Abstract

A PILOT STUDY: THE EFFECT OF HEALING TOUCH ON ANXIETY, STRESS, PAIN, PAIN MEDICATION USAGE, AND PHYSIOLOGICAL MEASURES IN HOSPITALIZED SICKLE CELL DISEASE ADULTS EXPERIENCING A VASO-OCCLUSIVE PAIN EPISODE.

by

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Sickle cell disease (SCD), a common genetic blood disorder affecting primarily African-Americans (Edwards, Scales, Loughlin, Bennett, Harris-Peterson, et al., 2005) causes a vaso-occlusive pain episode (VOPE) affecting both men and women across their life span. Both physical and psychological stress has been reported to precipitate a VOPE (Anie & Green, 2006) placing them at risk for early death. In fact, 78% of the patients who die from SCD do so during a VOPE.

Healing Touch (HT), a complementary therapy, has been shown to decrease anxiety, stress, and pain in other patient populations such as cancer, orthopedic, and post-cardiac surgery patients, but sickle cell pain has not been studied. The purpose of this parallel-group randomized control trial (RCT) was to determine the effectiveness of Healing Touch on anxiety, stress, pain, pain medication usage, and selected physiological measures of hospitalized SCD adults experiencing a VOPE. The outcome variables were measured, while controlling for the music and presence. The study

sample was 24 participants who ranged in age from 22 to 49 years with an average age of 31.4 years. Healing Touch sessions were administered for 30 minutes on four consecutive days, and the self-reported data on anxiety, stress, pain, and the selected physiological data were collected.

The results on the 16 patients who completed the study were not statistically significant across the two groups due to the small sample size. Overall, there were no statistically significant changes in any between group comparisons, except for present pain on day 4 for the Attention Control with Music (ACM) group. For both Healing Touch with Music (HTM) and the ACM, the within groups comparison showed a reduction in physiological parameters, but was not statistically significant. For anxiety, the within groups comparison showed a statistically significant reduction for the ACM group ($p=.01$). For stress, the ACM group reached a statistically significant reduction ($p=.03$), after day 4, however the HTM group also reached statistical significance after day 2 ($p=.02$) and again after day 4 ($p=01$), consistent with the findings from previous studies in HT.

The pre- to post-intervention reductions in present pain were greater in the HTM group than the ACM group across all 4 days. The only statistically significant within groups findings for present pain reduction were in the HTM group ($p<.01$) on day 1, consistent with other studies done with HT. The trends identified in this study warrant further research on Healing Touch's effect on anxiety, stress, and pain using a larger sample.

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Linda Steedly Thomas

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A PILOT STUDY: THE EFFECT OF HEALING TOUCH ON ANXIETY, STRESS, PAIN, PAIN MEDICATION USAGE, AND PHYSIOLOGICAL MEASURES IN HOSPITALIZED SICKLE CELL DISEASE ADULTS EXPERIENCING A VASO-OCCLUSIVE PAIN EPISODE.

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DEDICATION

To my husband, Kirk, for his love and support, his relentless critique of my papers, and his willingness to drive me two and a half hours to class each week, and to my daughter, Jennifer, for her love and encouragement, as well as her technical expertise with my computer. Without both of your help, I could never had done this.

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I dedicate this achievement of my life's accomplishments to all those who travelled along the journey with me and hope that their own journeys will take them to the places they want to go. As my husband said in one of his poems, using the first line of one of Robert Herrick's verses:

Gather ye rosebuds while ye may,
Each day might be the last;
The future is not certain,
And may never come to pass.

So drink your fill of every moment,
For if life should end today,
What is it that you wish you'd done,
Or savored on the way?

Who will not risk, can never win,
The timid never know,
What adventures might have been,
What magic might have flown.

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CHAPTER 1: INTRODUCTION

Sickle cell disease (SCD) affects approximately one out of every 375 African-Americans in the United States (Edwards et al., 2005). Although SCD has been found to primarily affect people of African-American and Caribbean descent, it has also been found in a small portion of the population from Southern Europe, the Mediterranean area, the Middle East, and India (NAHAT, 1991). This common genetic blood disorder is a worldwide health problem that affects both men and women of all ages during their lifetime, with an average lifespan of 42 years for males and 48 for females (Platt et al., 1994). Seventy-eight percent of the patients who die from SCD will do so during an acute vaso-occlusive pain episode (VOPE), such as an episode of acute chest syndrome (Platt et al., 1994). Vaso-occlusive pain episodes are due to the insidious accumulation of vascular damage caused by the sickling of the red blood cells (Powars, Chan, Hiti, Ramicone, & Johnson, 2005). This pain is accompanied by physiological changes such as increased heart rate, blood pressure, and respirations, as well as a decrease in oxygen saturation and skin temperature (Kleinknecht, 2002).

The psychological state of anxiety has been reported as being a contributing factor in the frequency and severity of pain in SCD patients, as well as reinforcing the pain state (Gil, Abrams, Phillips, & Keefe, 1989; McCrae & Lumley, 1998; Vichinsky, Johnson, & Lubin, 1982). Stress has also been identified as one of the precipitating factors in the onset of VOPE (Gil et al., 2003; Gil et al., 2004; Leavell & Ford, 1983; Porter, Gil, Carson, Anthony, & Ready, 2000; Porter et al., 1998; Thompson, Gil, Abrams, & Phillips, 1992). Research directed toward reducing these two precipitating factors in SCD needs to be conducted in an effort to improve SCD patients' outcomes.

Healing Touch (HT), a non-invasive, complementary, energy-based therapy, has been shown to decrease anxiety, stress, and pain in cancer, orthopedic, and post-cardiac surgery patients, but no studies have been conducted in the area of sickle cell pain. The purpose of this pilot study was to examine the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, equianalgesic opioid medication usage, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE. The effect of HT on the outcome variables was measured by 1) selected physiological parameters, 2) self-reported levels of anxiety, stress, and pain, as well as 3) equianalgesic opioid medication received during the study period, while controlling for the variables music and presence.

The Purpose of the Study - Problem

Among the various complications of sickle cell disease, the numerous severe pain episodes present a challenge for the care given by the bedside nurse. Pain episodes can be acute or chronic, and have unpredictable frequency, severity, and location (National Heart, Lung, and Blood Institute, 2002). Sixty percent of patients with SCD will have three to ten episodes of severe pain every year (Platt et al., 1991). Acute VOPE have been found to be the cause of pain in most patients and will resolve in about five to seven days, but can last for several weeks to months (Yale, Nagib, & Guthrie, 2000).

Physical and psychological stress has been reported to precipitate a VOPE (Anie & Green, 2006). Examining anxiety and pain coping strategies in SCD patients, a significant correlation has been found between anxiety and the number of pain

episodes, duration, and severity of the pain (Gil, et al., 2003; Leavell & Ford, 1983). Higher levels of stress have also been shown to predict pain severity (Gil, et al., 2003). Anxiety and stress activate the neural impulses that stimulate the sympathetic nervous system to release the hormones epinephrine and norepinephrine, which causes an increase in heart rate (HR), blood pressure (BP), respiratory rate (RR), and oxygen consumption as well as dilating the bronchi and decreasing blood flow to the periphery (Kleinknecht, 2002). The effect of emotion-induced sympathetic activation related to stressful life experiences in the activation of the body's sympathetic responses (i.e. respiratory and blood flow patterns) needs to be examined, therefore the physiological measures that reflect a relaxation response (i.e. a decrease in HR, BP, and RR) were collected in this study to determine what role sympathetic arousal plays in the precipitation, exacerbation, and prolonging of VOPE (McCrae & Lumley, 1998).

Sickle cell disease patients, a health disparity population, are vulnerable to the biases of many healthcare providers who fear the SCD patient's potential for addiction to narcotics used to control pain (Elander & Midence, 1996; Shapiro & Ballas, 1994), yet inadequate pain management by the healthcare provider can cause stress induced VOPE and repeated hospital admissions (Ballas & Lusardi, 2005). Increased VOPE have been found to have a negative impact on the patients' quality of life and to increase their overall morbidity and mortality (Ballas & Lusardi, 2005).

The pathophysiology of SCD, the psychological and social factors, can contribute to the SCD patient's complaints of pain (Anie, Steptoe, Ball, Dick, & Smalling, 2002; Edwards, Telfair, Cecil & Lenoci, 2001). Current management of SCD is directed toward relieving the symptoms and complications, because the more disease symptoms

experienced during a VOPE by the SCD patient, the higher the risk for an early death (Edwards et al., 2005; Platt et al., 1994). Maville, Bowen, and Benham (2008) reported measuring selected physiological parameters after providing a HT session for healthy adults and found changes in their HR and peripheral temperature, which suggested a reduction in sympathetic tone with resultant relaxation occurring. This was consistent with findings from five other studies, which reported selected physiological data related to anxiety and/or stress (Heidt, 1981; Meehan, 1993; Wardell & Engebretson, 2001; Wardell & Weymouth, 2004; Wilkinson et al., 2002). This study was directed toward using a noninvasive nursing intervention, HT, to determine if it can be effective in lessening or delaying some of the symptoms and complications (i.e. anxiety, stress, and pain) associated with SCD.

The majority of the interventional research for SCD management use invasive techniques such as blood transfusions, IV hydroxyurea, and bone marrow transplantation, which carry much higher complication rates (Dunlop & Bennett, 2007; Steinberg & Brugnara, 2003). Cognitive-behavioral techniques have been the primary focus of non-pharmacological research for SCD patients and often include primary coping strategies, hypnosis, thermal biofeedback, and acupuncture (Elander & Midence, 1996). There is limited data to support the use of these complementary therapies and their effectiveness on pain management in the SCD patient. There have been, however, a few clinical trials that have shown some positive results with these non-pharmacological approaches. For example, subjects who learned self-hypnosis or biofeedback techniques reported decreased hospitalization and medication usage; others, who used biofeedback and self-hypnosis, along with progressive relaxation and

cognitive strategies, showed a significant reduction in anxiety and intensity of pain (Elander & Midence, 1996).

No non-pharmacological studies were found using HT as an intervention for reducing anxiety, stress, or pain in the hospitalized SCD adults experiencing a VOPE. If HT could be shown to be effective, then it could be administered by the bedside nurse as a complementary therapy to reduce pain medications, and it could impact the amount of pharmacological interventions needed as well as reduce the number of side effects, complications, and costs associated with these medications. Also, with the reduction in symptoms and complications, the risk of an early death for the SCD patient could potentially be decreased. Therefore, the purpose of this pilot study was to examine the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, equianalgesic opioid medication, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE.

The Intervention Group – Healing Touch with Background Music (HTM)

Healing Touch (HT), developed by Janet Mentgen, BSN, RN in 1980, has been classified as a biofield therapy by the National Center for Complementary and Alternative Medicine (NCCAM, 2008). Mentgen, building on Martha Rogers (1979) description of the energy system that surrounds the body as rhythmical vibrations oscillating between man and the environment, developed Healing Touch, an energy-based therapy, based on the premise that the human body has an energy field that is not only part of the physical body, but also extends out several feet from the body. Leddy (2004) using Rogers' Science of Unitary Human Beings, created a model to

explain these pattern manifestations within the energy field. The North American Nurses Diagnosis Association (NANDA) has established the nursing diagnosis of Energy Field Disturbance that describes “a condition in which a disturbance of the human energy field manifests a disharmony in the human-environmental energy field’s mutual process” (Carpenito-Moyet, 2004, p.344). Leddy’s Human Energy Model (HEM) describes how this field can be modified whenever a person experiences anxiety and pain, through energetic patterning (participation) using nursing interventions, such as HT, which was examined in this study using Betty Neuman’s Health Care System’s Model. Based on Neuman’s concept of the patient as “wholes whose parts are in dynamic interaction” in an open system “where its elements are continuously exchanging information and energy” (Toomey & Alligood, 2006, p 320), this study examined the effects of administering HT to the SCD patient experiencing a VOPE to determine if interacting with their energy field would strengthen their lines of resistance and lines of defense against the stressors, anxiety and stress, and thereby reduce their pain.

Healing Touch, using therapeutic presence (a way of being with another person), provides the intentional exchange of energy that can foster harmonious synchronization of these energy field vibrations and increase their coherence (Oschman, 2000). This coherence will help to strengthen the lines of resistance and lines of defense described in Betty Neuman’s Health Care System Model, as an open system in which there is a continuous and dynamic interaction between the patient and the environment (Neuman & Fawcett, 2002).

Measurement of this energy field is difficult however, and until science can directly and accurately measure the human energy field, research will continue

measuring the indirect effects of various interventions on the field (Eschiti, 2007). This present study did just that by examining the effectiveness of the non-invasive nursing intervention, HT (on the sickle cell patient's lines of resistance and defense within his/her internal and external environments) on anxiety, stress, pain, equianalgesic opioid medication and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE.

Healing Touch incorporates a group of non-invasive techniques using the hands to help balance these dynamic energy systems surrounding the body, energizing and balancing both the human and environmental fields. By balancing these energy fields, it is thought that the practitioner can assist patients in their healing process (Hoover-Kramer, 2002). Healing Touch, a technique designed to work along with conventional medicine, helps restore harmony (accord, agreement) and balance in both the patient's internal and external energy, allowing for self-healing and promoting wellness within the whole system.

Healing Touch has been shown to reduce such factors as anxiety and stress in several different patient populations. A reduction in anxiety along with decreased pain was reported in one study with several groups of patients who had multiple diagnoses (Welcher & Kish, 2001), as well as another group with end-stage liver disease (Hjersted-Smith & Jones, 2006). A more recent study conducted by Maville, Bowen, and Benham (2008) investigated the effect of HT on anxiety and physiological measures of HR, BP, and skin temperature in healthy adults, and found changes in a number of physiological measures which suggested a reduction in anxiety. The literature on stress

reduction after receiving HT is limited, but one well-designed study did find decreased stress after receiving HT. That particular study examined a group of young college students and found that after receiving HT there was an immediate decrease in overall stress at the end of the study (Dowd, Kolcaba, Steiner, & Fashinpaur, 2007).

The assertion of this study is that there are physiological and psychosocial stressors related to sickle cell disease pain, which disrupt the natural flow of energy in the patient. Healing Touch seeks to use the interaction between man and environment to strengthen the internal environment, making it more coherent (consistent) and strengthening the lines of defense by balancing the energy field and making it more stable in order to maximize the patient's health potential. This study examined the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, equianalgesic opioid medication, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE.

For purposes of this study, the patient population was SCD adults experiencing a VOPE, who were receiving standard care, which is the usual diagnostics, fluids, blood, and pharmacological treatments that are typically provided (Yale, Nagib, & Guthrie, 2000). Healing Touch, a non-invasive, complementary, energy-based therapy, is added to the standard care, to determine the effectiveness of this type of complementary treatment option. The addition of therapeutic background music to the HT intervention was to address the distraction of ambient noise levels in the acute care setting, which have been reported to be in the range of 50-75 dB during the day. The

US Environmental Protection Agency (1974) recommends that the noise level of hospitals be less than 45 dB during the day.

The Attention Control Group with Background Music (ACM)

The ACM group was designed to control for the effect of the music as well as the physical presence of the research assistant during the HT intervention. The research assistant (RA) in the ACM group remained in the room for the same amount of time as in the HT intervention group to account for the physical presence of the healthcare provider, while performing a mundane task (i.e. working a cross word puzzle) to control the RA from focusing his/her intent on the patient, as would occur in the HT intervention group. The same pre-selected music CD was played for both intervention groups to control for the music variable.

Music is a type of complementary healing therapy that uses an intentional auditory stimulus to affect both the patient's physiological and psychological outcomes (Kemper & Danhauer, 2005). Music as a therapeutic intervention has been used in various age groups including premature infants (Lorch et al., 1994), children (Malone, 1996), and adults (Cowan, 1991) for various conditions and procedures. Even though numerous studies have shown a decrease in anxiety (Gillen, Biley, & Allen, 2008; White, 1992; White, 1999; Wong, Lopex-Nahas, & Molassiotis, 2001) and pain (Nilsson, Rawal, & Unosson, 2003; Aragon, Farris, & Byers, 2002; Good, Anderson, Staton-Hicks, et al., 2002) not all of them reached statistical significance, and therefore the relevance for clinical practice is unclear. Bally, Campbell, Chesnick, and Tranmer (2003) suggested that music therapy may be more effective in subgroups of patients with higher levels of anxiety, stress, or pain like those in this study with SCD. No studies

were found using music to reduce anxiety, stress, or pain for SCD adults experiencing a VOPE. The purpose of this pilot study was to examine the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, equianalgesic opioid medication, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE. The effect of HT on the outcome variables was measured by 1) selected physiological parameters, 2) self-reported levels of anxiety, stress, and pain, as well as 3) equianalgesic opioid medication received during the study period, while controlling for the variables music and presence. By comparing both the HTM group and the ACM group, the change in the outcome measures between the two interventions can be shown to be the result of HT, since the music used to reduce outside distractions and the presence of the RA was identical in both groups.

Effect of Presence

The concept of therapeutic presence has entered the mainstream of nursing without clear definition and with little critical examination or evidence-based analysis. Exactly how therapeutic presence impacts the outcomes seen in complementary interventions such as HT or Music is still being addressed in the literature. For this study, therapeutic presence is defined as a way of being with another person, fully present in body, mind and spirit, open to the situation (Paterson & Zderad, 1976), setting intentionality for the patient's highest good, and developing a trusting relationship (McKivergen & Daubenmire, 1994). Having established a therapeutic presence between the nurse and the patient, the current literature suggests that this will increase patient satisfaction and improve patient outcomes. Osterman and Schwartz-

Barcott (1996) describe four ways of being present as presence, partial presence, full presence, and transcendent presence. It is thought that transcendent presence can create a positive change in the affective state, therefore decreasing anxiety because of the peaceful, comforting feeling it creates. A review of the literature reveals a general consensus that the nurse-patient relationship encountered with the introduction of the component of presence is perceived as also having a positive impact on the patients and their healing process. Rogers (1996) described these beneficial outcomes for patients as feelings of support, hope, relaxation, and the ability to cope better. There is little research on exactly how this impacts the physiological outcomes of the patient. Since it is believed to occur however, it is necessary to account for its effect on the patient, and it was addressed in this study by having a RA "present" during both interventions.

Theoretical Framework

Betty Neuman's Health Care System Model was used to develop the theoretical perspective for this study on the use of HT as a non-invasive nursing intervention in the SCD patient population who were experiencing a VOPE. Using ideas from a variety of sources such as the Gestalt theory and the General System theory, Neuman identified several major concepts in her model, which creates the foundation for this study. Based on Neuman's theoretical framework, it is postulated that the patient as a system, exchanges information and energy through a continuous and dynamic interaction with the environment, and that the administration of HT can assist in creating system stability and balance, resulting in a homeostatic body system, the reduction of pain, and overall wellness (Neuman & Fawcett, 2002; Tomey & Alligood, 2006).

In Neuman's concepts of the "wholistic" patient approach, which included not only the whole patient, but an open system, the environment, and stressors, are all shown interacting with five components of the patient: physiological, psychological, developmental, socio-cultural, and spiritual. This approach shows the components intermingling with the patient's basic structure (i.e. cognitive ability, physical strength, and value systems, etc.), lines of resistance (defends against stressors) and lines of defense (protects the system's stability) in order to maintain homeostasis in the system (Neuman & Fawcett, 2002). This study did not explore the developmental and spiritual components of Neuman's model. The holistic effect of Healing Touch, which does encompass the spiritual aspect of healing, may be present, but for purposes of this study was not examined. It is hypothesized however, that using Neuman's model, the SCD patients' normal line of defense is their usual state of health prior to hospitalization. Adjusting this line of defense, which changed in response to their VOPE, is one of the mechanisms used to restore their state of equilibrium or balance (George, 2002). Healing Touch can assist with balancing the system's stability by working with the energy surrounding the body, utilizing this energy source to impact the environmental forces (stressors) which influence their dynamic system as the patient moves towards wellness. The SCD patients' lines of resistance constitute part of their defense mechanisms that attempts to address the states (i.e. stress and anxiety) created by their internal and external environments, which cause instability. In this study, three of the core components, (the physiological, the psychological, and the socio cultural component) played a role in determining how SCD patients respond to the stressors

related to their disease and will ultimately determine their ability to adapt to these stressors.

