ABSTRACT

Music and Suggestion to Manage Chronic Pain and Improve Quality of Life:
A Feasibility Study

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Chronic pain is a growing health concern. Chronic pain is a complex and subjective experience that places significant burden on patients, their families and society. Chronic pain is difficult to treat and traditional medical treatments may not be effective. There is evidence that music and suggestion may be useful in managing chronic pain, however, this knowledge is limited. This thesis tested the feasibility of music and therapeutic suggestion among 10 chronic pain sufferers through accrual rates, acceptability, attrition, and treatment satisfaction. The potential effects of the intervention were explored through baseline and endpoint measures of pain, pain bothersomeness, distress, fatigue, quality of life, anxiety and depression. Results indicate the intervention was well accepted and participants reported decreases in pain, pain bothersomeness, fatigue, anxiety, and depression from baseline to endpoint. This thesis provides information about the feasibility and possible effects of music and suggestion for chronic pain management.

Music and Suggestion to Manage Chronic Pain and Improve Quality of Life:
A Feasibility Study

by

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A Thesis

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DEDICATION

To my husband who continues to inspire me

CHAPTER ONE

Introduction

Overview

Chronic pain is a growing health care concern in the United States (Institute of Medicine, 2011; Turk, Wilson, & Cahana, 2011). The prevalence and associated costs of chronic pain make finding effective treatment approaches a top research priority (Institute of Medicine, 2011). Chronic pain is a complex and subjective experience that poses significant burden on patients, their families and society (Jensen & Turk, 2014). Chronic pain has been associated with poor quality of life, negative health outcomes, disability, and great personal and financial costs (Institute of Medicine, 2011; Jensen & Turk, 2014). The need to supplement traditional medical treatments is evident in the increased number of people living with chronic pain despite recent advances in pharmacological pain management (Turk et at., 2011).

There is initial evidence for the use of psychosocial interventions to supplement pharmacological treatment regimens for chronic pain (Portenoy, 2011). Recent systematic reviews show that using music may be helpful in reducing pain and anxiety and may be an effective adjunct treatment for pain reduction when used in combination with therapeutic suggestions (Cepeda, Carr, Lau, & Alvarez, 2006; Milling, Kirsch, Allen, & Reutenauer, 2005; Nilsson, Rawal, Uneståhl, Zetterberg, & Unosson, 2001). However, there have been very few clinical studies aimed at understanding the feasibility

and impact of music and suggestion for chronic pain management (Cole & LoBiondo-Wood, 2014).

The underlying mechanisms by which music and suggestion may exert their effects remains unknown (Bernatzky, Presch, Anderson, & Panksepp, 2011). It is theorized that chronic pain is associated with psychological and social factors as well as physiological factors. It is possible that music helps to optimize pain management by mitigating common comorbid psychological and physiological symptoms of chronic pain such as depression, anxiety, and fatigue. Music may be effective in reducing pain because: (1) listening to music is an enjoyable experience for most people and thereby may improve emotional states; (2) music facilitates relaxation and reduces pain-related stress responses; (3) music may serve as a distraction from the perception of pain and influence cognitive content; and, (4) music may influence neurophysiology in a way that is consistent with pain reduction. Music may be more effective in combination with therapeutic suggestions (i.e. suggestions for absorption, relaxation, imagery, positive expectancy for symptom reduction) due to cognitive expectancies and the placebo effect (Pascalis, Chiaradia, & Carotenuto, 2002).

This pilot study was designed to explore the feasibility and potential effectiveness of music combined with therapeutic suggestions for chronic pain management. The results (e.g. recruitment rates, retention rates, measurement burden, and acceptability) of this study may be used to design a larger clinical trial investigating the effects of music and suggestion for chronic pain management. Furthermore, this study may inform medical science of the potential benefits of music and therapeutic suggestions for chronic pain management. In addition, patient care may be enhanced, as the study will provide

the opportunity for more patients to experience and learn about the use of music and therapeutic suggestions for chronic pain management.

Specific Aims

> *Aim 1.* Determine the feasibility of using a music and therapeutic suggestion intervention for chronic pain management. Feasibility will be assessed through: (1) recruitment and retention; (2) assessment procedures; and, (3) patients' satisfaction with the intervention.
>
> *Aim 2.* Develop consistent practices to improve integrity and safety of study design. This includes, but is not limited to the following procedures: (1) screening; (2) informed consent; (3) data collection; (4) delivery of intervention; (5) reporting; and, (6) monitoring/ oversight.
>
> *Aim 3.* Explore changes in pain symptoms that may be due to the music and suggestion intervention using pre- and post- pain and pain bothersomeness ratings. Baseline and endpoint pain and pain bothersomeness ratings will also be explored.
>
> *Aim 4.* Describe any reported change in measures of fatigue, depression and anxiety from baseline to endpoint.

Thesis Format

Chapter one provides an overview of chronic pain, the purpose of this study, a proposed definition of chronic pain, the prevalence rates and population risk factors for chronic pain. Chapter two presents a biopsychosocial model of chronic pain, a review of currently used treatments for chronic pain, explores the use of music in chronic pain management and proposes a theoretical model for understanding the possible mechanisms of music and therapeutic suggestion in chronic pain. Chapter three describes the Methods, including the study sample, materials and procedures. The results of the thesis study are reported in chapter four followed by a discussion of the findings, their implications, and future directions for research in chapter five.

Defining Chronic Pain

The International Association for the Study of Pain (IASP; 2015) defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage". Pain is unpleasant and subjective experience that consists of psychological, emotional, and physiological components. Chronic pain can be defined as pain lasting longer than 12 weeks and/or pain that persists in the absence of actual tissue damage or physiological cause (IASP, 2015; Jensen & Patterson, 2008). Researchers agree that chronic pain is "a biopsychosocial condition that often requires integrated, multimodal, and interdisciplinary treatment" strategies (National Pain Strategy Report, 2016, p. 3).

Chronic pain may result from traumatic injury (e.g., fall, motor vehicle accident, traumatic brain injury), an ongoing disease process (e.g., cancer, multiple sclerosis, cerebral palsy, degenerative disc disease), or may be the primary symptom of a specific chronic condition (e.g. complex regional pain syndrome, fibromyalgia, diabetic neuropathy) (Jensen & Patterson, 2008). Unlike acute pain that is relieved when the tissue damage heals or the noxious stimulus abates, chronic pain may persist or worsen even when there is no known biological cause and no tissue damage present (Turk et al., 2011).

Prevalence

Approximately twenty percent of the world population suffers from chronic pain with ten percent increases each year (Goldberg & McGee, 2011). The Institute of Medicine (Institute of Medicine, 2011) estimated in 2010 that 116 million adults in America were suffering from chronic pain and that eighty percent of physician visits

were attributable to pain (Gatchel et al., 2007). Recent projections estimate that up to fifty percent of the American population will experience chronic pain at some point in their lives (Silver, 2004).

Chronic pain is a growing problem. Prevalence rates are predicated to rise due to: (1) an aging population; (2) a rise in obesity and associated pain related health complications; (3) higher survival rates for people in catastrophic accidents; and, (4) more surgical procedures (Gatchel at al., 2007; Institute of Medicine, 2011). In addition, an increased awareness and acceptance of chronic pain may encourage more people to seek treatment thereby increasing the demand for therapeutic interventions (Institute of Medicine, 2011). Chronic pain is a growing problem and there is an urgent need to find treatments that can "reduce the burden of pain for individuals, their families, and society as a whole" (National Pain Strategy Report, 2016, p.6).

Populations at Risk

Chronic pain is a problem for many people. Approximately eighty percent of physician visits are due to a condition with a pain component (Silver, 2004). Chronic pain is a complex and subjective experience, which may present without known cause (Silver, 2004), and can pose a significant challenge for patients and healthcare practitioners (Jensen & Turk, 2014). This section will briefly review certain populations that have been identified as being more susceptible to the development and persistence of chronic pain (Institute of Medicine, 2011).

Chronic Illness

Patients suffering from chronic illness (e.g. arthritis, cancer) have an increased chance of experiencing chronic pain as their disease progresses (Moens, Higginson, & Harding, 2014; Walsh & McWilliam, 2014). In the case of such degenerative diseases, pain increases as the tissues continue to break down (Fairchild, 2010). This degenerative process is characteristic of patients in palliative care (Teunissen et al., 2007). Pain management is a primary goal in palliative care (van den Beuken-van Everdingen et al., 2016). Yet, thirty-four percent of palliative care patients report at least moderate levels of pain, even with access to a palliative care pain specialist (Wilson et al., 2009). In a systematic review of pain among cancer patients van den Beuken-van Everdingen et al., (2016) report over thirty percent of patients experience moderate to severe pain despite improved pain management strategies.

Overlapping Pain Conditions

People suffering from certain chronic pain conditions (e.g., temporomandibular joint disorder (TMD), fibromyalgia (FM), vulvodynia, gastrointestinal disorders, migraine, and urologic and pelvic pain syndromes) may experience overlapping chronic pain conditions (Crane et al., 2016; LeDrury, 2011; Munzenmaier, Wilentz, Cowely Jr., 2014). The onset of secondary or tertiary pain conditions can occur several years after the initial chronic pain condition. Multiple pain conditions complicate treatment efforts (Drury, 2011), and may be tied to underlying neurological (e.g. plasticity, hypersensitivity) and psychological (e.g. maladaptive cognitions, negative emotions) components of chronic pain (Jensen, 2010). The experience of multiple, simultaneously occurring pain conditions may become overwhelming and lead to greater suffering.

Women

A number of chronic pain conditions primarily affect women. For example, fibromyalgia, endometriosis, interstitial cystitis, irritable bowel syndrome, temporomandibular disorders, and vulvodynia are found predominately (or solely) in the female population (Drury, 2011). Many of these conditions are also involved in overlapping chronic pain conditions (*see above*). In addition, women may experience certain types of pain more intensely than men may. Ruau et al. (2012) found out of 160,000 hospital and clinic pain scores, women reported higher clinical pain scores across multiple disease categories, including musculoskeletal diseases. The underlying reasons for some of the differences in reported pain and disease prevalence are unknown but warrant further investigation (Drury, 2011; Ruau et al., 2012).

