Effects of duration of selected music as an intervention on postoperative pain in open-heart surgery patients during chair rest on the first postoperative day

Tzu-Ting Shu

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EFFECTS OF DURATION OF SELECTED MUSIC AS AN INTERVENTION ON
POSTOPERATIVE PAIN IN OPEN-HEART SURGERY PATIENTS DURING CHAIR REST
ON THE FIRST POSTOPERATIVE DAY

By

Tzu-Ting Shu, BSN, RN

Thesis

Submitted to the School of Nursing
College of Health and Human Services
Eastern Michigan University
In partial fulfillment of the requirement for the degree of:

MASTER OF SCIENCE IN NURSING

Thesis Committee:
Lorraine M. Wilson, PhD, RN: Chair
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December 16, 2010
Ypsilanti, Michigan
THESIS APPROVAL

Effects of Duration of Selected Music as an Intervention on Postoperative Pain in Open-heart Surgery Patients during Chair Rest on the First Postoperative Day

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Dedication

This study is dedicated to God, first of all. Without him, I would not have been able to finish this.

This study is also dedicated to my dad, who encouraged me to pursue nursing as my career and had taught me to persevere but cannot share this joy with me, and my mom, who supports me in many ways to complete advanced nursing degree.

I would like to dedicate this study to my church, King of Love. They have encouraged me and been walking with me through difficult times with grace and love.
Acknowledgement

I would like to express my sincere gratefulness to several people. This study would not have been possible without their help. First of all, I would like to give thanks to Dr. Ruth Moore at St. John Providence IRB; Administrative Nursing Director, Julie Gorczyca; Clinical Practice Manager of SICU, Brooke Johnson; and all staff members of SICU at St. John Providence.

Many thanks and appreciation to my advisors: Dr. Lorraine Wilson and Dr. Tsu-Yin Wu, who have supported me and given me guidance throughout my years at Eastern Michigan University.
Abstract

The purpose of this study was to test the effects of selected music on reducing postoperative pain and use of pain relief medications in open-heart surgery patients during chair rest on the first postoperative day. This study was conducted using a pretest-posttest experimental design. A convenience sample of 13 open-heart surgery patients from a metropolitan hospital in southeastern Michigan were randomly assigned to the music group (n = 6) and the control group (n = 7). T-test analysis showed that pain scores (numeric rating scale, NRS = 0-10) were lower in the music group than the control group after 30, 45, and 60 minutes of chair rest, and sense of well-being rated by using the visual analog scale (VAS = 0-100) was also higher in the music group at 60 minutes than the control group although the difference was not statistically significant. Optimal duration of music to reduce postoperative pain and the frequency of the use of pain medication could not be determined due to the small sample size. A replication study with a larger study group is recommended to ensure greater statistical power to test the usefulness of music as an adjuvant therapy in reducing postoperative pain.
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CHAPTER I

Introduction

Pain, the most common problem for patients after coronary artery bypass grafting or valve replacement, is caused by the stimulation of peripheral nerve endings in the muscles and tissue that have been cut and traumatized during surgery (Complementary and alternative medicine, 2005). The effective management of acute postoperative pain primarily relies on pharmacologic interventions, such as patient-controlled analgesic devices and spinal analgesics (Miaskowski, 1996). However, the use of nonpharmacologic strategies is considered as an adjuvant intervention for acute postoperative pain management (Miaskowski).

Music therapy has been utilized as an intervention in pain management for decades. The use of sedative music in combination with pharmacological treatment on pain control was strongly supported by the study of Voss, Good, Yates, Baun, Thompson, and Hertzog (2004). Phumdoung and Good (2003) also found that women who listened to soft music without lyrics for 3 hours had significantly less sensation and distress of labor pain than the control group. Therefore, the effects of music therapy on pain management in various types of population have been supported by numerous research studies.

*Background and Significance of the Study*

Effective management of postoperative pain can be a vital factor in overall recovery; pain may affect patients’ recovery by causing them to be unwilling to perform activities (Zimmerman, Nieveen, Barnason, & Schmaderer, 1996). Although pharmacologic interventions have been utilized as a main way for pain control, none of them provides complete pain relief; most of the pharmacologic agents have deleterious side effects (Miaskowski, 1996). Yet music therapy, as a non-invasive intervention, reduces the use of analgesics and pain level without giving patients
side effects. Koch et al. (1998), Kemper & Danhauer (2005) indicated that playing music during and after surgery reduced the use of sedatives, anxiolytics and analgesics. Therefore, understanding how to intervene with music therapy helps patients manage pain more effectively and decreases the side effects caused by pain relievers.

Several research studies concerning effective techniques of administering music therapy have been done. Most studies were about the effects of different types of music and preferred music; nonetheless, few studies were conducted to examine how different durations of music influence pain level. Thus, knowing the optimal amount of time of music therapy would assist health care professionals with a more effective way to administer the intervention.

Research Purpose

According to Broscious (1999), if music is used to decrease procedure or postoperative pain, research related to the most effective time to start the music in relation to the start of the procedure and the most appropriate length and frequency of music must be determined. The research study conducted by Voss et al. (2004) found that listening to music for 30 minutes reduced the level of pain in patients after open-heart surgery. However, Macdonald, Mitchell, Dillon, Serpell, Davis, and Ashley (2003) indicated that participants who received music intervention varying between 2 and 6 hours a day had no significant difference in the level of pain from those who did not listen to any music. Thus, it is imperative to obtain empirical data on whether the duration of music impacts the effects of pain management. The purpose of this study was to examine how the duration of the music impacts the effect of music as an intervention in pain management in post open-heart surgery patients during chair rest on the first postoperative day.
Research Questions

The specific research questions are:

1. Do postoperative open-heart surgery patients who receive selected music as an intervention have significantly different scores on the pain numeric rating scale (NRS) and visual analog scale (VAS) during chair rest on the first postoperative day compared to the control group?

2. Do postoperative open-heart surgery patients who listen to selected music during chair rest on the first postoperative day for longer than 45 minutes show significant difference in self-reported pain on the pain NRS compared to the control group who do not listen to music?

3. Do postoperative open-heart surgery patients who listen to 15-minute, 30-minute, and 45-minute selected music during chair rest on the first postoperative day use pain relief medications significantly less frequently than the control group who do not listen to music during the chair rest?
CHAPTER II
Review of Literature

Relevant theoretical and empirical literature was reviewed. Theoretical literature included pain theories, acute pain management, and music therapy as an intervention for pain control. However, empirical literature covered research studies on music therapy for pain control in various clinical settings.

Theoretical Research Literature

Pain Theories

Gate Control Theory. Melzack and Wall in 1965 created the gate control theory. In this theory, it is as if a gate were present at the level of the dorsal horn in the spinal cord. The gate controls the passage of the nociceptive pain message to the central nervous system sensory cortex; when the gate is fully closed, the message can go no further than the axon terminal of the nociceptive neuron in the spinal cord (Toates, 2007). Melzack and Wall (1996) also indicated that the action people take to reduce pain affects brain centers serving attention, cognition, and emotion that activate descending nerve impulses to close the “gate” located in the dorsal horn of the spinal cord (cited in Phumdoung & Good, 2003). The “gate” is open and closed based on the amount of noxious stimulation, the amount of sensation in other peripheral fibers, and the messages that descend from the brain (Gfeller, 1999).

Endogenous Analgesic Theories. The discovery of endogenous opiates, known as enkephalins and endorphins, in the periaqueductal gray area of the brain, and opioid receptors in the central nervous system support the gate control theory (Good, 2004; Oborski, 1996). Descending control of noxious impulse transmission is known to occur through neurons, neurotransmitters, opioid receptors and indirectly through the sympathetic nervous system.
(Good, 2004). Instead of solely in lamina II of the dorsal horn, the “gate” now is referred to repeated modulation, filtering, and abstraction of input in many areas of the central nervous system through numerous mechanisms (Melzack, 1982, cited in Good, 2004).

*Acute Pain Management Guidelines.* According to the Acute Pain Management Guideline Panel (1992), there are four major goals of acute pain management:

- To reduce the incidence and severity of acute postoperative or posttraumatic pain.
- To educate patients about the need to communicate about their unrelieved pain.
- To enhance patient comfort and satisfaction.
- To reduce postoperative complications and, in some cases, shorten stays after surgical procedures.

