recovery from mental illness with possible scores of 0 (no recovery) to 120 (high degree of recovery).

After orientation of the research assistants, they acted as the patients' advocates by partnering with them as they met with appropriate healthcare professionals regarding medication regimens and attending both one-on-one and group counseling sessions. The

essence of the intervention was the dynamic partnering relationship between the research assistants and the participants. After the three-month period, all 56 participants were assessed using the MHRM.

The Partnership in Coping intervention group showed dramatic improvement when compared to the treatment as usual group. The mean score for the experimental group was 97.79 versus 34.93 in the control group ($p<.001$). This finding appears to validate the efficacy of structuring interventions in mental healthcare consistent with the Recovery Alliance Theory's constructs (humanistic philosophy, common humanity, empowerment, strengths focus, partnership relation, and recovery).

Although the researchers were very careful to match the two groups as to age, religion, education, and main diagnosis, a definite strength of the study, there was no pre-test MHRM measurement of the control group. Therefore, one must assume that because the groups were statistically homogeneous, they would have started the study with statistically non-differing baseline scores, a study limitation. However, a strength of the study was the careful choosing of research assistants using the ProQOL R-IV, so as to expose each participant in the intervention group to the same degree of quality partner, demonstrating characteristics the researchers believed to be essential in administering their intervention.

The originators of the RAT, Shanley and Jubb-Shanley (2007) translated their theory into a method of mental health nursing practice, Coping Focus Counselling (CFC) (Shanley & Jubb-Shanley, 2012). In this paper, they note that there are several counseling techniques, each with their strengths and weaknesses, but they proposed integration of several widely-used techniques (i e. Gestalt, CBT, Client-centered Therapy, and Attachment Theory), removing the professional jargon (instead, they value everyday

speech) in order to promote insight in patients' symptoms and behaviors rather than grouping them in a diagnostic category as is promoted in the medical model. Patients begin to understand that the nature of humanity involves struggle and the counselor (mental health nurse) fosters self-efficacy in the development of coping by cultivation of an authentic alliance-type relationship.

The ultimate goal of CFC was to facilitate productive coping strategies centered around an individual's mental health concern(s). Emphasis was placed on the patient's coping concern and was never labeled as a diagnosis, thus amenable to learning and unlearning, which was empowering and emphasizes an internal locus of control. A patient's reluctance to engage in therapy was seen as a form of coping (though it may be mal-adaptive), and not as non-adherence or some other negative term often used by providers. The working alliance was characterized by interactions between two equals, rather than healthcare provider (superior) to patient (inferior), and patients' coping strategies are explored and understood by this therapeutic dyad, providing the option for patients to choose more productive coping patterns.

The CALM Project was developed using the RAT constructs as the rationale for many of the elements such as project topic, content, population, and setting based on the project administrator's own clinical experience as a nurse practitioner providing primary care in an internal medicine clinic. As a group, patients with anxiety generally present initially, as described earlier, with somatic complaints. Eventually, once physical pathology is ruled out, patients are usually quick to agree that their pattern of coping with life's uncertainties is to worry and experience anxiety. All the barriers to counseling and/or pharmacotherapy described in the literature can be confirmed by this project administrator's own experience.

The RAT was based on a concept of a recovery-based approach to the treatment of mental disorders using a working alliance between the nurse and patient. A search for evidence-based alternative or adjunctive therapies that could be initiated in a busy primary care office favored mindfulness-based meditation as a logical choice due to low cost and no need for additional staff, such as would be the case with other treatments (i e. acupuncture, massage, in-house behavioral health counseling, etc.). Figure 2 demonstrates how the project aligns with the constructs of the theoretical framework.

