

IS MUSIC AN EFFECTIVE INTERVENTION FOR IMPROVING
SLEEP QUALITY AMONG ADULT POSTOPERATIVE
OPEN-HEART PATIENTS: A FEASIBILITY PROJECT

by

Jenna Leann Olds

A scholarly project submitted in partial fulfillment
of the requirements for the degree

of

Doctor of Nursing Practice

in

Family and Individual Health

MONTANA STATE UNIVERSITY
Bozeman, Montana

April 2019

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DEDICATION

I would like to dedicate this paper and project to my husband and best friend, Scott. Without your unwavering support and encouragement, I may not have pursued this dream. I am incredibly grateful for your constant reminders that I can do whatever I put my mind to. I will never be able to adequately express how much your steadfast reassurance and praise means to me. Through it all, you were often my light at the end of the tunnel. Thank you, my love.

ACKNOWLEDGEMENTS

First and foremost, I would like to thank and acknowledge my project chair, Dr. Alice Running, PhD, APRN. You have my unfailing gratitude for your support and guidance throughout this project. Thank you for your patience, encouragement, and understanding, especially when I was completely overwhelmed. I could not have done this without you. To my project committee, Dr. Polly Petersen, PhD, RN, Dr. Jean Sheffler-Grant, PhD, RN, and Dr. Stacy Stellflug, PhD, APRN, FNP-BC, thank you for your willingness to see this project through to fruition.

I would also like to thank Kara Johnson, MS, for her assistance with the statistical analysis for this project. I appreciate all of you, along with the rest of the faculty at Montana State University, for your passion and willingness to educate and improve the field of nursing. Finally, I would like to thank my amazing family and friends for their support on this journey. Thank you all for listening to my stories, encouraging me to occasionally take a break, and cheering me on when I wasn't sure I would make it.

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ABSTRACT

Sleep deprivation is a common disorder known to impair the immune system and healing. Noise, pain, anxiety, and illness in general contribute to sleep deprivation. Patients admitted to the hospital setting are at heightened risk for complications related to decreased quality of sleep. Pharmacological interventions such as opioids and sleep aids are frequently administered to combat this issue. Integrative therapies are often overlooked as a way to increase quality sleep while hospitalized. One of the safest and easiest alternative interventions to employ is music. The purpose of this pilot feasibility project was to determine whether implementing music at the bedside during hours of sleep in the acute coronary-care setting addressed quality of sleep for postoperative open-heart patients. While statistical significance was not met in this project, promising results were found.

INTRODUCTION

The National Institute of Health (NIH) suggests that adults age 18 and older should sleep seven to eight hours per night. Approximately 7% to 19% of United States adults report that they do not get enough sleep. In fact, nearly 40% of adults report falling asleep without intention in the last month. Furthermore, an estimated 50 to 70 million Americans suffer from chronic sleep disorders (NIH, 2018).

There are a multitude of pharmaceutical options available to treat sleep disorders. While pharmacotherapies have good, short-term effects, the negative side effects impede long-term use (Jepperson, Otto, Kringlebach, Van Someren, & Vuust, 2019). For example, melatonin, diphenhydramine, and zolpidem are often-prescribed drugs with known side effects such as dizziness, gastrointestinal issues including nausea and diarrhea, possible allergic reaction, and prolonged somnolence (Mayo Clinic, 2014). These side effects highlight the need for non-pharmaceutical interventions when attempting to induce or enhance sleep.

Integrative therapies such as massage, acupuncture, aromatherapy, and music are often used for the treatment of poor-quality sleep in lieu of or accompanied by pharmaceutical options. Music has been used throughout history as a way to express culture, identity, and mood. Music can be heard in all manner of places and situations and is often used to cope with and alleviate negative feelings including anxiety, boredom, and loneliness (North & Lonsdale, 2011). For those who sleep an average of eight hours per night, more than 15% of their waking hours are spent listening to music (Rentfrow, 2012). Music is also a common intervention used by individuals suffering from insomnia.

In 2006, one study revealed that 43.6% of insomnia sufferers in that study had used music to promote sleep (Morin, Leblanc, Daley, Gregoire, & Mérette, 2006).

Background and Literature Review

Hospital environments are inherently noisy, unfamiliar, and uncomfortable for the majority of patients. Interventions such as medication administration, as well as other factors such as noise and pain, all contribute to poor sleep quality in the acute-care setting (Auckley, 2016). Negative physical effects typically associated with inflammation and sympathetic activation caused by sleep disorders (Sauvet, et al., 2010, p. 68) include “increased peripheral vascular resistance, heart rate, and blood pressure leading to enforced ventricular contractility, hypertension, and subsequent cardiac hypertrophy” (Hsu, Ko, Liao, Huang, Chen, & Hwang, 2010).

Researchers have consistently shown that sleep deprivation has a detrimental effect on healing. Prior to implementing this project, an extensive literature review was conducted. Studies including meta-analyses, systematic reviews, randomized controlled trials, and qualitative research were found regarding the consequences of sleep deprivation and the effects of music on sleep quality (see Evidence Table in Appendix A).

In a systematic review, Rabin and Krauss (2012) found that, even though evidence that insomnia is overwhelmingly linked with physical and mental illness, the importance of sleep has largely been overlooked as a necessary component of health. Individuals with insomnia typically resort to various self-help remedies prior to

consulting with a healthcare provider. The first-line self-help remedies are typically over-the-counter (OTC) antihistamines such as diphenhydramine and doxylamine. While this class of medication does cause drowsiness, there is little evidence that these drugs are effective in improving sleep. In fact, sleep quality may be reduced with continued use. Furthermore, even “good sleepers” suffering from occasional sleep disruptions are quickly at risk for affective dysfunction following bouts of insomnia.

Effects of Sleep Deprivation on Cardiac Health

According to Ryu, Park, and Park (2012), during sleep, systolic blood pressure decreases which reduces stress on the heart, but disruptive sleep patterns stimulate the sympathetic nervous system and cause an increase of vasoconstrictors that increase cardiac load. Patients diagnosed with coronary artery disease (CAD) frequently experience pain related to procedures such as open-heart surgery, insufficient myocardial function, and anxiety due to hospitalization and treatments for the disease (Krantz, Shep, Carney, & Natelson, 2000).

In 2014, Krinsky, Murillo, and Johnson revealed that, when patients experience sleep deprivation, they may suffer consequences such as increased heart rate and elevated blood pressure, which can lead to increased stress to the myocardium, in turn exacerbating existing conditions (Krinsky, Murillo, & Johnson, 2014). States of pain and anxiety often contribute to sleep deprivation, which can compromise healing (Irwin et al., 2012) as sleep deprivation may result in increased fatigue and immune-system impairment (Njawe, 2003). An increase in postoperative complications is possible as

these states can contribute to a decrease in activities necessary for rehabilitation such as early ambulation and cough and deep breathing.

Effects of Music on Sleep

A meta-analysis of 10 randomized studies by Wang, Sun, and Zang (2014) examined whether music therapy improves sleep quality in acute and chronic sleep disorders. The results of this review found that sleep quality was significantly improved by music (standard mean difference: -0.63; 95% CI: -0.92 to -0.34; $p < 0.001$) with significant heterogeneity across studies.

Wang, Chair, Wong, and Li (2016) conducted a two-armed randomized controlled trial with 64 elderly people (mean age 69) with poor Pittsburgh Sleep Quality Index (PSQI) scores ($PSQI > 7$) in four urban communities to determine if listening to music before bedtime improved quality of sleep. Participants were randomly assigned to either the control group (one sleep hygiene education session provided) or the intervention group (listening to music prior to sleep). Participants in the intervention group received an MP3 player with a music database. The participants then selected their preferred music for the database and listened for 30–45 minutes per night for three months. At the end of this period:

The intervention group demonstrated continuous improvements in sleep quality, with a global PSQI score of 13.53 at baseline, 9.28 at 1 month, 8.28 at 2 months, and 7.28 at 3 months. Although the global PSQI score in the control group also decreased...the intervention group achieved greater improvements at each measurement (all $p < 0.05$). (Wang, Chair, Wong, & Li, 2016, p. 576).

The use of therapeutic music played at the bedside helps “design environments that promote comfort and well-being [and] fits well within the scope of holistic nursing practice” (Sand-Jecklin & Emerson, 2010, p. 8). The implementation of music at the bedside addresses the holistic needs of hospitalized patients by increasing quality of sleep without adverse or unwanted side effects. Music is also related to increased release of oxytocin and decreased levels of cytokine and catecholamine in plasma. These changes often contribute to decreased sensation of pain and increased ability to sleep (Wang, Chair, Long, & Li, 2016, p. 577).

Weeks and Nilsson (2010) note that there is a “strong positive correlation between the pleasurable aspects of music listening and emotional arousal” (p.91), as well as improved feelings of wellbeing and decreased stress levels. Bringman, Giesecke, Thorne, & Bringman (2009) conducted a randomized controlled trial that examined the effects of music on anxiety levels prior to surgical procedures. Participants were randomly selected to either listen to relaxing music for up to 80 minutes ($n = 177$) or receive 0.05–0.1mg/kg of midazolam orally ($n = 150$). Researchers utilized the State Trait Anxiety Inventory (STAIX-1) to measure anxiety levels pre- and post intervention. The improvement in anxiety scores for the music group was significantly greater than those in the midazolam group, which indicates that relaxing music was more effective at decreasing anxiety in the preoperative setting than an oral anxiolytic.

In a 2008 systematic review, Nilsson found that benefits of listening to music include reduced stress, reduced pain perception, increased relaxation, and improved quality of sleep. In 2009, Nilsson went on to explore the effect music has on stress

response in cardiac surgical patients in two randomized clinical trials. In the first trial (Nilsson, 2009a), 40 patients on bed rest following open-heart surgery were randomly allocated to listening to music while on bed rest ($n=20$) or bed rest alone ($n=20$) to determine if relaxation and oxytocin levels increased with musical intervention. Plasma oxytocin, vital signs, and subjective relaxation levels were measured. Nilsson found that, oxytocin levels increased by 3.9pml/l after 30 minutes of music and 5.90 pml/l after one hour of music in the intervention-group participants. Patients in the control group had an opposite effect with oxytocin decreasing -5.45 pml/l after 30 minutes of usual care and -3.90 after one hour. The differences between the intervention and control groups were statistically significant at the two time periods compared with the baseline levels of the groups ($P < .001$). Subjective relaxation levels were also statistically significant over time between the groups and followed the same trends as the oxytocin levels.