Acute Injury

Other populations that are at risk for developing chronic pain include those who have had surgery or have suffered from a traumatic injury (Jensen & Patterson, 2008). Clark et al. (2015) reports approximately fifteen to thirty percent of people who undergo surgery or experience a traumatic injury develop chronic pain that may persist for life. Also, severe pre- and/or post- amputation pain has been associated with the onset of chronic pain (Hanley et al., 2007; Lavand'Homme, 2011). High levels of acute pain may cause over-sensitization of the central nervous system thereby increasing subacute pain levels (transition period between acute and chronic pain), and psychosocial vulnerability (Lavand'Homme, 2011). The complex interplay of neuropsychological processes during acute and subacute phases of trauma may predispose a person to the persistence of pain after tissue healing (Voscopoulos & Lema, 2010). The development of dynamic

approaches to resolve acute pain before it becomes chronic is a focus of healthcare (Lavand'Homme, 2011).

Mood Disorders

There is strong evidence that people who experience mood disorders are at an increased risk for developing chronic pain (Wiech & Tracey, 2009). There is a growing body of evidence to support the recursive relationship between emotion and chronic pain (Price, 2000; Rainville, Wiech & Tracey, 2009). For example, depression is associated with a higher risk for developing chronic back pain, with risk being proportional to the level of depression (Currie & Wang, 2005; Carroll, Cassidy, & Cote, 2004; Larson, Clark, & Eaton, 2004; Pinheiro et al., 2015). People who suffer from anxiety disorders may also be more susceptible to developing chronic pain (Roy-Byrne et al., 2008). An international study of 5,438 patients found a fourfold increase in anxiety and depressive disorders in people who reported chronic pain (pain for more than 6 months) (Gureje, Simon, & Von Korff, 2001).

Elderly

People over the age of 50 are twice as likely to experience chronic pain (Gatchel, 2004), and sixty to seventy-five percent of people aged 65 or older report persistent pain (Molton & Terrill, 2014). Prevalence rates of chronic pain are even higher in assisted living facilities and nursing home settings (Molton & Terrill, 2014). Findings suggest that with age comes an increased risk for persistent pain, especially for women (Tsang et al., 2008). The most common sources for pain among this population are osteoarthritic back

pain, musculoskeletal pain, peripheral neuropathic pain, and chronic joint pain (see Molton & Terrill, 2014).

Summary

In summary, several populations are at a higher risk for developing chronic pain. The increased vulnerability for chronic pain development in these populations may be a function of the inherent biopsychosocial characteristics of chronic pain. Interdisciplinary approaches to chronic pain management that include psychosocial approaches may provide more acceptable and efficacious treatment strategies and improvement patient care and quality of life.

Impact

Chronic pain is costly—financially, emotionally, psychologically and physically—impacting every aspect of a patient's life. Chronic pain sufferers report greater financial hardships, increased levels of disability and distress, lower quality of life, and higher risks for additional health problems than their pain-free counterparts (Jensen & Turk, 2014; Turner et a., 2004). The estimated economic costs associated with chronic pain range from $560 billion to $635 billion per year in the United States alone (Gaskin & Richard, 2012). These financial costs are attributed to lost wages, disability expenses, medical costs, and additional financial responsibilities assumed by the sufferer's family (Gaskin, & Richard, 2012; Institute of Medicine, 2011). Chronic back pain alone accounts for $20 billion to $60 billion annually in lost productivity, social security disability benefits and treatment costs (Gatchel & Mayer, 2000). It is worth noting that these cost estimates exclude data from children, military personnel, and those

incarcerated or in psychiatric facilities, thereby lowering overall estimates (Institute of Medicine, 2011).

The financial burdens of chronic pain are often secondary to the personal costs chronic pain sufferers experience. Chronic pain can contribute to poor quality of life (QOL), negative mood, depression, anxiety, and decreased activity levels (Jensen & Turk, 2014; Siedliecki & Good, 2006; Wilson et al., 2009). In addition, symptom clustering is commonly reported by chronic pain sufferers and may include fatigue, sleep disturbances, anxiety and depression (Davis, Kroenke, Monahan, Kean, & Stump, 2016). These additional symptoms of chronic pain may further contribute to a decrease in quality of life and tension in personal relationships. The personal costs of chronic pain can be detrimental to the family structure and society as a whole (Gatchel, 2004; Silver, 2004).

The hardships associated with chronic pain extend beyond the patient; spouses, family members and friends of chronic pain sufferers also report experiencing distress (Silver, 2004). Loss of intimacy and sexual relationships, role reversals, and feelings of neglect may lead to strained family dynamics (Silver, 2004). In previous studies, researchers have demonstrated higher levels of distress in spouses of patients with chronic pain than in spouses of pain-free individuals (even if they had a chronic illness) (Flor, Turk, & Scholz, 1987). In addition, children of parents with chronic pain have higher rates of pain problems and may learn ineffective coping strategies from their parents (Turkat, 1982). The effects of chronic pain on the family should not be underestimated and may contribute to decreased QOL and negative affect among chronic pain sufferers.

Summary

Chronic pain is a growing health concern. The primary purpose of this thesis is to describe the feasibility and possible effect of a psychosocial intervention for chronic pain management in a clinical population. A combined intervention using music and suggestion may be an acceptable and effective treatment option in the management of chronic pain. This thesis explores the feasibility of a two-week music and suggestion intervention for patients experiencing chronic pain to obtain a greater understanding of the possible effect of this intervention on the experience of pain. This study will provide information about the acceptability and possible effect of music and suggestion for chronic pain.

Findings from this study may be used to develop future clinical trials investigating individualized psychosocial treatments for the reduction of pain symptoms and improvement of quality of life among chronic pain sufferers. Considering the costs and prevalence of chronic pain, it is imperative that researchers continue to explore possible techniques that will provide maximum benefit while minimizing burden.

CHAPTER TWO

Literature Review

Chronic pain is a complex condition that has multiple causes and effects (Institute of Medicine, 2011), and can influence every aspect of a person's life (Gatchel et al., 2007). The biopsychosocial model of chronic pain states that chronic pain is comprised of biological (e.g. genetic composition, neurophysiology), psychological (e.g. affect, experience, cognitions), and social-cultural factors (e.g. family support, cultural norms) (Linton, 2005; Gatchel et al., 2007). The biopsychosocial model of chronic pain provides an integrative framework for better understanding how psychosocial interventions, like music and suggestion, may be effective for managing chronic pain (Institute of Medicine, 2011).

Biopsychosocial Model

The biopsychosocial model has become the most widely accepted model of pain. The biopsychosocial model is a systems-based model that recognizes the reciprocal contribution of multiple levels of organization (e.g., molecular, cellular, organ, person, family, and community) and their contributions to health, disease, and disability (Engel, 1979). A biopsychosocial model for chronic pain considers the reciprocal contribution of biological, psychological and social-cultural factors that contribute to illness and provides a framework for better understanding the underlying mechanisms of chronic pain development and persistence (Bingel & Tracey, 2008; Gatchel, 2004; Gatchel et al., 2007; Jensen, 2009; Turk & Okifuji, 2002). The biopsychosocial model of chronic pain

has replaced earlier models (e.g., specificity theory, pattern response, biomedical models), and is now the most widely accepted model of pain (Gatchel et al., 2007; Institute of Medicine, 2011). A conceptual model is illustrated in Figure 1.

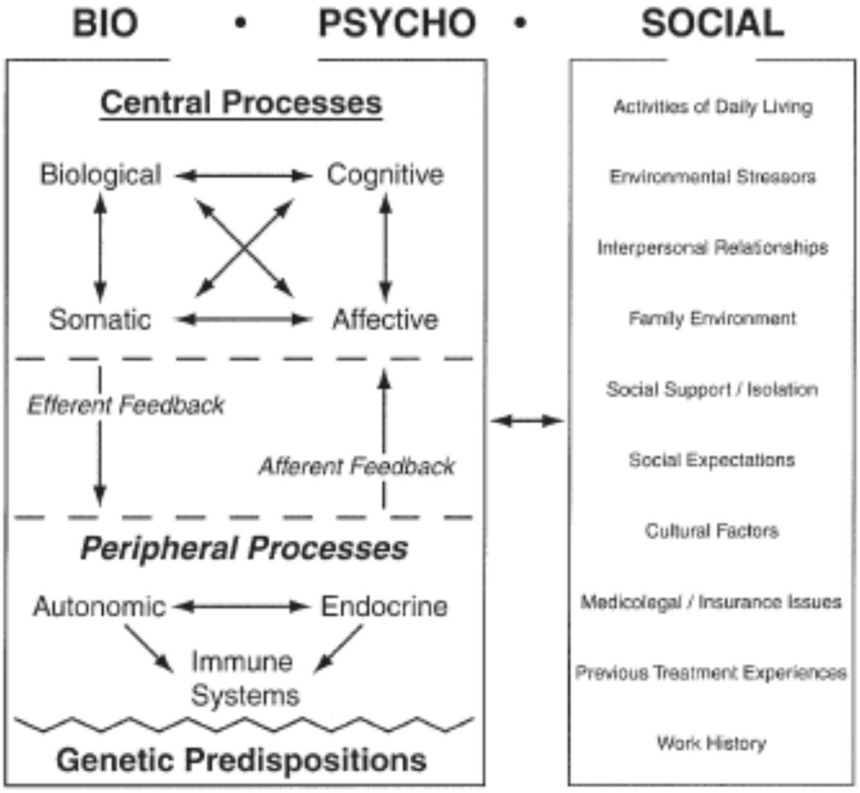

Figure 1. *A Conceptual Model of the Biopsychosocial Interactive Processes Involved in Health and Illness* (Gatchel, 2004).

Treatments for Chronic Pain

Effective treatment strategies for chronic pain may consist of interdisciplinary, multimodal approaches that include traditional medical treatments, psychosocial interventions, and complementary therapies. Because total pain relief may not be feasible in many cases of chronic pain, treatment strategies that: (1) optimize pain control; (2) improve physical and emotional functioning; and, (3) maximize symptom management,

are needed (Linton, 2005; Turk et al., 2011). Treatment strategies designed to meet these goals will help ensure that chronic pain sufferers have the best possible quality of care and improved quality of life (Jensen & Turk, 2014; Silver, 2004, Turk et al., 2011).

Historically, pharmacological interventions have been the foremost treatment option for pain (Rosenblum, Marsch, Joseph, & Portenoy, 2008). Opioids are considered standard care for acute severe pain and chronic pain related to advanced illness (Rosenblum et al., 2008), and are currently the "most common class of drug prescribed in the USA" (Turk et al., 2011, p. 2227). Despite their wide spread use opioids are not universally effective for chronic pain (Ballantyne, 2006), and carry with them significant side effects and risks for dependency and overdose (Rudd, Aleshire, Zibbell, & Gladden, 2016; Turk et al., 2011). Opioid related deaths in the United States have more than tripled since 2000 (Rudd et al., 2016). The long-term use of opioids for the treatment of chronic pain remains controversial. There is little evidence for their effectiveness past a few months and prolonged usage carries high risks for developing hyperalgesia, an increased sensitivity to pain (Ballantyne, 2006; Deleo, Tanga, & Tawfik, 2004; Rosenblum et al., 2008; Scott & Lewis, 2016).