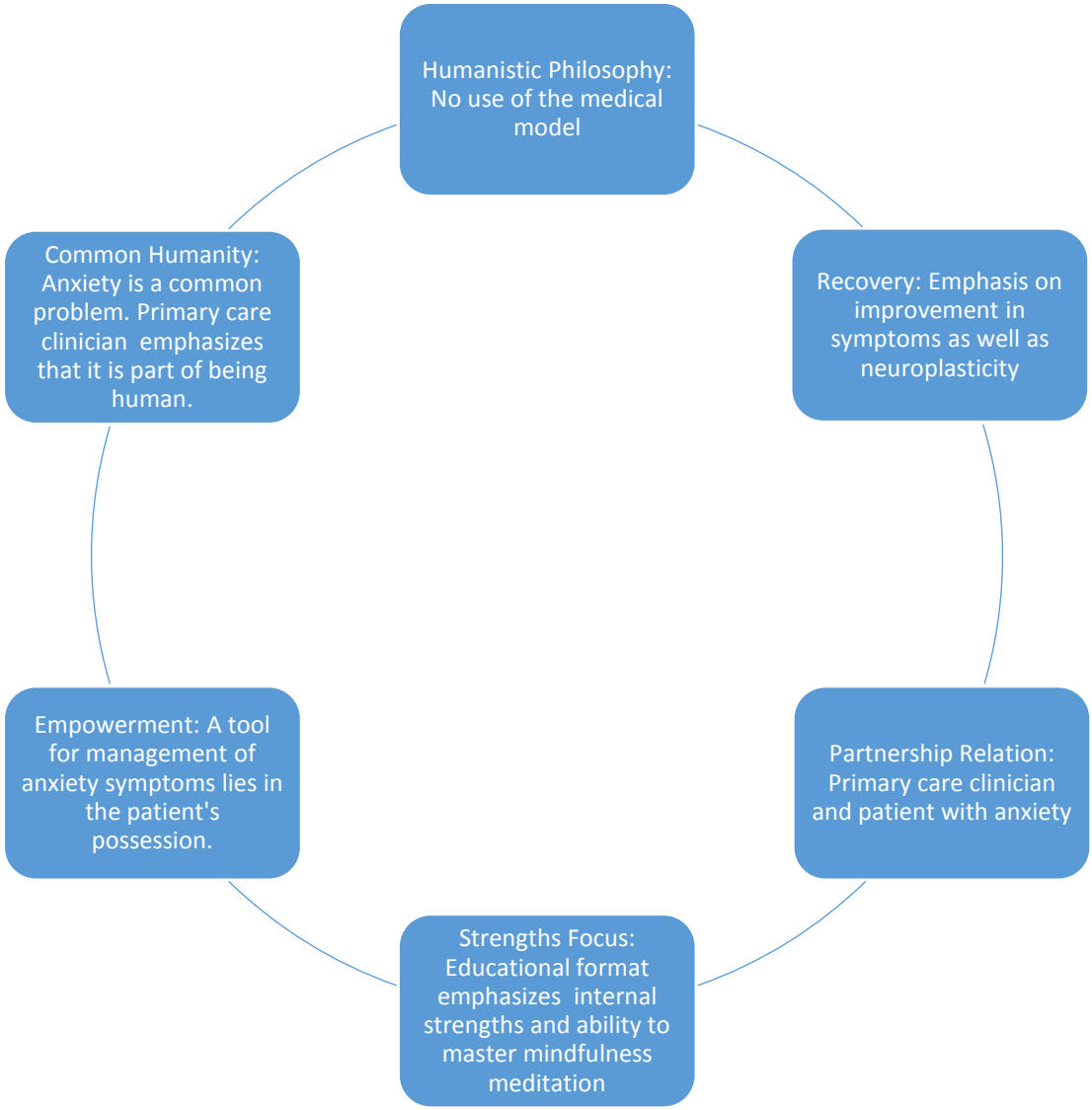


Figure 2. Recovery Alliance Therapy Constructs and Project Design

Summary

This literature review represents research of the mindfulness movement from its infancy beginning in 1979, with Jon Kabat-Zinn's MBSR program at the University of Massachusetts Medical School, to the most current work involving highly technological methods in an attempt to understand the neuroplasticity observed in practitioners of MBSR and similar mindfulness meditation techniques. After years of research involving a wide variety of populations, settings, and study methods, the research bears out the efficacy of mindfulness meditation as a therapeutic technique which has earned its place in the practice of evidence-based healthcare.

However, adoption of MBSR by primary care clinicians was lagging due to the lack of a simple, cost-effective way to introduce the technique to appropriate patients within the constraints of a time-limited office visit. Therefore, it is essential that there is more testing of computer-based apps, presented to patients in their PCP's office, requiring just a few minutes of clinician time. This was where the justification of the CALM Project lies.

Chapter III

Project Description

Anxiety disorders are common and costly, both in the degree of patient suffering and in dollars spent annually treating the disorder. The purpose of this DNP project was to measure the effect of the use of a computer-based mindfulness meditation app on anxiety levels in adult primary care patients. Also, since there is mixed evidence indicating a positive dose response to this intervention, this project included tracking of client usage of the program to recognize any relationship between amount of time the app was used and improvement in anxiety levels at the end of the project. Qualitative feedback from participants regarding their experience of using the app was also of interest to determine feasibility of the intervention, and learn of any common technical problems.