Nilsson (2009b) also evaluated the cortisol levels, anxiety indices, and vital signs in 58 patients following open-heart surgery. The intervention group (music group) ($n = 28$) listened to 30 minutes of music at noon the day after surgery. The control group (no music) ($n = 30$) had usual care. Cortisol levels were significantly lower in the intervention group (484.4 mmol/l) compared to the control group (618.8 mmol/l) ($p < 0.02$). There were no significant differences in heart rate, blood pressure, respiration, and oxygen saturation between the groups.

Bernardi et al. (2009) discovered that music can “synchronize cardiovascular variability as a result of listening to phrases at a frequency close to that of circulatory oscillations” (p. 3178), which could affect arousal states. In 2001, Krout explored the use

of music for acute-care cardiac patients to promote sleep and found that this intervention has minimal to no side effects, induces relaxation, and increases physical comfort.

Because music therapy is a safe, integrative intervention, this project focused on the impact it has on sleep quality in hospitalized coronary-care patients. This intervention is often overlooked and, while nursing staff reliably demonstrate knowledge of the negative effects of sleep deprivation, quality sleep in the acute-care setting is generally not addressed in a consistent and dependable manner (Radtke, Ohermann, & Teymer, 2014).

Local Problem

This project took place on the acute coronary care unit at one of the largest tertiary-care hospitals in Montana. This facility has 201 staffed beds; 32 are reserved for patients experiencing cardiac, respiratory, and vascular issues. At the time of implementation, the county in south-central Montana where this hospital is located had an estimated population of 110,000 (City Data, 2018). This area also serves as the medical corridor for several regions including northern Wyoming.

Between the years 2000 and 2008, 8% of all hospitalizations in Montana were attributed to coronary artery disease (CAD), heart failure, cerebrovascular diseases, and acute myocardial infarction (Montana DPHHS, 2010). According to the 2016–2017 Community Health Assessment (Yellowstone County, 2017), in 2014, heart disease and stroke accounted for 25.6% of deaths in the local population.

Heart disease was also the number-one cause of death in 2014 with 20.1% of the deaths attributable to heart disease alone. According to the aforementioned Community Health Assessment, 65.8% of adults in this community are overweight. More than 80% of this adult population exhibit heart disease and stroke risk factors including hypertension, hyperlipidemia, smoking, physical inactivity, and obesity (Yellowstone County, 2017).

Project Question and Intended Improvement

The implementation portion of this project was conducted on an adult acute coronary care unit at a hospital in south-central Montana. The hospital environment is not conducive to quality sleep for patients. Many different factors interrupt patients' nighttime rest and contribute to poor sleep quality and impaired healing including symptoms of illness, painful procedures such as blood draws, and a noisy environment. In this project, the effect that music played at the bedside prior to bedtime would have on self-reported quality of sleep for postoperative open-heart patients was evaluated.

The aim of this project was to determine whether music as an integrative therapy should be implemented in a more consistent manner for hospitalized patients. Simple surveys were employed to determine each participant's quality of sleep over a two-night period following open-heart surgery. Results from this project could influence consistent standards of care for postoperative open-heart patients. Since sleep deprivation affects many different aspects of life, the long term goals of employing music as an intervention are to improve self-reported quality of sleep, increase comfort, and decrease stress. By improving these factors, patients are more likely to have better pain control in order to

participate in rehabilitation activities such as early ambulation, which may decrease postoperative complications.

Theoretical Framework

Kolcaba's Theory of Comfort was used as the theoretical framework for this project. The midrange nursing theory addresses physical, spiritual, cognitive, or social needs and contributes appropriately to practice in acute care (Kolcaba & Kolcaba, 1991). The theory also addresses the nursing model's philosophy to treat and care for patients on a holistic level and considers healthcare needs that require interventions not traditionally addressed by the medical model. Kolcaba's Theory expands on Florence Nightingale's theory that comfort is essential to maintaining and restoring health; therefore, by improving the environment, pain and suffering may be diminished (Creasia & Friberg, 2011).

Components of this theory include physical, psycho-spiritual, sociocultural, and environmental comfort. When needs are not met in any of these four realms, a healthcare concern often arises. Physical comfort addresses homeostasis and physical sensations. Psycho-spiritual comfort pertains to self-esteem, purpose or meaning in one's life, faith, and sexuality. Sociocultural comfort regards interpersonal relationships, including family and society, and cultural traditions (Masters, 2015). Finally, Kolcaba described environmental comfort as "pertaining to the external background of the human experience, which includes light, noise, color, temperature, ambience, and natural versus synthetic elements" (as cited in Masters, 2015, p. 331).

The two components of the Theory of Comfort (Kolcaba & Kolcaba, 1991) that guided the decision-making process for this project are physical comfort and environmental comfort. Physical comfort was chosen because inadequate quality of sleep is a common problem in the hospital as patients are subjected to frequent interruptions including assessments, lab draws, and various consultations with providers. Furthermore, many diagnoses and procedures are painful or produce some level of discomfort. Environmental comfort plays a larger role in the decision-making process for this project. Complex stimuli such as alarms, loud conversations, call lights, uncomfortable bedding and gowns, dietary restrictions, and a variety of strange equipment contribute to a compromised healing environment. In the realm of physical comfort, offering soothing music to adult acute-care coronary patients may slow down the bodies' sympathetic system and activate the parasympathetic system (Ellis & Thayer, 2010).

While physical pain and side effects from medications are often pervasive components of a patient's hospitalization, environment is an extrinsic aspect that is easier to manipulate to exert enhanced comfort. Providing patients with the opportunity to access music may provide distraction from physical discomfort and overwhelming environmental factors and potentially lead to increased relaxation and comfort. While many hospitalized patients will not be completely free of physical pain, and most will not be free of interruptions, music therapy is an empathetic, appropriate intervention that meets Kolcaba's intent to comfort (Masters, 2015).

METHODS

Ethical Issues

Prior to implementation of this project, Institutional Review Board (IRB) approval was obtained from the local IRB as well as Montana State University-Bozeman IRB (Appendix B). Enrollment in the project began in June, 2018, after providing education to clinical supervisors, registered nurses, and certified nursing assistants at several shift huddles on the project floor.

In August, 2018, the local IRB discontinued oversight for the facility where the project was implemented. Due to the loss of IRB supervision, the project was then resubmitted for approval to the appropriate IRB team located in Denver, Colorado, which assumed oversight for the healthcare facility where the project was conducted. Upon approval, enrollment of participants resumed in September, 2018, and was completed in February, 2019.

In order to complete this project, information from participants of both the intervention and comparison groups' medical records was collected. Information included pulse, blood pressure, self-reported pain rating based on a numeric visual analogue scale (VAS), and pain medication usage during overnight participation in the project. Protected health information was coded to protect privacy. Patients that chose not to listen to music at bedtime were offered the opportunity to be a part of the project as a member of the comparison group. No financial compensation was offered for taking part in the project.

Participation was contingent on signing the consent and authorization form that was approved by each IRB (Appendix C).

Design

The project was an observational, feasibility project design to evaluate the beginning indicators of whether music is a good intervention to improve quality of sleep for adult patients while hospitalized. The paired design utilized pre- and post-implementation surveys between two groups: intervention and comparison. Along with the usual care, the intervention group was asked to listen to music for two nights at bedtime. The comparison group did not listen to music and received usual care.

Sample

The sample was comprised of postsurgical open-heart patients. Recruitment was completed on a face-to-face basis after patients were transferred from the intensive care unit (ICU) to the adult acute coronary care unit (CCU). Initially, 27 people were recruited. Three participants who had agreed to participate reversed their decision prior to signing consent or filling out surveys. The final sample ($n=24$) ranged in age from 27 to 83 years old. The participants were evenly split between the intervention group ($n=12$) and the comparison group ($n=12$). Fifteen participants were male and nine were female. Nine underwent valve-replacement surgery, while the other 14 were postoperative coronary artery bypass graft (CABG) patients.

Inclusion and Exclusion Criteria

Adults admitted to the CCU following cardiothoracic surgeries were considered for this project. The surgical procedures included coronary artery bypass grafts (CABG), aortic valve replacement (AVR), and mitral valve replacement (MVR). Cardiothoracic patients are transferred during day shift from the ICU approximately one to three days postop and are typically admitted to CCU for two to five days depending on how well they progress. The recovery process and protocol is typically the same for CABG, AVR, and MVR procedures.

Potential participants had a transfer cutoff time of 2:00 p.m. to be considered for enrollment for the same evening. The cutoff time allowed for patients to adjust to the differences in environment between the ICU and the CCU prior to enrollment. Per the cardiovascular surgeon's protocol, expectations were for patients to be out of bed to the chair by 6:00 a.m., ambulate four times per day in the hallway, and be able to walk up one flight of stairs prior to discharge.

Individuals excluded from this project included those under the age of 21 because they are not typically admitted to CCU. Patients who were cognitively unable to consent (dementia patients or those with developmental delays) or give reliable reports were also excluded. Deaf patients were excluded only because the project involved the use of music as the primary intervention. Patients unable to read or speak English were excluded because the evaluation tools are only available in English and funding was not available for an interpreter. Finally, if the potential participant was already asleep at the time of

enrollment, he or she was excluded as it was counterproductive to wake someone to offer the intervention.

Data Collection

Data collection began with review of the protocol and obtaining consent and authorization from all eligible participants in both the intervention and comparison groups. If a participant had poor vision, the consent and authorization as well as data collection tools were read aloud by the project manager. Both groups then received the Pittsburgh Sleep Quality Index (PSQI) (Appendix D), which has a high test-retest reliability (Cronbach's alpha of 0.85) and good validity for patients with primary insomnia (Backhaus, Junghanns, Broocks, Riemann, & Hohagen, 2002). The PSQI is a self-rating questionnaire used to determine baseline quality of sleep over the previous month, easily completed within five minutes. The Index consists of seven sub-scores in the following categories: (1) subjective sleep quality, (2) latency, (3) duration, (4) habitual sleep efficiency, (5) sleep disturbances, (6) use of sleep medications, and (7) daytime dysfunction. The results of the sub-scores are further calculated to reach a global score between 0 and 21. The PSQI was filled out by all consenting participants after enrollment on the first night to get a baseline measure of quality of sleep.

