

**THE EFFECTS OF VIBROACOUSTIC THERAPY (VT) AND MUSIC
ON ANXIETY IN PATIENTS UNDERGOING BREAST BIOPSY**

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The work reported in this thesis is original and carried out by me solely, except for the acknowledged direction and assistance gratefully received from colleagues and mentors.

Deborah Anne Pratt

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ABSTRACT

The Effects of Vibroacoustic Therapy (VT) and Music on Anxiety in Patients Undergoing Breast Biopsy

The objective of this study was to evaluate the effects of Vibroacoustic Therapy and music in reducing anxiety in patients undergoing breast biopsies. Anxiety levels were measured using the State-Trait Anxiety Inventory (STAI) and relaxation levels were measured by The Self-Report Rating Scale for Tension and Relaxation. The pre/post experimental design consisted of three groups of breast biopsy patients, utilizing a non-randomized convenience sample. A participant was assigned to the control group (N=17) when time prior to the biopsy procedure was limited. All other participants were randomly assigned among the two intervention groups: Vibroacoustic Therapy (N=17), an intervention that uses music which is felt in the body, as well as heard through the ears while reclining in the Somatron Clinical Recliner; or Music Alone (N=17), an intervention of music without the tactile stimulation heard while reclining in the Somatron Clinical Recliner. The music used was composed by a music therapist at approximately 50 beats per minute to entrain the body to relaxation. Each music session lasted approximately fifteen minutes. Patients who received a Vibroacoustic Therapy intervention or Music alone intervention experienced statistically lower levels of anxiety and statistically higher levels of relaxation as compared to the control, ($p < .01$). Conclusions and suggestions for future research are provided.

Key Words: Vibroacoustic, vibroacoustic therapy, music, music therapy, vibration, Somatron, Somatron Clinical Recliner, anxiety, relaxation, State-Trait Anxiety Inventory (STAI), The Self-Report Rating Scale for Tension and Relaxation, breast biopsy.

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CHAPTER 1: INTRODUCTION AND RESEARCH QUESTION

Introduction

A breast biopsy is carried out for only one reason, to screen for cancer. This can be a very frightening and stressful event. While approximately 80% of breast biopsies are benign, the experience of facing a diagnosis of cancer tends to be fraught with anxiety.¹ Past research has shown that anxiety is greatest for the patient at the time of the biopsy, even more so than 24 hours post-procedure when results are still unknown.² Alleviating some or all of this anxiety could facilitate the emotional well-being of patients undergoing breast biopsy, and thus warrants further research.

Past research has shown that music may be effective in reducing anxiety levels of women awaiting breast biopsy.³ Another therapy that could be effective in reducing anxiety in women awaiting breast biopsy is Vibroacoustic Therapy (VT). Vibroacoustic Therapy is an intervention that uses music which is felt in the body as well as heard through the ears and engages two of the five senses, namely the auditory sense and the tactile sense. Thus, research was undertaken to determine whether music and VT have an effect, and if so, to understand the effects of music and VT on patients awaiting breast biopsy. For this research project, VT was carried out in specially crafted Somatron Clinical Recliners, where the feet were elevated above the heart. This chair has strategically placed speakers which surround the participant and bathes the individual in sound. Music, coupled with vibration in a special chair, potentially could create an added level of healing beyond just music alone.⁴

Vibroacoustic Therapy and the Field of Energy Medicine

Vibroacoustic Therapy (VT) and music as therapy fall under the umbrella of energy medicine. Energy medicine is the discipline that investigates the energy fields within and around living systems, which are important to the health of the organism.⁵ This view of energy medicine takes into consideration the totality of the organism.

Energy medicine is receiving greater acceptance within the healthcare community, primarily for the following three reasons. First, within the biomedical community, awareness has increased with regard to the impact of electrical and magnetic fields as well as light and sound on cellular processes and how these fields stimulate healing in various tissues.⁶ The second reason lies in the increased interest of the marketplace in complementary and alternative therapies for healing, which has led to the integration of complementary and alternative therapies with more traditional allopathic methods to form integrative medical practices. The demand for these complementary and alternative therapies is such that consumers are willing to pay, even if insurance does not.⁷ Interest in human performance can be identified as the third reason for the emergence in energy medicine. This interest in human performance has led trainers, athletes, and performers to explore numerous ways to achieve their goals, as therapies within energy medicine have proven to enhance human performance and achieve goals.⁸ Regardless of the reasoning, the interest in energy medicine is ever increasing and allowing new ways of healing to emerge.

The Research Question and Research Hypotheses

Given the potential to promote healing through music and vibration, is it possible to use Vibroacoustic Therapy (VT) for patients experiencing anxiety prior to a medical

procedure? Specifically, can VT work to reduce anxiety in patients undergoing breast biopsy?

Focus on this research question led to six research hypotheses: 1) There is a significant impact on the anxiety level in patients undergoing breast biopsy if they have prior exposure to Vibroacoustic Therapy (VT) before the procedure. 2) There is a significant impact on the anxiety level in patients undergoing breast biopsy if they have prior exposure to Music Alone before the procedure. 3) There is a significant impact on the relaxation level in patients undergoing breast biopsy if they have prior exposure to VT before the biopsy procedure. 4) There is a significant impact on the relaxation level in patients undergoing breast biopsy if they have prior exposure to Music Alone before the biopsy procedure. 5) There is a significant difference between the intervention of VT and the intervention of Music Alone. 6) The beliefs patients hold with regard to VT and/or music have an impact on the efficacy of the respective intervention.

The Study Objective

The objective of the research study was to evaluate the effects of Vibroacoustic Therapy (VT) and music on anxiety in patients undergoing breast biopsy. As previously stated, VT is an intervention that uses music which is felt in the body as well as heard through the ears. This intervention was done in specially crafted Somatron Clinical Recliners, where the feet were elevated above the heart in the Trendelenburg position. In order to understand the impact of the vibration when it is accompanied with music, VT was compared to an intervention of Music Alone, without the tactile stimulation. This, too, was done in the specially crafted Somatron Clinical Recliners, with the feet elevated in the same way as participants in the first group. The music was on a CD that was

composed by a music therapist specifically for relaxation. Instruments used are cello, flute, harp, bells, violin and alto recorder. Each patient received one session on the day of the biopsy up to one hour prior to the biopsy procedure, lasting approximately fifteen minutes. The control consisted of patients undergoing breast biopsy who did not receive an intervention of VT or music and sat in the waiting room along with other patients.

Proposed Scope of the Study

Within the present study structure, five potential interventions existed.

The first intervention (Group 1, called the VT group) was Vibroacoustic Therapy (VT), conducted with participants in a chair where the feet are elevated above the heart in the Trendelenburg position, thereby reducing pressure on the spine, relieving muscle tension and aiding circulation.⁹ This chair has strategically placed speakers which surround the participant and bathes them in sound.

The second potential intervention (Group 2, called the Music Alone group) consisted of music alone, where the participant heard the music without tactile stimulation. This intervention included listening to the same music as in the VT intervention, but from a separate stereo system located directly behind the chair. A separate stereo system was required because the vibration components of the Somatron Clinical Recliner are extremely difficult to disconnect. However, the speakers were placed as precisely as possible to replicate the location of the speakers built within the chair. As this intervention of music by itself also utilized the specially crafted Somatron Clinical Recliners, with the feet elevated in the Trendelenburg position, the impact of vibration could be isolated when compared to the VT intervention.

The third potential intervention (Group 3, the Recliner Elevated group) consisted of resting without music or tactile stimulation in the specially crafted Somatron Clinical Recliners, with the feet elevated in the Trendelenburg position. When the Recliner Elevated intervention was compared to the Music Alone intervention, it was possible to isolate the impact of listening to music.

The fourth potential intervention (Group 4, Recliner Non-elevated) consisted of resting in the specially crafted Somatron Clinical Recliners with the feet down. This intervention did not include music, vibration or reclined position. The participant sat in the Somatron Clinical Recliner and rested without the addition of their feet elevated in the Trendelenburg position. By comparing a sitting position in the Somatron Clinical Recliner to a reclining position in the Somatron Clinical Recliner, it was possible to isolate the impact of reclining in the Trendelenburg position.

The fifth group in this study was the Static Control (Group 5) consisting of patients who waited alone in the waiting room without using recliners or subject to music or VT intervention.

Reclining in the Somatron Clinical Recliner and experiencing vibration alone would have been an interesting sixth intervention for this study. However, experiencing vibration only is, unfortunately, not technically possible with the current Somatron Clinical Recliner. Thus, this intervention was not considered.

Scope of Study Conducted

Two primary constraints played into the intervention selection process: time and quantity of sample (See Delimitations, Chapter Five). Working with these constraints, two interventions (VT – Group 1 and Music Alone – Group 2) and one control (Group 5)

were utilized within the research study. Music and vibration are the main components of Vibroacoustic Therapy (VT), and warrant the priority for investigation. While much research has been done as to the psychological benefits of music alone, only a few studies have been conducted as to the efficacy of VT. By incorporating Music Alone within the study, the incremental benefit of vibration along with music was assessed.

Definition of Terms

Anxiety – a normal response to perceived danger or the absence of people or objects that assure safety.¹⁰

Breast Biopsy – A breast biopsy is a procedure where samples from a breast lump or breast abnormality are taken to determine whether the suspicious area is cancerous.

Core Needle Biopsy – A type of breast biopsy procedure where the needle is spring-loaded which cuts and removes tissue. Only one sample is obtained with each needle insertion, leading to the need for four to six insertions to get sufficient tissue sample. While results are accurate, the limited sample gathered may underestimate a more serious diagnosis. There is minimal scarring and immediate recovery.¹¹

Energetic Arousal – A psychological measure, energetic arousal is a continuum ranging from tiredness to energy.¹²

Energy Medicine – Energy medicine is the discipline that investigates the energy fields within and around living systems, which are important to the health of the organism.¹³ This view of energy medicine takes into consideration the totality of the organism.

Entrainment – Entrainment occurs when the vibration of one object is projected upon a second object with a similar frequency, causing the second object to vibrate in resonance with the first.¹⁴ Entrainment can happen at the physical, emotional and/or spiritual level within the human system, supporting a mind-body connection.¹⁵

Extremely Low Frequency (ELF) – a band of radio frequencies from 30 Hz to 300 Hz.¹⁶

Frequency – Frequencies refer to the pitch of the sound and are measured in hertz (Hz). The higher the pitch of the sound, the faster it vibrates; and the lower the pitch of the sound, the slower it vibrates.¹⁷

Full-Frequency Music Model (FFM) – Vibroacoustic Therapy equipment pioneered by Byron Eakin designed such that a single sound source is used and music is played with a wide range of frequencies.¹⁸

General Arousal – a state where a patient is more sensitive to sensory stimuli, is physically more active; and reacts more emotionally.¹⁹

Hedonic Measures – measurement of happiness and well-being.

Hertz (Hz) – The number of cycles per second at which the sound wave vibrates.

Low Frequency Sound Massage – Olav Skille, a pioneer in Vibroacoustic Therapy, initially called his work Low Frequency Sound Massage, and later changed it to VT.²⁰

Mamotome® Biopsy – A Mamotome® biopsy is a type of breast biopsy which is a minimally invasive technique using a needle with a hollow chamber that draws, cuts and removes tissue. The results are highly accurate due to the ability to gather several samples with one needle, with minimal scarring and immediate recovery.²¹

Music Vibration Table – developed by Kris Chesky, at the Texas Centre for Music and Medicine, after reviewing research that failed to control and measure the vibrations used, which made it difficult for him to interpret the results accurately.²² This patented system is constructed from a typical hospital procedural stretcher and consists of a base table, sound system, a computerized vibration feedback processing system and a vibrating membrane – the table top, which has three separate modules positioned under the torso, lower leg and thigh.²³

Power Analysis – A technique used to anticipate the likelihood that the study will yield a significant effect and is based on the same factors as the significance test itself.²⁴

Physioacoustics – variation of Vibroacoustic Therapy pioneered by Petri Lehtikainen. The main difference between Vibroacoustic Therapy and physioacoustics is that VT blends a single frequency sinusoidal sound with music, while physioacoustics generates and combines a range of sinusoidal frequencies with the music.²⁵ The physioacoustic system, consisting of a mattress, a computer unit, an audio system and a power source, holds four transducers that are in the mattress which get placed under the neck, lower back, thigh and lower leg areas.²⁶

Physiotones Therapy – a form of physioacoustics that involves only vibration, administered as inaudible, pure tonal, low frequency sound waves.²⁷

Self Report Rating Scale for Tension and Relaxation (SRRSTR) – The self Report Rating Scale for Tension and Relaxation (SRRSTR) was developed by Roger Poppen and designed to study levels of tension and relaxation in the current moment. The scale is just one part of Poppen's method, which is a multi-modal approach in measuring relaxation.

Somatron Clinical Recliner – a specially crafted chair created by Byron Eakin and Somatron specifically for VT, where the feet are elevated above the heart in the Trendelenburg position.

Somatron Mat – A specially crafted mat for VT which permeates the whole body with stimulating and soothing sound vibrations. This portable mat can be placed on a variety of surfaces.²⁸

State Anxiety – State anxiety consists of subjective feelings of tension, apprehension, nervousness and worry, and activation of the autonomic nervous system that fluctuate over time as a function of a perceived threat. This type of anxiety is temporary.²⁹

State-Trait Anxiety Inventory (STAI) – The State-Trait Anxiety Inventory (STAI) is a self-report assessment instrument that measures levels of state and trait anxiety.

Tactile Stimulation – vibration felt on the skin.

Tension Arousal – A psychological measure, tense arousal is a continuum ranging from calmness to anxiety.³⁰

Trait Anxiety – Trait anxiety consists of relatively stable individual differences in anxiety proneness and the disposition to respond with more frequent and intense elevation in state anxiety. Trait anxiety scores are more stable over time and do not widely fluctuate.³¹

Trendelenburg Position – a reclined position where the client has their head lower than the rest of the body³², thereby reducing pressure on the spine, relieving muscle tension and aiding circulation.³³

Vibroacoustic Therapy (VT) – an intervention that uses music which is felt in the body as well as heard through the ears. This is done in specially crafted Somatron Clinical Recliners, where the feet are elevated above the heart.

Chapter 1 Endnotes:

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CHAPTER 2: REVIEW OF LITERATURE

Music as Medicine

Music has been used for centuries to aid the patient in healing and to reduce pain and suffering. Some of the earliest practitioners of music for healing were the shamans, who used their drums and rattles to attain altered states of consciousness and facilitate the process of healing.¹ More recently, music therapy has emerged to study systematically the effects of music through evidence-based interventions to bring about healing, both from a psychological as well as a physiological perspective. Understanding the healing effects of music is critical, as music was one of the interventions utilized within this research study, *The Effects of Vibroacoustic Therapy (VT) and Music on Anxiety in Patients Undergoing Breast Biopsy*.

Healing through Sound

Healing with sound can be traced back in time to Pythagoras, who is given credit for formally putting a structure to music and using music for healing. Pythagoras was a mathematician and philosopher who lived in Greece from 580 to 500 B.C.E. While listening to blacksmiths working, he realized that some hammering sounds were more pleasing than others. Through his observations, he was able to create the musical scale.² Healing with sound also dates back to the great ancient Mystery Schools, as these schools associated rhythm with the body, melody with the emotions and harmony with spiritual awareness.³

Sound has also been used throughout time for healing in spiritual and mystical traditions. Shamans have worked with sound in healing rituals for more than 20,000

years, and in all parts of the world from Siberia to South America.⁴ By using the steady beat of drums and rattles, shamans move into an altered state of consciousness that enables them and their patients to take a mental journey that has the potential to lead them back to health.⁵ Buddhist monks and Indian yogis have used chanting for thousands of years to lead them into altered states of consciousness to promote healing.⁶ Christian nuns, like Hildegard von Bingen, also used chants,⁷ as did aboriginal bush medicine men.⁸

Sound healing has been used to restore inner imbalances to their natural state of balance. This way of using sound for healing is based on the theory that internal organs and cells vibrate at specific frequencies, and any disruption is symptomatic of disease. By matching the frequencies, balance can be restored.⁹ This theory is similar to the Five Element Theory of acupuncture and Traditional Chinese Medicine, which assigns different musical notes to different parts of the body. Each acupuncture meridian and organ within the body corresponds to a different element, such as fire, earth, metal, water or wood. In addition to an element, these meridians and organs are assigned a particular musical note.¹⁰ Different musical notes affect each organ differently to restore the organ to health.

Sound affects the patient at all levels for healing as it may take the patient into altered states of consciousness, affecting the alpha wave cycle in the brain.¹¹ These altered states of consciousness affect the spiritual level and allow the physical body to heal. At the physical level, sound healing creates a sense of balance in the body and thus eliminates illness, as all illness is viewed as something being out of balance within the body. Sound also impacts the limbic system within the body, which is the center for our

emotions, feelings and sensations. The limbic system is influenced by the pitch and rhythm of the sound, which then impacts our emotions and feelings.¹² Thus, sound healing facilitates healing at the physical, emotional and perhaps spiritual level.

History of Music as Therapy

Anne Woodham and David Peters, in the *Encyclopedia of Healing Therapies*, discuss the first documented use of sound in Western medicine in 1896 when American doctors discovered that different types of music stimulated blood flow and increased mental clarity.¹³ Whether these doctors knew it or not, their discoveries are now considered the beginning of music therapy.

The more formalized discipline of music therapy started some time in the first half of the 20th century after World War I and World War II. According to the American Music Therapy Association, musicians visited Veterans Hospitals around the country to play music for the veterans who were suffering both physically and emotionally from trauma after the war. Because of the patients' positive response to the music, doctors and nurses requested the hospitals to hire musicians.¹⁴ The hospitals soon determined the need for formal training in using music as therapy, a concept that ultimately grew into college curricula. The first music therapy degree program in the world was started at Michigan State University in 1944.¹⁵

Founded in 1998, The American Music Therapy Association (AMTA) is the largest professional association in this field, with over 5,000 music therapists, corporate members and related associations worldwide.¹⁶ The American Music Therapy Association defines music therapy as “the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a

credentialed professional who has completed an approved music therapy program.”¹⁷

Based on this definition, extensive research is conducted to explore the benefits of music as therapy in healing. Much of this research is published in the *Journal of Music Therapy*, *Music Therapy Perspectives* and other relevant sources.

Healing with Music as Therapy

In the article “Music as Therapy,” Kathi Kemper and Suzanne Danhauer propose that music has dual benefits to the patient as music may promote physiological benefits through the autonomic nervous system and psychological benefits by reducing anxiety and improving moods.¹⁸ The proposition of dual benefits supports a view that music promotes a mind-body connection, working at the cognitive and the somatic levels. Many researchers have attributed these same cognitive and somatic qualities to relaxation, and its antithesis, anxiety.¹⁹ The proposition of dual benefits of music also supports the hypothesis for the proposed research study, “The Effects of Vibroacoustic Therapy (VT) and Music on Anxiety in Patients Undergoing Breast Biopsy,” in that music plays a role in psychological benefits by reducing anxiety. While not a part of this study, physiological benefits are suspected.