Hypothesized outcomes are as follows:

1. Use of the app (Calm.com) would reduce anxiety levels in participants.
2. Due to the mixed data on dose response, no hypothesis was made.
3. There would be important themes in participant feedback that could improve on aspects of the intervention for future use.

Project Implementation

This DNP project was a longitudinal study collecting a mix of quantitative and qualitative data. Prior to implementation of the project, Institutional Review Board (IRB) approval was granted by the project administrator's university. Permission was obtained from the project clinical site.

The project administrator first collaborated with the chief medical officer of an urban primary care practice located in Southeastern North Carolina to establish a

relationship and buy-in to perform the project at this site. A meeting was scheduled for the project administrator to meet the clinic providers during which a Power Point presentation describing the project was shown. Flyers promoting the benefits of mindfulness meditation on anxiety and related symptoms were posted throughout the facility, giving patients the opportunity to self-refer as participants. Clinicians also provided contact information of patients with which the project was discussed during an office visit, with a mutual decision made by clinician and client to participate. The project coordinator was on site weekly to answer questions, enroll subjects, and to collect pre-and-post data for six weeks during March and April of 2017.

Setting

The CALM project setting was a federally-funded urban primary healthcare clinic supported and subsidized by the Bureau of Primary Care. This clinic offers primary care, dental care, and behavioral health services to patients of all ages. The clinical staff included three family physicians, three family nurse practitioners, one pediatrician, two licensed medical social workers, one psychiatrist, and a staff of dentists, dental assistants, dental hygienists, lab technicians, pharmacists and pharmacy assistants.

Sample

Subjects were recruited using posted flyers as well as by recommendation from their PCP. There was no attempt to select subjects based on any formal psychiatric diagnosis, but rather, individuals who described themselves with anxiety symptoms of any degree were accepted. The age range of participants was 23-67 and overwhelmingly female (F=14, M=1).

Project Design

This project was designed as a pilot study (pre-test/post-test) to determine the feasibility of using a smart phone, computer, or tablet to educate interested individuals with symptoms of anxiety in the primary care setting on mindfulness meditation. The education was delivered by a computer-based smart phone app, Calm.com. Complimentary vouchers supplied by Calm.com provided free access to the app for 30 days.

The app provided a 28-day course in the use of mindfulness meditation with opportunities to practice using guided meditation. Sessions varied in length from 9-18 minutes each. The app screen displays are composed of a number of calming visual scenes, complete with accompanying sound and motion, that may be changed by the user according to preference or need for variety. There are other guided meditations on a variety of topics available in case a participant wanted to supplement the basic course. There are sleep aid features using guided meditation and a feature known as sleep stories, bedtime stories for adults. Time-keeping is done automatically by the app, so the inherent limitation of patient self-report regarding time spent using the intervention was averted.

Protection of Human Subjects

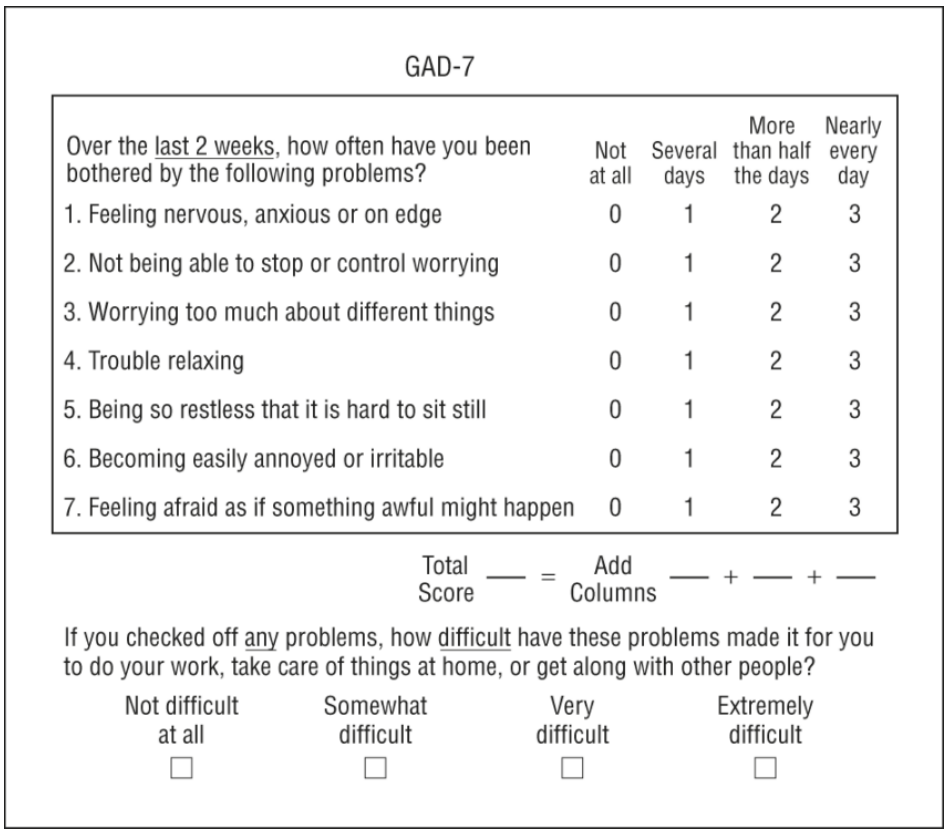
Prior to the start of the project, the project administrator completed an orientation to the clinic site and completed their HIPAA course. During enrollment, subjects signed a consent to engage in the project. Questions were elicited and answered by the project administrator. All participants were given full disclosure that participation was voluntary and discontinuation would be an option at any time. It was emphasized that the project administrator would not have access to their medical records or any private information about the participants, nor would the project administrator share any information with