The Richards Campbell Sleep Questionnaire (RCSQ) (Appendix E) is a visual analogue scale (VAS) that evaluates perceptions of the domains of depth of sleep, sleep onset latency, number of awakenings, time spent awake, and overall sleep quality. The assessment is accomplished by evaluating where the participants recorded their perceived

sleep quality between two distinct points in the five aforementioned domains (e.g., “awake very little” or “awake all night long”). After the intervention period each morning between 5:00 and 7:00 a.m., all participants completed the survey by marking responses on a 0 to 100 mm scale line between the two variables. A total score is found by adding each individual domain score (1 to 100) and dividing the sum total by five. Higher scores are indicative of healthier sleep quality (Shahid, Wilkinson, Marcu, & Shapiro, 2011).

In 2011, Shahid et al., determined that the RCSQ has an “internal consistency of .90 and demonstrated that scores on the scale have a correlation of .58 with the same sleep variables as measured by [polysomnography]” (p.299). Participants were invited to share comments about their experience and then were subsequently disenrolled on the second morning following completion of the RCSQ.

Intervention

Both groups of participants filled out the PSQI baseline sleep quality survey after signing the consent and authorization form. Along with receiving usual care for comfort, those in the intervention group were asked to listen at bedtime to music that was preselected by the hospital and played on the GetWell Network© through the in-room television. Participants were asked to listen to the music for as long as they liked and to tell staff when they were ready to turn it off or restart the loop. The amount of time that music was played was noted on the whiteboard in the patient’s room.

Some participants fell asleep before calling staff to turn off the music or restart it. Consequently, time increments that the music was played were estimated at 15-minute intervals to coincide with typical rounding times. The comparison group received usual

care for comfort, which included pain medication, repositioning, temperature control, dimming the lights, etc. Both groups completed the PSQI the first evening of enrollment and the RCSQ each morning of the enrollment period. Participants were disenrolled on the second morning of the enrollment period.

Data Analysis

The long-term goal of this feasibility project was to evaluate whether the integrative therapy of music should be implemented in a more consistent manner in the inpatient setting in order to improve self-reported quality of sleep and pain control for open-heart surgical patients. Data was collected to address two questions:

1. Does music impact the RCSQ score, which indicates self-reported quality of sleep for patients who have undergone open-heart surgery?
2. Does music impact pain medication use for patients who have undergone open-heart surgery?

To answer the questions, descriptive, statistical analyses utilizing the R Project for Statistical Counseling were used and included survey responses, length of time music was played, pain scores, and pain medication dosages. An alpha level of 0.05 for all statistical tests was used.

OUTCOMES AND RESULTS

Outcomes

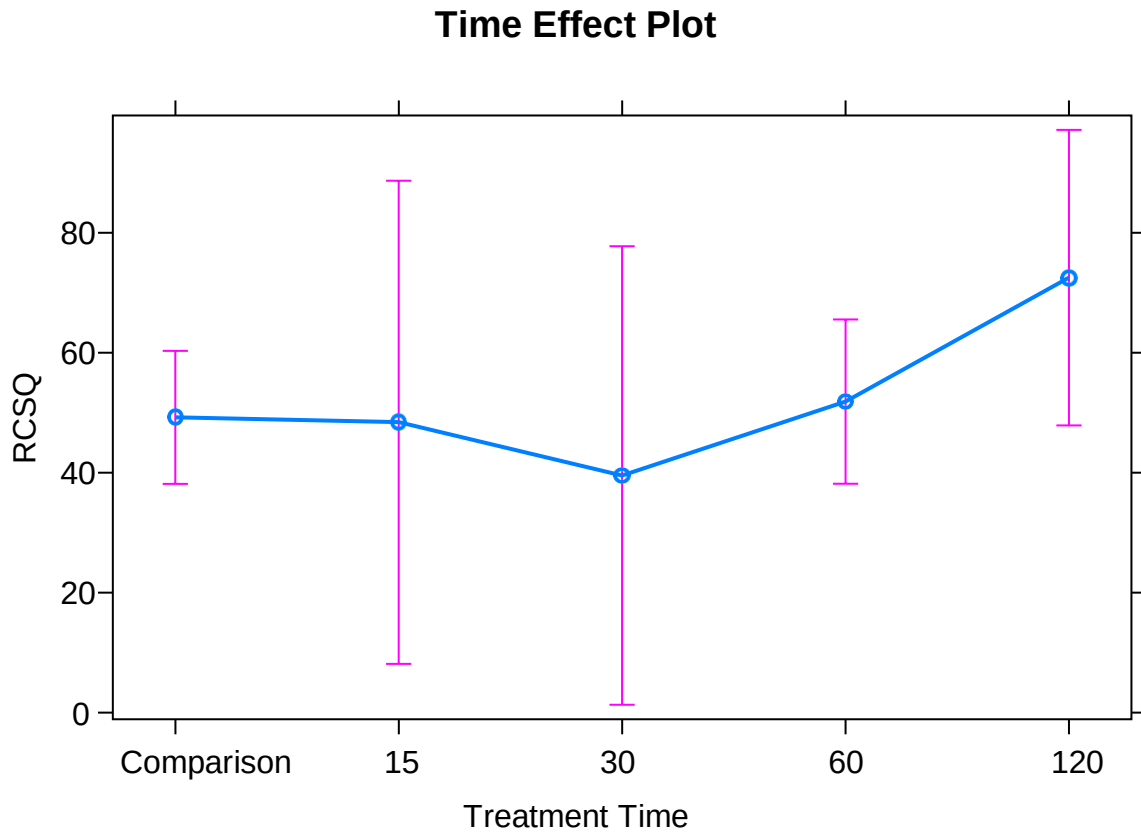
The first question addressed whether the amount of time participants listened to music had an effect on the RCSQ score. Comparison-group participants had zero minutes of music. Intervention participants listened to music at 15-, 30-, 60-, or 120-minute intervals (treatment time). Statistical significance was not achieved at any of the timed intervals (Table 1).

Table 1. RCSQ Analysis

Fixed effects:						
	Estimate	Std. Error	df	t	value	Pr(> t)
(Intercept)	59.4174	13.1828	21.9104	4.507	0.000176	
Time15	-0.8127	20.8422	36.1958	-0.039	0.969112	
Time30	-9.7018	19.6076	36.2741	-0.495	0.623727	
Time60	2.6174	8.7264	35.3455	0.300	0.765982	
Time120	23.2805	12.8733	40.8722	1.808	0.077901	
PSQI	-2.5090	1.3713	20.9639	-1.830	0.081559	
Dose	6.6995	4.0516	37.1702	1.654	0.106642	

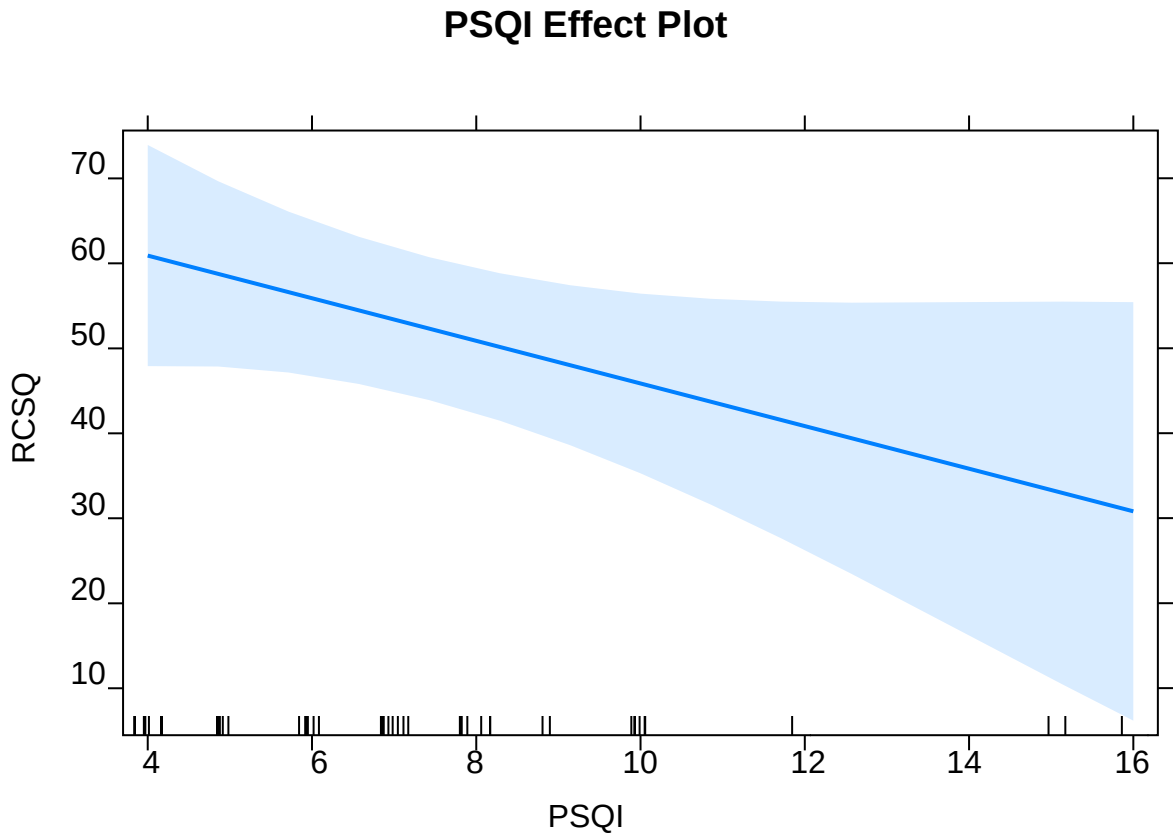
The "Time Effect Plot" (see Figure 1) shows the estimated RCSQ (y-axis) for all of the different treatment times including the comparison group, which is noted as comparison on the x-axis. Some patients only listened for 15 minutes, while others listened for 30, 60, or 120 minutes. The RCSQ scores are represented by blue dots on the plot at each treatment time. The RCSQ estimate for 120 minutes is much higher, indicating that people who listened to 120 minutes of music did better than those in the comparison group.