Psychological Benefits of Music as Therapy

Many studies have been conducted over the past few decades that examined the positive impact of music on patients faced with healthcare challenges. Research has found that using music with patients in hospitals has proven to be effective in reducing the level of anxiety,²⁰ and clinically depressed women have also experienced some success when listening to music to alter their moods.²¹

Music may positively impact the level of confusion occurring postoperatively in patients. Research was conducted to understand the effect of music listening on acute confusion and delirium in elders undergoing elective hip and knee surgery, as confusion and delirium can cause complications that negatively effect recovery.²² Results showed a significant decrease in postoperative confusion in the experimental group who listened to music when compared to those in the non-listening control group.²³

Of particular relevance to this research study is the work done by Haun and colleagues who investigated the effect of music on the state anxiety of patients awaiting breast biopsy at a suburban medical facility. After a twenty-minute music intervention, the posttest state anxiety of the patients in the experimental group was significantly lower than those of the patients in the control group.²⁴

Types of Music for Healing

The types of music can have an impact on moods and emotions. Using the Profile of Mood States (POMS) to measure mood before and after exposure to different pieces of contemporary music, researchers found that moods can be altered based on the type of music that is heard.²⁵ To determine which pieces of music to include in the study, researchers performed a pilot test to correlate music with five POMS categories (tense, depressed, angry, fatigued and vigorous).²⁶ This research supplied another data point to validate that music may significantly alter our mood states, and supports the hypothesis for this research study that music can alter our psychological states.

The music for this research study, *Musical Acupuncture* by Janalea Hoffman, the music therapist at Shawnee Mission Medical Center, was selected with the goal of relaxation. The music, consisting of cello, flute, harp, violin, bells and alto recorder, is

composed at exactly fifty beats per minute to cause entrainment and synchronize the body's rhythm with the music being played.²⁷

Music and Entrainment

One concept relevant to healing and music is the concept of entrainment. Entrainment occurs when the vibration of one object is projected upon a second object with a similar frequency, causing the second object to vibrate in resonance with the first.²⁸ Entrainment can happen at the physical, emotional and/or spiritual level within the human system, supporting a mind-body connection.²⁹ We can think of the concept of entrainment as it relates to a symphony. Our bodies are constantly moving and functioning with a symphony of vibrations. For instance, if the gall bladder fulfills the role of the second violin section, and the second violin section starts playing in another key, it affects the entire performance of the symphony. The violins are no longer playing in harmony with the rest of the orchestra, thus causing a cacophony of sound that is disharmonious. Through entrainment, the second violins learn to play in the right key with the rest of the orchestra, thus creating harmony.

Certain musical instruments have an effect on healing through entrainment. Studies have shown that when instruments emit Extremely Low Frequency (ELF) sounds between four and eight cycles per second, they mirror the theta range of brain waves that occur during meditation, thus entraining the brain waves to these same frequencies.³⁰ The Tibetan hand cymbals, called Ting-Sha's, are just one example of a musical instrument that emits ELF sounds. The same effect can be seen with Peruvian whistles and crystal bowls. The ELF sounds from musical instruments entrain the brain and

provide one way of healing by bringing us into harmony with ourselves and the world around us.

Summary

Sound has been used for centuries for healing. More recently, music therapy was established and currently uses evidence-based interventions to bring about healing. The type of music used is also important to consider as different types of music have impacts on our moods and emotions. The beat of the music can affect healing through entrainment, which occurs when the body rhythms synchronize with an external rhythm.

While many research studies have been conducted to support this type of healing therapy, more research is warranted to understand better the efficacy of music as therapy in healing. Past research on music therapy supports the hypothesis for the current research study, “The Effects of Vibroacoustic Therapy (VT) and Music on Anxiety in Patients Undergoing Breast Biopsy,” postulating that music may positively impact patients’ psychological state by potentially reducing anxiety.

Vibration as Medicine

In addition to the use of sound, Vibroacoustic Therapy (VT) also uses tactile stimulation, which provides a secondary categorization within energy medicine as healing through touch. However, touch is not defined in this study as the physical contact from another human. Rather, it is understood as the vibration that is touching the skin, which is the largest organ of the human body and protects the body, regulates temperature and metabolism, and eliminates waste.³¹ The skin holds receptors that alert us to touch, temperature and pain.³² It is through these receptors that VT impacts the body with vibration.

Research has been conducted to understand vibration, the impact of vibration to the skin receptors and how the receptors respond to pain. To date, very little has been found in past research that addresses the impact of vibration beyond the physical level. Many questions are left unanswered with regard to the impact of vibration on emotional and spiritual levels of healing. Is it possible that vibration directly applied to the skin impacts the human body in ways beyond physical healing? Is it possible for vibration to impact the limbic system and promote states of well-being? From a spiritual perspective, is it possible that tactile stimulation may promote altered states of consciousness? Until now, little research addressing these questions appears to exist. The proposed research study on VT may take one small step in addressing some of the gaps in past research on vibration and healing.

Psychological Impacts of Vibration and Healing

Only two studies appear to explore the psychological impact of vibration in healing. Miguel Diego and colleagues used three massage therapy techniques on healthy

adults in order to assess their impact on anxiety and stress. The three therapies included moderate massage, light massage and vibratory stimulation. Anxiety scores decreased for all three groups. However, the vibratory group also showed increased arousal, as indicated by increased heart rate and increased theta, alpha, and beta activity.³³ The Primary Investigator proposes that the increases in arousal, heart rate, theta, alpha and beta activity do not suggest a relaxation response and potentially would hinder the ability to heal.

Ann Gill Taylor et al. studied the effects of Swedish massage and an inaudible vibration therapy, called physiotones, on short-term postoperative outcomes, including state anxiety measured by the State-Trait Anxiety Inventory. No significant differences were reported between the interventions of Swedish massage, vibration therapy or the control with regard to state anxiety.³⁴

Past Vibroacoustic Therapy (VT) research supports the hypothesis that the efficacy of VT in reducing anxiety surpasses that of Music Alone.³⁵ Perhaps it is the cumulative effect of music with vibration that creates the increase in efficacy. Unfortunately, due to the limitations of the Somatron Clinical recliner as mentioned in Chapter One, the proposed research study will not be using an intervention of vibration alone, as this would help to address the psychological benefits of vibration. Further research on this topic is warranted to understand more fully the effect of vibration alone on anxiety.

Summary

Little research to date has been conducted on the use of vibration without sound in the pursuit of psychological healing. Thus, the hypothesis of the efficacy of

Vibroacoustic Therapy (VT) over Music Alone is contingent on the research done for VT, which has tested vibration in conjunction with music. Clearly, more research needs to be done to address the psychological benefits of vibration alone.

Vibroacoustic Therapy: Past and Present

Vibroacoustic Therapy (VT) emerged out of the work developed by music therapists and doctors as a treatment for a variety of medical conditions.³⁶ Because of the newness of VT, only very few research studies have been conducted to date. In this section, the history of VT will be explored and relevant research will be discussed that is germane to the study, “The Effects of Vibroacoustic Therapy (VT) and Music on Anxiety in Patients Undergoing Breast Biopsy.”

History of Vibroacoustic Therapy

As previously mentioned in Chapter One, Olav Skille was one of the main contributors to the birth of Vibroacoustic Therapy (VT). This Norwegian educator and therapist was working with severe physically and mentally handicapped children and was looking for a way to relieve their painful muscle spasms. He put the children in beanbag chairs with large speakers pressed up against them playing music to see if sound vibration transmitted through a beanbag chair would be helpful in reducing muscle tone and relaxing the children. Skille’s investigations led to a working hypothesis that slow relaxing music had an effect in relaxing the children.³⁷

The foundation of Skille’s work consisted of three fairly accepted universal principles of sound and music: 1) low frequencies can relax; high frequencies can raise tension; 2) rhythmic music can invigorate; non-rhythmic music can pacify; and 3) loud music can create aggression; soft music can act as a sedative.³⁸ Out of this premise, Skille experimented with different forms of music to create what he called “music baths,” as he was bathing his clients in sound.³⁹ He found great success in his work, which he first presented at the International Society for Music and Medicine in 1982. He initially

called his work Low Frequency Sound Massage, and latter changed it to Vibroacoustic Therapy.⁴⁰ As part of his work, Skille manufactured a vibroacoustic chair and bed in 1988; however, these products went out of production in 1994.⁴¹

Another pioneer in this field was Petri Lehtikoinen, who was a researcher and lecturer at Helsinki University. Lehtikoinen created a system, called physioacoustics, during the same time that vibroacoustic therapy was being developed.⁴² The main difference between vibroacoustic therapy and physioacoustics is that VT blends a single frequency sinusoidal sound with music, while physioacoustics generates and combines a range of sinusoidal frequencies with the music.⁴³ The physioacoustic system, consisting of a mattress, a computer unit, an audio system and a power source, holds four transducers that are in the mattress. The transducers in the mattress get placed under the neck, lower back, thigh and lower leg areas.⁴⁴

Byron Eakin worked to develop VT equipment in the United States, starting in 1985.⁴⁵ His system is termed a full-frequency music (FFM) model, whereby a single sound source is used and music is played with a wide range of frequencies.⁴⁶ Somatron Corporation, headed by Byron Eakin, produces a wide range of products geared toward VT. With the majority of products in the United States, this company boasts as being the most widely used set of devices in the world for VT.⁴⁷ The company makes treatment tables, recliners, chairs and mattresses with varying specifications.

Other contributions to VT came from Kris Chesky, at the Texas Centre for Music and Medicine, who developed the Music Vibration Table. Mr. Chesky developed this table after reviewing research that failed to control and measure the vibrations used, which made it difficult for him to interpret the results accurately.⁴⁸ This patented system

is constructed from a typical hospital procedural stretcher and consists of a base table, sound system, a computerized vibration feedback processing system and a vibrating membrane – the table top, which has three separate modules positioned under the torso, lower leg and thigh.⁴⁹

Other VT products are currently on the market by Quantum Rest, Bodysonic and Thor of Genesis.⁵⁰ It is anticipated that many more will enter the marketplace as VT increases in popularity.

Past Research on Vibroacoustic Therapy

Pioneering work with Vibroacoustic Therapy (VT) started to appear in the 1980s. To date, a small number of studies have been published, designed to explore the efficacy of VT. Of these studies many have addressed the efficacy of VT through case studies and anecdotal reports, most of which have focused on muscle tone, range of motion, pain relief and psychological issues such as anxiety, mood and relaxation. Few of these studies have applied rigor to determine the benefits of this therapy. The only existing three research studies that relate to psychological issues will be explored here, as anxiety classified as a psychological issue is the focus of the proposed research study.

In 1995, Catherine Walters investigated the psychological and physiological effects of using a Somatron mat (a portable vibroacoustic mat with two speakers that can easily connect to any stereo system) on thirty-nine patients who were awaiting a scheduled gynecological surgery procedure. Walters allowed these women to select music that reflected their musical taste for the music intervention. One group listened to this music lying on a Somatron mat immediately before having surgery, while another group listened to the same music via a tape player lying down without the Somatron mat

prior to their surgery. A third group did not receive any type of musical intervention as they were awaiting surgery. Women who used the Somatron mat experienced significantly lower levels of apprehension when compared to women who did not listen to music.⁵¹ In addition, patients self-reported that the musical intervention “increased relaxation” and “helped to ease anxiety.” The results showed no significant differences among the groups with regard to physiological measures.⁵² This study suggests the value of using VT to ease anxiety prior to a stressful procedure.

At the National Institutes of Health, George Patrick evaluated a VT program to reduce symptoms across hospitalized patients with varying conditions. Dr. Patrick used a visual analog scale to rate the top three reported symptoms for each patient. Symptoms most reported included tension, fatigue, pain, headache, depression and nausea. Collectively, these six symptoms covered 92% of all symptoms mentioned. For a single session of VT, Dr. Patrick saw an overall reduction in symptoms by 53% ($p < .0001$).⁵³ While this evaluation did not utilize random assignment or control groups, it did utilize a large population ($N=272$). Thus, the results are worthy of consideration.

Tony Wigram, Associate Professor and Head of Ph.D. Studies at the Institute for Music and Music Therapy in Denmark, also sought to understand the efficacy of VT on psychological responses. In his study, he applied VT to non-clinical subjects (hospital staff) to ascertain the impact of this therapy on their mood and their level of relaxation.⁵⁴ The dependent variables included blood pressure and heart rate, along with the administration of a psychometric test (University of Wales Institute of Science and Technology (UWIST)-Mood Adjective Check List). Respondents were either given VT, music alone, or a period of rest. The results showed a significant reduction in energetic

arousal, general arousal and tension arousal in the VT group, with no significant difference in blood pressure measures, heart rates or hedonic measures.⁵⁵

Summary

Vibroacoustic Therapy (VT) is relatively new in treating a variety of medical conditions. However, as we have seen above, a few studies have used VT as a therapy for psychological issues. Initial results from past research are hopeful and support the hypothesized results of VT intervention being statistically significant in reducing anxiety when compared to the intervention of Music Alone or the control, consisting of those individuals who wait in the waiting area with no intervention.

Anxiety in Patients Undergoing Breast Biopsy

As previously mentioned in Chapter One, getting a breast biopsy is a very stressful event as the objective of a breast biopsy is to screen for cancer. Past research has shown that anxiety is greatest for the patient at the time of the biopsy, even more so than 24 hours post-procedure when results are still unknown.⁵⁶ Women awaiting a breast biopsy have heightened anxiety because of the threat of cancer, and wanting the answer to this unknown has been identified as the information most important to women undergoing breast biopsy.⁵⁷

Breast Biopsy

A breast biopsy is a procedure where samples from a breast lump or breast abnormality are taken to determine whether the suspicious area is cancerous. Three primary techniques are used for performing a breast biopsy, including Mamotome® biopsy, core needle biopsy and open surgical biopsy. In the research study, the Effects of Vibroacoustic Therapy (VT) and Music on Anxiety in Patients Undergoing Breast Biopsy, only patients who received a Mamotome® biopsy were included.

A Mamotome® biopsy is a minimally invasive technique using a needle with a hollow chamber that draws, cuts and removes tissue. The results are highly accurate due to the ability to gather several samples with one needle, with minimal scarring and immediate recovery.⁵⁸

Measurement of Anxiety

The objective of the research study is to evaluate the effects of Vibroacoustic Therapy (VT) and music on anxiety in patients undergoing breast biopsy. The State-Trait

Anxiety Inventory (STAI) was selected as the standard psychological assessment instrument given its leadership in measuring anxiety worldwide.⁵⁹ Selected past research on VT has used the Self-Report Rating Scale for Tension and Relaxation (SRRSTR) to study relaxation as a secondary measure to anxiety. Thus, anxiety levels will be measured using the STAI and relaxation will be evaluated with the SRRSTR.

State-Trait Anxiety Inventory (STAI)

The State-Trait Anxiety Inventory (STAI) is a self-report assessment instrument that measures levels of state and trait anxiety, with two distinct tests of twenty questions each. The questions include statements pertaining to levels of state anxiety and refer to how one is feeling right now. The participant is asked to answer each statement on how they feel right now by using a four-point scale including: (1) not at all, (2) somewhat, (3) moderately, and (4) very. The questions pertaining to levels of trait anxiety refer to how one generally feels, and is measured using a four-point scale, including: (1) almost never, (2) sometimes, (3) often and (4) almost always.⁶⁰ Targeted for adults and written at the sixth grade level, the STAI is the most widely used self-report measurement tool for anxiety today,⁶¹ and is appropriate for the proposed research study as the primary measurement for anxiety. Given its popularity, the STAI has also been used in several studies exploring the efficacy of music, which will be helpful in validating the use of the STAI in the proposed research by serving as a comparison.

The STAI was developed in 1970 by Spielberger, Gorsuch and Lushene as a reliable, relatively brief self-report instrument, that can be used for assessing both state and trait anxiety, in the research setting and the clinical practice.⁶² The focus of this research study is state anxiety, which consists of subjective feelings of tension, apprehension,

nervousness and worry, and activation of the autonomic nervous system that fluctuate over time as a function of a perceived threat. This type of anxiety is temporary.⁶³

For this research study, levels of state anxiety were captured before and after each of the interventions and the control. Measuring state anxiety before and after each intervention and the control allowed for analysis of the impact of Vibroacoustic Therapy (VT) and music on temporary or state anxiety. Because measurement of state anxiety levels were taken within very short timeframes (approximately sixty minutes), it was imperative that the sensitivity of the measurement tool be such as to discern differences in a short amount of time. Charles Spielberger, one of the authors of the STAI, confirmed usage of the STAI within short timeframes as appropriate.⁶⁴

The Self-Report Rating Scale for Tension and Relaxation (SRRSTR)

Roger Poppen, retired Professor and Coordinator of the Behavior Analysis and Therapy Program in the Rehabilitation Institute at Southern Illinois University at Carbondale, has developed a method of assessing the degree to which individuals show a relaxation response. Relaxation, as a secondary measurement for anxiety in the proposed research, was relevant in that many researchers have identified relaxation as the antithesis to anxiety.⁶⁵

Poppen's method is a multi-modal approach in measuring relaxation and includes three separate measures: self-report measures, physiological measures and behavioral observations using the Behavior Response Scale.⁶⁶ In the proposed research study, only the Self-Report Rating Scale for Tension and Relaxation was used. Physiological measures were explored, but were discounted due to absence of feasibility and reliability. Behavioral observations require some training prior to administration, which are not part

of the purview of the Principal Investigator. Because reduction in tension and the attainment of relaxation are internal states, they must be subjectively monitored by the participant.⁶⁷ The scale is a labeled seven-point scale, allowing the participant to categorize their level of tension and/or relaxation in the moment. It has been used historically in behavior relaxation training. The scale is as follows:

Question: Which of the following best describes the way you feel right now?

1. Feeling more deeply and completely relaxed than I ever have.
2. Feeling completely relaxed throughout my entire body.
3. Feeling more relaxed than usual.
4. Feeling relaxed as in my normal resting state.
5. Feeling some tension in some parts of my body.
6. Feeling generally tense throughout my body.
7. Feeling extremely tense and upset throughout my body.⁶⁸

This self-report rating scale was used at the National Institutes of Health by George Patrick in a VT program evaluation across hospitalized patients with varying conditions, with the largest sample (N=272) of any study done on Vibroacoustic Therapy (VT). Because of the size of Patrick's study, the Principal Investigator included this seven-point scale in the current study as a secondary measure for anxiety for study comparability.

Summary

Given the varying levels of anxiety in patients undergoing breast biopsy, measuring the participants' anxiety levels pre- and post-intervention with the State-Trait Anxiety Inventory prior to the breast biopsy revealed the level of efficacy of Vibroacoustic Therapy (VT) versus Music Alone in a Somatron Clinical Recliner. The State-Trait Anxiety Inventory has been used in many studies evaluating the efficacy of music on anxiety, therefore providing the comparability and validity of the results.

Relaxation is the antithesis of anxiety. The use of The Self-Report Rating Scale for Tension and Relaxation as a secondary measure for anxiety allowed for comparability of results to other work done on VT. The combination of both measures provided a solid foundation to measure the efficacy of VT and music on anxiety in patients undergoing breast biopsy.