From the findings of more than 7,000 published studies, the Acute Pain Management Guideline Panel (1992) concluded:

- Most of the 23 million surgical cases each year do not get adequate relief. These patients continue to feel moderate to severe pain.
- Providing patients with pain medicine only “as needed” can result in prolonged delays because patients may delay asking for help.
- Aggressive prevention of pain is better than treatment because, once established, pain is more difficult to suppress.
- Patients have a right to treatment that includes prevention of or adequate relief from pain. Physicians need to develop pain control plans before surgery and inform the patient what to expect in terms of pain during and after surgery.
• Fears of postsurgical addiction to opioids are generally groundless.
• Patient-controlled medication via infusion pumps is safe.

*Music Therapy Intervention for Pain Control.* The principle of music therapy is based on the gate control theory of pain. While pain stimuli are occurring, the central nervous system is also receiving other stimuli, but because the central nervous system processes a limited number of messages at the same time, these sensations compete with pain stimuli (Gfeller, 1999). Therefore, if conscious awareness (attention) can be focused on a strong, positive stimulus such as music rather than pain, the perception of pain could be attenuated (Gfeller, 1999).

*Empirical Research Literature*

A four-group randomized clinical trial (RCT) was conducted by Hekmat and Hertel (1993) to examine the effect of preferred music on alleviating cold-pressor pain. Group 1 listened to their preferred music; Group 2 was exposed to non-preferred music; Group 3 submerged their hands in ice water with the presence of the experimenter without listening to any music, and Group 4 submerged their hands without the presence of the experimenter and music. The results supported the researchers’ conclusion that participants listening to preferred music had a significant increase of pain tolerance.

The research done by Zimmerman et al. (1996) was to determine the effects of second and third day postoperative music intervention (music, music video, and scheduled rest) on pain and sleep in patients who had coronary artery bypass grafting (CABG) surgery. The results showed that pain decreased during each session, but there was no difference between those three groups. However, the evaluative component of the McGill Pain Questionnaire (MPQ) demonstrated that on the second day after CABG surgery, participants in the music group had significantly lower evaluative pain scores than the resting group.
Siedliecki and Good (2006) examined the effect of music on power, pain, depression, and disability for patients with nonmalignant chronic pain, and the results showed that participants who received researcher-provided music (standard music) and subject-preferred music (patterning music) had significantly more power and less pain than the control group. However, there was no significant difference found between the two music groups.

In the three-group (sedative music, schedule rest, control) RCT (N = 61) conducted by Voss et al. (2004), the results supported their hypotheses that less pain was reported in participants who experienced either 30-minute music chosen by the participants than scheduled rest sessions and the treatment-as-usual group after open-heart surgery. In addition, Voss et al. (2004) also found that most participants in the music group remained with their eyes closed during the 30 minutes. When interviewing the participants later, 47% reported that they used music just to relax. Six percent of the participants used the music only as a distraction.

Macdonald et al. (2003) conducted two RCT research studies on the effects of music on postoperative pain reduction. In both experiments, experimental groups were encouraged to listen to selected music as much as possible during the 4-hour postoperative assessment on the day of operation. It was found that there was no significant difference in pain levels between experimental and control groups.

In Winters’ research study in 2005 on the effect of timing and frequency of relaxing music during acute recovery from acute myocardial infarction, five different groups of participants received music once per day, twice per day, three times per day, quiet rest, and usual treatment. The findings of the study showed that all the music groups had significant improvement for all dependent variables (heart rate, respiratory rate, blood pressure, myocardial oxygen demand, and
state of anxiety). Thus, the effects of music as an intervention were supported. Nevertheless, the differences between the music groups were not addressed.

Summary

Pain is a complex and common condition when patients seek assistance in hospitals. Successful acute pain management during the postoperative stage could be beneficial for patients’ recovery. The research literature showed that music therapy is effective in reducing various types of pain. Therefore, it is essential to have continual research to determine the outcome of music therapy. Furthermore, research on the factors which could influence the effect of music therapy such as the length of music is also imperative in order to improve the quality of music therapy on pain management.
CHAPTER III

Framework

Framework Development

The conceptual framework used in this study was the gate control theory (Fig. 1). “Pain is a phenomenon that is both psychological and biological” (Toates, 2007, p. 2); the gate control theory provides biological and psychological understanding of pain therapy (Toates). The biological aspect of the theory explains the role of music as a positive stimulus to compete with the negative stimulus, pain. Using music to relax and distract could inhibit transmission of noxious impulses (Phumdoung & Good, 2003).

According to Phumdoung and Good (2003), one of the propositions of gate control theory is that pain is an interaction of sensory, motivational, and central control components, and the sensory component stimulates motivational and cognitive processes to cause emotional responses known as the affective component of pain. The psychological approach of the gate control theory illustrates that psychological factors can block the incoming information from the pathway descending from the brain to the gate in the nociceptive pathway (Toates, 2007).

The gate control theory of pain provides a plausible rationale for the potential efficacy of the nonpharmacological adjuvants of pain control (Barbour, McGuire, & Kirchhoff, 1986 as cited in Zimmerman et al., 1996). Thus it is a suitable theory for the framework of this study. The desired outcome of music therapy is that music as a stimulus and a positive effect on emotions would prohibit the transmission of pain and result in the reduction of pain level.
Definitions

Pain. “Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage and described in terms of such damage” (International Association for the Study of Pain, 1979; Merskey, 1964 as cited in Cook, 1998); it is a subjective phenomenon, and much variation exists among patients (Zimmerman et al., 1996). To measure pain intensity, several tools could be chosen. In this study, the pain numeric rating scale (NRS) will be used (Appendix B).

Pain Management. Pain management is ”the process of providing medical care that alleviates or reduces pain” (MedicineNet.com, n.d.). The treatment includes both pharmacological and nonpharmalological adjuvant therapy.

Nonpharmacological Adjuvant Therapy. The theoretical definition of nonpharmacological adjuvant therapy is “complementary nursing therapies: relaxation, music, imagery, massage, or
cold for pain relief” (Good, 2004, p 64). However, the operational definition is “technique, dose, frequency given, and mastery of use” (Good, 2004, p. 64).

Music Therapy. According to Docchterman and Bulechek (2004), music therapy is “using music to help achieve a specific change in behavior, feeling, or physiology” (cited in Winters, 2008, p. 524). Music can be sedative music, favorite music, fast or slow tempos, or instruments (Good, 2004).

**Formulation of Hypotheses**

The hypotheses of this study are:

H1 Postoperative open-heart surgery patients who listen to selected music during chair rest on the first postoperative day will have significantly lower scores on the pain NRS (at 15, 30, and 45 minutes) and higher posttest scores on VAS than the control group.

H2 Postoperative open-heart surgery patients who listen to selected music during chair rest on the first postoperative day for longer than 45 minutes will show no significant difference in self-reported pain on the pain NRS compared to the control group who do not listen to music.

H3 Postoperative open-heart surgery patients who listen to 15-minute, 30-minute, and 45-minute selected music during chair rest on the first postoperative day would use pain relief medications significantly less frequently than the control group who do not listen to music during the chair rest.
CHAPTER IV
Methods and Procedures

Research Design

An experimental, pretest and posttest two group design was utilized for this randomized clinical trial (RCT). According to Burns and Grove (2005), experimental study designs provide the greatest amount of control possible to test hypotheses that the intervention causes the desired outcome; however, they exert much effort to control variance (See Fig. 2).

**Fig. 2** The Intervention of the Control Group and the Experimental Group.

In this RCT, numeric rating scale (NRS) to assess pain and visual analog scale (VAS) to assess how the participants feel overall was administered as the pretest (prior to chair rest) and posttest (after the intervention). The two groups for this study were the control group and the music group. The control group had the treatment as usual. This study was conducted on all participants during chair rest on the first postoperative day. Chair rest is an activity in which the
patient is in a sitting position in a chair with the back elevated between 45 and 90 degrees, and the lower extremities are in either in a dependent position on the floor or elevated on a footrest (Voss, 2001, as cited in Voss, 2003). Posttests for both groups were given at 15 minutes, 30 minutes, 45 minutes, and 60 minutes. The options of music were jazz, rhythm and blues, musicals, rock and roll, gospel, Christian worship music, popular music, classical, sedative music, and country music. Participants were randomly assigned to either the control or music group from a computer-generated pre-prepared randomization list. Participants were able to adjust the volume of the music anytime. In addition, participants were asked to pay attention to the music. During the intervention, participants were not allowed to talk on the phone, and visitors were kept outside of participants’ rooms for the entire procedure.

