The study purpose was to examine the effects of a perioperative music intervention on changes in mean arterial pressure (MAP), heart rate (HR), anxiety, and pain in women with a diagnosis of breast cancer undergoing mastectomy surgery. The convenience sample included 30 women between the ages of 42 and 70 who were undergoing mastectomy in a large urban hospital in the southern United States. Exclusion criteria included male gender, psychiatric disorder, use of psychotropic medications, cognitive mental disability, and American Society of Anesthesiologists (ASA) status 4 or greater. In a quasi-experimental, repeated measures design, participants were randomized equally into music intervention and control groups. Women in the intervention group listened to music throughout the perioperative period, and women in the control group did not listen to music. Study variables were measured preoperatively (T1) and postoperatively (T2) at the time of discharge from the recovery room. Independent t-tests were used for statistical analyses of change scores. Results indicated significant effects in favor of women in the music group for the variables of MAP, anxiety, and pain. Women in the music group had a decreased MAP from T1 to T2, whereas women in the control group had an increase in MAP (p=.003). Women in the music group had a decrease in level of anxiety from T1
to T2, whereas anxiety levels increased from T1 to T2 for women in the control group (p=.000). Women in the intervention and control groups had increased levels of pain from T1 to T2, but this increase was significantly lower for women in the intervention group (p=.007). There were no significant group differences for heart rate change scores. The findings supported the conceptual model for the study which hypothesized that a perioperative music intervention can decrease anxiety, pain, and mean arterial pressure by reducing the stress response in women undergoing mastectomy through audioanalgesia, entrainment, and the relaxation response. The findings suggest that a perioperative music intervention can improve immediate postoperative outcomes for women undergoing a mastectomy for breast cancer. Further research is needed to determine whether the results can be generalized to other patient populations.
DEDICATION

I dedicate this dissertation to my family, (husband Andy, sons Joshua and Jacob), who have lovingly and patiently supported my work with this research for five years. Thank you to my Mom posthumously, who was always supportive and proud of all of my accomplishments and knew the value of education. Ultimately, I give all the praise and honor to my savior, Jesus and my desire is this work is pleasing in His sight.
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CHAPTER 1
INTRODUCTION

In the United States from 2000-2004, the incidence of breast cancer in women was 132.5 per 100,000 for Whites and 118.3 per 100,000 for Blacks (Breast Cancer Facts & Figures 2007 to 2008, 2008). Although breast cancer is found in men, it is rare and found in less than 1% of all breast cancer diagnoses (Giordano, Cohen, Buzdar, Perkins, & Hortobagyi, 2004).

A diagnosis of breast cancer, the future possibility of a mastectomy or a lumpectomy, and the agonizing and often confusing choices of post-surgical treatment represent traumatic events. Individuals, both women and men, who are confronted with a diagnosis of breast cancer experience stress and anxiety related to their future prognosis and potential mortality, as well as uncertainty about changes in their body image and treatment options. The anxiety may include concerns about the surgical experience, coping with acute pain, treatment regimens, financial burdens of care, and disruptions of their personal and professional lives (Poleshuck, Katz, Andrus, Hogan, Jung, Kulick, & Dworkin, 2006; Shelby, Taylor, Kerner, Coleman, & Blum, 2002). For younger women 30-40 years old, breast cancer interrupts ordinary life plans such as future childbearing, retaining the energy to raise young children, and the fear of the cancer recurring (Stuyck, 2006).
Anxiety is frequently a concern for surgical patients preoperatively. Elevated anxiety resulting in increased sympathetic nervous system activation can depress the function of the immune system and delay wound healing (Kim & Yoon, 1998). There is extensive evidence in the literature that women diagnosed with breast cancer have elevated anxiety (Kim, Duhamel, Vladimarsdottir & Bovbjerg, 2005; Rees, Fry, & Cull, 2001; Spittle & Morgan, 1999).

Stress and Anxiety

The experience of receiving a breast cancer diagnosis and its implications can produce significant stress for a woman. This stress is often manifested as the emotion of anxiety. Stressors related to losses (loss of role functioning, loss of physical functioning, potential loss of life), illness, and disease have been found to be the most powerful stressors capable of impacting patients’ lives (Werner & Frost, 2000). Stress is defined as “reactions of the body to forces of a deleterious nature, infections and various abnormal states that tend to disturb its normal physiologic homeostasis” (Dirckx, 2001, p. 943). Emotional anxiety resulting from stress (stressors) is often associated with changes in blood pressure, heart rate, and respiratory rate.

Anesthetic and Surgical Implications of Stress and Anxiety Associated with Breast Cancer Diagnosis and Surgery

Anxious patients require larger doses of anesthetic agents for induction and maintenance and often manifest fluctuations in hemodynamic parameters
such as mean arterial pressure (MAP) and heart rate (HR) (Eisenman & Cohen, 1995). Traditional methods of reducing anxiety in pre-surgical patients have been focused primarily on the use of pharmacologic interventions. However, such medications may result in delayed awakening and discharge from postoperative care, and sometimes an untoward reaction to the medication itself (Mitchell, 2003).

The pharmacologic intervention most often employed to reduce preoperative anxiety is administration of an anxiolytic medication midazolam, a benzodiazepine. Although midazolam is an effective anxiolytic for many patients, a number of researchers and clinicians have proposed pairing the pharmacologic treatment with non-pharmacologic interventions in order to minimize the dose of medication needed and reduce potential untoward effects. Non-pharmacologic agents include the use of music, massage therapy, guided imagery, touch therapy, and aromatherapy (Lepage, Drolet, Girard, Grenier, & DeGagne, 2001; McRee, Noble, & Pasvogel, 2003; Norred, 2000; Reves, Glass, & Lubarsky, 2000) Research is needed to evaluate the effects of pairing these non-pharmacologic interventions with the traditional pharmacologic treatment (benzodiazepine) for the reduction of perioperative anxiety (Kain, Sevarino, Pincus, Alexander, Wang, & Ayoub, 2000).

Music as a Non-Pharmacologic Intervention to Reduce Stress

A non-pharmacologic intervention that may be beneficial for women undergoing surgery for breast cancer is the use of a music intervention during the
perioperative period. Music is the art of combining sound to express beauty or emotion and is bound by specific cultural standards of rhythm, melody, and harmony (Music, 2006). Therapeutic music is used within the context of a relationship between music therapist and client to address the physical, emotional, cognitive, and social needs of the client (American Music Therapy Association, 1999, http://www.musictherapy.org/quotes.html, retrieved December 19, 2005). Music therapy “is 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” (American Music Therapy Association, 2007, http://musictherapy.org/quotes.html, retrieved March 17, 2008). Music therapy is generally provided by a credentialed professional who has completed an accredited music therapy program. Although a credentialed professional, Dr. Carol Prickett, PhD, MT-BC, Professor of Music, University of Alabama School of Music, provided valuable insight into the understanding and selection of music used in this research, the intervention was provided by the researcher who is not a credentialed music therapist. Furthermore, the intervention was not provided within the context of a therapeutic relationship with the study participants. Therefore the music used for this research was a music intervention, and not music therapy.

Allowing the patient a choice of music that is a slow tempo of 60-72 beats per minute (similar to a normal baseline resting heart rate) promotes relaxation and contemplation, and lowers anxiety (Lane, 1992). McClellan (1991), Pelletier
(2004), and Watkins (1997) recommended that to reduce anxiety and stress, therapeutic music should have a slow tempo, low pitch, no lyrics, no tremendous changes in dynamics, and should be produced primarily by stringed instruments. Over the past 40 years, a number of studies have examined the effects of music on physiological (e.g. blood pressure, heart rate, respiratory rate, temperature) and psychological (e.g. anxiety, stress, coping, pain perception) responses in a variety of clinical and non-clinical conditions. Overall, findings from these studies have suggested that music that is slow, quiet, and non-vocal decreases the physiological and psychological indices associated with stress (Standley, 2000).

Studies evaluating the effects of music interventions in surgical patients have examined music provided at different times (preoperatively, intraoperatively, and/or postoperatively); with different patient populations, and using different types of musical selections. Because of these differences, it is difficult to compare findings across studies.

Many of the existing studies have limitations that preclude generalizing their findings, such as uncontrolled confounders (Augustin & Hains, 1996; Haun, Mainous, & Looney, 2001; Koch, Kain, Ayoub, & Rosenbaum, 1998; Nilsson, Rawal, & Unosson, 2003; Steelman, 1990; Taylor, Kuttler, Parks, & Milton, 1998), small sample sizes (Allen, Golden, & Izzo, 2002; Brunges & Avigne, 2003; Haun et al. 2001; Heiser, Chiles, Fudge, & Gray, 1997; Ikonomidou, Rehnstrom, & Naesh, 2004; Migneault, Girard, Albert, Chouinard, Boudreault, Provencher, & 2004; Yung, Chui-Kam, French, & Chan, 2002), non-random assignment to groups (Mok & Wong, 2003), and the use of music selected by the researcher

Although findings from some studies have indicated significant effects of music on selected outcomes (Allen et al., 2002; Augustin & Hains, 1996; Ayoub et al., 2005; Brunges & Avigne, 2003; Haun et al., 2001; Koch et al., 1998; LePage et al., 2001; Lewis et al., 2004; McRee et al., 2003; Miluk-Kolasa et al., 1996; Mok & Wong, 2003; Nilsson et al., 2001; Nilsson et al., 2003; Steelman, 1990; Wang et al., 2002; Winter, Paskin, & Baker, 1994; Yung et al., 2002), others have reported no effects (Gaberson, 1995; Heiser et al., 1997; Migneault et al., 2004; Taylor et al., 1998).

Because of the limitations of existing studies and inconsistency of findings across studies, there is a need for further research to evaluate the use of music during the perioperative period. This study examined the effects of a perioperative music intervention on physiologic variables (MAP and HR), and psychological variables (pain and anxiety) in women who are undergoing mastectomy for a diagnosis of breast cancer.

Conceptual Framework

For many people, music evokes a variety of spiritual, emotional, sensual, and physiologic responses. The responses vary with the characteristics of the music, as well as with the characteristics of the individual listener (experience,
age, gender, culture, and perhaps even physical characteristics such as genetics and auditory processing abilities). Music has been a part of the human experience of life since the beginnings of human history. In biblical times, David was asked to play his harp to soothe King Saul’s anguish. “Whenever the spirit from God came upon Saul, David would take his harp and play. Then relief would come to Saul; he would feel better, and the evil spirit would leave him” (Life Application Study Bible, 1 Samuel 16:23, p. 420). Even ancient Greeks thought that music was the gods’ language; they worshiped Apollo as the god of music and medicine thus making an ancient connection between both (Tame, 1984). Music is more than just pleasant sound, it has the ability to bridge the physical and psychological domains and affect the subconscious domain of the spirit (Rodgers, 1995).

Although research exists illustrating the use of music to lower anxiety levels as evidenced by physiological and psychological outcomes, most of the research is not based on any one specific theoretical model that illustrates the relationships between music and the outcome variables that were studied. The primary mechanisms suggested by previous research as explaining the effects of music on physiologic and psychological outcomes are: (a) promoting distraction from stressful stimuli (Augustin & Hains, 1996; Ganidagli, Cengiz, Yanik, Becerik, & Unal, 2005; Heiser, Chiles, Fudge, & Gray, 1997; Koch, Kain, Ayoub, & Rosenbaum, 1998; Lepage, Drolet, Girard, Grenier, & DeGagne, 2001; Mok & Wong, 2003; Nilsson, Rawal, Unestahl, Zetterberg, & Unosson, 2001; Taylor, Kuttler, Parks, & Milton, 1998); (b) promoting entrainment (Chlan, 2004;
McCaffrey & Locsin, 2002); and (c) promoting audioanalgesia (Colwell, 1997; Koch et al., 1998; McCaffrey & Locsin, 2002; Shertzer & Keck, 2001) Distraction provides an alternative focus from the stressor or anxiety; entrainment describes the process of two varying rhythms coming into a compatible rate together; audioanalgesia occurs when the body releases endorphins resulting in pain relief. The conceptual framework used in this study is based on these three hypothesized mechanisms. In addition, the framework incorporated concepts from the Theory of Stress proposed by Selye (1952), the Gate Control Theory of Pain proposed by Melzack and Wall (1965), and Benson’s (1975) Relaxation Theory.

The problems addressed by this study are the stress, anxiety, and pain experienced by women who undergo surgery for a diagnosis of breast cancer. Stress is defined as “reactions of the body to forces of a deleterious nature, infections and various abnormal states that tend to disturb its normal physiologic homeostasis” (Dirckx, 2001, p. 943). The body’s reaction to physical (e.g. trauma, infection, extreme temperature, surgery) or mental stress results in higher secretion of neurotransmitters triggered through sympathetic activation (Guyton & Hall, 2000). This can result in lowering immune function and thus slow the healing process (Koh, 1998). Stress can result in activation of the sympathetic nervous system eliciting a “fight or flight” response (Selye, 1952). Thus, emotional anxiety resulting from stress (stressors) is often associated with changes in blood pressure, heart rate, and respiratory rate.
A state of anxiety is identified by subjective tension, apprehension, worry, and sympathetic nervous system arousal. Anxiety as a result of situational stress or a stressor is termed state anxiety by Spielberger (1983). State anxiety is transient and a result of current stressors or threats to the person’s well-being (i.e. how you feel right now). Trait anxiety is a measure of relatively stable baseline levels of anxiety varying by individual (i.e. how you generally feel).

Theory of Stress

First described in 1936, the General Adaptation Syndrome (GAS) theory developed by Hungarian-born Hans Selye (1936) is based upon a description of how the body confronts “stress” or noxious agents. Selye defined the stress response as a biologic reaction that is nonspecifically produced but yet, is quite specific in its effects (Selye, 1952). The GAS suggests that an individual responds to the perception of a stressor (e.g. surgery; experiencing unpleasant and uncomfortable things; apprehension about loss of control or unfamiliar surroundings) with the emotional response of anxiety and with a physiologic response of sympathetic nervous system activation (Selye, 1952).