clinic providers or staff. It was also stressed that the information collected during the project would not become a part of the patient's medical record. As a token of appreciation for participation, a $10 gift card was given to each participant.

All data was locked in a drawer in the project administrator's office. Participants were reassured that the reporting of any data would be presented as aggregate data only. There would be no means by which any individual participant could be identified.

Instrument

The instrument chosen to measure anxiety was the Generalized Anxiety Disorder 7-Item Scale (GAD-7) created by Spritzer, Kroenke, Williams, and Lowe (2006). The scale is shown in Figure 3. It has become a very well-accepted measure used in many practice settings and is in the public domain. There are seven questions, and a level of difficulty that any selected item(s) interfered with "ability to do your work, take care of things at home, or get along with other people" (Spitzer et al., 2006, p. 1094). Scoring of the scale is displayed in Table 6. The internal consistency of the tool is excellent (Cronbach $\alpha = .92$). The procedural validity and test-retest reliability were assessed by calculation of the intraclass correlation coefficient (0.83). Sensitivity and specificity were maximal (89% and 82% respectively) at a score of ten. Therefore, the authors recommended using a score of ≥ 10 as the marker for the need for further evaluation and/or treatment.



GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Total Score ___ = Add Columns ___ + ___ + ___

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

Not difficult at all ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult ☐

Figure 3. The GAD-7 (Spitzer et al., 2006, p. 3)

Table 6

Interpretation of GAD-7 Results (Spitzer et al., 2006, p. 1095)

Total Score	Interpretation
0-5	Mild
6-10	Moderate
11-15	Severe

Data Collection

All data from The CALM Project was collected by the project administrator between March 15 and April 26, 2017. The majority of the data was collected during a face-to-face meeting, but in several cases data was collected by telephone due to participants' inability to come in to the clinic. Demographic data included the age and gender of the participant as well as a preferred method of contact. The GAD-7 was administered at the enrollment visit and again at the end of the project. A questionnaire was also administered at the end of the study to collect qualitative data regarding the study as well as time spent using the app.

Data Analysis

Data from the study was initially recorded in an excel spreadsheet by the project administrator. Descriptive statistics were calculated on the GAD-7 pre-scores, post-scores, and difference score (i e. post-score minus pre-score). Pre-and-post scores were compared using the paired *t*-test. To test for associations between minutes used and difference in scores, Pearson correlation coefficients were calculated. P-values less than 0.05 were considered statistically significant. All statistical analysis was performed using SAS Enterprise Guide 6.1 (SAS Institute Inc., Cary, NC, USA).

Budget

The budget included travel from project administrator's home to the clinical site, although no mileage was recorded. There was minimal cost for printing to create patient packets. Gift cards to patients at study's end equaled $150, or $10 for each of the participants completing the project. Statistician's fee was $250 dollars.

Limitations

Improvisation regarding enrollment and data collection occurred in a few instances when the participant could not meet with the study administrator in person. Due to limitations in time to complete the study, there was no post-study follow up to document endurance of the effect of the intervention.

Summary

The need to know if primary care patients suffering from anxiety symptoms would use a smart phone app to learn mindfulness meditation as a possible solution to symptom relief is needed information as there are known barriers to other therapies. New, practical evidence-based interventions will be critical as we continue to see the gap increasing in demand for services and diminishing resources.