**Rationale for Research Design**

The purpose of this research study was to examine the effects of different durations of selected music on pain management in postoperative open-heart surgery patients during chair rest on the first postoperative day. It was hypothesized that the 15-minute, 30-minute, and 45-minute selected music group would show reduced pain levels in open-heart surgery patients, but selected music left on longer than 45 minutes would not decrease patients’ pain level. Consequently, it was expected that participants who received 15-minute, 30-minute, and 45-minute selected music would have lower scores on the pain NRS than the control group. However, the experimental group who listened to music for 60 minutes would not have significantly different scores on NRS than the control group. A RCT study design allows the researcher to collect data prior to and after the intervention to evaluate the relationships between the experimental (music) group and the control group. In addition, this design was also used to test the author’s hypotheses that different durations of selected music cause different desired
outcome. Burns and Grove (2005) indicated that well-designed, well-conducted, controlled clinical trials provide a strong level of evidence for evidence-based practice. For these reasons, RCT study design is chosen for this research study.

**Sampling Design and Setting**

The sampling design selected for this study was a nonprobability convenience sampling method. The target population was obtained from a surgical intensive care unit in a large medical center in southeastern Michigan.

Eligibility criteria for inclusion were:

1. First postoperative day after an open-heart surgery.
2. Stable condition and oriented.
3. Absence of hearing impairment.
4. Ability to follow commands and understand and read English.

According to the criteria of exclusion in the study conducted by Voss et al. (2004), patients with a femoral artery sheath in place after surgery should be excluded because 6 to 8 hours bed rest is necessary to prevent hemorrhage after removal. Therefore, in this study, patients who have retained a femoral artery sheath in place were excluded from the study.

**Rationale for Sampling Design**

Convenience sampling was used in this study because it is cost-effective and potential participants are readily accessible. In addition, convenience sampling provides a means to conduct research on topics that could not be examined through the use of random sampling; thus, it provides a means of attaining information in unexplored areas (Burns & Grove, 2005).

On the downside, nonprobability sampling does not allow every element of the population to be included in the sample; therefore, it increases the tendency to obtain samples that are not
representative of the target population (Burns & Grove, 2005). Convenience sampling is considered a weak approach to sampling owing to reduced opportunity provided to control for biases (Burns & Grove, 2005).

**Ethical Considerations**

Permission to conduct this study was sought by Eastern Michigan University CHHS Human Subjects Review Committee and from the hospital Institutional Review Board (see letters of approval in Appendix A). Participation in this research study was voluntary. Potential participants who met the inclusion criteria for the study were asked to participate in the study after being given an oral explanation of the study (Appendix C). If the participant agreed to participate, he or she would be asked to sign a written consent form (Appendix D). Consent forms were signed before any intervention started. Participants were informed of the right to withdraw at any time without penalty. Music as an intervention was considered to benefit participants who were in the experimental (music) group. The selected music was also considered to reduce their pain level during chair rest on first postoperative day. Moreover, as a part of this research, participants contributed to discovering and refining nursing knowledge. The findings of this research provided researchers with more effective interventions for future postoperative pain management.

Music therapy is a noninvasive intervention. It is not likely to cause serious physical harm to participants. According to Winters (2005), no applicable published research was found indicating that music therapy could be harmful. However, music therapy could cause stress and discomfort if not administered carefully. The American Cancer Society (n.d.) stated that “musical intervention by untrained people can be ineffective, or even cause increased stress and discomfort.”
Participants’ right to self-determination, privacy, anonymity and confidentiality, fair treatment, and protection from discomfort and harm was protected. As mentioned above, participants were informed of their right to determine whether to be a part of this research and discontinue participation at any time. The data collected from participants were stored in a locked file in order to assure that confidentiality was protected. Besides that, each questionnaire was coded so that no link to names could be found. Each participant received fair treatment. The researcher and participants had a specific agreement about participants’ participation involved and what the role of the researcher will be (Burns & Grove, 2005). The researcher did not change any activity or procedure without participants’ permission (Burns & Grove, 2005). To avoid the discomfort or stress caused by music therapy, before this study was conducted, consultation of music therapists and the researchers who had conducted previous studies on music therapy was held.

Measurement Methods

An ordinal-scale measurement, numeric rating scale (NRS), was used to measure the intensity of postoperative pain. It is a 11-point numeric rating scale with 0-10 vertical or horizontal scale (0 = no pain, 10 = the worst possible pain); participants rated the intensity by verbalizing a number based on their subjective feelings of pain. Also, a visual analog scale (VAS) was used to assess participants’ state of well-being prior to chair rest (pretest) and 60 minutes after the chair rest began.

The research study conducted by Farrar, Troxel, Stott, Duncombe, and Jensen (2008), using a patient-rated 0-10 NRS, was revealed to be both reliable and valid. The stability of NRS was evaluated by the test-retest method. The test-retest reliability analysis in the study by Farrar et al. (2008) found an interclass correlation coefficient (ICC) of 0.83. According to Fleiss, Levin, and
Paik (2003), an ICC of 0.40 to 0.59 is considered “fair,” while the value of 0.60 to 0.75 is considered “good,” and those values greater than 0.75 are considered “excellent” (as cited in Farrar et al., 2008). Therefore, the NRS is a reliable instrument which provides “excellent” consistency.

Content-related validity is examined by literature representative of the relevant populations and content experts (Burns & Grove, 2005). The research studies of Farrar, Berlin, and Strom (1993) and Jensen, Tuner, and Romano (1999) both supported that 0-10 NRS for measuring change in pain had reliability and validity (as cited in Farrar et al., 2008). In addition, the study conducted by Downie, Leatham, Rhind, Wright, Branco, and Anderson (1978) also found evidence that an 11-point (0-10) NRS performs better than both a 4-point simple descriptive scale or a visual analogue scale (VAS) to assess pain.

Data Collection

Demographic and Descriptive Variables. Demographic and descriptive variables were collected to determine the differences between the experimental (music) and control groups. The variables included age, gender, ethnicity, medical and surgical diagnosis and history, medications received within the first eight hours, and time of chair rest initiation (Voss, 2003; See Appendix E).

Procedure (Fig. 3). The researcher explained the purpose of the study to the participants (See Appendix C). The anticipated outcomes were not addressed to avoid influencing participants’ responses. The researcher also explained participants’ right to self-determination, privacy, anonymity and confidentiality, fair treatment, and protection from discomfort and harm. After patients agreed to participate in the study, the researcher had them sign a consent form. The researcher read the verbal instruction on how to use the music to participants and explained the
approximate time for finishing the demographic questions, the pain NRS, and VAS. It was estimated that the demographic questions took about 5 minutes and the pain NRS and VAS took about 30 seconds to complete. Participants were asked to complete a demographic data sheet, and the pretest examined by the pain NRS was also given at the same time. After randomly being assigned to groups, participants assigned to the music group selected the type of music they preferred to use during the chair rest. Participants were able to adjust the volume of the music anytime. In addition, participants were asked to pay attention to the music. During the intervention, participants were not allowed to talk on the phone; visitors were kept outside of participants’ rooms for the entire procedure. Participants’ responses were recorded. Internal validity of a study is affected by the mortality threat when those who refuse to participate are different in some way from those who choose to participate (Burns & Groves, 2005). Thus, the numbers of patients who refused and the reason they refused to participate in the study were recorded.

Participants were informed that the results of the study would be shared with Eastern Michigan University and possibly published in nursing research journals. After collecting data, the researcher offered her contact information to participants.
Data were entered into an Excel file, which was imported into Statistical Package Social Sciences (SPSS), the statistical program that was used.