Figure 1: RCSQ Time Effect Plot



The "PSQI Effect Plot" (Figure 2) shows the estimated RCSQ (y-axis) for different PSQIs (x-axis) for the comparison group with a pain medication dose of zero. The key takeaway here is that there is a negative relationship between PSQI and RCSQ scores, which is to be expected. For example, a PSQI of > 5 indicates compromised baseline sleep quality, whereas a RCSQ score of > 60 indicates good sleep quality (Shahid, Wilkinson, Marcu, & Shapiro, 2011). Figure 2 illustrates the relationship between the PSQI and RCSQ scores.

Figure 2. RCSQ/PSQI Effect Plot



The next question assessed the effect of music on pain rating and pain medication dosage. Findings were not significant at any treatment time interval (Table 2).

Table 2. Pain Rating Analysis

Fixed effects:

	Estimate	Std. Error	df	t value	Pr(> t)
(Intercept)	1.6650	0.5288	25.2593	3.148	0.00418
Time15	0.8942	1.7701	75.5722	0.505	0.61490
Time30	1.4126	1.6866	77.3435	0.838	0.40487
Time60	0.6959	0.6287	32.0648	1.107	0.27659
Time120	1.1620	1.0053	44.5506	1.156	0.25390
Dose	0.3202	0.3084	33.9721	1.038	0.30656

The mean pain rating was consistent in both intervention and comparison groups. Pain medication dosages increased as pain ratings increased, which is to be expected as usual treatment includes administering pain meds with increased pain rating. The mean pain rating and pain medication dosage were consistent across all treatments, though the control group had the lowest estimate as shown in the “Pain Rating/Time Effect Plot” (Figure 3) and “Pain Rating/Dose Effect Plot” (Figure 4).

Figure 3. Pain Rating/Time Effect Plot

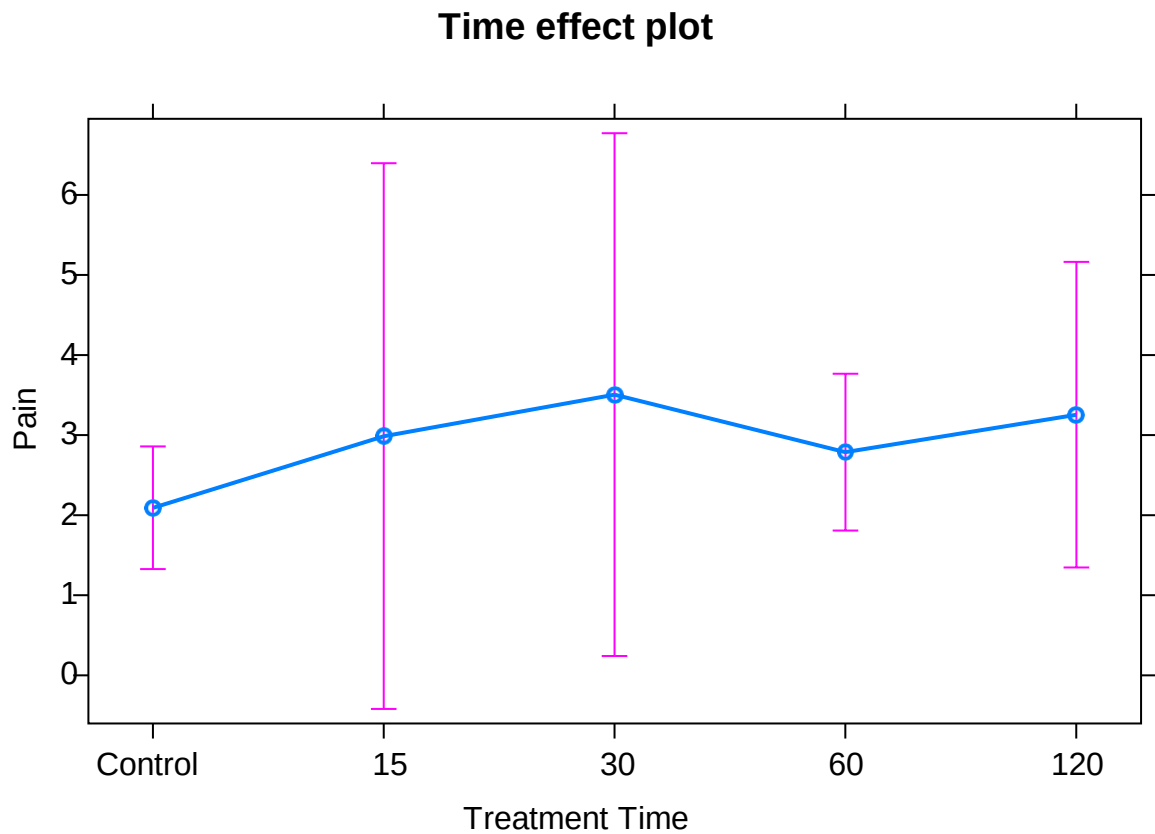
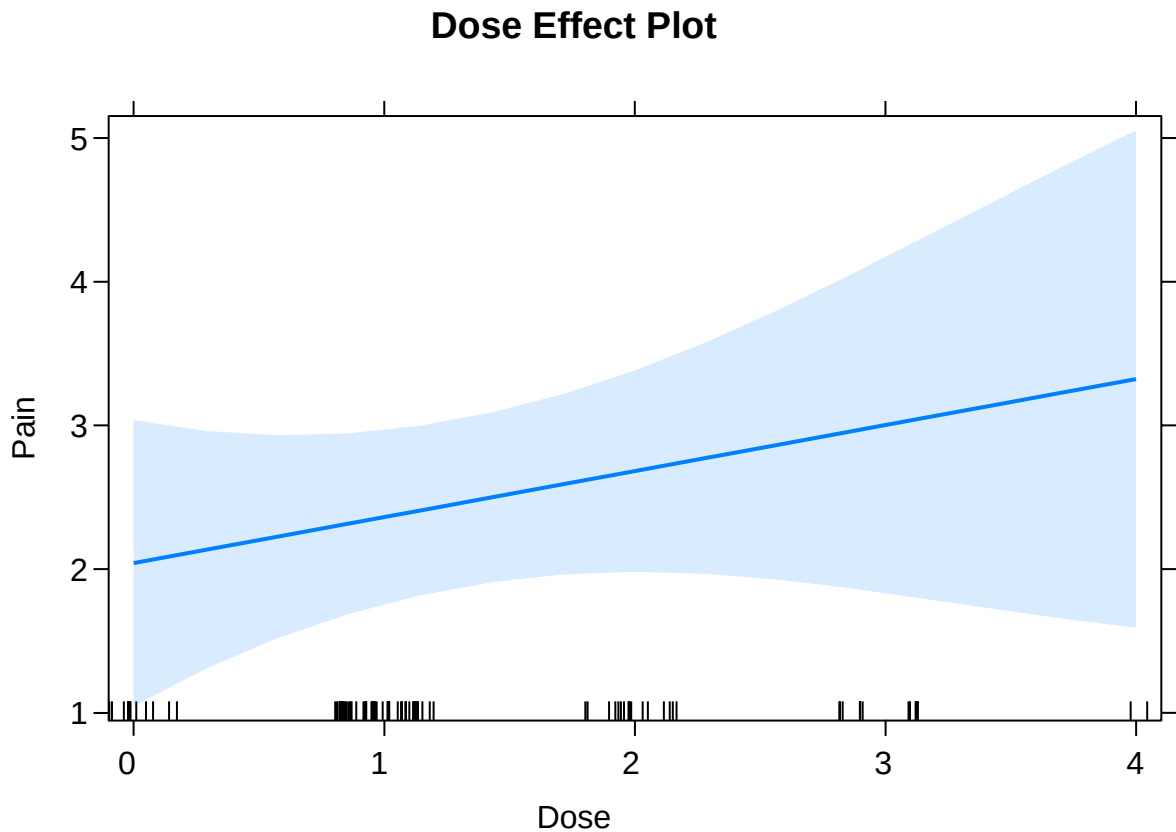


Figure 4: Pain Rating/Dose Effect Plot



Qualitative Data

Participants were invited to share their perceptions of how the project affected their stay. Most offered generic comments such as “I liked it” or “It was good,” but a few participants did offer more in-depth insights. On the last day of enrollment, one comparison group participant noted, “I wish I would have listened to the music. Music makes people feel good.” Another participant stated, “I loved it. It definitely helped me fall asleep.”

Family and friends of patients frequently stay overnight in the hospital room with their loved one. The spouse of one of the intervention participants made the following statement. “[Participant] slept great, and so did I! We both really enjoyed it.” Not all

comments were positive. An intervention-group member noted that, while initially falling asleep with the music was pleasant, “I couldn’t get back to sleep when they woke me up to give me meds, so I had it turned off.” Also, a participant that was younger than 30 stated, “I don’t like this type of music. It’s annoying me and I can’t sleep.”

Summary

Significant findings were not found for the two questions asked in this project. The first question of whether music impacts RCSQ score did come close to statistical significance for those patients that listened to music for 120 minutes. The second question addressing whether music impacts pain medication use for patients who have undergone open-heart surgery did not reach significance at any treatment time. In general, the qualitative comments were very positive with the exception of an intervention member that did not like the genre of music played during the intervention.

DISCUSSION

Introduction

Music as an effective intervention to improve quality of sleep for hospitalized cardiac-surgical patients was explored using a simple survey method in a convenience sample. A total of 24 patients participated in the project with the sample split evenly between the intervention and comparison groups. Three participants in the intervention group listened to music on the first night, but chose not to on the second night. They did, however, complete the RCSQ both mornings prior to disenrollment and were moved from the intervention to the comparison group for the second night.

Results

The results of this pilot feasibility project were not statistically significant to indicate that music improved quality of sleep in this sample. It should be noted, however, that the mean RCSQ score for a participant who listened to 120 minutes of music was estimated to be 23.28 points higher ($p=0.078$) than for a subject in the comparison group that did not listen to music. In regards to pain medication dosage, participants who listened to music the longest (120 minutes) reported higher pain scores in the morning versus bedtime. This finding could possibly be explained by deeper and longer periods of sleep, which typically precludes the patient from receiving pain medication.

