

12-2016

The Effects of a Brief Mindfulness-Based Meditation Intervention on Chronic Pain

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The Effects of a Brief Mindfulness-Based Meditation Intervention on Chronic Pain

by

Jolena B. Allred

A capstone project submitted to the faculty of
Gardner-Webb University Hunt School of Nursing
In partial fulfillment of the requirements for the degree of
Doctorate of Nursing Practice

Boiling Springs

2016

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Abstract

As the number of individuals suffering with chronic pain escalates, management is shifting from pain specialists to primary care providers. Nurse practitioners are becoming increasingly responsible for the management of this complex patient population. Analgesics, primarily opioids, have been the standard of chronic pain management with a resulting national crisis related to overuse, improper use, and illegal use of these substances. Mindfulness-based meditation has gained increasing interest and acceptance by both the individuals suffering with chronic pain and the providers managing those who suffer, however, limited investigation is available related to brief interventions provided at point-of-care. This Capstone Project evaluated the effect of a brief mindfulness-based meditation intervention implemented at point-of-care to patients diagnosed with chronic pain over a four week time span measuring pain level, mindfulness self-efficacy, and quality of life. Findings demonstrated that an individual's level of mindfulness self-efficacy positively relates to quality of life measures after use of a brief mindfulness-based meditation intervention. Additionally, individuals diagnosed with chronic pain less than five years demonstrated an improved response in mindfulness self-efficacy and quality of life measures after implementation of a brief mindfulness-based meditation intervention.

Acknowledgments

The accomplishments in my life have never been attributable to my solitary efforts, skills, knowledge, or gifts. First, God has always had His attention on me, despite my routine focus away from Him. Although I have not been methodical or organized in my endeavors, God has always had a plan. God gave me two earthly parents, Parks and Frances Allred, who consistently demonstrated unconditional love and belief in my ability to accomplish educational goals. At the beginning of this doctoral journey, both of my parents were with me in body, mind, and spirit. As this journey concludes, my wonderful father has departed this earth, and my loving mother is by my side, however, she has the daily challenges of dementia. Their wisdom has set a precedent for our family, and our future generations. That future generation includes my children, Jackson and Anna, who are intelligent, insightful, successful, and who, without question, are my greatest accomplishment on this earth.

Beyond my family, I must acknowledge Dr. Anna Hamrick, who served as my chair, and Dr. Phillip Stover, who served as my preceptor during my doctoral immersion and Capstone Project implementation. Dr. Hamrick patiently guided me through this process with sound advice and support routinely. Dr. Phillip Stover, MD not only gave me my first opportunity to practice as a licensed Family Nurse Practitioner when he employed me in 1995, but also provided his knowledge, staff, and private practice to me, many years later, facilitating my pursuit of this advanced degree. Dr. Stover's generosity has taught me more than he will probably ever know.

Lastly, I must acknowledge all of the wonderful patients and families that I have encountered in my career. I am blessed beyond measure to have the opportunity to serve

others as a family nurse practitioner, and I have always received so much more than I have given. Again, this has all been God's plan.

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CHAPTER I

Introduction

An estimated 116 million American adults suffer with chronic pain representing \$560 to \$650 billion annually in direct medical treatment costs and loss of individual productivity (Institute of Medicine [IOM], 2011). The number of American adult individuals suffering with chronic pain outnumbers those suffering with heart disease, diabetes, and cancer combined (IOM, 2011). The assessment and treatment of pain gained significant public health attention in the mid to late 1990's in response to documented inadequacies in addressing pain, resulting in public health policies, standards, recommendations, and initiatives aimed at routine inquiry of all individuals related to pain, often referred to as the 5th vital sign (American Pain Society Quality Care Committee [APS], 1995; Morone & Weiner, 2013; Veterans Health Administration, 2005). In response to this public health outcry, pain assessment improved, and the identification of individuals suffering with acute and chronic pain subsequently increased. This increase in assessment and identification of individuals suffering with pain, either acute or chronic, has yielded a substantial increase and reliance on opioid analgesics as the mainstay of pain management, with an increase of 402% use by individuals reported from 1997 to 2007 (Manchikanti, Fellows, Ailinani, & Pampati, 2010). Opioids are one of the most frequently prescribed analgesics in chronic pain management, however; in fewer than 50% of chronic pain patients, only a 30% to 40% reduction in pain is reported routinely (Furlan, Sandoval, Mailis-Gagnon, & Tunks, 2006; Kalso, Edwards, Moore, & McQuay, 2004; Turk, 2002).

Often thought of as a specialty area of medical management, the escalation of individuals suffering with chronic pain has challenged the availability of pain specialists resulting in the need for primary care providers to accept responsibility for the management of this complex patient population (Dubois & Follett, 2014). Nurse practitioners represent one of the largest groups of professionals providing primary care in the United States (Naylor & Kurtzman, 2010) and will continue to be impacted by this shift in patient care responsibility. Recommendations by the American Association of Colleges of Nursing (AACN) (2004, 2010) and IOM (2010) support the autonomous provision of specialty care by nurse practitioners in meeting the healthcare needs of individuals.

Chronic pain is a complicated entity encompassing pathophysiologic, psychological/mental, physical, and spiritual phenomena. The inability to objectively measure an individual's pain adds to the frustrations encountered by healthcare providers and chronic pain sufferers. The National Institutes of Health (NIH)(2013) acknowledges patient self-reports as the most reliable measure of pain quality and intensity available to date. Other scientific endeavors report that the experience of pain is physiologically linked to increased activity in multiple neurologic pathways which may yield possible objective measurements through neurologic system imaging and neurotransmitter assays (Apkarian, Bushnell, Treede, & Zubieta, 2005; Coghill, McHaffie & Yen, 2003). Chronic pain sufferers experience not only physical distress, but also suffer emotionally, functionally, and economically (Chiesa & Serretti, 2011).

The opio-centric, medical model for chronic pain management has been the standard for decades, however; recognition and interest in the benefits of employing a

bio-psychosocial model approach for chronic pain management has increased recently (Keefe, Porter, Somers, Shelby, & Wren, 2013). The bio-psychosocial model incorporates not only use of medicinal analgesics, but also spiritual, physical, and psychosocial interventions. Psychological therapies for chronic pain fall under the umbrella of complementary and alternative medicine (CAM) and include cognitive behavioral therapy (CBT), emotional disclosure, and mind-body interventions (Keefe et al., 2013). Mindfulness concepts, such as mindfulness meditation date back centuries, and are referred to as mind-body interventions that incorporate purposeful concentration on the present moment often facilitated through focusing on one's breath, body position, visual and/or auditory distraction, and body awareness (Alexander et al., 2012; Morone, Greco, & Weiner, 2008). Mindfulness-based interventions (MBIs) have been utilized in chronic pain management with varying degrees of improvement in pain level, psychological/emotional health, and quality of life (Alexander et al., 2012; Chiesa & Serretti, 2011). The majority of the interventions studied have required a lengthy time commitment for the patient, and have utilized a practitioner specifically trained in mindfulness psychological therapies (Kabat-Zinn, 1982; Kabat-Zinn, Lipworth, & Burney, 1985; Plews-Ogan, Owens, Goodman, Wolfe, & Schorling, 2005; Sagula & Rice, 2004). These requirements are often prohibitive for the patient and the provider managing the chronic pain.

The individual suffering with chronic pain experiences overlapping physical, psychological, emotional, and spiritual distress (Chiesa & Serretti, 2011). Formulation of a treatment plan for the individual suffering with chronic pain must address these overlapping areas. In applying the bio-psychosocial model to chronic pain management,

pain experts recommend a treatment plan that includes physical therapy and activity, occupational therapy, prudent analgesics, and psychosocial interventions (Reiner, Tibi, & Lipsitz, 2013). Use of MBIs, to include meditation, have demonstrated improvement in psychological well-being, reduction of anxiety and depression, improvement in quality of life, and reduction in pain (Alexander et al., 2012; Chiesa & Serretti, 2011; Kabat-Zinn, 1982; Kabat-Zinn et al., 1985; Plews-Ogan et al., 2005; Sagula & Rice, 2004).

The increase in numbers of individuals suffering with chronic pain, the escalating incidences of opioid overuse, abuse, and ineffectiveness, and the unavailability of pain specialists will require that healthcare practitioners expand their knowledge, skill, and utilization of chronic pain management regimens to include alternative and complementary interventions. Nurse practitioners, as one of the largest groups of healthcare practitioners delivering primary care, will be responsible for the management of chronic pain, adhering to current standards of care. Mindfulness-based interventions implemented at the point-of-care in a timely manner, and delivered by the nurse practitioner caring for this population requires investigation.

Problem Statement

The IOM's 2011 report "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research" highlighted not only the country's significant burden of chronic pain, but suggested that in meeting this burden "a cultural transformation in the way pain is understood, assessed, and treated" (p. 1) must occur. As noted in the IOM's 2011 report, over 116 million Americans suffer from chronic pain, affecting one in three individuals on a daily basis with estimates that over one-half of these individuals report that their pain is not optimally controlled

(Rosenzweig et al., 2010; Turk, 2002). The economic burden in the United States is estimated at \$560 to \$635 billion annually in direct medical treatment costs and loss of individual productivity, not to mention the emotional impact on the suffering individual, the family, and the community/society (IOM, 2011). Additionally, chronic pain management in America is challenged by lack of access to pain specialists, a shift of management to primary care, overuse, abuse, and overdosing of opioids, and general ineffectiveness of medicinal therapies alone (Breuer, Cruciani, & Portenoy, 2010; Rosenzweig et al., 2010; Turk, 2002).

The majority of individuals suffering with chronic pain receive initial and often ongoing treatment from primary care providers and not specialists (APS, 2005; Breuer et al., 2010). Primary care providers (PCPs) currently provide treatment to 52% of the chronic pain patients in the United States (Breuer et al., 2010). Although specialists exists in the field of pain management, between the years of 2000 and 2010, only 3,500 physician specialists certified in chronic pain management existed yielding a patient load of 30,000 patients per specialist (Dubois & Follett, 2014; IOM, 2011). Interestingly, the majority of prescriptions for controlled analgesics are prescribed by either primary care physicians, internal medicine physicians, or dentists representing 80% of prescriptions being written by 20% of prescribers (Volkow, McLellan, Cotto, Karithanom, & Weiss, 2011). As the burden of responsibility for management of chronic pain shifts to primary care, it is imperative that primary care practitioners be skilled and knowledgeable in assessment and treatment modalities that are evidenced-based, medically prudent, patient-centered, and safe. Nurse practitioners represent one of the largest groups of

professionals providing primary care in the United States (Naylor & Kurtzman, 2010) and will need to be prepared to deliver chronic pain management confidently.

The medical model of chronic pain management has relied heavily on the use of analgesics, primarily opioids, with an increase in opioid prescriptions of over 400% from 1997 to 2007 (Manchikanti et al., 2010). This increase in opioid prescriptions has resulted in a public health outcry regarding accidental opioid overdoses, drug diversion, opioid addiction, and inappropriate prescribing (Dasgupta, Sandford, Albert, & Brason, 2010). Accidental drug overdose is a leading cause of death in the United States, with a tripling of overdose death rates since 1990 (Centers for Disease Control and Prevention [CDC], 2011). Opioids as monotherapy for chronic pain management have yielded not only ineffective clinical outcomes, but also an increase in the incidences of addiction, overdose, and diversion (Dasgupta et al., 2010; Jovey, 2012; Turk, 2002). Expert pain organizations emphasize that the traditional biomedical model alone is inadequate in meeting the needs of chronic pain patients and recommend a focus on an interdisciplinary approach and use of adjunctive therapies (International Association for the Study of Pain [IASP], 2012).

As the complexities of chronic pain management have been identified, an increased shift from the biomedical model to a bio-psychosocial model approach incorporating the physical, mental, psychosocial, and spiritual needs of the individual, has occurred (Chiesa & Serretti, 2011; IASP, 2012; Keefe et al., 2013). As this shift continues, all healthcare providers will be required to have not only a sound knowledge of pathophysiologic etiologies, psychosocial and psychological influences, and safe analgesic options, but also alternative treatments including psychosocial interventions

and complementary medicine. Mindfulness-based interventions, like mindfulness meditation, have shown encouraging outcomes in the adjunctive treatment of chronic pain patients, however; many of the mindfulness-based therapies studied require a lengthy, formal commitment by the patient which can be prohibitive (Teixeira, 2008). Additionally, these interventions have been commonly delivered by practitioners specifically trained in psychology, which can be equally prohibitive due to availability. Keefe et al. (2013) recommend alternative delivery models for psychosocial interventions to include where the therapy is being provided, how long the therapy takes, and who delivers the therapy emphasizing that the patient's needs should be the highest priority.

Healthcare reform has emphasized the need for access to care for all individuals with NPs highlighted as a key solution to the goal of healthcare access (IOM, 2011). Additionally, the IOM recommends and supports that NPs practice at their highest level clinically. Nurse practitioners, as well as other primary care providers, must be equipped to manage a range of acute and chronic illnesses, to include chronic pain. It is inevitable that chronic pain will become a common diagnosis group managed by all primary care providers, including NPs (Breuer et al., 2010). As NPs continue to accept more responsibility for the primary care needs of individuals, chronic pain management will need to be addressed in an evidence-based, safe, efficient, and patient-centered manner.

In summary, as the population of individuals suffering with chronic pain continues to escalate, and primary care continues to acquire more and more responsibility for management of chronic pain, NPs will need to be equipped with knowledge and skills to efficiently, safely, and effectively provide care to this complex patient population. Standard medical care with opioid analgesics alone has demonstrated ineffectiveness and

significant side effects, yielding an increased interest in shifting to a bio-psychosocial model. Complementary and alternative therapies, specifically MBIs, demonstrate encouraging improvement in an individual's physical and psychological health and wellness, however; deterrents for patient participation include program time commitment, geographical availability, and financial barriers. Nurse practitioners are in an opportune role to provide guidance and education on the use of brief MBIs as part of a holistic, bio-psychosocial treatment plan in the management of chronic pain.