Demographic variables were characterized by descriptive statistics. Pain ratings from 0 to 10 and VAS from 0 to 100 were analyzed using t-test analysis. Demographic covariates were
accounted using Chi-square analysis. Anecdotal notes were utilized to determine possible reasons for the statistical findings.
CHAPTER V

Results

This chapter presents the results of the study on the effects of duration of music as an intervention on postoperative pain in open-heart surgery patients on the first postoperative day. The sample demographics were presented first, followed by the results for the research questions.

Description of the Sample

Analyses of the research hypotheses were conducted after 13 participants were enrolled in and completed the study. The participants randomly assigned to the music group listened to the selected music for 60 minutes during chair rest. The participants assigned to the control group did not receive any music during chair rest. The dependent variables were pain scores and state of well-being scores. Pain scores were measured prior to chair rest and then 15 minutes, 30 minutes, 45 minutes, and 60 minutes after chair rest began, by using numeric rating scale (NRS), 0-10, and state of well-being were measured prior to and 60 minutes after chair rest began by using the visual analog scale (VAS). The dependent variables of the two groups (music and control) were compared by using the Statistic Package of the Social Sciences (SPSS), version 18 software.

The characteristics of the music group and the control group are listed in Table 1. Among 13 participants, ages 46-85, six were randomly assigned to the music group and seven to the control group. Chi-square analysis was used to examine the differences in the characteristics between the music and control groups.

Possible Confounding Variables

Possible confounding variables with the baseline pain scores and the rating of sense of well-being on the visual analog scale were compared. Because the confounding variables (e.g. age,
gender, race, occupation, educational background, marital status, the use of pharmacological agents prior to the study, previous numbers of chair rests received, time between the end of surgery and the chair rest, and the use of complementary and alternative therapy) may have affected participants’ pain scores and the sense of well-being, these variables were investigated at the baseline. No significant difference was found in regard to age, gender, race, occupation, educational background, and marital status between the two groups.

Some participants chose to receive foot massage by a certified massage therapist from the hospital as a complementary and alternative therapy (CAT). No significant difference was found between the music and control groups as to whether they had received foot massage before chair rest (Table 1). The time between the end of the surgery and the chair rest and the numbers of previous chair rests received were recorded and analyzed as well. No significant difference between the two groups was found on the time between the end of the surgery and the chair rest and the numbers of previous chair rests received (Table 1).

Cardiovascular medications administered to both groups are described in Tables 2 and 3. Table 2 shows that there were no significant differences between the music and control groups on the use of cardiovascular medications eight hours prior to chair rest. These medications, including diuretics, angiotensin converting enzyme (ACE) inhibitors, anti-anginals, beta-adrenergic blockers, calcium channel blockers, vasodilators, anti-arrhythmics, and aspirin, were generally given no more frequently than every eight hours or twice a day. Table 3 shows that there were also no significant differences between the music and control groups on the use of pain medications four hours prior to chair rest. The pain medications included acetaminophen, hydrocodone, morphine, tramadol, and non-steroidal anti-inflammatory drugs (NSAID). These pain medications were generally ordered every two to four hours.
Table 1

**Characteristics of the Sample.**

<table>
<thead>
<tr>
<th></th>
<th>Music</th>
<th>Control</th>
<th>Statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 6</td>
<td>n = 7</td>
<td>Chi-Square</td>
</tr>
<tr>
<td><strong>Age (year)</strong></td>
<td>46-83</td>
<td>51-85</td>
<td>$x^2 (3) = 0.07$</td>
</tr>
<tr>
<td></td>
<td>M = 64.67</td>
<td>M = 64.14</td>
<td>p &lt; 1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>M = 64.38</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td>$x^2 (1) = 0.63$</td>
</tr>
<tr>
<td>Male</td>
<td>3</td>
<td>2</td>
<td>p = 0.43</td>
</tr>
<tr>
<td>Female</td>
<td>3</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td>$x^2 (1) = 0.63$</td>
</tr>
<tr>
<td>African America</td>
<td>3</td>
<td>2</td>
<td>p = 0.43</td>
</tr>
<tr>
<td>Caucasian</td>
<td>3</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
<td>$x^2 (1) = 0.26$</td>
</tr>
<tr>
<td>Work outside of home</td>
<td>1</td>
<td>2</td>
<td>p = 1.0</td>
</tr>
<tr>
<td>Unemployed</td>
<td>5</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><strong>Educational Background</strong></td>
<td></td>
<td></td>
<td>$x^2 (2) = 0.93$</td>
</tr>
<tr>
<td>High School</td>
<td>5</td>
<td>5</td>
<td>p = 0.63</td>
</tr>
<tr>
<td>Some College</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Graduate School</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
Table 1 (Continued)

*Characteristics of the Sample.*

<table>
<thead>
<tr>
<th></th>
<th>Music n=6</th>
<th>Control n=7</th>
<th>Statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never Married</td>
<td>1</td>
<td>0</td>
<td>$x^2 (3) = 2.94$</td>
</tr>
<tr>
<td>Married</td>
<td>4</td>
<td>4</td>
<td>$p = 0.40$</td>
</tr>
<tr>
<td>Divorce</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Widow</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Second Time Chair Rest</strong></td>
<td></td>
<td></td>
<td>$x^2 (1) = 1.04$</td>
</tr>
<tr>
<td><strong>Third Time Chair Rest</strong></td>
<td>1</td>
<td>3</td>
<td>$p = 0.31$</td>
</tr>
<tr>
<td><strong>CAT 2 hrs prior to Chair Rest</strong></td>
<td></td>
<td></td>
<td>$x^2 = 2.76$</td>
</tr>
<tr>
<td>Yes</td>
<td>2</td>
<td>0</td>
<td>$p = 0.10$</td>
</tr>
<tr>
<td>No</td>
<td>4</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td><strong>Time between the end of the surgery and Chair Rest (hrs)</strong></td>
<td>M = 23.6</td>
<td>M = 21.2</td>
<td>$t = 1.483$, $p = 0.166$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>SD = 3.011,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>M = 22.3</td>
</tr>
</tbody>
</table>
Table 2

*Between Groups Comparison on Use of Cardiovascular Medications Eight Hours prior to Chair Rest*

<table>
<thead>
<tr>
<th>Medication Type</th>
<th>Music (n=6)</th>
<th>Control (n=7)</th>
<th>Chi-Square</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE Inhibitors</td>
<td>2</td>
<td>1</td>
<td>$x^2(1) = 0.66, p = 0.42$</td>
</tr>
<tr>
<td>Anti-hypertensives</td>
<td>2</td>
<td>3</td>
<td>$x^2(1) = 0.12, p = 0.73$</td>
</tr>
<tr>
<td>Anti-anginals</td>
<td>1</td>
<td>1</td>
<td>$x^2(1) = 0.01, p = 0.91$</td>
</tr>
<tr>
<td>Beta-adrenergic Blockers</td>
<td>3</td>
<td>4</td>
<td>$x^2(1) = 0.07, p = 0.80$</td>
</tr>
<tr>
<td>Calcium Channel Blockers</td>
<td>1</td>
<td>1</td>
<td>$x^2(1) = 0.01, p = 0.91$</td>
</tr>
<tr>
<td>Diuretics</td>
<td>2</td>
<td>4</td>
<td>$x^2(1) = 0.74, p = 0.39$</td>
</tr>
<tr>
<td>Vasodilators</td>
<td>0</td>
<td>2</td>
<td>$x^2(1) = 2.03, p = 0.16$</td>
</tr>
<tr>
<td>Anti-arrhythmics</td>
<td>1</td>
<td>1</td>
<td>$x^2(1) = 0.01, p = 0.91$</td>
</tr>
<tr>
<td>Aspirin</td>
<td>5</td>
<td>5</td>
<td>$x^2(1) = 0.26, p = 0.61$</td>
</tr>
</tbody>
</table>
Table 3

*Between Groups Comparison on Use of Pain Medications Four Hours prior to and during Chair Rest*