Gate Control Theory of Pain

The conceptual model for this study also incorporated concepts from the Gate Control Theory (GCT) of pain that was first proposed in 1965 by Melzack and Wall. The GCT of pain is based upon the theory that certain nerve fibers (Aδ myelinated fast transmission fibers and C unmyelinated slow transmission fibers)
send pain perceptions to the dorsal horn of the spinal cord for transmission to the cerebral cortex; whereas other fibers (A β myelinated fast nonnociceptive fibers) can inhibit pain transmission to the cerebral cortex (Melzack & Wall, 1965). Stimulation of these different fibers results in the perception of pain (opening the gate), or relief from pain (closing the gate). Melzack and Wall suggested that the pain experience also encompasses three psychological dimensions: sensory-discriminative, motivational-affective, and cognitive-evaluative. Once pain impulses have ascended to the cerebral cortex, emotion and past experience is evoked and the A β fibers may close the descending track from the periaqueductal gray matter at the dorsal horn of the spinal cord. The impulses from this descending track also activate opioid receptors within the spinal cord. Thus, cognitive processes are an integral component and influence the intensity and quality of pain experiences (Melzack & Wall, 1965). For example, an auditory stimulus such as music that is perceived as pleasant may result in a lower level of pain perception. Conversely, a stimulus that is perceived as noxious (such as an auditory stimulus like clanging metal instruments or music that is perceived as unpleasant) may cause the pain stimulus to be transmitted without inhibition by A β fibers. Melzack and Wall suggested that the “opening” and “closing” of the gate was influenced by the balance between the firing of the C and A δ pain fibers and the A β non-nociceptive fibers.
Mechanisms by Which Music Might Influence Stress, Anxiety, and Pain

The mechanisms of distraction, entrainment, and audio-analgesia by which music might influence an individual's perception of stress, anxiety, and pain, are components of the Relaxation Response. Benson (1975) proposed a theory explaining this response, suggesting that relaxation quiets the sympathetic nervous system (SNS) and is an involuntary response opposing the flight or fight response of SNS activation resulting in decreased blood pressure, heart rate, breathing and metabolic rate. This autonomic response can be intentionally invoked through meditation, progressive muscle relaxation, distraction, audio-analgesia, and entrainment which are components of the Relaxation Response (Benson, 1975). Listening to relaxing sedative music can produce a feeling of calm and quiet through these three mechanisms. Music that is instrumental, slow, and quiet shares some of the characteristics of meditation by allowing the listener to enter that quiet environment, have a focus object, allow passive thoughts to dominate, and feel physical comfort (Benson, 1975). However music that is loud with a quick tempo may elicit arousal as a result of sympathetic outflow with little to no decrease in anxiety (Burns, Labbe, Arke, Capeless, Cooksey, & Steadman, 2002).

Distraction is a mechanism by which music might reduce anxiety, stress, and pain and is a component of Benson’s Relaxation Response theory (Benson, 1975). By providing an alternative focal point that is familiar, comforting, and pleasant, the stressful stimulus is diminished in importance (Chlan, 1998; McCaffrey & Locsin, 2002). According to the GCT: distraction that leads to a
pleasant emotional response originating in the cerebral cortex can cause inhibition of pain transmission through the neuromodulation of A β fibers.

Another mechanism by which music might promote relaxation and reduce anxiety and pain is through entrainment produced by synchronization of in vivo body rhythms with a different in vitro rhythm (Chlan, 1998). Entrainment occurs when a rhythm that is physiologically close to the participant’s innate rhythm (e.g. heart rate, breathing) is introduced and then slowly changed, thus changing the innate rhythm (Taylor, 1981). Entrainment can be used to either slow a person’s innate rhythm causing relaxation, or increase the innate rhythm thus stimulating one out of a melancholic state (McCaffrey & Locsin, 2002). McCaffery (1990) found that music initially matching participant’s innate rhythm preoperatively and then slowing and becoming softer with a lowered pitch encouraged positive outcomes such as quicker recovery from surgery.

The final mechanism by which music might reduce stress, anxiety, and pain is through an audioanalgesic mechanism (Colwell, 1997; Standley, 2000). Menon and Levitin (2005) suggested that music may promote the release of dopamine in the ventral tegmental area through opioid transmission in the nucleus accumbens. Findings from a study reported by Goldstein (1980) supported the proposed audio-analgesic effect of music. Goldstein performed a preliminary experiment in which healthy volunteers who listened to a passage of music for 5 minutes reported feeling an emotional thrill that disappeared after they received an intravenous injection of naloxone, an opioid antagonist.
In summary, music is more than simply an acoustic stimulant; it transcends the physical domain by affecting the cognitive psyche of the psychological domain. The evidence found in the literature supports the proposed psychological outcomes (decreased anxiety and pain) and physical outcomes (decreased HR and MAP) through three mechanisms: distraction, entrainment, and audioanalgesia. Appendix A includes a diagram illustrating these hypothesized mechanisms and the conceptual framework that guided the study.

Purpose

The purpose of this study was to examine the effects of a perioperative music intervention (provided continuously throughout the preoperative, intraoperative, and postoperative periods) on changes in mean arterial pressure (MAP), heart rate (HR), anxiety, and pain in women with a diagnosis of breast cancer undergoing mastectomy surgery.

Hypotheses

The hypotheses that guided the study were as follows:

1. Women who receive a perioperative music intervention will have a significantly greater decrease in MAP from time 1 (T1) to time 2 (T2) compared to women in a randomly assigned control group;
2. Women who receive a perioperative music intervention will have a significantly greater decrease in heart rate from T1 to T2 compared to women in a randomly assigned control group;

3. Women who receive a perioperative music intervention will have a significantly greater reduction in anxiety from T1 to T2 compared to women in a randomly assigned control group; and

4. Women who receive a perioperative music intervention will have a significantly greater reduction in pain from T1 to T2 compared to women in a randomly assigned control group.

Definition of Terms

The conceptual and operational definitions of the major study concepts were as follows.

**Anxiety**

A feeling of apprehension that can range from concern to dread; an indistinct emotion whose cause is not always easy to identify (Taylor-Loughran, 1989).

**State Anxiety**

A transient emotional state at a specific moment in time (Davis & Thaut, 1989). State anxiety was measured by the state portion (Y-1) of Spielberger’s State-Trait Anxiety Inventory (STAI) (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983).
Stress

A situation or event influencing a person’s psychological emotion and manifested specifically as anxiety.

Mean Arterial Pressure

A measure of the force exerted by blood flow through the aorta and the arterial system, and is an accurate representation of tissue and organ perfusion (Sesso, Stampfer, Rosner, Hennekens, Gaziano, & Manson, 2000). Mean arterial pressure was measured by the Phillips IntelliVue MP90 monitoring system.

Heart Rate

The number of contractions of the heart in one minute. Heart rate was measured with the Phillips IntelliVue MP90 monitoring system as beats per minute.

Pain

A personal and subjective unpleasant experience related to potential or actual damage to tissue of the body (Dirckx, 2001). For the purpose of this study, pain was measured by a 0-100 mm Visual Analogue Scale (VAS) in the PACU prior to discharge.
Music

Music is the art of combining sound to express beauty or emotion and is bound by specific cultural standards of rhythm, melody, and harmony (Music, 2006). For the purpose of this study, music was defined as music that is slow tempo, low pitch, non-vocal, having regular rhythmicity, and no tremendous changes in dynamics. In this study, participants chose one of four types of pre-selected music: classical, new age, easy listening, and inspirational, which was played throughout the perioperative period via an iPod player attached to earphones.

Assumptions

The following assumptions guided this study:

1. Participants will benefit from a decreased level of anxiety.
2. Participants will adequately hear the music intervention.
3. Participants will accurately report their subjective levels of anxiety and pain.
4. Music intervention will be applied consistently as defined by the research protocol.
5. The general anesthetic will be provided consistent with the research protocol guidelines.
6. Participants will find a music selection acceptable to them.

Limitations

The following limitations were identified within this study:
1. Use of a convenience sample.
2. Use of subjective, self-report instruments to measure anxiety and pain.
3. Repeated measures design using self-report instruments to measure anxiety and pain may introduce a response bias by the participants.
4. Lack of control over the perioperative hospital environment – noise, temperature, and time spent in each perioperative phase.

Summary

Women who have been diagnosed with breast cancer and subsequently undergo mastectomy often have high levels of anxiety and pain in the perioperative period. There are limitations of existing pharmacologic methods used to treat pain and anxiety, and thus studies are needed to examine the effects of non-pharmacologic interventions that can complement more traditional pharmacologic therapies. Although findings from previous studies have suggested that music has beneficial effects on reducing pain and anxiety, there have been few studies examining the use of music throughout the perioperative period, the study designs have not encompassed physiologic and psychological variables, no clear conceptual model has been proposed, and the outcomes have been inconsistent across studies. This study was designed to minimize the presence of a floor effect from low baseline anxiety levels, and carefully control for surgical procedure, surgical technique, consistency of music application, blinding of observers, and homogenous patient characteristics. The study was further strengthened by using the participants as their own control group as
evidenced by the study’s hypotheses. In addition, this study used precise and appropriate instruments well supported in the literature to measure the outcome variables. The study was designed to examine the effects of a perioperative music intervention on blood pressure, heart rate, anxiety, and pain levels during the perioperative period by women undergoing a mastectomy for breast cancer.
CHAPTER 2
REVIEW OF LITERATURE

Introduction

The concept of music as an adjunct for patient care is not new. The Journal of the American Medical Association published a report in 1929 of a physician using music to alleviate the sensory stimuli of the operative experience for patients undergoing regional or local anesthesia (Kane, 1929). The National Association of Music Therapy, Inc., formed in 1950, has encouraged interest by other health care specialties (nursing, medicine, dentistry, etc.) in using music therapy. This association evolved into today’s American Music Therapy Association in 1994 (http://www.musictherapy.org/faqs.html). Studies examining the influence of music have been performed since the latter half of the 20th century.

Table 1, at the end of this chapter, summarizes findings from 30 studies published between 1986-2006 that evaluated the effects of music interventions provided during the perioperative period on the psychological variables of pain and anxiety and/or the physiological variables of blood pressure and heart rate. Studies were included if they met the following criteria: included adult surgical patients and evaluated effects of music during the perioperative period, evaluated the effects of music on dependent variables of anxiety, blood pressure,
heart rate or pain; and did not combine music intervention with another intervention (e.g. therapeutic suggestion).

The review of these studies is organized according to the main outcome variables: anxiety, mean arterial pressure (MAP), heart rate (HR), and pain. Areas of consistency and inconsistency across studies are identified, and possible contributing factors are examined as they relate to the studies that are reviewed. These factors include: whether the patient or researcher selected the music, the timing of the intervention (preoperative, intraoperative, or postoperative), data collection instruments and methods; levels of baseline anxiety; type of music intervention (including consistency of application and choice of music), small sample size (defined as less than 20 participants per sample group) and characteristics, and other extraneous variables. Finally, a seminal meta-analysis by Standley in 2000 that examined the use of music as an intervention in medicine will be discussed. The literature review concludes with a summary of the strengths and limitations of existing studies.

Thirty studies evaluated the use of a music intervention applied at various perioperative time periods (preoperative, intraoperative, postoperative or various combinations of time periods). A variety of psychological and physiological dependent variables were examined in these studies: anxiety, level of pain and amount of pain medication used postoperatively, amount of sedation, urinary epinephrine levels, systolic and diastolic blood pressure, heart rate, respiratory rate, cardiac output, stroke volume, glucose level, hospital length of stay, perceived stress and coping, level of satisfaction with the music, and bispectral
index (BIS) values. Bispectral Index is a measure of the depth of anesthesia based upon a mathematical algorithm of electroencephalogram waves within the brain. The summary of the 30 studies within Table 1 is organized by the timing of the music intervention. The summary also provides information on the study design, sample size, population, type of music utilized and whether patients or the researcher chose the type of music, dependent variables measured, the presence of a conceptual or theoretical basis, outcomes, and limitations.

Anxiety as an Outcome Variable

Fifteen studies examined the effects of music on anxiety (Augustin & Hains, 1996; Gaberson, 1995; Chang & Chen, 2005, Haun, Mainous, & Looney, 2001; Heiser, Chiles, Fudge, & Gray, 1997; McRee, Noble, & Pasvogel, 2003; Mok & Wong, 2003; Nilsson et al., 2003; Nilsson et al., 2005, Padmanabhan, Hildreth & Laws, 2005, Sanderson, 1986; Steelman, 1990; Twiss, Seaver, & McCaffrey, 2006; Wang, Kulkarni, Dolev, & Kain, 2002; Yung, Chui-Kam, French, & Chan, 2002). Gaberson (1995), Heiser et al. (1997), and Nilsson et al. (2003) found that a music intervention had no significant effect on anxiety using a visual analogue scale (VAS) as the measurement instrument, although Nilsson et al. (2005) and Chang and Chen (2005) found a reduction in anxiety using the VAS. A visual analogue scale is a simple measurement tool with a horizontal line which has an anchor at each end (usually the left anchor represents 0 and the right anchor represents 10). The participant is instructed to make a vertical mark across the line at the point that represents the concept of interest. The mark is
then measured to obtain a numerical value. Researchers in eight studies used the State-Trait Anxiety Inventory (STAI) as the measurement tool and found that music decreased anxiety (Augustin & Hains, 1996; Haun et al., 2001; McRee et al., 2003; Mok & Wong, 2003; Padmanabhan et al., 2005; Twiss et al., 2006; Wang et al., 2002; Yung et al., 2002). Steelman (1990) used the STAI to measure anxiety and found that both the control and music group had decreased anxiety postoperatively, although there were no differences in levels of anxiety between the two groups. Lepage, Drolet, Girard, Grenier, and DeGagne (2001) found only a moderate correlation between the STAI and the VAS (.53 - .68), and recommended the STAI as a more precise and reliable measure of anxiety in comparison to the VAS. These findings reflect the psychometric rigor with which the STAI was developed and tested. Furthermore LePage et al. (2001) recommended that caution be used when comparing results of studies that use the VAS to studies that use the STAI to synthesize outcomes in anxiety. The use of the VAS may explain the absence of significant findings in three out of four studies. Conversely, findings from nine of eleven studies using the STAI indicated that anxiety was decreased by music.

Another explanation for the lack of significant findings related to anxiety in the studies by Gaberson (1995) and Nilsson et al. (2003) may be a floor effect, because overall baseline anxiety levels were low in these two studies. The Nilsson et al. (2005) study reported a reduction in anxiety in the music group but also noted that baseline anxiety levels were low.
In six of the eleven studies that reported reductions in anxiety (Augustin et al., 1996, Chang, & Chen, 2005, Mok & Wong, 2003, Twiss et al., 2006, Wang et al., 2002, Yung et al., 2002) participants selected the type of music that was used and in two of the four studies in which there were no reductions in anxiety, participants also selected the music (Heiser et al., 1997, Steelman, 1990). Thus, it appears that researcher versus participant selection may be a factor explaining the differences in findings related to anxiety as a dependent variable.

In 11 studies that reported lowered anxiety, the music was implemented preoperatively (Augustin & Hains, 1996; Haun et al., 2001; McRee et al., 2003; Padmanabhan et al., 2005; Wang et al., 2002; Yung et al., 2002), intraoperatively (Chang & Chen, 2005; Mok & Wong, 2004), or a combination of preoperatively, intraoperatively, or postoperatively (Nilsson et al., 2005; Sanderson, 1986; Twiss et al., 2006). In four studies that reported no significant reduction in anxiety, Gaberson (1995) offered music preoperatively and Steelman (1990) intraoperatively, whereas Nilsson, Rawal, & Unosson, (2003) and Heiser, Chiles, Fudge, & Gray, (1997) used intraoperative and postoperative music interventions. These findings suggest that timing of the music intervention may be important, and that music is most likely to reduce anxiety if it is offered beginning in the preoperative period. This conclusion is consistent with Standley’s findings in her 2000 meta-analysis in which she recommended that music begin preoperatively.