Justification of Project

Nurse practitioners have played, and will continue to play, a crucial role in providing primary care to individuals in need of primary healthcare. As noted in the IOM report "The Future of Nursing", nurse practitioners have filled deficit areas of primary care with increasing autonomy and will continue to acquire more and more responsibility in providing primary care to American patients (2011). As the demand for providers of primary care increases, nurse practitioners will be faced with an array of clinical management issues, to include chronic pain management. Unfortunately, the ability to routinely refer a patient to a specialist for pain management is not feasible in most settings due to lack of specialization available geographically, lack of adequate insurance coverage, and when geographically available, the unavailability of adequate and timely appointments (Dubois & Follett, 2014). Nurse practitioners will need to be knowledgeable and skilled in assessment and management of chronic pain in accordance with current standards of care, and additionally, provide effective, evidence-based, and economic interventions to the individual suffering with chronic pain.

The medical model of chronic pain management has focused on medicinal therapies, most specifically opioid treatment, which has yielded ineffective outcomes, overuse, and abuse of opioids (Rosenzweig et al., 2010). Opioid use continues to be the standard of care, however, alternative and adjunctive therapies exist that can benefit the patient who is suffering. Complementary and alternative therapies, specifically MBIs demonstrate encouraging improvement in an individual's physical and psychological health and wellness; however, deterrents for patient participation include program time commitment, geographical availability, and financial barriers. Again, NPs are in an opportune role to incorporate MBIs in chronic pain management as part of a holistic, bio-psycho-social treatment plan.

Purpose

This Capstone Project assessed the effects of implementation of clinical instruction and guidance to chronic pain patients utilizing a brief mindfulness-based meditation intervention. The project utilized point-of-care mindfulness-based meditation education and a brief intervention provided by a nurse practitioner to patients diagnosed with chronic pain. It is of immense importance that healthcare providers have the knowledge and tools to appropriately and effectively prescribe treatment plans incorporating all available therapies in the management of chronic pain. There is increasing interest in mindfulness-based meditation interventions in chronic pain management; however, the majority of studies have addressed extended exposure of six to eight weeks of training of the patient which is not routinely feasible to the routine patient due to time and economic restrictions (Alexander et al., 2012).

As nurse practitioners continue to absorb a large majority of the primary care needs in the United States, evidence-based education, training, and skills will need to be available in the area of chronic pain management. In order to provide holistic, bio-psychosocial treatment regimens to chronic pain patients, NPs will need to provide point-of-care interventions that include alternative therapies such as mindfulness-based meditation. This Capstone Project addressed the ability to provide a point-of-care, brief mindfulness-based intervention delivered by a nurse practitioner, and its effect on three patient outcome measures: level of pain, self-efficacy, and health-related quality of life.

Project Questions

This Capstone Project focused on utilization of a mind-body therapy as an adjunctive therapy for chronic pain management. This project evaluated implementation of a brief mindfulness-based meditation intervention delivered as a point-of-care therapy, by a nurse practitioner to adults diagnosed with chronic pain. Specifically, reported pain, level of mindfulness self-efficacy, and health-related quality of life were measured in adults diagnosed with chronic pain. These outcome areas were measured at baseline and after exposure to the mindfulness-based meditation intervention at two weeks and four weeks.

The project's research questions include:

- Can a brief nurse practitioner-led intervention utilizing mindfulness-based meditation improve mindfulness self-efficacy in patients diagnosed with chronic pain?
- Can a brief nurse practitioner-led intervention utilizing mindfulness-based meditation improve reported pain levels in patients diagnosed with chronic pain?

- Can a brief nurse practitioner-led intervention utilizing mindfulness-based meditation improve health-related quality of life in patients diagnosed with chronic pain?
- Is there a relationship between level of mindfulness self-efficacy and health-related quality of life in patients diagnosed with chronic pain?
- Is there a relationship between level of mindfulness self-efficacy and reported pain level in patients diagnosed with chronic pain?

The hypothesis of this Capstone Project was the following:

Brief, mindfulness-based meditation interventions led by a nurse practitioner will reduce reported pain levels, improve mindfulness self-efficacy, and improve overall quality of life in patients diagnosed with chronic pain.

Definition of Terms

Chronic Pain

The International Association for the Study of Pain (IASP) has described chronic pain as an unpleasant physical and emotional feeling that has been present for six months or more with or without known pathology (2012). Although the precise etiology of the pain is not always identifiable, experts describe a maladaptive process linked to specific pathways yielding a disease of the nervous system (Costigan, Scholz, & Woolf, 2009). Sturgeon (2014) eloquently describes chronic pain as “a complex stressor that presents a significant challenge to most aspects of functioning and contributes to substantial physical, psychological, occupational, and financial cost” (p. 115). Chronic pain is categorized most frequently by specialty organizations and in the literature into two categories: Chronic cancer-related pain and non-cancer related pain (IASP, 2012).

Additionally, chronic pain can be categorized related to the known or speculated source of the pain, such as fibromyalgia, migraine, neuropathy, and/or area of body impacted. For the purposes of this project, chronic pain was defined as individuals suffering with pain for over six months that is not related to an etiology related to cancer.

Self-Efficacy

An individual's ability to feel and experience inner confidence in incorporating a behavioral change into his/her lifestyle embraces the definition of self-efficacy (Bandura, 1977). Self-efficacy encompasses psychological, physical, and spiritual domains in which the individual believes he/she can change or "do" a behavior or action (Alexander et al., 2012). The concept of self-efficacy originates from Albert Bandura's 1977 theoretical framework and has been connected to an array of health-related behaviors as a predictor of an individual's ability to change negative actions and/or acquire positive actions.

The belief and confidence that an individual feels in adapting changes in current behaviors and implementing new behaviors will be defined in this study as self-efficacy as measured by the clinical instrument "Mindfulness-Based Self -Efficacy Scale-Revised" (Cayoun, 2010).

Mindfulness-Based Meditation

Meditation, as a mental training entity, has often been divided into two fairly broad categories in the literature: Focused attention (FA) and open monitoring (OM) (Grant, 2014). Both categories relate to practices of mental concentration with FA often referring to those practices where the practitioner focuses on something externally (an object, breathing, heart beat) and OM relating to practices where the practitioner focuses

internally (Lutz, Slagter, Dunne, & Davidson, 2008). The overlap of characteristics within varying practices of meditation is common, however, the endpoint goals of calmness, improved cognition, mental alertness, and psychological control of physical issues remains constant regardless of the labeling of the practice (Grant, 2014).

Mindful meditation has been described in the literature as a simple awareness of the present moment and situation that an individual experiences through purposeful distraction and focus (Alexander et al., 2012; Kabat-Zinn, 1982; Teixeira, 2008). Described as one of the most commonly reported complementary alternative medicine (CAM) modalities used by individuals (Wolsko, Eisenberg, Davis, & Phillips, 2004), experts describe it as a sustained attention to cognitive, sensory, and emotional activities, active avoidance of cognitive or emotional appraisal of events, and focused insight that can be acquired through purposeful training and practice (Zeidan, Grant, Brown, McHaffie, & Coghill, 2012). The phenomena of mindfulness meditation originates from a Buddhist-centered philosophy with a Western adaptation of the framework by Dr. Kabat-Zinn who describes mindfulness meditation as a devoted attention to the moment an individual is experiencing in a purposeful awareness, lacking any judgment of the situation, lacking expectations, and best achieved with repetitive practice (2003). This awareness can be guided through distraction practices such as breathing, body position awareness, yoga, and body sensation awareness (Alexander et al., 2012).

For the purposes of this project, mindfulness-based meditation will be defined as the practice of a five minute intervention introduced and guided initially by a nurse practitioner (project administrator) using both auditory and visual guidance.

Health-Related Quality of Life

There have been multiple definitions and measurements of quality of life (CDC, 2000; Ferrans, Zerwic, Wilbur, & Larson, 2005; World Health Organization [WHO], 2005). As defined by Ferrans et al. (2005) and by the World Health Organization (WHO) (2005), health-related quality of life (HRQoL) incorporates many conceptual dimensions to include physical, mental, emotional, and social functioning and is an important measurement of community and societal overall health. The Center for Disease Control and Prevention's (CDC) "Measuring Healthy Days: Population Assessment of Health-Related Quality of Life" (2000) referred to HRQoL as a sense of wellness an individual experiences impacted by an array of internal and external factors.

Assessing HRQoL is emphasized by the CDC as a national health standard warranting routine surveillance to gauge general population health and the overall burden of disease and disability on society (2012). The measuring and surveillance of HRQoL is viewed as a public health interest that impacts communities and general society (CDC, 2012). Additionally, the results of measuring and surveillance of a community's HRQoL can influence healthcare policy.

Several instruments/tools have been used to measure HRQoL and related concepts of functional status. Among these instruments/tools are the Medical Outcomes Study Short Forms (SF-12 and SF-36), the Sickness Impact Profile, and the Quality of Well-Being Scale. The SF-36 measures are now used by the Health Care Financing Administration (HCFA) and the National Committee for Quality Assurance's Health Plan Employer Data and Information Set (HEDIS 3.0) to help evaluate the quality of care in managed care plans and other health care applications. While these measures have been

widely used and extensively validated in clinical settings and special population studies, the length of these instruments often makes their use impractical in population surveillance.

For the purposes of this study, HRQoL will be defined as measures obtained on the Quality of Life Scale (QOLS) which incorporates measures of relationships with others, personal fulfillment, independence, and recreation (Burckhardt & Anderson, 2003).

Summary

The medical model of management of chronic pain has centered primarily on analgesic therapy, specifically opioids, which has yielded not only ineffective outcomes, but also a significant increase in drug overdoses, addictions/dependences, and drug diversion. Although specialists do exist in the area of chronic pain management, the access to qualified providers is limited, yielding a shift of chronic pain management to primary care providers (Breuer et al., 2010). Even when a pain specialist is available, patients often encounter financial barriers and personal inconveniences related to travel for initial evaluation and the recommended follow-up intervals. Additionally, long wait times for appointments with the specialist, inadequate availability and economic burden of adjunctive therapy such as psychological counseling and physical therapy, and lack of coordinated “holistic” care for the individual and family serve as barriers. The combination of both limited access to pain specialists and the public health concerns related to opioid use has resulted in a shift of chronic pain management to primary care and an increasing focus to a bio-psychosocial model approach.

The bio-psychosocial model incorporates therapies that include not only medicinal therapies, but also CAM, including mindfulness-based techniques.

Mindfulness-based meditation is commonly evaluated in the literature, however; most therapies require the patient to make lengthy time commitments and have been delivered by a specially-trained practitioner. These prohibitive issues can be addressed through innovative initiatives.

Use of a brief mindfulness-based intervention delivered by a nurse practitioner in a point-of-care format meets the definition of innovation and avoids many of the prohibitive barriers faced by patients diagnosed with chronic pain.

CHAPTER II

Research Based Evidence

Chronic pain affects an estimated 116 million American adults on a daily basis with an annual cost between \$560 and \$635 billion (IOM, 2011). Current therapy for chronic pain follows a biomedical model with analgesics, primarily opioids, as the foundation for treatment. Over the past two decades, opioid prescriptions have increased substantially, mirrored by an increase in misuse, addiction, and overdose (Chou et al., 2009). The overuse and increased mortality related to opioid analgesics has ignited a public health response calling for significant changes in the treatment of pain to include an array of guidelines, policy initiatives, screening tools, monitoring of prescribers and prescriber habits, and emphasis on focused education for all providers. Despite an increase in the use of opioids and other analgesics, chronic pain patients report only a 30% to 40% reduction in pain in fewer than 50% of the patients (Turk, 2002). Additionally, the crisis of chronic pain management is met with a shortage of trained specialists to meet the needs of this population which has resulted in an estimated 52% of patients suffering with chronic pain receiving management from a primary care provider (Breuer et al., 2010).

The IOM's 2011 report "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research" emphasized a need for responding to the burden of pain with a "cultural transformation in the way pain is understood, assessed, and treated" (p. 1). One area of growing interest and use is complimentary alternative medicine (CAM) techniques in a bio-psychosocial model of treatment for an array of acute and chronic health issues, to include chronic pain

(Sturgeon, 2014). In 2008, through a national survey sponsored by the CDC, Barnes, Bloom, and Nahin (2008) reported that 9.4% of adult respondents had used some form of CAM in the preceding 12 months, representing over 20 million adults.

In addressing the IOM's 2011 recommendations, healthcare must include treatment alternatives, improved patient access, and an increase of non-specialist providers capable of diagnosing and treating the increasing population of individuals diagnosed with chronic pain. A literature search was conducted utilizing the following databases: Medline, CINAHL, Cochrane Library, PubMed, Google Scholar, PsycINFO, and ProQuest. Key words and phrases employed in the literature inquiry include "chronic pain", "chronic pain guidelines", "opioid use in chronic pain", "mindfulness", "complimentary alternative medicine/treatment", "mindfulness-based meditation", "mindfulness-based interventions", and "nurse practitioner management of chronic pain".