<table>
<thead>
<tr>
<th></th>
<th>Music (n=6)</th>
<th>Control (n=7)</th>
<th>Chi-Square</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acetaminophen</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4hrs</td>
<td>2</td>
<td>1</td>
<td>$x^2(1) = 0.66, p = 0.42$</td>
</tr>
<tr>
<td>CR</td>
<td>1</td>
<td>1</td>
<td>$x^2(1) = 0.01, p = 0.91$</td>
</tr>
<tr>
<td><strong>Hydrocodone</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4hrs</td>
<td>2</td>
<td>1</td>
<td>$x^2(1) = 0.66, p = 0.42$</td>
</tr>
<tr>
<td>CR</td>
<td>1</td>
<td>1</td>
<td>$x^2(1) = 0.01, p = 0.91$</td>
</tr>
<tr>
<td><strong>Morphine</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4hrs</td>
<td>2</td>
<td>5</td>
<td>$x^2(1) = 1.89, p = 0.17$</td>
</tr>
<tr>
<td>CR</td>
<td>0</td>
<td>1</td>
<td>$x^2(1) = 0.93, p = 0.34$</td>
</tr>
<tr>
<td><strong>NSAID</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4hrs</td>
<td>4</td>
<td>4</td>
<td>$x^2(1) = 0.12, p = 0.73$</td>
</tr>
<tr>
<td>CR</td>
<td>0</td>
<td>1</td>
<td>$x^2(1) = 0.93, p = 0.34$</td>
</tr>
<tr>
<td><strong>Tramadol</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4hrs</td>
<td>0</td>
<td>1</td>
<td>$x^2(1) = 0.93, p = 0.34$</td>
</tr>
</tbody>
</table>

*Note.* 4hrs: 4 hours prior to chair rest. CR: chair rest.
The Effect of Music as an Intervention on Pain and Well-Being of First Day Post Open-heart Surgery Patients

#1: Do postoperative open-heart surgery patients who receive selected music as an intervention have significantly different scores on the pain numeric rating scale (NRS) and visual analog scale (VAS) during chair rest on the first postoperative day than the control group?

The primary aim of this study was to examine the effect of music on pain and well-being on postoperative open-heart surgery patients during chair rest on the first day after surgery. Each participant was asked to rate his or her pain level on the numeric rating scale (NRS, 0 = no pain, 10 = the worse pain) prior to chair rest and every 15 minutes during chair rest and state how they feel on the visual analog scale (VAS, 0 = the worst state, 100 = the best state) prior to and after chair rest.

Pain scores for the music group and control group are described and compared in Table 4 and Figure 4. T-test analysis was used to compare the differences of pain scores between the music and control groups at different time periods of chair rest. No significant statistical difference of pain scores at 0, 15, 30, 45, and 60 minutes of chair rest were found between the two groups.

The difference of scores on VAS and the mean difference of VAS from pretest to posttest were examined by using t-test (Table 5 & Figure 5). No significant difference was found on pretest and posttest scores on VAS or the mean difference of VAS from pretest to posttest between the two groups.
Table 4

Comparison of the Mean Pain Scores for the Music and Control Groups during 0 (pre-test), 15, 30, 45, and 60 minutes of Chair Rest.

<table>
<thead>
<tr>
<th></th>
<th>Music</th>
<th></th>
<th>Control</th>
<th></th>
<th>T-test</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>t</td>
<td>p</td>
</tr>
<tr>
<td></td>
<td>n = 6</td>
<td></td>
<td>n = 7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pre-chair Rest</strong></td>
<td>3.67</td>
<td>2.58</td>
<td>6.43</td>
<td>3.36</td>
<td>t = -1.64,</td>
<td>p = 0.13</td>
</tr>
<tr>
<td><strong>15 min</strong></td>
<td>3.83</td>
<td>1.47</td>
<td>3.71</td>
<td>2.75</td>
<td>t = 0.99</td>
<td>p = 0.92</td>
</tr>
<tr>
<td><strong>30 min</strong></td>
<td>2.83</td>
<td>2.32</td>
<td>5.14</td>
<td>4.02</td>
<td>t = -1.24</td>
<td>p = 0.24</td>
</tr>
<tr>
<td><strong>45 min</strong></td>
<td>3.17</td>
<td>3.06</td>
<td>4.29</td>
<td>3.30</td>
<td>t = -0.63</td>
<td>p = 0.54</td>
</tr>
<tr>
<td><strong>60 min</strong></td>
<td>1.67</td>
<td>2.07</td>
<td>4.43</td>
<td>2.99</td>
<td>t = -1.90</td>
<td>p = 0.08</td>
</tr>
</tbody>
</table>
Table 5

Comparison of the Mean Pretest and Posttest Scores on the VAS for the Music and Control Groups

<table>
<thead>
<tr>
<th></th>
<th>Music</th>
<th>Control</th>
<th>T-test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 6</td>
<td>n = 7</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>PreVAS</td>
<td>65.00</td>
<td>20.98</td>
<td>51.14</td>
</tr>
<tr>
<td>PostVAS</td>
<td>74.83</td>
<td>24.09</td>
<td>60.43</td>
</tr>
<tr>
<td>VAS 60-0</td>
<td>9.833</td>
<td>8.26</td>
<td>9.286</td>
</tr>
</tbody>
</table>

Note. VAS 60-0: postVAS subtracts preVAS.
Fig. 4. Comparison of the mean pain scores on a numeric rating scale (NRS) for the music and control groups.
Fig. 5. Comparison of the mean pretest and posttest scores for well-being on a 100 mm visual analog scale (VAS) for the music and control groups.
The Effect of the Duration of Music as an Intervention on Pain of First Day Post Open-heart Surgery Patients

#2: Do postoperative open-heart surgery patients who listen to selected music during chair rest on the first postoperative day for longer than 45 minutes show significant difference in self-reported pain on the pain NRS than the control group who do not listen to music?

The t-test analysis was used to analyze the difference of the mean difference of pain scores between 1) the pairs of the baseline and posttests and 2) the pairs in each 15-minute period (Table 6). The mean difference of pain score between 60 minutes of chair rest and baseline of the music group (-2.00) was the same as of the control group (-2.00). On the contrary, between 45 minutes and 60 minutes of chair rest, the pain scores of the music group decreased and the control group increased. However, no statistical significant difference was found in both comparisons.
Table 6

*Comparison of the Mean Difference of Pain Scores between Pretests and Posttests and in each 15-Minute Period*

<table>
<thead>
<tr>
<th></th>
<th>Music</th>
<th>Control</th>
<th>T-test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 6</td>
<td>n = 7</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>PS 15-0</td>
<td>0.17</td>
<td>2.04</td>
<td>-2.71</td>
</tr>
<tr>
<td>PS 30-0</td>
<td>-0.83</td>
<td>3.54</td>
<td>-1.29</td>
</tr>
<tr>
<td>PS 45-0</td>
<td>-0.50</td>
<td>3.15</td>
<td>-2.14</td>
</tr>
<tr>
<td>PS 60-0</td>
<td>-2.00</td>
<td>2.45</td>
<td>-2.00</td>
</tr>
<tr>
<td>PS 30-15</td>
<td>-1.00</td>
<td>1.67</td>
<td>1.43</td>
</tr>
<tr>
<td>PS 45-30</td>
<td>0.33</td>
<td>1.97</td>
<td>-0.86</td>
</tr>
<tr>
<td>PS 60-45</td>
<td>-1.50</td>
<td>2.51</td>
<td>0.14</td>
</tr>
</tbody>
</table>
The Use of Pain Medications during Chair Rest

# 3: Do postoperative open-heart surgery patients who listen to 15-minute, 30-minute, and 45-minute selected music during chair rest on the first postoperative day use pain relief medications significantly less frequently than the control group who do not listen to music during the chair rest?

The use of pain medications during chair rest is described above (Table 3). No significant difference in the use of pain medications during chair rest was found for the use of acetaminophen (p = 0.91), hydrocodone (p = 0.91), morphine (p = 0.34), and ketorolac (a NSAID) (p = 0.34) and tramadol (p = 0.34) between the two groups during chair rest.
CHAPTER VI

Discussion

The primary goal of this study was to observe the effect of music as an intervention on postoperative pain in open-heart surgery patients during chair rest on the first postoperative day. The discussion includes the sample profile, results of the effect of music on pain and the sense of well-being, study limitations, research and practice implications, and conclusions.