Other types of pharmacology often used for chronic pain includes: non-steroidal anti-inflammatory drugs (NSAIDS), antidepressants, anticonvulsants, and muscle relaxants (Turk et al., 2011). These treatments are not effective for all types of chronic pain and expose patients to serious side effects that may further reduce quality of life, including: nausea, constipation, somnolence, NSAID gastrophy, cardiovascular risks, hypertension, falls, fatigue, weight gain, dizziness, and sedation (Turk et al., 2011). Many chronic pain sufferers stop taking pain medications due to the side effects thereby further

limiting the effectiveness of pharmacological treatment approaches (Lister, 1996; Turk et al., 2011).

Psychosocial interventions (e.g., music, suggestion, hypnosis, relaxation training, mindfulness/meditation, CBT) have been shown efficacious in improving both pain control and quality of life (Jensen, 2011; Portenoy, 2011). Research suggests psychosocial interventions are effective adjuncts to pharmacological treatments for chronic pain and may be effective for pain management as stand-alone treatments (Jensen, 2011; Portenoy, 2011). It is theorized that psychosocial interventions are generally effective for pain management because of their influence on: (1) environmental factors; (2) brain states; (3) cognitive content; (4) cognitive coping; (5) behaviors; and, (6) the reciprocal interaction among these factors (Jensen, 2010). For example, research indicates that music and suggestion may decrease pain intensity and improve recovery following surgery by altering pain perception through cognitive coping strategies (Fernandez & Turk, 1989; Nilsson, Rawal, Enqvist, & Unosson, 2003). Music interventions are easy to use, cost effective, and carry little to no risk of adverse events (Chlan, 2002; Cole & LoBiondo-Wood, 2014).

Music and Suggestion for Chronic Pain

There is strong evidence for the use of music for pain reduction. In a recent review, Cole and LoBiondo-Wood (2014) reported music was effective in reducing analgesic (opioid) requirements, anxiety, and stress among hospitalized adults. Of the 17 studies reviewed, 11 reported significantly reduced pain levels following a music intervention (Cole & LoBindo-Wood, 2014). Researchers have also indicated that music is an effective pain management strategy for patients suffering from chronic pain

associated with: fibromyalgia (Garza-Villarreal et al., 2014; Mercadie, Mick, Guetin, & Bigand, 2015); osteoarthritis and repetitive strain injuries (Finlay, 2014); chronic illness (Gutgsell et al., 2013); neuropathic pain (Korhan et al., 2014); inflammatory disease (Guetin et al., 2012); and, low back pain (Guétin et al., 2005; Guétin et al., 2012).

In a study of 22 fibromyalgia patients, Garza-Villarreal et al. (2014) found patients who listened to music reported significantly reduced pain levels and improved functional mobility. Mercadie et al. (2015) also reported decreased pain and fatigue and no increases of pain during activity among a sample of fibromyalgia patients assigned to a 20-minute music listening intervention. The findings of these studies are noteworthy because of the known difficulty in treating chronic pain associated with fibromyalgia and the associated fatigue and risk for disability (Garza-Villarreal et al., 2014; Mercadie et al., 2015)

Guetin et al. (2012) provide further evidence for the utility of a music intervention for chronic pain. In a randomized controlled trial, researchers compared the effects of two daily sessions of music listening (up to 10 days) with standard treatment among eighty-seven patients suffering from chronic pain associated with fibromyalgia, inflammatory disease, neurological disease, and lumbar pain. Those in the music listening intervention reported significant reductions in pain, anxiety, depression, and analgesic consumption over the standard care group (Guetin et al., 2012). These findings provide additional support for music's ability to reduce pain and common comorbid symptoms (e.g., stress, distress, depression) (Cepeda, Carr, Lau, & Alvarez, 2006; Chan, Wong, & Thayala, 2011), and the need for pharmacological analgesia (Bernatzky, Presch, Anderson, & Panksepp, 2011).

Music has been reported to be beneficial for patients suffering from osteoarthritis. In a randomized clinical trial, McCaffrey and Freeman (2003) reported significant pain reductions in older men and women suffering from osteoarthritis. In this randomized clinical trial, participants in the treatment group listened to researcher-provided music each day for two weeks. Reported pain levels for the intervention group were significantly lower at every measurement point (day 1, day 7, and day 14) compared to the control group (McCaffrey & Freeman, 2003).

Therapeutic suggestions combined with music may further reduce pain perception. Positive expectancies have been associated with improved pain control (Bingel et al., 2011; Kam-Hansen et al., 2014). Nilsson et al. (2003) found therapeutic suggestions in combination with music were more effective than music or no music in reducing pain following ambulatory surgery. Participants included 182 surgical patients randomized to music (M), music with therapeutic suggestion (M/TS), or a control group. Average pain intensity ratings (VAS) were significantly lower in the M and M/TS groups compared to the control group ($p = 0.002$), and were lower for the M/TS participants ($M = 1.9$) than for the music alone participants ($M = 2.1$).

Research provides support for the use of music in combination with therapeutic suggestions immediately following surgery (Nilsson et al., 2003). However, it is unknown whether these results are generalizable to patients suffering from chronic pain. In addition, Oktay, Eken, Goksu, and Dora (2015) reported therapeutic suggestions were not associated with greater decreases in pain. Further research is needed to determine the possible effects of therapeutic suggestions for pain management among chronic pain patients (Bingel et al., 2011; Kam-Hansen et al., 2014; Oktay et al., 2015).

A Model for Understanding the Influence of Music and Suggestion

While the underlying mechanisms by which music and suggestion may be effective in reducing pain are unknown, several possible mechanisms have been identified. Music may act on pain through the facilitation of positive emotional processes and feelings, relaxation processes, serving as a distraction, positively influencing cognitive appraisals, facilitating adaptive coping strategies, and altering biological responses (Le Scouarnec et al., 2001; Mitchell, MacDonald, Knussen & Serpell, 2007; Salimpoor, Benovoy, Larcher, Dagher, & Zatorre, 2011; Thaut, 2005). Based on previous research, a model is proposed to explain the possible mechanistic action of music and suggestion on chronic pain (Figure 2).

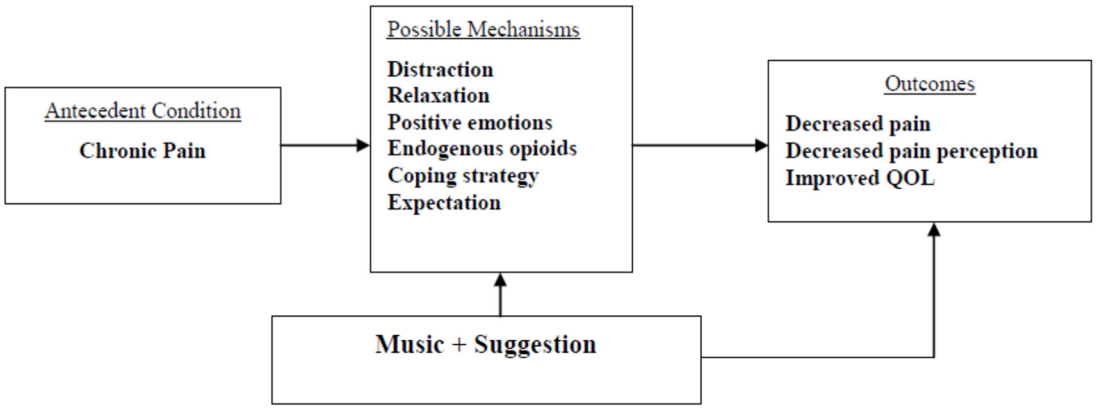

Figure 2. *A Model of Music and Suggestion for Chronic Pain.*

Researchers agree that chronic pain is comprised of interrelated biological, psychological, and sociocultural processes, and that these processes are influential in pain perception (Bernatzky et al, 2011; Institute of Medicine, 2011; Renn & Dorsey, 2005). Music and suggestion may be effective for pain reduction due to their individual and combined influence on the biopsychosocial components of chronic pain.

Chronic pain can negatively influence mood and emotional states. Listening to music is an enjoyable experience for most people and is thought to positively influence emotions (Korhan et al., 2014), and mood (Dileo, Bradt, Grocke, Magill, 2008), and may be effective in reducing pain by evoking more pleasant emotional states (Bernatzky et al., 2011; Roy, Peretz, & Rainville, 2008). In a review of emotional responses to music, Juslin and Västfjäll's (2008) describe multiple ways that music affects the listener. These include: (1) positive emotions; (2) physiological responses (heart rate, blood pressure, skin temperature); (3) brain activation in areas thought to be implicated in emotional processing (thalamus, hippocampus, amygdala, prefrontal cortex, periaqueductal gray region); (4) emotional expression; (5) action tendency (e.g. tendency to help other people); and, (6) emotional regulation. Through some or all of these responses, music may influence the perception of chronic pain.

Chronic pain is associated with psychological stress and increased activity in the sympathetic nervous system (see Gatchel et al., 2007). Using measures of heart rate, respiratory rate, and blood pressure, researchers have demonstrated that listening to music has a strong positive effect on states of relaxation (Colwell, Edwards, Hernandez, & Brees, 2013; Guétin et al., 2005; Jaber et al., 2007), and can significantly reduce pain and anxiety and improve quality of life (Kullich et al., 2003). For example, music has been used as an effective adjunct therapy to help cancer patients manage stress and reduce physical pain resulting in an improved quality of life (Richardson et al., 2008).

There is a growing recognition that chronic pain is a perceptual experience influenced by cognitive processes such as attention and appraisal and that chronic pain interferes with cognitive processing (Finlay, 2014; Turk & Okifuji, 2002). Listening to

music may reduce pain perception by serving as a distraction (see Garza-Villarreal et al., 2014), and disrupting the pain-stress-pain feedback loop thereby decreasing the perception of pain (Bernatzky et al., 2012). Using a primary-task paradigm, researchers investigated the effect of music as distraction and reported that music is capable of consistently reducing pain intensity, unpleasantness, and anxiety levels through distraction and cognitive reappraisal (Finlay, 2014).