Review of Literature

Pain Science and Current Treatment

The phenomenon of pain is complicated and perplexing even to the most experienced and educated scientist. Unlike many other disease entities, pain cannot be easily measured using customary objective techniques, yielding a reliance on subjective, self-reporting, which has shown the greatest amount of validity in assessing level and quality of pain in the individual suffering (National Institutes of Health [NIH], 2002). Endeavors to better understand the physiological and psychological components of pain syndromes continue today with increased tenacity. Dating back to the early 1950s, the writings of anesthesiologist Dr. John Bonica highlighted the need for improved scientific explanations of pain, more aggressive treatments, and a multi-specialty approach to

management Bonica (1953). Current theoretical concepts describe pain as a multidimensional entity complicated by individual genetics, experience, and environment referred to in the literature as “neuromatrix” (IOM, 2011). The biomedical model theorizes that chronic pain results from persistent nociceptive, inflammatory, or neural insult leading to a distinct change in the neuronal pathways causing, among other things, a hypersensitivity and amplification of the central nervous system’s sensory signaling (Costigan et al., 2009; Voscopoulos & Lema, 2010). Research aimed at measuring the experience of pain has emphasized increased activity in multiple neurologic pathways with physiologic links, yielding possible objective measurements through neurologic system imaging and neurotransmitter assays (Apkarian et al., 2005; Coghill et al., 2003). Following this pathophysiologic theory, medicinal therapies that reduce the hypersensitivity and block the sensory center, primarily opioids, have been the mainstay of medical treatment (Chou et al., 2009). Opioid prescriptions have increased over 400% from 1997 to 2007, with a paralleling increase in misuse, addiction, diversion, and even death (Manchikanti et al., 2010). To add insult to injury, only one-half of patients treated with opioids report a 30% to 40% reduction in pain level (Turk, 2002; Vowles, Wetherel, & Sorrell, 2009). Randomized controlled trials measuring effectiveness of opioids in treating chronic pain syndromes, showed modest relief of pain for the short to medium time frame (12 weeks) with significant occurrence of side effects to include sedation, cognitive impairment, constipation, and bladder dysfunction (Kalso et al., 2004; Furlan et al., 2006).

In addition to analgesics, two common adjunctive therapies have been recommended in the management of chronic pain, physical therapy and spinal injections

(Fitzgibbon et al., 2004). Although these adjunctive treatment modalities have shown some benefit, they are costly and carry risks that are often unacceptable to the patient (Fitzgibbon et al., 2004).

Guidelines for management of chronic pain outline a standardized system of assessment/screenings, interventions, evaluation, documentation, and even recommended frequency of office visits (Chou et al., 2009). Travel, time away from work or family, and cost for visits pose additional challenges to the individual diagnosed with chronic pain.

Pharmacologic treatments have been the primary intervention in management of chronic pain, however, non-pharmacologic treatments such as massage, acupuncture, exercise, yoga, and meditation are receiving increase attention and use for such chronic pain (Chou & Huffman, 2007). The majority of the research available regarding effectiveness of non-pharmacologic therapies, focuses on specific chronic pain syndromes such as back pain, fibromyalgia, headaches, or neuropathy (Chou & Huffman, 2007; Plews-Organ et al., 2005; Manheimer, White, Berman, Forys, & Ernst, 2005; Sherman, Cherkin, Erro, Miglioretti, & Devo, 2005). Results of studies provide an inconsistency in effectiveness outcomes. Chou and Huffman performed an academic review of the literature focused on systematic reviews and randomized trials related to nonpharmacological treatment of back pain and found that meditation, yoga, exercise, and other cognitive-behavioral treatments yielded a moderate amount of effectiveness (2007).

Endeavors to identify pathophysiologic components of chronic pain are ongoing. As evidence continues to show low to medium effectiveness of opioids in management of

chronic pain, accompanied by high risks of abuse, misuse, and death, pursuit of alternative and/or adjunctive therapies is warranted.

Complementary and Alternative Medicine

Complementary and alternative medicine (CAM) has been defined in many ways. The National Center for Complementary and Alternative Medicine [NCCAM], 2014 delineates complementary medicine as non-mainstream therapies that are used in addition to mainstream therapies and alternative as those same non-mainstream therapies used in place of traditional mainstream therapies. Over the past few decades, other nomenclature has surfaced to include “integrative medicine” which is defined essentially as the integration of mainstream and non-mainstream therapies and philosophies in treatment of a variety of health disorders such as cancer, headaches, and acute and chronic pain (NCCAM, 2014). The terms and definitions overlap one another; however, the popularity of use on non-conventional or non-mainstream practices continues to increase. The NIH reports nearly 40% of Americans use non-mainstream approaches to health and wellness in addition to the more typical medicinal mainstream therapies (2014). The National Center for Complementary and Alternative Medicine (NCCAM) uses the term “complementary health approaches” and divides therapies into two groupings: natural products and mind and body practices (2014).

The term “natural products” refers to actual substances used for health and wellness that includes herbs, vitamins, minerals, and probiotics (NCCAM, 2014). In 2007, the National Health Interview Survey (NHIS) revealed that 17.7% of Americans had used some form of a natural product within the past year that did not include the

typical vitamin or mineral supplement, with use of omega-3-Fish Oil and Echinacea as the top two substances (NCCAM, 2014).

The term “mind and body practices” refers to large group of diverse practices to include acupuncture, massage, touch therapy, yoga, spinal manipulation, hypnotherapy, relaxation therapy, movement therapy, and several forms of meditation (NCCAM, 2014). These techniques are frequently used by individuals with multiple health issues and also used as preventive or maintenance health. In 2007, the percentage of adults who used the top ten most common therapies includes: natural products 17.7%, deep breathing 12.7%, meditation 9.4%, chiropractic/osteopathic 8.6%, massage 8.3%, yoga 6.1%, diet-based therapies 3.6%, progressive relaxation 2.9%, guided imagery 2.2%, and homeopathic treatment 1.8% (NCCAM, 2014).

The availability of solid scientific research regarding the effectiveness, usefulness, safety, and best means for implementing in healthcare is insufficient, with one of the key missions of NCCAM being rigorous, valid, and credible investigation into NCCAM (2014). As evidence builds showing not only effectiveness in using NCCAM, but safety, efficiency of use, and economic feasibility, it is anticipated that more healthcare providers will incorporate into their practice regimens.

Complementary and Alternative Medicine Application

Several of the aforementioned CAM techniques have been implemented in treatment of an array of health issues to include heart disease, autoimmune disease, obesity, eating disorders, gastrointestinal disorders, metabolic syndrome, and chronic pain syndromes (Purdy, 2013). The literature evaluating and primarily supporting the use of CAM in a variety of health disorders is abundant.

Participation in an eight-week yoga program by women diagnosed with fibromyalgia demonstrated improvement in psychological functioning, pain levels, mindfulness, and cortisol levels (Curtis, Osadchuk, & Katz, 2011). Yoga is also associated with improved function and pain levels in management of arthritis (Flor, 2003; Sherman et al., 2005).

In their comparison of aromatherapy with music therapy, paired with either hand massage or self-induced still point therapy, on pain level and comfort level of individuals with diagnosis of chronic pain, Townsend, Bonham, Chase, Dunscomb and McAlister (2014) found that all interventions showed statistical significant results in improving pain and comfort and that neither protocol showed statistical superiority (2014). This study did not have a control group, however, and enlisted only 22 participants with a multitude of diagnoses in an inpatient setting (Townsend et al., 2014).

Healing touch, which includes such practices as brushing, light touch, tapping, reiki, polarity therapy, and qigong have been practiced in the United States for decades (Teets, Dahmer, & Scott, 2010). In a Cochrane Review, touch therapies were found to positively impact pain, however, sufficient amounts of data/studies with trained practitioners was lacking yielding an overall inconclusive outcome (So, Jiang, & Qin, 2008).

Keefe et al. (2013) evaluated current research related to the impact of psychosocial interventions which fall under the umbrella of CAM (Cognitive Behavioral Therapy [CBT], Emotional Disclosure, Mind-Body) on chronic pain in older adults and found efficacy of CBT and emotional disclosure revealed good evidence, but mind-body interventions were lacking. These findings are supported by Sturgeon (2014) in his

review of psychological therapies for chronic pain including mindfulness-based stress reduction (MBSR), yielding recommendations for more empirical research regarding chronic pain management and use of psychological and medicinal combinations of treatment. In his review of literature related to use of psychological therapies in management of chronic pain, Sturgeon (2014) divides therapies into four categories: operant-behavioral, cognitive-behavioral, mindfulness-based, and acceptance and commitment (ACT). In a meta-analysis of studies focused on use of CBT for pain, it was concluded that impact on pain and functioning of the individual was comparable to standard medical therapy (Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012). Additionally, Veehof, Oskam, Schreurs, & Bohlmeijer (2011) reported in their systematic and meta-analysis of ACT in relationship to pain management, that ACT did not show any greater effectiveness in treatment of chronic pain as compared to other psychological therapies.

Interest in CAM techniques is increasing in both consumers of healthcare (patients) and providers of healthcare (Keefe et al., 2013).

Mindfulness-Based Meditation and Pain

The phenomena of mindfulness meditation originates from a Buddhist-centered philosophy with a Western adaptation of the framework by Dr. Kabat-Zinn, who describes mindfulness meditation as a devoted attention to the moment an individual is experiencing in a purposeful awareness, lacking any judgment of the situation, lacking expectations, and best achieved with repetitive practice (1982). No discussion of MBIs' impact on health and wellness, to include chronic pain management, would be complete without inclusion of the work of Dr. Kabat-Zinn, a psychologist, who is internationally

known for his work as a scientist, writer, and meditation teacher credited with mainstreaming mindful meditation into medicine and Western society (1982, 2003). Dr. Kabat-Zinn originated some of the earliest studies of the effect of mindful meditation on chronic pain using his Mindfulness-Based Stress Reduction Program (MBSR) which is a structured 8-to 10-week program requiring participants to attend a two-hour session weekly and an eight hour retreat at the end of program (1982). In one of Dr. Kabat-Zinn's landmark studies using MBSR, he found that over a five-year time span, study participants experienced an improvement in pain level and in quality of life (Kabat-Zinn, Lipworth, Burney, & Sellers (1986). The framework of his studies have been replicated in evaluating MBSR's effect on a variety of physical and psychological diagnoses to include pain entities such as headache, fibromyalgia, musculoskeletal pain, and chronic pain (Brown & Jones, 2013; Teixeira, 2010; Wong et al., 2011).

Elizabeth Teixeira (2008) has been engaged in studying the impact of meditative practices on chronic pain for a number of years. As a nurse practitioner, she has studied the impact of mindfulness meditation on diabetic peripheral neuropathy pain and conducted an integrative inquiry into studies using meditation as a therapy for chronic pain (Teixeira, 2008, 2010). Her review of research dating from 1982 to 2006 utilizing mindfulness meditative practices in the treatment of chronic pain focused on experimental and non-experimental studies with varying outcomes (Teixeira, 2008). Ten studies, eight published and two dissertations were included in the final analysis, with nine of the studies implementing the routine eight to ten week MBSR protocol and one study implementing a hybrid protocol of concentration meditation with similar time commitment by the participants. Four of the ten studies used a non-experimental design

with the remaining studies formatted as either randomized control trials or quasi-experimental (Teixeira, 2008). Outcome measures for the 10 studies were all self-reported and included level of pain, anxiety, depression, health-related quality of life, mood, physical symptoms, sleep and coping strategies with an average participant age of 47.7 years, primarily female and Caucasian (Teixeira, 2008). Study participants of all but one study were reported as well educated and middle-class, with one study purposely utilizing participants who were lower socioeconomic status and lower education level (Teixeira, 2008). Some of the general findings across all of the 10 studies analyzed, included improved coping skills to deal with the pain and improved psychological health measures (Teixeira, 2008). There was not a consistency in reduction of reported pain level that met statistical significance across all studies, however, one-half of the studies evaluated did report improved pain level and/or reduced pain sensation (Teixeira, 2008). Some of the limitations identified by Teixeira regarding these 10 studies, included lack of focus on one entity of chronic pain and lack of use of mindful meditation solely as the intervention.

Chiesa and Serrati's 2011 systematic review of research utilizing mindfulness-based interventions (MBIs) and impact on chronic pain evaluated 10 studies ranging from 1994 to 2008. The 10 studies in their final review included controlled trials and randomized control trials over an eight to ten week period that evaluated the impact on several types of chronic pain utilizing primarily the structured MBSR intervention (Chiesa & Serrati, 2011). Some of the key findings of this study related to reduction in depressive symptoms in participants and improvement in psychological parameters of stress, pain acceptance, and pain tolerance, but no statistically significant improvement in

pain level (Chiesa & Serrati, 2011). Limitations encountered in these studies included length of intervention and required time commitment, use of self-rated measurement tools, and skewed gender representation (Chiesa & Serrati, 2011).

Veehof et al. (2011) critique Treixera's 2008 analysis of studies stating that she did not address the actual quality of the studies evaluated and the evaluation of the studies was not a meta-analysis. Veehof et al. conducted a meta-analysis of studies utilizing acceptance-based interventions which included mindfulness-based stress reduction programs and acceptance and commitment therapies (ACT) which fall under the umbrella of cognitive behavioral therapies (CBT) (2011). There were a total of 22 studies evaluated with nine RCTs, five clinically controlled, and eight noncontrolled with outcome measurements primarily focused on pain intensity and level of depression (Veehof et al., 2011). Utilization of the standard protocol of the MBSR intervention was used in the majority of the studies included for analysis. Similar means for age, gender, and socioeconomic status were found on the 22 studies included in Veehof et al.'s meta-analysis with only one study showing a majority of participants being male (2011). Although varying instruments were employed, Beck's Depression Inventory (BDI) and the visual analog scale for pain (VAS) were two of the most frequently utilized measurement tools found in the 22 studies analyzed (Veehof et al., 2011). Findings of this meta-analysis, unfortunately, did not show a statistically significant pattern of improvement of either pain level and/or mental health improvement such as reduction in depression level or anxiety (Veehof et al., 2011). Recommendations for further study echoed previous studies emphasizing the need for consistency in measurement tools,

uniformity in the type of chronic pain evaluated or a homogenous sampling, use of one intervention only, and use of a control group (Teixeira, 2008; Veehof et al., 2011).

Reiner et al. (2013) published a critical review of 16 published studies focused on the impact of mindfulness-based interventions in the reduction of pain intensity. The majority of the studies analyzed were published in the mid- to late-2000's and used the standard MBSR protocol or mild variation as the intervention. The analyzed studies were represented equally as controlled trials or uncontrolled trials and all used some form of self-reported numerical pain measurement as the variable of pain intensity (Reiner et al., 2013). Results from the uncontrolled studies showed only a statistical significant reduction in pain intensity in three studies, all of which employed ACT and not MBSR, however, 75% of the controlled studies reviewed showed statistically significant reduction in pain intensity, with the majority using some form of MBSR (Reiner et al., 2013). Three of the controlled studies published follow-up results ranging from three months to three years and found that pain intensity reduction was consistently maintained as study participants continued to incorporate mindfulness activities (Reiner et al., 2013). The authors suggest that attaining skills using mindfulness techniques has life-long benefit and warrants further research (Reiner et al., 2013). General conclusions from this critical review do parallel previous systematic reviews and meta-analyses in that utilization of mindfulness techniques may benefit practitioners through mechanisms of cognitive detachment, increasing acceptance, decreasing avoidance, and improved sense of control (Chiesa & Seretti, 2011; Reiner et al., 2013, Veehof et al., 2011).