Sample size did not appear to be a factor in the significant findings of music on anxiety. Three studies had small sample sizes (ten or fewer subjects per group) but found significant reductions in anxiety (Augustin & Hains, 1996;
McRee et al., 2003; Yung et al., 2002) whereas three studies with adequate sample sizes (Gaberson, 1995; Steelman, 1990; Nilsson et al., 2003) reported no significance on anxiety.

In addition, patient characteristics appeared to have little effect in these studies examining music’s effects on anxiety. Five of the ten studies included a specific culture in the sample: Chinese – anxiety reduced (Chang & Chen, 2005, Mok & Wong, 2003, Yung et al., 2002) and Swedish – anxiety not significantly reduced (Nilsson et al., 2003) and Swedish – anxiety reduced (Nilsson et al., 2005). The remaining seven studies finding significance or non-significance had samples that were male and female, middle-aged, American adults.

Studies that reported significant effects of music on anxiety reported various extraneous variables, which may confound findings, including the failure to control for the type of surgery (Augustin & Hains, 1996; McRee et al., 2003; Padmanabhan et al., 2005, Sanderson, 1986), and potential distraction when the music intervention was implemented (August & Hains, 1996; Haun et al., 2001; Wang et al., 2002). Two studies that reported no significant effects of music on anxiety also failed to control for type of anesthesia and participant history (Heiser et al., 1997; Steelman, 1990). Thus, although extraneous variables may threaten the validity of a study, studies that reported both significant effects and no effects of music on anxiety failed to control for potentially significant extraneous variables.
Blood Pressure and Heart Rate as an Outcome Variables

Thirteen studies examined the effects of music on blood pressure and heart rate (Allen, Golden, & Izzo, 2002; Augustin & Hains, 1996; Haun et al., 2001; Heiser et al., 1997; Ikonomidou, Rehnstrom, & Naesh, 2004; McRee et al., 2003; Migneault, Girard, Albert, Chouinard, Boudreau, Provencher, et al. 2004; Miluk-Kolasa, Matejek, & Stupnicki, 1996; Mok & Wong, 2003; Nilsson, Unosson, & Rawal, 2005; Updike & Charles, 1987; Wang, Kulkarni, Dolev, & Kain, 2002; Yung, Chui-Kam, French, & Chan, 2002). One additional study evaluated the effects of music on blood pressure but did not include heart rate as a dependent variable (Steelman, 1990). In 6 of the 13 studies there was no reported effect of music on blood pressure or heart rate (Haun et al., 2001; Heiser et al., 1997; McRee et al., 2003; Migniteault et al., 1996; Nilsson et al. 2005; and Wang et al., 2002). With the exception of Nilsson et al. (2005) and Wang et al. (2002), all studies reporting no effects on blood pressure and heart rate had small sample sizes. Haun et al. (2001) included 20 patients divided into two groups; Heiser et al. (1997) included only 10 patients divided into two groups, McRee et al. (2003) included 52 patients divided into four groups, and Migniteault et al. (1996) included 30 patients divided into two groups.

In the seven studies that reported effects on blood pressure and heart rate, the sample sizes ranged from 10 to 100 (Allen et al., 2002; Augustin & Hains, 1996; Ikonomidou et al., 2004; Miluk-Kolasa et al., 1996; Mok & Wong, 2003; Updike & Charles, 1987; Yung et al., 2002). One study that reported significant reductions in blood pressure and heart rate had small sample sizes
(Updike & Charles, 1987). Because there can be limited variability in blood pressure and heart rate, it may be especially important to have adequate sample sizes to detect differences in these outcome variables.

Patient characteristics appeared to have little effect in these studies examining music’s effects on blood pressure and heart rate. Four of the fourteen studies included a specific culture in the sample: Chinese – blood pressure and heart rate reduced (Yung et al., 2002; Mok & Wong, 2003), Swedish – blood pressure and heart rate reduced (Ikonomidou et al., 2004), and Swedish – blood pressure and heart rate not significantly reduced (Nilsson et al., 2005). The remaining ten studies finding significance or non-significance had samples that were male and female, middle-aged, American adults.

Migneault et al. (1996) allowed the participants to undergo a “light” general anesthetic to examine whether any participants would be able to recall hearing the intraoperative music; no participants recalled hearing the music while under general anesthesia. Elevated heart rate and blood pressure are seen when anesthesia is inadequate. In this study, the BIS monitor was used to titrate the anesthetic depth to a predetermined value range. A “light” general anesthetic would result in a higher level of consciousness (as reflected by a BIS level of 50-60 versus a BIS level of 40-50 for a typical general anesthetic) and would result in a more elevated blood pressure and heart rate. The use of “light” general anesthesia in the Migneault et al. (2004) study may have contributed to the absence of significant effects of music on blood pressure or heart rate.
Music choice may be a factor in the reduction of blood pressure and heart rate. Of the studies finding significant effects on blood pressure and heart rate, only Ikonomidou et al. (2004) used researcher-selected music whereas the remaining five studies allowed the participants to choose their style of music (Allen et al., 2002; Augustin & Hains, 1996; Miluk-Kolasa et al., 1996; Mok & Wong, 2003; Updike & Charles, 1987). Steelman (1990) found effects on blood pressure from patient selected music, but did not include heart rate as an outcome variable.

Studies reporting both non-significant and significant effects of music on blood pressure and heart rate were divided between various implementation times of the music intervention (preoperatively, intraoperatively, preoperatively/postoperatively, and perioperatively). However, in the six out of eight studies that reported significant effects on blood pressure and the five out of six studies that reported significant effects on heart rate, music was begun preoperatively. These findings suggest that music intervention may be more likely to reduce blood pressure and heart rate if begun preoperatively. This finding again confirms Standley’s (2000) recommendations based on her meta-analysis.

Studies that reported significant effects of music on blood pressure and heart rate reported extraneous variables: type of surgery not controlled for (Augustin & Hains, 1996;), patient history not controlled for (Steelman, 1990), and potential distraction when the music intervention was implemented (Augustin & Hains, 1996; Miluk-Kolasa et al., 1996). Also studies that reported no
significant effects of music on blood pressure and heart rate reported extraneous variables: type of anesthesia not controlled for (Heiser et al., 1997) and potential distraction when the music intervention was implemented (Haun et al., 2001; Wang et al., 2002). Thus, although extraneous variables threaten the validity of a research study, studies in this review that found both significance and non-significance included extraneous variables.

**Pain as an Outcome Variable**

Eleven studies examined the effects of music on pain (Heiser, Chiles, Fudge, & Gray, 1997; Ikonomidou, Rehnstrom & Naesh, 2004; Koch, Kain, Ayoub, & Rosenbaum, 1998; Lewis, Osborn, & Roth, 2004; McRee, Noble, & Pasvogel, 2003; Nilsson, Rawal, Unestahl, Zetterberg, & Unosson, 2001; Nilsson, Rawal, & Unosson, 2003; Nilsson, Unosson & Rawal, 2005, Sanderson, 1986; Shertzer, & Keck, 2001; Taylor, Kuttler, Parks, & Milton, 1998). Heiser et al. (1997), McRee et al. (2003), and Taylor et al. (1998) found no significant results on pain from the music intervention. Consistencies among these studies included the fact that the samples were small (Heiser et al., 1997; McRee et al., 2003), there was no control over the type of pain medication (Taylor et al., 1998), and there was no control over the type of anesthesia administered (Heiser et al., 1997; McRee et al., 2003). Lewis et al. (2004) evaluated the effects of music therapy in patients undergoing either laparoscopic bariatric surgery or a lumbar laminectomy surgery. Pain was assessed by measuring the amount of opioid given intraoperatively. These researchers found that levels of pain were
decreased by music in the bariatric surgery group, but not in the lumbar laminectomy group. There are two possible explanations for these results. First, laparoscopic surgery produces less postoperative pain than open incision procedures. Second, the patients in the lumbar laminectomy group had experienced chronic back pain with a history of using analgesic medications preoperatively, and thus they may have required more opioids intraoperatively than the bariatric surgery group. Each surgical procedure may have specific inherent characteristics and the findings from the Lewis et al. (2004) study illustrate the importance of controlling for the type of surgery and anesthetic.

There were eight studies in which researchers found significant effects of music on pain (Ikonomidou et al., 2004; Koch et al., 1998; Lewis et al., 2004; Nilsson, et al., 2001; Nilsson et al., 2003; Nilsson et al., 2005, Sanderson, 1986; Shertzer & Keck, 2001). Sanderson (1986) and Shertzer and Keck (2001) did not control for surgery and type of anesthesia; whereas the six remaining studies controlled for the type of surgery and anesthesia.

Patient characteristics appeared to have little effect in these studies examining music’s effects on pain. Four of the ten studies included a specific culture in the sample: Swedish – pain was reduced (Ikonomidou et al., 2004; Nilsson et al., 2001; Nilsson et al., 2003, Nilsson et al., 2005). The remaining seven studies finding significance or non-significance had samples that were male and female, middle-aged, American adults.

Studies that reported significant findings of music on pain reported extraneous variables: type of surgery and anesthesia not controlled for
(Sanderson, 1986; Shertzer & Keck, 2001) and pain medication not controlled for (Ikonomidou et al., 2004; Nilsson et al., 2003). Also studies that reported no significant findings of music on pain reported extraneous variables: type of surgery and anesthesia not controlled for (Heiser et al., 1997; McRee et al., 2003; Taylor et al., 1998). Thus, although extraneous variables may threaten the validity of a research study, studies in this review that found both significance and non-significance included extraneous variables.

Of the studies that reported significant effects on pain, only Koch et al. (1998) allowed the participant a choice of music. The remaining seven studies used researcher-selected music (Ikonomidou et al., 2004; Lewis et al., 2004; Nilsson et al., 2001; Nilsson et al., 2003; Nilsson et al., 2005, Sanderson, 1986; Shertzer & Keck, 2001). In contrast, of the studies that reported no significance on pain, two studies used researcher-selected music (McRee et al., 2003; Lewis et al., 2004) and two studies offered participants a choice of music (Heiser et al., 1997; Taylor et al., 1998). Although the literature recommends that patients be allowed to select their preferred style of music, perhaps it is the characteristics of the music itself (slow tempo, low pitch, no lyrics, no tremendous changes in dynamics, produced primarily by stringed instruments) that are most effective in reducing anxiety, blood pressure, heart rate, and pain.

Timing of the music intervention did not appear to be a factor because studies finding significant and non-significant effects of music on pain were divided between all phases of the surgical experience. However, not one of the
studies reviewed examined the effects of music throughout the entire surgical experience (perioperatively) on pain as this study did.

Standley’s Meta-Analysis of Music and Medical Treatment

Standley (2000) conducted a seminal meta-analysis of 92 studies that included 232 dependent variables related to the use of music in medicine, in order to ascertain overall procedures guiding the use of music therapy, compare the effects within the various populations and variables studied, and develop recommended protocols for clinical application of music therapy based upon the findings of the meta-analyses. Thirteen of the reviewed studies included surgical populations, and five of these studies (Augustin & Hains, 1996; Sanderson, 1986; Steelman, 1990; Taylor et al., 1998; Updike & Charles, 1987) were included in this review of the literature. The remaining eight studies that included surgical populations were excluded because they also included non-surgical patients, did not address the main variables of interest in the proposed study (anxiety, pain, blood pressure, or heart rate), studied the outcome variables beyond the immediate perioperative time interval (e.g. postoperative day 1 or 2), or included music paired with other interventions (e.g. therapeutic suggestion). Standley (2000) concluded that music could be used as an audioanalgesic, anxiolytic, or sedative for the reduction of pain, anxiety, or stress. Music had beneficial effects perioperatively, but was most effective if begun prior to surgery. Standley (2000) recommended further study of the effects of music on variables such as blood pressure, heart rate, levels of anxiety (measured by the STAI), and levels of pain.
(measured by the amount of pain medication used). Standley proposed protocols for implementation of the music therapy focused on providing the participant a preference of musical genre and thus a feeling of control, beginning the therapy prior to painful or anxiety provoking stimuli, and the delivery of the music through earphones.

Summary

Findings from this review of music interventions in the surgical setting have revealed that while participant choice in musical style may be important, perhaps equally important is the music’s characteristics (slow tempo, low pitch, no lyrics, no tremendous changes in dynamics, produced primarily by stringed instruments) in eliciting a reduction in anxiety, hemodynamics, and pain. In addition, it is apparent that music should begin preoperatively, as this is the time that the participant has left the comfortable familiar environment and entered the foreign environment of medical care. The fight or flight response has begun within the physical domain and anxiety is beginning to mount from the psychological response to stress. Thus music may decrease the extent to which the participant experiences this response. The review of these studies also use of the STAI as the most precise and reliable instrument to measure anxiety. These findings are consistent with the findings reported in Standley’s meta-analysis (2000).

Several themes emerged from the review of literature that were considered when designing this study. A power analysis was performed a priori
to assure that the sample size for the planned two-group analyses would be adequate. The STAI rather than a VAS was selected as the measure of anxiety based on the recommendation of Standley (2000). Based on findings related to extraneous variables that might influence the effect of a music intervention, this study was designed to reduce the influence of such variables as follows: (1) using a homogenous sample that did not exhibit a low baseline anxiety level, (2) ensuring consistency in the type of surgery and anesthesia, (3) introducing the music intervention preoperatively, (4) using music that had characteristics conducive to reducing anxiety, hemodynamics, and pain, and (5) ensuring consistent application of the music intervention perioperatively without interruption.
Table 1
Summary of Music Intervention Studies

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<tr>
<td>McRee (2003)</td>
<td>Experimental – 4 grps</td>
<td>Adult, mean age 43, 37% male, race NP</td>
<td>N=52</td>
<td>Variety</td>
<td>Any type anesthesia</td>
<td>Preoperative</td>
<td>Researcher selected – soft piano</td>
<td>30 minutes</td>
<td>NP</td>
<td>NP</td>
<td>NP</td>
<td>Postoperative: Anxiety ↓ STAI BP, HR, Pain NS Other: cortisol NS prolactin↑</td>
<td>SS; pilot NBO EV: type of surgery not controlled for, anesthesia not controlled for</td>
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<tr>
<td>Miluk-Kolasa (1996)</td>
<td>Experimental – 2 grps</td>
<td>Adult, 72% male, age &amp; race NP</td>
<td>N=100</td>
<td>ENT &amp; varicectomy</td>
<td>NP</td>
<td>Preoperative</td>
<td>Patient choice – selections NP</td>
<td>30 minutes</td>
<td>NP</td>
<td>NP</td>
<td>Earphones</td>
<td>Preoperative: MAP &amp; HR Other: cardiac output, glucose - returned to baseline quicker, stroke vol and temp NS</td>
<td>EV:Non-Private rooms</td>
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<td>Padmanabhan (2005)</td>
<td>Quasi-experimental- 3 grps</td>
<td>Adult– 37.5% male, age &amp; race NP</td>
<td>N=104</td>
<td>Variety day surgery</td>
<td>General anesthesia</td>
<td>Preoperative</td>
<td>Researcher selected (1) Binaural beat (2) audio alone</td>
<td>30 minutes</td>
<td>NP</td>
<td>Earphones</td>
<td>Earphones</td>
<td>Preoperative: Anxiety ↓ STAI binaural grp</td>
<td>EV: type of surgery not controlled for</td>
</tr>
<tr>
<td>Wang (2002)</td>
<td>Experimental – 2 grps</td>
<td>Adult, mean age 44, race &amp; gender NP</td>
<td>N=93</td>
<td>Variety ambulatory surgery</td>
<td>Any type anesthesia</td>
<td>Preoperative</td>
<td>Patient brought own music</td>
<td>30 minutes</td>
<td>NP</td>
<td>Headphones</td>
<td>NP</td>
<td>Preoperative: Anxiety ↓ STAI BP NS HR NS Other: electrodermal activity, serum cortisol, epi, &amp; norepinephrine NS</td>
<td>EV: both control and music had visitors, conversed, or read materials from home</td>
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Table 1
Summary of Music Intervention Studies (Continued)