Music may also improve feelings of power and control over pain. Perceived control over pain is associated with improved coping and functioning (Jensen, Turner, Romano, & Karoly, 1991). Music listening has been reported to increase perceived control over pain thereby reducing pain perception (Linnemann et al., 2015). For example, Strong, Ashton, Cramond, and Chant (1990) found that low back pain patients who felt they had control over their pain were less likely to report that pain interfered with their daily lives. Siedliecki and Good (2006) found chronic pain sufferers who listened to music for seven consecutive days experienced significantly more power and less pain, depression, and disability than a control group. Music may provide feelings of self-efficacy and control that alter negative cognitions (e.g. helplessness, hopelessness) associated with pain perception.

Neurological processes may further contribute to the development and persistence of pain. There is evidence to suggest that music's influence on the limbic system results in the release of endogenous opioids (e.g. dopamine) which may increase overall analgesia (Le Scouarnec et al., 2001; Panksepp, 1995; Salimpoor et al., 2011; Wood, 2008), and improve pain treatment outcomes.

It is also possible that positive suggestion will improve upon the effectiveness of music listening and further reduce pain perception through alterations in cognitive expectancies (see Pascalis, Chiaradia, & Carotenuto, 2002). Positive suggestions have been demonstrated to produce positive placebo effects and higher pain tolerance in laboratory settings (Staats, Hekmat, & Staats, 1998). In addition, pain reductions during placebo analgesia are accompanied by decreased activity in pain-related brain regions (e.g. thalamus, insular, and somatosensory cortices) indicating positive suggestions may be capable of reducing pain signaling (Bingel & Tracey, 2008).

Treating chronic pain is complex and there is a recognized need for improved treatments (Dworkin et al., 2008). There is initial evidence for the effect of music and suggestion on symptom reduction in patients suffering from chronic pain. Interdisciplinary approaches to pain management utilizing psychosocial approaches, such as music and suggestion have the potential to significantly reduce suffering and health care costs, disability, and analgesic requirements associated with chronic pain (Institute of Medicine, 2011; see Schatman, 2012).

CHAPTER THREE

Materials and Methods

Objectives

The objective of this thesis is to gather pilot data on the feasibility, acceptability and possible effect of a combined music and therapeutic suggestion intervention for chronic pain management. This preliminary study may provide evidence for the use of music and suggestion to manage chronic pain and inform the development of a larger controlled trial of music and therapeutic suggestion for chronic pain management.

Specific Aims

This thesis has four specific aims:

Aim 1. Determine the feasibility of a combined music and therapeutic suggestion intervention for chronic pain through accrual, adherence and retention rates.

Aim 2. Develop consistent investigation and implantation practices to improve the study design. This includes, but is not limited to the following aspects: (1) screening; (2) informed consent; (3) data collection; (4) delivery of intervention; (5) reporting; and (6) monitoring/ oversight procedures.

Aim 3. Explore changes in patient reported pain and pain bothersomeness symptoms that occur during the study period.

Aim 4. Describe any reported changes in quality of life, fatigue, depression, and anxiety during the study period.

Study Design

The current feasibility study is designed to investigate a combined music and therapeutic suggestion intervention for the management of chronic pain. The sample size reflects the available resources and estimated accrual rate. This descriptive study is not powered for inferential statistics and is purposed as a first step in better understanding the possibility of using music combined with suggestion for chronic pain management.

Informed Consent

The Baylor University ethics committee (IRB) approved this study prior to implementation. Potential participants discussed the study intervention, implementation of the intervention, and the possible risks and benefits with a trained research assistant before their inclusion in the study. Eligible participants that wanted to participate in the study were asked to sign an informed consent form indicating their understanding of the study and their willingness to participate. Each consenting participant received a copy of their signed informed consent for their records.

Sample Size

The sample size was based on the potentially available participants, the capacity of the research staff and the length of the funding period. The sample size was restricted to 10 participants in order to meet the study goals within the predetermined accrual period (6 months) and budgetary constraints. This sample size is acceptable for the current study design (Leon, Davis, & Kraemer, 2011).

Recruitment

Participants were recruited for this study from January 2016 through May 2016. Two phases of participant recruitment occurred. Phase 1 consisted of a palliative care sample. This recruitment phase lasted from January 2016 through the first week of April 2016. The second phase of recruitment (Phase 2) consisted of a clinical sample of individuals reporting chronic pain. Phase 2 recruitment began in mid-April 2016 and continued through May 2016. Eligibility requirements for each sample are outlined below.

Participants

Palliative care sample. Participants were recruited from an integrative cancer clinic located within a major medical center in Central Texas from January 2016 to April 2016. Participants were recruited through physician referrals, fliers posted at the medical center, and through personal contact with research personnel at the cancer center. Eligibility was determined using the following inclusion criteria: (1) age 18 years or older; (2) enrolled in palliative care; (3) diagnosed with cancer or other serious illness; and (4) English or Spanish speaking. Patients were excluded if they: a) were unable to give informed consent for any reason; or, b) reported an average pain rating for the past week of four or lower on a 11-point numerical rating scale (NRS).

Clinical sample. Participants were recruited through newspaper advertisements, personal contact and physician referrals in Central Texas from April 2016 to May 2016. Inclusion was determined by: (1) age 18 years or older; (2) a self-report of chronic pain; and, (3) English or Spanish speaking. Participants were excluded if they: a) were unable

to give informed consent for any reason; or, b) reported an average pain rating of four or less on a 11-point numerical rating scale (NRS) for the past week. Participants were screened for eligibility until enrollment goals were met.

Measures

Demographics. Participants completed a demographic questionnaire at the beginning of the survey that included questions about age, ethnicity, marital status, SES, education, and health status.

Worst Fatigue Numerical Rating Scale (WF- NRS). The WF-NRS is a one item numerical rating scale that asks respondents to "Please rate your fatigue (weariness, tiredness) by circling the number that best describes your WORST level of fatigue during the past 24 hours". Item anchors are zero (No fatigue) to 10 (As bad as you can imagine). This measure is a unidimensional measure of fatigue severity that is understandable by patients and shows utility for clinical trials (Naegeli, Flood, Tucker, Devlen, & Edson-Heredia, 2013).

Hospital Anxiety and Depression Scale (HADS). The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was designed to screen for mood disorders in general (non-psychiatric) medical outpatients. It focuses on subjective disturbances of mood rather than physical signs, and aims at distinguishing depression from anxiety. It consists of 14 self-report items that are divided into two subscales, Anxiety subscale (HADS-A) and Depression subscale (HADS-D) (Zigmond & Snaith, 1983). Each subscale consists of seven items that are scored on a 4-point scale (0-3).

Items can be summed to produce subscale (i.e., anxiety, depression) scores (0-21) and a total score (0-42), with higher scores indicating more of the measured construct. The HADS has been shown to be a reliable (HADS-A $\alpha = .83$, HADS-D $\alpha = .82$) and valid measure of anxiety and depression (Bjelland, Dahl, Haug, & Neckelmann, 2002; Herrmann, 1996; Snaith, 2003). The HADS is easy to administer and is usually well accepted by patients (Herrmann, 1996; Zigmond & Snaith, 1983).

Pain, Pain Bothersomeness, and Overall Distress Numerical Rating Scale (NRS). The Pain, Pain Bothersomeness, and Overall Distress Numerical Rating Scale (NRS) is an 11-point scale consisting of integers from 0 through 10; 0 representing ‘‘No pain’’, “Not bothered”, or “Not distressed”, and 10 representing ‘‘Worst possible pain’’, “Extremely bothered”, or “Extremely distressed”, respectively. Respondents select the single number that best represents their pain intensity, pain bothersomeness and overall distress. The NRS is a valid and sensitive test of pain intensity for the measurement of both acute and chronic pain (Ferreira-Valente, Pais-Ribeiro, & Jensen, 2011; Farrar, Young, LaMoreaux, Werth, Poole, 2001). The NRS’s were used to measure daily average pain and pain bothersomeness and weekly average pain and pain bothersomeness, and overall distress at baseline and endpoint. A Pain NRS was also used to measure participants’ current pain level before and after listening to the treatment recording.

McGill Quality of Life Questionnaire (MQOL). The McGill Quality of Life Questionnaire (MQOL; Cohen, Mount, Strobel, & Bui, 1995; Cohen, Mount, Tomas, Lauren, & Mount, 1996) is a 17-item measure of quality of life (QOL). The multidimensional instrument evaluates QOL through physical well-being, physical

symptoms, psychological well-being, psychological symptoms, existential well-being, social support, and overall QOL (Cohen, 2014). The scale consists of three parts: (1) a single-item measuring overall quality of life; (2) subscales for physical symptom, physical well-being, psychological, existential, and support; (3) a total mean score of the five subscales (Cohen, 2014). A full description of the scoring process can be found in Cohen (2014). The MQOL is completed through self-report or administered aloud and takes approximately 10 minutes to complete (Cohen, 2014). The MQOL displays good reliability (α = .83, ICC = .75), and validity (Cohen et al., 1996; Cohen et al., 1997; Cohen & Mount, 2000).

National Institutes of Health Brief Fatigue Inventory (NIH-BFI). The National Institutes of Health Brief Fatigue Inventory (NIH-BFI; Saligan, Luckenbaugh, Slonena, Machado-Vieira, & Zarate, Jr., 2015) is a 7-item clinician administered measure of fatigue. The scale is comprised of selected items from the Hamilton Depression Rating Scale (HDRS; Hamilton, 1960), the Montgomery-Asberg Depression Rating Scale (MADRS; Montgomery & Asberg, 1979), the Young Mania Rating Scale (Young, Biggs, Ziegler, & Meyer, 1978), and the Structured Interview Guide for HDRS with Atypical Depression (Williams, 1988). Items are summed for a total fatigue score (0-34), with higher scores representing more fatigue. The scale is reported to have an internal consistency of .87 (α) and good convergent validity (Saligan et al., 2015).

Treatment Satisfaction Numerical Rating Scale (NRS). The Treatment Satisfaction Numerical Rating Scale (NRS) is an 11-point scale that asks participants to rate "How satisfied [they are] with the therapy applied in this study on a scale of 0 – 10,

where 0 means ‘not satisfied at all’ and 10 means ‘totally satisfied’”. NRS’s have been shown capable of discriminating between important clinical findings, including treatment satisfaction (Myrvik et al., 2013).

Daily Diary. Participants were provided with a daily pain diary to keep for the duration of the study. The diary consisted of two pages that asked participants to rate their average pain intensity and pain bothersomeness (how much pain bothers you) for the past 24 hours. Ratings were based on the Pain and Pain Bothersomeness NRS’s previously described. Participants were asked to complete each of these rating scales upon awakening. The daily diary also included a pre- and post- listening pain intensity rating that was to be completed one time each day before and after listening to the recorded intervention. This was also a Pain NRS and was attached to the top of the CD player for convenience.