Cramer, Haller, Lauche, and Dobos (2012) conducted a systematic review of research studies utilizing mindfulness-based stress reduction practices in the treatment of

low back pain. This literature analysis and review employed the recommendations from previous systematic reviews and meta-analyses to focus on a homogenous pain category. Specific criteria for a study's inclusion were utilization of the routine eight-week mindfulness-based protocol as an intervention, a randomized controlled trial research design, being published as full-text manuscripts in reputable journals, and evaluation of chronic low back pain (Cramer et al., 2012). Final studies meeting the criteria for this review included only three studies with inconclusive findings related to reduction of low back pain from utilization of mindfulness-based techniques (Cramer et al., 2012). One of the most critical outcomes of this limited review centers around the recommendations that research focus on homogenous groups of pain sufferers, use equivalent interventions, and employ the randomized, control research design.

Many studies related to the use of mindfulness-based techniques and chronic pain have focused on the psychological impact on the individual to include measurements of anxiety, depression, stress, cognitive functioning, and subjective quality of life (Alexander et al., 2012; Brown & Jones, 2013; Kabat-Zinn, 1982; Keefe et al., 2013; Rosenzweig et al., 2010; Wong et al., 2011). Endeavors to better understand and connect the pathophysiology of pain in to the improvement of pain through psychological interventions continue to be pursued (Holzel et al., 2011; Sturgeon, 2014; Zeidan et al., 2012). The occurrence of both improved psychological health and reduction in subjective pain experience as a result of use of mindfulness-based interventions has been repeatedly demonstrated in the literature, however, no causative inferences can be made due to inadequacies in the research design, sampling, and measurement tools

incorporated (Alexander et al., 2012; Brown & Jones, 2013; Kabat-Zinn, 1982; Keefe et al., 2013; Rosenzweig et al., 2010; Wong et al., 2011).

Gaps in the Literature

Interest in health effects related to use of mindfulness-based interventions has significantly grown in the research community since the landmark studies of the 1980's conducted by Dr. Kabat-Zinn (1982); Kabat-Zinn et al. 1985. Review of the studies conducted and literature published shows a repeated pattern related to time commitment and length of intervention evaluated, socioeconomic level of subjects, and professional training of individual delivering the intervention (Alexander et al., 2012; Brown & Jones, 2013; Kabat-Zinn, 1982; Kabat-Zinn et al., 1985; Keefe et al., 2013; Rosenzweig et al., 2010; Wong et al., 2011). These precise areas of inquiry demonstrate significant gaps within the literature warranting further investigation and study. Specifically, delivery of a brief intervention at point-of service, led by a professional not primarily trained in the discipline of psychology, and delivered to a population that has limited resources due to lower socioeconomic and lower education level has not been evaluated in the current published literature.

The majority of the literature investigating the effectiveness of mindfulness-based interventions on chronic pain has utilized the standard eight to ten week MBSR formal training sessions averaging a commitment of two hours per session by study participants (Alexander et al., 2012; Brown & Jones, 2013; Kabat-Zinn, 1982; Keefe et al., 2013; Rosenzweig et al., 2010; Wong et al., 2011). The time commitment required is significant to the average individual, not to mention the individual who is not only suffering with chronic pain, but may also be dealing with employment issues, routine

family demands, healthcare costs, travel limitations, and co-morbidities such as depression, fatigue, cognitive impairment, and anxiety (Bergan-Cico, Possemato, & Cheon, 2013).

The majority of literature available related to mindfulness-based interventions and chronic pain do not specifically focus on any one socioeconomic group of individuals (Alexander et al., 2012; Brown & Jones, 2013; Kabat-Zinn, 1982; Keefe et al., 2013; Rosenzweig et al., 2010; Wong et al., 2011). Socioeconomic status and educational level of subjects have been reported in studies, primarily as a demographic characteristic. Plews-Ogan et al. (2005) evaluated the impact of mindfulness-based stress reduction and massage on chronic pain without intended regard for socioeconomic status, however, when their study was included in a meta-analysis, the lower socioeconomic level of the sampling was cited as a possible variable impacting results (Veehof et al., 2011). As chronic pain does not discriminate on the basis of gender, age, education level, or socioeconomic level, current studies have not intentionally incorporated these variables. Educational level and socioeconomic level can impact an individual's cognitive understanding of an intervention, ability to comply, and access to treatment (Plews-Ogan et al., 2005; Teixeira, 2010).

Most studies utilize individuals that are primarily trained in psychology professionally, and specifically trained in mindfulness-based techniques to implement the intervention or variable of interest (Alexander et al., 2012; Brown & Jones, 2013; Kabat-Zinn, 1982; Keefe et al., 2013; Rosenzweig et al., 2010; Wong et al., 2011). Some studies have incorporated the delivery of the intervention by a chief investigator or research assistant who has received additional training in the intervention (Townsend et

al., 2014; Wong et al., 2011). The current healthcare system reveals an environment where practitioners will need to acquire additional skills in order to provide comprehensive care to patients. The lack of available specialists to absorb the escalating numbers of individuals diagnosed with chronic pain, and the unavailability of adjunctive treatment resources pose significant barriers in meeting this population's health needs.

Chronic pain management has been labeled a "specialty" medical practice, however; practitioners, including PCPs, seeking board certification or additional credentialing and/or additional training in the field is limited (Dubois & Follett, 2014). As the number of individuals suffering with chronic pain continues to escalate, alternatives to meet the needs of this complex patient population must be addressed. Nurse practitioners provide a significant amount of the primary care health services in the United States of America (USA). Studies have supported not only the high quality skill levels of nurse practitioners, but also patient outcomes equal to, and/or surpassing those of physician colleagues (Horrocks, Anderson, & Salisbury, 2002; Laurant et al., 2005; Lenz, Mundinger, Kane, Hopkins, & Lin, 2004; Newhouse et al., 2011). Primary care providers, including nurse practitioners, often are the first contact with the patient suffering with chronic pain, accounting for initial treatment of some 52% of pain patients in the USA (Breuer et al., 2010). The literature to date is void of mindful-based meditation techniques being delivered by a nurse practitioner in relationship to chronic pain management.

Strengths and Limitations of the Literature

The current literature strongly supports the use of CAM to assist in management of chronic pain with a large body of research focused on mindfulness-based techniques

(Kabat-Zinn, 1982; Keefe et al., 2013; Rosenzweig et al., 2010; Wong et al., 2011).

Acknowledgement of the benefits of alternative treatments for chronic pain, supported by scientific data helps foster professional and public interest and utilization. Current strengths within the literature include consistency in the definition of chronic pain, MBSR, and subjective measurement of pain (Alexander et al., 2012; Brown & Jones, 2013; Kabat-Zinn, 1982; Keefe et al., 2013; Rosenzweig et al., 2010; Wong et al., 2011). The mere amount of studies focused on alternative treatments for chronic pain sufferers provides encouragement for future treatment.

Weaknesses within the literature include lack of studies evaluating utilization of brief mindfulness-based interventions in contrast to eight to ten week interventions, lack of incorporation of demographic variables that may impact a populations' response, and use of primarily subjective measurements (Alexander et al., 2012; Brown & Jones, 2013; Kabat-Zinn, 1982; Keefe et al., 2013; Rosenzweig et al., 2010; Wong et al., 2011). Additionally, many of the published studies related to mindfulness meditation demonstrated limitations due to lack of control group, effect size, low retention rates of subjects, and low sample sizes (Alexander et al., 2012; Brown & Jones, 2013; Kabat-Zinn, 1982; Keefe et al., 2013; Rosenzweig et al., 2010; Wong et al., 2011). A further weakness within the literature is lack of follow-up measurements of subjects.

Theoretical and Conceptual Framework: Bandura

The theoretical framework utilized in this project comes from Albert Bandura's social cognitive theory (SCT) structured on the idea that individuals will perform behaviors if they feel confident that they are able to do so, or are competent (2001). Self-efficacy was a key variable in this project and is a central concept of Bandura's SCT

reflecting the idea that humans will repeat behaviors if they possess an inner belief in self (1986). Individuals naturally avoid situations and/or behaviors that they feel inadequate or incapable of performing (Bandura, 1986). This theory is often applied to health promotion and behavioral change encompassing cognitive, social, emotional, and sensorimotor domains (Bandura, 2001).

SCT focuses on the individual learner with four possible stages experienced, described by Bandura as the attentional phase, the retention phase, the reproduction phase, and the motivational phase (Butts & Rich, 2011). Successful progression through each stage yields change in the individual's behavior and an increase in self-confidence or self-efficacy. As this project introduced a mindfulness-based intervention to individuals naïve to using this type of therapy, it was anticipated that behavioral changes would need to occur in the individual and, therefore, progression through the SCT stages. Successful progression yields an increase in self-efficacy which was a central variable in this project.

The individual may continue to repeat the new behavior leading to increased self-efficacy until the behavior is embedded into the individual's routine. Butts and Rich state "one goal of behavior change and wellness in health care is to promote feelings of self-efficacy in clients trying to break bad habits or cope with their illness" (2011, p. 222).

As noted in the conceptual-theoretical-empirical (C-T-E) structure, use of Bandura's SCT theory with focus on the concept of self-efficacy provided the framework for this project (Figure 1). Using a theory-testing design, this project endeavored to support Bandura's concept of self-efficacy and the impact of increased confidence by the individual in utilization of the mindfulness-meditation intervention and outcomes in pain level and quality of life measures. According to Bandura's theory, when the individual

becomes proficient and confident (self-efficacy) in the behavior (mindfulness-based meditation), and the behavior yields favorable outcomes (improved pain level and improved health related quality of life), then the individual will continue the behavior. This cycle can continue with benefits to the individual physically, psychologically, spiritually, and socially.

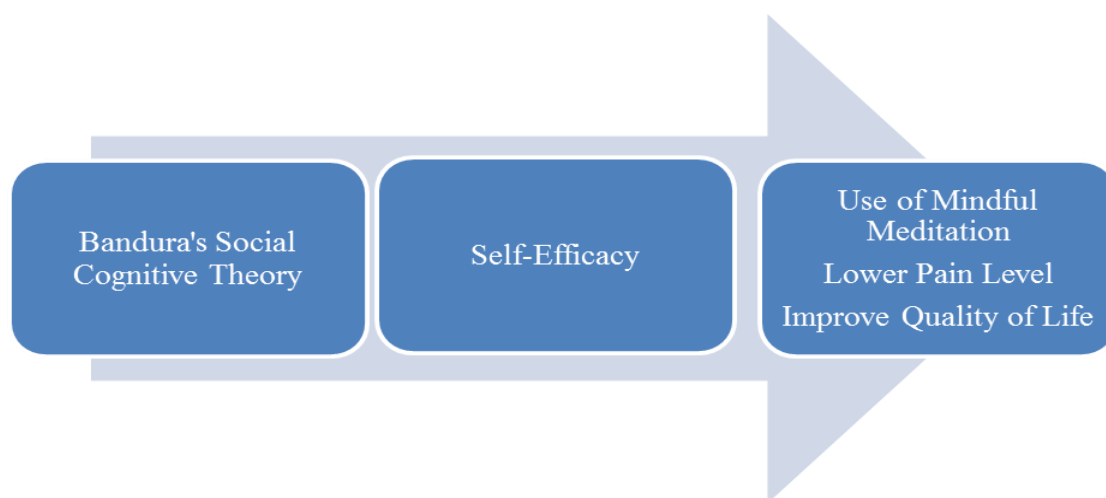


Figure 1. *Conceptual-Theoretical-Empirical Structure*

Summary

The purpose of this Capstone Project was to assess the feasibility and effect of implementation of a nurse practitioner led brief clinical intervention based on mindfulness (MBI) to adults diagnosed with chronic pain. Chronic pain is a complicated diagnosis encompassing physical, psychological, spiritual, and social factors that are interrelated. The medical model approach which incorporates primarily analgesics and focus on the physiologic domain of the patient has yielded inadequate outcomes. Keefe et al. 2013 (p.89) recommends use of the bio-psychosocial model in addressing chronic pain, emphasizing a complex system where “contributing factors in one context

(biological) can influence factors in the other contexts (emotional, social) and interventions aimed at one context can influence other context” The bio-psycho-social model incorporates use of both analgesics and alternative treatments to include CAM. MBIs have demonstrated encouraging results in the literature; however investigational gaps exist including limited inquiry regarding utilization of brief interventions and delivery of therapies by a primary care provider at point-of-care. Additionally, implementation of MBIs with lower socioeconomic populations and individuals with lower educational levels has limited discussion in the literature.

Following the framework of Bandura’s SCT, this project evaluated mindfulness self-efficacy levels, as well as outcome measures of pain level and health-related quality of life in adults diagnosed with chronic pain. Research supports use of MBIs, including meditation, however; optimal outcomes have been correlated with frequency of use by the individual. As an individual’s confidence in performing a new behavior (self-efficacy) increases, the probability that the behavior will be repeated increases. Application of this theory to this project yields the hypothesis that as levels of self-efficacy improve through education, training, and repeated use of mindfulness-based meditation, a reduction in reported pain level and an increase in quality of life will result.

CHAPTER III

Project Description

The purpose of this Capstone Project was to assess the feasibility and effect of implementing a brief clinical intervention based on mindfulness to adults diagnosed with chronic pain. Implementation of this project took place in a rural primary care clinic utilizing established patients volunteering to participate. This project addressed use of mindfulness-based meditation education and guidance delivered by a trained nurse practitioner to adults diagnosed with chronic pain. Evaluation of the effect of this project included measurements of level of pain, mindfulness self-efficacy, and health-related quality of life.