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<tr>
<td>Ayoub (2005)</td>
<td>Quasi-experimental – 3 grps</td>
<td>American &amp; Lebanese adults, mean age 55, 90% male</td>
<td>N=80</td>
<td>Urologic surgery</td>
<td>Spinal anesthesia</td>
<td>Intraoperative</td>
<td>Patient brought own music</td>
<td>Duration of surgery</td>
<td>NP</td>
<td>Earphones</td>
<td>NP</td>
<td>Intraoperative: Anxiety ↓</td>
<td>Other: ↓ sedative requirements (Lebanese used less sedation than Americans)</td>
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</table>
### Table 1

**Summary of Music Intervention Studies (Continued)**

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**Table 1**

*Summary of Music Intervention Studies (Continued)*

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<tr>
<td>Shertzer (2001)</td>
<td>Postoperative</td>
<td>Researcher selected – ocean waves &amp; Mozart</td>
<td>1 hour</td>
<td>NP</td>
<td>Speakers</td>
<td>Audio-analgesia</td>
<td>Postoperative: Pain ↓</td>
<td>Other: perception of comfort and positive perception of music ↑</td>
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<tr>
<td>Quasi-experimental – 2 grps</td>
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<td>EV: Analgesic medications not controlled for perioperatively &amp; in PACU</td>
<td>RV: Reliability &amp; validity not established for Likert scale instrument</td>
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<tr>
<td>Adults, mean age 59, male, white</td>
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<td>N=97</td>
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<td>Same day surgery</td>
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<td>NP</td>
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| Quasi-experimental – 3 grps | | | | | | | |
| Adult women, age & race | | | | | | | |
| NP | | | | | | | |
| N=61 | | | | | | | |
| Hysterectomy | | | | | | | |
| General anesthesia | | | | | | | |
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Table 1
Summary of Music Intervention Studies (Continued)

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<tr>
<td>Twiss (2006)</td>
<td>Quasi-experimental -2 grps</td>
<td>Adults – gender (67% female-33%male), mean age 72.6 yrs, race NP</td>
<td>N=60</td>
<td>CABG</td>
<td>General anesthesia</td>
<td>Intraoperative &amp; Postoperative</td>
<td>Patient choice – familiar, timeless, piano, Mozart</td>
<td>Intraoperative &amp; Postoperative</td>
<td>NP</td>
<td>Headphones</td>
<td>Nightingale’s therapeutic environment</td>
<td>Postoperative: Anxiety ↓ STAI, time to extubation ↓</td>
<td>RV: attrition 26 participants SS, one hospital</td>
</tr>
</tbody>
</table>
Table 1
Summary of Music Intervention Studies (Continued)

|------------------|---------------|----------------|----------------|-----------------------|----------------------|-----------------------|--------------------------|----------------|-------------|-------------------|-------------------------|------------------------|----------------------|

**KEY**

<table>
<thead>
<tr>
<th>NP</th>
<th>information not provided</th>
<th>SS</th>
<th>Small Sample (&lt; 20 per group)</th>
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<tr>
<td>HR</td>
<td>heart rate</td>
<td>NBO</td>
<td>No Blinding Observers</td>
</tr>
<tr>
<td>SBP</td>
<td>Systolic Blood Pressure</td>
<td>EV</td>
<td>Extraneous Variable</td>
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<tr>
<td>DBP</td>
<td>Diastolic Blood Pressure</td>
<td>RV</td>
<td>Reliability &amp; Validity</td>
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<tr>
<td>MAP</td>
<td>Mean Arterial Pressure</td>
<td>NR</td>
<td>Not Randomized</td>
</tr>
<tr>
<td>RR</td>
<td>Respiratory Rate</td>
<td>DPI</td>
<td>Double Product Index (HR x SBP/100)</td>
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<tr>
<td>NS</td>
<td>Not significant</td>
<td>Grps</td>
<td>groups</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual Analogue Scale</td>
<td>STAI</td>
<td>State-Trait Anxiety Inventory</td>
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**NOTE:** Studies are listed by the first author’s last name due to space limitations.
CHAPTER 3

METHODS

This study used a repeated measures quasi-experimental design in a sample of women undergoing mastectomy surgery under general anesthesia for a breast malignancy. The following hypotheses were tested:

1. Women who receive a perioperative music intervention will have a significantly greater decrease in MAP from T1 to T2 compared to women in a randomly assigned control group;

2. Women who receive a perioperative music intervention will have a significantly greater decrease in heart rate from T1 to T2 compared to women in a randomly assigned control group;

3. Women who receive a perioperative music intervention will have a significantly greater reduction in anxiety from T1 to T2 compared to women in a randomly assigned control group; and

4. Women who receive a perioperative music intervention will have a significantly greater reduction in pain from T1 to T2 compared to women in a randomly assigned control group.

Women were assigned randomly to either a control or intervention group. Women in the intervention group listened to music throughout the perioperative period (during the preoperative, intraoperative, and postoperative periods). Data
were collected preoperatively at time 1 (T1) and postoperatively at time 2 (T2) to
determine the effects of the music intervention on mean arterial pressure (MAP),
heart rate (HR), levels of state anxiety and pain. Time 1 measurements were
collected preoperatively in the pre-surgical area and T2 measurements were
collected when the participant was ready for discharge from the Post Anesthesia
Care Unit (PACU).

Sample and Setting

A convenience sample (n=30) of women with a breast malignancy was
assigned randomly to either the control group or intervention group. This
population was chosen because of the potential for elevated anxiety among
women who are facing surgery for a breast malignancy, and the ability to control
for gender and surgical procedure. The findings of the literature review indicated
that when a music intervention is applied, dependent variables such as levels of
blood pressure, pain, or anxiety are reduced or do not change. No studies were
identified in which there were increases in levels of these dependent variables.
Therefore it was decided that it was appropriate to use directional hypotheses
and one-tailed tests for statistical analyses. A projected sample size of 40
participants (20 per group) was determined a priori based upon utilization of a
one-tailed independent t-test, an alpha significance of .05, a power of .80, and a
large effect size of .70 (Cohen, 1988). Standley (2000) reported a large effect
size of .83 in her meta-analysis of studies examining the effects of music in
medical treatment research. After 10 months of data collection, only 30
participants had enrolled in the study (15 per group) and the dissertation committee agreed to conclude data collection to facilitate the analysis of results and the conclusion of the research study.

A total of 30 women were recruited from two general surgery practices after having received a diagnosis of breast cancer and deciding to undergo mastectomy. These women received their surgery from one urban hospital in a city in West Tennessee with a population of approximately 95,000 people. Recruitment procedures are described in detail in the section on Protection of Human Subjects.

Participants were between the ages of 20 and 70. Exclusion criteria included American Society of Anesthesiologists (ASA) status IV and V. The ASA status indicates a progressive accumulation of comorbidities (e.g. hypertension, coronary artery disease, diabetes, emphysema) therefore those participants with more than two serious comorbidities were excluded. Additional exclusions were previous diagnosis and treatment for breast cancer, diagnosis with chronic obstructive pulmonary disorder (COPD), diagnosis with mental disorders (e.g. bipolar, schizophrenia, or cognitive impairment), use of antipsychotic and benzodiazepine medications, inability to receive midazolam, and use of hearing aids. Use of antidepressant medications (e.g. escitaolopram, bupropion, fluoxetine) did not exclude a participant from the study. Cognitive impairment and other psychological disorders were assessed by medical diagnosis included within the participant’s history and physical in the preoperative chart.
Instruments

Three data collection instruments were used:

1. Investigator-developed perioperative music intervention demographic and data collection form (Appendix B)
2. Spielberger State Anxiety Inventory Scale (SAI) (Appendix C)
3. Visual Analogue Scale for Pain (VAS) (Appendix D)

Perioperative Music Intervention Demographic and Data Collection Form

Demographic data that were collected included age, race, years of education, marital status, level of spirituality, preferred style of music, music listening habits, and previous music training. A preoperative anesthetic health history was obtained and included the presence of breast cancer in the participant’s immediate family, as well as any previous occurrence and treatment for breast cancer. Additional data reported on this form included: (a) Time 1 data (SAI score, VAS score, MAP, HR, preoperative assessment, time music intervention began); (b) Intraoperative data collected from review of the anesthetic record (time anesthetic began and ended, MAP, HR, anesthetic agent concentration every 15 minutes, drugs and nitrous oxide used, and intraoperative complications); and (c) Time 2 data (just prior to PACU discharge): Aldrete score, MAP, HR, time music stopped, SAI score, VAS score, and time discharged from the PACU. The Aldrete score assesses adequacy of respiratory effort, vital signs in comparison to baseline, skin warmth and color, level of alertness and orientation, and presence of purposeful movements (Aldrete & Kroulik, 1970).
Each of the five categories of the Aldrete score is given a score of 0, 1, or 2 based upon the quality of the category. For example, within respiration apnea (absence of respiratory effort) is scored as a 0, hypoxia is scored as a 1, and normal respiratory effort is scored as a 2. Thus the minimum score a patient may receive is a 0 whereas the maximum score possible is a 10. A score of 9 would be interpreted as all categories except one given the maximum score indicating readiness for PACU discharge. Appendix E includes a description and scoring of the categories. When the patient had an Aldrete score \( \geq 9 \), and was ready for discharge from the PACU, T2 data were collected. Figure 1 illustrates a timeline describing the data collection procedures.

<table>
<thead>
<tr>
<th>Preoperative Time 1</th>
<th>Intraoperative</th>
<th>Postoperative Time 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Collection and recording of demographic data</td>
<td>*Midazolam</td>
<td>*Aldrete score ( \geq 9 )</td>
</tr>
<tr>
<td>*Preoperative assessment</td>
<td>*All patients wear ear buds attached to iPod player</td>
<td>*Time music ends for experimental group</td>
</tr>
<tr>
<td>*SAI (anxiety)</td>
<td>*Music begins for experimental group</td>
<td>*Ear buds removed from all patients</td>
</tr>
<tr>
<td>*VAS (pain)</td>
<td>*General anesthetic</td>
<td>*SAI (anxiety)</td>
</tr>
<tr>
<td>*MAP</td>
<td>*Music continues for experimental group</td>
<td>*VAS (pain)</td>
</tr>
<tr>
<td>*HR</td>
<td>*Emergence</td>
<td>*MAP</td>
</tr>
<tr>
<td></td>
<td>To PACU</td>
<td>*HR</td>
</tr>
</tbody>
</table>

Figure 1. Study Time Line.
Measurement of Mean Arterial Pressure (MAP)

Mean arterial pressure, which is calculated from systolic and diastolic blood pressure, is influenced by blood flow through the aorta and the arterial system. Both cardiac output and vascular resistance are evaluated by measurement of MAP (Sesso, Stampfer, Rosner, Hennekens, Gaziano, & Manson, 2000). Mean arterial pressure for this study was measured by the HP M3000A non-invasive blood pressure monitoring instrument. Accuracy is reported to be within +/- 5 mm Hg maximum mean error (HP M3000-A Multi-Measurement Server, 2004). Amadasun and Isa (2005) found a .95 correlation between MAP measurements taken by a sphygmomanometer versus an oscillometric device. Guidelines from the Association for the Advancement of Medical Instrumentation and American Nation Standard (e.g. ANSI/AAMI SP10:2002 & ANSI/AAMI SP10:2002/A1:2003) specify readings will be within +/- 8 mm Hg standard deviation (Friedman & Prisant, 2003). Reliability of the automated non-invasive blood pressure (NIBP) monitoring was tested prior to data collection by measurement and calculation of a mean arterial pressure with a manual sphygmomanometer in three volunteers. When compared with the automated NIBP mean arterial pressure, both readings were within 5 points 100 percent of the time.

Measurement of Heart Rate

Heart rate is defined as a measure of beats per minute representing the frequency of the cardiac cycle. Electrocardiograph (ECG) technology was used
to measure heart rate by the HP M3000A. The accuracy is reported to be +/- 2.5-4% (1 standard deviation) for 70-100% reliability (HP M3000-A Multi-Measurement Server, 2004). The software has the ability to operate in the diagnostic or filter mode which allows for greater accuracy in blocking electrical interference from electrosurgical cautery which might cause artifact tracings on the ECG. Guidelines from the Association for the Advancement of Medical Instrumentation and American Nation Standard (e.g. ANSI/AAMI EC13:2002) specify readings will be within + 5 beats per minute standard deviation (Bailey & Mortara, 2002). Reliability of the automated heart rate monitoring was tested prior to data collection by manual measurement of the carotid pulsation for 60 seconds to obtain beats per minute in three volunteers. When compared with the automated heart rate readings, both readings were within 5 points of each other 89 percent of the time.

**Spielberger State Anxiety Inventory Scale (SAI)**

A state of anxiety is identified by subjective tension, apprehension, worry, and sympathetic nervous system arousal. State anxiety is current, transient, and a result of stressors or threats to the person’s well-being (Spielberger, Gorusch, Lushene, Vagg, & Jacobs, 1983). For the purpose of this study, state anxiety was measured by the SAI. The SAI measures state anxiety and consists of 20 questions with a 4 point Likert scale response (1 – not at all; 2 – somewhat; 3 – moderately so; 4 – very much so). The summary score provides interval level data. This scale has been used extensively to assess state anxiety induced by
stressful procedures and stressors (e.g. surgery, dental treatment, job interviews, testing) (Spielberger et al., 1983). The SAI is norm referenced and based upon comparison of the participants’ score in relation to scores of others. Behavioral indicators are used to measure anxiety such as feelings of apprehension, tension, nervousness, and worry. The instrument for state anxiety is scored from a minimum of 20 to a maximum of 80. Each item is given a weighted score of 1 to 4 with some scores being reversed, thus the scoring key was used to appropriately assess the weight of each item in its relation to anxiety. A lower score was interpreted as a lower anxiety level, whereas a higher score was indicative of the presence of higher anxiety.