A stressor, anything that can affect the stability of the system, can be categorized as intrapersonal (occurs within the person), interpersonal (occurs between individuals), or extrapersonal (occurs outside the individual) (Neuman & Fawcett, 2002). The patient's reaction to the stressor depends in part on the strength of their lines of resistance and defense. According to Neuman's model, interventions by either the patient or the nurse are done to restore or maintain the stability of the system. Assessment of the total situation in which the patient presents requires knowing the relationship between the internal (forces that affect patients within their system such as a VOPE) and external environmental factors (forces affecting patients outside their system such as environmental temperatures) as well as the created environmental factors (forces created unconsciously by the patient such as anxiety and stress) (Neuman & Fawcett, 2002; Tomey & Alligood, 2006). Based on the assessment of these stressors, assisting the patient in making adjustments to maintain an optimal level of wellness by the use of primary, secondary and tertiary prevention strategies as interventions is part of the nursing process (Neuman & Fawcett, 2002). The HT intervention served as both a secondary as well as a tertiary prevention strategy in this study.

The patients' expectations, defined for this study as anxiety about impending pain, and the stress created by their lifestyle, influence their lines of defense and resistance causing the destabilization of the internal core structure. The hospitalized SCD adults often have numerous stressors or disturbances in the lines of defense due

to the pathophysiology as well as the psychosocial aspects of their disease (i.e. anxiety due to biases of healthcare workers and the isolation experienced) (Elander & Midence, 1996; Shapiro & Ballas, 1994). By working with the SCD patient's lines of defense and resistance and thereby interacting with their internal and external environments, HT improves their defenses against these disturbances, addressing those pathophysiological responses caused by increased sympathetic nervous system responses (i.e. increase blood pressure, heart rate, respiratory rate, oxygen consumption, and decreased skin temperature due to vasoconstriction of blood vessels) that result in pain. Healing Touch, which has been shown to reduce psychosocial disturbances such as anxiety and stress in other patient populations (Dowd, Kolcaba, Steiner, & Fashinpaur, 2007; Hjersted-Smith & Jones, 2006; Welcher & Kish, 2001), was postulated to also assist in strengthening the SCD adult's lines of defense and resistance against these disturbances.

Secondary prevention as described by Neuman is what occurs after the patient's system reacts to a disturbance, in this case the VOPE. The secondary prevention attempts to strengthen the lines of resistance so as to help the patient defend against disturbances, (e.g. anxiety and stress), resulting in an overall reduction in pain (Neuman & Fawcett, 2002). It was proposed that HT, due to its ability to relax, restore, and balance the patient's energy system, would decrease the release of catecholamines (physiological stressors) caused by stimulation of the sympathetic nervous system and help to prevent additional disturbances that cause the SCD patient's VOPE. The effects of HT as a secondary prevention was postulated to be a decrease in the self-reported anxiety, stress, and pain scores as well as changes in the physiological parameters.

Tertiary prevention occurs after secondary prevention has been provided. It focuses on strengthening the resistance to stress factors or disturbances and preventing recurrence of the reaction, thereby providing stability to the system (Neuman & Fawcett, 2002). As a tertiary prevention, the accumulative effectiveness of HT was hypothesized to result in a decrease in anxiety and stress, as well as decreases in pain intensity and longer periods of time between pain events, resulting in a decrease in the amount of medication required. In this study, HT was used as a secondary and tertiary prevention in the hospitalized SCD adults experiencing a VOPE. Working with the SCD patient's lines of defense and lines of resistance and interacting with their internal and external environments, HT, which has been shown to produce relaxation and reduce anxiety, was postulated to assist patients in improving their defenses against these stress factors and reducing the patients' reactions to these disturbances (Figure 1).

In this study, the proposition of the conceptual framework based on Betty Neuman's Health Care System Model was:

If HT in other patient populations has been shown to:

- Reduce anxiety (a psychological stressor) (Post-White et al., 2003; Welcher & Kish, 2001), and
- Reduce stress (a psychological stressor) (Dowd, Kolcaba, Steiner, & Fashinpaur, 2007; Wilkinson et al., 2002), and
- Reduce pain (a physiological stressor) (Darbonne, 1997; Merritt & Randall, 2002; Slater, 1996; Wardell, Rintala, Daun & Tan, 2006),
- Then HT, through its repatterning of the energy field, will strengthen the lines of resistance and the lines of defense, thus reducing the

psychologiacal stressors, anxiety and stress, and thereby reducing the frequency and severity of the pain experiences in this SCD patient population experiencing a VOPE (Platt et al., 1994).

Conceptual Definitions

Healing Touch with background music is a type of non-invasive, complementary, energy-based therapy that uses various techniques to work with the energy fields that surround the body, re-patterning and re-aligning the fields, thus restoring harmony and balance to the human energy system (Mentgen, 2001), while the music is used as a distractor for the ambient noise level in the acute care setting.

Music is a type of complementary healing therapy that uses an intentional auditory stimulus to affect both the patient's physiological and psychological outcomes (Kemper & Danhauer, 2005).

Therapeutic presence is a way of being with another person, fully present in body, mind, and spirit, open to the situation (Paterson & Zderad, 1976), setting intentionality for the patient's highest good, and developing a trusting relationship (McKivergen & Daubenmire, 1994).

Physical presence is physically being in the room and communicating with another person, but not being present in mind, body, and spirit and not focusing positive intent for the other person.

Sickle cell disease is inherited as an autosomal recessive trait that is characterized by the presence of sickle or crescent shaped red blood cells (erythrocytes) in the bloodstream (SCD Association of America, Inc. 2008).

Vaso-occlusive episodes are when sickled red blood cells obstruct blood flow to the various organs and tissues, causing the complications associated with SCD such as pain, stroke, etc. (Yale, Nagib, & Guthrie, 2000). It is often, but not always, associated with objective physical signs of autonomic nervous system activity such as tachycardia, hypertension, diaphoresis, mydriasis, and pallor (Godfrey, 2005).

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. (International Association for the Study of Pain, 1994)

Anxiety is defined as a feeling of nervousness, apprehension, fear, or worry characterized by physical symptoms such as palpitations, sweating, and feelings of stress (American Academy of Family Physicians, 2009).

Stress is defined as the non-specific, tension-producing response of the body to any demand for change (Neuman & Fawcett, 2002; Selye, 1974).

Basic structure **–** basic individual survival factors (i.e. heart rate, blood pressure, respiratory rate, oxygen saturation, and skin temperature) or energy resources as well as other characteristics available to the patient (i.e. cognitive ability or value system) (Neuman & Fawcett, 2002).

Environment – the factors that affect or are affected by forces, both internal and external, to the patient's system.

- The *internal environment* - forces that affect patients within their system.
- The *external environment* - forces affecting patients outside their system.

- The *created environment* - forces created unconsciously by the patient and represent the patient's attempt to cope with the stressor in order to maintain system wholeness (Neuman & Fawcett, 2002; Tomey & Alligood, 2006).

Lines of resistance (LOR) – protects the basic structure, defends against stress factors or disturbances (Neuman & Fawcett, 2002).

Lines of defense (LOD) – protective buffer against stress factors or disturbances, represent system stability over time (Neuman & Fawcett, 2002).

Secondary prevention – occurs after the system reacts to a stress factor or disturbance and focuses on preventing damage to the basic structure by strengthening the internal lines of resistance and/or removing the stress factor or disturbance (Neuman & Fawcett, 2002).

Tertiary prevention – occurs after the system has been treated through secondary prevention strategies and functions to strengthen the resistance to stress factors or disturbances and helps prevent recurrence of the reaction (Neuman & Fawcett, 2002).

Operational Definitions

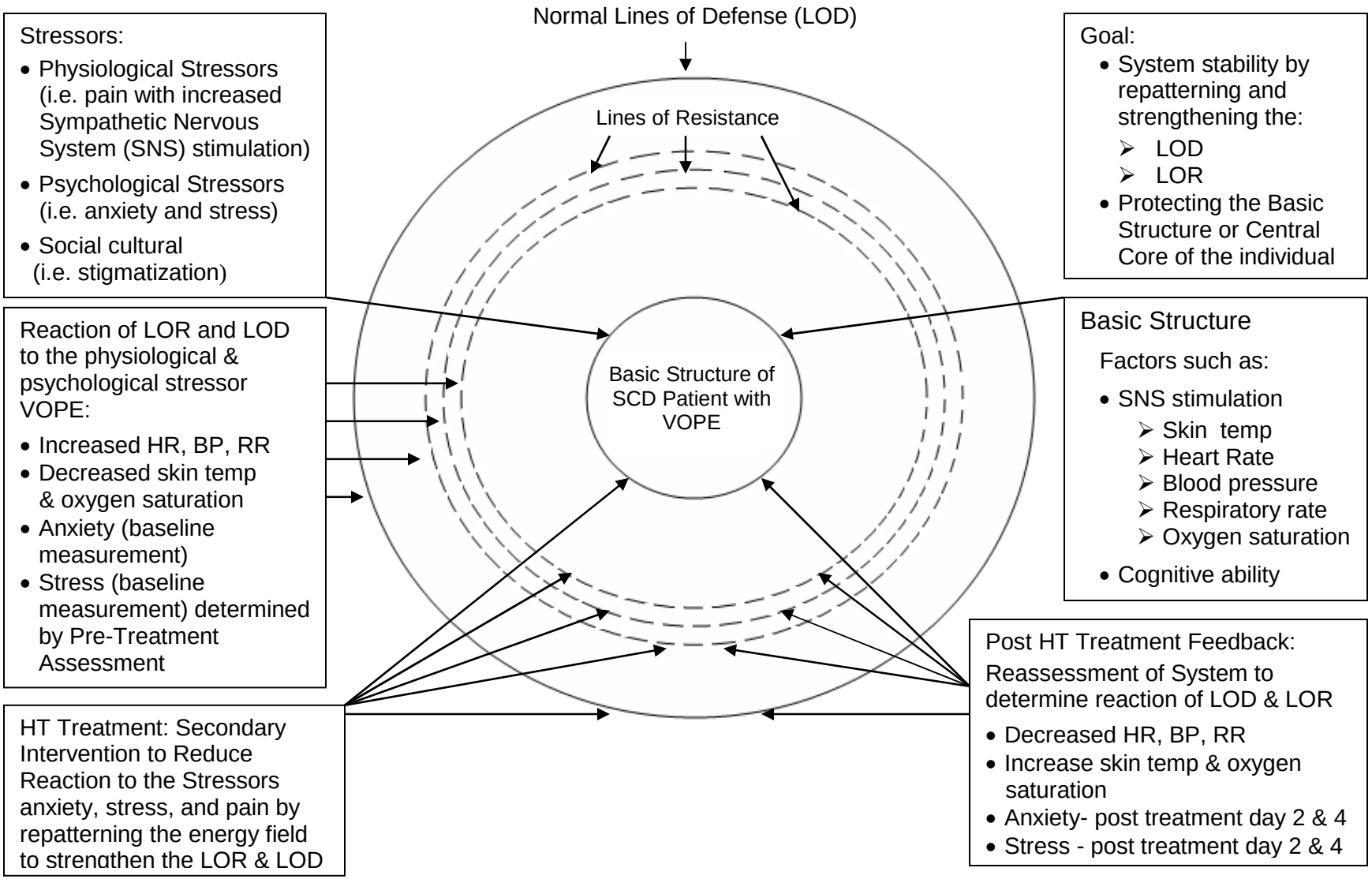
Healing Touch energy assessment: Hand Scanning was used to sense the energy, while a pendulum was used to determine flow or spin of the chakra based on the speed of the pendulum, direction of the pendulum movement (i.e. clockwise or counterclockwise) and the shape of movement of pendulum (Hover-Kramer, 2002).

Pain as measured on the Numeric (pain intensity) Rating Scale (NRS) which assess pain intensity on a scale of 0 to 10, with 0 representing no pain to 10 representing the worst pain ever.

Anxiety as measured by the completion of *t*he Generalized Anxiety Disorder Scale (GAD-7), which consists of seven items measured on a four-point response scale ranging from 0 (not at all) to 3 (nearly every day). A total score ranging from 0 to 21, with higher scores associated with greater levels of anxiety.

Stress as measured by the Modified Perceived Stress Scale (PSS-10), which was a self reporting measure of the perception of stress or the degree to which situations in one's life are appraised as stressful. Measured on a five point Likert scale (0 = never, 4= very often) with total scores range from 0 to 40, with higher scores associated with greater levels of perceived stress.

Figure 1: The Effect of Healing Touch on Anxiety, Stress, Pain, Equianalgesic Opioid Medication, and Selected Physiological Parameters in Hospitalized Sickle Cell Disease Adults Experiencing a Vaso-occlusive Episode.



Purpose

The purpose of this pilot study was to examine the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, equianalgesic opioid medication, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE. The effect of HT on the outcome variables was measured by 1) participant's selected physiological parameters, 2) self-reported levels of anxiety, stress, and pain, as well as 3) equilanalgesic opioid medication received during the study period, while controlling for the variables music and presence.

Hypotheses

Research hypotheses related to the proposed intervention in hospitalized SCD adults experiencing a VOPE and who are receiving HTM were to:

1. Experience lower blood pressure, heart rate, respiratory rate, and a higher oxygen saturation and skin temperature than patients receiving the ACM at completion of the interventions day 1, day 2, day 3, and day 4.
2. Experience lower anxiety scores than patients receiving the ACM at completion of the interventions day 2 and day 4.
3. Experience lower stress scores than patients receiving the ACM at completion of the interventions day 2 and day 4.
4. Experience lower pain scores than patients receiving the ACM at completion of the interventions day 1, day 2, day 3, and day 4.
5. Require less pain medication than patients receiving the ACM at completion of the interventions day 1, day 2, day 3, and day 4.

The above hypotheses were measured by the participant's self-reported levels of anxiety, stress, and pain, as well as changes in the selected physiological parameters and the amount of equianalgesic opioid medication used. The relationship between the independent variable and the outcome variables, anxiety, stress, pain, equianalgesic opioid medication, and the selected physiological measures were examined in this parallel-group randomized control trial (RCT) to determine if the main effect for the intervention was significant over the four day time period. The data to be analyzed were: self-reported measures of anxiety taken from the 7-item Modified Generalized Anxiety Disorders scale (GAD-7), stress, taken from the 10-item Modified Perceived Stress Scale (PSS-10), pain, taken from the Numeric Rating Scale (NRS), medical records documentation of medication usage, and selected physiological data of hospital SCD adults experiencing a VOPE. For the anxiety and stress measures, an independent sample t-test was used to compare the baseline, day 2 and day 4 mean scores between the treatment and control groups. For the pain intensity and physiological variables, change scores were computed between pre and post intervention at each treatment day, and a paired sample t-test was used to compare the mean change at each day between the two groups. A one-way analysis of variance was used to compare the total mean equianalgesic opioid medication during the four days of the study between the two groups. In summary, this analysis compared the two intervention groups to determine the effectiveness of each in reducing anxiety, stress and/or pain and if this change was different between the two study groups over the four-day period.

Gap in the Research

Most of the research being done in SCD has been conducted to better understand the disease process in hopes of being able to find a cure or at least reduce the number and severity of its complications. There has been limited research into non-invasive therapies, except for the work done in cognitive-behavioral therapies (CBT). These CBTs have focused on reducing symptoms or on assisting SCD patients in coping with the disease. No studies have been found using HT for reducing anxiety, stress, pain, and equianalgesic opioid medication usage in the hospitalized SCD adult population experiencing a VOPE. The cost of invasive interventions, the risk of complications, and the loss of time from work or school to visit healthcare facilities for treatments all add to the need for a more cost-effective treatment.

This research is important because there have been only a limited number of well-designed, adequately-powered, clinical trials addressing the effects of HT on the patient's physical outcomes (i. e. anxiety, stress, and pain). Of the work that has been done with HT, many of the studies have not been published in peer reviewed, research-based journals or if published, lacked vital information, resulting in problems with both internal and external validity (Wardell & Weymouth, 2004). Some of the studies reported small sample sizes, inadequate controls for effects from other variables such as the practitioner's presence, or the placebo effect (Cook, Guerrerio, & Slater, 2004) and generally lacked adequate methodological rigor. The research design in the present study is an attempt to address these areas of limitations by using an ACM group to address the extraneous variable of presence and address the distractors such as excessive noise in the acute care setting with the addition of background music. Healing

Touch is an energy-based therapy, but a quantitative measure of actual energy exchange or movement is difficult to obtain. This is why controlling for the variable of music and presence will allow the researcher to establish that the only difference in the two groups is the HT intervention that was given.

Much of the research done in HT has been conducted with cancer, cardiovascular, endocrine/ immune/HIV patients and the elderly or dying, looking at the reduction of anxiety and pain. What has not been examined is the effect of HT on anxiety, stress, pain, equianalgesic opioid medication usage, and physiological measures in hospitalized SCD adults experiencing a VOPE. Lastly, since no research has been done with HT in the SCD population, the safety of this type of intervention has not been determined; therefore this study will contribute to the knowledge about the safety of this type of intervention in the hospitalized SCD adult experiencing a VOPE.

Significance of Study

Sickle cell disease is a devastating illness and current management is directed toward invasive treatments, which carry many possible complications. The identification of a non-invasive, cost-effective, complementary therapy such as HT, adds to the various treatment options available to the bedside nurse. Pain, a major distressor in this patient population, is under-treated (Jacob, 2001) and has been found to be related to an increase in mortality and morbidity (Platt et al., 1994), therefore reducing the number of pain episodes and the amount of pain would improve overall patient outcomes. Healing Touch has been shown to reduce anxiety, stress, and pain in other patient populations; therefore it is hypothesized that it will also reduce these same stressors, anxiety and stress, in the hospitalized SCD adults experiencing a VOPE.

Based on findings from previous studies looking at behaviorally based psychosocial approaches in the treatment of SCD pain, the importance of this study is in determining the effect of HT on anxiety and stress (i.e. psychological issues) on SCD pain and emphasizes the need to quantify the impact of psychological interventional strategies in the management of SCD pain. Music is used to provide a distraction to the ambient noise level of the acute care setting, but since it is also a psychotherapeutic intervention, this effect must be accounted for in order to determine the true effect of the HT intervention.

Summary

Healing Touch, a non-invasive nursing intervention, was examined to determine its effectiveness on anxiety, stress, pain, equianalgesic opioid medication usage, and physiological measures in hospitalized SCD adults experiencing a VOPE. The literature reveals that many physical as well as psychosocial factors create stress in the SCD patient population, which triggers a SCD pain episode (Edwards, Fillingim, & Keefe, 2001). By identifying these stress factors, which interrupt the patient's energy field, HT can reorient this energy within the patient's internal and external environments, thereby strengthening their lines of resistance or lines of defense, promoting self-healing and wellness. This study examined the effectiveness and safety of the complementary therapy, HT, in the hospitalized SCD adult experiencing a VOPE in addressing the patient as a whole system.

CHAPTER 2: REVIEW OF LITERATURE

The purpose of this pilot study was to examine the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, pain medication usage, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE. The effect of HT on the outcome variables were measured by 1) selected physiological parameters, 2) self-reported levels of anxiety, stress, and pain, as well as 3) equianalgesic opioid medication received during the study period, while controlling for the variables music and presence.

This chapter discusses the relevant literature in each of the three main sections. The first section discusses SCD and the problems encountered by SCD adults experiencing a VOPE, along with the current treatment options, both pharmacological and non-pharmacological, in order to establish why there is a need to evaluate new treatment options in this patient population. It also examines the role that stress and anxiety play in the SCD adult experiencing a VOPE. The second section looks at complementary therapies, specifically the proposed intervention for the study, HT, as well as the accumulative effect of the addition of music to the control group. The first portion of this section examines Therapeutic Touch (TT), because much of the earlier work with energy was done with TT and laid the groundwork for HT. This is followed by the current literature on HT and the work that has been done with HT on anxiety and stress, as well as pain, in other patient populations such as cancer patients, post-operative orthopedic and cardiovascular patients. The second half examines the literature on music as a healing modality and its effect on anxiety and pain as well as

the effect of presence. Finally, the third section of this review explores Betty Neuman's theoretical framework in order to establish the theoretical basis for this study. The following review supports the importance of this study because of the limited number of non-invasive nursing interventions found in the literature.

