

Bispectral Index Monitoring to Assess the Effect of a Healing Touch Treatment

By

Mario Chavez

A Project presented to the

FACULTY OF THE SCHOOL OF NURSING

POINT LOMA NAZARENE UNIVERSITY

in partial fulfillment of the

requirements for the degree of

MASTER OF SCIENCE IN NURSING

July 2014

Committee

Michelle Federe Riingen, DNP, RN, CNS-BC, Chair

Barbara Taylor, Ph.D., RN, Member

POINT LOMA NAZARENE UNIVERSITY

School of Nursing

Master of Science in Nursing

NAME OF STUDENT: Mario Chavez

TITLE OF PROJECT: Bispectral Index Monitoring to Assess the
Effect of a Healing Touch Treatment

COMMITTEE:

Michelle Federe Riingen, DNP, RN

Date

Barb Taylor, Ph.D., RN

Date

Abstract

Objectives: The objective of this study is to investigate the effects of Healing Touch (HT) therapies, a form of subtle energy (biofield) therapy, on Bispectral Index (BIS) measurements, State Trait Anxiety Index (STAI) scores, and physiological measures of heart rate, blood pressure, and respiratory rate in healthy adults.

Design: A single blind randomized crossover design will compare measurements during a HT therapy and placebo session.

Interventions: One HT session and one placebo session will be performed per participant on separate days. The HT treatment session involves a scripted sequence of near touch techniques performed by a Certified Healing Touch Practitioner (CHTP) while the participant lays supine. The placebo session will have the same set up except the CHTP will simply be walking around the room. Eye pillows and headphones ensure participants are blind to which session they are receiving.

Outcome Measures: Continuous Bispectral Index measurements, State Trait Anxiety Index scores, and vital signs.

Conclusions: The results of this study will describe the usefulness of BIS monitoring as an instrument for measuring the effects of biofield therapies. The data collected from this study could be used to make a correlation between BIS data, vital signs, and perceptions of state and trait anxiety.

TABLE OF CONTENTS

Chapter One: Introduction1

 Significance of the Problem2

 Statement of the Problem3

 Statement of the Purpose5

Chapter Two: Literature Review6

 Biofield Therapies6

 Healing Touch8

 Instruments12

 Electrograms13

 Bispectral Index Monitor14

 Conceptual Framework15

Chapter Three: Methods17

 Design17

 Sample17

 Setting17

 Instruments18

Chapter Four: Results21

Data Analysis	21
Chapter Five: Discussion	22
Implications for Nursing	22
Limitations of the Study	23
Areas for Future Research	23
Conclusion	25
References	26

CHAPTER ONE

Introduction

Energy therapies have been practiced in cultures around the world and throughout history. Laying of hands, Qi Gong, Healing Touch, Reiki, and Therapeutic Touch are just a few of the energy therapies currently practiced in the United States. Energy therapies are considered Complementary and Alternative Medicine (CAM) by the National Institute of Health (NIH) (Horowitz, 2012). The Centers for Disease Control and Prevention's 2007 National Health Interview Survey (NHIS) found that approximately 38 percent of U.S. adults, up from 36% in 2002, used some form of CAM in the year 2007 (Barnes, Bloom, & Nahin, 2008). That translates into an estimated \$33.9 billion dollars spent on CAM visits, products, and classes by U.S. adults in the year 2007 alone. (Nahin, Barnes, Stussman, & Bloom, 2009). The 2007 NHIS also found that 0.5 percent of American adults (roughly 1.5 million people) had used energy therapies or Reiki (Barnes, Bloom, & Nahin, 2008).

Hospitals across the country, including Scripps and Sharp Healthcare in San Diego, are offering Healing Touch services (a form of energy therapy) to patients and staff. People seek out CAM treatments for many reasons including: increase calmness and relaxation, relief from pain, anxiety, and emotional distress, as well as to enhance overall health and well being (Horowitz, 2012). Therapies such as Healing Touch are considered CAM, by definition, lack the empirically proven efficacy and safety of conventional medicine (Barnes, Bloom, Nahin, 2008). If HT is to be promoted in the hospital setting, then it should be evaluated using the same criteria and scientific methods as medical research.

Significance of the Problem

Healing Touch is a form of energy healing founded by registered nurses and remains a popular form of energy healing within the nursing community (Dossey, Keegan, & Guzetta, 2000). When performing HT treatments, practitioners use their hands, *biofields*, and intention in order to affect the entire well being of clients, promote a relaxed state, and promote self healing (Hover-Kramer, 2009). The HT certification program, which has been endorsed by the American Holistic Nurses' Association, have trained thousands of nurses. The practice of HT has gained enough support that the North American Nursing Diagnosis Association even approved the diagnostic category of *Disturbed Energy Field* in support of the practice of energy healing techniques such as HT (North American Nursing Diagnosis Association, 2007)

In the stressful and hectic acute care environment, the low tech, cheap, and non-invasive HT treatments offer nurses a non-pharmacologic technique to improve patient outcomes and connect with patients (Cotter, et al., 2012). HT modalities have demonstrated positive improvements in patient's perceptions of pain (Cotter, et al., 2012; Fazzino, Griffin, McNulty, & Fitzpatrick, 2010), stress, fatigue (Wong, Ghiasuddin, Kimata, Patelesion & Siu, 2013), and agitated behaviors in dementia (Wesa, Cassileth, & Jain, 2011). HT has promise as a CAM therapy for the hospital setting if there were sufficient proof to demonstrate its efficacy and safety. There has not been sufficient published quantitative research studies on HT to demonstrate efficacy and safety (Anderson & Taylor, 2011b; Fazzino, et al., 2010; Wardell, Decker, & Engebretson, 2012; So, Jiang, & Qin, 2012).