Study Completion/Dropout Interview. Participants were asked to provide feedback at the end of the study regarding their experience. This qualitative information is useful for understanding the acceptability of the intervention and the fidelity of the study processes. The questions asked were: (1)” Overall, was the treatment beneficial to you?” (2) “If yes, what kinds of benefits did it provide?” (3) “Was the initial talk with the researcher helpful for you?” (4) “Was the Week 1 phone call helpful? Would you have preferred an in-person meeting instead?” (5) “What did you like/dislike about the recording and the treatment itself?” (6) “What do you think about the frequency of listening (too much or too little)?” (7) “Is there anything that should be changed in the recording and the treatment itself (music or script)?” (8) “Were you able to use the audio

player (Did you need assistance)?" (9) "Was completing the study tasks feasible for you?" (10) "Did you read the information sheet? If yes, was it helpful?" (11) "Do we need to provide more information at any point during the study?" (12) "Was it convenient for you to come to the MBMRL for the visits?" (13) "How did you learn about the study?" (14) "If you saw the advertisement materials, what did you think about them? What should we change in them?" (15) "If you learned about this study from a physician/healthcare worker, what did they tell you about the study? Was it accurate? Should they do something differently?" and, (16) "What was your experience with the enrollment process?" All of these items were used to further determine the feasibility of the intervention and study design.

Intervention

The intervention, a standard protocol for all participants, consisted of music and therapeutic suggestions for the purpose of pain reduction and its bothersomeness in people experiencing chronic pain. The intervention was delivered on a recording (CD) and was approximately 20 minutes in length. The intervention began with suggestions for focusing attention, pleasantness, and relaxation followed by approximately 15 minutes of instrumental music (*Fantasia on a Theme of Thomas Tallis* by Ralph Vaughn-Williams). This string orchestra selection is thought to create a state of relaxed wakefulness whereby the listener is pulled into a deep state of relaxation while remaining cognitively aware and alert (Crowe, 2004). Participants were instructed to listen to the recording from the beginning at least one time each day. Additional listening was encouraged during times when participants felt the need for additional pain relief. Interested readers may contact the investigator to request a recording of the intervention.

Procedures

Adults reporting chronic pain were recruited from January 2016 through May 2016 through flyers, newspaper ads, personal contacts, and physician referrals. Interested individuals were screened for eligibility. Once eligibility was determined, participant candidates visited the Mind-Body Medicine Research Laboratory (MBMRL) and met with a research assistant who explained the details of the study and answered any questions. If still interested, the potential participant completed written informed consent indicating their willingness to participate in the study. After informed consent was completed each participant was assigned a unique id number. Informed consent forms were removed from participant charts and kept in a separate locked file cabinet.

Baseline measures were administered by a research assistant following informed consent. Participants were left in private to complete the measures. Baseline measures consisted of self-report measures of pain, pain bothersomeness, distress, fatigue, quality of life, and anxiety and depression.

After baseline measures were completed, participants met with the researcher who explained the details of the intervention and how to complete their daily diaries. Participants were provided with instruction sheets that explained the details of the study requirements and intervention. Each participant received a toolkit that contained a CD (intervention), CD player, batteries, and new ear buds. Toolkits were provided for the study period and to keep afterwards.

Participants were provided the opportunity to complete a practice session (e.g., listen to the recording and rate pre-post pain levels) while at the MBMRL. The practice session was designed to give participants the chance to practice the listening to the

intervention and recording their pain levels pre- and post-listening. All participants took advantage of this opportunity except for two who declined due to time constraints.

During the practice session, participants were reclined in a comfortable chair with ambient lighting in a private room. Every effort was made to ensure participants were comfortable during the practice session. Before practicing the intervention, participants were asked to rate their current pain on a 0 to 10 NRS located on the top of the CD player. This rating was to be taken one time each day before and after listening to the intervention for the duration of the study. Once the practice session was complete, participants rated their current pain level on the same diary and opened the door to signal to the researcher that they were done. The researcher again met with the participant and reviewed the study procedures, answered any questions and scheduled a phone call appointment for one week later (Week 1 measures). The research assistant scheduled an appointment with the participant two weeks from baseline (Week 2 measures) before they left the lab.

A researcher contacted each participant by phone at the scheduled Week 1 appointment to review their progress, answer questions, and assess their average daily and weekly pain and pain bothersomeness levels as well as their experience with the study. At Week 2, participants completed endpoint measures administered by a research assistant. To reduce response bias during the phone interview, research personnel reminded the participant that they were neutral observers and that their answers were confidential. After completion of the endpoint visit, participants were thanked for their participation and feedback and received monetary compensation (*Palliative care sample* = $100; *Clinical sample* = $50). Data collection schedules for each sample are shown in

Table 1 (*Palliative care sample*) and Table 2 (*Clinical sample*). Data was entered by a research assistant into SPSS v 21.0 for exploratory analyses. Data was then audited and analyzed by the researcher.

Table 1. *Data collection schedule for Palliative Care Sample*

Measure	Baseline Visit	Daily through Week 1	End of Week 1	Daily through Week 2	Endpoint Visit
Aim 1					
Enrollment Log	X				
Study Completion/Dropout Interview					X[a]
Treatment Satisfaction Numerical Rating (NRS)					X
Aim 2					
Daily Average Pain Numerical Rating (NRS)		X		X	
Daily Average Pain Bother Numerical Rating (NRS)		X		X	
Pre- and Post-Practice Numerical Rating (NRS)		X		X	
Weekly Average Pain Numerical Rating (NRS)	X		X		X
Weekly Average Pain Bother Numerical Rating (NRS)	X		X		X
National Institutes of Health Brief Fatigue Inventory (NIH-BFI)	X				X
Overall Distress Numerical Rating (NRS)	X				X
Aim 3					
McGill Quality of Life Questionnaire (MQOL)	X				X
Hospital Anxiety and Depression Scale (HADS)	X				X

Table 2. *Data collection schedule for Clinical Sample*

Measure	Baseline Visit	Daily through Week 1	Week 1 Call	Daily through Week 2	Week 2 Call
Aim 1					
Enrollment Log	X				
Study Completion/Dropout Interview					X[a]
Treatment Satisfaction Numerical Rating (NRS)					X
Aim 2					
Daily Pain Numerical Rating (NRS)	X		X		X
Daily Pain Bothersomeness Numerical Rating (NRS)	X		X		X
Pre- and Post-Practice Numerical Rating (NRS)		X		X	
Weekly Average Pain Numerical Rating (NRS)	X		X		X
Weekly Average Pain Bothersomeness Numerical Rating (NRS)	X		X		X
Aim 3					
Worst-Fatigue Numerical Rating (WF-NRS)	X				X
Overall Distress Numerical Rating Scale (NRS)	X				X
Hospital Anxiety and Depression Scale (HADS)	X				X

CHAPTER FOUR

Results

The primary purpose of this study was to assess the feasibility of music and therapeutic suggestion for pain reduction among chronic pain sufferers. Feasibility was assessed through recruitment rates, retention rates, acceptability and a review of study processes (e.g. eligibility requirements, data collection assessments, laboratory capacity).

Feasibility

Participant recruitment began January 2016 and ended May 2016. Participants were recruited according to the eligibility requirements outlined for the *Palliative care sample* from January 2016 to April 2016. In April 2016, study progress was reviewed. Based on low accrual rates and feedback from participants, it was determined that the lab visit requirements and duration of assessments placed undue burden on participants and staff. In addition, it was also determined that the eligibility requirements may be too restrictive.

Based on the review, eligibility requirements were lessened (*Clinical sample),* measures at baseline and endpoint were reduced, and the Week 2 visit was changed from an in-person visit at the lab to a phone call conducted by research staff. Six participants were enrolled under the *Palliative care sample* procedures and six participants were enrolled under the *Clinical sample* procedures. The flow of participants through the study is illustrated in Figure 3.

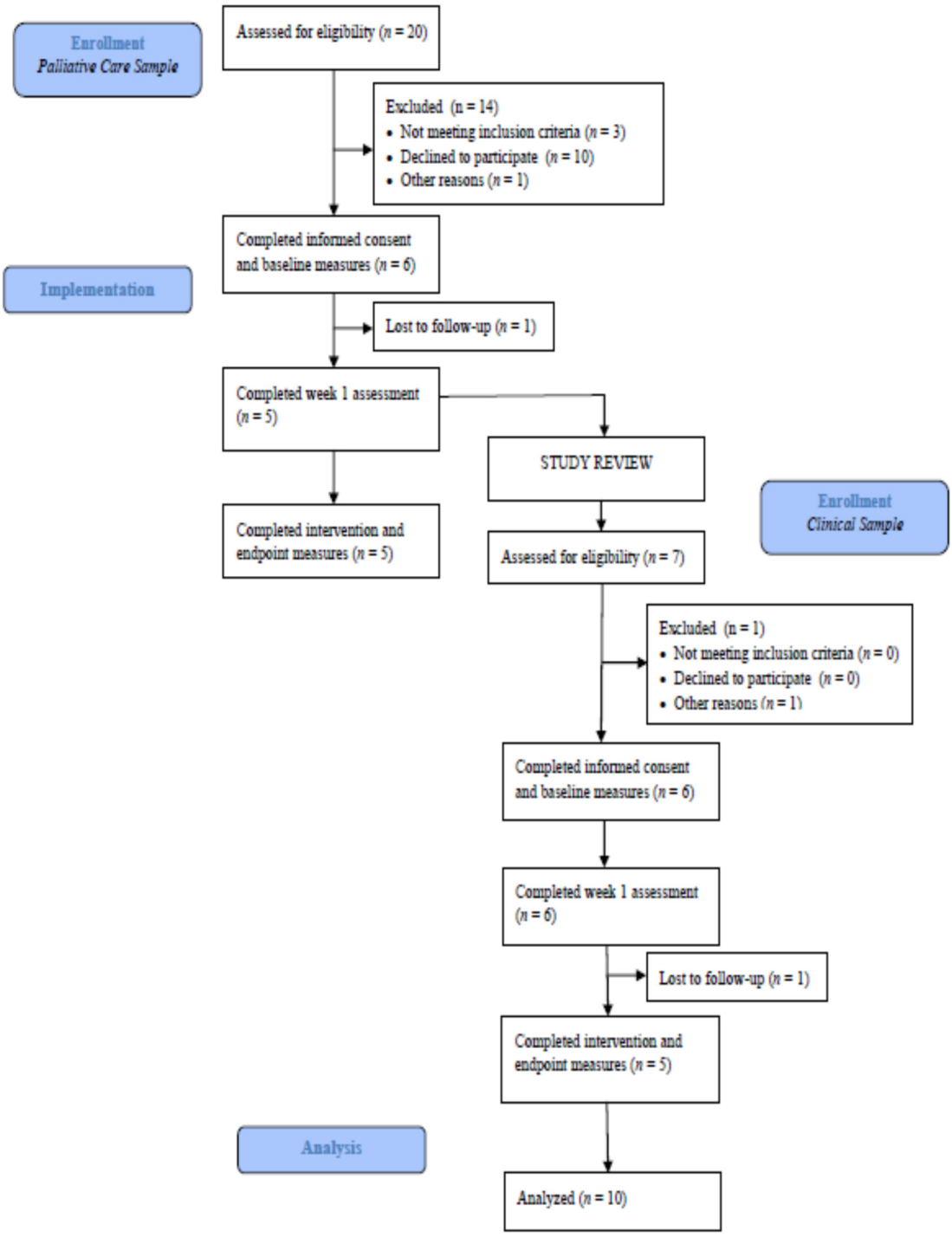

Figure 3. *Flowchart of Participants through the Study.*

Accrual goals (n = 10) were met for the total enrollment period, with 12 participants recruited within the 6 month timeframe. Reasons for declining to participate included lack of interest, not enough time to commit, and disbelief that the intervention would be effective. Two potential participants not included in the study repeatedly did not show up for their schedule appointments ("Other reasons"). Of the 12 participants enrolled, two were lost to follow-up (n = 1 at Week 1; n = 1 at Week 2) due to medical complications, resulting in a 16% attrition rate. Five participants completed the study under the *Palliative care sample* protocol and five participants completed the study under the *Clinical* sample protocol.