Sickle Cell Disease

The management of SCD is targeted toward two aspects of the disease, prevention of complications and the management of pain episodes. This study only focused on the non-invasive nursing intervention HT with hospitalized SCD adults, therefore the management techniques specific to younger children is not discussed. The focus of this portion of the literature review, however, is on the treatment options, pharmacological and non-pharmacological, specific to relief of the symptoms of hospitalized SCD adults experiencing a VOPE.

Sickle cell disease (SCD) is a major healthcare problem affecting approximately one out of every 375 African-Americans in the United States (Edwards et al., 2005), as well as a small portion of the population from the Caribbean, Southern Europe, the Mediterranean area, the Middle East, and India (NAHAT, 1991). This worldwide health problem affects both men and women of all ages across their entire lifespan. The major complication of SCD is the occlusion of the vascular beds and the resultant ischemia, which causes the VOPE most often experienced in the back, chest, abdomen, and legs (Metha, Afenyi-Annan, Byrns, & Lottenberg, 2006; Steinberg & Brugnara, 2003). The optimal management of SCD requires a multidisciplinary team approach due to the multidimensional aspect of the reoccurring SCD pain, related to the biological,

psychological, behavioral, social, and cultural components of the disease (Yale, Nagib, & Guthrie, 2000).

Sickle Cell Disease – Anxiety and Pain

Examining pain coping strategies in SCD patients, Gil, Abrams, Phillips, and Keefe (1989) found a significant correlation between the psychological distress factors, one of which was anxiety and the negative thinking and passive adherence factors to the number of pain episodes, their duration, and the severity of pain. These biological and psychosocial processes experienced by SCD adults have been shown to cause anxiety (Thompson, Gil, Abrams, & Phillips, 1992; Vichinsky, Johnson & Lubin, 1982) in regard to their illness. The role of these negative emotions and stressful life experiences in the activation of a neurophysiologic stimulus (i.e. anxiety) and the body's pathologic responses in the precipitation, exacerbation, and prolonging of VOPE needs to be examined (McCae & Lumley, 1998). It has been documented that anxiety can increase pain (Thomas, Heath, Rose, & Fiery, 1995; Thomas, Wilson-Barnett, & Goodhart, 1998) and that these negative emotions (i.e. anxiety, stress) can increase pain medication usage, visits to the Emergency Departments, and hospitalizations, and that simply managing the physical aspects of VOPE will not improve the person's quality of life (Gil et al., 2004). Research on anxiety and its impact on VOPE however, has not been firmly established in the literature (Anie, 2005; Leavell & Ford, 1983), which supports the premise of this study that stress and anxiety need to be investigated further as to their interrelatedness to pain in the SCD patient.

Sickle Cell Disease – Stress and Pain

Pain episodes can be triggered by a variety of causes, such as an infection, physical or emotional stress, extreme temperatures, or for no known reason (Steinberg, 1999). Life stress has been found to markedly increase the probability of developing SCD symptoms (Leavell & Ford, 1983). In examining the psychosocial stressors, previous research has proposed that increases in stress resulted in increases in pain, and that these stressors can be used to predict the onset of pain (Gil et al., 2003; Porter, Gil, Carson, Anthony, & Ready, 2000; Porter et al., 1998). Higher levels of daily stress were shown to predict pain severity with participants experiencing an average of 6.5 days with pain and a pain intensity of 4.4 on a 0 to 10-point scale during the painful episode (Porter et al., 1998). Looking at whether stress predicts pain, Gil et al. (2004) found that there were bi-directional effects indicating that pain leads to fluctuation in stress, thereby leading to a subsequent escalation of pain. This study recommended that further research be conducted in the relationships of stress and pain to the biopsychosocial mechanisms that underlie these stressors, which supports the need for the current study.

Sickle cell disease patients, a health disparity population, are vulnerable to the biases of healthcare providers who fear their potential for addiction (Elander & Midence, 1996; Shapiro & Ballas, 1994), resulting in inadequate pain management. The interruption of normal routines and repeated hospital admissions due to VOPE create a stressful time, which can precipitate more pain episodes. These VOPE have been found to have a negative impact on patients' quality of life and increase their overall morbidity and mortality (Ballas & Lusardi, 2005). This study suggests that the standard of care for

the management of pain in SCD patients should also focus on exploring new treatment options for improving the SCD patients' pain, by addressing both internal and external environmental factors such as anxiety and stress as precipitating factors.

Because VOPE impact patients physically, psychologically, emotionally, socially, and financially, there is a need to explore all possible options for treatment of these episodes. In this study, the social and financial impacts of SCD were not explored. Instead, the effect of Healing Touch on the physiological, psychological, and emotional aspects (e.g. anxiety, stress) of SCD patients experiencing a VOPE was examined.

Current Management of VOPE in Sickle Cell Disease

Pharmacological treatment for VOPE.

There is currently no standard treatment method for the acute pain episodes of SCD; each patient is treated individually. Treatments for sickle cell patients having a VOPE focus on treating the physiological aspects with pharmacological methods. In a meta-analysis of randomized controlled trials (RCTs) between 1965 and June 2002 conducted by Dunlop and Bennett (2007), the types of interventions assessed were all pharmacological analgesics, including: non-opioid analgesics, weak opioids, and strong opioids. Co-analgesics such as corticosteroids, antidepressants, and anticonvulsants were also examined in this review. The results of this study revealed that no particular analgesic intervention provided complete relief from acute sickle cell pain (Dunlop & Bennett, 2007), therefore the most commonly used regimen is: treating the cause, giving analgesic-drug therapy promptly, replacing fluids as necessary, treating the pain with opiates, and considering the use of adjunctive therapy such as anti-nausea, non-steroidal anti-inflammatory drugs or sedatives and anxiolytics (Ballas, 1998; Elander &

Midence, 1996). These adjunct therapies are used to increase the analgesic effect of opioids, reduce the side effects of primary medications, or manage associated symptoms such as anxiety.

Another treatment option that has been reported in the literature for VOPE in SCD adults is transfusion therapy to treat the hypoxia associated most often with acute chest syndrome. Treatment options such as hydroxyurea aim to prevent complications by increasing the amount of “good” hemoglobin, hemoglobin F, thereby reducing the amount of sickling (Metha et al., 2006; Steinberg & Brugnara, 2003). One final treatment discussed is bone marrow transplantation and the transplantation of cord-blood stem cells, but the research on these treatment options versus the conventional treatment is still fairly new and continues to be studied (Dunlop & Bennett, 2007; Steinberg & Brugnara, 2003). Although bone marrow transplantation can be a cure, the availability of donors, the complications, and risk involved limit its use. The need to explore new treatment options that are non-invasive, that can limit the number of side effects, and present minimal risk was one of the reasons for this study.

Non-pharmacological treatment for VOPE.

Non-pharmacological treatment options being used are: self-hypnosis, biofeedback, acupuncture, and transcutaneous electrical nerve stimulation (TENS). The findings on the effectiveness of these pain management treatment options were mixed, but generally encouraging (Elander & Midence, 1996). The self-hypnosis and biofeedback along with progressive muscle relaxation (PMR) and cognitive strategies enable participants to raise their peripheral body temperature by visualizing vasodilation of peripheral vessels, and have been shown to decrease hospitalizations and

medication usage as well as physiological changes which were associated with anxiety and pain intensity (Elander & Midence, 1996). The use of non-pharmacological treatment methods have shown promise, but again no studies were found using HT in relation to anxiety, stress, or pain management in SCD patients.

Psychological therapies for SCD.

While psychological interventions with SCD patients have yielded encouraging results, only a limited number of studies have been conducted on the impact of including these interventions in the medical treatment for SCD patients. In a systematic review of the literature to determine what research had been conducted on the effects of psychological therapies on SCD pain, Anie and Green (2006) found a significant reduction in the affective component of pain, providing some evidence for the efficacy of psychological interventions in SCD. However, the quality of the studies precluded definitive conclusions and more well-designed, adequately powered, multi-center randomized controlled trials are needed to assess the importance of psychological interventions relevant to the different SCD groups.

A literature review by Edwards et al. (2005) describes the pathophysiology of SCD. The authors outline the impact SCD has on the public health system and the significance of psychosocial issues in the management of the disease. Again, this study showed that psychological and social factors contribute to the SCD patient's complaints of pain, and that a more comprehensive approach to the management of SCD pain is needed.

The analysis of behavioral and interpersonal influences on pain management in the literature review by Elander and Midence (1996) showed that patients' different

styles of thinking about pain affected their ability to manage their pain. A recommendation for further research in pain management for SCD patients using cognitive and behavioral coping strategies to reduce pain was suggested. This supports the purpose of this study, which was to examine the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, pain medication usage, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE.

Understanding the dynamic relationship between psychological stressors and the pathophysiology of SCD is necessary in order to conceptualize the basic needs of the SCD patient. Early intervention on the psychological stressors, anxiety and stress, are thought to prevent the manifestations and psychosocial complications in SCD (Edwards et al., 2005). In summary, most of the current research on management of SCD is looking at invasive techniques such as the administration of high dose IV methylprednisolone, IV hydroxyurea, blood transfusions, or bone marrow transplantation, which carry much higher complication rates. The focus in non-pharmacological research has been directed toward cognitive-behavioral techniques, primarily coping strategies for the SCD patient. Other non-pharmacological treatment options that are currently in use, such as self-hypnosis and thermal biofeedback (Cozzi, Tryon, & Sedlacek, 1987), have limited data to support their use, but a few small group clinical trials have shown some positive results. No research was found that reported the use of Healing Touch for the management of anxiety, stress, and pain in the hospitalized SCD adults experiencing a VOPE.

Complementary Therapies

This next section focuses on the previous research in the area of complementary therapies in an effort to establish what work has been done in energy-based therapies. The use of complementary and alternative medicine (CAM) has been defined as those interventions or health care practices that are not integrated into the predominant healthcare model because of societal beliefs and practices (Dossey, Keegan, & Guzzetta, 2005). In 1992, The Office of Alternative Medicine (OAM) was created by The National Institute of Health (NIH) to evaluate the various types of alternative therapies. In 1993, OAM was renamed the National Center for Complementary and Alternative Medicine (NCCAM), and its mission is to study CAM therapies being widely used by the public to determine which of these therapies are safe, beneficial, and cost-effective. CAM therapies are adjuncts to conventional medicine and can allow healthcare providers to expand treatment strategies in the care of the patient (NCCAM, 2008). The purpose of this pilot study was to examine the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, pain medication usage, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE. The effect of HT on the outcome variables was measured by 1) selected physiological parameters, 2) self-reported levels of anxiety, stress, and pain, as well as 3) equianalgesic opioid medication received during the study period, while controlling for the variables music and presence.

Complementary Therapy - Therapeutic Touch

Healing Touch, which is derived from Therapeutic Touch (TT), uses the concepts of energy fields that surround the body, and is an energy-based therapy that can involve touching or not touching the patient in order to re-pattern these energy fields. Therapeutic Touch is included in this literature review because it laid the groundwork for current research in this area of energetic healing and provided the basis for much of the HT research that has followed this earlier work.

One of the first comprehensive reviews of TT research looked at studies conducted between the years of 1974 to 1986 (Quinn, 1988). Quinn examined the operational definition of TT along with the theoretical frameworks used to explain and predict its outcome. Quinn related that the foundation for future research had been established with the consistent expansion of each new study. Quinn examined one of the earlier studies (Krieger, 1979), which looked at the effect of TT on hemoglobin in hospitalized adults and found a significant increase in hemoglobin in the TT group. Another area of research which Quinn examined was studies done by Heidt, Parkes, and Quinn, who researched the effect of anxiety on different patient populations to determine what effect working with the energy fields using TT had on anxiety. Heidt's experimental study examined anxiety in adult hospitalized cardiovascular patients, while Quinn's experimental study examined anxiety in adult hospitalized cardiovascular patients using non-contact TT. Heidt (1981) and Quinn (1982, 1984, 1988b) both found a decrease in the level of anxiety in the patient population that was studied. A third study by Parkes (1985) found no significant effect of TT on the anxiety level in gerontological hospitalized patients compared to those in the control group.

In the area of stress, Quinn examined two earlier studies and found differing effects on the two patient populations studied. Randolph's (1979) study on the effect of TT on the physiologic response to stressful stimuli in college students showed no significant difference between the groups, while Fedoruk's (1984) quasi-experimental study, examined the effect of non-contact TT on neonates' stress and found significant differences in their responses.

The last content area examined by Quinn in her review was the effect of TT on pain, in which conflicting results were found. Meehan (1985) reported no significant differences in pain scores between the intervention and control groups in their adult post-operative patients, while Keller and Bzdek's (1986) experimental study found a significant decrease in tension headache pain in adult patients as compared to the control group. In summary, based on these early studies, there is a need to continue building the body of knowledge about energy medicine like TT and HT in order to better understand the effect of this phenomenon. This current study contributes to the body of knowledge of the effect of one type of energetic healing practice, HT.

More recently, two different meta-analyses of TT were conducted. Peters (1999) examined the published evidence supporting TT as a nursing intervention, while Winstead-Fry and Kijek (1999) conducted a meta-analyses and an integrative review examining research design and outcomes of TT. In the meta-analysis done by Peters, numerous limitations were found, including small sample sizes, which made it impossible to accurately identify a statistically significant effect. Four major weaknesses were noted that needed to be addressed in future TT research, including: sampling procedures (lack of randomization), practitioner skill level, intervention practices (no

time limit to the intervention), and the under-reporting of data, which hampered analysis and the ability to determine the effectiveness of the interventions.

The meta-analysis reported by Winstead-Fry and Kijek (1999) supported the findings of Peters. The samples were described incompletely and intervention practices varied from study to study, making it impossible to do comparisons. The study did look at a meta-analysis on 13 of the studies, which reported means and standard deviations of treatment and control groups. On average, a moderate effect size (.39) was noted and using the chi-square test, the combined effect was analyzed and found to be statistically significant ($p < .001$), indicating a high degree of variation among the studies. The authors noted that without "standardizing the treatment" the researcher could be measuring something besides the TT intervention. The authors recommended more randomized clinical trials or other outcomes research methodologies, with attention to internal and external validity, clear operational definitions and valid, reliable measures of the outcomes for TT. The design for this study addressed many of the limitations that were identified in this earlier work.

Complementary Therapy - Healing Touch

Healing Touch, the intervention for this study, is the focus for the next section in this review. Healing Touch is a type of complementary, energy-based therapy that works with the energy fields that surround the body, re-patterning and re-aligning the fields, thus restoring harmony and balance to the human energy system. Healing Touch was developed in 1980 by Janet Mentgen, BSN, RN (Mentgen, 2001). It began as a certificate program sponsored by the American Holistic Nurses Association (AHNA) in 1989. In 1993, the AHNA began to provide certification for healing touch practitioners.

Then in 1996, Healing Touch International, Inc. became the certifying authority with AHNA's endorsement (HTI, 2007). The certifying board, Healing Touch International, uses standardized criteria to acknowledge learning experiences and demonstration of competence as a Healing Touch Practitioner (Hoover-Kramer, 2002). In 2007 Healing Touch Program (HTP) and Healing Touch International (HTI) split and became two separate entities with separate certifying bodies: Certified Healing Touch Practitioner (CHTP) from HTI or Healing Touch Certified Practitioner (HTCP) from HTP.

Research on the efficacy of HT is still very new, and while only about 70-plus research-based studies/articles have been published on the effect of HT in the past 20 years, the research thus far is promising. Healing Touch, a complementary therapy derived from Therapeutic Touch, has been shown to decrease anxiety, stress, and pain in areas such as cancer, orthopedic, and post-cardiac surgery patients, but no studies have been conducted in the area of sickle cell pain. The purpose of this pilot study was to examine the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, pain medication usage, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE. The effect of HT on the outcome variables was measured by 1) selected physiological parameters, 2) self-reported levels of anxiety, stress, and pain, as well as 3) equianalgesic opioid medication received during the study period, while controlling for the variables music and presence.

In this study, the proposition for the conceptual framework based on Betty Neuman's Health Care System Model was:

If HT in other patient populations has been shown to:

- Reduce anxiety (a psychological stressor) (Post-White et al., 2003; Welcher & Kish, 2001), and
- Reduce stress (a psychological stressor) (Dowd, Kolcaba, Steiner, & Fashinpaur, 2007; Wilkinson et al., 2002), and
- Reduce pain (a physiological stressor) (Darbonne, 1997; Merritt & Randall, 2002; Slater, 1996; Wardell, Rintala, Daun & Tan, 2006),
- Then HT, through its repatterning of the energy field, will strengthen the lines of resistance and the lines of defense, thus reducing the psychologiacal stressors, anxiety and stress, and thereby reducing the frequency and severity of the pain experiences in this SCD patient population experiencing a VOPE (Platt et al., 1994)

Studies of energy-based modalities that have been conducted suggest that energetic healing techniques like HT are effective (Engebretson & Wardell, 2007). A literature review of published quantitative research on HT from 1996 to June 2003, excluding case studies and qualitative works, was conducted by Wardell and Weymouth (2004). Thirty-two studies using HT as an intervention were described, but due to limitations/weakness in the design and/or methods, the authors reported that the results of the studies were promising, but non-conclusive. Many of them lacked vital information, resulting in weakness in their internal and external validity. Even though the studies were not well designed, HT had an overall effect on levels of stress, anxiety, and pain, as well as improved healing and improvement in other physiological

parameters. The following is an analysis of the research that has been done with HT in the areas of anxiety, stress, and pain.

Healing Touch - effect on anxiety and pain.

Many of the Healing Touch research studies have been conducted with cancer patients and the side effects from cancer treatments. A randomized crossover intervention study by Post-White et al. (2003) examined the effects of HT and therapeutic massage on anxiety and pain in 230 chemotherapy patients as compared to a caring presence or a standard cancer treatment alone. The authors found a significant reduction in immediate pain after the HT session, as well as after the massage intervention, but there was no significant difference in the overall pain index one month after each intervention. HT and massage therapy (MT) both reduced anxiety during the interventions, but only the massage group reached significance. The authors concluded that both HT and massage were more effective than the presence of a caring professional alone or standard care in inducing a relaxed state and reducing short-term pain and anxiety in adult cancer patients undergoing chemotherapy. The authors recommended that even though the study provided support for the short-term effects of MT and HT, further study is needed to test for long-term effects. In this present study, only two of these stressors evaluated above, anxiety and stress, were examined to determine their effect on the patient's ability to reduce pain by strengthening their lines of defense during their hospital stay.

Several studies (Merritt & Randal, 2002; Slater, 1996; Stouffer, 2004; Welcher and Kish, 2001) examining the before and after effect of the HT intervention on either anxiety and/or pain reported significantly decreased effects in patients with differing

diagnoses. Sixty-two women receiving radiation treatment for breast cancer in a randomized controlled trial (Cook, Guerrerio, & Slater, 2004) were given non-contact HT or Mock treatments to determine the effect of HT. The HT group reported better outcomes with statistically significant differences in the areas of pain in the HT group compared to the Mock/control group. The result of this study lends support to the use of HT to improve factors such as quality of life and pain in cancer patients.

In examining the effect of HT and progressive relaxation on chronic neuropathic pain in persons with spinal cord injury, Wardell, Rintala, Daun & Tan's (2006) pilot study looked at twelve participants who were randomly assigned to six sessions with either the HT treatment group or the guided progressive relaxation group. A significant difference was found in the composite of interference on the Brief Pain Inventory (BPI). The reduction in pain was seen in both treatment groups, but the pain intensity returned to pretreatment levels before the next session. The authors reported that the HT group showed improvement in all outcome measures, but they did not reach significance and further studies are needed.