Spielberger reported alpha reliability coefficients of .89 to .94, and reported evidence of the STAI’s construct validity for college students by noting that STAI scores were lower after relaxation training and higher under stressful exam conditions (Spielberger et al., 1983). Test-retest reliability for the STAI ranged from .16 to .62 for students. Low correlations reflect the accuracy of measuring the dynamic and transient characteristics of state anxiety (Spielberger et al., 1983). Within Spielberger’s manual there was no description regarding the process for establishing content validity for the STAI. Internal consistency reliability was assessed on SAI scores in this study: The T1 alpha reliability coefficient was .958 and T2 alpha reliability coefficient was .973. These reliability coefficients are consistent with those reported by Spielberger et al. (1983).
**Visual Analogue Pain Scale**

Pain is defined as a personal and subjective unpleasant experience related to potential or actual damage to tissue of the body (Dirckx, 2001). For the purpose of this study, pain was defined operationally as the score on a Visual Analogue Scale (VAS) measuring pain perception. Visual analogue scales (VAS) measure a participant’s subjective feelings about a stimulus. The VAS provides ordinal level data and has been used extensively to measure patients’ perceptions of pain. The scale is represented by a horizontal line 100 mm in length (Appendix D). At each end, a perpendicular anchor describes two extremes of the sensation of pain. The left anchor represents no pain (0) and the right anchor represents the worst possible pain (100). Participants made a mark anywhere between the two extremes to represent their level of perceived pain. The mark was then measured in millimeters to give an ordinal level data point (Waltz et al., 2005).

The test-retest method is often used to establish reliability of the VAS. Bijur, Silver, and Gallagher (2001) found test-retest intraclass correlation coefficients were .97 for a VAS for pain. However, acute pain in the recovery room varies from minute to minute depending on delivery of pain medication, thus rendering this method inappropriate. In addition, the short time interval required to perform a test-retest could introduce recall bias by the participant (Waltz, Strickland, & Lenz, 2005).

The validity of the VAS has been supported through correlation studies with other self-reported measures of pain intensity such as the McGill Pain
Questionnaire and the Visual Rating Scale, which is a Likert-type scale (Jensen, Karoly, O’Riordan, Bland & Burns, 1989). Due to the many potential scoring values, VAS is extremely sensitive to pain intensity (Joyce, Zutshi, Hrubes, & Mason, 1975). Bijur, Latimer, and Gallagher (2003) reported a correlation of .94 between the VAS and a numerical rating scale (NRS) for acute pain.

Protection of Human Subjects

Prior to beginning this study, approval was obtained through the University of Alabama at Birmingham (UAB) Institutional Review Board (IRB) and the Jackson-Madison County General Hospital IRB. Appendix F includes a copy of the consent form and the approval from the UAB IRB, and Appendix G includes a copy of the consent form and the approval from the Jackson-Madison County General Hospital IRB. Because the two IRBs had different requirements for consent form format, all participants signed both approved consent forms (Appendices F and G).

The researcher visited each surgery practice and provided a description of the research study and protocol. The physicians and nurses agreed to provide the study information to their patients newly diagnosed with breast cancer and scheduled to undergo mastectomy surgery (Appendices H & I). Information fliers were posted in the waiting room of the surgeon’s offices to create interest in the study (Appendix J). An office staff member identified potential participants who met sample selection criteria, and informed them about the study. At the conclusion of recruitment, these staff members received a thank you gift of a
Christmas cactus plant from the investigator for assisting with sample recruitment. The staff member asked women who were interested in learning more about the study to sign permission forms allowing the investigator to contact them to discuss the study in more detail. This protocol was designed to ensure compliance with HIPAA regulations. Appendix K contains a copy of the permission form. The staff member also provided potential participants with a patient information brochure (Appendix L), and a copy of the informed consents to take home and to examine prior to surgery. The investigator called potential participants who signed the permission forms to explain the study in further detail, answer questions, determine eligibility, and inform potential participants that they would be asked to provide written consent on the day of their surgery. Therefore this protocol provided a minimum of 24 hours from the time of explanation of the study to the time of asking potential participants to sign the consent form. Each participant that the investigator called agreed to participate in the study, was enrolled, and completed the study. In describing the study, the investigator carefully described the design of the study (i.e. experimental randomized trial) and the value of obtaining data on the dependant variables from the control group as well as the music group. There were no refusals to participate whether the participant was in the control or the music group.

On the day of the scheduled surgery, the investigator met the participant preoperatively to review the study, answer any questions, and obtain written informed consent (Appendices F and G). The investigator explained that the study’s purpose was to evaluate the effects of music because it was not known if
it provided the hypothesized benefits. Participants were assured that participation was voluntary and no changes would be made in their anesthetic care based upon participation. In addition, assurance was given that data collected had no patient identifying information, would remain confidential, and would be secured on a personal computer that was password-protected at the investigator’s home office. The survey and data collection forms were coded with the participant’s study code number (with no identifying information), and were stored in a locked file drawer with access only by the investigator. At the time of PACU discharge, each participant received a music CD as a thank you for being in the study.

Study Procedures

After the participants were checked into the preoperative area and had signed the informed consent, the investigator collected T1 baseline measurements of mean arterial pressure (MAP) and heart rate (HR) preoperatively in the pre-surgical area (Figure 1 – Study Time Line). Participants also completed the SAI and the VAS at T1 (appendices C and D). Then the participants were assigned by the investigator to experimental or control groups by selecting numbers from an envelope which contained papers numbered 1 to 30. (Odd numbers were assigned to the experimental group and even numbers to the control group).

The National Institute of Occupational Safety and Health (NIOSH) and Centers for Disease Control (CDC standards) published in 2002 recommend that
noise not exceed 85 decibels (dB) for more than 8 hours to prevent permanent hearing damage (http://www.cdc.gov/niosh/hptermsh.html). Music players (such as iPOD) at a maximum volume can produce up to 115 dB (http://playlistmag.com/news/2006/02/02/ipodhearing/index.php). Thus the music choices to be used in this study were measured via audiometry within a simulated ear canal and the volume of the music player was specified to produce a maximum volume range of 70 dB. This maximum volume setting was set and locked by software offered by iPOD’s manufacturer Apple. The equipment was approved by the hospital's Biomedical Department.

Participants in the intervention group chose from four types of music: classical, easy listening, inspirational, or new age after they listened for 5 minutes to a selection of each genre. The order in which the participant heard the genre selection was randomly presented each time to each participant. The music intervention was begun after the participant received midazolam preoperatively. The participants’ music selection contained 4 hours of continuous non-repeating music to prevent potential satiation.

The investigator then provided the participant with an iPOD with earphones that allowed ambient conversation to be heard. If the patient was in the intervention group, the investigator asked her to confirm that the volume and style of the music was acceptable and the iPOD was be placed in a carrying case which concealed the function of the player. Each participant in the music group was allowed to set the volume within this maximum volume range of 70 dB and all participants selected a lower setting than that maximum. The music
intervention was started in the preoperative holding area and continued throughout anesthesia induction, the surgical process, emergence from anesthesia, and recovery from anesthesia, until just prior to discharge to the nursing floor. Women in the control group also wore earphones attached to an iPod player in a carrying case, but there was no music playing, in order to minimize bias that might result if nurse anesthetists, surgical, and recovery staff were aware of the women’s treatment group assignment. The investigator asked women in both groups not to mention the absence or presence of music.

In order to minimize differences in anesthesia care that might influence the study outcomes, all anesthesia was provided by three nurse anesthetists who were familiar with the study protocol. All anesthetists used the same anesthesia protocol, using a combination of intravenous drugs that are standardized. Unless contraindicated by patient allergies, each participant received 2 mg of midazolam IV preoperatively. The anesthetic began with pre-oxygenation (100% O₂) for 3 minutes. The following drugs were given: fentanyl 1.5 mcg/kg, lidocaine 1.5 mg/kg, propofol 2 mg/kg, and rocuronium 0.6 mg/kg. Anesthesia was maintained with nitrous oxide/oxygen 1:1, and an end-tidal desflurane concentration of 5%. Fentanyl was given 1 mcg/kg whenever the patient’s HR increased by more than 20% over the baseline value. Ondansetron 4 mg was given for prevention of nausea and vomiting 15 minutes prior to emergence. The nurse anesthetist administered intravenous fluids (lactated Ringer’s) to replace each participant’s fluid deficit due to fasting, maintained intraoperative hourly fluid rate, replaced blood lost, as well as replaced insensible losses from the surgical field.
Data collected intraoperatively included information contained within the anesthetic record: the percentage volatile gas, use of nitrous oxide, medications given, vital signs, and any intraoperative complications (see appendix B). The data collected by the anesthesia provider were utilized to ensure that these variables were distributed equally between the intervention and control groups.

In the PACU when the patient had an Aldrete score $\geq 9$, (Appendix J) and was ready for discharge, data collection for T2 began. This Aldrete score indicated that respiratory effort was adequate, vital signs were within 20-50% of baseline measures, skin was warm with good color, the patient was alert and oriented, and had purposeful movement. At T2 the investigator recorded each patient’s MAP and HR, and participants recorded their level of pain on the VAS and completed the SAI. The investigator also recorded the time the music intervention was stopped and the time discharged from the PACU. Interrater reliability of measures of MAP and HR score were assessed between the investigator and PACU nurse on a random sample of 20% (6 out of 30) of participants at T1 and T2 using a percentage agreement method (counting as agreement if the readings were within 5 points of each other). The percentage agreement reliability across these 12 readings was 83.3% for MAP and 91.7% for HR.
CHAPTER 4

RESULTS

The purpose of this study was to examine the effects of a perioperative music intervention (provided continuously throughout the preoperative, intraoperative, and postoperative periods) on changes in mean arterial pressure (MAP), heart rate (HR), anxiety, and pain in women with a diagnosis of breast cancer undergoing mastectomy surgery. Thirty women were assigned randomly to either a treatment group that received a music intervention perioperatively or a control group. This chapter describes the data analysis procedures that were used, and presents the study findings.

Data Analysis Procedures

At the conclusion of data collection, entry into SPSS 15.0 was verified by checking 20% of the data for accuracy by the investigator reading all data entries for six study participants to another person, and no errors were discovered. Descriptive statistics (mean, median, standard deviation) were analyzed from the demographic data and outcome variables. Box and whisker plots were utilized to detect outliers within the distributions. With the exception of years of education, T1 STAI, T2 STAI, and T1 VAS for pain, the data were normally distributed according to these analyses. Years of education and T1 VAS for pain had
outliers that were determined to be valid and therefore were included in the statistical analyses.

Each of the dependent variables (MAP, HR, levels of anxiety, and pain) were measured preoperatively (T1) and postoperatively (T2). The difference from T1 to T2 resulted in a change score from which an independent sample t-test was calculated for each dependent variable. Levene’s test for homogeneity of variance was met in all dependent variables: MAP (p=.613), HR (p=.936), anxiety (p=.061), and pain (p=.741). Although the sample size of 30 was decreased from a projected size of 40, the observed power of all dependent variables except one was greater than 80%: MAP (.892), HR (.207), anxiety (.999), and pain (.810).

Description of the Sample

The sample consisted of 30 female participants ranging from 42 to 70 years of age undergoing mastectomy surgery for breast cancer. The mean age was 56.63 years. Seven participants (23.3%) were 49 years and younger, 10 participants (33.3%) were between 50-59 years, 11 participants (36.7%) were between 60-69 years, and 2 participants (6.7%) were 70 years of age. Three participants represented ASA risk status one (10%), 19 participants represented ASA risk status two (63.3%) and 8 participants represented ASA risk status three (26.7%). A total of 24 participants were white (80%) and 6 were black (20%). All but 2 participants completed high school and 14 (46.7%) had between 1 and 6 years of college education.
Table 2 illustrates the data related to race, ASA risk status, marital status, level of spirituality, history of diabetes, and use of preoperative beta blocker for the women in the music intervention and control groups. Results of Chi-square analyses indicated that there was no significant difference between the two groups on these variables at baseline.

Table 3 illustrates the mean and standard deviation for the Time 1, Time 2, and change scores for MAP, HR, anxiety, and pain for women in the intervention (music) and control groups. Results of independent samples T-tests revealed that there were no differences in the variables at T1 (p=.440-.875), indicating that the randomization procedures resulted in equivalent groups.
Table 2
Race, ASA Risk Status, Marital Status, Level of Spirituality, Diabetes, and Preoperative Beta Blocker for Women in Intervention (Music) and Control Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Music</th>
<th>Control</th>
<th>Chi-square statistic</th>
<th>Probability*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>13 (43.3)</td>
<td>11 (36.7)</td>
<td>.833</td>
<td>.326</td>
</tr>
<tr>
<td>Black</td>
<td>2 (6.7)</td>
<td>4 (13.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ASA Risk Status</strong></td>
<td></td>
<td></td>
<td>3.553</td>
<td>.236</td>
</tr>
<tr>
<td>1</td>
<td>3 (10.0)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>9 (30.0)</td>
<td>10 (33.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>3 (10.0)</td>
<td>5 (16.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
<td>.556</td>
<td>.355</td>
</tr>
<tr>
<td>Married</td>
<td>8 (26.7)</td>
<td>10 (33.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other**</td>
<td>7 (23.3)</td>
<td>5 (16.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Level of Spirituality</strong></td>
<td></td>
<td></td>
<td>.150</td>
<td>1.000</td>
</tr>
<tr>
<td>moderate</td>
<td>5 (17.9)</td>
<td>6 (21.4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>high</td>
<td>9 (32.1)</td>
<td>8 (28.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td></td>
<td></td>
<td>.240</td>
<td>1.000</td>
</tr>
<tr>
<td>present</td>
<td>2 (6.7)</td>
<td>3 (10.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>absent</td>
<td>13 (43.3)</td>
<td>12 (40.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Preoperative Beta Blocker</strong></td>
<td></td>
<td></td>
<td>.000</td>
<td>1.000</td>
</tr>
<tr>
<td>yes</td>
<td>1 (3.3)</td>
<td>1 (3.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>no</td>
<td>14 (46.7)</td>
<td>14 (46.7)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: ASA, Diabetes, Preoperative Beta Blocker - Fisher’s Exact Test 2-sided significance
** Single, divorced, widowed
Table 3
Mean and Standard Deviation for Time 1, Time 2 and Change scores for MAP, HR, Anxiety, and Pain for Women in the Intervention (Music) and Control Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>MAP</th>
<th>HR</th>
<th>Anxiety</th>
<th>Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>T1-Mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Music</td>
<td>98.7 (15.7)</td>
<td>77.9 (10.7)</td>
<td>41.5 (15.8)</td>
<td>11.8 (17.6)</td>
</tr>
<tr>
<td>Control</td>
<td>92.1 (18.2)</td>
<td>79.1 (12.4)</td>
<td>41.9 (14.5)</td>
<td>14.2 (14.3)</td>
</tr>
<tr>
<td><strong>T2-Mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Music</td>
<td>83.6 (13.0)</td>
<td>79.9 (14.9)</td>
<td>30.7 (12.3)</td>
<td>41.5 (30.2)</td>
</tr>
<tr>
<td>Control</td>
<td>96.6 (14.3)</td>
<td>85.9 (12.7)</td>
<td>49.7 (18.9)</td>
<td>64.9 (20.9)</td>
</tr>
<tr>
<td><strong>T1-T2 Change</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Music</td>
<td>15.1 (17.1)</td>
<td>-2.0 (11.4)</td>
<td>10.8 (7.7)</td>
<td>-29.7 (19.8)</td>
</tr>
<tr>
<td>Control</td>
<td>-4.5 (15.3)</td>
<td>-6.8 (10.9)</td>
<td>-7.7 (11.6)</td>
<td>-50.7 (19.2)</td>
</tr>
<tr>
<td><strong>t value</strong></td>
<td>-3.312</td>
<td>-1.180</td>
<td>-5.164</td>
<td>-2.940</td>
</tr>
<tr>
<td><strong>Significance</strong></td>
<td>p&lt;.05</td>
<td>.248</td>
<td>.000*</td>
<td>.007*</td>
</tr>
</tbody>
</table>

Note: df = 28

Research Hypotheses

*Hypothesis 1. Women who receive a perioperative music intervention will have a significantly greater decrease in MAP from T1 to T2 compared to women in a randomly assigned control group.*

Change scores were calculated for MAP from T1 to T2 for both groups, and an independent samples t-test was used to analyze these scores. The findings presented in Table 2 indicate there was a statistically significant difference (p=.003) in the MAP change scores from T1 to T2 comparing the women in the music intervention and control groups. In addition to statistical
significance, there was clinical significance supporting this hypothesis because the MAP for the control group increased postoperatively by a mean of 4.5 mmHg, whereas the MAP for the music group decreased postoperatively by 15.1 mmHg. The range of these change scores for MAP was from -54 mmHg to +10 mmHg for the music group and -33 mmHg to +30 mmHg for the control group.

**Hypothesis 2. Women who receive a perioperative music intervention will have a significantly greater decrease in heart rate from T1 to T2 compared to women in a randomly assigned control group.**

Change scores were calculated for HR from T1 to T2 for both groups. The findings presented in Table 2 indicate that the dependent variable of HR did not reach statistical significance (p=.248) although postoperatively the music group had a smaller increase in HR (2 beats per minute) than the control group (6.8 beats per minute). The range of these change scores for HR was from -23 beats per minute to +23 beats per minute for the music group and -12 beats per minute to +32 beats per minute for the control group.

**Hypothesis 3. Women who receive a perioperative music intervention will have a significantly greater reduction in anxiety from T1 to T2 compared to women in a randomly assigned control group.**

Change scores were calculated for anxiety from T1 to T2 for both groups. The findings in Table 2 indicate there was a statistically significant difference in the music group (p<.001) compared to the control group. The postoperative
anxiety score for the control group increased by a mean of 7.7, whereas the anxiety score for the music group decreased by 10.8. The range of these change scores for anxiety was from -24 to +1 for the music group and -8 to +33 for the control group.

_Hypothesis 4. Women who receive a perioperative music intervention will have a significantly greater reduction in pain from T1 to T2 compared to women in a randomly assigned control group._

Change scores were calculated for pain from T1 to T2 for both groups. The findings in Table 3 indicate a significant difference (p=.007) postoperatively in pain level in women listening to music compared to the control group. In addition to statistical significance, there was clinical significance in this result because the VAS for the control group increased by a mean of 50.7, whereas the VAS for the music group increased by only 29.7. The music group experienced 41.3% less increase in pain than the music group experienced. The range of the changes scores for pain was from 6-66 for the music group and 18-88 for the control group.

*Additional Analyses for Pain*

Data were collected on the total amount of intraoperative opioid (fentanyl in micrograms), whether or not participants received an opioid in the PACU, time in minutes between the last dose of opioid and the measurement of pain via the VAS, and the total amount of postoperative opioid (morphine, hydromorphone, or meperidine in milligrams) given in the PACU. To maintain consistency, all
postoperative pain medication given in the PACU was converted into morphine equivalent milligrams using the Epocrates opioid analgesic converter (Epocrates, 2008). Chi-square or independent t-tests were calculated to compare groups. Table 4 presents data comparing the intervention and control groups on amount of intraoperative opioid medications received, time between administration of opioid in the PACU and completion of the VAS and anxiety measures, and amount of opioid medication received in the PACU. The music group and control group were not statistically different on the amount of intraoperative opioid received or on the number who received opioid analgesics in the PACU (10/15 music group vs. 11/15 control group; Fisher’s Exact 1-sided p=.500). Similarly, the groups were not significantly different on the mean time in minutes between the last dose of postoperative opioid and measurement of pain via the VAS or on the mean total amount of postoperative opioid in morphine equivalents. Thus the finding of the music group experiencing 41.3% less pain than the control group in Hypothesis 4 via the VAS was not associated with any of these potential covariates.
Table 4: Mean, Standard Deviation (SD), t-statistic, and p value for Intraoperative Opioid, Minutes Between PACU Opioid Administration & VAS, and Amount of Opioid in the PACU for Women in the Intervention (Music) and Control Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intraoperative Opioid (mcg fentanyl)</th>
<th>Minutes PACU Opioid &amp; VAS</th>
<th>Amount Opioid PACU (morphine equivalent mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Music</strong></td>
<td>mean 220.0</td>
<td>19.13</td>
<td>17.67</td>
</tr>
<tr>
<td></td>
<td>SD 49.28</td>
<td>18.05</td>
<td>21.26</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>mean 233.3</td>
<td>28.33</td>
<td>22.10</td>
</tr>
<tr>
<td></td>
<td>SD 40.82</td>
<td>20.36</td>
<td>17.52</td>
</tr>
<tr>
<td>t statistic</td>
<td>.807</td>
<td>1.310</td>
<td>.623</td>
</tr>
<tr>
<td>p value</td>
<td>.426</td>
<td>.201</td>
<td>.538</td>
</tr>
</tbody>
</table>

Note: df = 28
CHAPTER 5
DISCUSSION

Summary of Findings

The purpose of this study was to examine the effects of a perioperative music intervention (provided continuously throughout the preoperative, intraoperative, and postoperative periods) on changes in MAP, HR, anxiety, and pain in women with a diagnosis of breast cancer undergoing mastectomy surgery. Psychological (anxiety and pain) and physiological (MAP and HR) outcomes were measured, and the study findings indicated that levels of MAP, anxiety, and pain were significantly lowered or improved postoperatively in the experimental music group as compared with the control group. Women in the intervention group had lower postoperative HR levels, but the difference was not statistically different from the change in HR for women in the control group. This chapter discusses the findings in comparison with findings from previously reported research and as they relate to the conceptual framework that was proposed for this study. The chapter concludes with a discussion of study strengths and limitations and recommendations for research and practice.
Relationship of Results with Literature

*Research Findings Related to Effects of Music on Anxiety*

The finding of reduced anxiety following a music intervention from this study were consistent with findings in 11 previous studies (Augustin & Hains, 1996; Chang & Chen, 2005; Haun, Mainous, & Looney, 2001; McRee, Noble, & Pasvogel, 2003; Mok & Wong, 2003; Nilsson, Unosson, & Rawal, 2005; Padmanabhan, Hildreth & Laws, 2005; Sanderson, 1986; Twiss, Seaver, & McCaffrey, 2006; Wang, Kulkarni, Dolev, & Kain, 2002; Yung, Chui-Kam, French, & Chan, 2002). Only 4 of 15 studies that were reviewed that included anxiety as a dependent variable reported no effect of music on anxiety (Gaberson, 1995; Heiser, Chiles, Fudge, & Gray, 1997; Nilsson, Rawal, Enqvist, & Unosson, 2003; Steelman, 1990). Studies that used the STAI to measure anxiety, as was used in the current study, were more likely to report significant effects of music on anxiety than were studies that used the VAS to measure anxiety (Gaberson, 1995; Heiser, Chiles, Fudge, & Gray, 1997; Nilsson, Rawal, Enqvist, & Unosson, 2003).

The studies by Gaberson (1995) and Nilsson et al. (2003) included participants who had a low level of baseline anxiety, and thus the failure to identify effects on anxiety in these studies may be due to a floor effect. The population for the current study included women undergoing breast cancer surgery who had moderate levels of anxiety (average score on the SAI 41.7 out of 80). This population was specifically selected to address the problem of a potential floor effect.
Six studies that reported significant reductions in anxiety initiated the music intervention during the preoperative period, as was done in the current study (Augustin & Hains, 1996; Haun et al., 2001; McRee et al., 2003; Padmanabhan et al., 2005; Wang et al., 2002; Yung et al., 2002). Three of the four studies that did not report significant effects on anxiety initiated the music during the intraoperative and/or postoperative period (Heiser et al., 1997; Nilsson et al., 2003; Steelman, 1990).

Research Findings Related to Effects of Music on Blood Pressure

The findings of this study were consistent with the findings from 8 of 14 studies that included blood pressure as an outcome variable, indicating that music had a significant effect on lowering blood pressure (Allen, Golden, & Izzo, 2002; Augustin & Hains, 1996; Ikonomidou, Rehnstrom, & Naesh, 2004; Miluk-Kolasa, Matejek, & Stupnicki, 1996; Mok & Wong, 2003; Steelman, 1990; Updike & Charles, 1987; and Yung et al., 2002). In seven of the eight previous studies that reported significant effects of music on blood pressure, patients were allowed to choose the type of music (Allen, Golden, & Izzo, 2002; Augustin & Hains, 1996; Miluk-Kolasa, Matejek, & Stupnicki, 1996; Mok & Wong, 2003; Steelman, 1990; Updike & Charles, 1987; and Yung et al., 2002) and in four of these studies with significant effects on blood pressure, the music intervention was initiated preoperatively, similar to the methods used in the current study (Augustin & Hains, 1996; Miluk-Kolasa, et al., 1996; Updike & Charles, 1987; and Yung et al., 2002). These findings suggest that music interventions may be most
effective in reducing blood pressure if patients are allowed to choose the type of music and if the music intervention is initiated preoperatively.

Research Findings Related to Effects of Music on Heart Rate

Six of 13 previous studies that included heart rate as an outcome variable reported a significant effect of music on heart rate (Allen et al., 2002; Augustin & Hains, 1996; Ikonomidou et al., 2004; Miluk-Kolasa et al., 1996; Mok & Wong, 2003; Updike & Charles, 1987). Seven of the 13 previous studies that examined the effects of music on heart rate did not report significant effects, consistent with the findings from the present study (Haun et al., 2001; Heiser et al., 1997; McRee et al., 2003; Migneault et al., 1996; Nilsson et al. 2005; Wang et al., 2002; Yung et al., 2002). The sample sizes in the seven studies that did not report significant effects on heart rate ranged from 10 to 75, but only two of these studies had more than 15 participants per treatment group. The sample sizes in the six studies that reported effects on heart rate ranged from 10-100 and five of these studies included at least 20 participants per treatment group. Therefore, one reason for the failure to identify an effect of music on heart rate in the current study may have been an inadequate sample size to detect the effect of music.

Research Findings Related to Effects of Music on Pain

The finding of a reduction in perception of pain is also consistent with findings from 8 of 11 previously reported studies evaluating perioperative music interventions in which pain was examined as an outcome variable (Ikonomidou,
Rehnstrom, & Naesh, 2004; Koch, Kain, Ayoub, & Rosenbaum, 1998; Lewis, Osborn, & Roth, 2004; Nilsson, Rawal, Unestahl, Zetterberg, & Unosson, 2001; Nilsson, Rawal & Unosson, 2003; Nilsson, Unosson, & Rawal, 2005; Sanderson, 1986; Shertzer & Keck, 2001). Six of the eight studies reporting positive effects of music on pain controlled for extraneous variables such as type of surgery and anesthesia (Ikonomidou et al., 2004; Koch et al., 1998; Lewis et al., 2004; Nilsson et al., 2001; Nilsson et al., 2003; Nilsson et al., 2005), whereas three of the four studies reporting no effects of music on pain failed to control for these variables (Heiser, Chiles, Fudge, & Gray, 1997; McRee, Noble & Pasvogel, 2003; Taylor, Kuttler, Parks, & Milton, 1998). A strength of the current study was the control over numerous potential extraneous variables including type of surgery and anesthesia. Another strength was the absence of significant differences between the music and control group on (1) the amount of intraoperative opioid, (2) the time between the last opioid dose and measurement of pain via the VAS at T2, and (3) the total amount of postoperative opioid in morphine equivalents.

Summary of Relationship to Previous Studies

Findings from this study were consistent with findings from previous studies that had incorporated the following elements similar to the current study (1) used the STAI to measure anxiety, (2) avoided participant groups with low baseline anxiety to offset a floor effect, (3) included an adequate sample size to detect differences in anxiety, blood pressure, and pain levels, (4) controlled for the type of surgery and anesthesia, and (5) initiated the music intervention
preoperatively. Findings were not congruent with findings from other studies that did not report differences in anxiety, blood pressure, or pain levels. Characteristics of these studies that differed from the current study were that they (1) measured anxiety with a VAS, (2) included patients with low baseline anxiety levels (and thus may have had a floor effect), (3) had inadequate sample size or power, and (4) did not initiate the music during the preoperative period. The failure to identify an effect of music on heart rate in this study may have been due to the relatively small sample size and lack of sufficient power to detect an effect on this variable.

Discussion of Results in Relation to Theoretical Framework

As illustrated in the conceptual model for this study, music may have both physiological and psychological effects. Three of the four relationships that were predicted in the conceptual model were supported by the findings from this research. The effects of music on psychological outcomes (decreased anxiety and pain levels) that were proposed by this model were supported. The effect of music on one of the two physiological outcomes (MAP) was supported. Although HR was decreased from baseline to the postoperative period, there were no significant differences among women in the experimental and control groups in the decrease in HR.

The mechanisms by which music is proposed to affect these domains are distraction, entrainment, and audioanalgesia which are all components of the relaxation response. The model identified the relaxation response as a means by which the individual could adapt positively to a stressor. Although these
proposed mechanisms were not tested in this study, the finding of decreased levels of pain in the music intervention group supports the gate control theory. The finding of decreased level of anxiety in the music intervention group supports the proposed mechanisms of distraction and entrainment. The finding that there were significant effects of music on MAP, anxiety, and pain support the relaxation response as a proposed mechanism explaining the effects of music interventions.

Approximately half of the studies reviewed (14 of 30) had no theoretical underpinnings to explain the effect of music within the study. None of the studies reviewed included a conceptual map illustrating how the proposed theory or theories might explain the findings of the study. This study proposed a conceptual map that explains the mechanism of the middle range theory of the relaxation response which has components of distraction, entrainment, audioanalgesia, and gate control of pain and its relationship to the physical and psychological variables measured. As part of Benson’s Relaxation Response, distraction and entrainment may work within both the psychological and physiological domains. These mechanisms may actually “close the gate” and thereby reduce pain, lower anxiety levels, and reduce MAP and HR. Audioanalgesia, also a component of the Relaxation Response, may actually inhibit the transmission of neuronal pain impulses by enhancing the release of dopamine. Finally, music may also assist in muting the ambient noise, which for many surgical patients, only serves to increase their anxiety. Overheard conversations, unusual equipment beeps and sounds, and perhaps even other
patients’ anxious comments are less noticeable when music is employed and thus anxiety is lowered or prevented from increasing to an elevated level.

Study Strengths

There were many strengths in this study. The sample of 30 participants was of adequate size and power. The power for the t-tests for all dependent variables was greater than .80 with the exception of heart rate. A homogenous sample that included only women with the same diagnosis and undergoing the same surgical procedure provided control of selected extraneous variables. The use of random assignment further controlled for potentially confounding variables such as type of anesthetic and participant characteristics. Including women with breast cancer as the study population helped avoid a floor effect in anxiety and pain, since numerous studies have suggested that these women have high levels of both anxiety and pain (Poleshuck et al., 2006; Shelby et al., 2002). An additional strength of the study was the use of Spielberger’s STAI rather than a VAS to measure anxiety as recommended by several researchers (Lepage et al., 2001).

All enrolled participants completed the study procedures. One potential participant expressed interest in the study, but was not enrolled because she chose to undergo surgery in another location. The observers were blinded to the participant’s group assignment, although the participants could not be blinded due to the timing of the music intervention. Participants in this study were allowed to choose from four categories of music and began listening
preoperatively, as recommended on the basis of previous studies (Lane, 1992, Standley, 2000). The music intervention was non-invasive, with no apparent deleterious effects for the participants listening to music on anxiety, MAP, HR, and pain. The maximum increases in HR and pain at T2 for the music group were within the range of values for the control group. Only one participant experienced an increase in MAP at T2, while one-third of the control group experienced an increase in MAP larger than this value at T2. In anxiety, only one participant experienced an increase at T2, while two-thirds of the control group experienced an increase at T2 equal to or greater that this value. In summary, the findings from this study provide new evidence about the effects of perioperative music on mean arterial pressure, anxiety, and pain. Most previous studies have examined music that was provided only during the pre, intra, or postoperative period, and rarely throughout the perioperative period.

Study Limitations

Because participants knew that their levels of pain and anxiety were being studied, a Hawthorne effect may have been present due to the nature of the self-reported instruments utilized and therefore may have introduced an element of response bias. Although this study was carefully designed to control for confounders, the researcher was unable to control the hospital perioperative environment (e.g. noise, temperature). However, because random assignment resulted in groups that were similar, both the music intervention and the control groups were exposed to these same conditions. The study used a convenience
sample and the sample size was relatively small, thus the results should be
generalized with caution to women undergoing mastectomy for breast cancer.
Since only women were included as participants, the ability to generalize the
results of this study to men is limited.

Recommendations

Implications for Practice

The findings of this research are not only statistically significant, but they
demonstrate clinical significance as well. Music is a non-invasive and low-cost
intervention that can be easily implemented in the perioperative setting and can
reduce pain, anxiety, and mean arterial pressure among women undergoing
mastectomy for breast cancer. Several participants receiving music volunteered
comments postoperatively about how much they enjoyed hearing the music and
that it provided comfort to them. As health care providers search for ways to
provide services to their clients that produce greater satisfaction, perioperative
music may be an efficacious intervention.

Future Research

Future research is needed to determine whether perioperative music
interventions might be helpful for other populations including children, men, and
patients undergoing other types of surgical procedures and other types of
anesthesia. Expanding the time line for data collection into the first several days
to several weeks during the post-mastectomy time frame would provide
additional information regarding the effects of music beyond the immediate perioperative period. Further explorations should be done regarding the correlation between the level of spirituality and levels of anxiety and pain between the music and control groups. Additional research is also needed to more specifically examine the mechanisms by which music produces beneficial effects, in order to further test the conceptual framework proposed for this study. Mixed-method studies using both qualitative and quantitative approaches would also provide enhanced understanding about the effects of music on patients and the mechanisms responsible for these effects.
REFERENCES


Wheaton, IL: Tyndale House Publishers, Inc.


APPENDIX A

CONCEPTUAL MODEL OF MUSIC
CONCEPTUAL MODEL OF MUSIC

Diagnosis Breast Cancer - Impending Surgery = STRESS

Relaxation Response Via
- Distraction
- Entrainment
- Audioanalgesia
  Closes Gate Blocking Pain Transmission

Physiologic outcomes
  ↓ HR
  ↓ MAP

Psychologic outcomes
  ↓ Anxiety
  ↓ Pain level
APPENDIX B

PERIOPERATIVE MUSIC INTERVENTION DEMOGRAPHICS AND DATA COLLECTION FORM
Appendix B

Perioperative Music Intervention
Demographics and Data Collection Form

Date Collected _______
Participant ID #______

DEMOGRAPHICS

Age _______
Race – White_____ Black_____ Other_____
Years of education_______________________
Single_____ Divorced____ Widowed_____ Married_____
Do you find comfort from spirituality?   Yes_____ No_____
Level of Spirituality – None_____ Low_____ Moderate_____ High_____
Have you received formal music training?_______________
    If yes, what type?___________________________
Do you listen to music for pleasure? _____ Yes  ___ No
If yes, about how often do you listen to music for pleasure?
    Daily _____ 1-3 times per week _____ 4-7 times per week _____ other
(please describe)
    ___________________________________________________________
If yes, what type of music do you like to listen to?
    ________________________________

DATA COLLECTION

Preoperative Time 1 Data:  (Time collected:____________________)
    1. SAI score_______
Appendix B

2. VAS score ______
3. MAP_______
4. HR_______
5. Preoperative assessment:
   • Previous surgery (each surgery with date)________________________________________
   • history of anesthetic complications (list each)__________________________________
   • daily medications (list name and dose of all meds)_______________________________
   • height____weight______
• Present illness:
  o If known, staging of present cancer?___________________________________________
  o Breast cancer ever occurred in immediate family? Yes____No____
  • abnormal physical findings by system:
    o head/neck/airway - __________________________________________________________
    o respiratory - ______________________________________________________________
    o cardiac - _________________________________________________________________
    o neuro/musculature - _______________________________________________________
    o gastrointestinal - __________________________________________________________
Appendix B

- genitourinary –
- endocrine –
- additional comments

6. Pre-op medications (med, dose, time, and route given):

7. ASA risk status

8. Time IPOD begun

Intraoperative Data:

Time anesthetic began ended (admitted to PACU)

(The following times are recorded in intervals after anesthetic began time above)

1. MAP - 15 min, 30 min, 45 min, 60 min, 75 min, 90 min, 105 min, 120 min, 135 min, 150 min, 165 min, 180 min.

2. HR - 15 min, 30 min, 45 min, 60 min, 75 min, 90 min, 105 min, 120 min, 135 min, 150 min, 165 min, 180 min.

3. Agent used (end-tidal %) - 15 min, 30 min, 45 min, 60 min, 75 min, 90 min, 105 min, 120 min, 135 min, 150 min, 165 min, 180 min.

4. Nitrous oxide? (yes/no)

5. Drugs given: (list name, dose, time given)
Appendix B

6. Any intraoperative complications?_____
   If yes, describe

________________________________________________________________________

Postoperative Time 2 Data:

(The following times are after admission to PACU)

1. Aldrete Score – 0 min____, 30 min____, 90 min____,
   120 min____, 150 min____, 180 min____
2. MAP – 0 min____, 15 min ____ , 30 min____, 45 min____, 60 min____,
   75 min____, 90 min____, 105 min____, 120 min____, 135 min____, 150
   min____,
   165 min____, 180 min____.
3. HR – 0 min____, 15 min ____ , 30 min____, 45 min____, 60 min____, 75
   min____,
   90 min____, 105 min____, 120 min____, 135 min____, 150 min____, 165
   min____,
   180 min____.
4. Time IPOD removed ________________
5. SAI score____ (time completed)____________
6. VAS score for pain______(time completed)___________
7. Time, dose, and type and route of pain medication
   administered

________________________________________________________________________

________________________________________________________________________

8. Time discharged from PACU_______________
APPENDIX C

SELF-EVALUATION QUESTIONNAIRE STAI
SELF-EVALUATION QUESTIONNAIRE

STA! Form Y-1

Please provide the following information:

Name_________________________ Date_________________________ S________

Age_________________________ Gender (Circle) M F T________

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate value to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

1. I feel calm .............................................. 1 2 3 4
2. I feel secure .............................................. 1 2 3 4
3. I am tense .............................................. 1 2 3 4
4. I feel strained .............................................. 1 2 3 4
5. I feel at ease .............................................. 1 2 3 4
6. I feel upset .............................................. 1 2 3 4
7. I am presently worrying over possible misfortunes .............................................. 1 2 3 4
8. I feel satisfied .............................................. 1 2 3 4
9. I feel frightened .............................................. 1 2 3 4
10. I feel comfortable .............................................. 1 2 3 4
11. I feel self-confident .............................................. 1 2 3 4
12. I feel nervous .............................................. 1 2 3 4
13. I am jittery .............................................. 1 2 3 4
14. I feel indecisive .............................................. 1 2 3 4
15. I am relaxed .............................................. 1 2 3 4
16. I feel content .............................................. 1 2 3 4
17. I am worried .............................................. 1 2 3 4
18. I feel confused .............................................. 1 2 3 4
19. I feel steady .............................................. 1 2 3 4
20. I feel pleasant .............................................. 1 2 3 4

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APPENDIX D

VISUAL ANALOGUE SCALE FOR PAIN
Appendix D

Visual Analogue Scale for Pain

Participant ID #__________
Date_____________________

What is your pain right now?

No Pain _________________________________ Worst Possible

0                                      100
APPENDIX E

ALDRETE SCORE
Appendix E

**Aldrete Score**

**Motor Activity**
- Able to move 4 extremities on command = 2
- Able to move 2 extremities voluntarily or on command = 1
- Able to move 0 extremities voluntarily or on command = 0

**Respiration**
- Able to deep breathe and cough freely = 2
- Hypoxia = 1
- Apneic = 0

**Circulation**
- Blood pressure +/- 20% preanesthetic value = 2
- Blood pressure +/- 20-50% preanesthetic value = 1
- Blood pressure +/- 50% preanesthetic value = 0

**Consciousness**
- Fully awake = 2
- Arousal to verbal stimuli = 1
- Not responding = 0

**Color**
- Pink = 2
- Pale, dusky, blotchy, jaundiced, other = 1
- Cyanotic = 0

**TOTAL SCORE**
APPENDIX F

UAB INFORMED CONSENT AND APPROVAL FORM
Informed Consent Form

TITLE OF RESEARCH: Perioperative Music And Its Effects On Anxiety, Hemodynamics, And Pain In Women Undergoing Mastectomy.

INVESTIGATOR: Pamela Binns-Turner, MNA, CRNA, Doctoral Student, University of Alabama School of Nursing, University of Alabama at Birmingham

FACULTY ADVISOR: Lynda Harrison, RN, PhD, Professor, University of Alabama School of Nursing, University of Alabama at Birmingham

SPONSOR: UAB School of Nursing

Explanation of Procedures

You are being asked to participate in a research study designed to evaluate the effects of music listened before, during, and after a surgical breast removal (mastectomy) for breast cancer. Although preliminary studies of music played during the surgical period suggest that listening to music may have positive effects on patients' levels of anxiety, blood pressure, heart rate, and pain, there is a need for additional research to validate these preliminary findings.

If you qualify for the study, you will be randomly (like the flip of a coin) assigned to receive music through a music player and earphones. Both the group listening to music and the group not listening to music will wear the earphones. This will be a blinded study, which means that your nurses, doctors, and staff will not know if you are listening to music or not. You will receive your anesthesia from one of three nurse anesthetists who will follow standard anesthesia practice and will work under the supervision of the Director of the Department of Anesthesiology.

If you participate in the study, a researcher will visit you in the preoperative holding room and perform a general health assessment, including measurement of your blood pressure and heart rate. At this time you will be asked to complete a short form rating your level of anxiety and pain. These assessments will take approximately 15 minutes. After these assessments, the researcher will give you a music player and earphones and ask you to wear these until you are ready to leave the postoperative recovery room.

---

UAB - IRB
Consent Form Approval 5/02/07
Expiration Date 5/02/08

Participant Initials__________________

Page 1 of 5
(10/17/06)
If you are assigned to the music group, you will be asked to select the type of music that you want to listen to, and the music will be started at this time.

The volume control on the music player has been tested and the volume is preset at a safe and acceptable hearing level to protect you from potential damage of the ear. The music will continue until you are ready to leave the postoperative recovery room. Information that is routinely recorded on your medical record during surgery and in the postoperative recovery room (such as your blood pressure, heart rate, and medications administered) will be collected for this study. When you are awake and alert in the postoperative recovery room, a researcher will again ask you to complete the short form measuring your anxiety, as well as a form rating your level of pain. If surgical complications should arise, your information will be removed from the study.

### Risks and Discomforts

There are no known risks of listening to music during surgery. There is a slight possibility that you may become more aware of your own level of anxiety by completing the anxiety measures, but if this occurs, you are free to discontinue your participation in the study.

### Benefits

You may not personally benefit from your participation in this research; however, your participation may provide valuable information to the medical community about the effects of music before, during, and after surgery.

### Alternatives

You may choose not to participate in this study.

### Confidentiality

The information gathered during this study will be kept confidential to the extent permitted by law. However, your doctor, the University of Alabama at Birmingham School of Nursing, and UAB’s Institutional Review Board (IRB) will be able to inspect your medical records and have access to confidential information that identifies you by a number only. The results of the treatment, including anxiety level, blood pressure, heart rate, level of pain, and amount of pain medication used may be published for scientific purposes; however, your identity will not be revealed.
Withdrawal Without Prejudice

You are free to withdraw your consent and to discontinue participation in this project at any time without prejudice against further care that you may receive at this institution.

Cost of Participation

There will be no cost to you from participation in the research. All study related equipment (music player, earphones, recorded music) will be provided for you during the study. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

Payment for Participation in Research

You will be given a thank you gift of a music CD for agreeing to participate in the study. Should you withdraw from the study, you may keep the thank you gift.

Payment for Research-Related Injuries

UAB has made no provisions for monetary compensation in the event of injury resulting from the research, and in the event of such injury, treatment is provided, but is not free of charge.

Questions

If you have any questions about the research or a research related injury, Pamela Binns-Turner, CRNA will be glad to answer them. Ms. Binns-Turner’s number is (731) 661-5236. Ms. Binns-Turner may also be reached after hours by her cell phone at (731) 267-9987. You may also contact Ms. Binns-Turner’s faculty advisor, Dr. Lynda Harrison at (205) 934 6787. If you have questions about your rights as a research participant, you may contact Ms. Sheila Moore, Director of the Office of the Institutional Review Board for Human Use (IRB). Ms. Moore may be reached at (205) 934-3789 or 1-800-822-8816, press the option for an operator/attendant and ask for extension 4-3789 between the hours of 8:00 a.m. and 5:00 p.m. CT, Monday through Friday.
Appendix F

**Legal Rights**

You are not waiving any of your legal rights by signing this consent form.

**Signatures**

Your signature below indicates that you agree to participate in this study. You will receive a copy of this signed informed consent.

Signature of Participant  
Date

Signature of Investigator  
Date

Signature of Witness  
Date

Participant Initials_____________________

Page 4 of 5
University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION
FOR RESEARCH

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant name: _____________________________
UAB IRB Protocol Number: F060123001

Research Protocol: Perioperative music and its effects on anxiety, hemodynamics, and pain in women undergoing mastectomy.
Principal Investigator: Pamela Binns-Turner, MNA, CRNA
Sponsor: UAB School of Nursing

What health information do the researchers want to use? All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, The Children’s Hospital of Alabama, Callahan Eye Foundation Hospital and the Jefferson County Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____________________________ Date: __________
or participants’ legally authorized representative: _____________________________ Date: __________
Printed Name of participant’s representative: _____________________________ Relationship to the participant: _____________________________
Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56 and ICH GCP Guidelines. The Assurance became effective on November 24, 2003 and expires on February 14, 2009. The Assurance number is FWA00005960.

Principal Investigator: BINNS-TURNER, PAMELA G
Co-Investigator(s): 
Protocol Number: F060123001
Protocol Title: Perioperative Music and Its Effects on Anxiety, Hemodynamics, and Pain in Women Undergoing Mastectomy

The IRB reviewed and approved the above named project on 5/2/2007. The review was conducted in accordance with UAB’s Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received FULL COMMITTEE review.

IRB Approval Date: 5/2/2007
Date IRB Approval Issued: 5/03/07
Identification Number: IRB00000196

Ferdinand Uritaler, M.D.
Chairman of the Institutional Review Board for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.
APPENDIX G

CONSENT FOR RESEARCH STUDY AND APPROVAL FORM
JACKSON-MADISON COUNTY GENERAL HOSPITAL
Appendix G

Consent for Research Study

TITLE OF RESEARCH: Perioperative Music And Its Effects On Anxiety, Hemodynamics, And Pain In Women Undergoing Mastectomy.

IRB# 464 Version Date of Consent 12/29/06

Name of Participant_____________________________ Age________________

Purpose of the Study

You are being asked to participate in a research study designed to evaluate the effects of music listened before, during, and after a surgical breast removal (mastectomy) for breast cancer. Although preliminary studies of music played during the surgical period suggest that listening to music may have positive effects on patients’ levels of anxiety, blood pressure, heart rate, and pain, there is a need for additional research to validate these preliminary findings. There will be approximately 40 participants enrolled in this study. This study will be performed in the peri-surgical areas (pre-anesthesia unit, operating room, recovery room) for the length of time you are in these areas at Jackson-Madison County General Hospital.

Procedure

If you qualify for the study, you will be randomly (like the flip of a coin) assigned to receive music through a music player and earphones. Both the group listening to music and the group not listening to music will wear the earphones. This will be a blinded study, which means that your nurses, doctors, and staff will not know if you are listening to music or not. You will receive your anesthesia from nurse anesthetists who will follow standard anesthesia practice and will work under the supervision of their supervising anesthesiologist.

If you participate in the study, a researcher will visit you in the preoperatively and perform a general health assessment, including measurement of your blood pressure and heart rate. At this time you will be asked to complete a short form rating your level of anxiety and pain. These assessments will take approximately 15 minutes.

If you are assigned to the music group, you will be asked to select the type of music that you want to listen to, and the music will be started at this time. You will be asked you to wear the headphones from this point until you are ready to leave the postoperative recovery room.

The volume control on the music player has been tested and the volume is preset at a safe and acceptable hearing level to protect you from potential damage of the ear. The music will continue until you are ready to leave the postoperative recovery room. Information that is routinely recorded on your medical record during surgery and in the postoperative recovery room (such as your blood pressure, heart rate, and medications

IRB

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APPROVED

Participant Initials________
Appendix G

administered) will be collected for this study. When you are awake and alert in the postoperative recovery room, a researcher will again ask you to complete the short form measuring your anxiety, as well as a form rating your level of pain. If surgical complications should arise, your information will be removed from the study. There is no follow up visit necessary at the conclusion of your participation in this study.

Risks or Discomforts

None - there are no known risks of listening to music during surgery. There is a slight possibility that you may become more aware of your own level of anxiety by completing the anxiety measures, but if this occurs, you are free to discontinue your participation in the study if you wish.

Benefits

You may not personally benefit from your participation in this research; however, your participation may provide valuable information to the medical community about the effects of music before, during, and after surgery.

Alternative Procedures

You may choose not to participate in this study.

Confidentiality

The information gathered during this study will be kept confidential to the extent permitted by law. This includes preoperative medical history and physical exam findings, blood pressure, heart rate, anxiety and pain levels, and other specific information such as years of education, level of spirituality, previous music experience, etc. However, your doctor, the University of Alabama at Birmingham School of Nursing, Pamela Binns-Turner (Principal Investigator), and the Jackson-Madison County General Hospital Institutional Review Board will be able to inspect your medical records and have access to confidential information that identifies you by a number only. The results of the treatment, including anxiety level, blood pressure, heart rate, level of pain, and amount of pain medication will be used to examine the effects of music on mastectomy patients and may be published for scientific purposes; however, your identity will not be revealed. This information will be used for the duration of the research study. Personal Health Information (PHI) if disclosed in the future may not be protected by the Privacy Rule.

You have the right to revoke this authorization to release your confidential information. If you wish to revoke the authorization, you may do so by sending a written notification to Pamela Binns-Turner, PhDc, CRNA at 23 Larkwood Drive, Jackson, TN 38305. If you revoke this authorization, your participation in this study will be terminated upon receipt of the revocation.

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Participant Initials ________
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Cost of Participation

There will be no cost to you from participation in the research. All study related equipment (music player, earphones, recorded music) will be provided for you during the study. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner. You will be responsible to the cost of treatment in this study as you would be if not in this study. There will be no monetary payment for participation in this study.

You will be given a thank you gift of a music CD for agreeing to participate in the study. Should you withdraw from the study, you may keep the thank you gift.

You understand that in the event of physical injury resulting from the research procedures, in which you are to participate, no form of compensation is available. Medical treatment may be provided at your own expense of your health care insurer, which may or may not provide coverage. If you have questions, you should contact your insurer.

Questions

If you have any questions about the research or a research related injury, Pamela Binns-Turner, PhDc, CRNA will be glad to answer them. Ms. Binns-Turner’s number is (731) 661-5236. Ms. Binns-Turner may also be reached after hours by her cell phone at (731) 267-9987. If you have general questions about giving consent or your rights as a participant in this study, you can contact the Jackson-Madison County General Hospital Institutional Review Board Office at (731) 425-5087.

Voluntary Participation

Participation in this study is voluntary; refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled. I understand that I may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled. I understand that my participation may be terminated by the investigator.

Statement by person agreeing to participate in this study

[ ] I have read this consent form. All of my questions have been answered, and I freely and voluntarily choose to participate. I understand that I may withdraw at any time.

[ ] The material contained in this consent form has been explained to me verbally. All of my questions have been answered, and I freely and voluntarily choose to participate. I understand that I may withdraw at any time.

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Participant Initials__________
Appendix G

Signature of Participant
(or legally authorized representative)  Date - Time

Signature of Witness  Date - Time

Signature of Investigator  Date - Time

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APPROVED

Participant Initials
Appendix G

JACKSON-MADISON COUNTY GENERAL HOSPITAL
INSTITUTIONAL REVIEW BOARD NOTIFICATION OF APPROVAL

Principal Investigator: Pamela Binns-Turner, CRNA

Study/IRB #464- Perioperative music and its effects on anxiety, hemodynamics, and pain in women undergoing mastectomy.

Actions: Approval of protocol and consent
IRB approval will not expire, no renewal or follow up with IRB required

IRB Approval Stamp:  
IRB  
JAN 03 2007  
APPROVED

IRB Expiration Date Stamp:  
N/A

OPRR Compliance Statement:  
The Jackson-Madison County General Hospital Institutional Review Board has reviewed and approved this protocol and informed consent for the aforementioned study. The IRB is organized and operates according to the GCP and applicable laws and regulations as outlined in 21 CFR part 50, 21 CFR, Part 50, 21 CFR Part 312, and ICH E6. The IRB membership is confidential and is not released to outside parties. The OPRR Assurance Number of the IRB is FWA00003521.

James L. Craig, M.D., Chairman of the IRB  
1/3/07  
Date

Please note the following:

1. A copy of the contract must be on file in the IRB office before patient accrual begins. The J.M.C.G.H. IRB protocol number should be visible on the signature page.

2. All changes or amendments to the protocol or consent form require review and approval by the Institutional Review Board before implementation of the changes or amendments.

3. Any serious or unexpected event or toxicity that occurs to the patients you enroll in this study must be reported to the IRB. Any of these events should be reported verbally within 24 hours to the IRB office (425-5087) and a written report for the next scheduled IRB meeting must be completed. MedWatch or serious adverse event reports from the sponsor can be submitted to any IRB meeting and do not require verbal notification.

4. Failure to submit annual renewal forms before the expiration date mentioned above will result in the closure of the study by the IRB.
APPENDIX H

APPROVAL LETTER DR. CURRIE
Appendix H

January 3, 2006

Carol Dashiff, PhD
Chair, Nursing Graduate Programs
University of Alabama at Birmingham
1530 3rd Ave. S., NB 302
Birmingham AL 35294-1210

Dear Dr. Dashiff,

As a surgeon with Jackson Surgical Associates providing surgical services at Jackson-Madison Count General Hospital, it is with pleasure that I write to you expressing my support for the proposed research study at our facility “Perioperative Music and Its Effects on Anxiety, Hemodynamics, and Pain in Women Undergoing Mastectomy” by Pamela Binns-Turner, MNA, CRNA. Our clinic will provide a recruitment flyer to women who might be eligible and allow them to have Ms. Binns-Turner contact them after their office visit to provide more information.

I look forward to contributing to the knowledge gained through this study. If you have any questions, please do not hesitate to contact me.

Sincerely,

Dean Currie, MD
Jackson Surgical Associates
395 Hospital Blvd.
Jackson, TN 38305
731-664-7395
APPENDIX I

APPROVAL LETTER DR. BROUSSARD
Appendix I

January 3, 2006

Carol Dashiff, PhD
Chair, Nursing Graduate Programs
University of Alabama at Birmingham
1530 3rd Ave. S., NB 302
Birmingham AL 35294-1210

Dear Dr. Dashiff,

As a surgeon with Jackson Clinic providing surgical services at Jackson-Madison Count General Hospital, it is with pleasure that I write to you expressing my support for the proposed research study at our facility “Perioperative Music and Its Effects on Anxiety, Hemodynamics, and Pain in Women Undergoing Mastectomy” by Pamela Binns-Turner, MNA, CRNA. Our clinic will provide a recruitment flyer to women who might be eligible and allow them to have Ms. Binns-Turner contact them after their office visit to provide more information.

I look forward to contributing to the knowledge gained through this study. If you have any questions, please do not hesitate to contact me.

Sincerely,

Heath J. Broussard, MD
Jackson Clinic
616 West Forest Avenue
Jackson, TN 38301
731-422-0330
APPENDIX J

OFFICE INFORMATION FLYER
INTERESTED IN PARTICIPATING IN A STUDY EVALUATING THE EFFECTS OF LISTENING TO MUSIC DURING SURGERY?

Women diagnosed with breast cancer who plan to undergo mastectomy are being recruited to participate in a research study to study the effects of a music intervention on anxiety, blood pressure, heart rate, and post surgical pain.

Women who participate in the study will be assigned to one of two study groups: women in one group will listen to music during the surgical experience, and women in the other group who will not listen to the music. Findings from the study will provide information about whether music during the surgical experience has beneficial effects on heart rate, blood pressure, anxiety levels, and pain. Women in both groups will be asked to complete a short measure of their level of anxiety before and after surgery, and they will be asked to rate their level of pain in the surgical recovery room. In addition, the researcher will collect information from the participants’ medical records. Women in both groups will receive a complimentary music CD as appreciation for their participation.

To participate you must be:

- Between the ages of 20-70
- Healthy with less than three major health problems (for example: hypertension, smoking history, or diabetes)
- No history of psychiatric disorders (for example: bipolar disorder, schizophrenia)
- No hearing impairment

If you are interested in learning more about the study, please contact your nurse
APPENDIX K

PERMISSION TO CONTACT PATIENT
PERMISSION TO CONTACT PATIENT

TITLE OF RESEARCH: Perioperative music and its effects on anxiety, hemodynamics, and pain in women undergoing mastectomy.

INVESTIGATOR: Pamela Binns-Turner, MNA, CRNA
Doctoral Student, University of Alabama School of Nursing, University of Alabama at Birmingham

You are being asked if you may be contacted by telephone by Pamela Binns-Turner, a nurse anesthetist who is also a doctoral student in the School of Nursing at the University of Alabama at Birmingham. The purpose of the study is to evaluate the effects of listening to music through earphones before, during, and after a surgical breast removal (mastectomy) for breast cancer. Your signature below indicates you give your permission to be contacted by Ms. Binns-Turner so that she can explain the study to you and determine whether you might be interested in participating in the study during your surgery.

I agree for Ms. Binns-Turner to telephone me to discuss the study about music during surgery for breast cancer.

Printed name____________________________
Signature______________________________Date____________
Phone number___________________________
Most convenient time to call______________
APPENDIX L

PATIENT INFORMATION BROCHURE
Appendix L

Pamela Binns-Turner, PhDc, CRNA

Pamela has been a staff CRNA at JMCGH for 1.5 years and is completing her doctoral study in Nursing at the University of Alabama at Birmingham (UAB). She also serves as the Assistant Program Director for Union University’s Nurse Anesthesia Track.

Purpose of Study

To examine if listening to music before, during, and after surgery will help lower anxiety, blood pressure, heart rate, and pain for women having mastectomy surgery.

Perioperative Music and Its Effects on Anxiety, Hemodynamics, and Pain in Women Undergoing Mastectomy

A study to identify ways to help women who are facing breast surgery

For more information contact:

Pamela Binns-Turner, PhDc, CRNA
(Certified Registered Nurse Anesthetist)
1050 Union University Dr.
Jackson, TN 38305
731-554-2387 (H)
731-661-5236 (O)
731-267-9987 (C)
What is this study about?

This study is designed to evaluate the effects of listening to music before, during, and after a surgical breast removal (mastectomy) for breast cancer.

- Preliminary studies suggest that listening to music may have positive effects on anxiety, blood pressure, heart rate, and pain.
- Additional research is needed to validate these preliminary findings.

What will I be involved in if I participate in the study?

- Random assignment to listen to music through earphones or to wear earphones without listening to music before, during, and after your surgery.
- The researcher will visit you in the preoperative holding room to assess your health and ask you to complete a short form rating your level of anxiety.
- The researcher will give you a music player and earphones and ask you to wear them throughout the surgical process.
- The researcher will ask you to complete the short form measuring anxiety and pain when you are alert and awake in the recovery room.

Breast Cancer Facts

- In the United States, breast cancer strikes about 1 woman in every 1000, and many of these women require surgical breast removal (mastectomy).
- There is a need for ongoing research to identify the best ways to help to reduce pain and anxiety following mastectomy surgery.