Project Implementation

This Capstone Project was conducted in a rural primary care clinic that provides chronic pain management. A one-on-one intervention aimed at educating adult patients diagnosed with chronic pain about the use of mindfulness-based meditation to augment their current treatment regimen was led by the project's administrator, a nurse practitioner. After obtaining Institutional Review Board (IRB) approval, the project administrator was on site weekly in the clinic to educate the clinic's staff regarding the project's purpose and structure. Posters (Appendix A) and educational pamphlets (Appendix B) highlighting key information about the use of mindfulness-based meditation were placed in the clinic's general waiting area and in each exam room.

The project administrator utilized clinic staff as project champions to identify patients who met the project's inclusion criteria and to obtain initial informed consent. Two of the clinic's staff were designated as project champions and aided in enlisting

individuals to participate in the project, assisted with data collection, and follow-up. Established/active patients diagnosed with the International Classification of Diseases (ICD) code series 338.2, a general code for nonspecific chronic pain, or 338.4, a code for chronic pain syndrome, and receiving routine follow-up specifically for the chronic pain were initially approached by clinic staff for inclusion in the project. Active patients were defined as individuals who had been established with the practice for at least six months and who had demonstrated consistent follow-up. Patients with documented, unexplained missed appointments were not included in the pool of potential participants. The clinic's protocol for chronic pain management adhered to an every four to eight week follow-up pattern routinely. An initial attempt to utilize the clinic's electronic health record (EHR) system (Allscripts) to formulate a patient list using ICD codes, cross-referenced with adherence to scheduled appointments was unsuccessful. A list of potential project participants utilizing the clinic's scheduling data was formulated by the project champions followed by either a phone call and/or face-to-face inquiry to gain initial permission to discuss the project. The initial phone calls and face-to-face inquiries occurred during the first few months of implementation facilitated by the project champions using the above formulated list. Information given to potential participants briefly described the project's purpose, initial basic screening of inclusion criteria, evaluation of individual's interest in participation, and plans for initial meeting with the project's administrator for participation enrollment. Initial contact and permission to discuss the project were obtained by the project champions who were clinic employees and followed HIPPA guidelines.

The project champions assisted in identifying patients that met the project's inclusion data and who were interested in learning more about the project. Individuals identified were then given more formal verbal and written information about the project by the project administrator face-to-face during a routine clinic follow-up appointment. Patients desiring to proceed with participation received more detailed education to meet informed consent requirements and a project folder. The project folder contained the following: "Meditation and You" pamphlet authored by the project administrator, step-by-step instruction guide for meditation (Appendix D), "The Mindfulness Bell" DVD, three sets of instruments with instructions, calendar form on orange paper, a demographic form (Appendix C), and two self-addressed stamped envelopes for return of instruments. The three instruments were color coded with green paper for baseline intake, yellow for week two intake, and red for week four intake. Each participant completed informed consent, the baseline instruments, and demographic form at the initial one-on-one meeting with project administrator. Once baseline intake completed, the participant watched the DVD privately on a laptop in the assigned office. The "Mindfulness Bell" is a five minute auditory and visual creation aimed at guiding individuals in meditation and refocusing individuals to the present moment (Clarke, 2003). The "Mindfulness Bell" DVD incorporates both auditory and visual stimulation which displays a moving blue wave form accompanied by a bell gong which fades slowly (Clarke, 2003). The DVD guides individuals to focus on the fading bell sound and to close one's eyes when focused comfortably on the fading sound (Clarke, 2003). The fading sound requires significant concentration which assists individuals in refocusing to the present moment which is central to mindfulness meditation (Clarke, 2003). Permission was granted by the creator

for use as the intervention for this project prior to implementation (Appendix E). The participant was guided through the initial five minute intervention of the “Mindfulness Bell” by the project administrator on site and questions answered as needed. Participants were instructed to use the “The Mindfulness Bell” at least once a week, but could use more often if desired with instructions to document use on the orange calendar in the packet. The participants were instructed to return the orange calendar and the last set of instruments at the completion of week four of project. Additionally, permission was obtained from participants to allow the project administrator and/or project champions to contact them either via phone, text or email each Wednesday after beginning the project as a reminder to use “The Mindfulness Bell”. Participants were additionally given a link to access the intervention. Participants were informed that at the completion of the four week process, a monetary gift card would be given in appreciation of their time. The gift card would be mailed or could be picked up at the clinic on receipt of final set of completed instruments and project forms. An email address, brainonpain@yahoo.com, was established to give participants access to project administrator for questions and communication, however, this resource was not used by any participants.

Setting

This Capstone Project was conducted in a private, rural primary care clinic in Eastern North Carolina with a sub-specialty of chronic pain management, palliative care, and addiction medicine. The clinic provides pain management to individuals over the age of 18 from the surrounding eight counties. The clinic averaged 60 appointments per week specifically for chronic pain management.

All participants were English-speaking patients over the age of 18 with a diagnosis of chronic pain identified by diagnostic coding of ICD 338.2 series or ICD 338.4 within the medical record and were naïve to mindfulness-based interventions as self-reported. Additionally, all participants were established patients in the pain specialty clinic over six months with adherence to follow-up as demonstrated by appointment history. Exclusion criteria included any individual diagnosed with significant mental illness, such as uncontrolled bipolar disorder or schizophrenia, cognitive impairment, diagnosis of any active cancer related illness, non-English speaking, and any reported use of mind-body or complimentary medical practices that paralleled mindfulness-based meditation. The initial sample size goal was set at 30 participants, or 30% of the clinic's average monthly appointments, which numbered 88 appointments at time of project planning.

The clinic's owner and sole provider is a family physician, certified in palliative and addiction medicine and has provided chronic pain management in the geographic area for numerous years. The clinic followed current medical standards regarding assessment, treatment, evaluation, and documentation consistent with recommendations of the American Pain Society [APS] (2005) and American Academy of Pain Medicine [APM] (1997). Prior to receiving any pain management, all patients were informed of policies, rules, and procedures related to the clinic's operations to include use of random urine testing, routine pill counts, missed appointments, and expected conduct. Acknowledgement of the clinic's standards and consent by each chronic pain patient were documented within the medical record in the form of a pain contract signed and dated by the patient and provider.

The one-on-one sessions with patients occurred in one office pre-selected due to its location within the clinic, privacy, availability, and comfort. The office had subdued lighting, desk with laptop for viewing DVD, chair with cushioned seat, and away from patient flow and exam rooms being used for patient appointments.

Sample

All participants were English-speaking patients over the age of 18 with a diagnosis of chronic pain identified by diagnostic coding of ICD 338.2 series or ICD 338.4 within the medical record and were naïve to mindfulness-based interventions as self-reported. Additionally, all participants were established patients in the pain specialty clinic over six months with adherence to follow-up as demonstrated by appointment history. All project participants lived in the surrounding area with 89% residing within the county, and 11% living in surrounding counties. Exclusion criteria included any individual diagnosed with significant mental illness, cognitive impairment, diagnosis of any active cancer related illness, non-English speaking, and any reported use of mind-body or complimentary medical practices that paralleled mindfulness-based meditation.

Project Design

A quasi-experimental, quantitative design was employed with a one group pre-, post-test measuring levels of pain, mindfulness-based self-efficacy, and quality of life at three separate time intervals: baseline, two weeks, and four weeks after introduction of a mindfulness-based meditation intervention. As the sample of participants was not randomized, this project aligned with characteristics of a quasi-experimental design. (Fawcett & Garity, 2009). Specifically, this project employed an outcomes research

format using a one-group pretest-posttest design. The three areas of interest in this project, as addressed in the research questions included self-reported pain level, mindfulness self-efficacy, and quality of life. Each area was measured utilizing a separate instrument focused on the measurement of the behavior of interest with collection of data pre-intervention, at two weeks and four weeks post- intervention. Each instrument is available in the public domain allowing use freely in research and written at a sixth grade reading level allowing ease of use (Cayoun, 2011).

Statistical analysis utilizing descriptive statistics and multivariate techniques was performed in the evaluation of degree of relationships between groups and within groups to include a one-way analysis of variance (ANOVA) and multiple regression (Mertler & Vannatta, 2013). Utilization of SPSS statistical software was employed for analysis of data.

Protection of Human Subjects

Project participants received verbal and written information related to the project's purpose, duration, intervention, benefits, any possible risks, data collection procedures and anticipated timing, proposed compensation, and project administrator's contact information, as well as, the contact for the University. The written information was written at the sixth-grade reading level and signature by the participant was required prior to any data collection or intervention (Appendix F). Participants were assured confidentiality and privacy, as the intervention was one-on-one with the project administrator, and only three other employees of the clinic were involved to include the physician, an administrative assistant, and a licensed practical nurse. Emphasis was provided in writing and verbally to each participant, that he/she may at any time and

without explanation, remove himself/herself from the participation in the project. Each participant was informed that participation in the project was completely voluntary and would not impact or change the relationship or course of treatment employed by the clinic's solo physician practitioner. Participants were informed that the project's information and intervention were additional interventions to their pain management regimen, and would not replace any prescribed analgesics, physical therapy, or other medicinal therapies currently in place. Participants were informed that at the completion of the four week process, a monetary gift card would be given in appreciation for time used to participate. The gift card would be mailed to participant on receipt of final set of completed instruments and project forms.

Privacy and confidentiality were maintained as individuals involved in contact with potential subjects, implementation of intervention, collection of data, and follow-up were clinic employees who had signed HIPPA agreements as part of their employment. The project administrator adhered to HIPPA standards and ethical rules of conduct. Additionally, approval in writing from the project site and the University's IRB was secured prior to implementation of this Capstone Project.

Potential harm to subjects was not anticipated and was not identified during or after the project's implementation, however, participants were informed that in the event of any distress related to the intervention or data collection, the clinic's physician would be consulted and the participant would receive assessment and management of the distress. Additionally, participants were informed that in the event of cessation of participation in the project, the contents of the project folder to include the "Mindfulness Bell" DVD were not required to be returned.

Instruments

As addressed in the project's research questions, self-reported pain level, mindfulness self-efficacy, and health related quality of life were areas of interest. Three individual instruments, one representing each area, were utilized with collection of data at three separate times: pre-intervention, two weeks, and four weeks post- intervention. Each instrument exists in the public domain allowing use freely in research, and each instrument was written at the sixth grade reading level allowing ease of use (Cayoun, 2011).

Measurement of Pain Level

Chronic pain is defined differently than acute pain, both in length and in pathophysiology. Although chronic pain can be an end result of an acute injury, tissue infection, nerve injury or tissue damage, its pathophysiologic course and etiology involves an array of complicated signaling pathways, neurotransmitters and neurological responses that are difficult to measure (Voscopoulos & Lema, 2010). As discussed earlier, one of the most accurate and useful measurements of pain level and intensity is an individual's self-report (NIH, 2013).

The numeric rating scale (NRS) for pain assessment is routinely used in evaluation of pain in adult patients. Several forms are available, however; the most common form incorporates a simple 11-item scale, often detailed on a horizontal line with numerals "0" (zero) to "10" (ten), denoting an individual's subjective pain intensity level (Hawker, Mian, Kendzerska, & French, 2011). A response of "0" corresponds to "no pain" and a response of "10" corresponds to "worst pain ever". The NRS is one of

the most commonly used scales verbally and visually in adults (Hawker et al., 2011). Higher reported scores indicate greater pain.

Evaluation of the scales reliability and validity in research yielded high test–retest reliability in both literate and illiterate individuals ($r = 0.96$ and 0.95 , respectively) (Hawker et al., 2011). Tool validity has been demonstrated at correlation levels from 0.86 to 0.95 when used with patients diagnosed with chronic pain (Hawker et al., 2011).

A very simple numeric pain scale was incorporated in this project utilizing a traditional scale ranging from “0” (zero), meaning no pain at all, to “10” (ten), meaning severe pain is experienced. The numeric instrument was included in the project folder and distributed to participants at time of enrollment in the project (Appendix G). Each participant received a total of 3 numeric pain instruments that were completed at baseline/pre-intervention, two weeks, and four weeks post-intervention.

Measurement of Mindfulness Self-Efficacy

Equally difficult to quantify, is one’s self-efficacy for use of mindfulness based techniques, including meditation. The Mindfulness Based Self-Efficacy Scale-Revised (MSES-R) was utilized in this project to evaluate mindfulness self-efficacy. The MSES-R is a 22-item instrument that originates from the 35-item instrument Mindfulness Based Self-Efficacy Scale (MSES) (Cayoun, 2011). This shortened instrument encompasses six subscales of self-efficacy: emotion regulation, equanimity, social skills, distress tolerance, taking responsibility, and interpersonal effectiveness (Cayoun, 2011). These subscale areas have been identified in the literature as skills that improve with mindfulness (Cayoun et al., 2011). The instrument utilizes a 5 point likert-scale with 0 (zero) meaning “not at all” and 4 (four) meaning “completely”. The original authors of

the condensed version and subscale interpretation have been involved in research related to mindful meditation and measurement of self-efficacy for many years (Cayoun, Francis, Kasselis, & Skilbeck, 2012; Cayoun, 2012).

Psychometric data related to this scale yields a test-retest reliability in the range of very good with $r=.88$, $N=100$, and $p. <.01$ with an internal consistency rated as reliably high with a Chronbach alpha $=.86$ (Cayoun et al., 2012). The 22-item instrument is easy to use with short description sentences (“I can deal with physical discomfort”) and, again, a 5 point scale ranging from 0 to 4 (Cayoun et al., 2012). It is written at the sixth grade level and has been used in other research endeavors related to pain (Cayoun et al., 2012).