Although there was limited research found on the effect of HT on anxiety, the studies reported here showed a decrease in anxiety after the HT intervention. Due to this limited amount of research, the need for further studies in this area has been established.

Healing Touch - effect on stress.

Wilkinson et al. (2002) conducted a quasi-experimental study examining the effect of the nurse practitioner's training and the effectiveness of HT on the reduction of stress in three treatment groups: no treatment (NT), HT only (standard HT care), and

Standard HT care plus music and guided imagery, was conducted by using the immune function (secretory IgA) as an outcome measure for stress reduction. The results showed a statistically significant effect on the reduction of stress levels with both HT conditions. Analysis of the qualitative data revealed themes of relaxation, connection, and enhanced awareness. One of the limitations noted in this study was that some of the practitioners had training in other energy healing modalities such as reiki, and this could have influenced the quality of the treatments.

Another study looking at stress compared HT and coaching for enhancing holistic comfort and reducing symptoms of stress in young college students (Dowd, Kolcaba, Steiner, and Fashinpaur, 2007). This experimental study revealed that all groups were the same on stress, but after the intervention, the HT group had the greatest percentage of decrease in stress, which was statistically significant. The findings revealed that HT had a better immediate result on stress and comfort, but that coaching had a better long-term effect. Several other studies done with HT looking at it across a time span of a week or more (Dubrey, 2003; Dubrey, 2006) reported a reduction in stress as well as pain in different patient populations (i.e. recovering from alcoholism, patients in a community-based practice).

In examining the literature on stress and HT, the results tend to suggest that HT does relieve stress even though some of the studies did not reach a statistically significant result. Additional studies on the effect of HT on stress need to be conducted to determine if reduction of stress will have an effect on the reduction of pain, which was the proposition examined in this study with the adult SCD patient population.

In summary, there are many more HT research studies that have been done or are currently being conducted in a variety of areas such as: cancer, cardiovascular, studies on death, dying, palliative care, the elderly, autoimmune disorders, HIV, endocrine problems, orthopedics, patient satisfaction, pediatrics, post operative, and psychology. Preliminary work in all these areas lends validity to establishing HT as an evidenced based treatment option, but there are still areas to be explored. To date, no published research has been found that has addressed the anxiety and stress of SCD patients or how reducing these symptoms can impact their pain. The focus of this RCT pilot study was to examine the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, pain medication usage, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE. The effect of HT on the outcome variables was measured by 1) selected physiological parameters, 2) self-reported levels of anxiety, stress, and pain, as well as 3) equianalgesic opioid medication received during the study period, while controlling for the variables music and presence. The work with HT in the area of reducing pain has been with patients whose pain typically has been either due to cancer or surgical procedures such as that experienced by post-cardiac surgery patients or post-operative orthopedic patients. Sickle cell disease pain, although similar to cardiac disease pain, ischemic in nature, has not been studied. The importance of this study in looking at the effect of HT on anxiety, stress, and pain is that this type of ischemic pain has not been well studied and no research has been found in the literature examining this issue in SCD patients.

In addressing the paucity of knowledge in the use of a complementary therapy, HT, in the reduction of anxiety, stress, and pain in the hospitalized SCD adult patient, this study has the capacity to contribute to the body of knowledge on the effectiveness of HT on pain relief in the SCD patient population. The study also provides information about the safety of this type of intervention and builds on previous work.

Complementary Therapy - Music

Music as a therapeutic intervention has been used throughout the ages from the Biblical account of David's harp music calming Saul (1 Samuel 16:22) to the Greek myth of Orpheus and the lyre that Apollo, the god of music, gave him. In Greek mythology, music was thought to have the power to help heal the mind, body, and spirit. Interestingly, Apollo's son Aesculapius was the god of healing and medicine (Dossey, Keegan, & Guzzetta, 2005). Music as a nursing intervention began with Florence Nightingale when she taught nurses that the effect of music on the sick was usually beneficial and could take away nervous irritations (Nightingale, 1860). Even today, music therapy, listed as sound energy therapy, sometimes referred to as vibrational or frequency therapy has been shown to help reduce pain and anxiety (NCCAM, 2008).

Music - effect on anxiety and pain.

Music is a type of complementary healing therapy that uses an intentional auditory stimulus to affect both the patient's physiological and psychological outcomes (Kemper & Danhauer, 2005). The psychophysiologic responses created by the vibrational aspect of music's key elements, pitch and rhythm, can influence the limbic system (the center of emotions), evoking memories, and stimulating the neurohormonal system to release endorphins. Music has been used in various age groups including

premature infants (Lorch et al., 1994), children (Malone, 1996), and adults (Cowan, 1991) for various conditions and procedures. The anxiolytic effect of music is seen as a physiological reduction in heart rate, blood pressure, respiratory rate, and oxygen consumption due to the release of endorphins and decrease in catecholamine levels (Chlan, 1998; Dossey, Keegan, & Guzzetta, 2005; McCaffery & Good, 2000; Updike, 1990). Music has also been reported to improve motivation, elevate mood, and increase feeling of responsibility (Bailey, 1986; Dossey, Keegan, & Guzzetta, 2005).

Evans (2002) conducted a systematic review on the effectiveness of music for hospital patients and found a total of 19 studies, which demonstrated the effectiveness of music for the reduction of anxiety during normal care delivery, but found there was a lack of evidence supporting music as an intervention itself. The effect of music on anxiety and stress was examined by Updike (1990), who found that after listening to music there were significant decreases in one indicator of anxiety and stress, the blood pressure, both systolic and diastolic. In a study comparing the effects of progressive muscle relaxation (PMR) to PMR with music, and just music therapy alone, it was found that all three interventions produced significant changes in anxiety and perceived relaxation in the pre/post-test period, but there were no differences among the groups (Robb, 2000). More recently, Richards, Johnson, Sparks, and Emerson (2007) conducted an extensive review from 1991 to 2004 to identify the clinical benefit of using music therapy in the hospital setting, focusing on pain, anxiety, and patient satisfaction. The review included ten articles, which supported the potential positive impact of music therapy in the health care setting. Six of the articles reported a reduction in the level of

anxiety, but only one study, Smolen, Topp, and Singer's (2002), reached statistical significance.

In summary, even though numerous studies have shown a decrease in anxiety (Gillen, Biley, & Allen, 2008; White, 1992; White, 1999; Wong, Lopex-Nahas, & Molassiotis, 2001), but not all of them reached statistical significance. No studies were found using music to reduce anxiety, stress, or pain for SCD adults experiencing a VOPE.

Music - effect on pain.

Music is thought to produce pain relief by facilitating release of endorphins, which are the body's natural opioid pain relievers, or by occupying sensory neurons, blocking the transmission of painful messages (Chlan, 1998). A significant difference in pain intensity has been shown with the use of music in a study of post cardiac surgery patients (Sendelbach et al., 2006) as well as in patients undergoing compression with a C-clamp after percutaneous cardiac intervention (Chang, Wong, Chan, et al., 2006). A Cochrane review conducted by Cepeda, Carr, Lau, and Alvarez (2006) examined fifty-one randomized controlled trials evaluating the effect of music on any type of pain in children or adults. This review concluded that listening to music does reduce pain intensity levels and opioid requirements, but the magnitude of these benefits, even after pooling of the studies with clinical and statistical homogeneity, was small, therefore the clinical importance is unclear.

Even though numerous studies have shown a decrease in anxiety, stress, and pain, not all of them reached statistical significance. Music therapy's effectiveness in subgroups of patients with higher levels of anxiety, stress, or pain, like those in this

study with SCD (Bally, Campbell, Chesnick, & Trannier, 2003), was addressed by providing music in both groups. By comparing the HT group with music and presence to the control group with music and presence alone, the change in the outcome measures between the two groups can be shown to be the result of HT, since the music used to reduce outside distractions and the physical presence of the RA was the same in both groups. No studies were found using music to reduce anxiety, stress, or pain for SCD adults experiencing a VOPE. The intervention piloted for this study was the effect of the non-invasive intervention, HT plus music, on anxiety and stress in the reduction of pain in hospitalized SCD adults experiencing a VOPE.

Presence.

The concept of presence entered nursing in the early 1960s and has been defined by using several different perspectives: a philosophical perspective (based on work by Marcel and Heidegger); a social science perspective (having a physical and psychological attachment to another, requiring openness between them); and from a spiritual ministry perspective for both nursing and non-nursing (Kostovich, 2002; Smith, 2001). Watson (1985) described presence from her concept of transpersonal caring in which there is a human-to-human relationship, where each person is fully present and feels a connection between them. Three levels of presence have been described by McKivergin and Daubenmire (1994), physical presence, psychological presence, and therapeutic presence. The concept of therapeutic presence entered the mainstream of nursing without clear definition and with little critical examination or evidence-based analysis (MacDonald du Mont, 2002). Exactly how therapeutic presence impacts the

outcomes seen in complementary interventions such as HT or music is still being addressed in the literature.

This review will focus on the nursing perspective of therapeutic presence as it relates to the nurse-patient relationship. For purposes of this study, therapeutic presence is defined as a way of being with another person, fully present in body, mind and spirit, open to the situation (Paterson & Zderad, 1976), setting intentionality for the patient's highest good, and developing a trusting relationship (McKivergen & Daubenmire, 1994). A review of the literature reveals a general consensus that when the nurse-patient relationship is examined using the component of presence, the relationship is perceived as having a positive impact on patients and their healing process. Osterman and Schwartz-Barcott (1996) describe four ways of being present: presence, partial presence, full presence, and transcendent presence. One of these, "transcendent presence," is thought to have a positive change in the affective state, therefore decreasing anxiety because of the peaceful, comforting feeling it creates.

More recently Easter (2000) described four modes of being present: physical, therapeutic, holistic, and spiritual. Fredriksson (1999) expands on this concept and identifies two sub-concepts of "being there" and "being with." "Being there" incorporates physical presence and includes communication and understanding, which produces the patient outcomes of: a sense of being heard, encouragement, motivation, and decreased feelings of loneliness and isolation (Pettigrew, 1990). "Being with" encompasses "interpersonal and intersubjective modes of being" that "makes available a space where the patient can be in deep contact with his/her suffering, share it with a caring other, and find his/her own way forward" (Fredriksson, 1999, p. 1171). Having

established a therapeutic presence between the nurse and the patient, the current literature suggests that this will also improve patient satisfaction and improve patient outcomes. The beneficial outcomes for the patients have been described as feelings of support, hope, relaxation, and the ability to cope better (Hines, 1992; Rogers, 1996). Much of the research that has been done on presence has been related to the interaction between the nurse and the patient. Little research has been done on exactly how this interaction impacts the physiological outcomes of the patient. Regardless, presence has been identified as an "intense and powerful phenomenon that can make a significant difference in the patient's experience" (Mohnkern, 1992, p. 182). Therefore, to account for this powerful effect of presence on the patient, in this study a RA was physically present during both interventions.

Theoretical Framework

The theoretical framework chosen for this study was Betty Neuman's Systems Model. Neuman's model was developed in 1970 as a nursing conceptual model in response to a request by graduate students at University of California, Los Angeles (UCLA) to help them better understand the concept of a wholistic approach to wellness. First published in 1972 as a conceptual framework for examining the interactions between people and their environment, Neuman describes this dynamic interaction as one in which the patient's core or basic structure is protected from stressors by their lines of defense and resistance (Neuman & Fawcett, 2002). Neuman's model is based on her own philosophical beliefs, clinical experiences, and personal views as well as ideas from a variety of sources which Neuman and Fawcett (2002) discuss. Examples of some of the various sources are the General System Theory, the Gestalt Theory,

portions of de Chardin's philosophy and Selye's definition of stress. The General System Theory is a process in which living organisms interact with each other and the environment (Bertalanffy, 1968). Neuman also used the Gestalt Theory, which deals with the process in which an organism maintains its dynamic equilibrium or homeostasis (Perls, 1973). Another influenced on Neuman's work was de Chardin's philosophy on the wholeness of life, which states the parts are determined partially by the whole (de Chardin, 2002). In defining stress for her model Neuman used Selye's (1974) definition of stress, the body's response to any demand made on it. And lastly, Neuman adapted Caplan's (1964) conceptual model of the levels of primary, secondary, and tertiary prevention for use in her model. This philosophical approach encompasses the idea of wholism, balance, homeostasis, and wellness for the client, all of which are maintained by their lines of resistance and defense in response to their environment.

The environment as defined by Neuman is one having three dimensions: the internal environment (found within the patient), the external environment (found outside the patient), and the created environment (an environment that is created and developed unconsciously by the patient), which surrounds the patient or patient's system. A stressor, anything that can affect the stability of the system, can be divided into intrapersonal (occurs within the person), interpersonal (occurs between individuals), or extrapersonal (occurs outside the individual). The patient's reaction to the stressor depends in part on the strength of their lines of resistance and defense. According to Neuman's model, interventions by either the patient or the nurse are done to restore or maintain the stability of the system. Assessment of the total situation in which the patient presents requires knowing the relationship between the internal and external

environmental factors as well as the created environmental factors. Based on the assessment of these stressors, assisting the patient in making adjustments to maintain an optimal wellness level by the use of primary, secondary and tertiary prevention strategies as interventions is part of the nursing process (George, 2002; Neuman & Fawcett, 2002).

Neuman describes primary prevention as a type of health intervention given prior to the system reacting to a stressor, thereby strengthening the patient's energy (line of defense) and allowing the patient to better respond to the stressor (Neuman & Fawcett, 2002). Providing primary prevention in the form of HT to strengthen the lines of resistance and defense in order to maintain the stability of the system, thereby affecting the stressor pain, is one aspect that was not examined in this study, since the participants had already reacted to the stressor pain prior to being admitted into the hospital.

Secondary prevention as described by Neuman, however, is what occurs after the patient's system reacts to the stressor. The secondary prevention attempts to strengthen the lines of resistance so as to help the patient defend against the stressor (George, 2002; Neuman & Fawcett, 2002). The hypothesis that was examined was that HT, due to its ability to relax and restore balance within the patient's energy system, would help to decrease the factors (i.e. anxiety and stress) that caused the hospitalized SCD adult's VOPE. The effects of HT as a secondary prevention was demonstrated by a decrease in the self-reported anxiety, stress, and pain scores as well as changes in the physiological parameters.

Tertiary prevention occurs after secondary prevention has been provided. It focuses on strengthening the resistance to the stressors and preventing recurrence of the reaction, thereby providing stability to the system (George, 2002; Neuman & Fawcett, 2002). In this study HT was used as a secondary and tertiary prevention to strengthen the lines of resistance and defense in the hospitalized SCD adult experiencing a VOPE.

Neuman's focus on "prevention as the intervention" (Randell, 1992, p.177) supports the premise of this study of introducing HT as a primary or secondary intervention aimed at reducing the stress factors (stress and anxiety) in order to affect the "client-optimal system stability" (Huch, 1991, p 34). In researching the literature, Neuman's Systems Model was not identified as a conceptual framework for HT, but it can be used to explain the effects of stress factors such as anxiety and stress in the reduction of pain.

Knight (1990) used Neuman's model as the framework to guide the nursing practice/care for a multiple sclerosis patient. Due to the unpredictable nature of the disease (similar to VOPE in SCD) and its many physiological and psychological aspects, this framework assisted the nurse in being able to address the various perceptions associated with the disease process, both internal and external. Knight stated that besides using Neuman's model as a means of identifying the stressors, the caregiver's perceptions, and the appropriate interventions, it also offered a means for implementing the interventions needed to assist the patients in conserving their energy and strengthening their lines of defense and resistance.

Neuman's Systems Model has been used in many different settings to include hospitals, rehabilitation centers, nursing homes, hospice centers, as well as to guide practice internationally. It has had application in many different areas in nursing from research to clinical practice, as well as in education and administration (Alligood & Tomey, 2006). However, in conducting this literature review there was only one reference that referred to Neuman's Systems Model with the complementary therapy, HT. This was a post hoc integrative theorizing of the research by Dowd, Kolcaba, Steiner, & Fashinpaur, (2007) on their Comfort Theory by Kolcaba and Kolcaba (2008). The authors discussed Neuman's model in terms of maintenance as an important aspect of "tertiary care." It is this part of her model that gives insights into maintaining stability gained from the treatments given. In this study on the effects of HT on anxiety, stress, and pain in hospitalized SCD adults experiencing a VOPE, one assumption is that if HT does reduce the anxiety, stress, and ultimately the pain, then this technique could be taught to the participants and their families to provide this maintenance of stability through the tertiary care provided.

In summary, Betty Neuman's Systems Model was selected as the conceptual framework for this study based on her idea of the dynamic interaction between people and the environment and the mechanisms used (i.e. lines of resistance and defense) to protect the system from stressors. Healing Touch works with the energy fields that surround the person, similar to Neuman's description of the dynamic interaction between the person and the environment, supporting the body's natural ability to maintain stability, which is comparable to adjusting their lines of resistance and defense as depicted by Neuman.

CHAPTER 3: METHODOLOGY

The purpose of this pilot study was to implement a parallel-group randomized control trial (RCT) to examine the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, pain medication usage, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE compared to a usual care control group not receiving the HT intervention. This chapter is divided into the following sections: 1) study participants; 2) sample size determination; 3) study approval procedure; 4) research design, 5) instruments; 6) pre-intervention activities; 7) research assistant's training; 8) interventions; 9) random allocation procedure; 10) statistical data analysis; 11) protection of human subjects; and 12) summary.

Study Participants

A convenience sample of SCD adult patients who were experiencing a VOPE and had been admitted to a 765-bed, urban not-for-profit health care system was approached between 24-48 hours after admission to allow for time for the participants to receive initial pain control prior to being asked about enrollment into the study. Treatments were given the same day as enrollment. Inclusion criteria were:

1. Age: 18 years or greater
2. Male or female
3. Medically diagnosed with SCD (to include hemoglobin SS, SD, SC or sickle-thalassemia)
4. At least one previous hospitalization for a VOPE within the past year

5. Admitted for treatment of a VOPE
6. English speaking

Exclusion criteria were:

1. Patients with sickle cell trait instead of SCD
2. Patients who were admitted to the ICU
3. Patients who were pregnant
4. Vulnerable participants (i.e. prisoners or children under the age of 18 years)
5. Patients hospitalized for more than three days prior to notification of admission

The age group of 18 years or greater was selected for this study based on the ages of SCD patients admitted to the research facility, which was consistent with the national average life span expectancy for SCD patients, which ranges up to the age of 48 years (Platt et al. 1994). This study only examined adults because of the strict regulations concerning the use of children in clinical trials.

Sample Size Determination

The predicted number of patients available over the five-month data collection time frame determined the proposed sample size for this study, 20 in each group. A sample size of 20 is a minimum recommendation (Tabachnik & Fidell, 2001), and would only detect a moderate to large effect size. As Cohen (1988) noted, in new areas of research inquiry, effect sizes are likely to be small.

Study Approval Procedure

The Research Coordinator (RC) contacted the Chief Nursing Officer and the Nursing Research Sub-council at the facility where the research study was conducted and asked for support for the study. Once approval and support was obtained, the RC sought approval from the University and Medical Center Institutional Review Board (UMCIRB) of East Carolina University and the Institutional Review Board (IRB) at the participating research facility in southeastern North Carolina.

Research Design

A parallel-group randomized control trial (RCT) was designed to test effects of 30 minutes of healing touch with music (HTM) versus an attention control group with music (ACM), given daily over four consecutive days. A four-day time frame was chosen based on the results of a previous RCT done by Cook, Guerrerio, and Slater (2004) looking at HT and the quality of life in women receiving radiation treatments for cancer. The authors stated that the effects of HT are believed to be cumulative over time and based on the authors' clinical experience and resources; HT was given over 6 weekly sessions. This study showed HT produced statistically significant results in improving the women's vitality, pain, and physical functioning. Post-White et al. (2003) noted that the HT intervention appeared to exhibit a consistent effect over a four-week period in cancer patients. Based on the premise that HT has cumulative effects, and these effects appear to be consistent, along with the anticipated length of stay for sickle cell patients in the research facility, four daily intervention treatments were done to insure that the participants would be available to participate during the entire study time. The use of

one therapeutic musical selection to mask the environmental distractions was employed for the HT interventions in an effort to control for the environmental noise.