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CHAPTER 3: RESEARCH METHODOLOGY

The General Perspective

The research reported in this paper is composed primarily of a quantitative approach, using an experimental design for a case controlled study with a non-randomized convenience sample. Within this research study, there were six research hypotheses: 1) There is a significant impact on the anxiety level in patients undergoing breast biopsy if they have prior exposure to Vibroacoustic Therapy (VT) before the procedure. 2) There is a significant impact on the anxiety level in patients undergoing breast biopsy if they have prior exposure to Music Alone before the procedure. 3) There is a significant impact on the relaxation level in patients undergoing breast biopsy if they have prior exposure to VT before the biopsy procedure. 4) There is a significant impact on the relaxation level in patients undergoing breast biopsy if they have prior exposure to Music Alone before the biopsy procedure. 5) There is a significant difference between the intervention of VT and the intervention of Music Alone. 6) The beliefs patients hold with regard to VT and/or music have an impact on the efficacy of the respective intervention.

The study design consisted of three groups of participants who were receiving breast biopsies. A participant was assigned to the control group when time prior to the biopsy procedure was limited, with all other participants randomly assigned among the two intervention groups: Vibroacoustic Therapy (VT) or Music Alone.

At the conclusion of this research study, a survey with one open-ended question was given to the Breast Center Director, two nurse navigators and five radiology technicians asking their perception regarding the impact of music, with or without vibration, on the

psychological state of breast biopsy patients. In their professional opinion, did VT or music have an impact on the anxiety level in patients undergoing breast biopsy?

The Research Context

The research study took place within the Women’s Center at Shawnee Mission Medical Center (SMMC), 7100 W. 74th Street, Shawnee Mission, Kansas, 66204. The Women’s Center at SMMC has an upscale atmosphere and does not reflect a typical hospital setting (Figure 1). Within this Center, two separate areas were utilized for this study in a common hallway, one area each for the different interventions of Vibroacoustic Therapy (VT) and Music Alone. The areas were separated by neutral Japanese folding screens, to address the potential concerns of conditioned space (Figure 1).



Figure 1. Reception Area and Hallway.

Shawnee Mission Medical Center currently owns four Somatron Clinical Recliners, two of which were used for this research study, one for the intervention of Vibroacoustic Therapy (VT) and one for the intervention of Music Alone. One chair was red, used for the VT intervention, and one chair was blue, used for the Music Alone intervention. The recorded music on CD used for this study was composed by a music therapist, Janalea Hoffman, and includes music that is played at exactly 50 beats per minute. Instruments used are cello, flute, harp, bells, violin, and alto recorder.¹ This CD was purchased from the composer's website, at www.rhythmicmedicine.com. Concurrent to the music used in the research study, easy listening music was also played in the waiting area within the Women's Center.

After submission of application and approval from the Internal Review Committee at SMMC (Appendix S), the research study commenced on April 16, 2007 and extended over an eight-month period, concluding on December 14, 2007.

The Research Participants

Once a patient is scheduled at Shawnee Mission Medical Center (SMMC) to receive a breast biopsy, the standard process is for the nurse navigator within the SMMC Breast Center to call the patient and conduct a medical history prior to the patient coming to the hospital. Upon completion of this medical history, the patient was invited by the nurse navigator to participate in the research study (Appendix C). While standard practice required the patient to arrive forty-five minutes prior to the biopsy, an additional fifteen minutes was needed to participate in the study. Thus, to participate in the research study, the patient needed to arrive one hour before their scheduled biopsy.

Any patient who was over the age of 18 and was scheduled to receive a breast biopsy during the time of the study was eligible to be a participant in this study. Participants were free to withdraw from the study at any time without any penalty.

No monetary compensation was given to participants.

There were a total of 51 female participants in the study, 17 participants in each intervention and the control, ranging in age from 35 to 86. The average age of participant in the VT intervention was 55.29; average age of participant in the music intervention was 57.65; and the average age of participant in the control was 51.06.

Instruments used in Data Collection

Two standardized measurement instruments were used in the data collection process: the State-Trait Anxiety Inventory (STAI) (Appendix D) and the Self-Report Rating Scale for Tension and Relaxation (SRRSTR) (Appendix E). In addition to the standardized measurement instruments, each participant was given a participant survey with five additional questions prior to their participation (Appendix F). These five questions addressed the stress of the participant's recent life, their anxiety about the impending biopsy, their belief that music, Vibroacoustic Therapy (VT) and/or rest can reduce anxiety, their overall health, and what, if anything, they do for relaxation or meditation.

Qualitative information was also gathered from the hospital staff. At the conclusion of this research study, a survey with one open-ended question was given to the Breast Center Director, two nurse navigators and five radiology technicians asking their perception regarding the impact of music, with or without vibration, on the psychological

state of breast biopsy patients (Appendix G). In their professional opinion, did VT or music have an impact on the anxiety level in patients undergoing breast biopsy?

State-Trait Anxiety Inventory

For this research study, levels of state anxiety were captured before and after each of the interventions and the control. Because measurement of state anxiety levels were taken within very short timeframes (approximately sixty minutes), it was imperative that the sensitivity of the measurement tool be such as to discern differences in a short amount of time. Charles Spielberger, one of the authors of the STAI, confirmed usage of the STAI within short timeframes as appropriate.² Levels of trait anxiety were captured prior to the interventions and the control to help in comparability between groups.

Scores are obtained by simply summing the scores of the twenty questions within each section. Scores on the STAI have a direct interpretation: high scores on their respective scales mean more trait or state anxiety and low scores mean less. Both percentile ranks and standard (T) scores are available for male and female working adults in three age groups (19-39, 40-49, 50-69), male and female high school and college students, male military recruits, male neuropsychiatric patients, male medical patients, and male prison inmates.³

The stability of the STAI scales was assessed on male and female samples of high school and college students for test-retest intervals ranging from one hour to 104 days. The magnitude of the reliability coefficients decreased as a function of interval length. For the Trait-anxiety scale the coefficients ranged from .65 to .86, whereas the range for the State-anxiety scale was .16 to .62. This low level of stability for the State-anxiety scale is expected since responses to the items on this scale are thought to reflect the

influence of whatever transient situational factors exist at the time of testing.⁴ The internal consistency for both State and Trait anxiety scales are quite high as measured by alpha coefficients and item-remainder correlations.⁵ This scale was also compared to other measures of trait anxiety, namely the Taylor Manifest Anxiety Scale, the IPAT Anxiety Scale, and the Multiple Affect Adjective Check List. The correlations are .80, .75 and .52, respectively.⁶

Self-Report Rating Scale for Tension and Relaxation

As mentioned in Chapter two, the Self-Report Rating Scale for Tension and Relaxation was used at the National Institutes of Health by George Patrick in a VT program evaluation across hospitalized patients with varying conditions, with the largest sample of any study done on VT (N=272). Because of the size of Patrick's study, the Principal Investigator included this seven-point scale as a secondary measure for anxiety for study comparability. The scale is as follows:

Question: Which of the following best describes the way you feel right now?

1. Feeling more deeply and completely relaxed than I ever have.
2. Feeling completely relaxed throughout my entire body.
3. Feeling more relaxed than usual.
4. Feeling relaxed as in my normal resting state.
5. Feeling some tension in some parts of my body.
6. Feeling generally tense throughout my body.
7. Feeling extremely tense and upset throughout my body.⁷

Procedures Used

Prior to each session, the Principal Investigator read an intentional statement (Appendix H), checked the chairs to make sure they were positioned appropriately and

could freely recline, and played the music to ensure the correct CD was in the stereo system.

A standardized process was followed by the Principal Investigator once the participant signed in at the front desk and alerted the hospital staff that they had arrived for their appointment (Appendix I). This standardized process started with the Principal Investigator greeting the participant in the waiting area and introducing herself as the person conducting the research study. The Principal Investigator also confirmed their agreement to participate in the music study. The participant was then instructed by the Principal Investigator on what would unfold prior to their participation in the research study, including admittance to the hospital and a conversation with the nurse navigator. The participant was handed a clipboard by the Principal Investigator with four forms: the consent form (Appendix J), a Health Insurance Portability & Accountability Act (HIPPA) Authorization Form (Appendix K), the State-Trait Anxiety Inventory (STAI) form (Appendix D), and a short participant survey with six questions (Appendix F), including the Self-Report Rating Scale for Tension and Relaxation (SRRSTR) (Appendix E). The participants were asked to fill out the forms on the clipboard while they were in the waiting area. At this point, the Principal Investigator left the participant in the waiting area until the participant had been admitted and had spoken with the nurse navigator. All participants gave consent prior to inclusion and signed the HIPPA Authorization Form.

Once the participant had been admitted to the hospital by the admitting staff and the nurse navigator consented the patient for the biopsy procedure, the participant was brought to the Principal Investigator by the nurse navigator for the research study. If at least twenty minutes remained before the scheduled biopsy procedure, the participant was

randomly assigned to either Vibroacoustic Therapy (VT) or Music Alone. If less than twenty minutes remained prior to the biopsy procedure, the participant was assigned to the control group.

GROUP 1 – Vibroacoustic Therapy in the Somatron Clinical Recliner



Figure 2. VT Intervention Area.

Having at least twenty minutes before the scheduled biopsy procedure, the Principal Investigator asked the participant to sit in the red Somatron Clinical Recliner and the chair was reclined back to the Trendelenburg position. The music was started by the Principal Investigator and the participant was asked by the Principal Investigator if she was able to comfortably hear the music and feel the vibration in the Somatron Clinical Recliner. The Principal Investigator adjusted the volume for the participant to a desired volume level, if needed. The Principal Investigator repeated her name, told the participant that she would be sitting on the other side of the screen in a chair and to call upon her if the participant needed anything. The Principal Investigator told the

participant that she would be back in fifteen minutes. Each participant was given fifteen minutes of VT in the Somatron Clinical Recliner, while the Principal Investigator waited on the other side of the screen in the hallway. At the conclusion of this session, the participant was once again handed a clipboard by the Principal Investigator with the STAI measures for state anxiety (Appendix D) and the SRRSTR (Appendix E) and asked to complete these questions. Once the measures were gathered, the participants were given the option of staying in the chair until the radiology staff was ready for the biopsy procedure, or they were allowed to return to the waiting area. Total time used was approximately twenty minutes.

GROUP 2 – Music Alone in the Somatron Clinical Recliner



Figure 3. Music Alone Intervention Area.

Having at least twenty minutes before the scheduled biopsy procedure, the Principal Investigator asked the participant to sit in the blue Somatron Clinical Recliner and the chair was reclined back to the Trendelenburg position. The music was started by

the Principal Investigator from a separate external stereo system not connected to the Somatron Clinical Recliner with the speakers of this external stereo system strategically placed next to the speakers in the Somatron Clinical Recliner. The participant was asked by the Principal Investigator if she was able to comfortably hear the music, and the Principal Investigator adjusted the volume for the participant to a desired volume level, if needed. The Principal Investigator repeated her name, told the participant that she would be sitting on the other side of the screen in a chair and to call upon her if the participant needed anything. The Principal Investigator told the participant that she would be back in fifteen minutes. Each participant was given fifteen minutes of Music Alone while sitting in the Somatron Clinical Recliner, with the Principal Investigator waiting on the other side of the screen in the hallway. At the conclusion of this session, the participant was once again handed a clipboard by the Principal Investigator with the STAI measures for state anxiety (Appendix D) and the SRRSTR (Appendix E) and asked to complete these questions. Once the measures were gathered, the participants were given three options: 1) stay in the chair until the radiology staff was ready for the biopsy procedure; 2) trial VT in the red Somatron Clinical Recliner; or 3) return to the waiting area. Total time used was approximately twenty minutes.

GROUP 3 – Control, no Intervention

If fewer than twenty minutes before the scheduled biopsy procedure remained, the participant was assigned to the control group and was handed a clipboard by the Principal Investigator with the STAI measures for state anxiety (Appendix D) and the SRRSTR (Appendix E) and asked to complete these questions. At this point, the participant had

completed the research study and nothing further was required. However, if time remained prior to the biopsy procedure, the participant was allowed to experience VT. The participant was invited by the Principal Investigator to sit in the red Somatron Clinical Recliner and the chair was reclined back to the Trendelenburg position. The music was started and the participant was asked by the Principal Investigator if they were able to comfortably hear the music and feel the vibration in the Somatron Clinical Recliner. The Principal Investigator adjusted the volume for the participant to a desired volume level, if needed. The Principal Investigator repeated her name, told the participant that she would be sitting on the other side of the screen in a chair and to call upon her if the participant needed anything. The participant was left in the chair until the radiology staff was ready for the biopsy procedure.

Data Analysis

As previously mentioned in this chapter, this study used an experimental design for a case controlled study with a non-randomized convenience sample. The study design consisted of three groups of participants who were receiving breast biopsies. A participant was assigned to the control group when time prior to the biopsy procedure was limited, with all other participants randomly assigned among the two intervention groups: Vibroacoustic Therapy (VT) or Music Alone.

For each participant in the research study, the pre- and post- scores for State-Anxiety and the pre- scores for Trait Anxiety were calculated and entered into an Excel spreadsheet, one row for each participant (Appendix L). The pre- and post- scores for the Self-Report Rating Scale for Tension and Relaxation (Appendix N) along with answers to

questions from the participant survey were entered into the Excel spreadsheet for each participant (Appendix M). The questions from the participant survey addressed the stress of the participant's recent life, their anxiety about the impending biopsy, their belief that music, Vibroacoustic Therapy (VT) and/or rest can reduce anxiety, their overall health, and what, if anything, they do for relaxation or meditation. What, if anything, they do for relaxation or meditation was an open-ended question and was entered into the Excel spreadsheet verbatim (Appendix O). To reduce input errors, the data entry was checked for accuracy by a third party.

The qualitative information gathered from the hospital staff at the conclusion of the study was analyzed separately from the research participants. This information included one open-ended question which was given to the Breast Center Director, two nurse navigators and five radiology technicians asking their perception regarding the impact of music, with or without vibration, on the psychological state of breast biopsy patients (Appendix P). In their professional opinion, did VT or music have an impact on the anxiety level in patients undergoing breast biopsy?

For this research study, a one-way ANOVA (Analysis of Variance) was utilized, along with chi-square and correlation analyses. The information from these analyses were reported in means and percentages and displayed in figures and tables with narrative text in chapter four of this report.

Chapter 3 Endnotes:

¹ Janalea Hoffman, *Rhythmic Medicine*, "Musical Acupuncture," [http://www.rhythmicmedicine.com/mcart/index.cgi?task=show&cat=Musical+ Acupuncture](http://www.rhythmicmedicine.com/mcart/index.cgi?task=show&cat=Musical+Acupuncture) (accessed December 8, 2006).

² Charles Spielberger, e-mail message to author, December 19, 2006.

³ Charles D. Spielberger, "State-Trait Anxiety Inventory for Adults," information sheet obtained from Charles D. Spielberger and Mind Garden, photocopied.

⁴ Ibid.

⁵ Charles D. Spielberger, R. L. Gorsuch, R. Lushene, P.R. Vagg, and G.A. Jacobs, *State-Trait Anxiety Inventory for Adults Sampler Set, Manual, Test Booklet and Scoring Key* (Mind Garden, Inc, 1983), p. 32.

⁶ Charles D. Spielberger, "State-Trait Anxiety Inventory for Adults," information sheet obtained from Charles D. Spielberger and Mind Garden, photocopied.

⁷ Ibid., 182.

CHAPTER 4: RESEARCH FINDINGS

Overview

As stated in Chapter One, the research question revolved around the potential of healing through music and vibration. Specifically, can Vibroacoustic Therapy (VT) work to reduce anxiety in patients undergoing breast biopsy? Focus on this research question led to six research hypotheses: 1) There is a significant impact on the anxiety level in patients undergoing breast biopsy if they have prior exposure to Vibroacoustic Therapy (VT) before the procedure. 2) There is a significant impact on the anxiety level in patients undergoing breast biopsy if they have prior exposure to Music Alone before the procedure. 3) There is a significant impact on the relaxation level in patients undergoing breast biopsy if they have prior exposure to VT before the biopsy procedure. 4) There is a significant impact on the relaxation level in patients undergoing breast biopsy if they have prior exposure to Music Alone before the biopsy procedure. 5) There is a significant difference between the intervention of VT and the intervention of Music Alone. 6) The beliefs patients hold with regard to VT and/or music have an impact on the efficacy of the respective intervention.

Within this chapter, detailed results will be reported by comparing three unique groups of participants: 1) One group of participants (N=17) who received VT prior to their breast biopsy; 2) One group of participants (N=17) who received Music Alone prior to their breast biopsy; and 3) One group of participants (N=17) who did not receive VT or music prior to their breast biopsy and waited in the waiting area with other patients. Detailed results will also be reported by looking at all participants in total to further

address the questions in this research study. Finally, qualitative insights from the hospital staff that had direct contact with the participants are included.

Detailed Results

For this research study, the independent variables consisted of the interventions of VT and Music Alone. The dependent variables for this research study consisted of state anxiety, as measured by the State-Trait Anxiety Inventory (STAI), and relaxation levels, as measured by the Self-Report Rating Scale for Tension and Relaxation (SRRSTR). As mentioned in Chapter Three, before the interventions of Vibroacoustic Therapy (VT) or Music Alone were conducted, information was gathered from each participant in addition to the STAI and the SRRSTR. This additional information included the stress level of their recent life, anxiety about their impending biopsy, belief statements about the proposed interventions, overall health, and what they do for relaxation and/or meditation. After the interventions, state anxiety as measured by the STAI and relaxation levels as measured by the SRRSTR were gathered as post measurements.

Comparisons between Groups

- ❖ There were statistically significant differences in the pre/post measurements of state anxiety (Table 1).
 - ◆ Specifically, there was a statistically significant reduction ($p < .01$) in state anxiety after the intervention of Vibroacoustic Therapy (VT) when compared to the control group.
 - ◆ There was a statistically significant reduction ($p < .01$) in state anxiety after the intervention of Music Alone when compared to the control group.

- ◆ There was no statistically significant difference between the intervention of VT and the intervention of Music Alone with regard to state anxiety.

Dependent Variable: State Anxiety Difference

Intervention	Intervention	Mean Diff	Sig.	90% Conf Level Lower Bound	90% Conf Level Upper Bound
VT	Music	.82	.789	-4.31	5.96
VT	Control	13.35	.000	8.22	18.49
Music	Control	12.53	.000	7.40	17.66

Table 1. Statistical Analysis of State Anxiety.

- ❖ There were statistically significant differences in the pre/post measurements of relaxation levels (Table 2).
 - ◆ There was a statistically significant increase in relaxation ($p < .01$) after the intervention of VT when compared to the control group.
 - ◆ There was a statistically significant increase in relaxation ($p < .01$) after the intervention of Music Alone when compared to the control group.
 - ◆ There was no significant difference between the intervention of VT and the intervention of Music Alone with regard to relaxation levels.