When enrolling for this project, participants self-selected to either the intervention group or comparison group. Subjects in the intervention group were also allowed to

determine how long they listened to music. This could be interpreted to mean that the subjects who were most open to the treatment were likely the ones who saw the most improvement in the RCSQ scores creating a placebo effect. While there is no evidence the improved RCSQ scores were caused by music, it should be noted that a placebo effect does not necessarily decrease the value of the results. If a participant experienced improved quality of sleep, whether because of a placebo effect or treatment effect, the fact that there was an improvement is still an important result.

A small sample size and overall design could have contributed to the lack of positive results in this case. While significant results were not found in this project, the review of literature does support music as a positive intervention for improving sleep quality in hospitalized patients. For example, the 2016 RCT by Wang, Chair, Wong, and Li that was discussed in the background and literature review had a larger sample size ($n = 64$) than this project and intervention participants self-selected the amount of treatment time in that trial. The results of the 2016 RCT found that the group that listened to music had statistically significant improvement in baseline quality of sleep over a three-month period of time.

Recommendations

Although findings were overall not statistically significant, results did reveal a nonsignificant yet positive trend at 120 minutes' treatment time. This project was implemented on a small scale to provide a foundation of knowledge that minimizes risk and decreases the amount of failures after initial assessments have concluded (Langley et

al., 2009). Employing a pilot feasibility project also has the advantage of reducing fear of change among stakeholders. Moving forward, the project could be expanded.

Recommendations suggested by this project include modifying and testing the project under other conditions before possibly implementing the project facility-wide. The first modification would be to increase the sample size and broaden the population of patients included in the project. For example, rather than limiting the sample to open-heart surgical patients, including all patients on the acute coronary care unit may be feasible. For example, adults having undergone heart catheterization for coronary artery disease, vascular surgeries such as carotid endarterectomy and fistula placements, and those suffering respiratory failure or dangerous dysrhythmias could be considered.

The second modification would be to increase staff education, including high-visibility informational flyers in the staff breakroom to remind staff members to offer enrollment. Increased staff assistance would help alleviate the burden on the project manager to enroll participants. Information should also be included in daily staff huddles during the implementation period to keep the project visible.

Third, a variety of music could be offered, appealing to personal taste, culture, etc. Rather than allowing participants to choose the amount of time they listen to music, they should be randomly assigned to the intervention or comparison group as well as the treatment time to eliminate the possibility of selection bias. Finally, in the future, time of actual sleep should be recorded and activity amounts such as daily ambulation distance could be considered as a possible indicator of improved sleep.

Limitations

Sample

Perhaps the most significant limitations in the project were the small sample size ($N = 24$) and the homogeneity of the candidates. The generalizability of findings is limited because eligibility for this project was dictated by inclusion criteria that narrowed the field to postoperative open-heart patients. The pool of potential participants was constrained because open-heart surgeries were limited in number at this particular facility.

Music Choice

According to Danhauser and Kemper (2005), characteristics such as age, cultural experience, personal taste, and musical aptitude may affect the influence that music has on the listener and musical taste is typically a very personal choice (Schäfer, Sedlmeier, Städtler, & Huron, 2013; Bryson, 1996). Frith (1996) noted that “we all hear the music we like as something special” (p. 275); however, factors such as tempo, pitch, harmony, melody, and rhythm all contribute to how music is perceived and what influence these elements may have on individuals (Danhauser & Kemper, 2005).

Trappe (2012) suggested that the “most beneficial music for the health of a patient is classical music” (p. 27) and that it particularly benefits cardiac patients and those with sleep disturbances. Other studies have also suggested that music played in the therapeutic setting should be instrumental and have a soothing, repetitive tempo between 60 and 80 beats per minute (Sand-Jecklin & Emerson, 2010). In this project setting, music was

preselected by the hospital and was limited to one loop recording lasting one hour. There was little variety to the type of music played, and several participants chose not to listen for an extended period of time for that reason.

Staffing

Only one cardiovascular (CV) surgeon was employed by the facility during the implementation period, so the census of open-heart surgical patients was sporadic. When the CV surgeon was unavailable, locum tenens physicians were available for emergent open-heart surgeries; however, scheduled cases were more common. Also, staffing amongst nurses and certified nurse's assistants (CNAs) was inadequate throughout the facility and particularly on CCU. The staffing matrix for the CCU calls for a 4:1 patient-to-nurse ratio; however, on night shift, nurses may have up to six patients, and CNAs are often pulled from the floor for 1:1 sitters, or the nurses are simply short staffed.

As a result of short staffing, it was difficult to enroll participants before they fell asleep. The busiest time of a night shift in this location is typically from 7:00 p.m. to 10:00 p.m. While staff were educated about the project and were supportive in general, time constraints and priorities such as vital signs, assessments, and medication administration took precedence over enrollment. Implementation was difficult because of the demands of the patient case load for the night, particularly when the project manager was the charge nurse on duty.

Measurements

Length of stay and activity levels may be better quality-of-sleep indicators than vital signs and pain ratings. While heart rate, blood pressure, and respiration rate are the most commonly measured vital signs investigated in relation to music (Ellis & Thayer, 2010), vital signs in this case might not have been a reliable indication that music helped improve these readings. Heart rate may be influenced by dysrhythmias common to open-heart surgery, especially atrial fibrillation (Afib), which can often have rapid ventricular response (RVR). In the case of Afib RVR, heart rates are often elevated above 120 beats per minute. Also, medications such as beta blockers are frequently administered to those with heart disease; heart rate and blood pressure are typically decreased with this treatment. Furthermore, pain scores may not be a reliable indicator of whether music improves quality of sleep because pain is subjective and expected in this type of surgical procedure.

Implications for Future Practice

Music has been shown in the literature to be a safe and affordable intervention and appears to be an intervention worthy of further investigation. The literature indicates that patient preference in music should be a factor when implementing music to improve quality of sleep in the inpatient setting (Weeks & Nilsson, 2011). When patients are admitted to the facility where this pilot feasibility project was conducted, screens and referrals are completed by nursing staff. The screens and referrals section of the

electronic health record allows for information such as patient preference for chaplain services, pet therapy visits, and specific spiritual practices that may impact care.

Referrals are triggered to implement these interventions when a patient indicates a preference for care. By adding music (to include preferences) to the screens and referrals section, hospital staff may be better able to identify if patients would like to employ music at the bedside to help improve quality of sleep. A facility-wide subscription to a music service such as Pandora© would allow for a wider range of music choices. Furthermore, music could be added to provider order sets, such as delirium prevention, for all inpatients. An order set such as this could work in conjunction with daily screenings for delirium and interventions to promote a normal circadian rhythm.

Future projects could be conducted in settings outside the acute-care facility. Not only is music a viable option for improving sleep quality in the acute-care setting, but also in long-term-care settings as well. One option is to implement music in assisted living and/or skilled nursing facilities near bedtime hours to see if this intervention could help promote sleep hygiene and improve quality of sleep for elderly long-term-care residents (Wang, Chair, Wong, & Li, 2016).

CONCLUSION

Existing evidence consistently indicates that sleep quality is a significant component of health, but is often overlooked by providers and patients alike. Current literature points out that clinicians routinely fail to inquire about sleep and typically will resort to pharmacological management as first-line treatment. Furthermore, those suffering from sleep disturbances typically do not seek out professional treatment until it begins interfering with daytime function.

While common in daily life for many people, sleep disruption becomes a greater issue when hospitalized. In this situation, patients are subjected to a foreign atmosphere that is often considerably more uncomfortable than their day-to-day environment. The effect of poor-quality sleep on healing and health in general is well documented. Therefore, when homeostasis is compromised by physiological/psychological disruptions such as surgery and general health crises, quality sleep should be a priority.

While significant differences were not observed in the groups developed for this project, music did appear to influence participants' quality of sleep as evidenced by improved RCSQ scores in the intervention group (120 minutes) and participant comments. Moving forward, testing in this project could be recreated with a broader pool of candidates to improve sample size. Staff education could be expanded to include high-visibility flyers and reminders during daily shift huddles to recruit participants when feasible. Participant groups and length of time music is played could be randomized rather than self-selected to decrease placebo effect.

The amount of time slept throughout the night could be recorded for comparison between the two groups. Also, length of stay and activity, such as daily ambulation distance, could be considered as possible indicators of improved sleep as opposed to vital signs, which are influenced by many different factors. Lastly, the current mode of music delivery was limited to one choice at the facility where this project was carried out and proved to be a hindrance. A variety of music should be available to account for personal taste and diversity keeping in mind that classical music may be the most beneficial (Trappe, 2012). This could be accomplished simply by using a music subscription service such as Pandora©.

After exploring the scholarly question of how to improve quality of sleep for patients hospitalized for open-heart surgery, music appears to be an intervention worthy of further investigation. This integrative therapy is affordable, has no known risks, and is easy to implement. The results from this project indicate that music has the potential to have a positive effect on hospitalized patients' quality of sleep.