Sample Profile

The study sample consisted of 13 patients who had open-heart surgery at one hospital in southeastern Michigan. Originally, there were 15 participants enrolled, but one dropped out because of a change of the physical condition. Another dropped out due to unwillingness to continue the study. Two eligible patients refused to participate because they were not interested in music. The age range of this sample was from 46 to 85 years, and the participants were primarily female (61.5%). The sample included Caucasians (61.5%) and African Americans (38.5%). The majority of the participants were unemployed (76.9%) and had completed high school education as the highest educational level (76.9%). The music and control groups had similar demographic characteristics listed in Table 1. In the music group, classical, country, gospel, jazz, and rhythm and blues were selected by the participants. rhythm and blues was chosen most frequently (33.3%).

The Effect of Music as an Intervention on Pain and Well-Being on First Postoperative Day in Open-heart Surgery Patients

It was hypothesized that postoperative open-heart surgery patients who listened to selected music during chair rest on the first postoperative day would have significantly lower scores on the pain numeric rating scale (NRS, 0-10) at 15, 30, and 45 minutes than the control group. The
results of the current study showed that pain scores were higher in the control group than in the music group at 0 (pre-chair rest), 30, and 45 minutes during chair rest. However, the differences of the pain scores between the music and control groups were not statistically significant. Thus, although the pain level was generally lower during chair rest in the music group, the hypothesis that postoperative open-heart surgery patients who listened to selected music during chair rest on the first postoperative day would have significantly lower scores on the pain numeric rating scale (NRS, 0-10) at 15, 30, and 45 minutes was not supported. Moreover, it was also hypothesized that postoperative open-heart surgery patients who listened to selected music during chair rest on the first postoperative day would have significantly higher scores on visual analog scale (VAS) than the control group, which means patients who listened to music during chair rest would have a higher satisfaction with their well-being. Although in the current study, the state of well-being as measured by the VAS was higher in the music group than in the control group, this difference was not found statistically significant. Therefore, this hypothesis cannot be supported.

Although the current study did not show a statistically significant effect of music on reducing postoperative pain and improving well-being, anecdotal notes recorded showed that some patients said that music could definitely help them relax. One participant stated that “listening to the music I like just makes me smile.” However, one participant expressed that if pain was not severe, music tended to help more, but that it did not really help severe pain.

*The Effect of the Duration of Music as an Intervention on Pain of First Day Post Open-heart Surgery Patients*

It was hypothesized that postoperative open-heart surgery patients who listen to selected music during chair rest on the first postoperative day for longer than 45 minutes will show no significant difference in self-reported pain on the pain NRS compared to the control group who
do not listen to music. It was found that after 45 minutes of chair rest, the difference in pain scores between the music and control group was not significant; therefore the result supported the hypothesis that music does not affect pain level when played longer than 45 minutes. In addition, the result also showed that the mean pretest pain score of the control was higher than that of the music group, and during the first 15 minutes of chair rest, pain in the music group increased slightly while that of the control group decreased dramatically. Since the use of pain medications prior to and during chair rest was similar between the two groups, the significant changes of the pain scores during the first 15 minutes of chair rest in both groups were less likely affected by the pain medications. The reason of a higher mean pain score on the control group could be because the participants were informed about the groups (music or control) they were assigned to before the pretests were done. Nevertheless, no evidence was discovered to explain this result. Furthermore, from 15 minutes to 30 minutes of chair rest, the music group had a significant decrease on the pain scores compared to the control group. Therefore, it is reckoned that music had a positive effect on the participants in the music group from 15 minutes to 30 minutes of chair rest more than other periods of chair rest. Although statistically, the difference of pain scores between the music and control group was not significant due to the small sample size, the decrease of mean pain score of the music group was consistent generally.

From the perspective of the participants’ reaction, during the study most participants in the music group enjoyed the music. One participant requested to continue after the study was over, but one stated that 60 minutes of music was too long and not effective after 30 minutes.
The Use of Pain Medications during Chair Rest

It was hypothesized that postoperative open-heart surgery patients who listen to 15-minute, 30-minute, and 45-minute selected music during chair rest on the first postoperative day will use pain relief medications significantly less frequently than the control group who do not listen to music during the chair rest. In this study, the use of pain medications during chair rest between the music and control group was similar. Therefore, this hypothesis is not supported.

Study Limitations

Several limitations have been identified related to the current study. First of all, due to the fact that open-heart surgery is being less frequently performed, it was not possible to recruit an adequate number of participants during the study period. Therefore, although some differences in the results were found, they were not considered significant statistically.

The ethnic background of the participants in this study was limited. Caucasians and African Americans were the only groups in this study. Differences in cultural and ethnic background could affect a person’s perceptions of pain and sense of well-being, so the lack of cultural diversity of the participants in this study could limit the generalizability.

Participants’ previous surgical experiences and pain experiences could have affected the result as well. And those factors were not controlled, recorded, or discussed. Furthermore, participants were informed that this study was about music therapy and pain on open-heart surgery patients, thus, participants’ knowledge of this study could have influenced their expectations of the outcome or behaviors.

Finally, the author found that participants in this study were confused by the tools (NRS & VAS) used to measure their pain level and sense of well-being. On the NRS, 0 means no pain at all, and 10 means the worst pain one has ever experienced. However, on the VAS, 0 means the
worst imaginable health state and 100 means the best imaginable health state. Therefore, for some elderly participants, it was not easy to comprehend the concept of the VAS.

*Implications for Research and Clinical Use of Music Therapy*

While the numbers of studies examining the effect of music on anxiety and pain are increasing, one can rarely find studies examining ways to implement music therapy. Some studies do not have significant findings because of small sample sizes. Therefore, it is suggested that research studies in regard to various ways to use music as a nursing intervention (i.e. types of music or duration of music) should be conducted with an adequate sample size. According to Voss et al. (2004), most studies only have examined short-term effects of music therapy; thus, more research is needed to determine if any long-term effects occur. Moreover, studies on the effect of the duration of music therapy on various ethnic populations are also needed.

From the point of view of clinical practice, this study suggested that the effect of music was limited after it was played longer than 30 minutes. Therefore, the length of music intervention should be considered when nurses implement music therapy. Since individuals have diverse preferences, nurses should be able to provide different options to implement music therapy and ask patients for feedback about their experience.

*Conclusion*

Because of the small sample size, results of the current study do not strongly support the use of selected music as an intervention to significantly relieve pain, decrease the use of pharmacological pain treatment, or enhance the state of well-being. Therefore it is suggested that similar studies need to be done using a larger sample size. The findings in this study suggest that selected music is more effective during 15 minutes to 30 minutes of chair rest. However, further
research with a larger sample size is recommended to determine the reliability and validity of this finding.
References


Complementary and alternative medicine; researchers say music eases pain, anxiety after open-heart surgery. (2005, Jan 1). *Obesity,Fitness & Wellness Week*, p. 405.


*Pain, 112*(1-2), 197-203.


Appendix A

EASTERN MICHIGAN UNIVERSITY

February 16, 2010

Tzu-Ting Shu
c/o Lorraine Wilson
Eastern Michigan University
School of Nursing
Ypsilanti, Michigan 48197

Dear Tzu-Ting Shu,

The CHHS Human Subjects Review Committee has reviewed the revisions to your proposal entitled: “Effects of Duration of Selected Music as an Intervention on Postoperative Pain in Open-heart Surgery Patients during First Time Chair Rest” (CHHS 10-012).

The committee reviewed your proposal and its revisions and concluded that the risk to participants is minimal. Your study is approved by the committee.

Good luck in your research endeavors.

Sincerely,

George Liepa, Ph.D.
Chair, CHHS Human Subjects Review Committee
December 1, 2010

Tzu-Ting Shu
c/o Lorraine Wilson
Eastern Michigan University
School of Nursing
Ypsilanti, Michigan 48197

Dear Tzu-Ting Shu,

The CHHS Human Subjects Review Committee has reviewed the revisions to your proposal entitled: “Effects of Duration of Selected Music as an Intervention on Postoperative Pain in Open-Heart Surgery Patients During Chair Rest on the First Postoperative Day” (CHHS 10-012).

The committee reviewed your proposal and its revisions and concluded that the risk to participants is minimal. Your study is approved by the committee.

Good luck in your research endeavors.