Dependent Variable: Relaxation Difference

Intervention	Intervention	Mean Diff	Sig.	90% Conf Level Lower Bound	90% Conf Level Upper Bound
VT	Music	.00	1.000	-.69	.69
VT	Control	2.05	.000	1.36	2.75
Music	Control	2.05	.000	1.36	2.75

Table 2. Statistical Analysis of Relaxation.

- ❖ The two intervention groups and the control group were comparable (Chi-Square tests), regarding age, pre-measurement levels of state and trait anxiety, levels of stress in the participant’s recent life, levels of anxiety about the impending biopsy, pre-measurement levels for relaxation, and beliefs that Vibroacoustic Therapy (VT) and/or Music Alone can reduce anxiety (see Table 3).

	χ^2
Age	.457
State Anxiety Pre-Measurement	.401
Trait Anxiety Pre-Measurement	.494
Level of Stress in Recent Life	.670
Level of Anxiety about Impending Biopsy	.712
Relaxation Level Pre-Measurement	.901
Belief in VT reducing Anxiety	.842
Belief in Music Alone reducing Anxiety	.318

Table 3. Chi-Square Analysis.

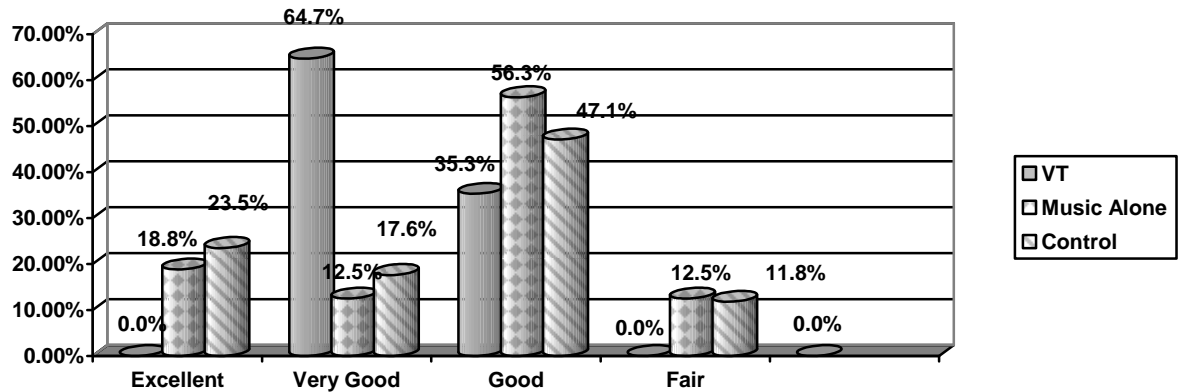
- ❖ As shown in Table 4, of those that received Music Alone as the intervention, 75% held the belief that music can reduce their anxiety. Of those that received VT as the intervention, only 41% held the belief that VT can reduce their anxiety. A correlation analysis showed no correlation between beliefs and state anxiety or relaxation levels (Appendix Q).

Vibroacoustic Therapy (VT) (Means)	Music Alone (Means)	Control (Means)
55.29	57.65	51.06
48.35	47.24	46.59
33.12	35.29	38.24
3.12	3.19	2.94
2.35	2.44	2.65
5.56	5.56	5.56
.41	.50	.41
.94	.75	.82

Table 4. Mean Scores.

- ❖ When examining responses from participants with regard to self-perceptions of overall health, there was a statistically significant difference between groups ($\chi^2=.018$). The VT group was more likely to say they were in very good health. The control group was more like to say they were in excellent health and the Music Alone group was more likely to say they were in good health. A correlation analysis revealed no correlation between overall health and state anxiety or relaxation levels (Appendix R).

Question: How would you rate your overall health?



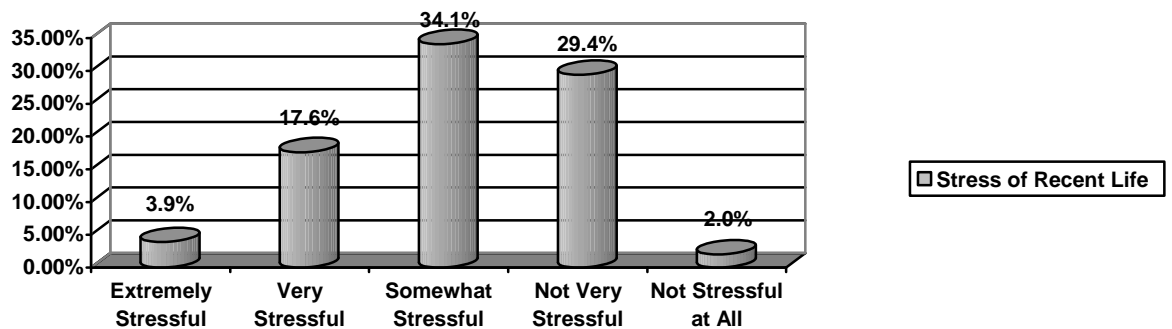
Note: Totals do not equal 100% due to missing responses. (N=51)

Figure 4. Overall Health Chart.

Results in Total

- ❖ Two-thirds of participants (66.6%) described their recent lives as at least somewhat stressful, while over one-fifth (21.5%) described their recent lives as very or extremely stressful.

Question: Besides having a biopsy, how stressful would you rate your recent life?

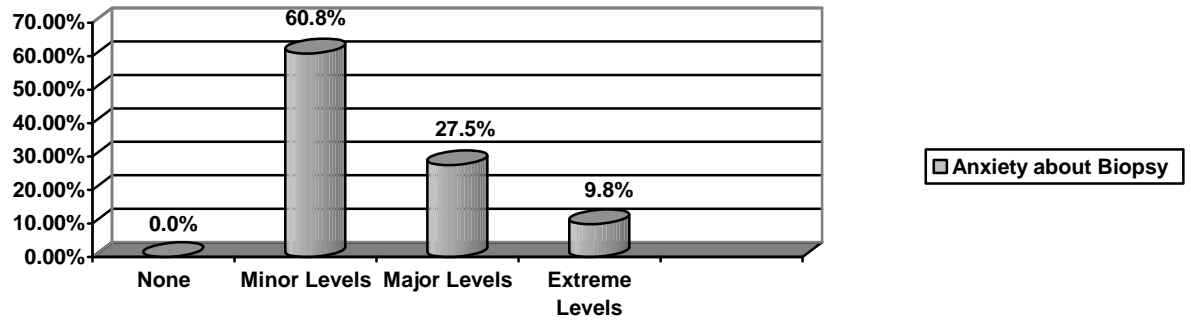


Note: Totals do not equal 100% due to missing responses. (N=51).

Figure 5. Stress of Recent Life Chart.

- ❖ Roughly two-thirds of participants had minor levels of anxiety about their impending biopsy while approximately one-third had major levels of anxiety.

Question: How much anxiety do you have about your impending biopsy?



Note: Totals do not equal 100% due to missing responses. (N=51)

Figure 6. Anxiety about Biopsy Chart.

- ❖ Over three-fourths (76.5%) of the participants listed something that they do for relaxation or meditation. The most frequently cited responses included listening to music, reading, exercising/walking, doing some form of art, praying/meditating/ breathing/yoga, being outside/gardening, and being with family, pets and friends (Appendix O).

- ❖ The norms established for the State-Trait Anxiety Inventory (STAI) are broken down by age ranges that did not allow for study comparison. Sixteen percent of the current study population fell outside of the normative boundaries, with the majority of participants falling within one age range. Thus, a comparison to STAI norms was not feasible (Table 5).

	Age 19-39	Age 40-49	Age 50-69	Age 70+
Number of Participants	3	15	25	8
Mean Trait Score	36.00	41.33	32.92	Not Available
Std. Deviation	6.245	8.829	5.462	
STAI Trait Norm	36.15	35.03	31.79	Not Available
Std. Deviation	9.53	9.31	7.78	

Table 5. Distribution of Age.

Qualitative Feedback from Hospital Staff

❖ Eight hospital staff members were asked to provide feedback regarding their experience with this research study. Specifically, the staff was asked the following: In your professional opinion, did VT or music have an impact on the anxiety level in patients undergoing breast biopsy? Please share any insights thoughts and/or experiences. Four staff members responded with the following comments.

- ◆ *Absolutely wonderful! Patients spoke very well of their experience in the music therapy chair. Plan to offer it as often as possible in the future. Getting a breast biopsy is a very personal intrusion emotionally to many women and being able to offer them the tangible evidence that we care and respect them and hope they feel “safe” and comforted by us is easily done when we provide them with this positive experience.*
- ◆ *I had many patients tell me that the music therapy chair was very calming to them. It helped to relax them before their procedure.*
- ◆ *I definitely think that the VT and music had a calming effect on our patients. The opportunity to recline, close their eyes and have a few minutes of soothing music before their procedure helped them cope. I believe that it was probably a combination of things that were helpful. Acknowledgement by the hospital staff that it is normal to be anxious prior to such a procedure and that we want to help reduce that anxiety tells the patient that we are concerned about them. My experience is that patients feel relief knowing that their reactions are normal. I also think that*

reclining and listening to the music took them away from the unfamiliar, anxiety-producing environment for a while which was calming. Perhaps lowering their blood pressure and pulse rate also helps take them back to a more neutral point emotionally. Involvement in the research study was not only a good experience for the patients, it was good for our staff. It reminds us to care for the whole patient, not just their breast or other ailments. And that any comfort measures we can offer patients will improve their health care experience.

- ◆ *As a nurse who provides education and support prior to breast biopsy, I routinely assist patients with managing high levels of anxiety and fear related to these procedures. Having this combination of relaxation therapies available was like giving each patient a gift. The great majority of the women soaked it up and emerged calm, relaxed and more prepared for their biopsy procedures.*

The results presented above indicate that Vibroacoustic Therapy (VT) may work to reduce anxiety in patients undergoing breast biopsy, as may Music Alone. The next chapter gives a discussion of the findings and how this study relates to prior research. Recommendations for study improvements and further research will also be discussed.

CHAPTER 5: SUMMARY AND DISCUSSION

Overview

This final chapter of the dissertation contains a restatement of the research question and research hypotheses, the study delimitations and a review of the methodology used in the study. The major sections of this chapter include a review of the research results and a discussion of these results structured around the research hypotheses outlined in Chapter One. At the conclusion of this chapter are study improvements and suggestions for future research.

Restatement of the Research Question and Research Hypotheses

As explained in Chapter One, the research question addressed in this study centered on the possibility of healing with music and vibration through Vibroacoustic Therapy (VT), an intervention that uses music which is felt in the body as well as heard through the ears. Specifically, the research explored the effects of VT and Music Alone on anxiety in patients undergoing breast biopsy. Focus on this research question led to six research hypotheses: 1) There is a significant impact on the anxiety level in patients undergoing breast biopsy if they have prior exposure to Vibroacoustic Therapy (VT) before the procedure. 2) There is a significant impact on the anxiety level in patients undergoing breast biopsy if they have prior exposure to Music Alone before the procedure. 3) There is a significant impact on the relaxation level in patients undergoing breast biopsy if they have prior exposure to VT before the biopsy procedure. 4) There is a significant impact on the relaxation level in patients undergoing breast biopsy if they have prior exposure to Music Alone before the biopsy procedure. 5) There is a

significant difference between the intervention of VT and the intervention of Music Alone. 6) The beliefs patients hold with regard to VT and/or music have an impact on the efficacy of the respective intervention.

Delimitations

Two primary constraints played into the intervention selection process: time and quantity of sample. The research was conducted during thirty weeks between April 16, 2007 and December 14, 2007, based upon the timeline specified by the Primary Investigator.

The Breast Center at Shawnee Mission Medical Center (SMMC) currently performs ten to fifteen breast biopsies per week. This quantity of patients gleans 300 – 450 breast biopsies during the research dates (30 x 10) – (30 x 15). A fifty percent consent rate was anticipated for this research study, which targeted an ending sample of 150 – 225 participants for the research study.

During April through July, SMMC was in dispute with a major healthcare insurance provider over contract negotiations and contract renewal. Patients with insurance with this healthcare insurance provider were not allowed to use SMMC, which constituted at least 25% of the patients in the Breast Center at SMMC. In addition, the Breast Center was experiencing some payment process changes which impacted the wait times in admitting patients. This constraint also had an impact on how many patients were able to participate in the research study.

Within the Breast Center at SMMC, two teams of nurse navigators work with women getting breast biopsies. One team works mainly with Mamotome® biopsy procedures and one team works with core needle biopsy procedures. Initially, both teams

agreed to support this research study. From the commencement of the study, the Mamotome® biopsy team supported the research study and the core needle team did not. Thus, only patients receiving a Mamotome® biopsy are included. This lowered the number of potential patients for the study significantly.

At Holos University Graduate Seminary, requirements state that a minimum of thirty participants is needed within each intervention and within the control. Based on the initial projections, three interventions and one control used for this study would supply an ending sample within each cell of thirty-seven to fifty-six participants (150/4 and 225/4). Thus, of the five previously outlined interventions in Chapter one, three could be used for this study with one control in order to have no fewer than thirty participants in each group. The three intervention groups selected included the VT group, the Music Alone group and the Recliner Elevated group.

The impact of the major healthcare insurance provider not allowing patients to use SMMC during contract negotiations dropped the targeted patient load, as did the inclusion of only Mamotome® biopsy patients. In June, with the agreement and support from the dissertation committee of the Principal Investigator, it was decided that only two interventions and one control could be accommodated with the number of patients currently coming through the Breast Center at SMMC. Thus, the intervention of Recliner Elevated was dropped from the study with the approval from the hospital internal review committee and the Primary Investigator's dissertation committee (Appendix A). By August, it was determined that meeting the thirty-minimum requirement for the two interventions of VT and Music Alone and the control was in jeopardy. A power analysis was conducted (Appendix B) to determine the minimum number of participants needed to

show statistical significance. The results from the power analysis revealed that seventeen participants were needed in each of the two interventions and the control to show statistical significance. The Primary Investigator's dissertation committee agreed to abide by the results of the power analysis, with a minimum target of seventeen participants in each intervention, including VT and Music Alone, and the control.

Review of Methodology

As discussed in Chapter Three, the research reported in this study was composed primarily of a quantitative approach, using an experimental design for a case controlled study with a non-randomized convenience sample. The study design consisted of three groups of participants who were receiving breast biopsies. A participant was assigned to the control group when time prior to the biopsy procedure was limited, with all other participants randomly assigned between the two intervention groups: Vibroacoustic Therapy (VT) or Music Alone.

The interventions of VT and Music Alone were done in specially crafted Somatron Clinical Recliners, where the feet were elevated above the heart in the Trendelenburg position. In order to understand the impact of vibration when it is accompanied with music, VT was compared to the intervention of Music Alone, without the tactile stimulation. The music which was used in this study was composed by a music therapist specifically for relaxation. Each patient received one session on the day of the biopsy up to one hour prior to the biopsy procedure, lasting approximately fifteen minutes. The control consisted of patients undergoing breast biopsy who did not receive an intervention of VT or music and sat in the waiting room along with other patients.

At the conclusion of this research study, a survey with one open-ended question was given to the Breast Center Director, two nurse navigators and five radiology technicians asking their perception regarding the impact of music, with or without vibration, on the psychological state of breast biopsy patients. In their professional opinion, did VT or music have an impact on the anxiety level in patients undergoing breast biopsy?

Review of Results

The results presented in Chapter Four suggest that Vibroacoustic Therapy (VT) may work to reduce anxiety in patients undergoing breast biopsy, as may Music Alone. There were statistically significant reductions in state anxiety ($p < .01$), as measured by the State-Trait Anxiety Inventory (STAI), after the interventions of both VT and Music Alone when compared to the control group. There were statistically significant increases in relaxation ($p < .01$), as measured by the Self-Report Rating Scale for Tension and Relaxation (SRRSTR), after the interventions of both VT and Music Alone when compared to the control group. However, there were no significant differences between the intervention of VT when compared to the intervention of Music Alone with regard to state anxiety or relaxation. Thus, VT and Music Alone were equally effective in reducing state anxiety and increasing relaxation.

The participant age distribution within the research study did not parallel the norms established for the STAI, which prevented any type of comparison. Unfortunately, sixteen percent of the current study population fell outside of the normative boundaries, with the majority of participants falling within one age range. Thus, a comparison to STAI norms was not feasible.

The two intervention groups and the control group were comparable with regard to age, pre-measurement levels of state and trait anxiety, levels of stress in the participant's recent life, levels of anxiety about the impending biopsy, pre-measurement levels for relaxation, and beliefs that VT and/or Music Alone can reduce anxiety.

However, when participants were asked to rate their self-perception of overall health (excellent, very good, good, fair, poor), the health levels reported by participants were significantly different between groups. The VT group was more likely to state they were in very good health. The control group was more like to say they were in excellent health and the Music Alone group was more likely to say they were in good health. A correlation analysis revealed no correlation between overall health and state anxiety or relaxation levels.

When examining the overall population for this study, two-thirds of participants described their recent lives as at least somewhat stressful, while over one-fifth described their recent lives as very or extremely stressful. Roughly two-thirds of participants had minor levels of anxiety about their impending biopsy while approximately one-third had major levels of anxiety.

The majority of participants believed that music could reduce anxiety. Less than half of participants believed that VT could reduce anxiety.

Over three-fourths of the participants listed something that they do for relaxation or meditation. The most frequently cited responses included listening to music, reading, exercising/walking, doing some form of art, praying/meditating/ breathing/yoga, being outside/gardening, and being with family, pets and friends.

Eight hospital staff members were asked to provide feedback regarding their experience with this research study. Specifically, the staff was asked the following: ‘In your professional opinion, did VT or music have an impact on the anxiety level in patients undergoing breast biopsy? Please share any insights thoughts and/or experiences.’ Four staff members responded with very positive comments.

Discussion

Research Hypothesis #1

There is a significant impact on the anxiety level in patients undergoing breast biopsy if they have prior exposure to Vibroacoustic Therapy (VT) before the procedure.

It was hypothesized that Vibroacoustic Therapy (VT) would significantly lower state anxiety levels as measured by the State-Trait Anxiety Inventory (STAI). This hypothesis may be realized and builds upon the work of Catherine Walters, who investigated the effects of vibrotactile stimulation via a Somatron mattress on patients awaiting scheduled gynecological surgery. Walters gathered psychological data by using eight visual analog scales, which recorded subjects’ reported levels of tension, anxiety, relaxation, stress, and general mood state. The results of Walters’ study indicated that VT appeared to be successful in significantly lowering levels of tension, anxiety, and stress, with increased levels of relaxation, and improvements in overall mood state.¹ The current study continues to build the case for the use of VT with psychological concerns, such as anxiety. Using VT would be a very easy option for hospitals and staff to provide to patients in that the use of the chair can be accomplished by the patient with minimal interaction from the hospital staff.

Feedback from the hospital staff at the conclusion of this study was very supportive of offering VT to patients going forward. It is another value-add service that is easy to offer and shows the patients that the hospital cares about them beyond just their physical well-being. Implementing VT as part of the overall protocol has very little downside once the initial investment in the chair has been made. Hospital staff members would need to start the music for the patient and show the patient how to recline the Somatron Clinical Recliner.