Measurement of Health Related Quality of Life

Health related quality of life was measured in this project utilizing the Quality of Life Scale (QOLS) which assesses an individual’s physical well-being, relationships, involvement in community/society, independence, and personal fulfillment (Appendix H). This instrument is a 16-item statement format with a likert-scale ranging from 1 to 5 with 1 being “dissatisfied” and 5 being “very satisfied”. This instrument was originally formulated and published by John Flanagan, an American psychologist, in the mid-1970’s and has evolved into a tool used with varying age groups and varying chronic illnesses (Burckhardt & Anderson, 2003). Transformations of the instrument have evolved to improve its applicability to measuring quality of life in individuals with chronic illnesses yielding construct validity acceptable for research use and interpretation (Burckhardt & Anderson, 2003).

Data Collection

Data collection occurred at three times during this project: pre-intervention, two weeks post-intervention, and four weeks post-intervention. Three sets of the project's instruments were included in the distributed project folder given to all participants at time of enrollment along with thorough review of contents and written instructions. Baseline data was collected from participants at initial project enrollment to include demographic information (Appendix D) and completion of the three instruments pre-intervention. Follow-up data collection at the two-week and four-week post-intervention points occurred either by mailing in the instruments in a pre-addressed and stamped envelope to the project administrator or returning instruments to the project champions in the clinic. Participants received reminder notifications via phone as warranted.

Data Analysis

Data was analyzed using the current SPSS electronic statistical software. As noted previously, use of descriptive statistics and multivariate techniques was performed to evaluate degree of relationships between groups and within groups to include a one-way analysis of variance (ANOVA) and multiple regressions (Mertler & Vannatta, 2013). Analysis of data utilizing the SPSS software was initially completed by the project administrator. Additionally, a statistician was consulted to review and assist with data analysis.

Timeline

This Capstone Project took place over a period of six months in an effort to enroll additional participants. The project administrator was on-site at least once weekly to coordinate implementation, enroll participants, and collect data.

Budget

The budget for this Capstone Project (Table 1) included cost for materials, printing, travel, staff appreciation, participant incentives, and assistance with statistical analysis. In addition, the budget for this project included funding a clinical event to review findings of the project.

Table 1

Capstone Budget

Description	Cost	Explanation
Promotion of Project	\$50.00	Posters, phone calls, letters
Travel	\$75.00	Gas
Printing/Materials	\$150.00	Tools, pamphlets, forms
Staff Compensation	\$50.00	Project champions
Participant Appreciation	\$270.00	\$15.00 gift card/participant
Statistical Analysis	\$120.00	\$60/hr. statistician
Research Event	\$150.00	Poster/Presentation/Food
TOTAL	\$865.00	

Limitations

There were several limitations encountered with this Capstone Project. Enrollment of participants proved to be one of the main obstacles. One early barrier was the process of attaining initial permission from the patient to discuss the project. This process was facilitated by the project champions due to HIPPA standards and often obstructed due to level of activity in the clinic. Enrollment was also impacted due to

patient's time limitations at his/her scheduled appointment to receive initial briefing and education. Additionally, several interested patients did not have access to a device to use the “Mindfulness Bell” DVD or access to other available delivery systems for the intervention. Several patients voiced lack of time to participate for the entire course of data collections. Frequently, the project administrator was not able to reach participants which impacted the collection of data at the two week and four week points.

Summary

This Capstone Project assessed the feasibility and effect of implementing a brief mindfulness-based intervention to adult patients diagnose with chronic pain. The project was conducted in rural primary care clinic in Eastern North Carolina that provides chronic pain management to patients in the extended surrounding counties by a family physician certified in palliative care. Point-of-care delivery of a mindfulness-based meditation intervention (“Mindfulness Bell”) guided by a nurse practitioner was evaluated specifically for the effect on pain level, mindfulness self-efficacy, and health related quality of life. The “Mindfulness Bell” DVD is a five minute visual and auditory exercise that was introduced to participants at time of enrollment after baseline instruments completed. Participants received verbal and written education and guidance related to mindfulness-meditation, including a project folder with the “Mindfulness Bell” DVD, project instruments, and other education material. Three separate instruments were utilized for each of the areas of interest for this project: pain level, mindfulness self-efficacy, and health related quality of life. Instruments were short, uncomplicated, numeric, and written at sixth grade level. Utilization of the clinic's staff as project

champions aided with identification and screening of potential participants, dissemination of information and data collection.

Guidelines to maintain an ethical research process were implemented including adhering to HIPPA standards and informed consent requirements. Participants received verbal and written instructions related to the project and assurance of confidentiality.

The implementation of this project spanned a total of six months, and incurred an estimated cost of \$865.00 for materials, incentives, travel, and staff appreciation.

The project incorporated sustainable and useable interventions appropriate not only for a specialty clinic, but also primary care practices. The project utilized a brief and uncomplicated intervention which proved to be easily implemented and repeated. This intervention can be initiated into a patient's plan of care by the provider, a nurse, an assistant or designated office champion.

CHAPTER IV

Results

The purpose of this Capstone Project was to evaluate the effect of a brief mindfulness-based meditation intervention on individuals diagnosed with chronic pain. Pain level, mindfulness-based self-efficacy, and quality of life were measured two-weeks and four-weeks post implementation of the brief intervention. The process of both recruitment of participants and data collection occurred over a six month time frame in a rural pain specialty clinic in Eastern North Carolina. The project administrator was on site one day a week for project recruitment, data collection, and follow-up. Participants returned the two-week and four-week instruments to the project administrator by mail or in person at the clinic. Data collected was analyzed utilizing the SPSS electronic statistical software.

Sample Characteristics

Forty-three patients received one-on-one education about the project, with 24 individuals agreeing to proceed with participation, and 18 individuals completing the full four week project. Twenty-four adults consented to participate and received introduction to project and project materials. Eighteen participants returned both the two-week and the four- week instrument sets. Six of the original 24 participants failed to return instrument sets at both the two-week and four-week collection times with 34% citing time constraints as a rationale for withdrawal from project. The remaining 66% of individuals were unable to be contacted, therefore, rationale for failure to complete project is unknown.

Sample characteristics are displayed in Table 2. The final sample (n=18) consisted of nine females and nine males, age range from 37 years of age to 78 years of age with median age being 58 years of age. Fifty-six percent of the sample was African American and 44% were Caucasian with a majority reporting high school level education or higher. All project participants lived in the surrounding area with 89% residing in the project site county, and 11% living in nearby counties, 39% utilized Medicare insurance, 39% utilized private insurance, and 22% paid out of pocket. Seventy-eight percent of participants reported suffering with chronic pain for over 10 years, with 5% reporting suffering for six to ten years, and 17% reporting suffering with chronic pain less than five years.

Table 2

Sample Characteristics

	<i>N</i>	<i>Percent</i>
Sex		
Male	9	50%
Female	9	50%
Race		
African American	10	56%
Caucasian	8	44%
Other		
Education		
HS/GED	17	94%
College	1	6%
Pain Length (years)		
1-5	3	17%
6-10	1	5%
>= 10	14	78%
Payer Source		
Private Insurance	7	39%
Medicaid	0	
Medicare	7	39%
Self-Pay	4	22%
Overall	18	100%

Major Findings

The effect of a brief intervention utilizing mindfulness-based meditation on pain, mindfulness self-efficacy, and quality of life in adult individuals diagnosed with chronic pain was analyzed utilizing descriptive and inferential statistical methods. Analysis of this data included basic descriptive statistics, repeated one-way ANOVA, and Pearson correlation in addressing the project's research questions.

Correlation between mindfulness self-efficacy and both pain level and quality of life at baseline, two-weeks, and four weeks showed statistical significance in three areas as displayed in the correlation matrix Table 3. Data related to level of mindfulness self-

efficacy at baseline and level of quality of life at all points of measurement yielded a statistically significant correlation.

Mindfulness self-efficacy at baseline and quality of life correlated at each level of measurement with quality of life baseline ($r = 0.505$, $p < 0.05$), two-weeks ($r = 0.60$, $p < 0.05$), and four weeks ($r = .613$, $p < 0.05$). In addressing the research question regarding a relationship between level of mindfulness self-efficacy and reported quality of life, correlation analysis supports a relationship as above. The correlation analysis of mindfulness self-efficacy at two-weeks and quality of life at baseline ($r = 0.233$), two-weeks ($r = 0.195$), and four-weeks ($r = 0.127$) did not show statistical significance. Additionally, the correlation analysis of mindfulness self-efficacy at four-weeks and quality of life at baseline ($r = 0.092$), two-weeks ($r = -0.049$), and four-weeks ($r = -0.099$), did not support a statistically significant relationship.

The research question investigating a relationship between level of mindfulness self-efficacy and pain level is not supported by the correlation analysis. Correlation between mindfulness self-efficacy at baseline and pain level at baseline ($r = 0.278$), pain level at two-weeks ($r = -0.168$), and pain level at four-weeks ($r = 0.097$) did not show a statistically significant relationship. Correlation between mindfulness self-efficacy at two-weeks and pain level at baseline ($r = -0.169$), pain level at two-weeks ($r = -0.234$), and pain level at four-weeks ($r = -0.160$) showed no statistical relationship or significance ($p > 0.050$). Similarly, correlation between mindfulness self-efficacy at four-weeks and pain level at baseline ($r = -0.384$), two-weeks ($r = -0.166$), and four-weeks ($r = -0.14$) did not show a statistically significant relationship.

Table 3

Correlations Pearson r

	Pain - Base	Pain Level– 2 weeks	Pain Level – 4 weeks	QOL - Base	QOL – 2 weeks	QOL – 4 weeks
MSES - Base	0.278	-0.168	0.097	0.505*	0.601*	0.613*
MSES – 2 weeks	-0.169	-0.234	-0.160	0.233	0.195	0.127
MSES – 4 weeks	-0.384	-0.166	-0.141	0.092	-0.049	-0.099

*. Correlation is significant at the 0.05 level (2-tailed).

Descriptive statistics are displayed in Table 4 for demographic identifiers and in Tables 5, 6, and 7, for each of the dependent variables addressed in the study.

Relationships and trends between demographic variables and the dependent variables in the study were analyzed utilizing repeated one-way ANOVA.

Table 4

Descriptive Statistics

		Age	Sex	Race	Pain Length	Education	Payer Source
			Male=1 Female =2	AA=1 Cauc=2	1-5yr=1 6-10=2 >10=3	<12=1 HS/GED=2 College=3	Priv. Ins=1 Medicaid=2 Medicare=3 Self=4
N	Valid	18	18	18	18	18	18
	Missing	0	0	0	0	0	0
Mean		57.9444	1.5000	1.4444	2.6111	2.0556	2.4444
Median		59.5000	1.5000	1.0000	3.0000	2.0000	3.0000
Mode		44.00 ^a	1.00 ^a	1.00	3.00	2.00	1.00 ^a

Repeated measures of each dependent variable at baseline, two-weeks, and four-weeks were evaluated utilizing one-way ANOVA statistical methods. Table 5 displays both descriptive statistics related to pain level and analysis of reported pain level at baseline, two-weeks, and four-weeks post-intervention to sex ($F = 0.080$, $p = 0.924$, $n_2 = 0.008$), race ($F=0.249$, $p=0.782$, $n_2 = 0.024$), education level ($F=0.571$, $p=0.574$, $n_2 = 0.054$), chronicity of pain ($F=0.812$, $p=0.532$, $n_2 = 0.140$), and payer source ($F=1.441$, $p=0.257$, $n_2 = 0.224$). Pain levels consistently improved for both females ($n=9$) and males ($n=9$) at both two-weeks and four-weeks. Race, educational level, and payer source did not demonstrate significant trends or differences in reported pain level. Length of pain suffering did show that individuals suffering from less than 10 years had the greatest reduction in pain at two-weeks and four-weeks ($n=4$) with an average

reduction from reported pain of “6” at baseline to “4.8” after four weeks. Although reported pain level consistently improved, no statistically significant findings existed.

Table 5

Pain Analysis

	<i>N</i>	Pain - Base		Pain Level – 2 weeks		Pain Level – 4 weeks		<i>F</i>	<i>p</i>	η^2
		<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>			
Sex								0.080	0.924	0.008
Male	9	6.67	1.80	6.22	1.09	5.78	1.64			
Female	9	6.11	1.45	5.78	.97	5.11	.78			
Race								0.249	0.782	0.024
Af. Am	10	6.60	1.71	6.10	1.10	5.80	1.55			
Caucasian	8	6.13	1.55	5.88	.99	5.00	.76			
Other	0	--	--	--	--	--	--			
Education								0.571	0.574	0.054
HS/GED	17	6.47	1.62	6.00	1.06	5.53	1.28			
College	1	5.00	--	6.00	--	4.00	--			
Chronicity of Pain (years)								0.812	0.532	0.140
1-5	3	6.00	1.73	5.67	.58	4.67	1.15			
6-10	1	7.00	--	5.00	--	5.00	--			
>= 10	14	6.43	1.70	6.14	1.10	5.64	1.34			
Payer Source								1.441	0.257	0.224
Private Insurance	7	6.14	1.86	5.86	.90	5.14	1.35			
Medicare	7	7.00	1.29	5.86	1.07	5.86	1.46			
Self-Pay	4	5.75	1.71	6.50	1.29	5.25	.96			
Overall	18	6.39	1.61	6.00	1.03	5.44	1.29	0.406	0.672	0.039

Analysis of mindfulness self-efficacy in relationship to demographic variables showed no relationship between mindfulness self-efficacy and sex ($F=2.573$, $p=0.101$), race ($F=0.385$, $p=0.685$), educational level ($F=0.164$, $p=0.850$), or payer source ($F=0.688$, $p=0.609$). Differences did exist between length of pain and mindfulness self-efficacy as individuals reporting suffering with pain from one to five years showed an

improvement in their mindfulness-based self-efficacy scores after intervention, specifically after two-weeks ($F=3.351$, $p=0.030$, $\eta^2=0.401$).