Demographics

Twelve participants (4 males, 8 females) were enrolled in the study, from which two (1 male, 1 female) were lost to follow-up. Participants ranged in age from 36 to 79 with an average age of 58.3 years. The majority of participants were married (n = 7), Caucasian (n = 9), and retired (n = 6). Participants reported multiple conditions for which they received medical care including musculoskeletal conditions (n = 5); cancer (n = 4); fibromyalgia (n = 2); mood disorders (n = 3); and, inflammatory conditions (n = 3). A complete description of participant demographics is provided in Table 3.

Feedback provided through the survey script indicated that the study was acceptable to participants in both samples. All participants who completed the study (n = 10) reported experiencing benefits from the intervention including: "Put me in a calmer place."; "Helped me to relax and sleep better."; "Pain relief"; "It's helped me a whole lot with the pain, helped me do things that I used to do. I have so much energy now."; "Able

to do more activities than usual with little to no pain."; "Felt physically relaxed, reduced back pain overall."; "Able to stop taking hydrocodone."

Table 3. *Demographic characteristics of the total sample*

Characteristics	*Frequency (%)*
Gender	
Male	4 (33)
Female	8 (67)
Age in years, mean (range)	58.3 (36-79)
Race	
Caucasian	9 (75)
Hispanic	2 (16.7)
African American	1 (8.3)
Asian	0 (0)
Other	0 (0)
Marital Status	
Married	7 (58.4)
Single	1 (8.3)
Divorced/Separated	1 (8.3)
Widowed	3 (25)
Education	
Less than high school	1 (8.3)
High School or GED	2 (16.7)
Some college	3 (25)
Associate Degree	3 (25)
Bachelors Degree	2 (16.7)
Masters Degree	1 (8.3)

Note: $n = 12$

Participants who completed the study ($n = 10$) reported the initial talk with the researcher was helpful, that the Week 1 phone call was helpful and sufficient, and that they had no problems using the audio equipment. Most found the music selection to be acceptable, yet there was feedback indicating a choice of music would be preferable. Five

participants reported becoming "annoyed" with the narrative suggestive portion of the intervention and wanting to go directly to the music. Participants found listening one time per day feasible and most (n = 9) reported they listened more than once per day for additional benefits. Overall, feedback indicated that the study tasks were feasible and acceptable, the instructions were adequate and recruitment materials were accurate and appropriate. Treatment satisfaction was rated at the completion of the study. On a scale of zero (not satisfied at all) to 10 (totally satisfied), the mean treatment satisfaction rating was 8.8 (SD = 1.68, n = 10).

An informal review between the researcher and research assistants revealed that adherence to the study protocol was not an issue. Study practices remained consistent throughout the study. There were no reports of adverse events by research staff or participants during the course of the study.

Pain and Pain Bothersomeness

For the 10 patients who completed the study, the average pain levels for the past week decreased from baseline (M = 6.6, SD = 2.86) to endpoint (M = 5.4, SD = 2.01) (Figure 4). Participants also reported decreased pain bothersomeness from baseline (M = 7.5, SD = 2.17) to endpoint (M = 5.4, SD = 2.01) (Figure 5). Pre- to post-listening pain intensity ratings showed decreased pain following the intervention throughout the study (Figures 6 and 7). Average daily pain and pain bothersomeness ratings fluctuated across the study but showed overall declines from baseline to Week 2 (Figures 8 and 9).

Fatigue, Anxiety, Depression, and QOL

Fatigue was assessed using both the NIH-BFI (n = 5) and the WF-NRS (n = 5). Ratings of fatigue indicated improvements from baseline to endpoint (Figure 10).

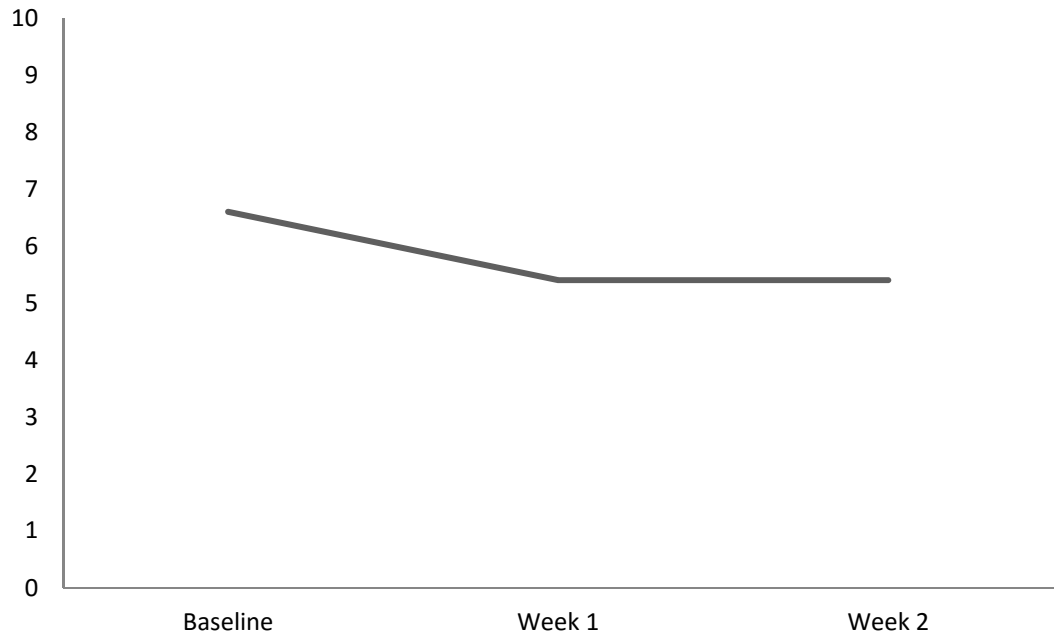

Figure 4. *Average Pain Ratings Over the Past Week on an 11-point Numerical Rating Scale.*

Scores for the Hospital Anxiety and Depression scale (HADS) also showed positive trends (Figure 11). Quality of life was assessed for five participants using the McGill Quality of Life (MQOL) scale. Total scores did not indicate improvements from baseline (M = 96.25, SD = 57.78) to endpoint (M = 94.25, SD = 7.58), however, ratings on the psychological symptoms subscale did show improvement from baseline (M = 29, SD = 15.5) to endpoint (M = 9.8, 15.4). The Distress Numerical Rating Scale (NRS) (n = 10) indicated improvements from baseline (M = 5.9, SD = 3.01) to endpoint (M = 4.9, SD = 3).

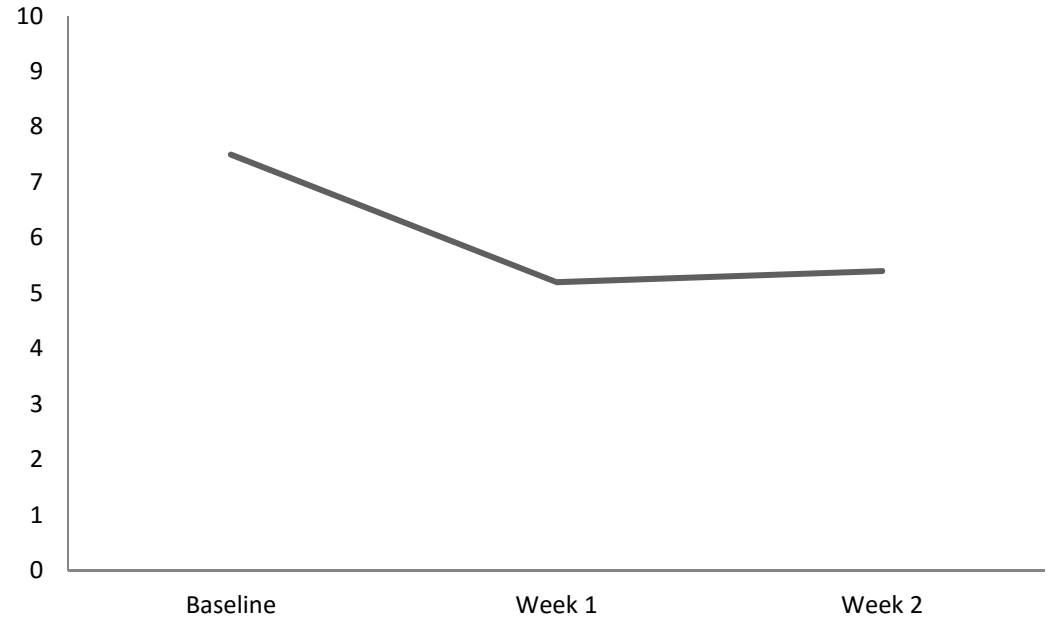

Figure 5. *Average Pain Bothersomeness Ratings over the Past Week on an 11-point Numerical Rating Scale*.

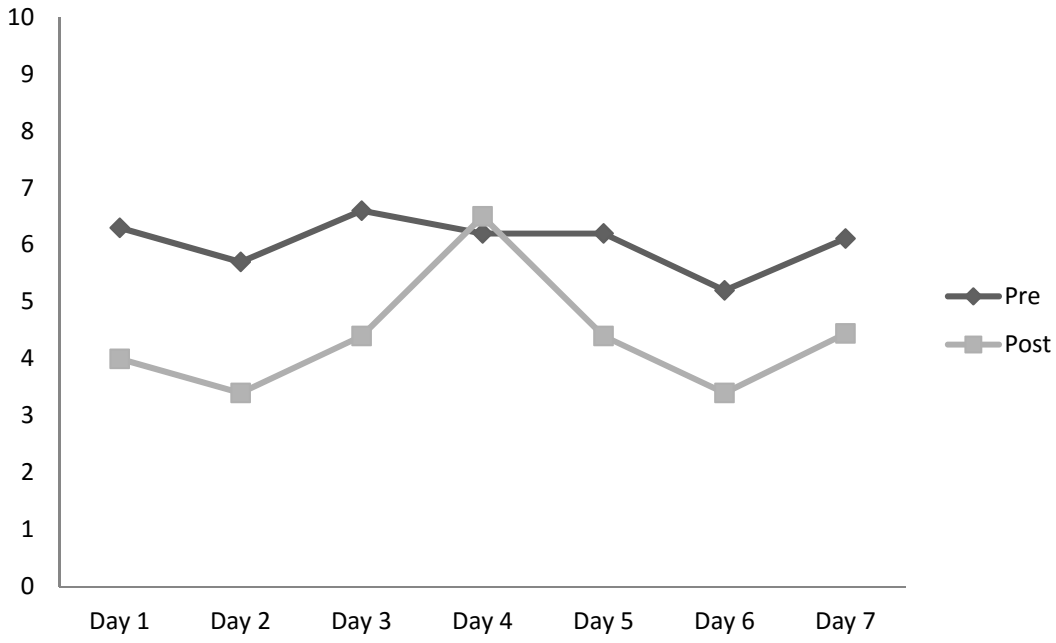

Figure 6. *Average Pain Pre-Post Listening for Week 1 on an 11-point Numerical Rating Scale.*

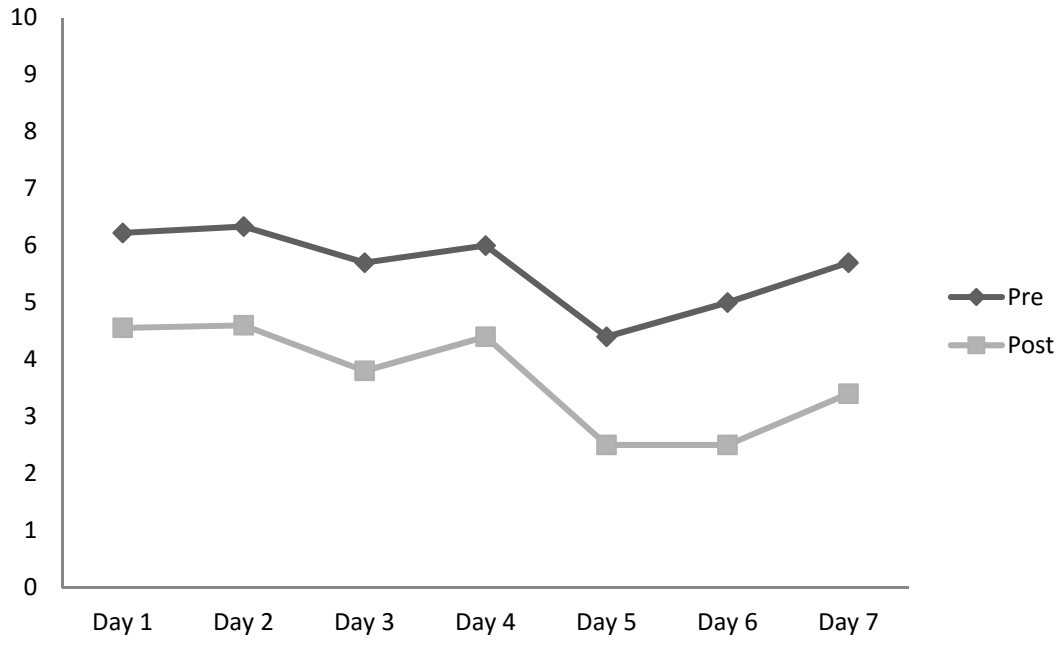

Figure 7. *Average Pain Pre-Post Listening for Week 2 on an 11-point Numerical Rating Scale.*

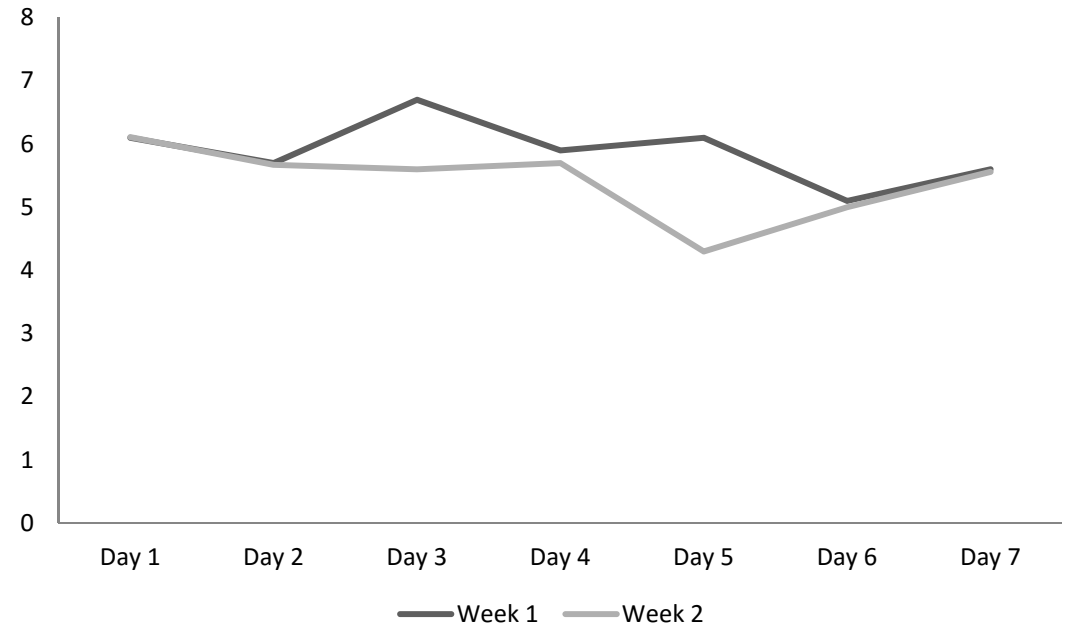

Figure 8. *Average Daily Pain Intensity for Week 1 and Week 2.*

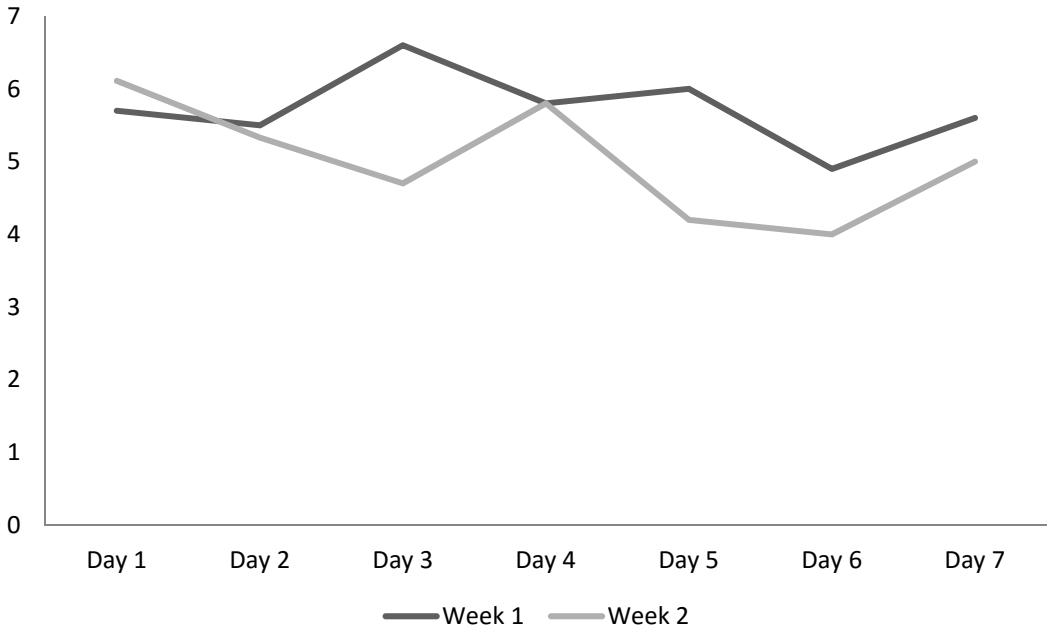

Figure 9. *Average Daily Pain Bothersomeness for Week 1 and Week 2.*

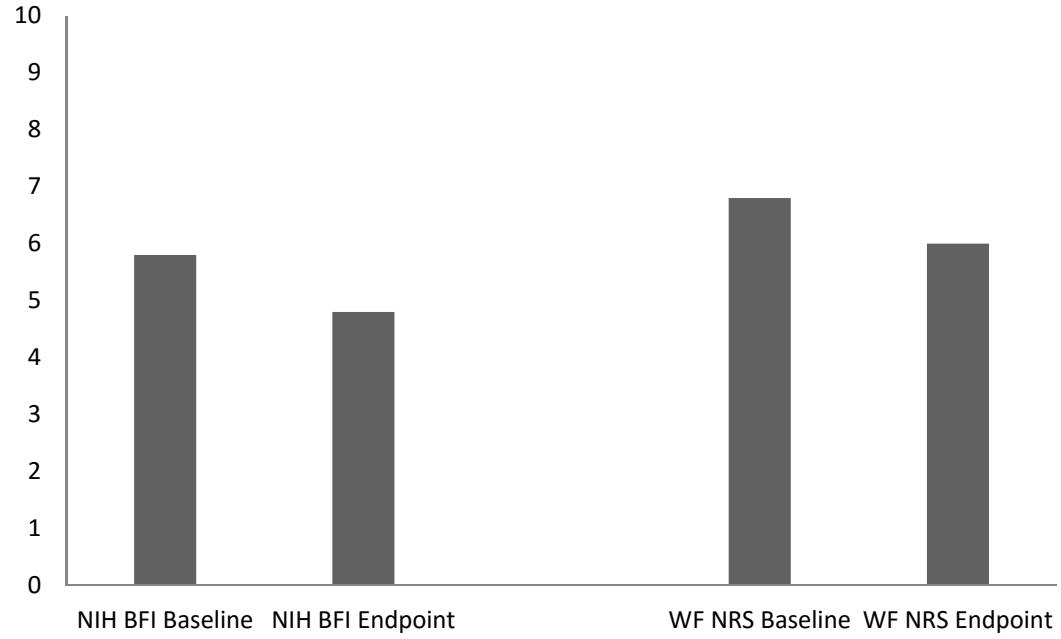

Figure 10. *Average Fatigue from Baseline to Endpoint on the NIH-BFI and the WF-NRS.*