The independent variable Healing Touch was studied to determine its effect on the following outcome variables:

1. Anxiety
2. Stress
3. Pain
4. Pain medication usage
5. Selected physiological measures
    - Heart rate
    - Respiratory rate
    - Blood pressure
    - Oxygen saturation
    - Skin temperature (taken from index finger of dominant hand)

The data for anxiety and stress were collected prior to the first intervention and again after the intervention on days 2 and 4 (Figure 2). The pain scores and selected physiological measures were obtained before and after each intervention on all four days (Figure 3). Data for the amount of medication used was collected by retrospective chart review for each day the intervention was given. Additional demographic information (Appendix A) was collected to assess the similarity of the randomly formed groups.

Figure 2: Experimental Pretest-Posttest Design for Anxiety and Stress

	Day 1	Day 2	Day 3	Day 4
HTM Group	R –O–X	X–O	X	X–O
ACM Group	R –O–X	X–O	X	X–O

R = randomization; X = treatment; O = observation/assessment

Figure 3: Experimental Pretest-Posttest Design for Numeric Rating Scale and Physiological Measures

	Day 1	Day 2	Day 3	Day 4
HTM Group	R –O–X–O	O–X–O	O–X–O	O–X–O
ACM Group	R –O–X–O	O–X–O	O–X–O	O–X–O

R = randomization; X = treatment; O = observation/assessment

Instruments

To assess for the physiological, psychological, and socio-cultural aspects of the sample participants the following questionnaires: Modified GAD-7, Modified PSS-10, NRS and selected physiological data, as well as demographic questionnaires were completed. The additional selected physiological measures of heart rate, blood pressure, and oxygen saturation were taken using GE Medical System's Dinamap portable vital signs machine. The skin temperature was recorded using the Stress Thermometer SC911. The respiratory rate was counted for one minute and recorded as well, and all measures were collected prior to and after each HTM or ACM interventions.

The research coordinator contacted the authors of the instruments used and obtained permission to use the tools with the modifications made for this study. These instruments were chosen to establish the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, pain medication usage, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE.

The Generalized Anxiety Disorder Scale (GAD-7) consists of seven items measured on a four-point response scale ranging from 0 (not at all) to 3 (nearly every day). A total score is derived from summing across the seven items, resulting in potential scores ranging from 0 to 21, with higher scores associated with greater levels of anxiety. The developers of the new scale (Spitzer, Kroenke, Williams, & Löwe, 2006), selected nine items from the criteria for GAD listed in the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSMD-IV), along with four more items based on reviews of existing anxiety scales. This led to a 13-item questionnaire that asked patients how often they were bothered by each symptom during the previous two weeks: "not at all", "several days", "more than half the days", or "nearly every day"; these were scored 0, 1, 2, or 3, respectively. The questionnaire was administered to 2740 patients situated at 15 primary care clinics in the USA. Of these patients, 965 had a telephone interview with a mental health professional - either a PhD clinical psychologist or a senior psychiatric social worker. The professionals made independent diagnoses with estimates of severity. The scores of the 13-item questionnaire were compared with the professionals' diagnoses, and the best matching seven items were selected for the final scale, which was called the GAD-7. Analyses of sensitivity and

specificity were done. They showed that a score of 10 or more on the GAD-7 represented a reasonable cut point for identifying cases of GAD. The sensitivity at this level was 89%, and the specificity was 82% - quite satisfactory. Cut points of 5, 10, and 15 may be interpreted as representing mild, moderate, and severe levels of anxiety on the GAD-7.

The GAD-7 was chosen for this study because of its usefulness in assessing anxiety in both males and females, as well as younger and older patients (Löwe et al., 2008). The GAD-7 was analyzed using a 2-week time frame, however for this study it was modified to assess the change in anxiety over time (2 & 4 days) in a hospital setting. Construct validity of the GAD-7 was also demonstrated by Spitzer, Kroenke, Williams, and Löwe (2006) to be strongly associated with general health perceptions, functional impairment, and bodily pain, which usually exists in SCD patients (Gil et al., 2004) and can affect their clinical outcomes.

The PSS-10, modified for this study, was developed by Cohen and Williamson (1988), and is a widely used psychological instrument for measuring the perception of stress. It is a measure of the degree to which situations in one's life are appraised as stressful. Items were designed to identify how unpredictable, uncontrollable, and overloaded respondents find their lives. The scale also includes a number of direct queries about current levels of experienced stress. The PSS-10 was designed for use in community samples with at least a junior high school education. The items are easy to understand, and the response alternatives are simple to grasp. Moreover, the questions are of a general nature and hence are relatively free of content specific to any subpopulation group. The questions in the PSS-10 ask about feelings and thoughts

during the last month. However, the test-retest reliability analyses for the PSS using a shorter time frame (two days) have been shown to have substantial correlations (Cohen, Kamarck & Mermelstein, 1983). For this study, the PSS-10 was evaluated at two days and again at 4 days to determine whether there was a change in stress levels related to the intervention or control group. Each PSS item was measured on a five point Likert scale, with responses ranging from never (0) to very often (4). A total score was obtained by reversing responses (e.g., 0 = 4, 1 = 3, 2 = 2, 3 = 1 & 4 = 0) to the four positively stated items (items 4, 5, 7, & 8) and then summing across all scale items (Cohen & Williamson, 1988). Total scores range from 0 to 40, with higher scores associated with greater levels of perceived stress.

The Numeric (pain intensity) Rating Scale (NRS) was used to assess pain intensity in this study. It employs a rating of pain on a scale of 0 to 10, with 0 representing no pain to 10 representing the worst pain ever. The NRS, considered a self-reported pain assessment tool, is recommended by the Society of Critical Care Medicine (Jacobi et al., 2002) and is used broadly in the clinical setting (Sessler, Grap, & Ramsay, 2008).

The NRS has been shown to be highly correlated (r=0.85) with the Visual Analog Scale (VAS), another documented pain assessment tool, supporting its validity (Paice & Cohen, 1997). Another study found a strong correlation between the VAS and the NRS measured at different time points (r = 0.77-0.89); however, a limitation of this study was that the sample size was small (n=15) (Wilkie, Lovejoy, Dodd, & Tesler, 1990). The NRS was used in this study to determine pain scores because this is the instrument currently in use at the facility where the research was conducted.

A retrospective chart review of medication usage was analyzed and the oral and parenteral pain medications was standardized for comparison by converting commonly prescribed doses into standard morphine equivalents using The Hopkins Opioid Conversion Program (Grossman, Nesbit, & Loscalzo, 2003). The overall pain medication usage and response was retrieved from the medical record upon discharge from the hospital for each day the treatment intervention was given. This information retrieved from the chart review was analyzed and a comparison made in total pain medication usage between the two groups for the study period.

The demographic data collected was used to determine if the two intervention groups were similar. The data collected included: age, sex, ethnicity, co-morbidities, number of previous hospitalizations for VOPE, pain management techniques, and whether the participant had experienced a HT or Music session previously.

Pre-Intervention Activities

Once IRB approval (see Appendix F) was obtained, the RC met with the Nursing Research Sub-council, as well as the Nursing Leadership and the Medical Staff to coordinate education of the staff about the study and to provide informational flyers that were posted. After notifying the various departments who were involved, all personnel assisting in the study were contacted and a meeting convened to discuss the RAs roles. Educational sessions were conducted to train the RAs in their roles, whether directly or indirectly involved in the study. Upon completion of this education, a final meeting was conducted to address issues that emerged during the educational process.

After all approvals were obtained, a start date was determined and appropriate staff notified by email, telephone, or personal communication. The Bed Placement

Coordinator, Case Managers, or nursing staff notified the RC of all SCD admissions via cell phone. The RC contacted the unit and verified whether the patient met criteria for admission to the study and whether the patient's physician had given permission to approach the patient. If the patient met criteria and the physician had given permission, the RC approached the patient after the first 24 to 48 hours about the study, explained its purpose, and answered any questions. If the patient agreed to participate, an informed consent was signed and a copy given to the participant.

Research Assistant's Training

The HT Research Assistants (HT-RAs) who administered the HT sessions had completed the NIH Protecting Human Research Participants course modules and were either a certified Healing Touch Practitioner (CHTP), a Healing Touch Practitioner (HTP), or a Healing Touch Practitioner Apprentice (HTP-A). Prior to the study, the HT-RAs had completed at least through Level IV of classroom instruction, which consists of a total of 103.7 continuing education hours of classroom instruction in HT. The HT-RA was trained in the use of the study HT protocols (Appendix D) prior to providing the HT sessions by viewing a videotape of the protocols and training sessions. Inter-rater reliability was conducted by four observations of the HT-RA to ensure consistency with the HT protocols (Appendix E).

The ACM-RAs who administered the ACM sessions were nurses who completed the NIH Protecting Human Research Participants course modules and have were trained on the ACM protocols. The ACM-RA introduced his/her self and assisted the patient in getting comfortable for the session (i.e. straightening the covers or placing a blanket over the patient). Next, the ACM-RA placed the disposable covers over the ear

pieces of the headphones, assisted the participant with putting them on, and then played the pre-selected music CD for the ACM session. While present in the room with the participant, ACM-RAs were instructed to sit quietly and perform a mundane task (i.e. working a cross word puzzle) while the session took place to control the ACM-RA from focusing their intent on the patient, as would occur in HT intervention. After the 30-minute session was complete, the ACM-RA turned off the CD, removed the headphones, threw away the covers, wiped down the headphones, and returned them to the research box.

The seven Data Collector RAs (DC-RAs) for this study were individuals who completed the NIH Protecting Human Research Participants course modules, and were nurses other than the HT-RAs or ACM-RAs who administered the treatment, who were trained in how to administer the anxiety (Appendix B), stress (Appendix B), and the pain (Appendix C) questionnaires, as well as how to obtain the physiological data before and after each HTM or ACM session. The DC-RAs were different from the RAs administering the interventions to decrease the chance of bias in the data collection.

Interventions

HTM day 1

Ten minutes before the HTM intervention began, the Modified GAD-7, the Modified PSS-10, the NRS, as well as the participant's physiological data (blood pressure, pulse, respirations, oxygen saturation, and skin temperature) were collected by the DC-RA. After completion of the pre-treatment data collection, the HT-RA entered the room, made the participants comfortable, turned off all distractions (i.e. TV, radio, phones) closed any window curtains, and placed a sign on the door indicating that the

HT session was in progress. Before the HT intervention began, the HT-RA insured that the participant was as comfortable as possible, assisted him/her with putting on the headphones, and then started the pre-selected music CD. The HT-RA then provided the HT intervention following the HT protocols (Appendix D). At the completion of the 30-minute session, HT-RA removed the headphones, cleaned the equipment, left the room, and notified the DC-RA that the HT session was completed. The DC-RA then entered the room and immediately (within 5 minutes) began the collection of pain intensity and physiological data.

ACM day 1

Ten minutes before the ACM intervention began, the Modified GAD-7, the Modified PSS-10, the NRS, as well as the participant's physiological data (blood pressure, pulse, respirations, oxygen saturation, and skin temperature) were collected by the DC-RA. The ACM-RA entered the room, made the participant comfortable, turned off all distractions (i.e. TV, radio, phones) closed any window curtains, and placed a sign on the door indicating that the music session was in progress. The ACM-RA insured that the participant was as comfortable as possible, assisted him/her with putting on the headphones and then played a music CD with the same pre-selected music as the HT intervention group for 30 minutes. The ACM-RA remained present in the room throughout the entire session and performed a mundane task (i.e. working a cross word puzzle) to control the ACM-RA from focusing his/her attention on the participant as occurred in HT intervention. At the completion of the 30-minute session, the ACM-RA removed the headphones, cleaned the equipment, answered any questions that the participant had, and notified the DC-RA that the ACM session was

completed. The DC-RA then entered the room and immediately (within 5 minutes) began the collection of pain intensity and physiological data.

HTM days 2 - 4

Ten minutes before the HTM intervention began at days 2 – 4, the DC-RA collected pain intensity and physiological data from the patient. After completion of the pre-treatment data collection, the HT-RA made the participants comfortable, turned off all distractions (i.e. TV, radio, phones) closed any window curtains, and placed a sign on the door indicating that the HT session was in progress. Before the HT intervention began, the HT-RA insured that the participant was as comfortable as possible, assisted him/her with putting on the headphones and then started the pre-selected music CD. The HT-RA then provided the HT intervention following the HT protocols (Appendix D). At the completion of the 30-minute session, the HT-RA removed the headphones, cleaned the equipment, answered any questions that the participant had, and notified the DC-RA that the HT session was completed. The DC-RA then entered the room and immediately (within 5 minutes) began the collection of pain intensity and physiological data (days 2 – 4), and anxiety and stress scores (days 2 and 4). After completion of the post-treatment data collection on day 4, the HT-RA reentered the room and thanked the participant for participating in the study, and then asked the participant for questions and feedback about the experience.

ACM days 2 - 4

Ten minutes before the ACM intervention began at days 2 – 4, the DC-RA collected pain intensity and physiological data from the patient. The ACM-RA entered the room, made the participant comfortable, turned off all distractions (i.e. TV, radio,

phones) closed any window curtains, and placed a sign on the door indicating that the music session was in progress. The ACM-RA insured that the participant was as comfortable as possible, assisted him/her with putting on the headphones and then played a music CD with the same pre-selected music as the HT intervention group for 30 minutes. The ACM-RA remained present in the room throughout the entire session and performed a mundane task (i.e. working a cross word puzzle) to control the ACM-RA from focusing his/her attention on the participant as occurred in HT intervention. At the completion of the 30-minute session, the ACM-RA removed the headphones, cleaned the equipment, answered any questions that the participant had, and then notified the DC-RA that the ACM session was completed. The DC-RA then entered the room and immediately (within 5 minutes) began the collection of pain intensity and physiological data (days 2 – 4), and anxiety and stress scores (days 2 and 4). After completion of the post-treatment data collection on day 4, the ACM-RA reentered the room and thanked the participant for participating in the study, and then asked the participant for questions and feedback about the experience.

Random Allocation Procedure

Once the consent had been signed, all the baseline data were collected before the participants were randomized into a group. The participants were allocated to a treatment (HTM) or control (ACM) group by using a permuted block randomization scheme (Beller, Gebski, & Keech, A.C., 2002; Polit & Beck, 2008) to ensure an equal number of patients in each group. The block size was four, with a random sequence of four digits (1, 2, 3, and 4) computer generated for each block. Ten blocks was generated, resulting in a total of 40 randomly generated digits. Even numbers assigned

the participant into the HTM group, while an odd number assigned the participant into the ACM group. Each block of four numbers was placed in a separate envelope, sealed, and the envelope labeled set 1, 2, 3 . . . 10. After the first participant was enrolled and the baseline data had been collected, the RC selected an envelope out of a box and assigned that participant to the ACM group if the first random digit was odd (1 or 3), or to the HTM group if the first digit was even (2 or 4). For the second participant, the RC looked at the second randomized digit in the first envelope, and then placed the second patient in either the HTM group or ACM group depending on whether the digit was odd or even. This process continued for the third and fourth patients, resulting in exactly 2 patients randomly assigned to the HTM group and 2 patients randomly assigned to the ACM group. When this first block of numbers had been used, then the RC repeated the same procedure until all the envelopes had been opened and the 24 study participants had been assigned to the two groups.

Statistical Data Analysis

All study data were entered into PASW Version 17. All variables were checked for out-of-range values. All the quantitative variables were checked for outliers and degree of skewness by examining the histograms of each variable. A one-way analysis of variance was used to compare the baseline anxiety, stress, pain severity, and physiological variables between the HTM and ACM groups. For the anxiety and stress measures, an independent sample t-tests was used to compare the baseline, day 2 and day 4 mean scores between the treatment and control groups. For the pain intensity and physiological variables, change scores were computed between pre and post intervention at each treatment day, and a paired sample t-test was used to compare the

mean change at each day between the two groups. A one-way analysis of variance was used to compare the total mean pain medication usage during the four days of the study between the two groups. All statistical significance was based on a p-value less than 0.05.

Protection of Human Subjects

East Carolina University's Institutional Review Board (IRB) and the IRB at the participating research facility approved the research study. A signed informed consent for participation in the study was obtained. To ensure the safety of the participants and address any foreseeable physical, psychological, economic, social, legal, and dignitary risks to the participants the following process was followed. All patients enrolled in the study continued to receive the standard of care for their sickle cell disease along with a HTM or ACM session. However, the effect of a HT session could possibly create some emotional reactions. The process of clearing the congested areas may result in clearing away emotional congestion as well as energy congestion. This could create some discomfort as bad memories or events emerge that need addressing during a session. Any issues identified were shared with the patient's healthcare provider for follow-up. In the pretreatment period, the HT-RA discussed with the patient the intent of the session based on the assessment done and any concerns either the HT-RA or participant had were addressed. The RC or any RA, along with the staff nurses on the units and the participants' physicians, monitored the participants during the study. If they determined that the HT sessions should be stopped or if the participants requested to stop, the participants were withdrawn from the study.

The participant's anonymity was maintained throughout the study by the process of coding all data collected with 5-digit alphanumerical identifiers. The RC was responsible for this process to prevent any possible identification of the participants. Confidentiality was maintained, since only those persons directly involved in the research had access to the data for purposes of performing analysis. Any information used for the purposes of publication was coded so as to protect participants' identification. Any data collection forms or other information collected during the study are preserved and archived in the RC's office in a locked file cabinet until the end of the research project or such time that the data is no longer needed. The RC will then shred all data.

The anticipated benefit of the research study to participants or others is that it adds to the body of knowledge of baseline data for the overall effectiveness of the HT therapy. It also provides information about the effectiveness of the survey tools chosen for the research study on the application of HT to sickle cell patients.

Summary

This chapter described: 1) study participants; 2) sample size determination; 3) study approval procedure; 4) research design, 5) instruments; 6) pre-intervention activities; 7) research assistant's training; 8) interventions; 9) random allocation procedure; 10) statistical data analysis; and 11) protection of human subjects used for this study in order to address the research questions posed. This parallel-group randomized control trial (RCT) was designed to test the effectiveness of a 30 minute non-invasive nursing intervention, HT, given daily for four consecutive days, on anxiety, stress, pain, pain medication usage, and physiological measures (i.e. blood pressure,

heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE as compared to an usual care control group not receiving the HT intervention. This design was chosen to address previous limitations in this area of research.

CHAPTER IV: FINDINGS

The purpose of this pilot study was to examine the effectiveness of a non-invasive nursing intervention, HT, on anxiety, stress, pain, pain medication usage, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) on hospitalized SCD adults experiencing a VOPE. The effect of HT on the outcome variables was measured by 1) selected physiological parameters, 2) self-reported levels of anxiety, stress, and pain, as well as 3) the amount of equianalgesic opioid medication equivalents received during the study period, while controlling for the variables of music and presence.

The research hypotheses that were explored related to the proposed intervention in hospitalized SCD adults experiencing a VOPE were those participants who received HTM would:

1. Experience lower blood pressure, heart rate, respiratory rate, and a higher oxygen saturation and skin temperature than patients receiving the ACM at completion of the interventions on day 1, day 2, day 3, and day 4.
2. Experience lower anxiety scores than patients receiving the ACM at completion of the interventions on day 2 and day 4.
3. Experience lower stress scores than patients receiving the ACM at completion of the interventions on day 2 and day 4.
4. Experience lower pain scores than patients receiving the ACM at completion of the interventions on day 1, day 2, day 3, and day 4.

5. Require less pain medication than patients receiving the ACM at completion of the interventions on day 1, day 2, day 3, and day 4.