Research Hypothesis #2

There is a significant impact on the anxiety level in patients undergoing breast biopsy if they have prior exposure to Music Alone before the procedure.

It was also hypothesized that music would effectively lower state anxiety levels as measured by the STAI. The findings from the current study were consistent with past research, which has shown that music may be effective in reducing anxiety levels of women awaiting breast biopsy. Michael Haun and colleagues investigated the effect of music on the state anxiety of patients awaiting breast biopsy at a suburban medical facility. After twenty minutes of a music intervention consisting of “new age” music played from a tape player through headphones, patients scored significantly lower on their state anxiety levels.² As with VT, placing the patient in the Somatron Clinical Recliner prior to a procedure, with or without vibration, might have a calming effect on patients.

Research Hypothesis #3

There is a significant impact on the relaxation level in patients undergoing breast biopsy if they have prior exposure to VT before the biopsy procedure.

Relaxation as measured by the SRRSTR was anticipated to be positively effected by an intervention of VT, based on the past work on a program evaluation by George Patrick at the National Institutes of Health. The SRRSTR is a seven-point scale that asks how the respondent feels right now, with the following answer options:

1. Feeling more deeply and completely relaxed than I ever have.
2. Feeling completely relaxed throughout my entire body.
3. Feeling more relaxed than usual.
4. Feeling relaxed as in my normal resting state.
5. Feeling some tension in some parts of my body.
6. Feeling generally tense throughout my body.
7. Feeling extremely tense and upset throughout my body.³

In Patrick's program evaluation, the pre-rating average score on the SRRSTR was 5.12 while the post-rating average score was 2.77, a statistically significant difference ($p < .0001$).⁴ In the current study, the pre-rating average score on the SRRSTR was 5.56 with a post-rating average score of 3.92. Thus, VT may have a positive effect on relaxation levels ($p < .01$).

Research Hypothesis #4

There is a significant impact on the relaxation level in patients undergoing breast biopsy if they have prior exposure to Music Alone before the biopsy procedure.

There were statistically significant increases in relaxation ($p < .01$), as measured by the Self-Report Rating Scale for Tension and Relaxation (SRRSTR), after the interventions of Music Alone when compared to the control group. Based on the results from the current research study, Music Alone may positively affect relaxation levels in patients undergoing breast biopsy.

Research Hypothesis #5

There is a significant difference between the intervention of VT and the intervention of Music Alone.

What was anticipated, but was not realized, was a significant difference between the intervention of Vibroacoustic Therapy (VT) and the intervention of Music Alone. This hypothesis was built on the work of Tony Wigram, Associate Professor and Head of Ph.D. Studies at the Institute for Music and Music Therapy in Denmark. In his study, he applied VT to non-clinical subjects (hospital staff) to ascertain the impact of this therapy on their mood and their level of relaxation.⁵ To measure mood and level of relaxation, Wigram administered a psychometric test (University of Wales Institute of Science and Technology (UWIST)-Mood Adjective Check List). Respondents were either given VT, Music Alone, or a period of rest. The results showed a significant reduction in energetic arousal, general arousal and tension arousal in the VT group when compared to the music only group.⁶

A hypothesis of a significant difference between the intervention of VT and the intervention of Music Alone was directionally supported by the work of Catherine Walters in her study with VT and music with patients awaiting scheduled gynecological surgery. In her study, the music only group showed improvements consistent with the VT group; however, these improvements were not as extreme as those identified with the intervention of VT.⁷ Thus, it was anticipated that the VT intervention would be significantly different than the music only group.

Several theories as to why this significant difference did not materialized in this research study are put forth for consideration. Perhaps length of the intervention

impacted the outcome of the VT intervention. The intervention in Wigram's study was thirty minutes. In Walters' study, the intervention lasted as long as the patient was in the surgical holding area. If a participant experienced VT for more than fifteen minutes, would their state anxiety levels decrease and their relaxation levels increase at a faster rate when compared to Music Alone? Fifteen minutes was sufficient to cause statistical significance over the control. This is a finding worth noting as a shorter intervention of VT or Music Alone has not been thoroughly researched. This finding may prove that fifteen minutes of VT or Music Alone is sufficient to reduce anxiety in patients undergoing breast biopsy. However, additional time within the interventions of VT or Music Alone within this research study may have proven the significance of VT over Music Alone.

Another potential factor with not realizing the expected significance of VT over Music Alone could be the music that was selected. In the current study, the music that was used was recorded music on a CD that was composed by a music therapist and included music that was played at exactly 50 beats per minute. Real instruments are used, including cello, flute, harp, bells, violin, and alto recorder.⁸ This particular music was written expressly to entrain the listener and bring about relaxation. Perhaps this music was much more effective at bringing about a decrease in state anxiety and an increase in relaxation over the music used in comparable studies. Within Wigram's study, the music used was described as "new age" and characterized as tonal, melodic and harmonic non-pulsed, arrhythmic music produced on a synthesizer. This music was selected because of the neutral character of the music in that it is meant to reduce the possibility of associations and prior experiences influencing responses.⁹ In Walters'

study, participants were allowed to select music from twelve different recordings, the most popular being the easy listening compilation followed by the compilation of country music.¹⁰ Music specifically written to bring about relaxation may more effectively bring about relaxation over music selected based on unfamiliarity or preference. The music in the current study was also unfamiliar to the participants. However, the intentionality of the music to bring about relaxation through the exactness of 50 beats per minute may have made this music selection more effective in reducing anxiety and increasing relaxation.

A difference within the study design worth noting was the color of the chair. The chair that was used for the VT intervention was red, while the chair that was used for the Music Alone intervention was blue. Perhaps the color blue was more relaxing to participants over the color red, which in turn had an impact on the participant's state anxiety and relaxation levels. Historically, the color red promotes vitality, energy, power, passion and anger, while the color blue brings about stillness, calm, faith, and aspiration.¹¹ The different colors of the chairs may have had an impact on the anxiety levels in participants while using the chairs.

Research Hypothesis #6

The beliefs patients hold with regard to VT and/or music have an impact on the efficacy of the respective intervention.

It was hypothesized that belief in the efficacy of an intervention would have a positive impact on the actual efficacy of the intervention. This hypothesis was not supported based on the current data. There was no correlation between beliefs and state anxiety or levels of relaxation. However, a larger sample size would have enabled

further analytics to understand this relationship at a deeper level. When reviewing the question in the participant survey regarding the participants' beliefs in music or VT, a binary choice of either yes or no was used. Perhaps a rating scale would have been more fruitful in understanding the impact of beliefs on the dependent variables.

Overall Results

The three distinct groups within the study were comparable with regard to age, pre-measurement levels of state and trait anxiety, levels of stress in the participant's recent life, levels of anxiety about the impending biopsy, pre-measurement levels for relaxation, and beliefs that VT and/or Music Alone can reduce anxiety. While this study incorporated a non-randomized convenience sample, some randomization was realized between the interventions. A participant was assigned to the control group when time prior to the biopsy procedure was limited, with all other participants randomly assigned among the two intervention groups: VT or Music Alone. Thus, knowing that the groups are balanced adds credibility to the findings.

Self-Reported Stress and Anxiety Levels

Stress levels regarding the participant's recent life and anxiety levels about the impending biopsy procedure were self-reported measures prior to the interventions. Study results showed that two-thirds of participants (66.6%) described their recent lives as at least somewhat stressful, while over one-fifth (21.5%) described their recent lives as very or extremely stressful. With regard to stress levels, roughly two-thirds of participants had minor levels of anxiety about their impending biopsy while approximately one-third had major levels of anxiety. Participants knew that their recent lives held some level of stress, and they also felt some level of anxiety about their

impending biopsy. The STAI measures confirmed what they already knew to be true. With this knowledge, it was not surprising that the vast majority of participants do something during their week for relaxation.

Age Distribution

Age seemed to be an anomaly when viewed with other comparable studies. Age ranged in the current study from 35 to 86. In Wigram's study, age ranged from 18 to 67 and in Walters' study, aged ranged from 19 to 65. In the research conducted by Haun et al. regarding the effects of music on anxiety of women awaiting breast biopsy, the mean age of the experimental group was 39.7 and the mean age of the control group was 37.2. In the current study, the mean age of the VT group was 55.29; the mean age of the music group was 57.65; and the mean age of the control was 51.06. Thus, participants in the current study were much older than those in any of the comparative studies. The distribution of age also impacted the ability to compare the study results to normative data established by the STAI. Perhaps the demographic profile at Shawnee Mission Medical Center (SMMC), specifically the Women's Center, supports an older population. Feedback about the age discrepancy from the Nurse Navigator at Shawnee Mission Medical Center suggested that SMMC has an extremely loyal customer base where their customers will only go to SMMC for care throughout their lives.¹² While strong loyalty is beneficial for the hospital, this does not seem to account for the higher mean age of participants in the current study when compared to other relevant studies and the STAI norms.

The difference in age between the current studies and other relevant studies could potentially be due to the time required to participate. Because a participant had to come

in to the hospital an additional fifteen minutes to participate in the research study, perhaps younger patients have more time constraints and therefore didn't consent to participate in the study.

Overall Health

While there was a significant difference between groups with regard to self-perception of overall health, the correlation analysis revealed no connection. Statistical testing revealed that the age between groups was not significant. However, it may be possible that the differences in the ages impacted the significant differences between groups with regard to overall health.

	VT	Music Alone	Control
Age Mean	55.29	57.65	51.06
Overall Health	Most likely to say health very good	Most likely to say health is good	Most likely to say health is excellent

Table 6. Distribution of Age and Overall Health.

Study Improvements

As mentioned in Chapter Three and shown in Figure One, this research study took place in a hallway within the Women's Center at Shawnee Mission Medical Center, partitioned off by the use of Japanese screens. The most common complaint by participants revolved around the hallway noise caused by traffic and the public announcement system that could be heard throughout the hospital. The hallway was outside a conference room and adjacent to the printer/copier for the work area. Finding a quiet room to conduct the study away from extraneous noise could possibly enhance the efficacy of future research studies on Vibroacoustic Therapy (VT).

Having Somatron Clinical Recliners that matched by color would have helped to alleviate the potential bias for color. The Women's Center owns the blue Somatron Clinical Recliner, while the red Somatron Clinical Recliner was borrowed from the oncology department. There were no other blue Somatron Clinical Recliners within the hospital. Thus, it was not possible to have matching colored recliners. Future studies might benefit from comparable equipment.

Taking a third measurement of state anxiety and relaxation levels would have been interesting and potentially beneficial to understanding the efficacy of VT and Music Alone. Upon arrival, the baseline measurement was captured, as well as after the intervention. It would have been interesting to take another measurement prior to the intervention to ascertain if anxiety went up, stayed the same or decreased after admittance to the hospital, waiting in the waiting room and talking with the nurse navigator. More frequent measurement might shed more light on the anxiety process and the efficacy of the interventions.

Adding two other interventions for study would provide further insights as to the efficacy of VT. Including a third intervention of resting without music or tactile stimulation in the specially crafted Somatron Clinical Recliners, with the feet elevated in the Trendelenburg position, would provide the ability to isolate the impact of listening to music, when compared to the Music Alone intervention. A fourth intervention consisting of resting in the specially crafted Somatron Clinical Recliners with the feet down, not including music, vibration or reclined position, would provide the ability to isolate the impact of reclining in the Trendelenburg position, when compared to a reclining position in the Somatron Clinical Recliner.

Finally, using a rating scale instead of a binary question to understand beliefs and their impact on the efficacy of the interventions might have been more fruitful. Thus, changing the question to a rating scale on the participant survey is recommended.

Suggestions for Future Research

Many questions arose during the process of this research study which provide fodder for future research with regard to Vibroacoustic Therapy (VT) and Energy Medicine.

1. Does vibration without music impact psychological healing?
2. Does the type of music used for VT have an impact on the efficacy of vibration?
3. Does the color of the Somatron Clinical Recliner have any impact on the efficacy of VT?
4. What is the impact of sitting in the Trendelenburg position when experiencing VT?
5. Would using the Somatron Mat be just as effective?

Chapter 5 Endnotes:

¹Catherine Walters, "The Psychological and Physiological Effects of Vibrotactile Stimulation, via a Somatron, on Patients Awaiting Scheduled Gynecological Surgery," *Journal of Music Therapy* 33, no. 4 (1996): 261-287.

²Michael Haun, Rosalie O. Mainous and Stephen W. Looney, "Effect of Music on Anxiety of Women Awaiting Breast Biopsy," *Behavioral Medicine* 27 (2001): 127-128.

³Ibid., 182.

⁴George Patrick, "The Effects of Vibroacoustic Music on Symptom Reduction Inducing the Relaxation Response through Good Vibrations," *IEEE Engineering in Medicine and Biology* (March/April 1999): 97-100.

⁵Tony Wigram, *The Measurement of Mood and Physiological Responses to Vibroacoustic Therapy in Non-Clinical Subjects*, Edited by Tony Wigram and Cheryl Dileo, *Music Vibration and Health* (Cherry Hill, NJ: Jeffrey Books, 1997), 87-98.

⁶Ibid.

⁷Catherine Walters, "The Psychological and Physiological Effects of Vibrotactile Stimulation, via a Somatron, on Patients Awaiting Scheduled Gynecological Surgery," *Journal of Music Therapy* 33, no. 4 (1996): 261-287.

⁸Janalea Hoffman, *Rhythmic Medicine*, "Musical Acupuncture," <http://www.rhythmicmedicine.com/mcart/index.cgi?task=show&cat=Musical+Acupuncture> (accessed December 8, 2006).

⁹Tony Wigram, *The Measurement of Mood and Physiological Responses to Vibroacoustic Therapy in Non-Clinical Subjects*, Edited by Tony Wigram and Cheryl Dileo, *Music Vibration and Health* (Cherry Hill, NJ: Jeffrey Books, 1997), 87-98.

¹⁰Catherine Walters, "The Psychological and Physiological Effects of Vibrotactile Stimulation, via a Somatron, on Patients Awaiting Scheduled Gynecological Surgery," *Journal of Music Therapy* 33, no. 4 (1996): 261-287.

¹¹C. Norman Shealy, "The Colour Energies," *Energetic Applications for Body/Mind/Spirit*, (Springfield, MO: Holos University Graduate Seminary, 2005, photocopied).

¹²Meg Hallway, E-mail message to author, January 6, 2008.

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APPENDIX A

Approval Letter from SMMC



May 1, 2007

Deborah A Pratt
4800 Fairmount Street
Kansas City Mo 64112

Dear Ms. Pratt:

This letter is to acknowledge the receipt of the information identified below.

Our Study # 07-0202

Protocol Title: The Effects of Vibroacoustic Therapy, Music, and Rest on Anxiety in Patients Undergoing Breast Biopsy

Our Internal #: 125
Type of Change: Amendment
Pre Meeting Action: Expedited
Date of Change: 5/1/2007
On Meeting Date: 5/25/2007

I have reviewed the requested changes to the protocol. The changes appear to be minor and pose minimal or no additional risk to subjects. Therefore, expedited approval is granted.

An annual report is due for this study 5/22/08.

Please feel free to contact me if you have any questions.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark Wilson", is written over a horizontal line.

Mark Wilson, PharmD, Chair
Institutional Review Committee

T 913-676-2000
F 913-676-2676

9100 W. 74th Street
Shawnee Mission, KS 66204
ShawneeMission.org

A Seventh-day Adventist Community Service

APPENDIX B Power Analysis

[Report Definitions

Power: probability of concluding that the means are different.

n: the number of subjects per group.

N: the total number of subjects in the study.

Multiply Means By: the means were multiplied by this constant.

Test Statistic: Wilks' Lambda (or other statistic) computed at the hypothesized values.

Aprox. F Statistic: this is the value of an approximate F from which the power is computed.

Df1: the numerator degrees of freedom of the approximate F statistic.

Df2: the denominator degrees of freedom of the approximate F statistic.

Alpha is the probability of rejecting a true null hypothesis.

Beta is the probability of accepting a false null hypothesis.

B – your group factor

W – your repeat factor

BW – the interaction

Effect size

.2 = small

.5 = medium

.8 = large

Advanced Repeated Measures ANOVA Power Analysis

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Results for Factor B (Levels =3)

Test	Power	n	N	Multiply Means By	SD of Effects (Sm)	Standard Deviation (Sigma)	Effect Size	Alpha	Beta
GG F	0.8240	17	51	1.00	0.40	0.87	0.46	0.0500	0.1760

Results for Factor W (Levels =2)

Test	Power	n	N	Multiply Means By	SD of Effects (Sm)	Standard Deviation (Sigma)	Effect Size	Alpha	Beta
GG F	0.9999	17	51	1.00	0.40	0.50	0.80	0.0500	0.0001

Results for Term BW

Test	Power	n	N	Multiply Means By	SD of Effects (Sm)	Standard Deviation (Sigma)	Effect Size	Alpha	Beta
GG F	0.9994	17	51	1.00	0.40	0.50	0.80	0.0500	0.0006

APPENDIX C

Recruitment Script for Breast Center Scheduling Staff

INVITATION: At the Breast Center, we are always looking for new ways that will help our patients. Currently, we are participating in a research study designed to look at the effects of Vibroacoustic Therapy, music and rest on anxiety in patients that are undergoing a breast biopsy. To date, there are no known risks. Vibroacoustic Therapy is an intervention that uses music which is felt in the body as well as heard through the ears. A specially crafted Somatron Clinical Recliner will be used in this study.

What is required of you is to come in thirty minutes earlier. This is not mandatory for your breast biopsy. Is this something with which you would be interested in participating?

IF ADDITIONAL INFORMATION IS NEEDED:

Each participant will be randomly assigned to one of four groups. One group will experience Vibroacoustic Therapy. To do this the participant will simply recline in this special chair and listen to music and feel gentle vibrations for thirty minutes prior to having the breast biopsy. A second group will experience music alone while sitting in the special chair for thirty minutes. A third group will simply rest in the special chair for thirty minutes. And the fourth group will sit in the waiting area.

A self-administered test will be given before and after the session to measure the level of anxiety.

If yes, schedule an additional thirty minutes prior to current biopsy protocol.

APPENDIX D

State-Trait Anxiety Inventory (STAI)

Purpose: Designed to study levels of anxiety for both state (how you feel right now) and trait (how you generally feel) anxiety.

Population: Can be used for both teenagers and adults.

Score: The test produces two separate scores: state anxiety and trait anxiety.

Time: 10-20 minutes in total.

Authors: Charles D. Spielberger, Richard L. Gorusch, and Robert E. Lushene.

Publisher: Consulting Psychologists Press, Inc.

Description: The State-Trait Anxiety Inventory (STAI) is a self-report assessment device which includes separate measures of state and trait anxiety. It consists of two different tests, each having twenty questions. The state questions refer to how one is feeling right now, and utilizes a four-point scale including: not at all, somewhat, moderately so and very much so. The trait questions refer to how one is generally feeling, and also utilizes a four-point scale, including: almost never, sometimes, often and almost always.¹

Scoring: Scores are obtained by simply summing the scores of the twenty questions within each section.

Suggested Uses: Recommended for studying anxiety in research and clinical settings.

¹ Charles D. Spielberger, "State-Trait Anxiety Inventory for Adults," information sheet obtained from Charles D. Spielberger and Mind Garden, photocopied.

APPENDIX E
Self-Report Rating Scale for Tension and Relaxation (SRRSTR)

Purpose: Designed to study levels of tension and relaxation in the current moment.

Time: two minutes

Author: Roger Poppen, *Behavioral Relaxation Training and Assessment*, New York: Pergamon Press, 1987.

Question: Which of the following best describes the way you feel right now?

1. Feeling more deeply and completely relaxed than I ever have.
2. Feeling completely relaxed throughout my entire body.
3. Feeling more relaxed than usual.
4. Feeling relaxed as in my normal resting state.
5. Feeling some tension in some parts of my body.
6. Feeling generally tense throughout my body.
7. Feeling extremely tense and upset throughout my body.

APPENDIX F Participant Survey

[Name _____ Date _____]

1. Besides having a biopsy, how stressful would you rate your recent life?
(Please check (✓) only one.)

- ₁ **Extremely Stressful**
- ₂ **Very Stressful**
- ₃ **Somewhat Stressful**
- ₄ **Not very Stressful**
- ₅ **Not stressful at all**

2. How much anxiety do you have about your impending biopsy?
(Please check (✓) only one.)

- ₁ **None**
- ₂ **Minor Levels of Anxiety**
- ₃ **Major Levels of Anxiety**
- ₄ **Extreme Levels Anxiety**

3. Of the following statements, which do you agree with?
(Please check (✓) all that apply.)

- ₁ **I believe that music can reduce my anxiety.**
- ₂ **I believe that Vibroacoustic Therapy can reduce my anxiety.**
- ₂ **I believe that resting can reduce my anxiety.**

4. How would you rate your overall health? (Please check (✓) only one.)

- ₁ **Excellent**
- ₂ **Very Good**
- ₃ **Good**
- ₄ **Fair**
- ₅ **Poor**

5. Please specify what you do, if anything, for relaxation or meditation. Please include the activity and the frequency.

6. Which of the following best describes the way you feel right now?
(Please check (✓) only one.)

- ₁ Feeling more deeply and completely relaxed than I ever have.
- ₂ Feeling completely relaxed throughout my entire body.
- ₃ Feeling more relaxed than usual.
- ₄ Feeling relaxed as in my normal resting state .
- ₅ Feeling some tension in some parts of my body.
- ₆ Feeling generally tense throughout my body.
- ₇ Feeling extremely tense and upset throughout my body.

APPENDIX H

Intentional Statement

Dear God,

- I go to my heart, where I can be centered and present.
- I affirm everything that happens here today is for the highest good and best interest for all.
- May the energy within this research space be balanced, clear and objective.
- May I be balanced, clear and objective as I move through this research process.
- I give gratitude to God, my Higher Self, my Guides, my Angels, and all those beings here to help me.
- I honor this research project and detach from outcome. Amen.

APPENDIX I

Standardized Process Script

- Once the patient has signed into the Women’s Center, the Principal Investigator greeted the participant in the waiting area.
- Thank you for agreeing to participate in this research study. My name is Debby Pratt and I am the person conducting the music study.
- Confirm with the participant that they have agreed to participate.
- Explain the process to participant, telling them they will first be admitted into the hospital, and then speak with a nurse navigator. After they speak with the nurse navigator, they will be brought to me for the music study.
- The participant was handed a clip board and asked to fill out the informed consent form, the HIPAA form, the STAI and the Participant Survey, answering any questions that arise.
- The Principal Investigator then leaves the participant in the waiting area to fill out the information.
- The nurse navigator brings the participant to the research area after being admitted and speaking with the nurse navigator.
- If at least 20 minutes remain before the biopsy procedure, the participant is randomly assigned between the VT intervention and the Music Alone intervention.
- If less than 20 minutes remain before the biopsy, the participant is asked to fill out the State Anxiety questions and the SRRSTR. They are then invited to sit in the Somatron Clinical Recliner if time permits before their biopsy procedure.
- **FOR ALL INTERVENTIONS:** Ask participant to sit in Somatron Clinical Recliner.
- **FOR ALL INTERVENTIONS:** This is the Somatron Clinical Recliner. This button on the side controls the reclining of the chair. I would like for you to recline the chair all the way back for this session. This button on the other side is for the volume of the music. We will check the volume once we get started.
- You will be listening to music for fifteen minutes. At the conclusion of this time, I will come back and ask you a few more questions.
- Do you have any questions?
- Again, my name is Debby. I will be sitting right outside, so just call my name any time if you need anything.
- **AFTER Fifteen MINUTES:**
- **FOR INTERVENTION:** Okay, let’s move your chair up to the sitting position.
- I would like you to complete this short survey about how you feel right now. (Give Patient STAI and have them fill out only State questions).
- And, one final question. (Self Report Rating Scale for Tension and Relaxation.)
- Any patient who did not get to experience Vibroacoustic Therapy is invited to do so once all research measures have been gathered, as long as time permits before the breast biopsy.

APPENDIX J

Informed Consent Form

As discussed in Chapter Three, this form was given to each participant prior to their inclusion in the research study.

The Effects of Vibroacoustic Therapy, Music and Rest on Anxiety in Patients Undergoing Breast Biopsy

- This study involves research. The purpose of the research is to understand the effects of Vibroacoustic Therapy, music and rest on anxiety in patients undergoing a breast biopsy.
- Vibroacoustic Therapy uses music which is felt in the body as well as heard through the ears. This is done in a specially crafted Somatron Clinical Recliner, where the feet are elevated above the heart.
- Each participant will be randomly assigned to one of four groups:
 - The first group will sit in the Somatron Clinical Recliner and experience Vibroacoustic Therapy.
 - The second group will sit in the Somatron Clinical Recliner and experience music alone.
 - The third group will sit in the Somatron Clinical Recliner and experience rest.
 - The fourth group will sit in the waiting room, along with other patients.
- The expected duration of your participation in the research is no more than one hour, and is completed prior to the biopsy procedure.
- The procedures to be followed are as follows:
 - Participant will be given two short questionnaires upon consent.
 - Questionnaires are to be filled out immediately prior to the intervention, which consists of music and vibration, music alone, rest, or waiting in the waiting area.
 - Participant will fill out one short questionnaire after thirty minutes of music and vibration, music alone, rest or waiting in the waiting area.
 - Participation in the research study will be completed prior to the breast biopsy.
- Of the above described procedures, Vibroacoustic Therapy is experimental.
- At this time, there are no known risks and no unforeseeable risks to participating in this study.
- The expected benefit associated with your participation in this study is a reduced anxiety level during the biopsy procedure.

- It is hereby understood that the results of this research may be published, but that your privacy will be protected and your name will not be published. It is also understood that these research documents may be examined by the Food and Drug Administration at its request.
- In the unlikely event of an injury occurring in the course of the research, no compensation is available to you.
- There are no costs to you to participate in the study.
- If injury occurs in the course of research, further information regarding said injury may be obtained by contacting: The principal investigator – Deborah A. Pratt, Evolving Insight LLC, 4800 Fairmount Street, Kansas City, MO 64112, 816-756-2012.
- The following persons may be contacted for answers to pertinent questions about the research and your rights concerning the research: The principal investigator - Deborah A. Pratt, Evolving Insight LLC, 4800 Fairmount Street, Kansas City, MO, 64112, 816-756-2012; The faculty supervisor - Dr. Martina Steiger, Holos University Graduate Seminary, 5607 South 222nd Road, Fair Grove, MO 65648, 609-314-7560; or the Shawnee Mission Medical Center Institutional Review Committee, 9100 West 74th Street, Box 2923, Shawnee Mission, KS 66201 or by telephone at 913-676-7797.
- The Shawnee Mission Medical Center Institutional Review committee was established for the purpose of protecting the rights of volunteers in a research study. It is not the policy of Shawnee Mission Medical Center to compensate subjects injured as a result of participation in a research study.
- Participation in this research is voluntary, and refusal to participate will involve no penalty or loss of benefits to which you may otherwise be entitled. Further, you may withdraw from participation in this research at any time without fear or prejudice or discrimination, and such withdrawal will not result in the loss of care or benefits to which you are normally entitled.

Patient's Signature _____

Patient's Name (Printed) _____

Age _____ Date _____ Time _____ Place _____

I have discussed this research with the subject.

Person Obtaining Consent _____ Date _____

Investigator's Signature _____ Date _____

APPENDIX K
Health Insurance Portability & Accountability Act (HIPAA)

As discussed in Chapter Three, this form was given to each participant prior to their inclusion in the research study.

**Authorization to Use and Disclose Protected Health Information for
Research Purposes**

The privacy laws, including the Health Insurance Portability & Accountability Act (HIPAA) and other federal and state laws, rules and regulations, protect your individually identifiable health information (“Protected Health Information”). The privacy laws require you to sign this Authorization which describes your rights and explains how your Protected Health Information will be used and disclosed for this research study entitled The Effect of Vibroacoustic Therapy, Music and Rest on Anxiety in Patients undergoing Breast Biopsy.

You authorize Deborah A. Pratt, Evolving Insight LLC, her research staff and Holos University (“Researchers”) to use and disclose your Protected Health Information for the purposes described below. You also authorize your doctors, Shawnee Mission Medical Center (“Medical Center”) personnel and individuals who provide health care services at Medical Center (“Health Care Providers”) to disclose your Protected Health Information for the purposes described below:

1. You understand that your Protected Health Information, which may be used and disclosed for this research study, include:
 - a. Tests or procedures, such as the questionnaires that you will fill out, that are performed as part of this research study.
 - b. Prior or future tests or procedures that may have an impact on this research study.
 - c. Portions of your medical record which are maintained at Medical Center or your doctor’s office that the Researchers or Health Care Providers believe are necessary to conduct this research study and monitor your treatment and participation in this research study.

2. You understand that your Protected Health Information will be used and disclosed by the Researchers and Health Care Providers for:
 - a. Conducting this research study.
 - b. Ensuring that the research meets legal, institutional or accreditation requirements.
 - c. Conducting public health activities, including reporting of adverse events where you or others may be at risk or harm.

- d. Treatment, payment or health care operations, as set forth in the Medical Center Notices of Patient Privacy Practices, if some or all of the Protected Health Information produced by this research study is maintained in your Medical Center medical record.
 - e. The purpose of the research is to understand the effects of Vibroacoustic Therapy, music and rest on reducing anxiety in patients undergoing breast biopsy.
3. You understand that the Researchers and Health Care Providers may disclose your Protected Health Information to:
 - a. Medical Center's Institutional Review Board/Office.
 - b. Government representatives, when required by law.
 - c. Hospital representatives.
 - d. Representatives of Holos University Graduate Seminary who are involved in the study.
4. You understand that to the extent any recipient of your Protected Health Information is not required to comply with these privacy laws, the information may no longer be protected by such privacy laws once it is disclosed to the recipient and, therefore, may be subject to redisclosure by the recipient.
5. The Researchers and Health Care Providers agree to safeguard your Protected Health Information by using and disclosing it only as stated in this Authorization and as directed by state and federal law.
6. You understand you will be allowed to review your Protected Health Information that is created or obtained specifically for this research study, or treatment information contained in your medical record that is applicable to this research study, until after this research study is complete. When this research study is over, you will once again have the right to access this Protected Health Information.
7. You understand that you do not have to sign this Authorization.
 - a. It will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
 - b. You may not be allowed to participate in this research study.
8. You understand that after signing the Authorization, you can change your mind and revoke this Authorization by sending a written letter to Deborah A. Pratt, Evolving Insight LLC, 4800 Fairmount Street, Kansas City, MO 64112, to inform her of your decision. If you revoke this Authorization, you understand that:

- a. Researchers may still use and disclose the Protected Health Information already collected for this research study to maintain the integrity of this research study.
- b. Your Protected Health Information may still be used and disclosed should you have an adverse event (a bad effect). If such adverse event occurs, the Researchers or Health Care Providers may need to review your entire medical record.
- c. You may not be allowed to continue to participate in this research study.
- d. You will not have access to your Protected Health Information created or obtained specifically for this research study or treatment information contained in your medical record that is applicable to this research study until the research study is complete.

9. You understand that this Authorization does not have an expiration date.

10. If you have not already received a copy of the Medical Center’s Privacy Notice, you may request one.

I am the Research Subject or am authorized to act on behalf of the Research Subject. I have read this Authorization, and I will receive a copy of this Authorization after it is signed.

Signature of Research Subject or
Research Subject’s Legal Representative*

Date

Printed Name of Research Subject or
Research Subject’s Legal Representative

Representative’s Relationship to
Research Subject

*Please explain Representative’s Relation to Research Subject and include a description of Representative’s Authority to act on behalf of Research Subject:

APPENDIX L

Data Spreadsheet – STAI

Respondent	Intervention	Age	State Anxiety		Difference	Trait Anxiety
			State Anxiety Pre	Post		Pre
1	A	70	39	39	0	45
2	B	86	55	42	13	31
3	Replace				0	
4	C	65	48	37	11	27
5	B	62	68	42	26	40
6	C	42	69	49	20	45
7	C	71	54	57	-3	33
8	A	50	38	23	15	26
9	B	46	35	24	11	43
10	C	40	39	33	6	34
11	C	59	48	47	1	31
12	C	48	62	67	-5	55
13	C	51	40	41	-1	24
14	A	57	62	35	27	35
15	C	54	51	54	-3	32
16	B	80	49	28	21	20
17	A	54	58	52	6	50
18	B	41	50	21	29	38
19	A	58	49	49	0	25
20	B	57	50	25	25	30
21	Replace				0	
22	C	48	34	45	-11	44
23	B	50	48	43	5	54
24	A	56	35	30	5	26
25	B	54	52	37	15	38
26	A	68	45	33	12	28
27	B	50	31	20	11	27
28	C	40	37	36	1	34
29	A	35	66	36	30	34
30	B	40	50	45	5	54
31	A	52	56	31	25	27
32	B	61	41	29	12	24
33	A	66	34	20	14	26
34	B	49	46	39	7	37
35	A	71	36	20	16	31
36	C	41	44	45	-1	47
37	B	64	52	22	30	29
38	C	49	33	34	-1	26
39	A	41	48	31	17	37
40	B	74	20	28	-8	23

41	A	35	47	34	13	31
42	C	48	65	59	6	56
43	C	74	34	34	0	37
44	C	52	45	45	0	48
45	C	39	48	44	4	43
46	B	53	55	30	25	29
47	A	42	59	39	20	36
	C	47	41	32	9	34
49	B	62	34	32	2	47
50	A	54	66	43	23	41
51	B	51	67	50	17	36
52	A	71	40	24	16	42
53	A	60	44	23	21	23

APPENDIX M
Data Spreadsheet – Participant Survey Q1, Q2, Q3, Q4

Respondent	Stress (Q1)	Anxiety (Q2)	Beliefs Music (Q3)	Beliefs VT	Beliefs Rest	Overall Health (Q4)
1	3	2	1	0	1	3
2	4	3	1	0	0	3
3						
4	3	2	1	1	1	3
5	3	3	1	1	0	3
6	3	3	1	1	1	3
7	4	2	1	0	0	1
8	4	2	1	1	1	2
9	3	2	0	0	1	3
10	2	2	1	0	0	1
11	3	4	0	0	0	1
12	2	3	1	1	0	4
13	4	2	1	0	0	4
14	3	2	1	0	0	3
15	4	3	0	0	1	2
16	5	2	1	0	0	1
17	3	3	1	0	0	2
18	3	2	1	1	1	3
19	3	2	1	1	1	2
20	3	2	1	0	1	3
21						
22	3	2	1	0	0	3
23	Blank	blank	blank	blank	blank	blank
24	4	2	0	0	0	3
25	3	3	0	1	0	3
26	3	2	1	0	0	2
27	3	2	1	1	1	2
28	3	2	1	0	1	3
29	2	4	1	0	1	2
30	3	3	1	1	1	3
31	4	3	1	1	1	2
32	3	2	0	0	1	4
33	4	2	1	0	0	2
34	2	3	1	1	0	2
35	4	2	1	0	1	3
36	2	3	1	0	1	2
37	4	2	1	0	0	3
38	4	2	1	1	1	1
39	3	3	1	1	0	2
40	4	2	1	1	1	3
41	2	2	1	0	1	3
42	2	4	1	1	0	3
43	4	2	1	0	1	3

44	1	3	1	1	1	3
45	3	4	0	0	1	3
46	3	2	1	1	0	1
47	2	2	1	1	0	2
	3	2	1	1	0	2
49	4	2	1	0	0	1
50	3	3	1	1	1	2
51	1	4	0	0	1	4
52	2	2	1	0	0	3
53	4	2	1	1	0	2

APPENDIX N
Data Spreadsheet – SRRSTR

Respondent	Pre-Relaxation (6)	Post-Relaxation (Q7)	Difference
1	4	3	1
2	6	4	2
3			0
4	5	5	0
5	6	5	1
6	6	6	0
7	6	6	0
8	5	2	3
9	4	3	1
10	5	5	0
11	7	7	0
12	5	7	-2
13	blank	3	#VALUE!
14	5	2	3
15	6	6	0
16	6	2	4
17	5	5	0
18	5	3	2
19	6	3	3
20	blank	2	#VALUE!
21			0
22	5	6	-1
23	5	3	2
24	5	4	1
25	7	3	4
26	blank	2	#VALUE!
27	4	3	1
28	5	5	0
29	7	5	2
30	7	5	2
31	6	4	2
32	5	2	3
33	5	2	3
34	6	3	3
35	5	2	3
36	5	5	0
37	6	2	4
38	4	4	0
39	6	3	3
40	5	5	0
41	7	5	2

42	7	6	1
43	4	2	2
44	6	6	0
45	7	5	2
46	6	3	3
47	6	5	1
	6	blank	#VALUE!
49	4	4	0
50	6	5	1
51	7	4	3
52	5	2	3
53	6	2	4

APPENDIX O

Data Spreadsheet – Participant Survey Q5

Respondent	Relaxation/Meditation open end (Q5)
1	I have devotions and prayer every morning. When anxious, I pray. At night I listen to soft music.
2	Walk often. Read.
3	
4	Read everyday. Exercise at least three times per week.
5	Walking daily, weather permitting.
6	Work in my garden 3 to 4 times a week. Go for walks 2 to 3 times a week. Make jewelry 2 to 3 times a month.
7	Listen to music daily. Prayer Daily. Gardening in spring and summer, 2-3 times per week. Read daily. Do puzzles 2-3 times per week.
8	Read. Sit outside and enjoy the day.
9	Read. Watch TV. Music.
10	I listen to music or just sit in pseudo yoga pose and breathe.
11	Farm work daily.
12	Deep breathing, walking 1-3 times per day.
13	
14	Read, sew, crochet.
15	Yard work. Time with family and friends.
16	
17	
18	Play with my 9 year old daughter.
19	Restorative yoga - daily. Meditation intermittent.
20	
21	
22	Pray. Talk to spouse and family often.
23	
24	Visualization.
25	Read books daily.
26	
27	Reading daily.
28	Pray, breathe.
29	Listen to music. Sit in a quiet place. Exercise 3 plus times per week.
30	
31	Reading daily before sleep. Napping in the afternoon when I can - maybe 1-2 days per week. Prayer - spontaneously throughout the day.
32	Sew.
33	Read. Sew.
34	
35	Walking twice a week. Reading three times weekly.
36	
37	
38	Read books everyday. Listen to music everyday. Music, aroma, candles, prayer, massage, pets, crystals, painting, crafts, hugs, all of these on a daily basis or as needed.
39	
40	Read whenever possible. Gardening.

41 Sleep or read.
42 Host pogo bowling tours online everyday.
43 Go to Weight Watchers.
44 Relaxation of my body when I am very stressed out. I have done it twice in the past week.
45 Nothing yet.
46 Quilting five times per week. Listen to music daily. Walk three to four times per week.
47
Read daily.
Walk dogs daily. Exercise five times weekly. Drink wine daily. Watch TV nightly.
49 Read five times per week.
50 Read, listen to music, pet my cats.
51 Try to keep busy with different things. Shopping. Busy work. To take my mind away from stress.
52 Music everyday. Do art, rubber stamping - three or four times a week. Read - every night.
53 Yoga at least three times per week. Walking daily if possible.

APPENDIX P

Hospital Staff Verbatims

- ❖ Eight hospital staff members were asked to provide feedback regarding their experience with this research study. Specifically, the staff was asked the following: In your professional opinion, did VT or music have an impact on the anxiety level in patients undergoing breast biopsy? Please share any insights thoughts and/or experiences. Four staff members responded with the following comments.
 - ◆ *Absolutely wonderful! Patients spoke very well of their experience in the music therapy chair. Plan to offer it as often as possible in the future. Getting a breast biopsy is a very personal intrusion emotionally to many women and being able to offer them the tangible evidence that we care and respect them and hope they feel “safe” and comforted by us is easily done when we provide them with this positive experience.*
 - ◆ *I had many patients tell me that the music therapy chair was very calming to them. It helped to relax them before their procedure.*
 - ◆ *I definitely think that the VT and music had a calming effect on our patients. The opportunity to recline, close their eyes and have a few minutes of soothing music before their procedure helped them cope. I believe that it was probably a combination of things that were helpful. Acknowledgement by the hospital staff that it is normal to be anxious prior to such a procedure and that we want to help reduce that anxiety tells the patient that we are concerned about them. My experience is that patients feel relief knowing that their reactions are normal. I also think that reclining and listening to the music took them away from the unfamiliar, anxiety-producing environment for a while which was calming. Perhaps lowering their blood pressure and pulse rate also helps take them back to a more neutral point emotionally. Involvement in the research study was not only a good experience for the patients, it was good for our staff. It reminds us to care for the whole patient, not just their breast or other ailments. And that any comfort measures we can offer patients will improve their health care experience.*
 - ◆ *As a nurse who provides education and support prior to breast biopsy, I routinely assist patients with managing high levels of anxiety and fear related to these procedures. Having this combination of relaxation therapies available was like giving each patient a gift. The great majority of the women soaked it up and emerged calm, relaxed and more prepared for their biopsy procedures.*

APPENDIX Q

Correlation Analysis - Beliefs

A correlation analysis was conducted to see if variables within the research study are related. This correlation analysis showed that there is no correlation between the belief that VT or music can reduce anxiety and their actual state anxiety levels.

Correlation Analysis – VT Group

** - Correlation is significant at the 0.01 level (2-tailed)

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

Total Sample	State Anxiety Pre	State Anxiety Post	VT can Reduce Anxiety
State Anxiety Pre	1	.635**	.243
State Anxiety Post	.635**	1	.099
VT can Reduce Anxiety	.243	.099	1

Correlation Analysis – Music Alone Group

** - Correlation is significant at the 0.01 level (2-tailed)

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

Total Sample	State Anxiety Pre	State Anxiety Post	Music can Reduce Anxiety
State Anxiety Pre	1	.548*	-.074
State Anxiety Post	.548*	1	-.185
Music can Reduce Anxiety	-.074	-.185	1

APPENDIX R

Correlation Analysis-Overall Health

A correlation analysis was conducted to see if variables within the research study are related. This correlation analysis showed that there is a highly significant positive correlation between state anxiety pre-measurement, state anxiety post-measurement, trait anxiety pre-measurement, relaxation pre-measurement, relaxation post-measurement and anxiety levels. This same correlation analysis showed that there is a highly significant negative correlation of these aforementioned measures and stress levels, as stress levels were measured with an inverted scale where the highest levels of stress were measured with “1” and the lowest levels of stress were measured with “5”.

Total Sample	State Anxiety Pre	State Anxiety Post	Trait Anxiety Pre	Relaxation Pre	Relaxation Post	Overall Health	Stress Level	Anxiety Level
State Anxiety Pre	1	.533**	.319*	.613**	.314*	.090	-.356*	.591*
State Anxiety Post	.533**	1	.551**	.365*	.744**	.108	-.358*	.580**
Trait Anxiety Pre	.319*	.551**	1	.035	.441**	.224	-.527**	.457**
Relaxation Pre	.613**	.365*	.035	1	.333*	.026	-.289*	.656**
Relaxation Post	.314*	.744**	.441**	.333*	1	-.041	-.359*	.528**
Overall Health	.090	.108	.224	.026	-.041	1		
Stress Level	-.356*	-.358*	-.527**	-.289*	-.359*		1	-.421**
Anxiety Level	.591**	.580**	.457**	.656**	.528**		-.421**	1

Correlation Analysis

** - Correlation is significant at the 0.01 level (2 tailed).

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

**APPENDIX S
IRC Proposal**



**The Effects of Vibroacoustic Therapy and Music on
Anxiety in Patients Undergoing Breast Biopsy**

**Proposed Dissertation Research
toward completion of
Doctor of Theology
with a focus on
Energetic & Integrative Healthcare**

31 January 07

Submitted by:

Name: Deborah A. Pratt, Evolving Insight, LLC
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RESEARCH PROJECT ABSTRACT

Project Title: The Effects of Vibroacoustic Therapy and Music on Anxiety in Patients Undergoing Breast Biopsy.

Proposed Study Date: April – December, 2007

Population: Patients over the age of 18 receiving a breast biopsy.

Interventions: Within this research, there are two interventions.

1. Vibroacoustic Therapy (VT): an intervention that uses music which is felt in the body as well as heard through the ears. This is done in specially crafted Somatron Clinical Recliners, where the feet are elevated above the heart.
2. Music alone: an intervention of music alone, without the tactile stimulation. This is done in specially crafted Somatron Clinical Recliners, with the feet elevated.

Control: Patients in the control group will not receive an intervention and sit in the waiting room, along with the other patients.

Music: Music on a CD that was composed by a music therapist specifically for relaxation. Instruments used are cello, flute, harp, bells, violin, and alto recorder.

Frequency: Patients will receive one session on the day of the biopsy approximately one hour prior to the biopsy procedure. Each session will last approximately fifteen minutes.

Benefit to Patients: The potential benefit to the patients may include reduced anxiety.

Benefit to Physicians: The potential benefit to the physicians may include more relaxed patients. This study is eligible to count toward the requirements that are part of the Plane Tree Initiatives at Shawnee Mission Medical Center.

Risks: There are no side effects known at this time for VT. Because of the newness of this type of therapy, no experimentation has been undertaken to determine the contraindications.

Funding: All costs to use the measurement instruments, music for the intervention and costs for copies, labels, and more are covered by the principal investigator. All sessions will be conducted by the principal investigator. Shawnee Mission Medical Center currently owns four Somatron Clinical Recliners and has agreed to allow these for use in this research. The hospital has successfully used these chairs in the past for patients with insomnia, pain, fear and anxiety, as well as patients receiving chemotherapy.

RESEARCH PROTOCOL

The Effects of Vibroacoustic Therapy and Music on Anxiety in Patients Undergoing Breast Biopsy

Study Date: April - December, 2007

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BACKGROUND

The only reason to get a breast biopsy is to screen for cancer. This can be a very frightening and stressful event. While approximately 80% of breast biopsies are benign, the experience of facing a diagnosis of cancer is fraught with anxiety.¹

Music can be used to promote relaxation and reduce anxiety. Music rhythm can enhance relaxation by impacting the body's rhythm through entrainment. According to Dr. Gaynor, author of *The Sounds of Healing*, entrainment is “the process by which the powerful rhythmic vibrations of one object are projected upon a second object with a similar frequency, thereby causing that object to vibrate in resonance with the first object. In terms of sound and healing, sound waves may entrain the human organism – causing us to vibrate in resonance with those waves – in a variety of interconnected ways.”² By using specially metered music as a point of reference for patients, individuals can change their body rhythms.³ By changing body rhythms, it is possible to increase the level of relaxation and decrease the level of anxiety.

Music, coupled with vibration in a special chair, potentially creates an added level of healing. VT is an intervention that uses music which is felt in the body, as well as heard through the ears. The name comes from the the root word *vibro*, meaning to vibrate and *acoustics*, meaning to hear.⁴

According to Tony Wigram, author of *The Development of Vibroacoustic Therapy*, “the basic process of this therapeutic intervention involves lying a patient on a bed or a chair unit into which has been built a number of loudspeakers. Sound is transferred through a mattress or some other means which can conduct sound waves directly to the body. The body vibrates in sympathetic resonance with the sound waves used.”⁵ This

type of process is classified as selective low-frequency (SLF), and has been used on many different types of conditions and ailments.⁶

The vibration of the sound in vibroacoustics creates a tactile stimulation in the body, giving the client a physiological experience as well as a psychological event.⁷ Chris Brewer, author of *Vibroacoustic Sound Therapy Improves Pain Management and More*, hypothesizes how vibroacoustics works by using an example for pain. She proposes a two-pronged approach for pain management with vibroacoustic therapy, stating that this type of therapy works by “engaging psychological processes (music listening) together with physiological processes (transcutaneously applied music vibration) activates pain-suppressive efferent neural activity as well as pain suppressive afferent neural activity. In conjunction, the 2 prongs also integrate somatic and auditory neural activity that may provide for synergistic mechanisms in the central nervous system.”⁸ Thus, both the felt sense as well as the auditory sense may contribute to the positive end results of this type of therapy, although currently there is no single explanation.

RESEARCH ON VIBROACOUSTIC THERAPY

Pioneering work with vibroacoustic therapy starting appearing in the 1980s. To date, there have been a small number of studies designed to explore the benefits of vibroacoustic therapy. Of these studies that have been conducted to date, many have addressed the benefits through case studies and anecdotal reports. Few of these studies have applied rigor to determine the benefits of this modality. Most of the research studies have focused on muscle tone, range of motion, pain relief and psychological issues such

as anxiety, mood and relaxation. The three research studies relating to psychological issues will be explored here, as this is the focus of the proposed research study.

Psychological Issues

In 1995, Catherine Walters investigated the psychological and physiological effects of using a Somatron mat on thirty-nine patients who were awaiting a scheduled gynecological surgery procedure. Walters allowed these women to select music that reflected their musical taste for the music intervention. One group listened to this music on a Somatron mat immediately before having surgery, while another group listened to the same music via a tape player without the Somatron mat prior to their surgery. A third group did not receive any type of musical intervention. According to Walters, “The women who used the Somatron equipment were found to experience lower reported apprehension (defined as combined ratings of their tension, anxiety, relaxation, stress, and mood) following its use than either the women who listened to music via a tape player, or the women who did not experience either.”⁹ In addition, patients self-reported that the musical intervention “increased relaxation” and “helped to ease anxiety.”¹⁰ This study suggests the value of using VT to ease anxiety prior to a stressful procedure.

At the National Institutes of Health, Dr. George Patrick evaluated a VT program to reduce symptoms across hospitalized patients with varying conditions. While this evaluation did not utilize random assignment or control groups, it did cover a large population (N=272). Thus, the results are worth consideration.

Dr. Patrick used a visual analog scale to rate the top three reported symptoms for each patient. Symptoms most reported included tension, fatigue, pain, headache, depression and nausea. Collectively, these six symptoms covered 92% of all symptoms

mentioned. For a single session of VT, Dr. Patrick saw an overall reduction in symptoms by 53% ($p < .0001$).¹¹

Mr. Wigram also sought to understand the impact of VT on psychological responses. In his study, he applied VT to non-clinical subjects (hospital staff) to ascertain the impact of this modality on their mood and their level of relaxation.¹² The dependent variables included blood pressure and heart rate, along with the administration of psychometric tests (University of Wales Institute of Science and Technology (UWIST)-Mood Adjective Check List). Respondents were either given VT, music alone, or a period of rest. The results showed that there was a significant reduction in energetic arousal, general arousal and tension arousal in the VT group. There was no significant difference in blood pressure measures, heart rates or hedonic measures.¹³

OBJECTIVE AND MEASUREMENT

The objective of the proposed research study is to evaluate the effects of VT and music on anxiety in patients undergoing breast biopsy. Anxiety levels will be measured using the State-Trait Anxiety Inventory (STAI). The Self Report Rating Scale for Tension and Relaxation will also be used.

In the STAI, state measures capture how one is feeling right now, in the present moment. This measurement will be captured before and after of the intervention. Trait measures capture how one generally feels. Because Trait measures are not likely to fluctuate within a short period of time, capturing these scores prior to the intervention is considered sufficient.

RESEARCH METHODS

The design for this research will be a case controlled study with a non-randomized convenience sample. However, within the study population, the groups will be randomized.

Study Design

The study design consists of using three groups of participants who will be receiving breast biopsies. All participants who receive an intervention will be randomly assigned among the two groups. Within this research, there are two interventions.

1. Vibroacoustic Therapy (VT): an intervention that uses music which is felt in the body as well as heard through the ears. This is done in specially crafted Somatron Clinical Recliners, where the feet are elevated above the heart.
2. Music alone: an intervention of music alone, without the tactile stimulation. This is done in specially crafted Somatron Clinical Recliners, with the feet elevated.

The control consists of participants who will receive no intervention and sit in the waiting room, along with the other patients. Patients will be counted toward the control group when there is no sufficient time to conduct an intervention.

Setting

The study will take place in the Breast Center at Shawnee Mission Medical Center, 7100 West 74th Street, Shawnee Mission, Kansas, 66204.

Selection and Withdrawal of Subjects

Any patient who is over the age of 18 and is scheduled to receive a breast biopsy during the time of the study is eligible for this study. Subjects are free to withdraw from the study at any time without any penalty.

Monetary Compensation to Subjects

No monetary compensation will be given to those patients who participate in this research study.

Intervention and Control Plan

Shawnee Mission Medical Center currently owns four VT chairs, two of which will be used for this study. The chair is called a Somatron Clinical Recliner. According to the Somatron website, the chair “reclines to the physician recommended Trendelenburg position, with your lower legs above your heart, reducing pressure on your spine, relieving muscle tension and aiding with circulation.”¹⁴ The chair is photographed below.

The Clinical Recliner¹⁵



The recorded music on a CD that will be used for this study is composed by a music therapist and includes music that is at exactly 50 beats per minute. Instruments used are cello, flute, harp, bells, violin, and alto recorder.¹⁶

Three groups of participants will be utilized for this research study. All participants will provide consent prior to inclusion, as well as provide a signed Health Insurance Portability & Accountability Act (HIPPA) Authorization Form.

GROUP 1: VT intervention, both music and vibration, in the Somatron Clinical Recliner
Target number of participants: 30 patients

After providing consent to participate in the study, the patient will be asked to take the STAI measures for both State and Trait to determine anxiety levels, as well as a short patient survey of six questions. This group will then be instructed by the principal investigator on how the session will unfold by reading a standard script. A demonstration on how the Somatron chair works will also be provided. Each participant will be given fifteen minutes of VT in the Somatron Clinical Recliner. At the conclusion of this session, the STAI measures for State will be gathered, and one follow-up question will be asked. Total time needed is twenty minutes.

GROUP 2: Music only intervention in the Somatron Clinical Recliner

Target number of participants: 30 patients

After providing consent to participate in the study, the patient will be asked to take the STAI measures for both State and Trait to determine anxiety levels, as well as a short patient survey of six questions. This group will then be instructed by the principal investigator on how the session will unfold by reading a standard script. A demonstration on how the Somatron chair works will also be provided. Each participant will be given

fifteen minutes of music alone in the Somatron Clinical Recliner. At the conclusion of this session, the STAI measures for State will be gathered, and one follow-up question will be asked. Total time needed is twenty minutes.

GROUP 4: No Intervention

Target number of participants: 30

After providing consent to participate in the study, the patient will be asked to take the STAI measures for both State and Trait to determine anxiety levels, as well as a short patient survey of six questions. This group will then be instructed by the principal investigator to go back to the waiting area within the Breast Center. Each participant will be given fifteen minutes to wait in the waiting area. At the conclusion of this time, the STAI measures for State will be gathered, and one follow-up question will be asked.

Total time needed is twenty.

After all information is gathered, and if time permits, the patient will be allowed to sit in the Somatron Clinical Recliner prior to the breast biopsy procedure and experience VT.

Safety Assessment

There are no known side effects at this time for VT. Because of the newness of this type of therapy, no experimentation has been undertaken to determine the contraindications. However, Mr. Wigram, contributing editor to *Music Vibration and Health*, outlines the following anecdotal contraindications:

- Acute Inflammatory Conditions – including things where inflammation is exacerbated. Examples of this include earache, toothache, slipped disc, etc.

- Psychotic Patients – these patients may not be able to understand the protocol.
- Pregnant Women – no trials to date have been done using vibroacoustic therapy on pregnant women.
- Acute Conditions – when patients are being treated for acute conditions, it is important to check with the physician before using vibroacoustic therapy. The therapy should be monitored.
- Hemorrhaging or Active Bleeding – because of the effect on blood pressure and heart rate.
- Thrombosis – patients diagnosed with thrombosis or any suspected embolism should not be treated with vibroacoustic therapy. This may have an effect of increasing the pain.
- Hypotension – patients with low blood pressure.
- Pacemakers – because of the magnetic fields.¹⁷

Statistical Analysis

For this research study, a mixed ANOVA (Analysis of Variance) will be utilized.

ANTICIPATED RESULTS

The hypothesized results are that patients who receive a VT intervention experience statistically lower levels of anxiety as compared to the intervention of music alone in the Somatron Clinical Recliner ($p < .05$). It is further hypothesized that both interventions of VT and music alone experience statistically lower levels of anxiety when compared to those in the control who waited in the waiting area ($p < .05$).

BUDGET AND FUNDING SOURCE

Budget and funding for this research project are as follows:

Item	Number Needed	Budget	Funding
State-Trait Anxiety Inventory	400	\$260	Principal Investigator
Music CD	2	\$30	Principal Investigator
Copies of surveys, labels, etc.	400	\$100	Principal Investigator
Vibroacoustic Chairs	2	0	SMMC already owns chairs

CURRENT STATUS, HOSPITAL STAFF EDUCATION AND NEXT STEPS

Charlene Wallace, Director of the Breast Center at Shawnee Mission Medical Center, has already agreed to participate in this study. Upon approval from the Internal Review Committee for Shawnee Mission Medical Center, the following steps will commence:

1. Meg Holloway, the Nurse Navigator in the Breast Center at Shawnee Mission Medical Center has agreed to provide further information and education on breast biopsies, including observation of procedures, to the Principal Investigator.
2. Principal Investigator will attend a Breast Center Staff Meeting to inform the entire department about the research study.
3. Principal Investigator will set up two Somatron chairs, separated by screen dividers, for the interventions within the Breast Center prior to the commencement of the study in April. The Somatron chairs will be set up in the

alcove where the current Somatron Clinical Recliner currently sits. This space will be dedicated to this research study through December, 2007.

Endnotes:

¹ “How Mamotome® Breast Biopsy Works,” http://www.Breastbiopsy.com/biopsyinfo_mamotome_howitworks.jsp (accessed January 10, 2007).

² Mitchell L. Gaynor, *Sounds of Healing: A Physician Reveals the Therapeutic Power of Sound, Voice, and Music* (New York: Broadway Books, 1999), 64.

³ Janalea Hoffman, *Rhythmic Medicine: Music with a Purpose*, (Leawood, KS: Jamillan Press, 1995), 18.

⁴ Chris Boyd Brewer and Ruth McCaffrey, “Vibroacoustic Sound Therapy Improves Pain Management and More,” *Holistic Nursing Practice* 18 n. 3 (May/June 2004): 111.

⁵ Tony Wigram, *The Development of Vibroacoustic Therapy*, Edited by Tony Wigram and Cheryl Dileo, *Music Vibration and Health*, (Cherry Hill, NJ: Jeffrey Books, 1997), 12.

⁶ Chris Boyd Brewer and Ruth McCaffrey, “Vibroacoustic Sound Therapy Improves Pain Management and More,” *Holistic Nursing Practice* 18 n. 3 (May/June 2004): 112.

⁷ Ibid.

⁸ Ibid.

⁹ Walters, Catherine Walters, “The Psychological and Physiological Effects of Vibrotactile Stimulation, via a Somatron, on Patients Awaiting Scheduled Gynecological Surgery,” *Journal of Music Therapy* 33 n. 4 (1996): 261-287.

¹⁰ Ibid.

¹¹ George Patrick, “The Effects of Vibroacoustic Music on Symptom Reduction Inducing the Relaxation Response through Good Vibrations,” *IEEE Engineering in Medicine and Biology* (March/April 1999): 97-100.

¹² Tony Wigram, *The Measurement of Mood and Physiological Responses to Vibroacoustic Therapy in Non-Clinical Subjects*, Edited by Tony Wigram and Cheryl Dileo, *Music Vibration and Health* (Cherry Hill, NJ: Jeffrey Books, 1997), 87-98.

¹³ Ibid.

¹⁴ Somatron “products”, <http://www.somatron.com/hprod/somaseat/recliner.html> (accessed December 8, 2006).

¹⁵ Ibid.

¹⁶ Janalea Hoffman, *Rhythmic Medicine*, “Musical Acupuncture,” <http://www.rhythmicmedicine.com/mcart/index.cgi?task=show&cat=Musical+Acupuncture> (accessed December 8, 2006).

¹⁷ Tony Wigram and Cheryl Dileo, *Clinical and Ethical Considerations*, Edited by Tony Wigram and Cheryl Dileo, *Music Vibration and Health* (Cherry Hill, NJ: Jeffrey Books, 1997), 231.

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Thank You Letter for Participants

Dear Participant:

Thank you for participating in this research study. This research is being conducted as part of a doctoral program at Holos University Graduate Seminary, which focuses on energetic and integrative healthcare.

The purpose of this study is to understand the effects of Vibroacoustic Therapy (VT), music and rest on anxiety in patients undergoing a breast biopsy. Your help in understanding these objectives is much appreciated. There are no risks known at this time for using Vibroacoustic Therapy.

If you have any questions or concerns about this research project, please do not hesitate to contact Deborah A. Pratt or Dr. Martina Steiger at the below contact information.

Thank you very kindly in this matter.

Best regards,

Deborah A. Pratt

Principal Investigator

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Recruitment Script for Breast Center Scheduling Staff

INVITATION: At the Breast Center, we are always looking for new ways that will help our patients. Currently, we are participating in a research study designed to look at the effects of Vibroacoustic Therapy, music and rest on anxiety in patients that are undergoing a breast biopsy. To date, there are no known risks. Vibroacoustic Therapy is an intervention that uses music which is felt in the body as well as heard through the ears. A specially crafted Somatron Clinical Recliner will be used in this study.

What is required of you is to come in thirty minutes earlier. This is not mandatory for your breast biopsy. Is this something with which you would be interested in participating?

IF ADDITIONAL INFORMATION IS NEEDED:

Each participant will be randomly assigned to one of four groups. One group will experience Vibroacoustic Therapy. To do this the participant will simply recline in this special chair and listen to music and feel gentle vibrations for thirty minutes prior to having the breast biopsy. A second group will experience music alone while sitting in the special chair for thirty minutes. A third group will simply rest in the special chair for thirty minutes. And the fourth group will sit in the waiting area.

A self-administered test will be given before and after the session to measure the level of anxiety.

If yes, schedule an additional thirty minutes prior to current biopsy protocol.

Standardized Script and Process for Session

- Thank you for agreeing to participate in this research study. My name is Debby Pratt and I will be working with you today. (Have them sit in a standard chair in research area to complete surveys. The surveys will be on a clipboard to allow ease for the patient.)
 - During this process, you will first be asked to fill out two questionnaires. Next, you will participate by either listening to music with vibration, music alone, rest or waiting in the waiting area for a total of thirty minutes. Finally, you will be asked to fill out one short questionnaire. Now I will lead you through the procedure step by step.
 - The first thing that I would like you to do is complete this short survey. This is the State-Trait Anxiety Inventory and will measure your level of anxiety. Please fill out both sides. It will only take you a few minutes. (Patient will be handed the STAI.)
 - Now could you please complete the second questionnaire for me? (Patient will be handed the Patient Survey, including the Self Report Rating Scale for Tension and Relaxation.)
 - FOR ALL INTERVENTIONS: Ask participant to sit in Somatron Clinical Recliner.
 - FOR CONTROL: Ask patient to be seated in the waiting area.
 - FOR ALL INTERVENTIONS: This is the Somatron Clinical Recliner. This button on the side controls the reclining of the chair. I would like for you to recline the chair all the way back for this session. This button on the other side is for the volume of the music. We will check the volume once we get started.
 - You will be (listening to music/resting) for thirty minutes. At the conclusion of this time, I will come back and ask you a few more questions.
 - Do you have any questions?
 - I will be sitting right outside, so just call my name any time if you need anything.
-
- **AFTER THIRTY MINUTES:**
 - FOR INTERVENTION: Okay, let's move your chair up to the sitting position.
 - FOR CONTROL: Bring patient back to standard chair in research area.
 - I would like you to complete this short survey about how you feel right now. (Give Patient STAI and have them fill out only State questions).
 - And, one final question. (Self Report Rating Scale for Tension and Relaxation.)
-
- **IF TIME PERMITS:**
 - Any patient who did not get to experience Vibroacoustic Therapy is invited to do so once all research measures have been gathered, as long as time permits before the breast biopsy.

**Informed Consent for Research Involving
The Effects of Vibroacoustic Therapy, Music and Rest on Anxiety in Patients
Undergoing Breast Biopsy**

- This study involves research. The purpose of the research is to understand the effects of Vibroacoustic Therapy, music and rest on anxiety in patients undergoing a breast biopsy.
- The expected duration of your participation in the research is no more than one hour.
- The procedures to be followed are as follows:
 - Participant will be given two short questionnaires upon consent.
 - Questionnaires are to be filled out immediately prior to the intervention, including music and vibration, music alone, rest, or waiting in the waiting area.
 - Participant will fill out one short questionnaire after thirty minutes.
- Of the above described procedures, Vibroacoustic Therapy is experimental.
- At this time, there are no known risks to participating in this study.
- The expected benefit associated with your participation in this study is a reduced anxiety level during the biopsy procedure.
- It is hereby understood that the results of this research may be published, but that your privacy will be protected and your name will not be published. It is also understood that these research documents may be examined by the Food and Drug Administration at its request.
- In the unlikely event of an injury occurring in the course of the research, no compensation is available to you.
- If injury occurs in the course of research, further information regarding said injury may be obtained by contacting: The principal investigator – Deborah A. Pratt, Evolving Insight LLC, 4800 Fairmount Street, Kansas City, MO 64112, 816-756-2012.
- The following persons may be contacted for answers to pertinent questions about the research and your rights concerning the research: The principal investigator - Deborah A. Pratt, Evolving Insight LLC, 4800 Fairmount Street, Kansas City, MO, 64112, 816-756-2012; The faculty supervisor - Dr. Martina Steiger, Holos University Graduate Seminary, 5607 South 222nd Road, Fair Grove, MO 65648, 609-314-7560.
- Participation in this research is voluntary, and refusal to participate will involve no penalty or loss of benefits to which you may otherwise be entitled. Further, you may withdraw from participation in this research at any time without fear or prejudice or discrimination, and such withdrawal will not result in the loss of care or benefits to which you are normally entitled.

Patient's Signature _____

Patient's Name (Printed) _____

Age _____ Date _____ Time _____ Place _____

I have discussed this research with the subject.

Witness Signature _____ Date _____

Investigator's Signature _____ Date _____

Person obtaining consent _____ Date _____

Authorization to Use and Disclose Protected Health Information for Research Purposes

The privacy laws, including the Health Insurance Portability & Accountability Act (HIPAA) and other federal and state laws, rules and regulations, protect your individually identifiable health information (“Protected Health Information”). The privacy laws require you to sign this Authorization which describes your rights and explains how your Protected Health Information will be used and disclosed for this research study entitled The Effect of Vibroacoustic Therapy, Music and Rest on Anxiety in Patients undergoing Breast Biopsy.

You authorize Deborah A. Pratt, Evolving Insight LLC, her research staff and Holos University (“Researchers”) to use and disclose your Protected Health Information for the purposes described below. You also authorize your doctors, Shawnee Mission Medical Center (“Medical Center”) personnel and individuals who provide health care services at Medical Center (“Health Care Providers”) to disclose your Protected Health Information for the purpose described below:

1. You understand that your Protected Health Information, which may be used and disclosed for this research study, include:
 - a. Tests or procedures that are performed as part of this research study.
 - b. Prior or future tests or procedures that may have an impact on this research study.
 - c. Portions of your medical record which are maintained at Medical Center or your doctor’s office that the Researchers or Health Care Providers believe are necessary to conduct this research study and monitor your treatment and participation in this research study.

2. You understand that your Protected Health Information will be used and disclosed by the Researchers and Health Care Providers for:
 - a. Conducting this research study.
 - b. Ensuring that the research meets legal, institutional or accreditation requirements.
 - c. Conducting public health activities, including reporting of adverse events where you or others may be at risk or harm.
 - d. Treatment, payment or health care operations, as set forth in the Medical Center Notices of Patient Privacy Practices, if some or all of the Protected Health Information produced by this research study is maintained in your Medical Center medical record.
 - e. The purpose of the research is to understand the effects of Vibroacoustic Therapy, music and rest on reducing anxiety in patients undergoing breast biopsy.

3. You understand that the Researchers and Health Care Providers may disclose your Protected Health Information to:
 - a. Medical Center's Institutional Review Board/Office.
 - b. Government representatives, when required by law.
 - c. Hospital representatives.
 - d. Holos University Graduate Seminary.
4. You understand that to the extent any recipient of your Protected Health Information is not required to comply with these privacy laws, the information may no longer be protected by such privacy laws once it is disclosed to the recipient and, therefore, may be subject to redisclosure by the recipient.
5. The Researchers and Health Care Providers agree to safeguard your Protected Health Information by using and disclosing it only as stated in this Authorization and as directed by state and federal law.
6. You understand you will be allowed to review your Protected Health Information that is created or obtained specifically for this research study, or treatment information contained in your medical record that is applicable to this research study, until after this research study is complete. When this research study is over, you will once again have the right to access this Protected Health Information.
7. You understand that you do not have to sign this Authorization.
 - a. It will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
 - b. You may not be allowed to participate in this research study.
8. You understand that after signing the Authorization, you can change your mind and revoke this Authorization by sending a written letter to Deborah A. Pratt, Evolving Insight LLC, 4800 Fairmount Street, Kansas City, MO 64112, to inform her of your decision. If you revoke this Authorization, you understand that:
 - a. Researchers may still use and disclose the Protected Health Information already collected for this research study to maintain the integrity of this research study.
 - b. Your Protected Health Information may still be used and disclosed should you have an adverse event (a bad effect). If such adverse event occurs, the Researchers or Health Care Providers may need to review your entire medical record.
 - c. You may not be allowed to continue to participate in this research study.
 - d. You will not have access to your Protected Health Information created or obtained specifically for this research study or treatment

information contained in your medical record that is applicable to this research study until the research study is complete.

9. You understand that this Authorization does not have an expiration date.

10. If you have not already received a copy of the Medical Center's Privacy Notice, you may request one.

I am the Research Subject or am authorized to act on behalf of the Research Subject. I have read this Authorization, and I will receive a copy of this Authorization after it is signed.

Signature of Research Subject or
Research Subject's Legal Representative*

Date

Printed Name of Research Subject or
Research Subject's Legal Representative

Representative's Relationship to
Research Subject

*Please explain Representative's Relation to Research Subject and include a description of Representative's Authority to act on behalf of Research Subject:

State-Trait Anxiety Inventory (STAI)

Purpose: Designed to study levels of anxiety for both state (how you feel right now) and trait (how you generally feel) anxiety.

Population: Can be used for both teenagers and adults.

Score: The test produces two separate scores: state anxiety and trait anxiety.

Time: 10-20 minutes in total.

Authors: Charles D. Spielberger, Richard L. Gorusch, and Robert E. Lushene.

Publisher: Consulting Psychologists Press, Inc.

Description: The State-Trait Anxiety Inventory (STAI) is a self-report assessment device which includes separate measures of state and trait anxiety. It consists of two different tests, each having twenty questions. The state questions refer to how one is feeling right now, and utilizes a four-point scale including: not at all, somewhat, moderately so and very much so. The trait questions refer to how one is generally feeling, and also utilizes a four-point scale, including: almost never, sometimes, often and almost always.²

Scoring: Scores are obtained by simply summing the scores of the twenty questions within each section.

Suggested Uses: Recommended for studying anxiety in research and clinical settings.

² Charles D. Spielberger, "State-Trait Anxiety Inventory for Adults," information sheet obtained from Charles D. Spielberger and Mind Garden, photocopied.

Self Report Rating Scale for Tension and Relaxation

Purpose: Designed to study levels of tension and relaxation in the current moment.

Time: two minutes

Author: Roger Poppen, *Behavioral Relaxation Training and Assessment*, New York: Pergamon Press, 1987.

Question: Which of the following best describes the way you feel right now?

1. Feeling more deeply and completely relaxed than I ever have.
2. Feeling completely relaxed throughout my entire body.
3. Feeling more relaxed than usual.
4. Feeling relaxed as in my normal resting state.
5. Feeling some tension in some parts of my body.
6. Feeling generally tense throughout my body.
7. Feeling extremely tense and upset throughout my body.

Patient Survey

Name _____ Date _____

Questions prior to intervention:

1. Besides having a biopsy, how stressful would you rate your recent life?
(Please check (✓) only one.)
 - ₁ Extremely Stressful
 - ₂ Very Stressful
 - ₃ Somewhat Stressful
 - ₄ Not very Stressful
 - ₅ Not stressful at all

2. How much anxiety do you have about your impending biopsy?
(Please check (✓) only one.)
 - ₁ None
 - ₂ Minor Levels of Anxiety
 - ₃ Major Levels of Anxiety
 - ₄ Extreme Levels Anxiety

3. Of the following statements, which do you agree with?
(Please check (✓) all that apply.)
 - ₁ I believe that music can reduce my anxiety.
 - ₂ I believe that Vibroacoustic Therapy can reduce my anxiety.
 - ₂ I believe that resting can reduce my anxiety.

4. How would you rate your overall health? (Please check (✓) only one.)
 - ₁ Excellent
 - ₂ Very Good
 - ₃ Good
 - ₄ Fair
 - ₅ Poor

5. Please specify what you do, if anything, for relaxation or meditation. Please include the activity and the frequency.

6. Which of the following best describes the way you feel right now?
(Please check (✓) only one.)

- ₁ Feeling more deeply and completely relaxed than I ever have.
- ₂ Feeling completely relaxed throughout my entire body.
- ₃ Feeling more relaxed than usual.
- ₄ Feeling relaxed as in my normal resting state .
- ₅ Feeling some tension in some parts of my body.
- ₆ Feeling generally tense throughout my body.
- ₇ Feeling extremely tense and upset throughout my body.

Question asked after intervention:

7. Which of the following best describes the way you feel right now?
(Please check (✓) only one.)

- ₁ Feeling more deeply and completely relaxed than I ever have.
- ₂ Feeling completely relaxed throughout my entire body.
- ₃ Feeling more relaxed than usual.
- ₄ Feeling relaxed as in my normal resting state.
- ₅ Feeling some tension in some parts of my body.
- ₆ Feeling generally tense throughout my body.
- ₇ Feeling extremely tense and upset throughout my body.

List of Contacts

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Credentials and References

Deborah A. Pratt

Deborah A. Pratt is a doctoral candidate at Holos University Graduate Seminary, where her anticipated graduation date is March 2008. Upon graduation, Ms. Pratt will have a Doctorate in Theology in Energy Medicine with an extended emphasis in Integrative Healthcare. Prior to attending Holos University, Ms. Pratt oversaw the market research function at Sprint for almost fourteen years. She is an enthusiastic, confident leader with over twenty years of progressive business experience, both as part of the executive marketing team at Sprint, as well as within small business organizations. Proven skills include strong leadership ability, coaching and building an effective team, research and communication. At the core of all actions is the foundation of integrity, compassion, and optimism.

References

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Holos University Graduate Seminary³

Holos University Graduate Seminary, founded in 2001 by C. Norman Shealy, MD, PhD, is an institution that is committed to education, research, and service in the areas of Integrative and Energetic Healthcare and Spiritual Healing. Holos University Graduate Seminary emphasizes completely ecumenical and spiritual approaches that fulfill a growing need for an inclusive and holistic approach to life in contemporary communities. As a Seminary, Holos places special emphasis on the spiritual aspects of its studies and research. As a University, Holos strives to uphold the highest standards of excellence in teaching and scientific research and seeks to serve as a bridge between primarily academic institutions and primarily religious institutions.

In July, 2006, Holos University Graduate Seminary was fully accredited by the New Thought Accreditation Commission.

³ Holos University Graduate Seminary, "Catalog", Fall 2006-Spring 2007.