Sincerely,

George Liepa, Ph.D.
Chair, CHHS Human Subjects Review Committee
February 5, 2010

Tzu-Ting Angela Shu RN
Department of Nursing
811 Lowell Street, Apt 4
Ypsilanti MI 48197

**Our Study # SJ 0210-04**

**Protocol Title:** Effects of Duration of Selected Music as an Intervention on Post-Operative Pain in Open-Heart Surgery Patients During First Time Chair Rest

Dear Ms. Shu:

This letter is to inform you that the Institutional Review Board of St. John Hospital and Medical Center approved by Expedited Review the above study.

**The period of IRB approval is valid through 2/4/2011.**

Expedited Review is granted as per FR Vol. 63, 216 (07).

As part of the Institutional Review Board’s requirements, which are mandated by the FDA, during the upcoming year, you are required to report back to the IRB in the event of any of the following: significant adverse reactions, changes to the study protocol, termination of the study.

In addition, the IRB and FDA require, at least, an annual review of all studies. *As the principal investigator, you are responsible for reporting on the progress of each study.*

The SJH&MC IRB operates in accordance with the International Conference on Harmonization, Good Clinical Practice Guidelines and applicable laws and regulations.

Sincerely,

[Suzanne Delaloah, A.A., CIM, CIP]

IRB Consultant for
Peter V. Nickles, MD, Chairperson
Institutional Review Board (IRB)
DATE: November 29, 2010

TO: Tzu-Ting Angela Shu, MD
FROM: St. John Hospital and Medical Center IRB

STUDY TITLE: [172873-2] Effects of Duration of Selected Music as an Intervention on Post-Operative Pain in Open-Heart Surgery Patients During Chair Rest on the First Postoperative Day

IRB REFERENCE #: SJ 0210-04
SUBMISSION TYPE: Amendment/Modification

ACTION: APPROVED
APPROVAL DATE: November 29, 2010
EXPIRATION DATE: February 4, 2011
REVIEW TYPE: Administrative Review
REVIEW CATEGORY: Expedited review - Minor revision to Project Title

This research presents Minimal Risk.

The St. John Hospital and Medical Center IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

Your protocol, #SJ 0210-04 was APPROVED for the following change:

- Title was revised to add "...on the First Postoperative Day" to the end of the study title.

As part of the Institutional Review Board requirements, which are mandated by the FDA and OHRP, you are required to report back to the IRB in the event of any of the following: significant adverse reactions, changes to the previously approved materials, non-compliance issues or complaints regarding the study, major protocol deviations, and termination of the study. Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

Please note that all research records must be retained for a minimum of three years.

If you have any questions, please contact Suzanne Leialoha at 313-343-3863 or suzanne.leialoha@stjohn.org. Please include your study title and reference number in all correspondence with this office.

St. John Hospital and Medical Center's Institutional Review Board is in full compliance with Good Clinical Practices as defined under the U.S. Food and Drug Administration (FDA) regulations and the International Conference on Harmonisation (ICH-GCP) Guidelines, as adopted by the FDA.
Sincerely,

Peter A. Nickles, MD, Chairperson
Institutional Review Board
St. John Hospital and Medical Center

This document was electronically signed by the chair of the IRB in accordance with all applicable regulations, and a copy is retained within our records.
Appendix B

The Pain Numeric Rating Scale (NRS)

Rate how much pain you have right now on the scale.
VISUAL ANALOG SCALE

To indicate how you can feel, below is a scale on which the best state you can imagine is 100, and the worst state you can imagine is 0.

Please tell me using this scale how you now feel.

100…………..Best Imaginable Health State

95
90
85
80
75
70
65
60
55
50
45
40
35
30
25
20
15
10
5

0…………..Worst Imaginable Health State
Appendix C

Oral Explanation of the Study to Potential Participants

Hello, my name is Angela Tzu-Ting Shu. I am a graduate nursing student working with the nurses in ____________ Hospital. I would like to invite you to participate in a study about using music for patients who are recovering from heart surgery. If you decide you would like to be part of this research study, I will have you sign a consent form and I will also ask you questions about yourself (which takes about 5 minutes). Besides this, you will be asked to rate how you feel at the beginning and the end of the chair rest on the scale from 0 to 100. Also, you will rate your pain on a scale from 0 to 10 once you get up to the chair and at 15 minutes, 30 minutes, 45 minutes and 60 minutes after you are in the chair. You will be assigned to either the control group or the music group randomly, like flipping a coin. Your primary care registered nurse will closely monitor you during this hour.

We will ask you to put your cell phone on silent during the study. We will also request visitors remain in the hall or the waiting room during this hour, to minimize interruptions. This is an anonymous research study and will not affect any of your usual treatments. You can also stop being in the study at anytime without any penalty and negative consequences. However, if you would like to get a copy of the results of this research study, you could give me your contact information. I will also give you my contact information.

Might you be interested in helping me with my research study?
CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY and
AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Title: Effects of Duration of Selected Music as an Intervention on Postoperative Pain in Open-heart Surgery Patients during Chair Rest on the First Postoperative Day

Principal Investigator: (Angela) Tzu-Ting Shu

Phone: (734) 487-3272

This form contains information about a clinical research study. You are being asked to participate in a research study sponsored by the Department of Nursing at St. John Hospital. If you choose to participate in this research study, you will agree by signing your name to the last page. After you sign the form, you will be given a copy, and an additional copy will remain in your medical chart.

You are being asked to participate in this research study because you are a patient who is going to have (or has had) open-heart surgery, meets the study requirements, and are being seen at St. John Hospital and Medical Center. All subjects participating in research must volunteer, and be informed about the purpose, risks, benefits if any, and alternatives. If you have any questions about this research or the consent form, please ask.

Why is this research being done?

The purpose of this study is to examine the effect of music on pain, and compare the effect of different durations of music on pain for patients who had open-heart surgery during the time a patient gets up from the bed to rest in a chair, called chair rest. We hope to compare chair rest without music to chair rest with music on how much pain you feel. We already know that music can reduce pain, but we don’t know how long this effect lasts, so we’ll be asking about your pain every 15 minutes for an hour. You will be randomized (put into one group by chance). Your chances of being in the music group are 1 in 2, like flipping a coin.

How many people will take part in this study?

Approximately 70 participants (both men and women) will be in this study.
**How long will I be in this study?**

You will participate for about 1 to 1.5 hours. Your part in the study is completed once you have given us your pain scores every 15 minutes after your chair rest, and your VAS score prior to chair rest and after.

**What will happen if I take part in this research study?**

This study will take approximately 1 to 1.5 hours to complete. You will be randomly assigned to a group (the control group or the music group). The control group will receive the usual treatment without any music. Patients in the music group will listen to music of their choice when at rest in the chair for 60 minutes.

A pain scale will be used as the pretest and posttests in this study. You will be asked to rate your pain level from 0 to 10. It takes approximately 30 seconds to give your pain rating while looking at the rating scale. You are eligible to participate because you are an adult and you had an open-heart surgery. You have to be able to understand and read English, and your condition has to be stable to participate in this study. You cannot have hearing impairment.

**What are the risks of the study?**

Possible symptoms you could have during this study are: pain, anxiety, abnormal heart beats, chest pain, difficulty breathing, nausea, dizziness, or low blood pressure. But these symptoms are not related to this study. Your assigned nurse will closely monitor you and administer pain medications upon your request to minimize your discomfort.

The possible risk from music is emotional discomfort. Some of the music you will hear could make you sad or otherwise uncomfortable. In order to minimize emotional discomforts, you will be able to select the music you prefer to use and adjust the volume of music anytime during the study.

You should tell the person obtaining your consent if you are currently participating in any other medical research studies.

**What are the benefits of the study?**

The effect of music in helping to help reduce pain is well supported by many research studies. Therefore, it could reduce patients’ pain level after open-heart surgery. However, we don’t know how long this effect lasts. If you are assigned to the music group and the music reduces your pain level, you may benefit from being in this study. If you are in the control group, it is not expected you will benefit from this study because you will be getting the same care as patients who aren’t in this study.

In the future, other patients may benefit from the results of this study, when they become known.

**What other options are there?**

One option is to not participate. You do not have to be in this research study to receive care after open-heart surgery.
Do I have to be in this study?