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APPENDICES

APPENDIX A

EVIDENCE TABLE

Evaluation Table All Studies

PICOT: In adult patients admitted to acute coronary care following open-heart surgery, does the use of music overnight improve quality of sleep as self-reported by the patient while hospitalized

Citation: (i.e., author(s), date of publication, & title)	Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables Studied and Their Definitions	Measurement of Major Variables	Data Analysis	Study Findings	Strength of the Evidence (i.e., level of evidence + quality [study strengths and weaknesses])
Bhana, Varshika M., & Botha, Annali D.H. (2014). The therapeutic use of music as experienced by cardiac surgery patients of an intensive care unit	Not Noted	Qualitative Research with descriptive, explorative, and contextual design.	Purposive Sampling Nine cardiac surgery patients between the ages of 30 and 70 years admitted to the ICU of a public hospital	Four main themes were identified: 1) practical and operational aspects of the music sessions; 2) participants' experiences; 3) discomfort due to therapeutic apparatus and the ICU environment; 4) the role of music and recommendations for music as a therapeutic intervention	In-depth interviews, field notes and participant observation Themes, categories and subcategories	1). Interviews were transcribed verbatim 2) Content analysis and coding procedures were used to analyze data 3) Data saturation occurred when the new data collected was repetitive 4) A co-coder ensured that the collected data was correctly interpreted	Participants found music with slow, harmonious rhythm and low pitch to have a positive effect. researcher concluded that the therapeutic use of music can be beneficial to the recovery of patients Participants themselves recommended that music sessions be	Study Strengths – Informative to practice Weaknesses – Limited by small purposive sampling. Limited by ability to generalize the results to different populations. Level of Evidence: VI USPSTF Level of Certainty: Low

						and coded.	implemented for other patients. As a guideline, music sessions should be 20 minutes long	
Coyle, M., & Salerno, Maria. (2009). The Relationship of Depressive Symptoms over Time on Self-care Behavior in Patients Who Experience a Myocardial Infarction, ProQuest Dissertations and Theses	Self Care Theory	Descriptive correlational design	62 patients hospitalized for AMI	Hypotheses included: Depressive sx after MI change over time; There is an inverse relationship between depressive symptoms and self care behaviors after MI	Medical and Demographic Questionnaire; BDI-II; Health Behavior Scale	Descriptive statistics	The first hypothesis was not supported. The second hypothesis was supported	Informs practice. Strong evidence that depression symptoms affect self-care behaviors at 30 days post MI Level of Evidence: VII USPSTF Level of Certainty: Low to Moderate
Jiang, X., Hegadoren, K.M., & Zhang, Y. (2015). Effects of	None Noted	RCT – Pilot study	prospective single-center parallel-group RCT performed at 21-bed		-Subjective sleep quality using RSCQ - Nocturnal melatonin and	Independent samples t-test or non-parametric Wilcoxon rank sum test -	Using earplugs and eye masks with relaxing background music is useful for promoting	Strength: provides a reasonable basis for promoting these non-pharmacological

earplugs and eye masks combined with relaxing music on sleep, melatonin and cortisol levels in ICU patients: A randomized controlled trial			CSICU Fujian Medical University Union Hospital, data analyses were carried out for 20 cases in the intervention group and 25 cases in the control group		cortisol levels - Nocturnal noise and light levels -	Group comparisons Chi-square test - Comparison of count data ANOVA - differences in 6-SMT and cortisol concentrations at different points in time. An alpha of 0.05 was considered significant	the sleep perception of the patient Using earplugs and eye masks with relaxing background music does not influence the nocturnal melatonin or cortisol levels	interventions for ICU patients Limitation: study has small homogenous population and limited time frame Level of Evidence: VI USPSTF Level of Certainty: Moderate
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Kamioka, H., Tsutani, K., Yamada, M., Park, H., Okuizumi, H., Tsuruoka, K., . . . Mutoh, Y. (2014). Effectiveness of music therapy: A summary of systematic reviews based on randomized controlled trials of music interventions	None noted	SR	SR which included 21 eligible RCTs (16 Cochrane Reviews) that included at least one MT treatment group	Mental and behavioural disorders (8 studies); Diseases of the nervous system (2 studies); Diseases of the respiratory system (2 studies); Endocrine, nutritional and metabolic diseases (1 study); Diseases of the circulatory system (1 study); Pregnancy, childbirth and the puerperium (1 study)	Measurement instruments were not specified	Data analysis was not noted	MT treatment improved the following: global and social functioning in schizophrenia and/or serious mental disorders, gait and related activities in Parkinson's disease, depressive symptoms, and sleep quality.	Strengths – 1) Methods and implementation registered high on the PROSPERO database; 2) Comprehensive search strategy across multiple databases with no data restrictions; 3) High agreement levels for quality assessment of articles. 4) No adverse effects or harmful phenomena noted in any of the studies Weaknesses – 1) Selection bias remained due to differences in eligibility for participation in each original RCT 2) Publication
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								bias 3) Did not describe all details on quality and quantity, such as type of MT, frequency of MT, and time on MT Level of Evidence: I USPSTF Level of Certainty: High
Kuhlmann, A.Y. R., Etnel, J. R. G., Roos-Hesselink, J.W., Jeekel, J., Bogers, Ad J. J. C., & Takkenberg, J. J. M.	None noted	SR	Ten RCTs evaluating the effect of music interventions in the treatment of hypertension	Patient and study characteristics including: age, sex, systolic and diastolic blood pressure at baseline, history of hypertension, use of antihypertensive	Measure instruments were not specified	Specific data analysis was not noted	1) There was a large variation in follow-up duration and in the type, timing and duration of music intervention sessions	Strengths - found a trend towards a decrease in blood pressure in hypertensive patients who received music interventions, however more

(2016). Systematic review and meta-analysis of music interventions in hypertension treatment: A quest for answers.				medication, comorbidities, details of music intervention and length of follow- up Primary outcome measures: reduction in SBP and DBP and mean SBP and DBP at last follow-up. Secondary outcome measures: effects of music on anxiety and quality of life.			among the included studies 2) Mean age of the patients in the music intervention arms was 65.2 [+ or -] 7.3 years 3) 42 % male 4) history of hypertension was reported in 92 % of the patients 5) 78 % used anti- hypertensive drugs 6) In the pooled analysis of mean SBP and DBP at baseline and last follow-up, music interventions were associated with a decrease in SBP from 144 mmHg to 134	research is needed Weaknesses - although evaluation of the effect of music interventions in the treatment of hypertension found a decrease in pooled mean SBP and DBP after application of music interventions, statistical significance was not reached Level of Evidence: I USPSTF Level of Certainty: Moderate
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							mmHg, as well as a decrease in DBP from 84 mmHg to 78 mmHg 7) Five studies evaluated the effects of the music intervention on quality of life and anxiety. Only One study found significant improvements in quality of life	
Nilsson, U. (2008). The Anxiety- and Pain-Reducing Effects of Music Interventions: A Systematic Review		SR	42 relevant RCTs met the inclusion criteria	clinical effects of music interventions for pain and anxiety for hospitalized patients in perioperative settings -outcome measure questionnaires -blinding - concealment of allocation at	STAI Numeric rating scale VAS	Specific data analysis was not noted	- studies were assessed for the quality of their methodology, and they were analyzed according to outcome measures. The majority of the music interventions (n = 15) were performed postoperatively	Level of Evidence: V USPSTF Level of Certainty: Moderate to High

				enrollment -completeness of f/u - sample size calculation		NO single included study was assessed to have the maximum quality score of 10 points A majority of the included studies (n = 30) had demonstrated validity and reliability measures in 90% of their outcomes Nine studies were single blind, two were double blind Only 8 studies reported random allocation Twenty-two studies reported 100% f/u	
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							12 of the 24 studies (50%), the music intervention significantly reduced anxiety scores In 7 of 15 studies, the music intervention resulted in a significant decrease (47%) in the use of analgesics.	
Norton, C., Flood, D., Brittin, A., & Miles, J. (2015). Improving sleep for patients in acute hospitals		QIP	Patients (n = 749) using convenience sampling of 18 wards in an acute hospital trust of three hospitals in London	Thematic analysis found four main themes of sleep disturbance: 1) other patients (15%) 2) environment (lighting, heat and noise) (37%) 3) equipment (22%) 4) staff (26%)	Electronic patient survey Observations of noise, temperature, light and humidity readings	Independent samples T-test	After intervention period: Overall sleep rating was significantly improved, from 47% (352/749) reporting sleep as good or excellent at baseline to 69% (540/783) at follow up (	Strength – Large sample size Limitations - no control group, unable to measure sleep directly Level of Evidence: VI USPSTF Level of Certainty: Low - Moderate

							P <0.001) Noise had reduced significantly (P = 0.014) and light was also improved (P = 0.059). Temperature was not significantly different (P = 0.72) and humidity was no different (independent samples T-test)	
Ryu, M., Park, J. S., & Park, H. (2012). Effect of sleep-inducing music on sleep in persons with percutaneous transluminal coronary angiography in the cardiac care unit	None noted	experimental research design, Randomized	conducted in CCU of a University Hospital. Fifty-eight subjects participated and were randomly assigned to the experimental group (n = 29) and the control group (no music, but earplugs and	(1) The quantity scores of sleeping in experimental group (sleep-inducing music) will be higher than in control group (ear plugs only) (2) The quality scores of sleeping in experimental group will be higher than in the control group	Quantity of sleeping questionnaire VSH sleeping scale	Descriptive statistics were used to describe demographic and sleeping characteristics. Independent t-test was used to test the two hypotheses	Participants in the experimental group reported that the sleeping quantity and quality were significantly higher than control group (t = 3.181, p = 0.002, t = 5.269, p < 0.001, respectively) Hypothesis 1:	Limitations: Homogenous group in ICU at one point in time. Level of Evidence: VI USPSTF Level of Certainty: Moderate