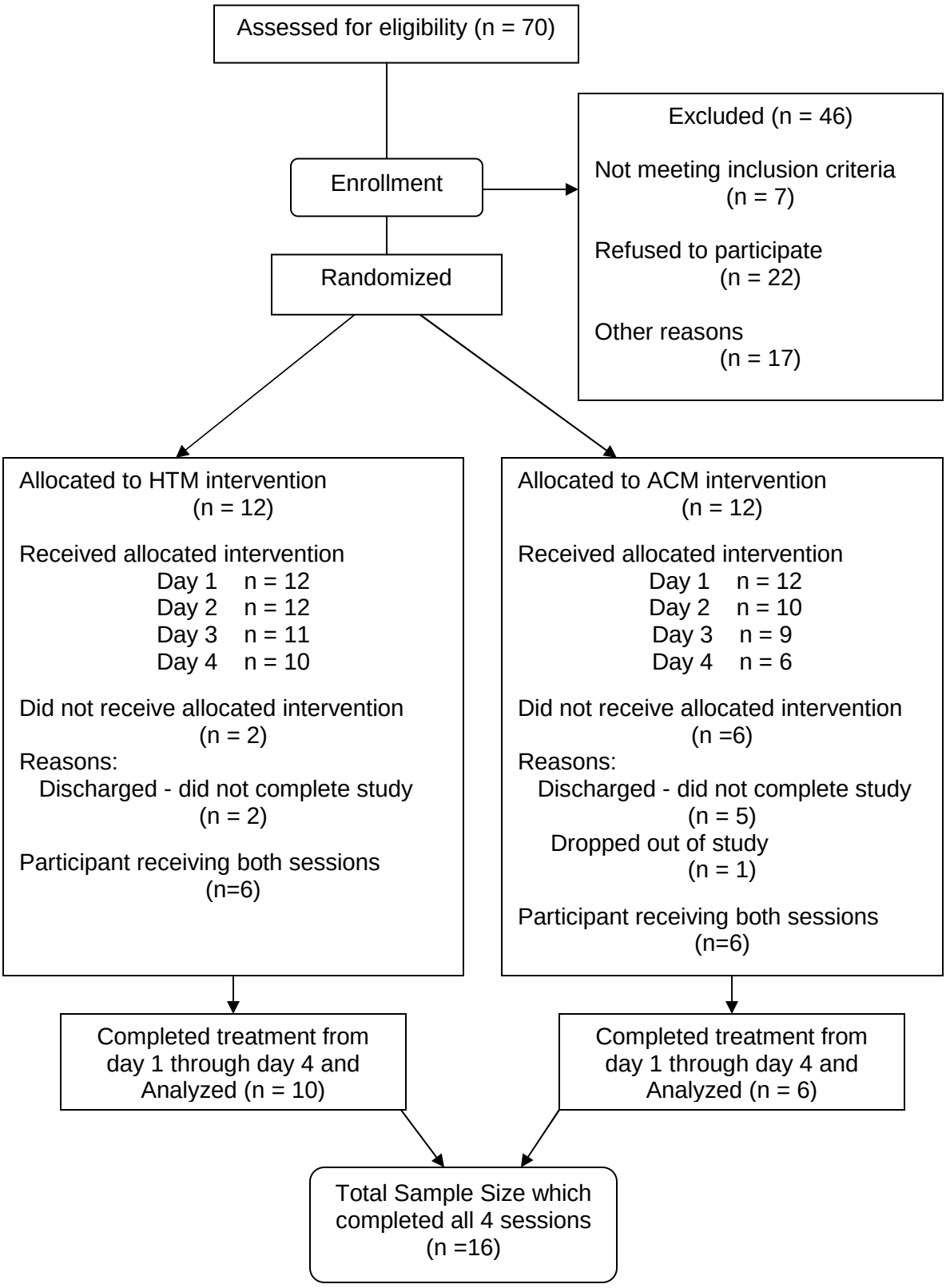
The assumption made by the study hypotheses was that the scores for pain, anxiety, stress, and physiological measures for the HTM group, when compared to the ACM group, would show greater improvement with respect to the pre- to post-intervention change at days 1, 2, 3, and 4. Another assumption was that the effects reflected in the score changes would be of a low to moderate effect size. Detecting whether these low to moderate effects would be statistically significant would require a relatively large sample size. Due to the slow enrollment of study participants into the RCT over the past six months, data on the 24 participants (12 in the HT group and 12 in the ACM group) was analyzed for this dissertation. This small sample size has reduced the power of the statistical methods used to detect statistically significant differences between the HTM and ACM groups. This chapter contains the sample description, statistical tests used, analysis, and data results obtained during the exploration of the previously stated research hypotheses**.**

Description of Sample

A total of 70 patients were assessed for eligibility for the study. The participants' flow through the study from assessment to final randomization is detailed in Figure 1. Forty-six participants were excluded from the study for the following reasons: seven did not meet inclusion criteria (i.e. admitted to ICU or pregnant), 22 refused to participate, and 17 were excluded for other reasons (i.e. admitted for greater than three days before notification of admission). The final study sample was comprised of 24 participants who ranged in age from 22 years to 49 years with an average age

of 31.4 years. Of the 24 participants who started the study, only 16 completed all four treatment sessions (Figure 4).

Figure 4 Flow of Participants through study



Descriptive Statistics

Descriptive statistics (means, standard deviations, percentages) were used to examine the demographic characteristics of the two study groups (Table 1). The chi-square test for independence was used to detect differences between the study groups. The average age of the HTM participants was 31.5 (ranging from 22 – 44) and 31.3 for the ACM group (ranging from 22 – 49). There were no statistically significant differences in age, gender, ethnicity, type of SCD, and number of co-morbidities between groups. The proportion of females in the ACM group (92%) was larger than in the HTM group (50%), and the ACM group had a larger proportion of subjects with no co-morbidities (42%) than the HTM group (8%). Fifty-eight percent of the participants reported using a complementary therapy (i.e. HT or Music) prior to the study to address pain, anxiety, and stress, with the majority stating that the complementary therapy did seem to help them to relax.

Table 1

Demographic Characteristics of the Study Sample (n=24)

	HTM	ACM	Total N
Age			
20-30 years	7 (58.3%)	8 (66.7%)	15 (62.5%)
31-40 years	2 (16.7%)	0 (.0%)	2 (8.3%)
41-50 years	3 (25%)	4 (33.3%)	7 (29.2%)
Gender			
Male	6 (50%)	1 (8.3%)	7 (29.2%)
Female	6 (50%)	11 (91.7%)	17 (70.8%)
Ethnicity			
African-American	12 (100%)	11 (91.7%)	23 (95.8%)
Mediterranean/Middle East	0 (0%)	1 (8.3%)	1 (4.2%)
Type of SCD			
Hemoglobin SS	7 (58.3%)	8 (66.7%)	15 (62.5%)
Hemoglobin SC	3 (25%)	4 (33.3%)	7 (29.2%)
Sickle-thalassemia	1 (8.3%)	0 (.0%)	1 (4.2 %)
Missing data	1 (8.3 %)	0 (.0%)	1 (4.2%)

Table 1 continued

Demographic Characteristics of the Study Sample (n=24)

	HTM	ACM	Total N
Co-morbidities			
None	1 (8.3%)	5 (41.7%)	6 (25%)
Smoker	3 (25%)	0 (.0%)	3 (12.5%)
Diabetes	1 (8.3%)	2 (16.7%)	3 (12.5%)
Renal Failure	2 (16.7%)	1 (8.3%)	3 (12.5%)
Cardiac Disease	0 (.0%)	1 (8.3%)	1 (4.2%)
Stroke	1 (8.3%)	1 (8.3%)	2 (8.3%)
Hypertension	1 (8.3%)	0 (.0%)	1 (4.2%)
Stroke & Hypertension	1 (8.3%)	0 (.0%)	1 (4.2%)
Other	2 (16.7%)	2 (16.7%)	4 (16.7%)
Previous HT session for pain, anxiety, or stress			
Yes	3 (25%)	5 (41.7%)	8 (33.3%)
No	9 (75%)	7 (58.3%)	16 (66.7%)
Previous Music session for pain, anxiety, or stress			
Yes	5 (41.7%)	1 (8.3%)	6 (25%)
No	7 (58.3%)	11(91.7%)	18 (75%)

Analysis and Results of Data

The relationship between the independent variable and the outcome variables (anxiety, stress, pain, pain medication usage, and the selected physiological

measures) was examined in this parallel-group randomized control trial (RCT). The data analyzed were: self-reported measures of anxiety taken from the 7-item Modified Generalized Anxiety Disorders scale (GAD-7), stress taken from the 10-item Modified Perceived Stress Scale (PSS-10), pain taken from the Numeric Rating Scale (NRS), medical records documentation of equianalgesic opioid medication usage, and selected physiological data of hospital SCD adults experiencing a VOPE.

Hypothesis 1

Hypothesis 1 stated that the HTM group would experience lower blood pressure, heart rate, respiratory rate, and a higher oxygen saturation and skin temperature than patients receiving the ACM at completion of the interventions on day 1, day 2, day 3, and day 4. Table 2 reports the means and standard deviations of the physiological measures for pre-intervention, post-intervention, and the changes in scores from pre- to post-intervention for days 1, 2, 3, and 4 between the HTM and ACM groups. There were three mean comparisons among the physiological measures with statistically significant p-values: day 3 pre-intervention systolic blood pressure; day 2 pre – to – post intervention changes in diastolic blood pressure; and day 2 pre – to – post intervention changes in heart rate. However, if the alpha levels were adjusted for statistical significance to 0.01 to compensate for multiple significance testing, none of the p-values would be statistically significant. Mean differences from pre – to – post intervention were greater in the HTM group for systolic and diastolic blood pressure on days 1 – 3, heart rate for days 1 and 3, and respiratory rate for days 1, 3, and 4. Oxygen saturation showed greater improvement, although not statistically significant for the HTM group on days 1 and

3, while skin temperature was increased on days 1 and 2 for the HT group, but again not statistically significant. Based on the findings from this pilot study, a trend was noted towards a reduction in the physiological parameters identified in this study that would tend to support hypothesis 1. A larger sample size is needed however, to determine if this trend would reach statistical significance.

Table 2

Between HTM and ACM Group Comparisons of Physiological Measures at Pre and Post Intervention, and Pre- to Post-Intervention Change on Each Treatment Day

		HTM			ACM			
		N	M	SD	N	M	SD	p[1]
Systolic BP								
Day 1	Pre	12	131.17	20.47	12	115.5	21.78	0.08
	Post	12	125.83	22.51	12	112.75	19.63	0.14
	Pre – Post	12	5.33	14.49	12	2.75	10.00	0.62
Day 2	Pre	12	127.17	20.95	10	120.10	24.22	0.47
	Post	12	120.58	18.28	10	126.00	18.15	0.50
	Pre – Post	12	6.58	20.00	10	-5.90	14.72	0.12
Day 3	Pre	11	129.91	24.95	9	107.56	13.62	0.03*
	Post	11	122.91	20.83	9	107.33	11.95	0.06
	Pre – Post	11	7.00	13.55	9	0.22	7.41	0.20
Day 4	Pre	11	128.00	26.22	6	112.67	17.97	0.22
	Post	11	123.91	22.98	6	108.00	15.82	0.15
	Pre – Post	11	4.09	13.12	6	4.67	8.71	0.93
Diastolic BP								
Day 1	Pre	12	73.33	12.43	12	68.50	15.99	0.42
	Post	12	71.75	15.43	12	69.17	14.63	0.68
	Pre – Post	12	1.58	9.86	12	-0.67	6.97	0.53
Day 2	Pre	12	75.08	12.4	10	67.90	15.68	0.24
	Post	12	66.42	10.55	10	72.30	11.09	0.22
	Pre – Post	12	8.67	11.29	10	-4.40	9.16	0.01*
Day 3	Pre	11	72.55	11.61	9	66.11	11.54	0.23
	Post	11	68.18	10.13	9	62.89	11.71	0.29
	Pre – Post	11	4.36	7.78	9	3.22	7.26	0.74
Day 4	Pre	11	72.27	11.8	6	69.00	11.10	0.59
	Post	11	72.45	13.91	6	66.00	10.16	0.34
	Pre – Post	11	-0.18	7.68	6	3.00	7.62	0.43

*p<.05; [1]p-values based on independent sample t-test

Table 2 continued

Between HTM and ACM Group Comparisons of Physiological Measures at Pre and Post Intervention, and Pre- to Post-Intervention Change on Each Treatment Day

		HTM			ACM			
		N	M	SD	N	M	SD	p[1]
Heart Rate								
Day 1	Pre	12	94.25	15.73	12	83.42	11.32	0.07
	Post	12	92.50	13.93	12	84.42	12.57	0.15
	Pre – Post	12	1.75	7.45	12	-1.00	6.41	0.34
Day 2	Pre	12	90.75	19.57	10	94.00	18.29	0.69
	Post	12	89.17	18.34	10	86.70	14.33	0.73
	Pre – Post	12	1.58	4.30	10	7.30	7.48	0.04*
Day 3	Pre	11	91.00	16.85	9	88.67	15.07	0.75
	Post	11	85.09	17.86	9	88.44	14.77	0.66
	Pre – Post	11	5.91	10.38	9	0.22	4.44	0.14
Day 4	Pre	11	83.73	17.00	6	90.33	16.78	0.45
	Post	11	83.64	19.78	6	90.00	12.41	0.49
	Pre – Post	11	0.09	8.25	6	0.33	8.24	0.96
Respiratory Rate								
Day 1	Pre	12	19.67	3.06	12	17.92	3.42	0.20
	Post	12	17.50	2.84	12	18.25	2.77	0.52
	Pre – Post	12	2.17	2.76	12	-0.33	3.17	0.05
Day 2	Pre	12	18.83	3.35	10	18.80	3.80	0.98
	Post	12	17.83	2.48	10	17.40	3.66	0.75
	Pre – Post	12	1.00	2.34	10	1.40	3.41	0.75
Day 3	Pre	11	20.73	4.76	9	18.00	2.00	0.13
	Post	11	18.82	4.79	9	16.67	2.45	0.24
	Pre – Post	11	1.91	1.92	9	1.33	1.73	0.50
Day 4	Pre	11	19.00	4.03	6	18.0	2.83	0.60
	Post	11	17.18	4.12	6	16.67	2.73	0.79
	Pre – Post	11	1.82	2.27	6	1.33	1.03	0.63

*p<.05; [1]p-values based on independent sample t-test

Table 2 continued

Between HTM and ACM Group Comparisons of Physiological Measures at Pre and Post Intervention, and Pre- to Post-Intervention Change on Each Treatment Day

		HTM			ACM			
		N	M	SD	N	M	SD	p[1]
Oxygen Saturation								
Day 1	Pre	12	97.08	2.31	12	98.17	1.95	0.23
	Post	12	97.42	3.06	12	98.17	1.80	0.47
	Pre – Post	12	-0.33	2.39	12	0.00	2.70	0.75
Day 2	Pre	12	97.75	2.14	10	97.70	2.16	0.96
	Post	12	96.92	1.88	10	97.80	3.12	0.42
	Pre – Post	12	0.83	1.70	10	-0.10	2.03	0.25
Day 3	Pre	11	97.09	2.70	9	98.22	2.11	0.32
	Post	11	97.55	2.84	9	97.78	2.28	0.85
	Pre – Post	12	-0.45	3.39	9	0.44	1.60	0.25
Day 4	Pre	11	97.84	2.01	6	97.83	2.40	1.00
	Post	11	97.91	2.12	6	98.33	1.97	0.69
	Pre – Post	11	-0.07	1.89	6	-0.50	0.84	0.61
Skin Temperature								
Day 1	Pre	12	83.24	7.64	12	84.24	9.18	0.77
	Post	12	85.74	6.92	12	84.68	8.96	0.75
	Pre – Post	12	-2.50	6.16	12	-0.43	2.35	0.29
Day 2	Pre	12	84.63	7.01	10	85.78	9.28	0.75
	Post	12	87.24	8.57	10	88.13	9.75	0.82
	Pre – Post	12	-2.61	2.81	10	-2.35	2.76	0.83
Day 3	Pre	11	84.56	8.23	9	84.62	8.06	0.99
	Post	11	86.76	9.18	9	87.96	8.85	0.77
	Pre – Post	11	-2.21	2.33	9	-3.33	5.64	0.55
Day 4	Pre	11	81.90	7.86	6	84.17	10.28	0.62
	Post	11	83.98	9.48	6	87.77	8.60	0.43
	Pre - Post	11	-2.08	2.51	6	-3.60	8.73	0.59

[1]p-values based on independent-samples t-test

Table 3 reports the means and standard deviations of the pre – to – post change scores in the physiological measures within the HTM and ACM groups for each day, and the mean and standard deviation of the mean pre – to – post change scores over the four day period between each group. Within group mean changes were consistently larger in the HTM group on respiratory rate. Mean changes over the four-day period were larger in the HTM group on all physiological measures except for oxygen saturation. After adjusting the level of significance for multiple significance tests to 0.01, none of the within group comparisons on the physiological measures were statistically significant.

Table 3

Within HTM and ACM Group Comparisons of Daily Pre- to Post-Intervention Changes and Between HTM and ACM Group Comparisons of the Mean Day 1 - 4 Pre- to Post-Intervention Changes in Physiological Measures

	HTM				ACM				
	N	M	SD	p^1	N	M	SD	p^1	p^2
Systolic BP									
Day 1	12.00	5.33	14.49	0.23	12.00	2.75	10.00	0.36	
Day 2	12.00	6.58	20.00	0.28	10.00	5.90	14.72	0.24	
Day 3	11.00	7.00	13.55	0.12	9.00	0.22	7.41	0.93	
Day 4	11.00	4.09	13.12	0.33	6.00	4.67	8.71	0.25	
Day 1 - Day 4	12.00	6.50	9.90		12.00	0.38	7.47		0.10
Diastolic BP									
Day 1	12.00	1.58	9.86	0.59	12.00	-0.67	6.97	0.75	
Day 2	12.00	8.67	11.29	0.02*	10.00	-4.40	9.16	0.16	
Day 3	11.00	4.36	7.78	0.09	9.00	3.22	7.26	0.22	
Day 4	11.00	-0.20	7.68	0.94	6.00	3.00	7.62	0.38	
Day 1 - Day 4	12.00	4.29	6.70		12.00	-0.28	5.62		0.08
Heart Rate									
Day 1	12.00	1.75	7.45	0.43	12.00	-1.00	6.41	0.60	
Day 2	12.00	1.58	4.30	0.23	10.00	7.30	7.48	0.01*	
Day 3	11.00	5.91	10.38	0.09	9.00	22.00	4.44	0.88	
Day 4	11.00	0.09	8.25	0.97	6.00	0.33	8.24	0.93	
Day 1 - Day 4	12.00	1.81	5.41		12.00	1.39	5.18	0.85	0.45

**p<.05; [1]p-value based on paired-samples t-test; [2] p-value based on independent-samples t-test

Table 3 Continued

Within HTM and ACM Group Comparisons of Daily Pre- to Post-Intervention Changes and Between HTM and ACM Group Comparisons of the Mean Day 1 - 4 Pre- to Post-Intervention Changes in Physiological Measures

	HTM				ACM				
	N	M	SD	p1	N	M	SD	p1	P2
Respiratory Rate									
Day 1	12.00	2.17	2.76	0 .02*	12.00	-0.33	3.17	0.72	
Day 2	12.00	1.00	2.34	0 .17	10.00	1.40	3.41	0.22	
Day 3	11.00	1.91	1.92	0.01*	9.00	1.33	1.73	0.05	
Day 4	11.00	1.82	2.27	0.02*	6.00	1.33	1.03	0.03*	
Day 1 - Day 4	12.00	1.73	1.36		12.00	0.49	1.58	0.05	0.05
Oxygen Saturation									
Day 1	12.00	-0.30	2.39	0.64	12.00	0.00	2.70	1.00	
Day 2	12.00	0.83	1.70	0.12	10.00	-0.10	2.03	0.88	
Day 3	11.00	-0.50	3.39	0.67	9.00	0.44	1.59	0.43	
Day 4	11.00	-0.10	1.89	0.90	6.00	-0.50	0.84	0.20	
Day 1 - Day 4	12.00	0.03	1.18		12.00	-0.44	2.32		0.54
Skin Temperature									
Day 1	12.00	-2.50	6.16	0.19	12.00	-0.43	2.35	0.54	
Day 2	12.00	-2.60	2.81	0.01*	10.00	-2.40	2.76	0.03*	
Day 3	11.00	-2.20	2.33	0.01*	9.00	-3.33	5.64	0.11	
Day 4	11.00	-2.10	2.51	0.02*	6.00	-3.60	8.73	0.36	
Day 1 - Day 4	12.00	-2.45	1.96		12.00	-1.77	3.44		0.56

**p<.05; [1]p-value based on paired-samples t-test; [2] p-value [1]p-values based on independent-samples t-test

Hypothesis 2

Hypothesis 2 stated that the HTM group would experience lower anxiety scores than patients receiving the ACM at completion of the interventions on day 2 and day 4. Table 4 presents the mean and standard deviations of the anxiety scores on the three observation days, and the day 1 – to – day 2 changes in anxiety, and the day 1 – to – day 4 changes in anxiety. There were no statistically significant between group differences on any of the anxiety measures. The day 1 – to – day 2 and day 1 – to – day 4 changes in anxiety although not statistically significant, were all larger in the ACM group, thereby not supporting hypothesis 2.

Table 4

Between HTM and ACM Group Comparisons of Anxiety Measured at Day 1, Day 2, and Day 4, and the Day 1- Day 2 and Day 1- Day 4 Changes in Anxiety

	HTM			AMC			
	N	M	SD	N	M	SD	P[1]
Anxiety							
Pre Day 1	12	12.83	5.72	6	14.08	6.16	0.61
Post Day 2	12	11.08	5.21	10	10.50	6.24	0.81
Post Day 4	11	9.45	7.13	6	7.83	4.62	0.63
Day 1 - Day 2	12	1.75	6.18	10	3.40	7.00	0.56
Day 1 - Day 4	11	3.18	7.59	6	6.83	2.48	0.28

[1]p-value based on independent-samples t-test

Table 5 presents the mean and standard deviations of the day 1 – to – day 2 and day 1 – to – day 4 within group changes in anxiety. There was a statistically

significant reduction in anxiety from day 1 – to – day 4 in the ACM group, again not supporting hypothesis 2.

Table 5

Within HTM and ACM Group Changes for Anxiety from Day 1 to Day 2 and from Day 1 to Day 4

	HTM				ACM			
	N	M	SD	P[1]	N	M	SD	P[1]
				Anxiety				
Total score GAD								
Day 1 – Day 2	12	1.75	6.18	0.35	12	3.40	7.00	0.16
Day 1 - Day 4	11	3.18	7.59	0.19	6	6.83	2.48	0.01**

p<.01; [1]p-value based on paired-samples t-test

Hypothesis 3

Hypothesis 3 stated that the HTM group would experience lower stress scores than patients receiving the ACM at the completion of the interventions on day 2 and day 4. Table 6 presents the mean and standard deviations of the stress scores on the three observation days, and the day 1 – to – day 2 changes in stress, and the day 1 – to – day 4 changes in stress. There were no statistically significant between groups differences on any of the stress measures. The day 1 – to – day 2 changes in stress was larger in the AMC group, while the day 1 – to – day 4 changes in stress was larger in the HTM group.

Table 6

Between HTM and ACM Group Comparisons of Stress Measured at Day 1, Day 2, and Day 4, and the Day 1- Day 2 and Day 1- Day 4 Changes in Stress

	HTM			AMC			
	N	M	SD	N	M	SD	p[1]
Stress							
Pre Day 1	12	25.42	8.28	12	24.33	7.63	0.74
Post Day 2	12	20.67	5.69	10	18.80	8.73	0.55
Post Day 4	11	17.09	9.01	6	17.00	6.81	0.98
Day 1 - Day 2	12	4.75	6.28	10	5.40	7.26	0.82
Day 1 - Day 4	11	8.64	9.39	6	6.33	4.97	0.59

[1]p-value based on independent-samples t-test

Table 7 presents the mean and standard deviations of the day 1 – to – day 2 and day 1 – to – day 4 within group changes in stress. There were statistically significant reductions in stress from day 1 – to – day 2 and from day 1 – to – day 4 for the HTM group, and a day 1 – to – day 4 statistically significant reductions in stress for the ACM group. These results support tend to partially support hypothesis 3, since there was statistically significant reductions at both assessment times for the HTM group indicating a quicker response to the intervention than seen in the ACM group.

Table 7

Within HTM and ACM Group Changes for Stress from Day 1 to Day 2 and from Day 1 to Day 4

	HTM				ACM			
	N	M	SD	p	N	M	SD	P
				Stress				
Total score PSS								
Day 1 –Day 2	12	4.75	6.28	0.02*	12	5.40	7.26	0.43
Day 1 - Day 4	11	8.64	9.39	0.01*	6	6.33	4.49	0.03*

p<.05, **p<.01, *p<.05; [1]p-value based on paired-samples t-test

Hypothesis 4

Hypothesis 4 stated that the HTM group would experience lower pain scores than patients receiving the ACM at the completion of the interventions on day 1, day 2, day 3, and day 4. Table 8 reports the means and standard deviations of present pain for pre-intervention, post-intervention, and the changes in scores from pre- to post-intervention for days 1, 2, 3, and 4 between the HTM and ACM groups. There was one mean comparison in present pain at post day 4 that was statistically significant. If the alpha level was adjusted for statistical significance to 0.01 to compensate for multiple, significance testing, this p-value would no longer be statistically significant. However, the pre – to – post intervention reductions in present pain were greater in the HTM group at all intervention days.

Table 8

Between HTM and ACM Group Comparisons of Present Pain at Pre and Post Intervention, and Pre- to Post-Intervention Change on Each Treatment Day

		HTM			ACM			
		N	M	SD	N	M	SD	p[1]
Present pain								
Day 1	Pre	12	6.83	1.85	12	7.83	1.59	0.17
	Post	12	5.17	2.79	12	6.92	2.47	0.12
	Pre - Post	12	1.67	1.50	12	0.92	1.44	0.23
Day 2	Pre	12	6.25	1.49	10	6.90	1.91	0.38
	Post	12	4.50	2.94	10	5.90	2.81	0.27
	Pre - Post	12	1.75	2.34	10	1.00	1.25	0.37
Day 3	Pre	11	5.68	1.55	9	6.78	1.79	0.16
	Post	11	4.23	2.60	9	5.78	2.11	0.17
	Pre - Post	11	1.45	1.81	9	1.00	2.06	0.61
Day 4	Pre	11	5.32	2.17	6	7.17	1.84	0.10
	Post	11	4.55	2.54	6	7.17	1.33	0.03*
	Pre - Post	11	0.77	1.57	6	0.00	1.10	0.30

$p<.05$; [1]p-values based on independent-samples t-test

Table 9 reports the means and standard deviations of the pre – to – post change in present pain within the HTM and ACM groups for each day, and the mean and standard deviation of the mean pre – to – post changes in pain over the four day period between each group. Within group mean changes in pain were larger in the HTM group compared to the ACM group at each day, but not statistically significant. Mean changes in pain over the four-day period were larger in the HTM group compared to the ACM group. After adjusting for multiple significance testing, only the within group comparison of pain at day 1 in the HTM group remained statistically significant for a reduction in pain. The between groups results did not support

hypothesis 4, but again the reduction in pain scores from pre to post intervention within the HTM group tends to support the hypothesis that HT does reduce pain in the SCD patient experiencing a VOPE.

Table 9

Within HTM and ACM Group Comparisons of Daily Pre- to Post-Intervention Changes and Between HTM and ACM Group Comparisons of the Mean Day 1 - 4 Pre- to Post-Intervention Changes in Present Pain

	HTM				ACM				
	N	M	SD	p^1	N	M	SD	p^1	p^2
Present Pain									
Day 1	12.00	1.67	1.50	0.00**	12.00	0.92	1.44	0.05	
Day 2	12.00	1.75	2.34	0.03*	10.00	1.00	1.25	0.03*	
Day 3	11.00	1.46	1.81	0.02*	9.00	1.00	2.06	0.18	
Day 4	11.00	0.77	1.57	0.13	6.00	0.00	1.10	1.00	
Day 1 - Day 4	12.00	1.41	1.36		12.00	0.85	1.36		0.33

*p<.05; **p<.01, [1]p-value based on paired-samples t-test; [2] p-value based on independent-samples t-test

Hypothesis 5

Hypothesis 5 stated that the HTM group would require less pain medication than patients receiving the ACM at the completion of the interventions on day 1, day 2, day 3, and day 4. Table 10 shows the results of an independent-sample t-test, which indicated no statistical significance in the amount of daily equianalgesic opioid medication used between the HTM and ACM groups. The overall equianalgesic opioids medication usage for the HTM group was consistently higher from pre

intervention throughout the four days studied and thereby hypothesis 5 was not supported by these results. This trend for higher medication in the HTM group was consistent with the fact that the other physiological parameters (i.e. B/P, HR) were higher as well, and may be due to the higher acuity of this group (more co-morbidities). In order to determine the rationale behind this however, a larger sample size would be needed.

Table 10

Between HTM and ACM Group Comparisons of Daily Equianalgesic Opioid Medication Usage

	HTM			ACM			
	N	M	SD	N	M	SD	P[1]
Day 1	12	164.90	139.05	12	98.23	51.27	0.13
Day 2	12	149.70	124.59	10	124.98	44.73	0.56
Day 3	11	191.50	177.09	9	116.66	77.29	0.26
Day 4	11	128.90	79.12	6	96.97	53.22	0.39
Day 1 – Day 4	11	601.89	499.34	6	338.35	198.42	0.10

[1]p-value based on independent-samples t-test

Summary

This chapter provides an analysis of the sample and the statistical tests used to analyze the two intervention groups, HTM and ACM, to determine the effectiveness of each in reducing anxiety, stress and/or pain, and the overall findings. Although there was no statistical significance found between HTM and ACM groups, probably due to the small sample size, the analysis of the data did show some important trends that will be discussed in Chapter 5.

CHAPTER V: DISCUSSION, CONCLUSIONS, RELEVANCE, AND RECOMMENDATIONS

Discussion

The analysis of the data collected during this study did not reveal statistically significant results between the HTM group and the ACM group, possibly due to the small sample size. However, the data did show some interesting trends within the groups that will be discussed in this chapter along with the biases, limitations of the study, barriers to real-world implementation, generalizability of the findings, and relevance to nursing.

Conclusions

Theoretical model.

Neuman's System Model, the theoretical model used to frame this study (Neuman & Fawcett, 2002), encompasses the idea of a dynamic interaction that occurs between people and the environment and the mechanisms that are used to protect against stressors (i.e. pain, anxiety, and stress). It was noted that those participants who experienced pain reduction at the first intervention time tended to sustain that reduction over the entire treatment period. This sustained response to the interventions seen with the HTM group is consistent with the secondary prevention described by Neuman that attempts to strengthen the lines of resistance to help the participant defend against the physiological stressors, as well as anxiety and stress in order to restore his/her balance in the energy system reflected in the trending of the physiological measures in a positive direction, partially supporting the study hypotheses 1-4.

Hypotheses.

Hypothesis 1 stated that the HTM group would experience lower blood pressure, heart rate, respiratory rate, and a higher oxygen saturation and skin temperature than patients receiving the ACM at completion of the interventions on day 1, day 2, day 3, and day 4. Participants in both groups experienced reductions in systolic blood pressure, diastolic blood pressure, and heart rate, as well as an increase in skin temperature, but these within group changes were greater in the HTM group.

The trend previously described in the data analysis implies an effect on some of the physiological measures in both the intervention and control group. This effect is what would be expected from the biological changes induced by relaxation, which has been previously demonstrated in music therapy studies by Updike (1990), Smolen, Topp, and Singer (2002), Sendelbach et al. (2006). In addition to the physiological measures, the pain and its resultant effects on the sympathetic nervous system's release of epinephrine and norepinephrine, would cause an increase in heart rate, blood pressure and a reduction in skin temperature (Kleinknecht, 2002; McCrae & Lumley, 1998). However, relaxation produces a decrease in the sympathetic nervous system's response, thereby reducing these physiological measures as seen in this study. This finding of reduced physiological measures is consistent with those found by Maville, Bowen, and Benham (2008) in their study using HT on healthy adults. These findings reflect the possible influence of the HT intervention, but the effect of the music therapy cannot be ruled out, therefore further study with HT is needed.

Hypotheses 2 and 3 stated that the HTM group would experience lower anxiety and stress scores than patients receiving the ACM at completion of the sessions on day

2 and day 4. When making between-groups comparisons for anxiety and stress, there were no statistically significant results to report. For anxiety, the within-group comparisons showed a larger improvement only for the ACM group for both time frames. However, for stress, the between-groups comparison showed a larger reduction initially for the ACM group, but this was not maintained at day 4, while the HTM group showed a larger reduction in stress at day 4. The within group improvement changes in stress were found to be statistically significant for the HTM group after day 2 and day 4, while the ACM group showed statistically significant improvement after day 4.

The finding of a statistically significant reduction in the stress for the HTM group seen at day 2 and again at day 4 is consistent with the findings of other studies (Heidt, 1981; Meehan, 1993; Wardell & Engebretson, 2001; Wardell & Weymouth, 2004; Wilkinson et al., 2002) in HT, which examined selected physiological data related to anxiety and/or stress, partially supporting hypothesis 3. The ACM group also showed some reduction in stress over time, which was possibly related to the interaction of the addition of music to the environment, but the HTM group showed a greater reaction to the intervention, pointing to an increased effect that resulted from adding HT to the intervention similar to the results seen by Dowd et al.(2007) in their study on stress with college students.

Hypothesis 4 stated that the HTM group would experience lower pain scores than patients receiving the ACM at the completion of the sessions on day 1, day 2, day 3, and day 4. When making between-groups comparisons, the only statistically significant result was the post-intervention score on day 4 for the ACM group. The pre to post intervention reductions in present pain were greater in the HTM group than the

ACM group across all 4 days. The only statistically significant findings for present pain reduction however, were found in the HTM group at post intervention on day 1, which was consistent with Weymouth and Sandburg-Lewis's (2000) findings in their study with chronic neuropathic pain. Again, the fact that the HTM group had a larger mean change in pain scores over the four-day period as compared to the ACM group tends to partially support Hypothesis 4.

Another interesting trend noted was that 50% of the HTM participants (n=6) reported a pain reduction of 2 or more points (SD $\pm$ 1.03) at the first intervention, but only 25% of the ACM participants (n=3) reported a pain reduction of 2 or more points (SD $\pm$ 1.64). Additionally, for both groups, those with pain reductions of 2 or more points at the first session had a larger mean pain reduction across all sessions than those participants whose pain reduction at the first session was less than 2 points. This finding is consistent with the results Post-White et al. (2003) found with the effects of HT on immediate pain reduction in the chemotherapy patients in their study. For the HTM group, the larger results (50% greater reduction) could be due to the outcome obtained by the HT intervention or maybe the anticipated effect of this new intervention by the study participant. More studies will need to be conducted in this area.

Attempts to control for the therapeutic presence versus the physical presence effect were addressed during the design of the study by having the RAs in the room for the ACM interventions, but more studies to address this aspect of the effect need to be conducted. Lastly, this current study will add to the body of knowledge that can be used in conducting systematic reviews of quantitative studies involving HT to establish credibility of this type of touch therapy for pain relief.

Hypothesis 5 stated that the HTM group would require less pain medication than patients receiving the ACM at the completion of the interventions on day 1, day 2, day 3, and day 4. This hypothesis was not supported by the findings; however there was a trend for reduction in overall pain usage among both groups.

Although the study findings were not statistically significant between the two groups, the changes noted within the HTM group do tend to partially support the original hypotheses, but a larger sample size is necessary to confirm this.

Study Validity and Threats

Internal validity.

Control for issues related to internal validity was addressed for this study by the research design that was developed, which was a parallel-group RCT using two interventional groups. A permuted block randomization scheme was used to control for selection bias, while ensuring an equal number of participants in each group. The use of specific selection criteria to limit preexisting differences in the intervention groups helped to reduce selection bias. The issue of maturation was addressed by the design of the study because all participants were enrolled and the first intervention given by day two of admission to the facility, and subsequent interventions were provided over the next four days for all participants. Attrition of participants was an issue however, due to the participants being discharged from the facility prior to completion of the study, except for one participant in the HTM group who chose to drop out after the first intervention. This attrition rate was greater for the ACM group; this may have been due to the fact that the ACM group had less co-morbidities and were discharged sooner than the HTM group.

By using already validated measurement instruments, the study design provided credibility for the information collected, however the mere collecting of data can impact the results obtained. This needs to be considered when analyzing the results of self-reported measures.

Construct validity.

In an effort to guarantee the accuracy of the findings in the study, the consistency of the sessions, both the HTM and the ACM, by the RAs were scripted to ensure that the interaction between the patients and the RAs was the same. To control for variation in the administration of the HT intervention, inter-rater reliability was conducted for four of the sessions for each of the HT RAs to ensure that the HT protocols were followed. This was done to establish that the HT intervention used in this study represented the general practice of HT.

Looking at the instruments chosen for this study, the construct validity for the GAD-7 has been previously established as an efficient tool for screening for anxiety in the clinical practice setting, however for this study the GAD-7 was modified to address the shorter study time. This modification in the GAD-7 may account for the lack of statistical significance in the between groups analysis in this study, since it has not been studied for this time frame. The PSS-10 instrument that was used to assess for changes in stress levels however, has been studied using this shorter time frame, and the test-retest reliability did show substantial correlations to PSS that was tested for a longer time frame. The last instrument used was the NRS, which has been shown to be highly correlated with other pain assessment tools. The use of valid instruments to measure our outcome variables adds to the construct validity of this study. Having established

that the HT intervention was representative of the general practice of HT and that the instruments used to measure the outcome variables (i.e. anxiety, stress, and pain) were reliable, added to the construct validity of the study design.

The study design also included the use of the participant's medical record in order to validate the reduction in pain by assessing the amount of pain medication used and comparing it to the self-reported pain scores. This was done to address the possibility of the Hawthorne effect. In reviewing the actual pain medication usage for the HTM group, the overall amount of pain medication did decrease over the study time, as did the pain scores, however the HTM group did use more pain medication than the ACM group. This again may have been related to the larger percentage of the HTM group's co-morbidities, however a definitive link between the actual medication usage and the decrease in pain scores cannot be made, since only the overall usage was studied.

Another threat to the construct validity is the novelty effect, since the HT intervention is a new complementary therapy technique that has not historically been used in the SCD patient population. Those participants receiving HTM could have been either enthusiastic or skeptical about it. The one participant who dropped out of the study revealed that she was indeed skeptical about the effect of the HT intervention and did not want to continue in the study.

Another potential threat to the construct validity would be the bias of the RC who is a CHTP and has a vested interest in obtaining a positive outcome from this study. An attempt to alleviate this possible threat to the construct validity was addressed by

having RAs, who were not providing the intervention, collect the data from the study participants.

External validity.

In addressing the generalizability of this current study to the overall healthcare system, the fact that HT is a non-invasive nursing intervention that can be administered to any patient at the bedside makes it easy to implement in any setting. The RA administering the HTM intervention in this study was a more experienced practitioner (CHTP and HTP-A), which would decrease the generalizability of this study, however previous studies examining the expertise of the HT provider on pain noted that the less experienced providers had less effect, but regardless, there was still an overall positive effect noted on pain reduction (So, Jiang, & Qin, 2008).

Another potential problem with generalizing these HT research findings to all healthcare facilities is the novelty of this type of complementary therapy and its acceptance in mainstream healthcare. Although complementary therapies are beginning to find their place in healthcare, the acute care facility is slow to accept this new treatment option and represents a possible limitation for implementing this study's findings.

Limitations.