The theoretical framework chosen for the CALM Project fits well to this patient population. The relationship between the PCP and the patient with anxiety is indeed a partnership between two human beings who can work together to accomplish coping strategies to life events that are more useful than anxiety and panic. Patients, especially those who have experienced these symptoms for long periods of time, or believe that "it's genetic", need to know that recovery is indeed possible and that the solution may lie within an app on their smart phone.

Chapter IV

Results

The CALM Project was designed to determine the feasibility and efficacy of using a smart phone app (Calm.com) as an educational tool to teach mindfulness meditation to primary care patients suffering from anxiety. The study participants were given free access to the app for one month, with instructions to access a daily lesson lasting just a few minutes for 28 days. The vouchers were supplied by Calm.com, but this is a routine practice, so clinicians can introduce the app without cost to patients they discern are candidates for mindfulness meditation.

Sample Characteristics

Twenty primary care patients identified interest in being a participant in the CALM Project. Three patients were lost to follow up, meaning no post-test data was obtained (after several attempts to contact). Two patients expressed interest during a visit with their primary care clinician, but failed to respond to attempts made by the project administrator to enroll using their preferred method of contact. The final count of participants with pre-and-post data was 15, or a 75% completion rate. The population consisted of 14 females and one male. The age range was 23-67 years, with a mean age of 46.7 years.

Major Findings

Quantitative Results

There were statistically significant findings in several analyses. First, the average total GAD-7 score decreased from a pre-test mean score of 10.2 (SD 5.5) to post-test mean score of 5.9 (SD 3.4) with a *p*-value of 0.01. There was also significant reduction of scores with regard to each question of the GAD-7 except Question 2 and Question 5.

No significant change was noted in level of difficulty experienced by participants regarding doing their work, taking care of things at home, or getting along with other people. The results are shown in Table 7.

Table 7

Comparisons of GAD-7 Pre-and-Post Scores

Variable	Pre-Mean Average (SD)	Post-Mean Average (SD)	*p*-value
Q1	1.8 (0.9)	1.2 (0.9)	0.01
Q2	1.3 (1.2)	0.9 (0.6)	0.16
Q3	1.8 (1.0)	1.1 (0.7)	0.03
Q4	1.8 (0.9)	0.8 (0.7)	0.004
Q5	0.9 (1.2)	0.4 (0.5)	0.07
Q6	1.4 (1.1)	0.8 (0.8)	0.003
Q7	1.2 (0.8)	0.5 (0.6)	0.01
Difficulty	1.7 (0.8)	1.3 (0.5)	0.14
Total Score	10.2 (5.5)	5.9 (3.4)	0.01

As seen in Table 8, all correlations between minutes used and difference in scores are negative, showing improvement in scores with number of minutes used, however the changes were not found to be statistically significant.

Table 8

Correlations between Minutes Used and Change in Scores

Variable	Correlation with minutes used (p-value)
Q1	-0.22 (0.44)
Q2	-0.27 (0.33)
Q3	-0.33 (0.22)
Q4	-0.39 (0.15)
Q5	-0.34 (0.21)
Q6	-0.49 (0.07)
Q7	-0.12 0.66)
Difficulty	-0.27 (0.33)
Total	-0.35 (0.20)

Qualitative Results

The qualitative data analysis was performed in three steps: (1) the data was organized by question, (2) analysis of trends and patterns emerged allowing a compression of the data due to homogeneity, and (3) a synthesis of the findings was reported (Seers, 2012).

Overall, the participants found the app helpful. Learning to relax was the predominant theme as to the manner in which the app specifically helped. Participants also commented on the value of short, structured sessions. Most of the participants did not experience technical difficulties using the app, but there was an issue with some participants of not being able to easily move from screen to screen. For a compilation of results, see Table 9.

Table 9

Qualitative Results of the CALM Project

Question	Responses	Trend
Did you find that using the Calm.com helped you reduce anxiety?	Yes, quite a bit helpful: 9 Helped some; 6 No, was not helpful: 0	All participants found the app quite a bit or at least of some help at reducing anxiety.
What did you find most helpful about using the app?	• Helped me relax ▪ "Quiet my mind ▪ "Takes me away from my anxiety" ▪ "Taught me to concentrate on breathing" ▪ "Enjoyed the relaxing scenes" ▪ "Helped me relax after work" ▪ "Use it for sleep every night" • Short sessions are "do-able" • The structure helped	The goal of relaxation was reached. The short sessions and having some sort of structure for practice was also helpful.
What problems did you experience while using the app?	▪ None: 9 ▪ Problems: 6 ▪ Sometimes could not see all the buttons needed to move about on the screen: 5 ▪ Couldn't get background sounds to stop even after app was closed. Had to restart the phone: 1	Most of the participants had no technical difficulty with their use of the app. If difficulty was experienced, it was most often due to not being able to easily move from screen to screen. One participant had a problem completely closing the app without restarting phone.