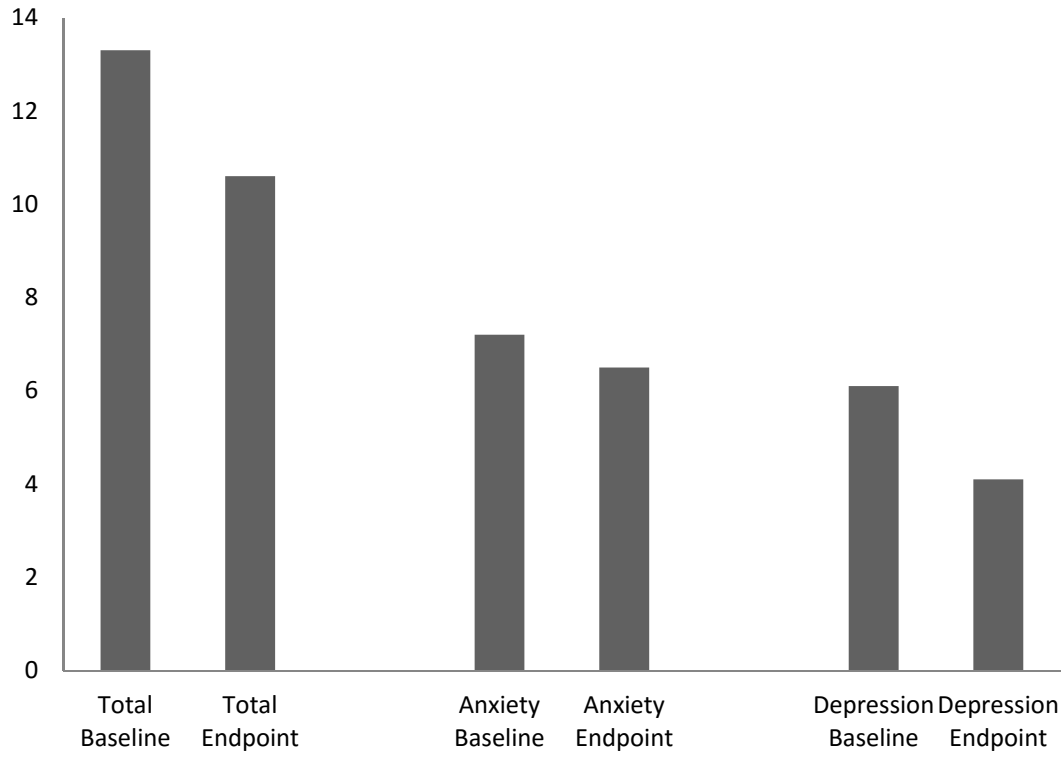

Figure 11. *Average Scores on the Hospital Anxiety and Depression Scale.*

Selected Case Studies

Case report data are provided for selected palliative care patients who completed the study.

Case 1. J. S. is a 66-year-old Caucasian male who currently receives palliative care for cancer. His participation in the study was based on his interest in finding additional methods to help control cancer-related pain, including nerve pain, bone pain and referred pain. J. S. reported consistent decreases in pain pre- to post-listening as shown in Table 4. The participant rated his average pain as 7 at baseline and 6 at endpoint. At the completion of the study, the participant reported "relaxation" and "definite reductions in pain" as benefits from participating in the study.

Case 2. P. X. is a 60-year-old Caucasian male who enrolled in the study to explore alternative methods for managing cancer-related pain, including nerve pain and phantom pain. Pre- to post-listening pain ratings showed declines overall (Table 4). P. X. rated his average pain at baseline as 7 and 6 at endpoint. The participant reported the intervention "helps relax you and takes your mind off the pain" and that benefits were "not momentary, but helps throughout the rest of the day." He also reported this study gave him "the chance to realize that music could be a part of healing."

Case 3. M. K. is 44-year-old Caucasian female who was currently being treated for Crohn's Disease and reported soft tissue pain. Pre- to post-listening pain ratings are displayed in Table 4 and show declines for most sessions. Participant reported average pain as 5 at baseline and 6 at endpoint. She reported "going off her pain medications" while being in the study which may explain a rise in reported pain levels. She also reported increased activity levels, including participating in a 5k walk, socializing with friends, and completing projects around the house. She also reported improved sleep and that she is waking up "feeling rested and repaired."

Case 4. U. M. is a 50-year-old female currently receiving care for fibromyalgia and anxiety. At the beginning of the study period she reported nerve and bone pain. She rated her pain as 8 at baseline and 4 at endpoint. Pre- to post-listening pain ratings are listed in Table 4. At the completion of the study, she reported that the intervention "has helped me a whole lot with the pain, helped me do things that I used to do. I have so much energy now." She was "excited that she was able to spend more time with friends" and engaging in activities she enjoyed.

Table 4. *Changes in pain pre-post listening*

Case	J. S.	P. X.	M. K.	U. M.
Day	Pre-Post	Pre-Post	Pre-Post	Pre-Post
1	4-3	8-6	5-4	7-5
2	3-2	7-4	7-5	8-6
3	4-2	6-5	8-6	7-5
4	8-4	7-6	4-4	6-5
5	7-4	7-5	3-3	6-5
6	8-3	7-6	4-3	5-4
7	8-3	8-6	3-3	4-4
8	5-3	7-6	4-3	4-3
9	4-2	8-6	6-5	3-3
10	7-3	7-4	6-6	4-3
11	8-3	7-5	6-6	3-3
12	4-2	8-5	5-4	3-2
13	4-2	7-5	6-5	2-0
14	8-2	8-8	5-5	2-0

Overall, the results indicate that a music and therapeutic suggestion intervention is a feasible and well-accepted adjunct to pain management. Descriptive statistics revealed possible positive effects of music and suggestion on pain and pain bothersomeness and on associated pain symptoms (e.g. fatigue, anxiety, depression, QOL).

CHAPTER FIVE

Discussion

The primary purpose of this study was to assess the feasibility of a music and therapeutic suggestion intervention for pain management among chronic pain sufferers. Feasibility was assessed based on accrual rates, acceptability, and attrition (Thabane et al., 2010). Accrual rates were determined successful if at least 10 participants could be accrued in six months. The accrual goals were met providing initial evidence for feasibility.

In response to participant feedback and low initial accrual rates, the inclusion criteria were expanded and participant burden was reduced. The changes in inclusion criteria from the *Palliative care sample* to the *Clinical sample* improved accrual rates from 35% to 85%, respectively. It is worth noting that even though the revised inclusion criteria did not evaluate require participants to be enrolled in palliative care, all participants in the clinical sample were all being treated for some pain-related medical condition. By removing the restriction that participants must currently be enrolled in palliative care, accrual rates improved dramatically. This finding is supported by previous research indicating the difficulty in recruiting palliative care samples for research purposes (see Henderson, Addington-Hall, & Hotopf, 2005).

All participants who completed the study reported that the intervention and study procedures were acceptable and that they perceived benefit from participating in this study. Attrition rates were under what was expected (20%) among a sample experiencing

various medical conditions. Overall, findings from this study support the feasibility and acceptability of a music and suggestion intervention for chronic pain.

Study processes were reviewed by the primary researcher and found to be consistent. Data records were complete with less than 10% missing data. No errors in data entry were found and no adverse events were reported during the course of the study. Measurements were refined during the course of the study to reduce patient burden. Each group of measures demonstrated sensitivity to capture meaningful changes in pain, pain bothersomeness, fatigue, anxiety and depression. A more robust quality of life measure could provide additional relevant information in a future study.

The primary purpose of this study was to assess the feasibility of a music and suggestion intervention for pain management. Therefore, it was not appropriate to conduct inferential statistics or compute effect sizes (Leon et al., 2011). Overall, descriptive reports suggest that music and suggestion may be effective adjuncts for the reduction of pain, pain bothersomeness and associated pain symptoms in a chronic pain population.

Descriptive statistics of pain, pain bothersomeness, fatigue, anxiety, depression, and quality of life support the use of music and suggestion for pain management in chronic pain patients. Descriptive statistics showed pain reductions were within the range of clinically meaningful improvements (Farrar et al., 2001), though caution must be taken when drawing conclusions based on this small descriptive study. Pain bothersomeness ratings showed consistent declines over the course of the study. This finding is in line with previous research indicating music and suggestion were effective in reducing pain perception (Bernatzky et al., 2011). Reductions in anxiety, depression, and fatigue were

demonstrated in both samples, a finding consistent with past research on the effects of music for pain management (Cepeda, Carr, Lau, & Alvarez, 2006; Chan, Wong, & Thayala, 2011; Kullich et al., 2003).

Evidence from this study may be used to inform a larger controlled trial of music and suggestion for chronic pain management. To further elucidate the possible mechanisms by which music and suggestion may exert their combined effects, future studies could include measures of cognitive expectancy, indicators of relaxation (e.g., subjective and objective), mood and affect, and attention. In addition, measures of self-efficacy and locus of control could provide a better understanding of what mechanisms may be involved in pain and pain bothersomeness reductions. Future studies may also consider comparing self-selected music with pre-selected music, music with and without suggestion, and the possible effects of the intervention on specific chronic pain conditions (e.g. low back pain, fibromyalgia, neuropathic pain conditions).

The goals of treating pain usually consist of providing relief from pain, restoration of physical function, and return to normal activity (Apakarian, Baliki, & Geha, 2009). Likened to other chronic diseases, chronic pain often requires multidisciplinary treatments due to the complex interaction of causal mechanisms (Institute of Medicine, 2011). Given its complexity, effective treatments for chronic pain will require interdisciplinary and multimodal treatment approaches that take into consideration the psychological, biological, and social-cultural factors that contribute to the patient's experience (Institute of Medicine, 2011; Turk, Wilson, & Cahana, 2011). The integration of several different treatment approaches may be more beneficial to the patient, reduce the associated costs of chronic pain, and prevent disability associated with chronic pain

(Dersh et al., 2006; Jensen & Turk, 2014). This study provides initial evidence for the use of music and suggestion as adjuncts for chronic pain management.

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