There were several limitations noted during the study related to the performance of the interventions. One such limitation was in the timing of the interventions. The study design was established such that the interventions would be given during the "quiet time" at the facility, but due to the day-to-day operations of the units (procedures, labs, x-rays, etc.) as well as timing of pain medications and blood transfusions, this was not

always possible. Whether the results of the participants' self-reported scores were influenced by the time of day would need to be examined. The timing of pain medication administration and the actual treatment was addressed in the study design by allowing at least one hour after medication administration prior to the intervention or control sessions. This however, did not address whether it had been two, three, or more hours since the participant had had pain medication, which did occur and could have impacted the self-reported scores of the participants.

Another limitation was related to the number of interruptions experienced during the intervention process. The study design attempted to address this by notifying the participant's nurse prior to the start of the intervention to ensure that there would not be a need for any nursing care procedures during the intervention time and by placing signs on the doors to alert staff and visitors of the intervention that was in progress. Unfortunately, this still did not prevent interruptions during some interventions.

Lack of knowledge about the HT therapy concept presented another limitation for the study due to lack of physician understanding of the practice. The PI addressed this by providing an hour lecture to a group of primary admitting physicians on the practice of Healing Touch and its expected benefits.

Lastly, the timely notification of potential study participants was a limitation that resulted in not being able to enroll possible study participants, therefore limiting the sample size. This was addressed initially in the study design by letters being sent to the entire medical staff at the facility. However, due to lack of acknowledgement and support, the PI then met individually with the primary admitting physicians for SCD patients, as well as the Medical Director for the facility, who then facilitated the

computer notification of admissions. This proved to enhance the notification of all SCD patient admissions, enabling timely screening for possible enrollment and primary physician approval. Barriers to access of the patient population should be addressed in the initial study design to ensure resolution of this problem and adequate sample size in future studies.

Relevance to Nursing

Sickle cell disease patients experiencing a VOPE require numerous nursing interventions (i.e. pain medication administration, blood transfusions, etc.), but this patient population also requires a lot of social interaction, which often times is avoided by healthcare providers. Healing Touch, a heart centered, caring practice, allows the nurse to provide that portion of nursing which is unique to the profession of nursing, that of caring. In today's highly technologically driven healthcare system, the practice of HT that provides a gentle, non-invasive intervention, restoring balance to the patients' energy system, and assisting them in their healing process, whether physiologically, psychologically, or socially, and could provide the nurse as well as the patient with a sense of well-being, is very much needed today.

With today's healthcare costs rising, finding an intervention that the bedside nurse can administer could help to address these costs. If statistical significance can be established showing that HT, a non-invasive therapy, can reduce the overall use of pharmaceuticals and their side effects, thereby reducing the length of stay in the hospital, then this could have clinical significance for the bedside nurse who could offer this beneficial treatment option to the SCD patient. In the SCD patient who experiences frequent admissions to the hospital, the nurse could also possibly impact the SCD

patient's care by developing clinical practice guidelines based on solid evidence based research. Lastly, educating the SCD patient in HT techniques that could help to promote wellness by reducing the stressors of anxiety and stress, could also have clinical significance for the SCD patient population.

Recommendations for Further Research

Even though this study had a small sample size, the positive results that were obtained within the HTM group indicates the evidence for further research to determine whether there would be statistically significant results seen across a larger sample size and in similar patient populations, with similar issues of pain, anxiety, and stress.

Further research is needed looking at not only the physiological variables, but also at biomarkers such as IgA to determine the impact of HT on the immune system in order to provide a more scientific basis for HT. There also needs to be more research into the use of HT in the psychosocial or behavioral aspects of this type of therapy, since there was statistically significant reduction noted in the stress levels of this SCD group.

Additional research should be conducted into the standardization of HT techniques, the optimal time for treatments, as well as the number and frequency of these interventions, in order to determine the best practice. Further research should also be conducted into the effect of the training of the HT practitioner to determine at what minimum level of training would be required for the bedside nurse.

Summary

Sickle cell disease is a devastating illness and is a major healthcare problem affecting approximately one out of every 375 African-Americans in the United States

(Edwards et al., 2005), as well as other populations from the Caribbean, Southern Europe, the Mediterranean area, the Middle East, and India (NAHAT, 1991). This worldwide health problem affects both men and women of all ages across their entire lifespan. The major complication of SCD is the occlusion of the vascular beds and the resultant ischemia, which causes the VOPE (Metha, Afenyi-Annan, Byrns, & Lottenberg, 2006; Steinberg & Brugnara, 2003). The optimal management of SCD requires a multidisciplinary team approach due to the multidimensional aspect of the reoccurring SCD pain, related to the biological, psychological, behavioral, social, and cultural components of the disease (Yale, Nagib, & Guthrie, 2000).

This pilot parallel-group RCT was conducted to examine a complementary therapy approach using HTM to manage a VOPE. Its purpose was to determine the effectiveness of this non-invasive nursing intervention on anxiety, stress, pain, pain medication usage, and physiological measures (i.e. blood pressure, heart rate, respirations, oxygen saturation, and skin temperature) of hospitalized SCD adults experiencing a VOPE. The effect of HTM on the outcome variables was measured, while controlling for the variables music and presence. The results, although not statistically significant across the two groups, did suggest a possible positive effect that should continue to be studied.

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Appendix A – Demographic Information

Study # _____ Date: _____ Time: _____

1. Age: ____

2. Sex: ____ Male ____ Female

3. Ethnicity:
____ African–American Black
____ Mediterranean/Middle East
____ Caribbean
____ Asian
____ Indian (India)
____ Other _____

4. Type of SCD:
□ Hemoglobin SS
□ Hemoglobin SC
□ Hemoglobin SD,
□ Sickle-thalassemia

5. Co-morbidities:
____ None
____ Cardiac Disease
____ Smoker
____ Diabetes
____ Renal Failure
____ Hypertension
____ Stroke
____ Other: _____

6. Number of previous hospitalizations for SCD:
____ 0
____ 1
____ 2
____ 3
____ 4
____ 5
____ 6
____ 7 or >

7. Current pain management techniques:
_____
_____
_____
_____
_____
_____

8. When did you last take something for pain and what was it?

Drug Name: _____
Dosage: _____
Time:_____

Drug Name: _____
Dosage: _____
Time:_____

9. Have you ever had a HT session? ____ Yes ___No

10. Have you ever had a Guided Relaxation session? ____ Yes ___ No

Appendix B – Numeric (Pain Intensity) Rating Scale (NRS)

Study ID # _____ Date: _____ Session # _____ Time: _____

1. Please rate your *present* pain on the above scale of 0-10, with 0 being no pain and 10 being the worst possible pain. Score: _____

2. Please rate your *worst* pain in the past 24 hours on the above scale of 0-10, with 0 being no pain and 10 being the worst possible pain. Score: _____

3. Please rate your *least* pain in the past 24 hours on the above scale of 0-10, with 0 being no pain and 10 being the worst possible pain. Score: _____

4. Please rate your *average* pain in the past 24 hours on the above scale of 0-10, with 0 being no pain and 10 being the worst possible pain. Score: _____

Physiological data:

Heart rate: _____ Respiratory rate: _____ Blood pressure: _____

O_2 Sats: _____ Skin Temp: _____ ^{0}F

Appendix C – Modified Generalized Anxiety Disorder Scale (GAD-7)

Study # _____ Date _____ Time _____ Session # _____

□ Pre-Assessment □ Post-Assessment

GAD - 7

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

Total Score = _____ Add Columns _____ + _____ + _____ + _____

*Modified from Generalized Anxiety Disorders Scale (GAD) 7 developed by Dr. Robert Spitzer

Appendix D: Modified Perceived Stress Scale

Study # _____ Date _____ Time _____ Session # _____

☐ **Pre-Assessment** ☐ **Post-Assessment**

The questions in this scale ask you about your feelings and thoughts. In each case, you will be asked to indicate by circling *how often* you felt or thought a certain way.

0 = Never 1 = Almost Never 2 = Sometimes 3 = Fairly Often 4 = Very Often

1. In the last 2 days, how often have you been upset because of something that happened unexpectedly? **0 1 2 3 4**
2. In the last 2 days, how often have you felt that you were unable to control the important things in your life?..... **0 1 2 3 4**
3. In the last 2 days, how often have you felt nervous and "stressed"? **0 1 2 3 4**
4. In the last 2 days, how often have you felt confident about your ability to handle your personal problems? **0 1 2 3 4**
5. In the last 2 days, how often have you felt that things were going your way?..... **0 1 2 3 4**
6. In the last 2 days, how often have you found that you could not cope with all the things that you had to do? **0 1 2 3 4**
7. In the last 2 days, how often have you been able to control irritations in your life?..... **0 1 2 3 4**
8. In the last 2 days, how often have you felt that you were on top of things?... **0 1 2 3 4**
9. In the last 2 days, how often have you been angered because of things that were outside of your control? **0 1 2 3 4**
10. In the last 2 days, how often have you felt difficulties were piling up so high that you could not overcome them?..... **0 1 2 3 4**

* Modified from The Perceived Stress Scale (PSS) developed by Sheldon Cohen

Appendix E: Healing Touch Protocols

Once the baseline data has been collected, a sign is placed on the participant's room door advising that a Healing Touch treatment is in session and Do Not Disturb until (_____) time. Next the participants are asked to lie on their back and if necessary, pillows are placed under the knees for comfort. Any other additional comfort measures that the participant requires are addressed prior to starting the HT treatment. The curtains are closed and any distractions (i.e. TV, phones, etc.) are turned off.

The HT-RA explains that the treatment will take approximately 25-30 minutes. The HT-RA asks the participants if there is any area that is currently bothering them or if there is anything that they would like the HT-RA to work on. The participant is told that the HT-RA will work on those areas where she feels there is blockage or congestion, but that all the work will be done off the body except for touching the feet. The HT-RAs then reminds the participants that this is a research study and that they will not be talking to them during the treatment, but at any time that they need to tell them anything, to please speak up.

Healing Touch Sequence/Protocols

1. Intake: Discuss with participants the purpose of the Healing Touch treatment and obtain permission.
2. Practitioner preparation: Ground and center self. Attune to participants by holding both feet.

3. Pre-treatment assessment: Perform a Hand Scan and pendulum to assess the openness of the chakras and the energy fields, looking for differences in the energy flow and document on the HT Assessment Form.

4. Discuss with participants any problems noted and if there are any areas that the participants would like the HT-RA to work on.

5. Perform the following HT intervention: Chakra Connection

   i. Participants are positioned lying on their back with pillow under knees.
   ii. HT-RAs stands on the right side of the participants and place their hands gently over the specific energy centers known as chakras.
   iii. Each position is held in place for one minute.
   iv. Move the hands one at a time, maintaining the connection.
   v. The pattern follows the sequence below:

      a. Right ankle and right knee
      b. Right knee and right hip
      c. Left ankle and left knee
      d. Left knee and left hip
      e. Both hips
      f. Root and sacral chakras
      g. Sacral and solar plexus chakras
      h. Solar plexus and spleen
      i. Solar plexus and heart chakra
      j. Heart chakra and high heart
      k. Right wrist and right elbow
      l. Right elbow and right shoulder
      m. Left wrist and left elbow
      n. Left elbow and left shoulder
      o. Both shoulders
      p. High heart and throat chakra
      q. Throat chakra and brow chakra
      r. Brow chakra and crown chakra
      s. Crown chakra and transpersonal point.

6. Based on assessment and intake of patient, perform the following: Hands in Motion, and Hands Still over the participant where needed for 5 minutes.

7. If the participant's pain score was 5 or >, perform the Ultrasound technique for 2 minutes followed by 3 minutes of a Pain Drain in the area where the pain is focused.

8. Perform a post-treatment assessment using a Hand Scan and pendulum to assess the openness of the chakras and the energy fields. Document the post-treatment assessment data.

9. End the session by grounding and releasing the patient by holding both feet and talking to them to bring them back into awareness of the room. Ask the participant to describe anything they may have experienced and document on HT Assessment Sheet.

10. Notify DC-RA to administer the pre-treatment surveys again to the participants approximately 10 minutes after the HT treatment.

11. Thank participants and schedule next session.

Magnetic Passes

Hands in Motion is a technique used to clear congestion from the field and Hands Still is used to re-establish flow and balance. Magnetic Passes help to relieve pain, promote relaxation, decrease anxiety, tension, and stress and promote a sense of well-being.

Procedure for Hands in Motion:

1. Place both hands one to six inches above the physical body in the energy field.
2. Hold hands open with palms facing the body, softly brushing down and away with either one hand following the other or both moving in a parallel motion downward and away from the body.
3. Start with the upper body and move to the lower body.
4. Hands should move completely off the body far enough for pain and congestion to dissipate.

5. This technique is done over entire body or over a specific site of injury or pain.

Procedure for Hands Still:

1. Rest the hands on or off the body in the area of concern.
2. Hands can be in front or back, next to each other or around a joint.
3. Hold in place for one minute, if energy flow not initiated, hold for one more minute.
4. Energy flow or release of energy should be noted such as either a fullness or change in temperature indicating the energy has shifted, resulting in balance or energy flow.

Ultrasound

Ultrasound uses light that is focused or channeled. By using the thumb, first and second fingers, which are held together to focus the light, the HT-RA energy penetrates the areas needing attention with the energy. Using this hand position the energy is circulated through the area using a constant circular motion.

Procedure:

1. Hold the thumb, first and second fingers together, directing the energy from the palm down the fingers.
2. Imagine a beam of light coming from the fingers and thumb that is directed into the participant's body.
3. Move the whole hand in any direction desired with the fingers pointed toward the area. Keep moving the hand continuously while doing ultrasound.

Pain Drain

Pain Drain is used to help remove any physical or emotional pain or congestion in the field.

Procedure:

1. Place the left hand on or over the area that hurts or feels congested. Hold the right hand downward and away from the body. This siphons the energy from the participant's body and out of the HT-RA's right hand. Hold the position until the movement or sensation of pulling stops, or the participant's feedback indicates relief.
2. Reverse the hands placing the right hand on or over the participant's area and hold the left hand palm upward. Allow healing energy from the Universal Energy Field to flow in, allowing the void created by the drain to fill with light.

* The above Healing Touch techniques were based on Hover-Kramer, D. (2002). *Healing Touch: A guidebook for practitioners* (2nd ed.). Albany, NY: Delmar Thomson Learning.

Appendix F: Healing Touch Inter-rater Form

Healing Touch RA's name: _____ Date: _____

Date:					
1. Intake: Discuss with patient the purpose of the HealingTouch treatment and Obtain permission.					
2. HT research assistant's preparation: Ground and center self. Attune to patient.					
3. Pre-treatment assessment: Perform a Hand Scan and pendulum to assess the openness of the chakras and the energy fields, looking for differences in the energy flow. Document the findings on the HT work sheet.					
4. Discuss with patient any problems noted and if there are any areas that the patient would like the HT research assistant to work on.					
5. Perform the following HT intervention: Chakra Connection					
i. Patient is positioned lying on their back with pillow under knees.					
ii. HT research assistant stands on the right side of the patient and places his/her hands gently over the following areas.					
iii. Each position is held in place for one minute.					
iv. Move the hands one at a time, maintaining the connection.					
iv. The pattern is as follows:					
a. Right ankle and right knee					
b. Right knee and right hip					
c. Left ankle and left knee					
d. Left knee and left hip					
e. Both hips					
f. Root and sacral chakras					
g. Sacral and solar plexus chakras					
h. Solar plexus and spleen					
i. Solar plexus and heart chakra					
j. Heart chakra and high heart					
k. Right wrist and right elbow					
l. Right elbow and right shoulder					
m. Left wrist and left elbow					

n. Left elbow and left shoulder						
o. Both shoulders						
p. High heart and throat chakra						
q. Throat chakra and brow chakra						
r. Brow chakra and crown chakra						
s. Crown chakra and transpersonal point.						
6. Based on assessment and intake of patient, perform the following: Hands in Motion, and Hands Still over the participant where needed for 5 minutes. (Write either HM for Hands in Motion or HS for Hands Still).						
7. If the patient's pain score was 5 or >, perform the Ultrasound technique for 2 minutes followed by 3 minutes of a Pain Drain in the area where the pain is focused. (If a Pain Drain done, place a "y" for yes "n" for no).						
8. Perform a post-treatment assessment using a Hand Scan and pendulum to assess the openness of the chakras and the energy fields. Document the post-treatment assessment data.						
9. End the session by grounding and releasing the patient by holding both feet and talking to them to bring them back into awareness of the room.						
10. Thank the patient and schedule next session.						

Comments:

_____
_____
_____
_____

_____ _____

Inter-rater signature Date

Appendix G: Script for Music Research Assistants

Hello, my name is _____. I am here to give you your Music Therapy treatment. Is this a good time for you?

If they say no, ask them when would be a good time and let them know you will be back at that time. Thank them, and then ask is there something that you can do for them before you go.

If they say yes, then ask if it is OK to turn off the TV, phones, etc. and put the sign on the door that says Music Therapy in Progress Do not Disturb. Explain to them that you will be using an IPOD with head phones to assist them with the music session.

Once you have placed the sign on the door, make the patient comfortable assist them with the headphones and adjust the volume so they can hear it.

Pull up a chair up next to the bed for you to sit in. Tell the patient that you are going to be sitting here with them during the session, but will not be talking to them. Tell the patient if they have any questions or need anything during the session to please let you know. When the Music session is over, you will allow them a few minutes to enjoy the relaxation before speaking to them.

Ask one final time if they are comfortable and tell them that you are going to start the session now.

Once the session is over, ask them if there is anything they need and thank them for allowing you to provide them with this Music Therapy session and that you look forward to seeing them again. Also tell them that another person will be in shortly to assist them in completing the questionnaires about how they are feeling now and take their vital signs.

End by telling them that you hope they have a nice day.

Appendix H: IRB Approval Letter

University and Medical Center Institutional Review Board
East Carolina University • Brody School of Medicine
600 Moye Boulevard • Old Health Sciences Library, Room 1L-09 • Greenville, NC 27834
Office **252-744-2914** • Fax **252-744-2284** • **www.ecu.edu/irb**
Chair and Director of Biomedical IRB: L. Wiley Nifong, MD
Chair and Director of Behavioral and Social Science IRB: Susan L. McCammon, PhD

TO: Linda Thomas, MSN, Doctoral Student, College of Nursing, ECU

FROM: UMCIRB

DATE: May 8, 2009

RE: Full Committee Approval of a Study

TITLE: "A Pilot Study: The Effect of Healing Touch on Anxiety, Stress, Pain, Pain Medication Usage, and Physiological Measures in Hospitalized Sickle Cell Disease Adults Experiencing a Vaso-occlusive Pain Episode"

UMCIRB #09-0367

The above referenced research study was initially reviewed by the convened University and Medical Center Institutional Review Board (UMCIRB) on **4/22/09.** The research study underwent a review and approval of requested modifications on 5/6/09 by Dr. W. Nifong. The UMCIRB deemed this **unfunded** study **no more than minimal risk** requiring a continuing review in **12 months.** Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

The above referenced research study has been given approval for the period of **4/22/09** to **4/21/10**. The approval includes the following items:

- Internal Processing Form (received 5/4/09)
- Appendix A: Demographic Information
- Appendix B: Numeric (Pain Intensity) Rating Scale (NRS)
- Appendix C: Modified Generalized Anxiety Disorder Scale (GAD-7)
- Appendix D: Modified Perceived Stress Scale (PSS-10)
- Appendix E: Healing Touch Protocols
- Appendix F: Healing Touch Inter-rater Form
- Informed consent document (dated 4/25/09)
- COI Disclosure Form (dated 4/6/09)
- Script for Staff to Use to Approach Patients
- Physician Information/Permission Form
- Notification of Enrollment Form
- Healing Touch Description/Study Advertisement

The following UMCIRB members were recused for reasons of potential for Conflict of Interest on this research study: None

NOTE: The following UMCIRB members with a potential Conflict of Interest did not attend this IRB meeting: None

The UMCIRB applies 45 CFR 46, Subparts A-D, to all research reviewed by the UMCIRB regardless of the funding source. 21 CFR 50 and 21 CFR 56 are applied to all research studies under the Food and Drug Administration regulation. The UMCIRB follows applicable International Conference on Harmonisation Good Clinical Practice guidelines.