Summary of Results

The project questions were all answered by the conclusion of the project. The use of a web-based computer app was significantly effective at reducing GAD-7 scores (p=0.01) in primary care patients experiencing anxiety. Even though there was improvement in GAD-7 scores in participants associated with more use of the app, the improvements did not reach statistical significance. Important themes were noted with analysis of the qualitative data. The app was found to be helpful by all participants and relief of anxiety was the predominant theme. Although most participants experienced no technical issues with the app, some participants found it difficult to move about within the app with ease.

Chapter V

Discussion

The purpose of the CALM Project was to test the feasibility and efficacy of using a computer-based app to teach primary care patients to manage anxiety by using mindfulness meditation. Another point of interest was whether this population demonstrated a dose response, meaning, more use of the app would affect more change. Finally, participants' feedback regarding use of the app would provide more understanding of their experiences and advice regarding future use of the intervention.

Implication of Findings

The literature was rich with documentation of successful interventions using mindfulness meditation to relieve anxiety in many settings and populations. This was an important motivating factor involving the choice of intervention to test with primary care patients. Just as expected, there was significant reduction in anxiety as measured by the GAD-7. There was a trend toward association with more use of the app as a factor for decreasing anxiety, but the association did not reach statistical significance. This mirrors the findings in the literature. The qualitative data demonstrated feasibility and acceptance of this novel intervention and relief of anxiety symptoms was significantly experienced by participants. As with any technology, there can be glitches, however the majority of participants experienced no problems.

Application to Theoretical Framework

The positive results seen in the CALM Project reinforce the constructs of the Recovery Alliance Theory (RAT) (Shanley & Jubb-Shanley, 2007). Likely more impact will be experienced ongoing, as the project administrator uses the app with her own primary care patients, with which she has already built a partnership relation. Now that

the theory has been used as a guiding framework for the CALM Project, the value of the constructs is clear. Helping patients to see that recovery is possible and empowering them to change their coping responses by concentrating on their strengths is the basis of holistic nursing care. The only obvious conflict is with the construct of humanistic philosophy versus a medical model diagnostic code as without it, there would be no reimbursement for care. However, this aspect of the care can easily be minimized during contact with patients.

Limitations

Limitations of this pilot project were consistent with many other studies described in the literature review. The sample size was small and over-populated with female participants, therefore not adequately powered to answer the question of if there is a dose response effect. There was no control group, therefore no randomization was possible. The sample could be described as a convenience sample and participants interacted with an outsider rather than their own PCP. The questions eliciting qualitative data could have been asked in a way to glean a deeper understanding of participants' lived experience. Even though the app has the capacity to track usage (time used in hours and minutes and number of sessions) and share this data with others easily by email, this feature was not used, due to the need for simplicity in this pilot study. Participant self-report was the method used instead, which is known to be less accurate. Technical difficulties experienced by some participants likely influenced usage and possibly impacted outcomes.

Implications for Nursing

This DNP project demonstrated the value of a brief mindfulness meditation intervention, introduced in the primary care setting with just a few minutes of instruction. This translates into a meaningful treatment option to suggest in patients with anxiety.

Recommendations

This intervention is not just for patients, but for anyone struggling with stress and anxiety. A future project involving a mix of healthcare workers is warranted. Other populations of interest may include caregivers and patients experiencing the stress and grief of the loss of a spouse or close loved one.

Modifications to the method of a repeat project are suggested. Taking the time to arrange for sharing of usage data would be quite valuable as the question of the existence of a dose response has not been answered conclusively. Gathering this data electronically would be highly superior to participant self-report. Also, since some participants experienced technical problems using the app, orientation to the content available, navigation from screen to screen, and assistance in setting up preferences would most likely decrease the likelihood of most problems.

Conclusion

The use of mindfulness meditation education, offered inexpensively using a computer app, is a viable strategy for treating anxiety in many patients encountered in primary care. The intervention demonstrated a significant decrease in GAD-7 scores and proved to be feasible and well-adopted by project participants.

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