			eyeshield worn, n = 29).				Supported Independent t-test revealed that the quantity of sleeping in the experimental group was significantly higher than control group (t =3.18, p < 0.05) Hypothesis 2: Supported Independent t-test revealed that the quality of sleeping in the experimental group was significantly higher than control group (t = 5.26, p < 0.001)	
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Vaajoki, A., Kankkunen, P., Pietilä, A., Kokki, H., & Vehviläinen-Julkunen, K. (2012). The impact of listening to music on analgesic use and length of hospital stay while recovering from laparotomy	None noted	prospective design with two parallel groups	Patients undergoing elective abdominal surgery (n = 168) were assigned to either a music group (n = 83) operated on odd weeks or a control group (n = 85) operated on even weeks.	The music group listened to music 7 times for 30 minutes at a time during the first 3 postoperative days. The control group did not listen to the music	Visual Analogue Scale pain scores Pre and post operative questionnaire	Frequencies and percentages were used to describe the demographics of patients, adverse effects of epidural analgesia, and patients' spontaneous comments after listening to music chi-square ([chi]2) test was used to test independence of treatment group assignment Duration of anesthesia, surgery, postanesthesia care unit stay, and epidural analgesia were analyzed by the nonparametric Mann–	Postoperative opioid consumption during the first 72 hours after surgery was less in the music group (21 mg) than in the control group (24 mg), but the difference was not significant ($p = .74$). In the music group, 51 (61%) subjects had a total of 90 adverse effects and in the control group, 51 (61%) subjects had 103 adverse effects ($p = .88$). In both groups, the average length of hospital stay was 12 days Hypotheses	Limitations: Lack of random assignment of the subjects to the music and control groups. The researcher was not blinded to group assignment Level of Evidence: VI USPSTF Level of Certainty: Moderate
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						Whitney U test for independent samples. Duration of epidural analgesia and the length of hospital stay were also analyzed by the Kaplan–Meier test. Differences were regarded as statistically significant if the two-sided P value was less than .05.	were not supported	
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Wang, Q., Chair, S., Wong, E., & Li, X. (2016). The Effects of Music Intervention on Sleep Quality in Community-Dwelling Elderly	None noted	Two-armed RCT	Sixty-four elderly people in four urban communities in Xi'an, China, with PSQI >7 Mean age of 69.38 ± 5.46 years. Randomly assigned to the control group (n = 32) or the intervention group (n = 32)	One session of sleep hygiene education (control) Music intervention (intervention group)	Sleep quality measured by PSQI at baseline, 1 month, 2 months, and 3 months.	Descriptive statistics of frequency, percentage, or mean and standard deviation independent t-test and chi-square test were used to test the homogeneity of the sample Independent t-tests were applied to compare the changes in sleep quality between groups at each time point. Repeated-measures ANOVA used to examine the effects of music intervention	The intervention group demonstrated continuous improvements in sleep quality, with a global PSQI score of 13.53 at baseline, 9.28 at 1 month, 8.28 at 2 months, and 7.28 at 3 months. Although the global PSQI score in the control group also decreased from 12.26 at baseline to 8.72 at 3 months, the intervention group achieved greater improvements at each measurement (all p < 0.05)	Limitations - listening to music was self-conducted; actual dose of music intervention may vary among individuals; sleep quality was measured by the PSQI, which could not provide more accurate and objective information of sleep quality Level of Evidence: VI USPSTF Level of Certainty: Moderate
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Wang, C., Sun, Y., & Zang, H. (2014). Music therapy improves sleep quality in acute and chronic sleep disorders: A meta-analysis of 10 randomized studies	None noted	SR – Meta-analysis	Ten studies involving 557 participants were identified. Studies with randomized controlled design and adult participants were included if music was applied in a passive way to improve sleep quality	Systematic search of publications in PubMed, Embase, and the Cochrane Library without language restriction	Studies were assessed for quality by randomization, blinding, reporting of withdrawals, generation of random numbers, and concealment of allocation	SMD was used as the measure of effect and the results were expressed as a SMD with 95% CIs heterogeneity among studies was tested by Qstatistic (significance level at $p < 0.10$) and I-statistic	Sleep quality was improved significantly by music (standard mean difference: -0.63; 95% CI: -0.92 to -0.34; $p < 0.001$), with significant heterogeneity across studies. I-statistic is 2, which describes the percentage of total variation across studies that is due to heterogeneity rather than due to chance, where high values of the index ($I^2 > 50\%$) indicate the existence of heterogeneity	Strengths - Subgroup analysis found heterogeneity between subgroups with objective or subjective assessing methods of sleep quality, and between subgroups with difference follow-up durations. No evidence of publication bias was observed. Limitations – Sample size of some studies is relatively small and some studies have low quality of evidence Level of Evidence: I USPSTF Level of Certainty: Moderate to
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								High
Weeks, B., & Nilsson, U. (2011). Music interventions in patients during coronary angiographic procedures: A randomized controlled study of the effect on patients' anxiety and well-being	None noted	Prospective RCT using convenience sampling	Patients undergoing (n = 98) elective coronary angiogram and/or percutaneous coronary intervention randomly allocated to three different groups of sound environments	a control group (the usual sound environment), a patient focused music group (audio pillow) (PF) a loudspeaker music group (LS)	Anxiety was measured by NRS scoring from 0= no anxiety to 10=worst possible anxiety questionnaire measuring well-being and sound environment	Kruskal–Wallis one-way analysis following by a Mann–Whitney test was used to compare the data among the three groups. ANOVA of a given variable was made by the Friedman test for pair wise comparison, if an overall difference was found. A p-value below 0.05 was considered to indicate a statistically significant difference	Anxiety decreased significantly and well-being increased significantly in the two music groups compared to the control group A significantly higher anxiety score was measured in the control group 5 (range: 1–10) when compared to group LS music group 2 (range 1–9), pb0.05 and PF music group: 2 (range: 1–8), pb0.05. No significant difference was measured between the anxiety score	Limitations - music delivered via loudspeakers seemed to distract the staff during the examination at the cardiac catheterization laboratory. Patient focused or chosen music seemed to be more preferable sound environment was rated more positively by the subjects listening to music via audio pillow Level of Evidence: II USPSTF Level of Certainty: Moderate to High

							between the two music groups. Significantly more positive well-being response was measured in the two groups exposed to the music intervention as compared to the group with the basic sound environment	
White, J., & Wierenga, Mary. (1996). Effects of Relaxing Music on Cardiac Autonomic Balance and Anxiety following Acute Myocardial Infarction, ProQuest Dissertations	Not noted	Repeated measure multiple analysis of variance design study	45 patients admitted to ICU with a diagnosis of AMI	Patients were randomly assigned to one of four groups: music, quiet, uninterrupted rest, or control	Obtained at baseline, immediately following, and one to two hours after intervention period.	MANOVA	Significant reductions in heart and respiratory rates found in the group that listened to music and those that had uninterrupted rest. The Music group exhibited greater reductions in stated anxiety than the	Inform practice; Strengths in the design method of randomized quantitative study. Weakness, - year of publication; more study needed Level of Evidence: VII USPSTF Level

and Theses.							control group.	of Certainty: Moderate

LEGEND:

AMI = Acute Myocardial Infarction

ANOVA = Analysis of Variance

BDI-II = Beck Depression Inventory

CI = Confidence Intervals

CSICU = Cardiac Surgical Intensive Care Unit

F/U = Follow-up

LS = Loudspeaker Music Group

MANOVA = Multiple Analysis of Variance

MT = Music Therapy

NRS = Numeric Rating Scale

PF = Patient Focused Group

QIP = Quality Improvement Project

RCSQ = Richards-Campbell Sleep
Questionnaire

RCT = Randomized Controlled Trial

SMD = The Standardized Mean Difference

SR = Systematic Review

STAI = State-Trait Anxiety Inventory

VAS = Visual Analogue Scale

VSH = Verran and Synder-Halpern Sleeping Scale

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APPENDIX B

INSTITUTIONAL REVIEW BOARD APPROVALS



SCL Health
IRB

September 5, 2018

Study #: 201837

Title: Is Music an Effective Intervention to Improve Sleep Quality Among Adult Post-Operative Open Heart Patients?

Dear Ms. Olds:

The IRB has received the response to minor modifications for the above referenced study, and the response has undergone an expedited review procedure [45 CFR 46.110; 21 CFR 56.110]. The study was approved on September 5, 2018. Future review may continue to be expedited under Categories # 5 and 7. The study is approved for twelve (12) months.

Approval will expire on September 4, 2019.

Please note that Chair requests that study subject numbers will be changed to random numbers (e.g., Subject 1, 2, 3, etc.) and will not include the room number, their sex, date of enrollment and the type of procedure performed (or any other identifying information) as was indicated in the email dated August 23, 2018.

The following are included in this approval:

1. Submission form for a new intervention study
2. Protocol (Application from submitted to Montana State University)
3. Consent and Privacy Authorization form (no version date)
4. Richards-Campbell Sleep questionnaire (no version date)
5. Sleep Quality Assessment (PSQI) (no version date)

Please note that subjects must sign the Consent and Authorization form with the IRB approval stamp prior to the initiation of any study procedures, unless waivers of consent and HIPAA authorization have been reviewed and approved by the IRB. In addition, each subject must be given a copy of the signed consent form.

As a reminder, written approval from the IRB must be obtained prior to initiating any changes in this study. This includes, but is not limited to, changes in procedures, co-investigators/study personnel, funding source, consent and authorization forms, protocol, recruitment materials and any other materials used with subjects, and investigator

brochures unless a change is necessary to eliminate an apparent immediate hazard to the subjects in the study.

Any reportable events, including but not limited to, noncompliance, adverse events/serious adverse events, breach of confidentiality or protocol deviations involving risks to subjects or others that may occur in the course of this study, must be reported in writing within 5 business days.

The study must be conducted in compliance with the processes identified in the following SCL Health Information Security policies:

Password Configuration & Management (to ensure length and complexity of passwords are adequate)

Electronically Storing and Sharing Confidential Information (proper location of where file is stored) Protection of Electronic Confidential Information

If you have any questions, please contact the IRB Office (irb@sclhs.net; 303-812-6489).

Thank you,
SCL Health Institutional Review Board

SCL Health IRB 1375 E. 19th Ave. 80218 Phone: 303-812-6489 Fax: 303-812-6488



INSTITUTIONAL REVIEW BOARD
For the Protection of Human Subjects
FWA 00000165

960 Technology Blvd. Room 127
 c/o Microbiology & Immunology
 Montana State University
 Bozeman, MT 59718
 Telephone: 406-994-6783
 FAX: 406-994-4303
 E-mail: cherylj@montana.edu

Chair: Mark Quinn
 406-994-4707
 mquinn@montana.edu
Administrator:
 Cheryl Johnson
 406-994-4706
 cherylj@montana.edu

MEMORANDUM

TO: Alice Running and Jenna Olds
FROM: Mark Quinn *Mark Quinn Chg*
 Chair, Institutional Review Board for the Protection of Human Subjects
DATE: April 12, 2018
SUBJECT: "Is Music an Effective Intervention to Improve Sleep Quality among adult Post-operative Open Heart Patients?" [AR041218]

The above proposal was reviewed by expedited review by the Institutional Review Board. This proposal is now approved for a period of one-year.

Please keep track of the number of subjects who participate in the study and of any unexpected or adverse consequences of the research. If there are any adverse consequences, please report them to the committee as soon as possible. If there are serious adverse consequences, please suspend the research until the situation has been reviewed by the Institutional Review Board.

Any changes in the human subjects' aspects of the research should be approved by the committee before they are implemented.

It is the investigator's responsibility to inform subjects about the risks and benefits of the research. Although the subject's signing of the consent form, documents this process, you, as the investigator should be sure that the subject understands it. Please remember that subjects should receive a copy of the consent form and that you should keep a signed copy for your records.