Statement of the Problem

Healing Touch International (HTI) is one of two professional organizations dedicated to the promotion and certification of Healing Touch Practitioners. HTI provides support and expertise to interested researchers as well as disseminating research findings in the organization's journal. The HTI website contains a cumulative list of over 90 research studies which have been performed on HT in categories ranging from stress, coping, patient satisfaction, geriatric populations, cancer, hospice and palliative care. The HTI collection of studies generally supports the efficacy of HT in a variety of settings, however reviewers have criticized the difficulty in accessing data held by HTI. Researchers So, Jiang, and Qin commented in a systematic review, that the significant body of work published by HTI shows positive results in general but the omission of important data leads to questions regarding how the studies were designed, conducted, and reported (2012). Weaknesses identified in the HTI collection of articles underscore the need for additional well designed studies to provide more definitive support to the efficacy of HT treatments.

The need for more rigorous study design is a common theme in published reviews of the literature regarding Healing Touch modalities (Freeman, 2009). At the time of this literature review there was no published meta analysis owing to the lack of homogeneity in the available research. Some areas to improve for future research include standardized approaches as to the duration of treatments and specific techniques used, reporting the experience level of the HT practitioner, larger clinical trials, and additional qualitative research to better describe the experience of HT (So, Jiang, & Qin, 2012; Turner, Clark, Gauthier, & Williams, 1998; Wilkinson, et al., 2002). Additional criticisms of HT research is that the studies are usually

performed by practitioners and therefore open to bias, inadequately control conditions, or fail to include controls for placebo effect (Freeman, 2009). Well designed quantitative research studies are needed in order to substantiate the positive results achieved by HT practitioners (Anderson & Taylor, 2011b).

Seeking to scientifically validate the effects of energy therapy treatments with empirical data, researchers have used a variety of instruments in research studies including electrograms such as surface electromyography (Forbes, Rust, & Becker, 2004), and electroencephalography (Uchida, et al., 2012). Electrograms measure electrical impulses in the body and could be used to determine if there is an electromagnetic component to the human biofield. Trials measuring the effects of biofield therapies using electrograms show potential because these are validated instruments providing empirical data that allow for the possibility of blind trials where the subjects may not know they are receiving treatments. The results of these trials are encouraging for HT supporters but there have not been subsequent studies to replicate their results. There are considerable hurdles to widespread adoption of electrograms use in biofield research. Electrograms are complex, the cost prohibitive devices requires specialized equipment, and a trained technician to apply electrodes, collect data, and interpret results.

One type of electrogram which has yet to be used in biofield research is the Bispectral Index (BIS) monitor. The Bispectral Index is a scale derived from the measurement of cerebral electrical activity in patients primarily used during surgery to ensure the optimum level of anesthesia is administered. The BIS monitor is used to provide objective information about the effects of sedatives on the brain but its processed EEG parameter and numerical scale would make it useful in biofield research. The BIS monitor analyzes the electroencephalogram data and

provides a single value between the range of 1-100 that shows real time changes in brain activity. The BIS monitor is an instrument already used in hospitals across the country that could be used to measure the effects of healing touch or other biofield therapies on the brain's electrical activity. If performed with scientific rigor then positive and significant results could be used to support the argument for more widespread use of these modalities.

Statement of the Purpose

The aims of this study are (i) investigate the effects of Healing Touch therapies on Bispectral Index measurements, State Trait Anxiety Index scores, and physiological measures of heart rate, blood pressure, and respiratory rate in healthy adults, (ii) to determine the utility of the BIS monitor as an instrument for measuring the effects of biofield therapy, (iii) to develop a methodology for objectively measuring the effects of Healing Touch modalities which allows for replication by the scientific community.

CHAPTER TWO

Literature Review

A review of relevant literature was conducted using the online article databases Cumulative Index to Nursing and Allied Health Literature (CINAHL) and PubMed with the keywords healing touch, touch therapies, biofield therapies and energy therapies. Additionally, a manual review of relevant references was conducted of these results as well as additional searches using medical subject heading (MeSH) terms “biofield therapy” and “energy medicine”. The search yielded several hundred clinical trials, reviews, and journal pieces.

Biofield Therapies

Biofield therapies involve a practitioner exerting energy to restore, enhance, and balance a recipient’s energy field using hands on techniques (Hover-Kramer, 2009). Reiki, Therapeutic Touch and Healing Touch are interventions classified as biofield therapies (Hart, 2012). Biofield therapies have foundations in hands on and energy based healing traditions practiced around the world. Reiki was introduced in Japan in the 1920s with a foundation based on the 3,000 year old Tibetan sutras. Therapeutic Touch (TT) is a form of energy healing developed in the United States in the 1970s and was influenced by the ancient practice of *laying-on* of hands. HT combines techniques and ideas found from a variety of healers including Therapeutic Touch, Reiki, and Native American traditions (Anderson & Taylor, 2012). Although the biofield therapies differ in techniques and philosophy, it is useful to consider all biofield research together for the purposes of literature review.

The strategy of grouping data from several biofield therapies in order to collect a larger data set has been used by several reviewers (Anderson & Taylor, 2011b; Hart, 2012). In a

systematic review conducted in 2008, Jackson, et al., searched the best available literature to determine the effectiveness of Touch Therapy at reducing pain and anxiety in cancer patients. The results of the study demonstrated a scarcity of quantitative data to support this one form of energy healing alone, so the results of Reiki, Therapeutic Touch and Healing Touch were combined to increase sample size. The standard seven level rating system for levels of evidence was used to rate the studies. From the data of twelve studies, only five were considered a high level of evidence at levels one or two. Jackson, et al. concluded that the research supports the effectiveness of touch therapies at reducing the perceptions of pain and anxiety in the cancer population but that additional high quality studies need to be performed in order to support touch therapies.

A systematic review undertaken by So, Jiang, and Qin published in the Cochrane Library found that there were more clinical trials involving Therapeutic Touch and Reiki than Healing Touch alone (2012). So, Jiang, and Qin grouped Reiki, Therapeutic Touch (TT), and Healing Touch (HT) to evaluate the effectiveness of touch therapies at reducing pain. The article search identified twenty four controlled clinical trials (3 Reiki, 16 TT, 5 HT) for a total sample size of 1153 participants. Data collected using different pain assessment instruments was extracted and assessed for quality by the reviewers. On a scale of zero to ten TT reduced pain scores by 0.83 units (95% CI -1.16 to -0.50). No adverse reactions were identified. The reviewers concluded that the results generally supported the use of TT as an intervention to reduce acute and chronic pain (2012).

Another study looking at the effects of TT on pain and anxiety was performed by Turner, et al., on patients recovering from burn injuries (1998). Turner, et al., created a randomized

clinical trial with single blinding to measure the effectiveness of TT alongside analgesia in reducing pain and anxiety. The researchers used a sham control group that mimicked the movements of a TT treatment but omitted the techniques used by a trained practitioner. The sham practitioners performed arithmetic calculations in their heads while performing random hand gestures unrelated to anything taught in TT. This study had a sample of 99 inpatients with severe burns who received either TT or a sham TT daily for five consecutive days. This study found significant pain and anxiety reduction in the experimental (TT) group when compared to the sham TT group.

Turner et al., found a significant reduction in pain was reported by TT subjects on the Pain Rating Index (PRI) scores, $t(61)=2.76$, $P=0.004$, and for the Number of Words Chosen scale (NWC), $t(61)=2.75$, $P=0.005$. The TT group adjusted mean score was 8.4 units lower than that of the control group on the PRI index scores representing a meaningful reduction in pain perception as the result of the TT treatment. In addition to the positive reductions to pain and anxiety levels, this study identified two important confounding variables that should be addressed in future studies. First, music therapy is a separate modality that must be accounted for in the study design. Second, sham therapy is not recommended as a control group since presence alone can have unintentionally relaxing effects.

Healing Touch

HT is a low tech, affordable and safe intervention that has been demonstrated to show increased levels of satisfaction from recipients and practitioners (Wong, et al., 2013). If Biofield therapies are to continue growing in acceptance in the hospital setting then the practice must be supported by strong levels of evidence. The effectiveness of HT has been studied many times

with generally positive results but many of these studies do not meet standards when compared to rigorous medical research (So, Jiang, & Qin, 2012). If HT is to be integrated into the health care system, then effectiveness and safety will need to be demonstrated using rigorous research methods (Forgues, 2009).

An experimental randomized control trial by MacIntyre, et al., was designed to show if providing Healing Touch to patients undergoing coronary artery bypass surgery would lead to improved patient outcomes (2008). The 237 patients were randomized into three groups including a treatment group that received HT before, during and after surgery, a visitation group that was allowed visitors, and a no intervention group. There was no significant difference in medication use or incidence of atrial fibrillation between the three groups. The State Trait Anxiety Index (STAI), a 40 question survey using a 4 point Likert scale, was the instrument used to measure changes in anxiety. The treatment group that received HT (6.3: 95% CI=2.0, 10.6) had significantly lower mean anxiety scores compared to the other groups, visitor (5.8: 95% CI=0.9, 10.8) and control (5.8: 95% CI=0.9, 10.8). The results of this study demonstrate that the HT treatment group had a shorter length of stay for patients undergoing coronary artery bypass surgery. The mean length of stay for patients in the HT group was 6.9 (95% CI=6.1, 7.7) days compared to 7.7 (95% CI=6.7, 8.7) days for the visitor group and 7.2 days (95% CI=6.4, 8.1) for the no treatment control group.

A trend found in the literature is the use of triangulation of study design to better describe the many aspects and experiences of HT. The combination of quantitative and qualitative measures give a well rounded explanation to this holistic intervention. One such study performed by Wilkinson, et al., used a mixed method, quasi experimental design to determine the

clinical effectiveness of Healing Touch (2002). Wilkinson, et al., measured secretory immunoglobulin A (sIgA) concentrations in saliva and self reports of stress levels along with implementation of a qualitative questionnaire. The sample size for this study was 22 adults. Results of this study are statistically significant and support the position that HT promotes health enhancement: the intervention (HT) group saw a rise in sIgA concentrations ($F = 5.63$, $p < 0.014$, observed power = 0.617, effect size 0.32), and significant stress reduction ($t = 6.086$, $p < 0.0003$). The strengths of this study included the previously mentioned triangulation of methods, a standard “no treatment” control, and a placebo control group to account for the confounding variable of ambient music. Wilkinson, et al., recommend that future studies look into the influence practitioner training and experience have on results.

In 2008, Maville, Bowen and Benham published a quasi-experimental pilot study to test for HT's effect on stress perception and biological correlates. The researchers administered the State-Trait Anxiety Inventory (STAI) on 30 nursing students to measure anxiety before and after a HT treatment. The median α coefficient for STAI state anxiety was 0.93, and the median α coefficient for trait anxiety was 0.90. Heart rate, blood pressure, skin conductance, muscle tension, and skin temperature were measured before and after a standardized fifty minute HT session performed by an experienced certified HT practitioner. The study reports post-treatment systolic blood pressure ($M = 110.8$, $SD = 11.2$) was significantly lower than pretreatment ($M = 116.7$, $SD = 13.9$; $t[29] = 4.02$, $P < .001$) levels. In addition, heart rate and temperature decreased significantly from baseline ($t[25] = 5.19$, $P < .001$ and $Z = 3.08$, $P = .002$, respectively). The average state anxiety score decreased significantly (40.2 to 20.9) and the trait anxiety scores decreased marginally (40.8 to 34.7) from the pretreatment to the post-treatment group. The

results demonstrate that the HT treatment was responsible for significant decreases in both state and trait stress perception as well as indicating physical relaxation. This study design used an experienced HT practitioner, performing a scripted routine, in a controlled environment. This pilot study, although limited by a small convenience sample, provides a model for replication as it controls for many previously published confounding variables while also making suggestions for future studies.

Another studied study that implemented a pilot, two-armed randomized controlled trial was published in 2012 by Jain, et al., looking to reduce post-traumatic stress disorder symptoms in combat exposed active duty military. A total of 123 participants were randomly assigned to either the intervention group, which received six separate one hour sessions of HT and Guided Imagery over 3 weeks, or the control group which received treatment as usual (TAU), consisting of various forms of psychotherapy and medications. Repeated measures analysis of covariance with intent-to-treat analyses was performed on the data. The data indicates the participants in the intervention group experienced significant reductions in PTSD symptoms as measured on the PTSD Checklist PCL-Military with scores dropping from 54.7 to 40.7 ($p < 0.0005$, Cohen's $d = 0.85$), depression ($F=15.3$, $p < 0.0005$, Cohen's $d = 0.70$), cynicism ($F=11.2$, $p = 0.001$, Cohen's $d = 0.49$), and quality of life ($p = 0.002$, Cohen's $d = 0.58$) were also improved when compared to the control group. The study found statistically and clinically significant results from a methodologically sound RCT that support the efficacy of HT in helping patients with PTSD.

Instruments

Seeking to scientifically validate the effects of HT treatments with empirical data, researchers have used a variety of instruments in research studies including:

- Secretory IgA concentrations (Wilkinson, et al., 2002),
- Profile of Mood States (Uchida, et al., 2012),
- PTSD Checklist-Military (Jain, et al., 2012),
- Opioid Analgesic Consumption (Hardwick, Pulido, & Adelson, 2012),
- Beck Depression Inventory BDI-II (Jain, et al., 2012),
- SF-36 (Jain, et al., 2012),
- Cook-Medley Hostility Inventory (Jain, et al., 2012),
- Visual Analog Scale Pain (Kemper, et al., 2009; Hardwick, Pulido, Adelson, 2012),
- Brief Fatigue Inventory (FitzHenry, et al., 2013),
- Hospital Anxiety and Depression Scale (FitzHenry, et al., 2013; Cotter, et al., 2012),
- Heart Rate Variance Monitor (Kemper, Fletcher, Hamilton, & McLean, 2009),
- Skin Conductivity (Anthes, 2012),
- State Trait Anxiety Inventory (MacIntyre, et al., 2008; Hardwick, Pulido, Adelson, 2012),
- surface Electromyography (Forbes, Rust, & Becker, 2004),
- Electroencephalograph (Anthes, 2012; Uchida, et al., 2012),
- Verbal Descriptor Scale Pain (Wardell, Decker, & Engebretson, 2012),
- Pain Assessment instrument in Cognitively Impaired Elders (Wardell, Decker, & Engebretson, 2012),

- Katz Index of Independence in Activities of Daily Living (Wardell, Decker, & Engebretson, 2012)

One of the major weaknesses in the body of research performed on HT has been the lack of homogeneity in designs as researchers attempt to find an appropriate methodological approach with effective instruments (So, Jiang, & Qin, 2012). Scientific knowledge about a topic is validated through the independent replication of studies which is not accomplished when each researcher takes a different approach.

Electrograms

Electrograms are devices that measure and record the electrical activity in the body used for diagnostic and research purposes. Researchers have used electromyography (EMG), a form of electrogram, in order to determine if there is an electromagnetic component to the human biofield (Hunt, 1996; Forbes, Rust, & Becker, 2004). The EMG apparatus measures electrical signals in the large voluntary muscles of the body but also detects heartbeat (ECG) signals as artifact. Forbes, Rust, and Becker used an EMG apparatus to measure the effects of a HT treatment (2004). Forbes, et al., controlled for voluntary muscle signals by having their subject resting prone and used filters on their equipment to control for the ECG readings, changes in electrical activity measurements are attributed to the effects of the HT intervention. There were amplitude increases for frequencies $>20\text{Hz}$ that reached 10dB for the duration of the HT treatment that returned to amplitudes in the resting state frequency spectrum when HT was finished. The results of the study demonstrated changes to the EMG recordings during a HT treatment. The authors concluded that EMG has potential as a measurement device for biofield research and that further experimentation is warranted (Forbes, Rust, & Becker, 2004).

The electroencephalogram (EEG) is an electrogram that measures the spontaneous electrical activity of the brain. Researchers in Japan developed a methodology to address the challenge of distinguishing between a biofield effect and possible placebo effect using electroencephalography. Uchida, et al., performed a single blind, randomized, crossover design study to investigate the effect of Okada Purifying Therapy (OPT), a form of biofield therapy, on EEG data (2012). Each of the study's 19 participants received the OPT intervention and also served as control in a placebo session. The two sessions (OPT and placebo) were identical except that in the intervention session the therapist directed the OPT at the participant and in the placebo session the therapist directed the OPT at themselves. EEG data was collected during both 15 minute sessions while participants wore headsets and had their backs to the practitioner's actions. EEG data demonstrated that participants had increased alpha wave activity in the frontal and central cortex during their OPT session when compared to the placebo session ($p < 0.05$). The blinding and randomization of the study design along with an objective EEG apparatus allowed the researchers to demonstrate a change in brain function as a result of a biofield therapy treatment versus the placebo effect.

Bispectral Index Monitor

In contrast to EEG and EMG, no studies have been found to use Bispectral Index (BIS) monitoring to measure the effects of a biofield therapy. However, researchers have used the BIS monitor in a variety of settings other than the original purpose in the operating room. The BIS monitor was found to provide a reliable index of neurologic status in awake, unседated, critically ill patients in a medical intensive care environment (Gilbert, et al., 2000). The BIS has been found effective not only in adults but in children as well as confirmed in sleep studies (Benini, et

al., 2005) in contrast BIS monitoring was studied in the Emergency Department (ED) and found to not reliably correlate with the Glasgow Coma Scale assessments performed by ED physicians on patients with altered levels of consciousness (Gill, Green, & Krauss, 2003).

Finally, BIS monitoring has been explored as a potential instrument for the early detection of brain death in adults (Misis, et al., 2008) and confirmation of brain death in children (Okuyaz, Birbicer, Doruk & Atici, 2006). These studies are mentioned only to demonstrate that researchers have sought out alternative uses for the BIS monitor outside of its role in the operating room.

Conceptual Framework

Despite research that demonstrates the positive effects of HT at reducing pain, anxiety, and depression, the mechanism which accounts for these results is not fully understood (Hover-Kramer, 2008). HT literature describes a biofield composed of layers that comprises each living being. The theoretical framework for this study is Martha Rogers' Science of Unitary Human Beings which states that all living things are composed of energy. Other theoretical frameworks used in HT research include Grounded Theory (Van Aken & Taylor, 2010), Benner's Novice to Expert (Anthes, 2012), and Benson's Relaxation Response (Anthes, 2012).

The Science of Unitary Human Beings, first published by Rogers in 1970, has been used in many research studies as a theoretical basis for nursing and energy healing. The theoretical framework recognizes that the complete human being is not a sum of its parts. As opposed to a holistic approach that looks at mind, body, and soul working together, the Unitary approach states that the pieces are indivisible and must be viewed together (Gunther, 2010). This view is in

contrast to a systems view in which the patient's health is viewed from one organ system at a time.

Rogers' ideas are broken down into four main postulates and three major principles. The first postulate states that all living and non living objects are comprised of energy fields that are constantly fluctuating and interacting with each other (Rogers, 1970; Gunther 2010). Through this postulate a mechanism is visualized in which a HT practitioner interacts with the patient. This single postulate of energy fields creates the foundation for the rest of the Science of Unitary Human Beings and is the basis for this study.

The other postulates of Rogerian theory are pattern, openness, and pandimensionality (Gunther, 2010). Each is essential to fully comprehending Rogerian philosophy but not essential to understanding the concepts of HT. Rogers' Science of Unitary Human Beings has been used in forming many different theories and research methods as well as having a unique view on cosmology, ethics and epistemology (Rogers, 1970). In this study only the first postulate of all bodies being comprised of energy fields as a way to understand what is occurring when the HT practitioner and patient interact will be used by the author.

CHAPTER THREE

Methods

Design

The purpose of the present study is to investigate the effect of HT therapy on Bispectral Index (BIS) measurements using a crossover design consisting of therapy and placebo treatments. State anxiety and vital signs are collected as measures of physiological statistics and serve as context for the BIS measurements. Data will be collected before, during and immediately after the session.

Sample

A sample size of 40 participants will ensure statistically significant results with an effect size of 0.25, an alpha of 0.05, and a power of 0.80. Approval from an Institutional Review Board must be obtained to verify the protection of privacy and participants' rights. Informed consent will be obtained from all participants prior to taking part in the study. Participants must be able to read, write and lay supine for 30 minutes. Individuals who have received any amount of HT training will be excluded. There will be no compensation for participation in this study. A homogenous population of similarly diagnosed medical patients would provide the most meaningful data for the purposes of future systematic reviews.

Setting

An identical setting will be ensured for both the intervention and control group to control for confounding factors. The standard treatment room will be quiet, private, climate controlled, with dim lighting. Every effort should be made to ensure the comfort of participants and practitioner including appropriately sized massage table, clean sheets, pillow cases, and available

hand sanitizer. Any empty classroom, conference room, or treatment room that satisfies these conditions would be adequate.

Instruments

Bispectral Index (BIS). The BIS is a scale derived from the measurement of cerebral electrical activity in patients. BIS monitoring is primarily performed during surgery to ensure the optimum level of anesthesia is administered. The BIS monitor is used to provide objective information about the effects of sedatives on the brain. The monitor provides a numerical value, 0-100, that corresponds to the level of electrical activity in the brain. The specific BIS monitor selected (e.g. Philips IntelliVue MP40 with attached Philips BIS module) for use in this study must be used according to manufacturers instructions.

State-Trait Anxiety Inventory (STAI). The STAI consists of a 4-point Likert scale and is made up of 40 self report questions. The STAI is used to measure state and trait anxiety or anxiety about an event as well as anxiety level as a personal characteristic. Scores range from 20-80 and higher scores are positively correlated with higher levels of anxiety.

Monitoring. Vital signs to include blood pressure, heart rate, respiratory rate, and oral temperature will be collected using the Philips IntelliVue MP40 vitals machine.

Demographics. A standard demographic questionnaire will be part of the paperwork given to each study participant to be filled out. Demographic information will be useful when analyzing the sample ultimately selected and provide context to the data collected.

Procedure

Pre Intervention. Each participant will take part in two sessions, a HT session and a placebo session. The two sessions will be performed on separate days, at the same time of day, a

week apart. Determination of sequencing between intervention and control groups will be randomized using a spreadsheet randomization program.

Each session begins when the participant enters the treatment room and is introduced to the Certified Healing Touch Practitioner (CHTP) and lead investigator. Introductions will be made, instructions given, and consent will once again be verified. The lead investigator will instruct participants to complete the STAI for adults. Once the inventory is complete participants will lie down on massage table, place eye pillows, and begin listening to relaxing music through headphones. The lead investigator will apply the BIS monitor electrodes on the forehead according to the manufacturer's instructions and begin BIS monitoring. Baseline vital signs will be performed by the lead investigator at this time. BIS measurements will be measured at rest for 10 minutes. The CHTP will be silent and careful not to touch the participant who has been instructed to rest with eyes closed. The lights will be dim, there will be soft music playing, and the CHTP will apply lavender lotion to own hands. Up to this point all conditions in the HT and placebo sessions are identical and the participant will be blind to the actions of the CHTP.

Intervention. The same time-sequenced set of techniques will be administered to each person in the intervention HT group with the participant lying comfortably supine. The techniques used for the sequence will be non touch based chakra connection, chakra spread, and mind clearing. The chakra connection involves placing hands still over the many energy sites of the body and is indicated to open the energy centers and enhance the flow of energy (Hover-Kramer, 2009). The chakra spread involves a pattern of movement through the patient's energy field from head to feet. The chakra spread is a gentle procedure used to release pain and stress effecting the body on many different levels (Hover-Kramer, 2009). Finally, the mind clearing

technique involves light or no touch along specific spots around the client's face and scalp and is useful for quieting the mind and promoting a state of relaxation. (Hover-Kramer, 2009). Each technique will be timed according to the background music to ensure the uniformity of each treatment at 15 minutes.

Control. All conditions in the placebo session will be the same except that the CHTP will perform HT on self and walk around the table, essentially ignoring the participant on the table. Following the experimental sessions, both HT and placebo, participants will have vital signs repeated and the STAI will once again be administered and BIS monitoring will be terminated.

Post Intervention. All interventions and data collection will be performed by the lead investigator. Every effort will be made to ensure the privacy of all study participants including keeping the results of the study anonymous. Raw data including the vital signs, BIS recordings, STAI results, signed consent forms, and any other materials collected during the experiment will be kept in a locked file cabinet or password protected electronic file of the lead investigator for 7 years.

CHAPTER FOUR

Results

Data Analysis

Descriptive statistics will be utilized to calculate the frequencies, percentage, means, medians and standard deviations of relevant results. Analyses will be performed using SPSS version 16.0. Statistical comparisons of group differences between the HT and placebo sessions will be done using Wilcoxon tests.

Data will be collected from approximately 40 participants before and after they receive an intervention is received. The data analysis will contain a discussion on the characteristics of the sample population. Total participation numbers as well as key information from the demographics questionnaire will be analyzed and discussed.

CHAPTER FIVE

Discussion

Healing Touch is a complementary modality that is growing in popularity. In order to better understand the positive work being done by HT practitioners, researchers must perform well designed quantitative studies. Use of the BIS monitor as an instrument for collecting empirical data in a blinded fashion for HT research is recommended. The goal of this study is to contribute to this body of research and to evaluate the effects of HT treatments on the brain using Bispectral Index monitoring.

Implications for Nursing

Well designed and reproducible quantitative research on the efficacy of HT has the potential to greatly influence nursing practice because nursing seeks to provide care that is evidence based. If the evidence greatly supports the use of complementary modalities such as HT, this modality can be better integrated into health delivery systems. Hospitals could encourage the practice of touch therapies in their facilities by providing additional incentives for nurses who seek training, tuition reimbursement, and even creating positions for CHTP. The research for HT generally supports the techniques but stronger evidence is needed before HT becomes conventional therapy.

Non-pharmacologic interventions for treating patients in the acute care setting are already a major focus of nursing education at the undergraduate level. With the better understanding that comes with quality research the education of future nurses could be expanded to include energy

therapies. If HT is found to achieve significant effects on pain, anxiety, and nausea reduction then HT would be essential component of curricula for prospective nurses.

Limitations of the Study

The HT treatment was standardized for the purposes of creating a rigorous scientific trial with meaningful data, however, HT practitioners believe that interaction between patient and practitioner is a key element of the treatment. The interview, assessment, and collaboration between practitioner and patient are eliminated in order to create a standardized approach in this study. This artificial environment is a limitation that needs to be highlighted when considering the results of this study.

There are many challenges to measuring the varied experiences of receiving a HT treatment and this has led many investigators to try mixed design studies. A qualitative component added to this study would broaden the focus but might result in a more comprehensive understanding of the effects of HT. The lack of triangulation of methods in this study was purposefully planned but limits the scope of the results as well.

A final confounding variable that may affect the results of this study are the presence of separate calming modalities in the procedure. The effects of music, quiet environments, and the lavender lotion may contribute to results.

Areas for future research

A simple, well designed method for measuring the effects of HT could serve as a model for replication by other researchers. This study could then be conducted on varied populations to better understand the results in different settings. For example, stress reduction on patients about to undergo surgery could be measured to see how outcomes such as length of stay are affected.

The study design could be repeated on pediatric patients undergoing medical procedures, college students during finals week, mental health patients undergoing evaluation, ICU patients experiencing acute delirium, etc. Homogenous data could then be compiled in a systematic review to make definitive statements about the efficacy of HT in different environments. There are many aspects of HT treatments that could be isolated and changed in order to study the effects of HT. HT practitioners could replicate this study substituting different HT techniques to better understand how each technique changes the data.

One of the most important purposes of this study is to create a streamlined study design for obtaining objective measures of HT efficacy. Therefore, more lessons are learned through the process of performing this study. Those lessons and experiences can then be applied to larger future studies.

With refined methodologies and more appropriate instruments, researchers in the future will be able to describe the aspects of biofield therapies. Davis further identifies the need to answer the following three questions (2006):

- What aspect of biofield therapies is being quantified?
- Are we measuring the biofield directly or simply measuring the effects of energy work?
- Are we in fact measuring the process of energy work?

Future researchers will be able to address these very questions with more precise instruments that can measure or visualize the human biofield directly.

The collection of data from large well designed studies on the effects of HT will lead to a better understanding of what can be accomplished through this complementary modality.

Controlled experiments will better describe and define the positive work that is already seen

anecdotally by practitioners worldwide. Additional questions to explore are what percentage of people receive stress reduction, by how much stress is reduced, how long can the effect be measured, and are there any side effects. A simple and clear methodology for measuring stress could then be applied to the other symptoms and effects that HT modalities are said to influence such as pain, nausea, and agitation.

Conclusion

The results of this study will describe the usefulness of BIS monitoring as an instrument for measuring the effects of a biofield therapy. The data collected from this study could be used to determine a correlation between BIS data, vital signs, and perceptions of state and trait anxiety. Experience gained from performing this study will serve to improve study designs in future biofield research.

References

- Anderson, J. G., & Taylor, A. G. (2011a). Biofield therapies in cardiovascular disease management: A brief review. *Holistic Nursing Practice*, 25(4), 199-204.
- Anderson, J. G., & Taylor, A. G. (2011b). Effects of Healing Touch in clinical practice A systematic review of randomized clinical trials. *Journal of Holistic Nursing*, 29(3), 221-228.
- Anderson, J. G., & Taylor, A. G. (2012). Biofield therapies and cancer pain. *Clinical Journal of Oncology Nursing*, 16(1), 43-48.
- Anthes, D. M. (2012). Assessment of changes in brainwave patterns and physiological markers of subjects receiving Healing Touch—A randomized controlled trial. Unpublished dissertation. Holos University, Bolivar, Missouri.
- Barnes PM, Bloom B, & Nahin R. (2007). CDC National health statistics report #12. Complementary and alternative medicine use among adults and children: United States, 2007.
- Benini, F., Trapanotto, M., Sartori, S., Capretta, A., Gobber, D., Boniver, C., & Zacchello, F. (2005). Analysis of the Bispectral Index during natural sleep in children. *Anesthesia & Analgesia*, 101(3), 641-644.
- Cotter, N., Dowling, W., Gatto, C., Gallagher, A., Smith, J., Evans, R., & Bustami, R. (2012). Efficacy of energy therapy in relieving anxiety and pain in patients undergoing lumbar spine fusion surgery. *BMC Complementary and Alternative Medicine*, 12, 198.
- Davis, L.A. (2006). Quantifying Healing Touch. *Visions*, 14(2), 66-70.

- Denner, S. S. (2009). The science of energy therapies and contemplative practice: A conceptual review and the application of zero balancing. *Holistic nursing practice, 23*(6), 315-334.
- Dossey, B., Keegan, L., & Guzzetta, C. (2000). *Holistic nursing: A handbook for practice* (3rd ed.). Gaithersburg, MD: Aspen Publishers.
- Fazzino, D., Griffin, M., McNulty, R., & Fitzpatrick, J. (2010). Energy healing and pain: A review of the literature. *Holistic Nursing Practice, 24*(2), 79-88.
- FitzHenry, F., Wells, N., Slater, V., Dietrich, M. S., Wisawatapnimit, P., & Chakravarthy, A. B. (2013). A randomized placebo-controlled pilot study of the impact of Healing Touch on fatigue in breast cancer patients undergoing radiation therapy. *Integrative Cancer Therapies, 13*(2) 105-113
- Forbes, M. A., Rust, R., & Becker, G. J. (2004). Surface electromyography apparatus as a measurement device for biofield research: results from a single case study. *Journal of Alternative & Complementary Medicine, 10*(4), 617-626.
- Forgues, E. (2009). Methodological issues pertaining to the evaluation of the effectiveness of energy-based therapies, avenues for a methodological guide. *Journal of Complementary and Integrative Medicine, 6*(1). DOI: 10.2202/1553-3840.1197
- Freeman, L.W. (2009). *Mosby's complementary & alternative medicine: A research-based approach* (3rd ed.). St. Louis, MO: Mosby, Inc.
- Gilbert, T. T., Wagner, M. R., Halukurike, V., Paz, H. L., & Garland, A. (2001). Use of bispectral electroencephalogram monitoring to assess neurologic status in unsedated, critically ill patients. *Critical Care Medicine, 29*(10), 1996-2000.

- Gill, M., Green, S. M., & Krauss, B. (2003). Can the Bispectral Index monitor quantify altered level of consciousness in emergency department patients?. *Academic Emergency Medicine, 10*(2), 175-179.
- Gunther, M. (2010). Nursing theory: Utilization & application (4th ed). M. R. Alligood & A. Marriner Tomey. (Eds) In *Rogers' science of unitary human beings in nursing practice*. St. Louis: Mosby, 2010. 287-308.
- Hardwick, M. E., Pulido, P., Adelson, W. (2012). Nursing intervention using healing touch in bilateral total knee arthroplasty. *Orthopaedic Nursing 31*(1): 5-11.
- Hart, J. (2012). Healing Touch, Therapeutic Touch, and Reiki: Energy medicine advances in the medical community. *Alternative & Complementary Therapies 18*(6): 309-313.
- Horowitz, S. (2012). CAM and the aging population: Trends and clinical implications. *Alternative & Complementary Therapies. 18*(6): 314-318.
- Hover-Kramer, D. (2009). Healing touch guide book: Practicing the art and science of human caring. San Antonio: Healing Touch Program.
- Hunt, V. (1996). Infinite Mind: Science of the Human Vibrations of Consciousness. Malibu, CA: Malibu Publishing Co.
- Jackson, E., Kelley, M., McNeil, P., Meyer, E., Schlegel, L., & Eaton, M. (2008). Does therapeutic touch help reduce pain and anxiety in patients with cancer?. *Clinical Journal of Oncology Nursing, 12*(1), 113-120. doi: 10.1188/08.CJON.113-120
- Jain, S., McMahon, G. F., Hasen, P., Kozub, M. P., Porter, V., King, R., & Guarneri, E. M. (2012). Healing Touch with Guided Imagery for PTSD in returning active duty military: A randomized controlled trial. *Military Medicine, 177*(9), 1015-1021.

- Kemper, K. J., Fletcher, N. B., Hamilton, C. A., & McLean, T. W. (2009). Impact of healing touch on pediatric oncology outpatients: pilot study. *Journal of the Society for Integrative Oncology*, 7(1).
- MacIntyre, B., Hamilton, J., Fricke, T., Ma, W., Mehie, S., & Michel, M. (2008). The efficacy of healing touch in coronary artery bypass surgery recovery: A randomized clinical trial. *Alternative Therapies in Health & Medicine*, 14(4), 24-32
- Maville, J., Bowen, J., Benham, G. (2008). Effect of healing touch on stress perception and biological correlates. *Holistic Nursing Practice*. 22 (2), 103-110.
- Misis, M., Raxach, J., Molto, H. P., Vega, S. M., & Rico, P. S. (2008). Bispectral Index monitoring for early detection of brain death. *In Transplantation Proceedings*. 40(5).
- Nahin, R.L., Barnes, P.M., Stussman, B.J., & Bloom, B. (2009). Costs of complementary and alternative medicine (CAM) and frequency of visits to CAM practitioners: United States, 2007. National health statistics reports; no 18. Hyattsville, MD:
- North American Nursing Diagnosis Association. (2007). NANDA Nursing Diagnoses. North American Nursing Diagnosis Association.
- Okuyaz, Ç., Birbiçer, H., Doruk, N., & Atici, A. (2006). Bispectral Index monitoring in confirmation of brain death in children. *Journal of Child Neurology*, 21(9), 799-801.
- Rogers, M. (1970). Introduction to the theoretical basis of nursing. Philadelphia, FA Davis.
- So, P.S., Jiang, Y., & Qin, Y. (2012). Touch therapies for pain relief in adults. *Cochrane Database of Systematic Reviews*, 4. doi: 10.1002/14651858.CD0065.pub2
- Thomas, L. S., Stephenson, N., Swanson, M., Jesse, D. E., & Brown, S. (2013). 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. *Journal of Holistic Nursing*, 31(4), 234-247.
- Turner, J., Clark, A., Gauthier, D., & Williams, M. (1998). The effect of therapeutic touch on pain and anxiety in burn patients. *Journal of Advanced Nursing*, 28(1), 10-20.
- Uchida, S., Iha, T., Yamaoka, K., Nitta, K., & Sugano, H. (2012). Effect of biofield therapy in the human brain. *The Journal of Alternative and Complementary Medicine*, 18(9), 875-879.
- Van Aken, R., & Taylor, B. (2010). Emerging from depression: The experiential process of Healing Touch explored through grounded theory and case study. *Complementary Therapies in Clinical Practice*, 16(3), 132-137.
- Wardell, D. W., Decker, S. A., & Engebretson, J. C. (2012). Healing touch for older adults with persistent pain. *Holistic Nursing Practice*, 26(4), 194-202.
- Wesa, K., Cassileth, B., & Jain, S. (2011). The effectiveness of biofield therapies for decreasing symptoms of pain and anxiety, and improving QoL. *Focus On Alternative & Complementary Therapies*, 16(1), 62-65.
- Wilkinson, D., Knox, P., Chatman, J., Johnson, T., Barbour, N., Myles, Y., & Reel, A. (2002). The clinical effectiveness of healing touch. *Journal of Alternative & Complementary Medicine*, 8(1), 33-47.
- Wong, J., Ghiasuddin, A., Kimata, C., Patelesio, B., & Siu, A. (2013). The impact of healing touch on pediatric oncology patients. *Integrative Cancer Therapies*, 12(1), 25-30.