Table 6

MSES-R Global Analysis

	N	MSES - Base		MSES - 2 weeks		MSES - 4 weeks		F	p	η^2
		M	SD	M	SD	M	SD			
Sex								0.115	0.892	0.011
Male	9	43.33	3.74	48.89	4.14	54.00	5.81			
Female	9	42.89	5.82	47.22	4.74	53.00	4.74			
Race								0.237	0.791	0.023
Af. Am	10	44.50	4.03	49.60	4.79	54.50	5.95			
Caucasian	8	41.38	5.26	46.13	3.14	52.25	4.03			
Education								1.809	0.190	0.153
HS/GED	17	43.29	4.83	48.29	4.41	53.94	4.97			
College	1	40.00	--	44.00	--	46.00	--			
Pain Length (years)								0.640	0.640	0.113
1-5	3	43.33	5.77	52.00	7.21	55.33	8.33			
6-10	1	38.00	--	44.00	--	58.00	--			
>= 10	14	43.43	4.72	47.50	3.48	52.79	4.63			
Payer Source								1.009	0.426	0.168
Private Insurance	7	40.86	2.27	48.00	4.47	54.71	6.99			
Medicare	7	45.14	3.93	47.43	3.60	52.14	3.76			
Self -Pay	4	43.50	8.06	49.25	6.40	53.75	4.19			
Overall	18	43.11	4.75	48.06	4.40	53.50	5.17	0.798	0.464	0.074

Quality of life (QOL) analysis is displayed in Table 7 showing a consistent improvement in scores reported among both male and female, among each race, each education level, all levels of pain length, and all categories of payer source. There was more of an improvement in QOL over time in individuals suffering over 10 years with chronic pain, with mean scores increasing from 59.86 at baseline to 71.14 at four-week measurement. Although raw scores consistently improved, no significance is identified between variables with overall significance being $p = 0.436$.

Analysis of relationship between sex and QOL at each point of measurement demonstrated no statistical significance ($F=0.009$, $p=0.991$, $n2=0.001$). Additionally, race ($F=0.072$, $p = 0.931$, $n2 = 0.007$), education level ($F = 0.084$, $p = 0.920$, $n2 = 0.008$), pain length ($F=0.167$, $p = 0.953$, $n2 = 0.032$), and payer source ($F = 0.290$, $p = 0.881$, $n2 = 0.055$) did not reveal statistical relationship with measures of QOL.

Table 7

QOL Analysis

		QOL - Base		QOL - 2 weeks		QOL - 4 weeks				
	<i>N</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>F</i>	<i>p</i>	η^2
Sex								0.009	0.991	0.001
Male	9	55.00	12.96	59.78	11.88	64.89	13.69			
Female	9	59.78	14.45	66.44	15.00	72.33	16.67			
Race								0.072	0.931	0.007
Af. Am	10	57.10	15.68	62.10	14.66	67.70	17.35			
Caucasian	8	57.75	11.35	64.38	12.94	69.75	13.32			
Other	0	--	--	--	--	--	--			
Education								0.084	0.920	0.008
<= 12yrs	0	--	--	--	--	--	--			
HS/GED	17	57.35	13.96	63.29	13.96	68.88	15.71			
College	1	58.00	--	60.00	--	64.00	--			
Pain Length (years)								0.167	0.953	0.032
1-5	3	53.33	5.03	58.33	2.89	62.00	2.65			
6-10	1	35.00	--	40.00	--	53.00	--			
>= 10	14	59.86	13.67	65.79	13.62	71.14	16.39			
Payer Source								0.290	0.881	0.055
Private Insurance	7	50.00	11.12	53.71	9.18	59.14	10.59			
Medicaid	0	--	--	--	--	--	--			
Medicare	7	64.00	15.62	70.71	13.84	78.29	14.43			
Self-Pay	4	58.75	8.46	66.25	11.73	68.25	15.97			
Overall	18	6.39	1.61	6.00	1.03	5.44	1.29	0.867	0.436	0.080

Summary

Eighteen participants completed and returned instruments for the full four week project time span. Sample characteristics consisted of equal distribution of males and females with a participant median age of 58 years. All participants reported an education level of high school completion or higher. The majority of the sample reported suffering with chronic pain for 10 years or greater. No relationships between demographic variables and the project's outcome measures were identified.

Correlation between mindfulness self-efficacy and both pain level and quality of life at baseline, two-weeks, and four-weeks showed statistical significance. Data related to level of mindfulness self-efficacy at baseline and level of quality of life at all points of measurement also yielded a statistically significant correlation.

The project research question inquiring about a relationship between level of mindfulness self-efficacy and reported quality of life was supported correlation analysis supports a relationship as above.

Key findings of the data analysis show that several areas of raw scores consistently demonstrated improvement; however, statistical significance was not shown. Quality of life measures showed a consistent improvement in scores among both male and female, among each race, each education level, all levels of pain length, and all categories of payer source. Specifically, individuals suffering over 10 years with chronic pain demonstrated the largest improvement, with mean scores increasing from 59.86 at baseline to 71.14 at four-week measurement. Although raw scores consistently improved, no significance was identified statistically.

CHAPTER V

Discussion

The purpose of this Capstone Project was to investigate the effect of a brief mindfulness-based meditation intervention on pain level, mindfulness-based self-efficacy, and quality of life in adults diagnosed with chronic pain. Additional interest included the feasibility of utilizing a point-of-care, brief mindfulness-based meditation intervention introduced and facilitated by a nurse practitioner with this patient population.

Implications of Findings

The data analysis revealed a relationship between mindfulness self-efficacy and length of pain. Individuals suffering less than five years demonstrated improvement in mindfulness self-efficacy after use of the “Mindfulness Bell”. This finding suggests that interventions incorporated earlier in the course of the patient's diagnosis, may be more beneficial in improving the individual's self-efficacy and the probability of repeated use of the behavior. Early introduction of mindfulness-based interventions to the patient diagnosed with chronic pain may be more effective and should be included as part of the patient's overall plan of care.

Additionally, no significant differences existed between demographic variables (race, sex, education level) and pain level, mindfulness self-efficacy, or quality of life pre or post intervention. This finding suggested that these variables are not influenced by race, sex or level of education, and, therefore, mindfulness-based interventions may be applicable and suitable for a wide range of adult patients.

Application of Theoretical/Conceptual Framework

Albert Bandura's Social Cognitive Theory (SCT) served as the framework for this project. Central to SCT and to this project is the entity of self-efficacy, focusing on the belief that when an individual feels confident in performing a behavior, that behavior will be repeated by the individual. Specifically, participants introduced to the mindfulness-based intervention, the "Mindfulness Bell", should gain increase self-confidence in incorporating this tool with repeated and routine use. Improvement in the individual's self-efficacy yields higher probability that the intervention or behavior will be repeated. As the individual repeats the use of the intervention, the goal would be that pain level and quality of life measures improve which further reinforces the individual's level of self-efficacy. Although, the results of this project did not support the project questions at a significant statistical level, Bandura's theory applies to the ideas and framework related to implementing a brief mindfulness-based intervention with patients diagnosed with chronic pain.

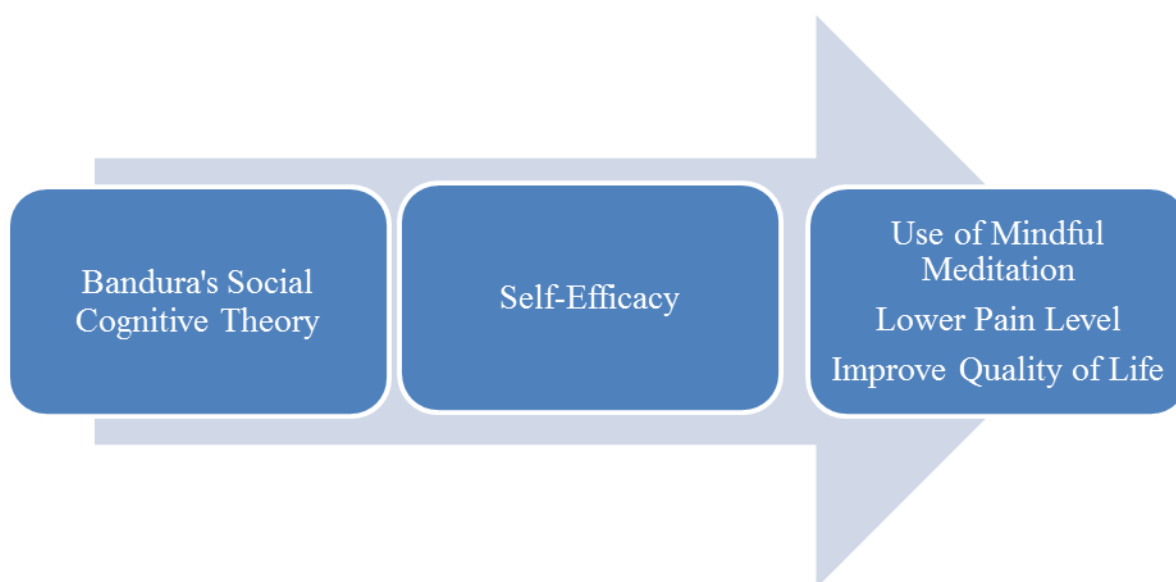


Figure 1. *Conceptual-Theoretical-Empirical Structure*

Limitations

The findings of this project, although lacking significant statistical outcomes, showed consistent improvements in pain levels, mindfulness self-efficacy measures, and quality of life measures after implementation of a brief mindfulness-based intervention. One of the primary limitations of this study was the low sample size. Increasing sample size would yield improvement in analysis of group relationships and a stronger evaluation of effect of intervention on study variables.

Another project limitation was inability to accurately quantify how often participants utilized the “Mindfulness Bell”, as return of calendar documentation was inadequate. Although participants received once weekly reminders, there is no data to definitively quantify the amount of individual use of the intervention.

Utilization of the MSES-R global score alone limited incorporation of the instruments subscales. These subscales may have yielded valuable information for both individual and group analysis related to emotion regulation, social skills, distress tolerance, responsibility, and interpersonal effectiveness (Cayoun, 2011).

The inability to control for variables such as source of chronic pain, co-morbidities, and quantity and/or type of analgesic being used may have effect on individual and group scores for level of pain, mindfulness self-efficacy, and quality of life. Additionally, data related to changes made in the participants’ treatment regimen during the four week project, such as increase in analgesic dosing, addition of other medications, and/or other therapies may impact outcomes and should be incorporated.

The use of only a DVD and link for the intervention limited access for many of the potential participants. It may be beneficial to include other means for delivery of the intervention, such as phone applications.

Implications for Nursing

Chronic pain is no longer a diagnosis exclusively managed by specialists. As the number of American individuals suffering with chronic pain continues to grow (IOM, 2011), management is shifting to primary care providers, including nurse practitioners. In addressing the specific needs of this complicated patient population, nurse practitioners will need to be equipped with knowledge, skills, and resources.

The current medical standard for chronic pain management focuses primarily on analgesic interventions, including escalating use of opioids in America. Although, nurse practitioners need to be experienced in the use and safety of all analgesics, including opioids, knowledge about additional management resources is imperative. Tools such as brief interventions utilizing mindfulness-meditation can be effectively implemented and facilitated in the office setting by nurse practitioners and nurses. Use of resources like the “Mindfulness Bell” tool can be incorporated in the office setting in a variety of ways to include implementing tools in the waiting room, as the patient waits in exam room to be seen, and/or supplying the patient with resources to use in the home setting.

Recommendations

The use of a brief mindfulness-based meditation intervention and the effect on chronic pain warrants further investigation. Replication of this study with alterations in the project design and variables is recommended. Specifically, measuring only pain level and self-efficacy utilizing the same instruments (Pain Scale, MSES-R) pre- and post-

intervention at one point in time may improve sample size yielding improved ability to comment on relationship and effect. This study's use of three separate instruments to be completed at three separate times over a four week time span, may have been too time consuming for participants. Recommendations for simplifying the project would include focusing more on the area of self-efficacy and pain level.

Additionally, use of a control group in the same setting is recommended in order to compare groups and further investigate the effect of the intervention. Analysis of additional characteristics of the study participants to include specific source of chronic pain, co-morbidities, and quantity and type of analgesic used is recommended to be included in further investigation. It is recommended that future investigation supply participants with improved access to the intervention through either supplying participants with a DVD player or incorporation of phone applications.

Conclusions

Management of chronic pain is increasingly becoming a responsibility and requirement of primary care providers. Nurse practitioners represent a substantial number of those providing primary care in the United States (Naylor & Kurtzman, 2010). As nurse practitioners are confronted with the management of this complex patient population, evidenced-based interventions are imperative. Although the predominant and traditional model of chronic pain management follows a biomedical framework with significant reliance on opioid analgesics, an increasing interest and shift to a bio-psychosocial ideology incorporating a variety of non-traditional therapies, such as mindfulness meditation, is evolving. This Capstone Project did demonstrate that implementation of a brief mindfulness-based intervention at point-of-care is feasible in

the clinic setting. More research is needed, however, to evaluate the effect such brief mindfulness-based interventions, as well as other alternative therapies, have on patient outcomes, to include reduction in pain level and improvement in quality of life. This Capstone Project did not demonstrate a significant effect on patient outcomes as proposed in the project questions, however, multiple limitations in the project design were encountered and a low sample size resulted. Repetition of this project and further inquiry into utilization of alternative therapies in this complex patient population is highly recommended.

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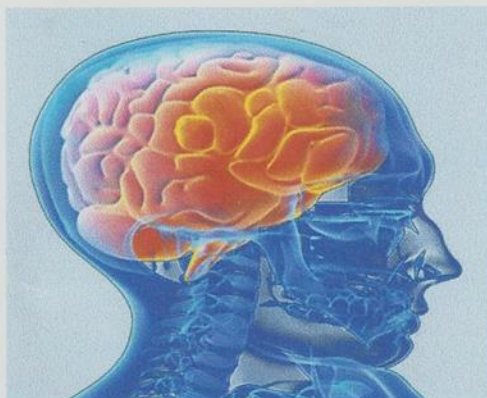
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Appendix A
Train Your Brain Poster



TRAIN YOUR BRAIN

(Can our BRAIN help our Pain?)

VOLUNTEERS NEEDED

RESEARCH STUDY

Do You:

- Suffer with CHRONIC PAIN ?
- Want to TRY MEDITATION **FREE** ?
- Have 5 MINUTES?