In one year, you will be sent a questionnaire asking for information about the progress of the research. The information that you provide will be used to determine whether the committee will give continuing approval for another year. If the research is still in progress in 5 years, a complete new application will be required.

APPENDIX C

CONSENT AND AUTHORIZATION FORM

SUBJECT CONSENT AND PRIVACY AUTHORIZATION
For Participation in Human Research at
Montana State University-Bozeman and St. Vincent Healthcare

Study Title: Is Music an Effective Intervention to Improve Sleep Quality Among Adult Post-Operative Open Heart Patients?

You are being asked to participate in a scholarly project about the effect that music has on sleep quality. This project may help us understand whether music is an appropriate intervention to help patients improve sleep quality and possibly decrease post-operative complications and length of stay in the hospital.

You were identified as a possible participant in this work because you have just had open heart surgery. All open heart patients transferred from the ICU to the acute coronary care unit (3 Tower) are eligible to participate. Participation in this study is voluntary. There will be no changes in your care if you choose not to participate.

STUDY PROCEDURES: If you agree to participate you will be asked to fill out one form (Pittsburgh Sleep Quality Index (PSQI)) prior to bedtime on the first night of participation and a second form (Richard-Campbell Sleep Questionnaire (RCSQ)) on the first and second morning after the intervention. It will take approximately 10 minutes to fill out these forms. You may stop at any time, and you can skip any questions you do not want to answer.

After consenting and filling out the PSQI, music will be played through the speaker on your call light/tv remote throughout the night. The time that the intervention starts and stops will be noted on the communication whiteboard in your room.

Discharge from the project will occur at approximately 6:00 a.m. after the second night of participation and will entail collecting the RCSQ form that contains your sleep quality data. We will also collect a small amount of information from your medical record related to your pulse, blood pressure, pain rating and medication usage during overnight participation in the project. This protected health information will be coded to protect your privacy.

If you choose not to listen to music at bedtime, you may still be a part of this project as part of the comparison group. We ask that you still fill out the PSQI form prior to bedtime and the RCSQ when you wake to compare to the intervention group. Only consenting patients can be part of the comparison *or* intervention groups.

RISKS and BENEFITS: This is a project to collect information about the quality of your sleep while in the hospital. There are no foreseen medical risks or benefits expected to you for participating in this project. The information learned through this work may be used to help future patients.

COSTS/COMPENSATION: You will not be paid nor will you be charged for participating in this project.

SCL Health

IRB

Approval Date: 9/5/18

CONFIDENTIALITY: Every effort will be made to maintain confidentiality of your personal information. However, personal information may be disclosed if required by law. If information from this study is published or is presented at scientific meetings, your name or other personal information will not be used. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include St. Vincent Healthcare, Montana State University-Bozeman, and the SCL Health IRB

POLICY REGARDING STUDY-RELATED INJURIES: The risk of injury resulting from participation in this study is minimal to none. This is a project to collect information only. No funds have been set aside to compensate you in the event of injury.

AUTHORIZATION TO SHARE PERSONAL HEALTH INFORMATION IN RESEARCH

We are asking you to take part in the project described in the attached consent form. To do this project, we need to collect health information that identifies you. We may collect the results of tests, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the project. This information is described in the attached consent form. For you to be in this project, we need your permission to collect and share this information.

We will share your health information with people at St. Vincent Healthcare and Montana State University - Bozeman who help with the project. We may share your information with other investigators outside of the hospital. We may also share your information with people outside of the hospital who are in charge of the research, pay for or work with us on the research. Some of these people make sure we do the research properly. The "confidentiality" section of the consent form says who these people are. Some of these people may share your health information with someone else. If they do, the same laws that the hospital must obey may not protect your health information.

If you sign this form, we will collect your health information until the end of the project. We may collect some information from your medical records even after your direct participation in the project ends. We will keep all the information for at least six years, in case we need to look at it again. We will protect the information and keep it confidential.

Your information may also be useful for other studies. We can only use your information again if the Institutional Review Board (IRB) gives us permission. This committee may ask us to talk to you again before doing the research. But the committee may also let us do the research without talking to you again if we keep your health information private.

If you sign this form, you are giving us permission to collect, use and share your health information. You do not need to sign this form. If you decide not to sign this form, you cannot be a participant in this project. You need to sign this form and the attached consent form if you want to be in the project. We cannot do the project if we cannot collect, use and share your health information.

SCL Health

IRB

Approval Date: 9/5/18

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to the investigator listed on the attached consent form. The letter needs to say that you have changed your mind and do not want the investigator to collect and share your health information. You may also need to leave the project if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who participates, not just those people who stay in it.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?: You are encouraged to ask questions before signing consent. For questions about the project contact Jenna Olds, Doctor of Nursing Practice Student at 406-860-0361 or Dr. Alice Running at (406) 580-8244. If you have additional questions about your rights as a research participant, you can contact SCL Health IRB at (303) 812-6489 and/or the chair of the Montana State University Institutional Review Board, Mark Quinn at (406) 994-4707 or mquinn@montana.edu.

The SCL Health IRB has reviewed this consent form for clarity of information. If you have any questions, comments, or concerns about this study or about your rights as a research subject, you may call the SCL Health IRB 303 812-6489.

CONSENT AND AUTHORIZATION

I have read all 3 pages of this consent and authorization form and have had the study procedures and discomforts, inconvenience and risk of these study described to me. I have had my questions answered to my satisfaction at this time.

I, _____ (name of subject), agree to participate in this research. I also agree that my health information can be collected and used by the investigators and staff for the project described in this consent and authorization form. I understand that I may later refuse to participate and that I may withdraw from the project at any time. Refusing to participate in research or discontinuing participating at any time will not jeopardize my access to care, treatment, and services unrelated to the research. I have received a copy of this consent and authorization form for my own records.

Signed: _____

Date: _____

SCL Health

IRB

Approval Date: 9/5/18

APPENDIX D

PITTSBURGH SLEEP QUALITY INDEX

Sleep Quality Assessment (PSQI)

What is PSQI, and what is it measuring?

The Pittsburgh Sleep Quality Index (PSQI) is an effective instrument used to measure the quality and patterns of sleep in adults. It differentiates "poor" from "good" sleep quality by measuring seven areas (components): subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over the last month.

INSTRUCTIONS:

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

During the past month,

1. When have you usually gone to bed? _____
2. How long (in minutes) has it taken you to fall asleep each night? _____
3. What time have you usually gotten up in the morning? _____
4. A. How many hours of actual sleep did you get at night? _____
B. How many hours were you in bed? _____

5. During the past month, how often have you had trouble sleeping because you	Not during the past month (0)	Less than once a week (1)	Once or twice a week (2)	Three or more times a week (3)
A. Cannot get to sleep within 30 minutes				
B. Wake up in the middle of the night or early morning				
C. Have to get up to use the bathroom				
D. Cannot breathe comfortably				
E. Cough or snore loudly				
F. Feel too cold				
G. Feel too hot				
H. Have bad dreams				
I. Have pain				
J. Other reason (s), please describe, including how often you have had trouble sleeping because of this reason (s):				
6. During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
8. During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?				
9. During the past month, how would you rate your sleep quality overall?	Very good (0)	Fairly good (1)	Fairly bad (2)	Very bad (3)

Scoring

Component 1	#9 Score	C1 _____
Component 2	#2 Score (<15min (0), 16-30min (1), 31-60 min (2), >60min (3)) + #5a Score (if sum is equal 0=0; 1-2=1; 3-4=2; 5-6=3)	C2 _____
Component 3	#4 Score (>7(0), 6-7 (1), 5-6 (2), <5 (3))	C3 _____
Component 4	(total # of hours asleep) / (total # of hours in bed) x 100 >85%=0, 75%-84%=1, 65%-74%=2, <65%=3	C4 _____
Component 5	# sum of scores 5b to 5j (0=0; 1-9=1; 10-18=2; 19-27=3)	C5 _____
Component 6	#6 Score	C6 _____
Component 7	#7 Score + #8 score (0=0; 1-2=1; 3-4=2; 5-6=3)	C7 _____

Add the seven component scores together _____ Global PSQI _____

A total score of "5" or greater is indicative of poor sleep quality.

If you scored "5" or more it is suggested that you discuss your sleep habits with a healthcare provider

APPENDIX E

RICHARDS CAMPBELL SLEEP QUESTIONNAIRE

Richards Campbell Sleep Questionnaire

Code Number _____	Date _____
-------------------	------------

Each of these questions is answered by placing an "X" on the answer line. Place your "X" **anywhere** on the line that you feel **best** describes your sleep last night. The following are examples of the type of questions you are to answer.

EXAMPLE A

Right now I feel:

Very Sleepy X _____ Not sleepy at all

If you were very sleepy, you would place an "X" as is shown at the beginning of the line next to the words "**Very Sleepy**"

EXAMPLE B

Right now I feel:

Very Sleepy _____ Not sleepy at all

If you were somewhat sleepy, you would place an "X" near the center of the line. Mark the answer line near the center to indicate the answer "**Somewhat Sleepy.**"

EXAMPLE C

Right now I feel:

Very Sleepy _____ Not sleepy at all

If you were not sleepy at all, you would place an "X" at the end of the line next to the words "**Not Sleepy At All.**"

Please turn to the next page

You are now ready to begin to answer the questions. Place your "X" **anywhere** on the answer line that you feel **best** describes your sleep last night.

1. My sleep last night was:

Deep _____ Light
Sleep _____ Sleep

2. Last night, the first time I got to sleep, I:

Fell _____ Just Never
Asleep _____ Could Fall
Almost _____ Asleep
Immediately _____

3. Last night I was:

Awake _____ Awake All
Very _____ Night Long
Little _____

4. Last night, when I woke up or was awakened, I:

Got Back _____ Couldn't
To Sleep _____ Get Back To
Immediately _____ Sleep

5. I would describe my sleep last night as:

A Good _____ A Bad
Night's _____ Night's
Sleep _____ Sleep

Richards Campbell Sleep Questionnaire

Scoring Directions

1. Scores may range from 0 (indicating the worst possible sleep) to 100 (indicating the best sleep).

100 _____ 0

2. A score for each question is given based on the length of the line in millimeters from the 0 point to the cross of the patient's "X".
3. The Total Sleep Score is derived by adding the individual scores for each question and dividing by five.