Your participation in this study is voluntary. Your refusal to participate will cause no penalty or loss of benefits which you would otherwise receive. If you decide to participate, you may change your mind about being in the study, and may quit at any time without penalty of loss of benefits regarding your future care. I will tell you about any new information that may affect your willingness to stay in the study. Also, your doctor may stop your participation at any time if he/she feels it is in your best interest.

Will it cost anything to participate?

There are no extra medical costs. We do not expect there to be any additional costs to you if you are in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or to your insurance company in the usual fashion.

Will I be paid to participate?

There will be no compensation to you for being in this study.

Confidentiality of Records

The principal investigators will have access to your medical records and your test results. While absolute confidentiality cannot be guaranteed, all medical records and research material which could identify you will be kept as confidential as possible within the state and federal laws. You should be aware that your medical records could be examined by the sponsor, the Institutional Review Board (a group of medical and lay people at this hospital charged with protecting the rights of human subjects), or government agencies in order to verify the data collected during this research study. If the results of this study are presented in any public forum, you will not be identified by name.

What if I am injured?

If you are injured as a direct result of being in this study, the study sponsor, (Angela) Tzu-Ting Shu, will cover the costs of medical treatment necessary to diagnose and/or treat your injury. Financial compensation for such things as lost wages, disability, or discomfort due to the injury is not routinely available. You are not giving up any of your legal rights by signing this consent form.

Who do I call with questions about the study or to report an injury?

If you have any questions regarding a research-related injury, you can contact:

Dr. Lorraine Wilson (lwilson1@emich.edu) at (734) 487-3272 or
Dr. George Liepa (gliepa@emich.edu)

If you would like to have know the result of this study, please leave your name and address with (Angela) Tzu-Ting Shu, or email her at: tshu@emich.edu

If you have any questions about your rights as a subject in this clinical research study, you may contact the IRB representative at 313-343-8314 or 313-343-3863 at St. John Hospital and Medical Center.

Authorization to Use and Disclose Protected Health Information (PHI)

Your participation in this study will require the use and disclosure of certain medical and other information about you. You will not be able to participate if you do not agree to the use and disclosure of
your information. Protected health information, or PHI, includes information such as name, birth date, or email address.

**The protected health information (PHI) that may be used or disclosed includes:**

- All information collected during the research study as described in this form,
- The information that is contained in any medical record that is created during your participation in this research, and
- Other information in your medical record that may be considered related to your participation in this research, which may include: your medical history, physical examination results, laboratory test results or other test results (like an x-ray scan, biopsy, EKG).

**Who may see, use or disclose your PHI:**

- The researchers and members of the research team.
- Other health care providers or employees of St. John Health who provide services to your for this study.
- Representatives of the Institutional Review Board, the FDA (Food and Drug Administration), or other governmental agencies involved in research monitoring.
- Members of the safety monitoring board.
- Other agencies as required by law.

- The sponsor
- A clinical research organization or other agent of the sponsor

**What this Authorization means**

We cannot guarantee that your protected health information (PHI) shared or disclosed under this Authorization may not additionally be shared or disclosed by the individual or organization that receives the information and your privacy may no longer be protected by the law.

You do not have to disclose your PHI; however, if you choose not to disclose your PHI you will not be able to participate in this study.

If you do sign below, you are agreeing to disclose your PHI. You have the right to withdraw your permission at any time. To withdraw your permission, you must do so in writing. You may send the written withdrawal to:

(Angela) Tzu-Ting Shu,
311 Marshall,
Eastern Michigan University,
Ypsilanti, MI 48197.

You will no longer be allowed to participate in the research if you withdraw your permission. Also, you should be aware that any information collected before written notice to withdraw your approval for the collection of your PHI is received may still be shared as you have agreed.

This Authorization expires when all data have been collected, analyzed, and conclusions about the study have been made.

You have the right to review your PHI. However, if you agree to participate in the research study and sign below, you will not be able to look at your research information until the research study is completed.
CONSENT

You have had the opportunity to fully discuss the purpose of this clinical research study and how it will be carried out. Your questions have been answered. Any technical terms you did not understand have been explained to you. You have read this consent form or it has been read to you. Your participation in this study is fully voluntary and you may withdraw at any time. If you refuse to participate or later withdraw from the study, it will not affect your care in any way. By consenting to participate in this study, you are not waiving any other legal rights you may have because you are a subject in this study or as a patient at St. John Hospital and Medical Center.

Your signature below acknowledges that you voluntarily agree to participate in this clinical research study, and you will receive a signed copy of this form.

__________________________
Printed Name of Research Subject / Legally Authorized Representative

____________________________  ______________________
Signature of Research Subject / Legally Authorized Representative    Date

__________________________
Printed Name of Witness to Signature, if subject is legally blind, or cannot read or write

____________________________  ______________________
Signature of Witness, if subject is legally blind, or cannot read or write    Date

__________________________
Printed Name of Person Obtaining Consent

____________________________  ______________________
Signature of Person Obtaining Consent    Date
Appendix E

Date: _____/_____/201__

Participant ID number______

Group: □ Music     □ Control

1. Age today: _____

2. Gender: □ Female     □ Male

3. Race
   □ African-American
   □ American Indian/Alaskan Native
   □ Asian
   □ Hawaiian/Pacific Islander
   □ White
   □ Other ______________________

4. Occupation
   □ Student
   □ Work outside the home
   □ Work from home
   □ Unemployed

5. Do you have any of the following? (check ALL that apply)
   □ Arthritis
   □ Chronic lung disease
   □ Circulatory problems
   □ Diabetes
   □ Heart disease
   □ High blood pressure
   □ Immunosuppression
   □ Kidney disease
   □ Osteoporosis
   □ Pregnancy
   □ Stroke

6. Years of education completed
   □ Some high school
   □ High school/GED
   □ Some College
   □ College
   □ Postgraduate

7. Marital Status
   □ Never married     □ Living with significant other
   □ Married          □ Living with family
   □ Separated
   □ Divorced
   □ Widowed

8. If you are assigned to the music group, which kind of music do you want to hear?
   □ Classical     □ Musicals
   □ Christian worship     □ Popular
   □ Country     □ R & B
   □ Gospel     □ Relaxation
   □ Jazz     □ Rock & Roll

Thank You!
Any complementary and alternative therapy used in the past 2 hours  □ Y □ N

□ First time chair rest □ Second time chair rest □ Third time chair rest

Time between the end of surgery and the study: _________ hours

**Medications within past 8 hours**

<table>
<thead>
<tr>
<th>Category</th>
<th>Drug</th>
<th>Time</th>
<th>Dose (mg)</th>
<th>Route</th>
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<tr>
<td>ACE inhibitor</td>
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<tr>
<td>Anti-Hypertensive</td>
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<tr>
<td>Anti-anginal</td>
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<tr>
<td>Beta-adrenergic blockers</td>
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<tr>
<td>Calcium channel blocker</td>
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<tr>
<td>Diuretics</td>
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<tr>
<td>Vasodilators</td>
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<tr>
<td>Antiarrythmics</td>
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<td>Anticholinergics</td>
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<td>Anticoagulants</td>
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<tr>
<td>Salicylate</td>
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<tr>
<td>Other</td>
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### Pain medications received within past 4 hours

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<th>Drug</th>
<th>Time</th>
<th>Dose (mg)</th>
<th>Route</th>
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<tbody>
<tr>
<td>Codeine</td>
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<tr>
<td>Acetaminophen</td>
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<td></td>
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<tr>
<td>Hydrocodone</td>
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<tr>
<td>Hydromorphine</td>
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<tr>
<td>Meperidine</td>
<td></td>
<td></td>
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<tr>
<td>Morphine Sulfate</td>
<td></td>
<td></td>
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<tr>
<td>Oxycodone</td>
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<td></td>
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<tr>
<td>Non-steroidal anti-inflammatory drug (NSAID)</td>
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<tr>
<td>Other</td>
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### Pain medication medications received during chair rest

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<th>Drug</th>
<th>Time</th>
<th>Dose (mg)</th>
<th>Route</th>
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<tbody>
<tr>
<td>Codeine</td>
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<td>Morphine Sulfate</td>
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<tr>
<td>Oxycodone</td>
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<td>NSAID</td>
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<td>VAS</td>
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</table>
Anecdotal Notes