SEE FRONT DESK FOR INFORMATION/BROCHURE

Compensation & Free Training Provided

Appendix B Mindfulness Pamphlet

RESOURCES

Meeting Pain with Awareness
<http://www.Mindful.org>

Centers for Disease Control and Prevention (CDC)
<http://www.cdc.gov/Features/Meditation/>

National Center for Complementary & Alternative Medicine
<http://nccam.nih.gov>

Meditation & YOU

Simple Ways to Relax and Refocus



Project Coordinator


Jolena Allred, Family Nurse Practitioner
 Doctoral Student
 Gardner-Webb University



CHRONIC PAIN PROJECT

Contact
 919-496-1247
 Or
brainonpain@yahoo.com

Meditation and Health



What is Mindful Meditation??

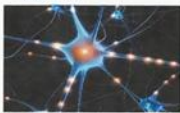
Mindful Meditation refers to a practice in which the individual learns to focus (or refocus) attention, become aware (mindful) of his/her thoughts, feelings and sensations in a non-judgmental way.

Practicing this over and over can result in calmness, a better sense of control, improved mood, improved sleep, and even a reduction in pain sensation.

WHY IT WORKS...

NOT completely understood, but some research gives us clues....

- May help the neurological or nervous system to respond better to stressors.
- May cause release of chemicals in the nervous system that help block the "pain" or help reduce the sensation of "pain".
- May cause actual changes in brain function helping an individual feel better.
- Helps with feeling "control" which can have powerful results.



FOCUS, BREATHE, FEEL, RELEASE

HOW TO MEDITATE....

Anyone can meditate. Try these simple first steps.

- A QUIET PLACE with LOW DISTRACTIONS
- COMFORTABLE POSITION
- FOCUS of ATTENTION...Can use an object to look at or a sound or both to help focus.
- OPEN ATTITUDE...sometimes feels "silly" to do, but opening your mind to try is an important first step...

Our brain and our thoughts can be POWERFUL.

If you are interested in learning to meditate and participate in a research project to help learn about meditation and pain, please ask at front desk, complete information packet, and you will be contacted.

Participants in the research project will receive free training and information about meditation and compensation at the end of the complete collection of the information. THANK YOU FOR YOUR INTEREST!

Appendix C Step-By-Step Meditation Guide

Mindfulness-Meditation Basic Guide

1. Find a QUIET place.
2. Get into a COMFORTABLE position (sitting, standing, or lying down)
3. Find a FOCUS (a word, a sound, a peaceful sight, a pleasant smell)
4. Keep your MIND open (believe, refocus your thoughts)

Use the DVD you received or the link:

<https://www.youtube.com/watch?v=wGFog-OuFDM>

Start by focusing on the bell movement with your eyes.

Once you have good focus, start listening to the sound with your ears.

Once you have focus on the sound, close your eyes.

KEEP focusing on the sound.

As you listen, take slow and deep breaths through you nose, and release the breath through your mouth.

After the 5 minute exercise is finished, be quiet for a brief time. You may keep your eyes closed.

TRY to repeat exercise daily.

PRACTICING regularly can produce the most benefit for you.

Appendix D Demographic Form

Project Participant Demographic Information

Name

Phone number

Address

Email Address

Date of Birth

PLEASE answer the following by circling the best response for you.

1. How long have you suffered with pain?

Less than 1 year 1-5 years 6-10 years Greater than 10 years

2. How much education have you received in your life?

Less than 12 yrs. High School GED Some College College Degree

3. Have you ever tried MEDITATION? Yes No

4. What is the best way to reach you? TEXT EMAIL PHONE

5. How do you pay for your medical visits?

Insurance Medicaid Medicare Out-of-Pocket

Appendix E

Permission to Use Mindfulness Bell



Special Permission

I, Christopher Lloyd Clarke, hereby grant Jolena B. Allred ("you") the right to use the music production entitled, Mindfulness Bell Volume 1 ("the music") in your research study into chronic pain. The terms of use of the music are as follows.

You may play the music to all participants in the study.

You may use the music to create and duplicate CDs to give to participants in the study, and/or you may provide participants in the study with a link to download the music in digital form. Participants shall not be charged to receive a copy of the music.

The maximum number of eligible participants is 100.

The permissions outlined in this document expire on June 30, 2015.

I will provide you with a copy of the music at no charge, and no other financial charges will apply to the use of the music as described herein.

I ask that you credit me (where appropriate) as the artist responsible for recording and contributing the music.

I warrant that I am the sole copyright owner of the music and that I have the full right, power and authority to grant these rights.

Christopher Lloyd Clarke

Name of Licensor

Signature of Licensor

January 4, 2015

Date

Appendix F Informed Consent Form

PROJECT NAME: The Impact of a Brief Mindfulness-Based Intervention on Chronic Pain

PROJECT COORDINATOR: Jolena B. Allred, Family Nurse Practitioner

UNIVERSITY: Gardner-Webb University

Why sign this document?

It is important that you feel informed about the project. To be in the project this consent form must be signed.

Why are you doing this research PROJECT?

The project is being conducted to learn more about how to help people who have chronic pain conditions. This project will help us learn more about using meditation to help with pain management. I am asking individuals like you who have chronic pain to help with the project.

What happens if I say yes, I want to be in the PROJECT?

If you say yes, I will:

- Ask you about identifying information like your age, how long you have had pain, your education, your employment status, your contact information, and your health care coverage. You will only be asked this at the beginning.
- You will be given 3 simple surveys to complete about your pain and quality of life before being taught about meditation.
- You will receive brief education and instruction on meditation and a CD to use at home.
- You will be asked to practice the meditation at least once weekly. You will be contacted once weekly and reminded. You may practice as much as you want to, but at least once weekly.
- You will be given the same 3 surveys to fill out at two separate times after being taught about meditation.
- You may read the questions out loud and you may ask any questions about the form at any time.

There are no right or wrong answers to any of the questions on the surveys.

How long will the PROJECT take?

The project will take about 15 minutes to fill out the 3 surveys. You will be asked to fill these surveys out at 3 different times. Additionally, you will be taught a meditation technique that takes 5 minutes and will be asked to practice this at least once a week. You may practice it more often if you can, but at least once weekly.

What happens if I say no, I do not want to be in the PROJECT?

No one will treat you differently. You will not be penalized. The care you get from your doctor will not change.

What happens if I say yes, but change my mind later?

You can stop being in the project at any time. You will not be penalized. You may keep any material given to you. The care you are receiving from your doctor will not change.

Who will see my answers?

The only people allowed to see your answers will be the people who work on the project and people who make sure we run our project the right way. All of these people are sworn to confidentiality.

Your survey answers, health information, and a copy of this document will be locked in our files. We will not put your answers into your medical record.

When the results of the project are shared, your personal information (name, address, etc) will not be included.

Will it cost me anything to be in the project?

No. You will be asked to complete surveys at 3 different times during the project which will require your time.

Will being in this project help me in any way?

You will be taught techniques in meditation which may help you. This cannot be guaranteed, however.

Will I be paid for my time?

Yes. You will be given a cash gift card at the end of project after you have completed all the surveys at the 3 set times. This is to pay you for your time and completion of the information.

Is there any way being in this project could be bad for me?

There is no way to guarantee that being in this project could be bad for you, however, there is a very low concern for this given the project plan. There is always a chance that:

- The questions on the surveys could make you sad or upset.
- Contacting you weekly may annoy you and be an inconvenience.
- Completing the surveys 3 separate times may annoy you and be an inconvenience

We will do our best to protect your privacy.

What if I have questions?

Please contact the project coordinator, Jolena Allred by either calling the clinic at 919-496-1247 and leaving a message or by email at brainonpain@yahoo.com.

- Have any questions about the study.
- Have questions about your rights.
- Feel you have been injured in any way by being in this study.

You can also call the project chair from the university, Anna S. Hamrick, DNP, FNP-C, ACHPN

Hunt School of Nursing at (704) 406-2460 fax questions to (704) 406-3919 to ask questions about this study.

Do I have to sign this document?

No. You only sign this document if you want to be in the study.

What should I do if I want to be in the project?

First you sign this document. I will give you a copy of the document to keep.

By signing the document you are saying:

- You agree to be in the project.
- We talked with you about the information in this document and answered all your questions.

You know that:

- You can skip questions you do not want to answer.
- You can stop answering our questions at any time and nothing will happen to you.
- You can call the office in charge of research at 704-406-3919 if you have any questions about the project or about your rights.

Your name (PLEASE PRINT)

Your signature

Date

If someone is signing this form for the subject, explain why:

Name of legally responsible person (PLEASE PRINT)

Signature of person signing for the subject

Date

Relationship to you: _____

Name of person conducting the consent discussion (PLEASE PRINT)

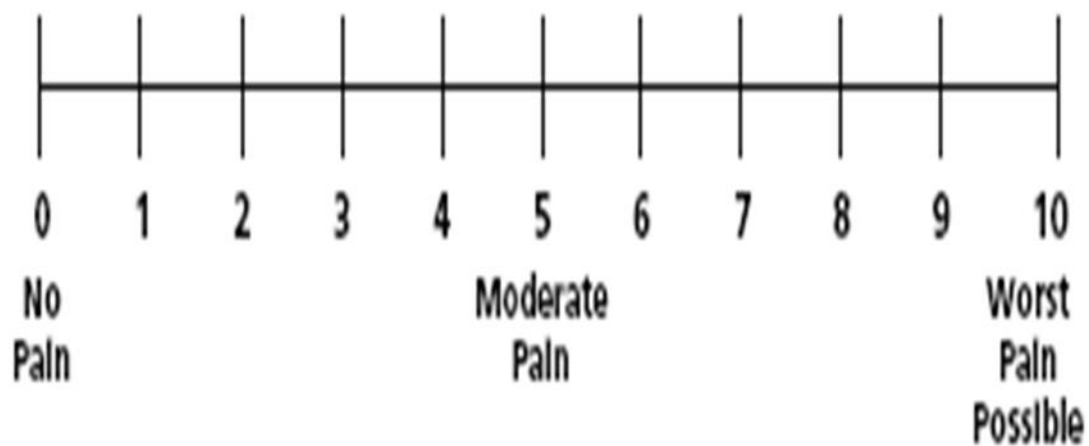
Signature of person conducting the consent discussion

Date

Thank you for your help.

Appendix G
Numeric Pain Scale

Circle the number that best describes your level of average pain.



Appendix H
Mindfulness-Based Self Efficacy Scale - Revised© (MSES-R)

Circle one number in the shaded column according to how much you now agree with each statement below, using the following scale:

Not at all	A little	Moderately	A lot	Completely
0	1	2	3	4

Try not to spend too much time on any one item. There are no right or wrong answers.

1. I get easily overwhelmed by my emotions	0	1	2	3	4
2. I find it difficult to make new friends	0	1	2	3	4
3. I try to avoid uncomfortable situations even when they are really important	0	1	2	3	4
4. When I feel very emotional, it takes a long time for it to pass	0	1	2	3	4
5. I feel comfortable saying sorry when I feel I am in the wrong	0	1	2	3	4
6. It is often too late when I realize I overreacted in a stressful situation	0	1	2	3	4
7. I get so caught up in my thoughts that I end up feeling very sad or anxious	0	1	2	3	4
8. When I have unpleasant feelings in my body, I prefer to push them away	0	1	2	3	4
9. I can resolve problems easily with my partner (or best friend if single)	0	1	2	3	4
10. I can face my thoughts, even if they are unpleasant	0	1	2	3	4
11. My actions are often controlled by other people or circumstances	0	1	2	3	4
12. I get caught up in unpleasant memories or anxious thoughts about the future	0	1	2	3	4
13. I can deal with physical discomfort	0	1	2	3	4
14. I feel I cannot love anyone	0	1	2	3	4
15. I am often in conflict with one (or more) family member	0	1	2	3	4
16. I avoid feeling my body when there is pain or other discomfort	0	1	2	3	4
17. I do things that make me feel good straightaway even if I will feel bad later	0	1	2	3	4
18. When I have a problem, I tend to believe it will ruin my whole life	0	1	2	3	4
19. When I feel physical discomfort, I relax because I know it will pass	0	1	2	3	4
20. I can feel comfortable around people	0	1	2	3	4
21. Seeing or hearing someone with strong emotions is unbearable to me	0	1	2	3	4
22. If I get angry or anxious, it is generally because of others	0	1	2	3	4

Appendix I

Health-Related Quality of Life Instrument

QUALITY OF LIFE SCALE (QOLS)

Name:**Age:****Date** (mm/dd/yyyy):

Please read each item and circle the number that best describes how satisfied you are at this time. Please answer each item even if you do not currently participate in an activity or have a relationship. You can be satisfied or dissatisfied with not doing the activity or having the relationship.

	Delighted	Mostly Pleased	Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
1. Material comforts home, food, conveniences, financial security	7	6	5	4	3	2	1
2. Health – being physically fit and vigorous	7	6	5	4	3	2	1
3. Relationships with parents, siblings & other relatives – communicating, visiting, helping	7	6	5	4	3	2	1
4. Having and rearing children	7	6	5	4	3	2	1
5. Close relationships with spouse or significant other	7	6	5	4	3	2	1
6. Close friends	7	6	5	4	3	2	1
7. Helping and encouraging others, volunteering, giving advice	7	6	5	4	3	2	1
8. Participating in organizations and public affairs	7	6	5	4	3	2	1
9. Learning – attending school, improving understanding, obtaining additional knowledge	7	6	5	4	3	2	1
10. Understanding yourself – knowing your assets and limitations – knowing what life is about	7	6	5	4	3	2	1
11. Work – job or in home	7	6	5	4	3	2	1
12. Expressing yourself creatively	7	6	5	4	3	2	1
13. Socializing – meeting other people, doing things, parties, etc	7	6	5	4	3	2	1
14. Reading, listening to music, or observing entertainment	7	6	5	4	3	2	1
15. Participating in active recreation	7	6	5	4	3	2	1
16. Independence, doing for yourself	7	6	5	4	3	2	1

Sub-total (for internal use only)							
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Total score: