THE EFFECTS OF MUSIC THERAPY ON COMFORT IN THE MECHANICALLY VENTILATED PATIENT IN THE INTENSIVE CARE UNIT

by

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Jamie Marie Besel April 2006 This work is dedicated to my husband, Rob, and my son, Daniel.

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ABSTRACT

The purpose of this pilot study was to assess the effects of music therapy on comfort in acute mechanically ventilated patients in the Intensive Care Unit. Mechanical ventilation leads to decreased comfort. Pain and anxiety may increase during this treatment modality, and the literature suggests this may directly affect patient comfort levels. Music therapy as a nursing intervention within the context of comfort, pain, and anxiety of mechanically ventilated patients was investigated.

This quasi-experiemental study used a pre-test and post-test design with subjects serving as their own control. The convenience sample consisted of 2 men and 3 women who were mechanically ventilated and fit the selection criteria. Dependent variables measured included comfort, pain, and anxiety. Physiologic dependent measures included heart rate, respiratory rate, and systolic and diastolic blood pressure collected at timed intervals. Comfort was measured using a modified version of the Hospice Comfort Questionnaire. Pain was measured using the Numerical Graphic Rating Pain Scale. Anxiety was measured using the Faces Anxiety Scale.

Important preliminary quantitative results are provided by this pilot study. The mean, standard deviation, significance, and paired t-tests were compared for each tool to determine changes in scoring before and after the intervention and control. This was also completed for physiological data including systolic and diastolic blood pressure, respiratory rate, and heart rate. Paired t-tests showed no significant mean differences between two points of measurement on systolic, diastolic, heart rate, and respiratory rate in both the intervention and control groups. Comfort, anxiety, and pain scores before and after the intervention and control also did not demonstrate significance. The small sample size makes generalization of these findings impossible to the entire population of acute mechanically ventilated patients in Billings, Montana.

CHAPTER 1

INTRODUCTION

Mechanical ventilation is a lifesaving and frequently used treatment modality for a variety of medical diagnoses in the Intensive Care Unit (ICU). Despite this fact, mechanical ventilation may be a distressing experience for the patient, and may result in a decrease in comfort. Ventilated patients are susceptible to numerous stressors such as fear, agitation, anxiety, communication problems, and loss of control (Wong, Lopez-Nahas, Molassiotis, 2001). Nurses frequently administer intravenous sedative medications to ventilated patients to counteract the negative effects of treatment. However, sedatives have a number of undesired side effects that may result in short or long term complications (Chlan, 1995). There is a need for additional research examining alternative nonpharmacologic interventions for patients requiring mechanical ventilation.

The effects of music therapy as an alternative nonpharmacologic intervention have been studied in various populations including post myocardial infarction patients (White, 1999), the elderly (Gerdner, 2000), pre and post operative patients (Koch, Kain, Ayoub, Rosenbaum, 1998), and mechanically ventilated patients (Chlan, 1995; Wong et al. 2001; Almerud & Peterson, 2003). Wong et al. (2001) defined music therapy as the therapeutic use of music to affect patient health and well-being. This controlled form of listening to music has been shown to influence the person physiologically, psychologically, and emotionally during treatment of illness or injury (Wong et al., 2001). The effectiveness of music therapy as a nonpharmacologic intervention in the reduction of pain, anxiety, and increased feeling of control and well-being has been demonstrated in mechanically ventilated patients (Chlan, 1995; Wong et al., 2001).

Interventions to promote comfort can be implemented by nurses without a physicians order. One such intervention can be the use of music therapy in the population of mechanically ventilated patients. Music can be used to manipulate the environment by the nurse to provide a comforting place for patients (McCaffrey & Locsin, 2002).

Background and Significance of Study

Comfort is not a new concept to nursing and is a desired holistic outcome for patients. Comfort can be obtained from various nursing interventions in a variety of healthcare settings. Nightingale (1859) recognized the importance of comfort for patients stating, "It must never be lost sight of what observation is for. It is not for the sake of piling up miscellaneous information or curious facts, but for the sake of saving life and increasing health and comfort" (p.70).

Throughout the 19th and 20th centuries the term comfort was used in a general sense. Making a patient comfortable was the role of a good nurse and a determining factor of the nurse's ability and character (Kolcaba, 2003). Goodnow's (1935) *The Technic of Nursing* highlighted the nurse's duty to make the patient comfortable, and identified comfort as both physical and mental in nature. Comfort was essential because

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cures for patient ailments were largely unavailable. Nurses' ability to help patients attain comfort was positive and sometimes related to an improvement in the patient's condition. In these early years comfort resulted from physical, emotional, and environmental interventions. Physicians often wrote orders for specific comfort measures including the use of heat and positioning of the bed (Kolcaba, 2003).

The context, meaning, and importance of comfort have changed significantly in recent years. This change is related, in part, to advancements in health care. Comfort has evolved into a more physical connotation with less importance to nursing as a valued skill and goal (Kolcaba, 2003). According to McIlveen & Morse (1995), as analgesics became more popular for pain control in the 1950's, few treatments for comfort were prescribed. Beginning in the 1970's, nurses' autonomy began to expand and allowed nurses to implement comfort measures without a physician's order. This change seemed to decrease the motivation and recognition by nurses to enhance patient comfort. Medical and surgical advances continued in the 1980's and pushed comfort further to the wayside as a secondary strategy for patient care (McIlveen & Morse, 1995).

Many changes have occurred in medicine since Nightingale's time, redefining the meaning and application of comfort in nursing. These changes necessitate the reinvestigation of comfort in a variety of settings. The goal for patient comfort does not have to be pushed to the wayside as medical advancements continue to threaten this integral part of nursing. As nurses continue to strive and work towards autonomy in the workplace, nursing interventions such as comfort measures are imperative and can be implemented without physicians' orders. Chinn (1992) supported this position, saying, "I

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hope that nurses will collectively move boldly into a future where knowing about, and doing something about human needs for comfort and relief from pain are clearly within nursing's realm" (p. vii).

Problem

Mechanical ventilation leads to decreased comfort. Patients receiving mechanical ventilation are often administered intravenous sedative and analgesic medications to help minimize stressors experienced during this treatment modality. Nurses rely heavily on these types of medical interventions to treat pain and anxiety, but they do not incorporate enough nursing interventions to increase comfort (McIlveen & Morse, 1995). Nursing interventions to promote comfort of mechanically ventilated patients may be beneficial and may decrease the need for these medications. Comfort measures must be examined more closely. Music therapy is an intervention that has not been investigated within the context of comfort is music therapy for mechanically ventilated patients.

Purpose

The purpose of this research study was to assess the effects of music therapy on comfort in acute mechanically ventilated patients in the Intensive Care Unit.

Definition of Terms for the Purpose of This Study

For purposes of this study, the terms comfort, music therapy, pain, anxiety, mechanical ventilation, sedation, and analgesic are defined.

<u>Comfort</u>

Kolcaba (2003) classified comfort as holistic and defined it as, "Comfort is the immediate experience of being strengthened by having needs for relief, ease, and transcendence met in four contexts (physical, psyschospiritual, social, and environmental); much more than the absence of pain" (p.251-252). Three properties of comfort as defined by Kolcaba are as follows:

1) Comfort is an essential outcome for healthcare and is patient focused.

2) Comfort is a holistic and complex state and aspects of comfort are perceived simultaneously by recipients of care.

3) The aspects of comfort are interrelated and attempts to target or measure them in a particularistic way are time consuming and inaccurate. (p. 16)

Music Therapy

According to Munro & Mount (1978), "music therapy is the controlled use of music and its influence on the human being to aid in physiologic, psychologic, and emotional integration of the individual during treatment of an illness or disability" (p.1029). The purpose of music therapy is also to promote the client's health and wellbeing (Chlan, 1995).

<u>Pain</u>

Pain is highly subjective and unique in nature (McGuire, 1997). The International Association for the Study of Pain (IASP) (1986) developed a list of pain terms and definitions, largely in part because of the wide range of definitions and the complexities of the phenomenon of pain. According to the IASP, pain is defined as "an unpleasant

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sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (1986, p.S217). Pain can be classified into types including acute and chronic pain. Acute pain is generally of short duration (days to weeks) and is associated with tissue damage. Chronic pain generally lasts 6 months or more, with real or impending tissue damage possibly a factor (McGuire, 1997, p.530).

Pain is always a subjective experience of the patient and should predominantly be recognized by the patient's complaint of pain. Patients who may have difficulty communicating such as during mechanical ventilation may be at risk for undertreatment of their pain. Objective observations that may indicate pain include grimacing, tachycardia, and possibly increased blood pressure (American Pain Society, 1992).

<u>Anxiety</u>

The word anxiety comes from the Greek word 'agon', from which the English words anguish and agony are derived. Anxiety can be considered a normal response to life stresses and may be an expected reaction to the demands of illness (Grimm, 1997). Physiological and behavioral signs such as heart rate, blood pressure, muscle tension, and facial expression may all be used to objectively assess anxiety. The patient's self-report of anxiety must also be considered (Andreassi, 2000).

Mechanical Ventilation

For purposes of this study, mechanical ventilation is defined as the use of an assistive device that is assisting a patient to breathe, requiring that an endotracheal tube or tracheotomy is in place, obstructing the patient's ability to speak.

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<u>Sedation</u>

The use of a continuous intravenous sedative or hypnotic medication to induce a state of quiet for the patient.

<u>Analgesia</u>

The use of a continuous intravenous narcotic medication to relieve pain and/or induce a state of quiet.

Conceptual/Theoretical Framework

Katherine Kolcaba's mid-range theory of holistic comfort was selected as the conceptual framework which guided this study. Assumptions of the theory of comfort include: human beings have holistic responses to complex stimuli, comfort is a desirable outcome of nursing, and human beings strive to have their basic comfort needs met (Kolcaba, 2003).

Kolcaba developed a General Comfort Questionnaire (GCQ) with 48 questions to be used, as appropriate, in a variety of healthcare settings. The purpose of the GCQ is to assist the nurse in identifying specific comfort needs of the patient and then to apply appropriate nursing interventions to increase patient comfort. Following interventions, nurses can use the GCQ again to measure effectiveness (Kolcaba, 1992). Kolcaba has encouraged adaptation of the GCQ to fit specific patient populations. One such adaptation, the Hospice Comfort Questionnaire (HCQ), was developed by hospice nurses. I chose to use a shortened 23 question format of the HCQ for the population of mechanically ventilated patients in this study because the questions were similar to the GCQ, were appropriate in relation to comfort and the population, and there were less questions to answer for the ventilated patient who may have decreased endurance.

Summary

Comfort is a desired outcome for patients receiving mechanical ventilation in the ICU. Comfort in relation to music therapy within the population of mechanically ventilated patients is relatively new. No research was identified that specifically targeted the effects of music therapy on comfort of patients who require acute mechanical ventilation. Both health care providers and patients could benefit from an increased awareness of music therapy as an intervention.

CHAPTER 2

REVIEW OF LITERATURE

Introduction

Two main areas of literature were reviewed for this study. The first was the literature on comfort. The comfort literature review included information about the concepts of comfort, Kolcaba's Comfort Theory, anxiety and pain in relation to comfort, comfort in the population of mechanically ventilated patients, and sedation and analgesia issues in the same population. The second area of literature reviewed was the history of music as a therapy and intervention.

Comfort

Historical Background

Comfort is a multidimensional, complex concept with a significant historical background and contemporary association with nursing. It has been cited as a desirable goal of nursing care since Nightingale. Historically, comfort has been defined in a general sense (Kolcaba, 2003). The word comfort is derived from the Latin word, confortare, meaning "to strengthen greatly" (Merriam-Webster's Collegiate Dictionary, 2003, p.248). The word comfort is defined as, "To give strength and hope; to ease the grief or trouble of; to console" (p.248).

Throughout the 19th and 20th centuries, the term comfort was used in a general sense with the basic understanding that making a patient comfortable was the role of a good nurse and a determining factor for the nurse's ability and character (Kolcaba, 2003). Nursing books such as Goodnow's (1935) *The Technic of Nursing* highlighted the nurse's duty to make the patient comfortable and that comfort was both physical and mental in nature.

In the early period, comfort was essential because cures for patient ailments were largely unavailable. The attainment of patient comfort with the help of nurses was positive and sometimes was related to an improvement in the patient's condition. In these early years, comfort resulted from several interventions including physical, emotional, and environmental. Physicians often wrote orders for specific comfort measures for the nurse to carry out, including application of heat and positioning of the bed (Kolcaba, 2003). According to McIlveen & Morse (1995), comfort played a large role in nursing care between the years 1900 to 1929. During this time period, medicine was limited in its ability to cure therefore a majority of the prescribed treatments were facilitated by the nurse, placing the nurse in close contact with patients. The nurse had time to attend to details influencing patient comfort as it was the central goal and moral duty of nursing at this time (McIlveen & Morse, 1995). Aikens (1908, p.422) stated, "There is nothing concerning the comfort of the patient that is small enough for her [the nurse] to be careless about...the comfort of the patient is her first and last consideration". From 1930 to 1959, comfort remained a moral obligation of the nurse, indicating the quality of nursing care provided (McIlveen & Morse, 1995). According to Goodnow

(1941), the nurse was "judged always by her ability to make the patient comfortable" (p.79). Between 1960 and 1980, comfort often was considered a minor nursing goal rather than a central focus of nursing care as technological advances took more of the nurses' time and energy (McIlveen & Morse, 1995).

The context, meaning, and importance of comfort have changed significantly since the early 19th and 20th centuries related in part to advancements in health care. Comfort has evolved into a more physical connotation with less importance to nursing as a valued skill and goal (Kolcaba, 2003). According to McIlveen & Morse (1995), few treatments for comfort were prescribed as analgesics became more popular for pain control in the 1950's. Beginning in the 1970's, nurses' autonomy began to expand, allowing nurses to implement comfort measures without a physician's order. Although beneficial on one hand, this seemed to decrease the motivation and recognition by nurses to enhance patient comfort. Medical and surgical advancements continued in the 1980's, further pushing comfort to the wayside as a secondary strategy for patient care (McIlveen & Morse, 1995).

Many changes have occurred in health care since Nightingale's time, redefining the meaning and application of comfort in nursing. Because of the complexities of the term, there has always remained a lack of clarity and possibly agreement as to what comfort really means. Often, comfort has been indicated in nursing practice as the absence of relief of discomfort or even the cessation of pain (Kolcaba, 1991). Although comfort has appeared in the titles of several research articles, the actual concept of comfort is seldom defined as an outcome variable (Morse, Bottorf, Hutchinson, 1994). The application of comfort measures are identified at many levels including patient and family, hospital and institution, community, nation and global (Kolcaba, 2003).

Contemporary Theorists

Several nursing theorists have identified comfort as an important concept including Watson (1979), Peplau (1952), Paterson and Zderad (1988), Roy and Roberts (1981), and Orlando (1961). In Orlando's theory of nurse-patient relationship, the nurse is to assess the physical and mental comforts of the patient both before and after a comfort measure is provided. Watson supported Orlando's idea that comfort was both physical and mental. Watson (1979) emphasized the importance of considering the patient's sociocultural, mental, physical, and spiritual background prior to providing comfort measures. Roy and Roberts (1981) identified physiological needs of the patient including exercise, rest, nutrition, elimination, fluids and electrolytes, oxygen and circulation, temperature, the senses, and the endocrine system. According to Roy and Roberts, nurses use traditional interventional techniques such as comfort measures to achieve comfort or relieve discomforts in the physiological mode. Paterson & Zderad (1988) defined comfort in psychiatric nursing as "an aim toward which persons' conditions of being move through relationship with others by internalizing freedom from painful controlling effects of the past" (p.103). Peplau (1952) examined comfort and discomfort as psychological tasks of the newborn infant. She identified ways in which the infant learns to communicate discomfort to others and how a satisfaction-response is

associated with the restoration of comfort. The infant counts on his mother for relieving discomfort and obtaining comfort, much like the patient learns to count on the nurse to meet their comfort needs.

Empirical Findings

Although there is evidence that nurses undervalue the importance of comfort, several researchers have demonstrated the value of comfort as a patient outcome. Bottorf (1991) examined the lived experience of being comforted by a nurse and identified comfort in such contexts as community, presence of others, language, touch, and home. Similar to Kolcaba's (1991) technical sense of comfort, Bottorf (1991) frequently referred to comfort as a state of ease. Morse (1992) described comfort as an outcome of nursing care, where the effectiveness of this care is identified by the patient's comfort level. Gropper (1992) recognized comfort not only as a basic human need but as an important nursing and patient objective. Walters (1994) analyzed comfort in the critical care setting and found that comfort was described in relation to providing support to the patient, relief from pain, relief from anxiety, communicating, using touch, facing death, and comforting family and friends. Ferrell & Ferrell (1990) indicated that all nursing care should be based on comfort and studied comfort as an outcome resulting from active approaches by both the nurse and the patient.

Cameron (1993) studied the nature of comfort in relation to hospitalized patients in a medical surgical unit, and addressed the current state of comfort care within nursing practice and the patient's view of comfort. Similar to studies conducted before and after, Cameron found that comfort was a complex and dynamic concept. A finding of the study was that comfort was not a passive process; rather, patients took a very active part increasing personal levels of comfort. Furthermore, the author indicated that comfort is not entirely a soothing activity; rather, it is a process during which individuals strengthen themselves. The individual makes the decision for an appropriate health care action and for personal growth to facilitate the attainment of self-determined goals of health and healing. Nurses remain close and assist the individuals through this process.

Comfort needs were studied from the patient's perspective by Morse (1983) who identified touching, talking, and listening as comforting to patients. The author conceptualized comfort as a positive and purposive action rather than an outcome. Morse et al. (1994) described comfort as, "a state of embodiment that is beyond awareness, and comfort is best recognized when the patient first leaves the state of discomfort" (p.190). In order to further understand lived comfort, the authors interviewed patients who had experienced pain or discomfort and injuries or life-threatening illnesses. Nine themes representing states of discomfort were identified by the authors. The themes were: the diseased body, disobedient body, deceiving body, vulnerable body, violated body, enduring body, betraying body, resigned body, and betraying mind. According to the authors, achieving comfort is based on the patients' needs to not be dominated by their bodies through illness or injury. The role of nursing is to provide comfort to these patients however total comfort is unattainable in patient care.

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Kolcaba's Comfort Theory

Kolcaba's Mid-Range Theory of Comfort has its roots in gerontological nursing, specifically with Alzheimer's patients, with whom the theorist spent a large amount of time during her graduate studies. The theorist indicated a lack of research that defined comfort as a nursing outcome. Kolcaba identified comfort as associated with nursing care and operationalized the concept of comfort as an important mission for nurses.

In 1994, Kolcaba conceptualized comfort within the context of nursing and created the mid-range theory of comfort. Kolcaba (1994) used the theory and model of human press (Murray, 1938) as the organizing framework for the theory. The essentials of the theory of comfort are that needs, or tensions induced by obstructing forces, originate from some kind of stimulus. Kolcaba (1994) defined a stimulus situation as "that part of the total environment to which people attend and react during a given episode in their life" (p.1180). There are obstructing, positive, and interacting forces within a stimulus situation. When negative tension arises and imbalances occur, nurses identify the subsequent needs for comfort and apply appropriate interventions to move tension in a positive direction. Patients help the nurse determine if the interventions increase their comfort while at the same time nurses assess patient comfort using subjective and objective information.

Kolcaba's studies of comfort led her to delineate the meanings of comfort in relation to ordinary language, historic reference in nursing, and as a current nursing term. A taxonomic structure was developed to provide a conceptual road map for future

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research of comfort. The taxonomic structure is made up of three technical senses of comfort (state, relief, and renewal sense) and four contexts of experience (physical, psychospirtual, environmental, and sociocultural comfort). All are interrelated and interdependent and define some aspect of comfort (Kolcaba, 1991). Kolcaba (2003) stated, "If a patient experiences comfort in every cell, or aspect, of comfort, we can say that he or she is comfortable" (p.16). Such a state is rare in healthcare situations where stress predominates and comfort needs are increased. The ultimate goal is that the patient's comfort is enhanced from a previous baseline, indicating that negative tensions are decreased and positive tensions are increased (Kolcaba, 1994, 2003).

Based on the taxonomic structure and the theorist's research, Kolcaba (2003) developed a technical definition of holistic comfort as, "the immediate experience of being strengthened by having needs for relief, ease, and transcendence met in four contexts (physical, psychospiritual, social, and environmental)" (p.251-252). Once this occurs, it can be said that the patient is comfortable.

Anxiety

Anxiety can be defined and identified in many contexts and settings. It can refer to a negative connotation or subjective experience such as the response to a stressor or fearful event. It can also be considered a normal response and in some realms, a necessity to face daily challenges. Anxiety can also impair cognitive functioning and interfere with daily life (Kellerman & Burry, 1991). Spielberger (1972) identified anxiety as an emotional state intertwined with numerous feelings including tension, apprehension, and nervousness that can be associated with a sympathetic nervous system response. How anxiety affects the individual is highly specific to the environment in which the subjective feeling of anxiety is experienced.

In the critical care setting and hospital alike, anxiety is referred to as an unpleasant emotional state associated with the numerous stressors that constantly bombard the patient (Frazier, Moser, Daley, et al., 2003). Anxiety experienced by the critical care patient has been demonstrated to produce complex changes and physiological responses that may adversely affect the outcome of recovery (McKinley, Stein-Parbury, Chehelnabi, Lovas, 2004). Researchers have indicated the relationship between anxiety and changes in autonomic tone and reduced immune response (Zeller, McCain, Swanson, 1996), increased myocardial workload (McFetridge & Yarandi, 1997), and increased coagulability (Camacho & Dimsdale, 2000). Additionally, an increase in morbidity and mortality in anxious critically ill patients has been found (Moser & Dracup, 1996; Tavazzi, Zotti, Rondaneli, 1986).

The subjective sensation of pain and subjective feeling of anxiety are often interrelated in critical care settings, with pain treated in an attempt to alleviate anxiety (Frazier, Moser, Riegal et al., 2002). McKinley, Stein-Parbury et al. (2004) indicated that the alleviation of anxiety led to the promotion of comfort in patients in the intensive care setting. A study looked at the assessment of patients' anxiety by critical care nurses and numerous indicators of anxiety were identified such as physiological, behavioral, somatic, and psychological. Possible causes of anxiety in the critical care patient included isolation, excessive and unfamiliar noises, sleep disturbances, inability to communicate effectively, and fear of death (Frazier, Moser, Riegal et al., 2002). Several objective observations of physiological and behavioral indicators of anxiety included heart rate, blood pressure, muscle tension, facial expression, restlessness, and even patient reports of anxiousness (Andreassi, 2000).

The effects of various interventions on anxiety have been extensively researched in a variety of diagnoses in critical care patients. In acute mycocardial infarction patients, several investigators have studied the effects of relaxing music on decreasing anxiety (Bolwerk, 1990; Davis-Rollans & Cunningham, 1987; Elliott, 1994; Guzzetta, 1989; White, 1999; Zimmerman, Pierson, Marker, 1988). McBride, Graydon, Sidani, Hall (1999) examined the therapeutic use of music for anxiety and dyspnea in patients with Chronic Obstructive Pulmonary Disease (COPD) who live at home. Pharmacological and nonpharmacological anxiety management practices and patient and clinician reports of anxiety were studied using the Spielberger State Anxiety Inventory with patients who were diagnosed with an acute myocardial infarction (Frazier, Moser, O'Brien et al., 2002).

As indicated by the literature, numerous types of interventions are used to reduce anxiety in the critical care environment. Some nursing interventions are focused on alleviating anxiety and promoting comfort including massage, giving a bed bath, communicating and talking with the patient, and promotion of rest (Frazier, Moser, Daley, et al., 2003). Other interventions are more non-traditional such as music therapy, relaxation techniques, biofeedback, and therapeutic touch (Chlan, 1998; Daake & Gueldner, 1989; LaRiccia, Katz, Peters, Atkinson, Weiss, 1985; Linn & Taylor, 1998). The most frequently used intervention to reduce anxiety is pharmacological, specifically sedatives to alleviate pain and anti-anxiety medications (Frazier, Moser, Daley et al., 2003).

Assessment of anxiety is varied and may rely on subjective feedback from patients, objective assessments by nurses and family, or even specially designed assessment tools to assist the clinician in identifying anxiety in a patient. Physiological measures are also used to measure anxiety including heart rate and blood pressure (Andreassi, 2000). Whatever assessment measurement or tool is utilized, it is important to appropriately fit the measurement tool with the type of patient (Grimm, 1997). In other words, it would not be beneficial to either the patient or clinician if the State Trait Anxiety Inventory were used for an unconscious patient.

Mechanical Ventilation and Anxiety

It is estimated that up to 80% of intensive care patients experience anxiety (Henry, 1995), an approximation that holds true in the mechanically ventilated patients (Wong et al., 2001). The sensation of breathlessness, frequent suctioning, inability to talk, and fear of the unknown all lead to feelings of anxiety in the mechanically ventilated patient (Fontaine, 1994). Anxiety can lead to shortness of breath and psychologic distress during weaning attempts (Grossbach-Landis, 1983). Johnson & Sexton (1990) indicated anxiety experienced by mechanically ventilated patients trigger the sympathetic nervous system leading to adverse responses including arterial and venous constriction and bronchoconstriction. Bronchoconstriction only increases the work of breathing and

oxygen demand for the patient, further increasing anxiety and delaying the weaning process.

Investigators interviewed patients two months after extubation about their experience while requiring mechanical ventilation (Bergbom-Engberg & Haljamae, 1989). Feelings of anxiety during mechanical ventilation were most directly related to the inability to talk. Several studies have focused on the clinicians assessment and beliefs of anxiety in relation to their patient population (O'Brien et al., 2001; Frazier, Moser, Riegal et al., 2002; Frazier, Moser, Daley, et al., 2003).

Wong et al. (2001) studied the effects of relaxing music on the anxiety of ventilator-dependent patients using a 6 item Spielberger State-Trait Anxiety Inventory, mean blood pressure, and respiratory rate as indicators of anxiety. All subjects were alert and able to communicate by holding up fingers in response to questions. Listening to relaxing music led to a reduction in state anxiety scores in comparison to only a rest period. Subjects listening to music had greater reduction in blood pressure and respiratory rate compared to the control group.

Chlan (1995) studied 20 ventilator-dependent patients to examine their psychophysiologic response to music. Subjects were randomized to either a music or nonmusic group and all were alert and able to communicate nonverbally. Physiologic variables were gathered including heart rate, cardiac rhythm, respiratory rate, and systolic and diastolic blood pressure. A short form of the Profile of Mood States (POMS) was used to measure the six mood states identified by the tool. Subjects who listened to music experienced decreased heart rate, respiratory rate, and POMS scores indicating relaxation and decreased distress when compared to the nonmusic group. In an extension of the pilot study, Chlan (1998) conducted a second study with 44 ventilator-dependent patients researching the effectiveness of music therapy as an intervention on relaxation and anxiety. Decreased anxiety and increased relaxation occurred in patients who listened to music when compared to the control group.

<u>Pain</u>

Pain is a multidimensional, individualized, and subjective experience. It can be triggered by many medical conditions and procedures frequently encountered in the critical care setting such as infections, immobilization, suctioning, and repositioning (Stanik-Hutt, 2003). Price & Pooler-Lunse (1996) identified pain as a symptom of critical illness, a result of treatment, or a barrier to care and healing. Several factors that greatly impact critically ill patients' perceptions of pain and pain management include the anxiety-pain cycle, sleep deprivation, noise, family-patient interaction, age, gender, ethnic culture, communication, and depression (Cullen, Greiner, Titler, 2001).

Although the literature supports numerous definitions of pain, pain manifests differently in each patient. Pain is often considered the fifth vital sign in hospital settings and is recognized as an important piece of the nurses' assessment of critically ill patients (Terai, Yukioka, Asada, 1998; Aslan, Badir, Selimen, 2003; Stanik-Hutt, 2003). Price & Pooler-Lunse (1996) emphasized nurses are legally and ethically accountable for effectively managing pain symptoms in patients. The authors identified pain management as an important aspect of patient comfort. Nurses work closely with patients to identify and manage pain, often using both subjective and objective information. Accurate assessment of a patient's pain is subject to frequent barriers such as communication, time constraints, and knowledge related to pain encountered in critical care settings (Shannon & Bucknall, 2003). Stanik-Hutt (2003) emphasized that intubated patients are at a higher risk for poor pain management simply because they are unable to vocally communicate.

Several authors indicated that pain is directly correlated to patient discomfort (Stanik-Hutt, 2003; Aslan et al., 2003). Additionally, poorly managed pain may result in physiological and psychological complications that may compromise recovery and negatively affect both morbidity and mortality (Stanik-Hutt, 2003; Dracup & Bryan-Brown, 1995). Summer & Puntillo (2001) recognized that pain is a stimulus for physiologic stress responses such as anxiety and restlessness. Halloran & Pohlman (1995) described pain and anxiety as comorbid conditions in critically ill patients. Conversely, anxiety may increase the perception of pain (Chapman, 1985). Treating this anxiety associated with pain leads to the promotion of patient comfort (Summer & Puntillo, 2001).

Assessment of pain in the critically ill patient is the first step towards management, although this presents unique challenges within this population related to severity of illness and intubation. There are numerous ways in which pain can be assessed in this population including patient report, behavioral and physiologic indicators, and the presence of a painful condition or procedure (Pasero, 2003). McCaffery & Pasero (1999) identified the 0-10 numerical pain rating scale as the most commonly used for patient report of pain. This scale is useful with intubated patients who are awake and oriented because they can point to a number to rate their pain. Puntillo et al. (1997) found that nurses frequently use both behavioral and physiologic cues to assess pain in critically ill patients. Pasero (2003) described behavioral indicators as "restlessness or grimacing" and physiologic indicators as "increased heart rate or blood pressure" (p. 423). The author emphasized the importance of performing systematic and frequent pain assessments in all critically ill patients. Ideally, the nurse should rely most heavily on the patients self report of pain rather than relying solely on behavioral and physiologic indicators (McCaffry & Pasero, 1999).

Pain is still regarded as misunderstood and poorly managed by critical care nurses (Price & Pooler-Lunse, 1996; Summer & Puntillo, 2001; Aslan et al., 2003; Shannon & Bucknall, 2003). Several studies have indicated a positive correlation between length of stay in the ICU and pain intensity and a negative correlation with function and recovery (Carroll et al., 1999; Desbiens et al., 1996). Although sedation and analgesic practices to reduce pain have evolved significantly in recent years, nurses administering these agents are often concerned about related complications that may place the patient in a compromising situation (Price & Pooler-Lunse, 1996; Summer & Puntillo, 2001). Nonpharmacologic interventions for pain cannot be underestimated and can help to decrease patients' perception of pain and subsequent anxiety (Summer & Puntillo, 2001; Stanik-Hutt, 2003; Price & Pooler-Lunse, 1996).

Sedation and Analgesia

Mechanically Ventilated Patients

Mechanically ventilated patients are frequently administered analgesics and/or sedatives with the goals of decreasing pain, anxiety, avoidance of adverse events such as self-extubation, and reduction of oxygen consumption (Yagan, White, Staab, 2000; Kress et al., 1996; Barrientos-Vega et al., 1997). Bizek (1995) stated that sedatives, analgesics or anxiolytics can also be used to promote patient comfort. Yagan, White, & Staab (2000) identified one goal of analgesic administration is to minimize patient discomfort. Carrasco, Molina, Costa, Soler, & Cabre (1993) identified continuous sedation as necessary to provide patient comfort.

Although sedatives and analgesics are used to promote comfort, they are not free of possible side effects, complications or adverse events. The medications administered to alleviate pain and anxiety amongst other things may in turn cause anxiety, agitation, or delirium (Arbour, 2000). Ledingham, Bion, Newman, McDonald, & Wallace (1988) stated that a specific action of a sedative or amount of sedation administered may lead to various harmful effects. The immobility resulting from the drug regimen may contribute to venous thrombosis or pressure damage to the nerves and skin. Furthermore, the immunological status may suffer from the continued use of sedative medications (Ledingham et al., 1988). All of these factors may lead to the prolongation of mechanical ventilation and subsequently longer length of hospitalization, and increased cost (Egerod,
2002; Kollef et al., 1998; Bobek, Hoffman-Hogg et al., 2001).

Kollef et al. (1998) studied 242 mechanically ventilated patients receiving either bolus or continuous intravenous sedation. Duration of mechanical ventilation, hospital mortality, and lengths of stay in the intensive care and hospital were compared between two groups. Of the 242 patients, ninety-three received continuous intravenous sedation. Mean duration of mechanical ventilation was greater among patients receiving continuous intravenous sedation. These patients had longer lengths of stay in both the intensive care and hospital, although there was no significant difference in mortality. In a similar study by Barrientos-Vega et al. (1997), mechanically ventilated patients who had previously been on a continuous midazolam infusion had statistically longer time intervals from discontinuation of the infusion until extubation compared with patients receiving propofol. The authors proposed that careful selection of the sedative along with careful sedative practices greatly influenced the weaning process, length of hospitalization, and cost for the mechanically ventilated patient. Bobek et al. (2001) studied 100 mechanically ventilated patients receiving intravenous sedative and analgesic medications. Of those patients receiving midazolam and lorazepam by continuous infusion, length of stay in the intensive care was the longest, compared with patients who received only intermittent intravenous doses. Additionally, as the number of medication classes increased, the length of stay increased.

Several authors have indicated the discrepancies that exist with the type of medication administered and sedation practices amongst nurses and physicians.

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Bizek (1995) identified the variation in opioid and benzodiazepines used as intravenous sedative agents in the intensive care. Opioids commonly used included morphine and fentanyl whereas common benzodiazepines were diazepam, lorazepam, midazolam, propofol, and haloperidol. Egerod (2002) looked at the differences between nurses and physicians with sedation management of mechanically ventilated patients. Sedation practices varied according to individual preferences and local traditions. The term 'sedation' was used by all professionals to indicate sedative or analgesic therapy. The reasons for sedation and the amount administered varied with each nurse, and specific guidelines were not followed. Less experienced nurses often expressed the short-term goal of sedation as promoting patient comfort, whereas the more experienced nurses indicated a long-term goal of minimizing sedation to decrease ventilation time.

Nursing implications resulting from this review of literature suggest that extreme care must be practiced when sedatives, analgesics, and anxiolytics are administered to the mechanically ventilated patient. The administration of these drugs has consequences for the patient and hospital. Nonpharmacologic interventions may reduce or eliminate the amount of medication needed (Yagan, White, Staab, 2000).

History of the Therapeutic Use of Music

There is a large body of literature that addresses the potential therapeutic applications of music as a therapy in various populations. A significant increase in interest for using music as an intervention seems to originate from several areas. Historical rediscovery of the music as a beneficial therapy from ancient times to the present is apparent in the literature. Earliest evidence of the very existence of music goes back to 10,000 B.C. when magical powers were attributed to sound (McClellan, 1991). The Greeks, Eqyptians, Chinese, and Hindus placed great importance on music as a basic healing force (Tame, 1984). Music has been associated with sacred rituals to relieve illness and pain and restore harmony in cultures throughout the world (Achterberg, 1986). For centuries people have used music in the form of song while working on farms, in the fields and ships, and in the home (Campbell, 1997). In early nursing history, Florence Nightingale used music as a nursing intervention in the healing process for injured soldiers. Recognizing the potential of music in caring for the sick, Nightingale declared, "wind instruments, including the human voice, and stringed instruments, capable of continuous sound, have generally a beneficial effect" (Nightingale, 1859, p.57).

The literature revealed evidence from several authors that tempo, volume, and tone influence the physiologic responses when listening to music. A tempo of 70 to 80 beats per minute, similar to a resting heart beat, is considered soothing and low pitched music causes relaxation. More specifically, music with a slow steady rhythm, lowfrequency tones, and orchestral effects is appropriate for reduction of anxiety (O'Sullivan, 1991; Updike, 1990; Bonny, 1978). Several authors suggest that musical selections should not have words to allow patients to flow with the music rather than focus on the meaning of the words (Halperon & Savary, 1985; Bonny, 1978). Several studies have isolated music compositions which evoke the above characteristics (Bonny, 1978; Bonny & Savary, 1973; Updike, 1990). Music that is played continuously may

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become a nuisance rather than a pleasure (O'Sullivan, 1991), therefore listening to music for 30-minute intervals is recommended (Zimmerman, Pozehl, Duncan, Schmitz, 1989).

Although music has been used therapeutically for thousands of years, its documented use as a therapy in healthcare settings has grown over the last several decades. The literature revealed evidence from a variety of fields and clinical specialties where therapeutic music has been studied, including critical care environments, surgical settings, mental healthcare, and oncology. Specific populations in which the effects of music therapy have been studied include post myocardial infarction patients (White, 1999), the elderly (Gerdner, 2000), pre and post operative patients (Koch et al., 1998), and mechanically ventilated patients (Chlan, 1995, 1998; Wong, 2001, Almerud & Peterson, 2003).

White (1999) studied the effects of relaxing music on cardiac autonomic balance and anxiety following an acute myocardial infarction. The study was designed to compare the effects of relaxing music with quiet, uninterrupted rest and usual treatment, on anxiety levels and physiological indicators of cardiac autonomic function. Forty-five patients who had had an acute myocardial infarction in the past seventy-two hours were randomly assigned to listen to twenty minutes of investigator-selected classical music with headphones. Participants completed the State-Trait Anxiety Inventory before and after the intervention period, and physiological parameters were measured pre and post intervention. White found that immediately following the intervention, reductions in heart rate, respiratory rate, and myocardial oxygen demand were significantly greater in the experimental group that in the control group. However, there was not a difference in systolic blood pressure amongst the groups. State anxiety level was reduced in the experimental group only. White concluded that patients recovering from an acute myocardial infarction may benefit from music therapy when applied in a quiet, restful environment.

Clark, Lipe & Bilbrey (1998) looked at how music affected aggressive behaviors in people with dementia. For this study, eighteen individuals with dementia and a history of aggressive behaviors were recruited from a nursing facility. They were randomly scheduled for observation during bath time under either a control (no music) or an experimental condition during which recorded selections of music were played with an audiotape recorder during bathing times. Clark et al. found that during the experimental condition, individuals demonstrated an improved affect and increase in cooperation with caregivers. The results suggested that preferred, recorded music may be beneficial in reducing the total number of aggressive behaviors in cognitively impaired older adults.

In order to examine the sedative and analgesic sparing effects of music, Koch et al. (1998) recruited seventy-eight adults undergoing urologic procedures or lithotripsy with spinal anesthesia, patient-controlled intravenous propofol sedation, and patientcontrolled intravenous opioid analgesia. Prior to the scheduled procedures, demographic data were obtained, a baseline sedation score was determined, and patients were instructed on the used of patient-controlled sedation devices. Two phases were conducted looking separately at the sedative and analgesic sparing effects of music. The investigators found that patients who listened to music required significantly less medication to achieve the same level of sedation as control patients and similarly required a smaller amount of opioids.

Therapeutic Music and Ventilated Patients

Chlan (1995) found that mechanically ventilated patients who listened to music demonstrated decreased heart rate, respiratory rate, and Profile of Mood States scores, which indicated mood was improved and relaxation occurred. A convenience sample of twenty subjects was recruited from three critical care units for this pilot study. All subjects had to be alert, mechanically ventilated, hemodynamically stable, and able to hear adequately. The study used a two-group experimental design with a pretest, posttest, and repeated measures. Subjects were randomly assigned to a control group who did not receive music or an experimental group with music. Subjects in the control group were given 30 minutes of quiet time during which they were instructed to close their eyes and rest. Those in the experimental group were asked to select a tape from a selection of classical music. According to Chlan (1995), classical music was used because patients who are severely ill tend to respond favorably to this type of music. Physiologic variables were collected before, at 5-minute intervals during, and 5 minutes after the intervention for each group and included heart rate, cardiac rhythm, respiratory rate, arterial oxygen saturation, airway pressure, and systolic and diastolic blood pressure. A short form of the Profile of Mood States was administered before and after the intervention period. Mechanically ventilated patients who listened to music experienced a decrease in heart rate and respiratory rate in comparison to patients who did not listen to music. Chlan (1995) considered these findings to indicate a state of relaxation. The

experimental group also demonstrated a decrease in total mood disturbance scores, indicating decreased distress and an improvement in mood.

In 1998, Chlan expanded on the 1995 study and researched the effectiveness of music therapy as an intervention on relaxation and anxiety for mechanically ventilated patients. Similar design and sampling methods were utilized, with a total of 54 subjects recruited over a 15-month period. Subjects were randomized to either a control (rest only) group or experimental (music therapy) group. Subjects in the experimental group selected their own music from a collection consisting of non-lyrical music with 60 to 80 beats per minute, considered to be of a relaxing nature. Outcome measures consisted of state anxiety (pretest and posttest), heart rate, and respiratory rate obtained every 5 minutes for 30 minutes. The experimental group. Additionally, heart rate and respiratory rate decreased over the intervention period, indicating decreased anxiety and increased relaxation.

In a study on mechanically ventilated patients conducted by Wong et al. (2001), music therapy was found to be an effective nursing intervention in decreasing anxiety. Convenience sampling was used to recruit 20 subjects from an Intensive Care Unit (ICU) who understood Cantonese or English, were 18-85 years old, were alert, mentally competent and without hearing problems, requiring mechanical ventilation, not receiving continuous intravenous analgesia, and hemodynamically stable. A pretest/posttest crossover experimental repeated measures design was used. State anxiety was measured before and after the intervention using a short version of the Spielberger State-Trait Anxiety Inventory. Respiratory rates and mean blood pressures were the physiologic measurements used to indicate relaxation. Each subject underwent an experimental intervention consisting of a 30-minute music listening session using a cassette and headphone and a 30-minute uninterrupted period of rest without music but still wearing headphone. The subject's room environment was enhanced by dimming the lights and closing the doors to minimize outside disturbances. Subjects chose relaxing music from a collection of 7 cassettes provided by the investigators. The results of the study indicated that subjects in the experimental group experienced less anxiety than the control group based on lower state anxiety scores. Significant differences were noted at the end of the intervention, with the experimental group demonstrating a greater amount of relaxation than the control group.

Almerud & Peterson (2003) found that intensive care nurses can beneficially apply music therapy as an intervention for mechanically ventilated patients. Quantitative and qualitative methods were applied in an attempt to better understand music therapy as a nonpharmacological nursing intervention. Twenty subjects were placed into the control (rest only) group or study (music therapy) group. Subjects in the study group listened to 30 minutes of classical music while those in the control group were provided 30 minutes of rest. Six of the ten subjects in the study group were interviewed following extubation with questions concerning recollections and experiences of treatment and music therapy. Both blood pressure and heart rate fell during music therapy, although the results were not significant. Subjects did not recall music therapy when interviewed.

Summary

The concept of comfort has been important throughout the history of nursing, and the literature included an array of theorists and researchers who conceptualized and defined comfort within the context of nursing. Although it was suggested nurses may undervalue the importance of comfort, several researchers have demonstrated the value of comfort as a patient outcome (Bottorf, 1991; Morse, 1992; Gropper, 1992; Walters, 1994; Ferrell & Ferrell, 1990). Additionally, several nursing theorists identified comfort as an important concept (Peplau, 1952; Orlando, 1961; Watson, 1979; Roy & Roberts, 1981; Paterson & Zderad, 1988; Kolcaba, 2003). Furthermore, nursing interventions can directly impact patients' comfort (Kolcaba, 2003). Comfort measures may be identified at many levels (Kolcaba, 2003), however the review of literature revealed the lack of research investigating the effects of music therapy on comfort in mechanically ventilated patients.

Few tools have been developed specifically to measure comfort as a patient outcome. Kolcaba (1991) developed a taxonomic structure to provide a conceptual road map for future research of comfort. Using the taxonomic structure as a guide, the theorist later developed, tested, and published several tools designed specifically to measure comfort as an outcome with various populations (Kolcaba, 2003).

Anxiety, pain and comfort are interrelated (Frazier, Moser, Riegal et al., 2002; Stanik-Hutt, 2003; Aslan et al., 2003), with the alleviation of anxiety and pain leading to promotion of comfort (McKinley, Stein-Parbury et al., 2004; Price & Pooler-Lunse,

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1996). Intubated patients were at a higher risk for poor pain management because of the inability to communicate, which may result in physiological and psychological complications that may compromise patient outcomes (Stanik-Hutt, 2003; Dracup & Bryan-Brown, 1995). Similarly, anxiety may adversely affect critically ill patients' outcome of recovery (McKinley, Stein-Parbury et al., 2004). Non-traditional nursing interventions to reduce anxiety such as music therapy, relaxation techniques, biofeedback, and therapeutic touch have been researched (Chlan, 1995, 1998; Daake & Gueldner, 1989, LaRiccia et al., 1985; Linn & Taylor, 1998). Additionally, nonpharmacologic interventions for pain can help to decrease patients' perception of pain and anxiety (Summer & Puntillo, 2001; Stanik-Hutt, 2003; Price & Pooler-Lunse, 1996).

There are numerous ways in which pain and anxiety was assessed. McCaffery & Pasero (1999) identified the 0-10 numerical pain rating scale as useful with intubated patients. The literature indicates assessment of anxiety is varied, including subjective and objective findings that may include the use of specially designed assessment tools (Andreassi, 2000).

Mechanically ventilated patients are frequently administered analgesics and/or sedatives with the goal of decreasing pain and anxiety (Yagan et al., 2000; Kress et al., 1996; Varrientos-Vega et al., 1997). Analgesics and/or sedatives have been used to promote patient comfort (Bizek, 1995; Yagan et al., 2000; Carrasco et al., 1993). The literature revealed that administration of sedatives and analgesics may be accompanied by side effects, complications or adverse events (Arbour, 2000) and the use of nonpharmacologic interventions may reduce or eliminate the amount of medication needed (Yagan et al., 2000).

A large body of literature addressed the potential therapeutic applications of music a therapy in various populations. Several researchers have studied the effects of music therapy on mechanically ventilated patients. The patients who listened to music demonstrated decreased heart rate, respiratory rate, improved mood and relaxation (Chlan, 1995) and lower state anxiety scores (Wong et al., 2001).

CHAPTER 3

METHODS

Introduction

The purpose of this quantitative study was to examine the relationship between comfort and music therapy among mechanically ventilated patients. A quantitative method was ideal to examine cause and effect relationships among variables (Burns & Grove, 2001).

Design

This quasi-experimental pilot study used a pre-test and post-test design with subjects serving as their own control. Dependent variables measured included comfort, pain, and anxiety. Comfort was measured using a modified version of the Hospice Comfort Questionnaire (Novak, Kolcaba, Steiner, Dowd, 2001). The Numerical Graphic Rating Pain Scale measured the participant's pain (Jensen & Karoly, 1992). Anxiety was measured using the Faces Anxiety Scale (McKinley, Coote, Stein-Parbury, 2003).

Sample

A convenience, purposive sampling procedure was used to recruit participants who fit the selection criteria. Participant selection occurred through the ICU's of both Deaconess Billings Clinic and St. Vincent Healthcare, hospitals in Billings, Montana. A target population of ten participants was the goal at the beginning of the study. The actual number of recruited participants was five. The data gathered with the five participants revealed nine sets of data for analysis.

<u>Sample Size.</u> The sample consisted of 2 men and 3 women. Criteria for inclusion included being mechanically ventilated for an acute period of time (14 days or less), at least 18 years of age, alert enough to participate, able to sign a consent form, mentally competent, able to hear, English speaking, and not receiving continuous intravenous sedation and/or analgesia. Two women and two men who met the criteria declined to participate.

Protection of Human Subjects

Prior to obtaining permission from the Montana State University-Bozeman Human Subjects Committee and the Institutional Review Board (IRB) of Billings, the researcher was required to complete the National Institutes of Health (NIH) online tutorial: "Human Participant Protections: Education for Research Teams." Common concepts and issues involved in the protection of human subjects were covered in the tutorial. Upon completion of the tutorial, the researcher was issued a certificate of completion and submission of a copy of this certificate was required as part of the application for approval from the MSU-Bozeman Human Subjects Committee and the IRB of Billings.

Protection of human rights was ensured, as the MSU-Bozeman Human Subjects Committee as well as the IRB of Billings approved the study. The researcher also obtained permission from both hospitals where the patients were receiving care. Informed consent was obtained from all participants using a consent form approved by the MSU-Bozeman Human Subjects Committee and the IRB of Billings. The consent form included the title, purpose of the study, a description of the expectations for participating, discussion of the procedures, risks, and benefits, and the process for maintaining confidentiality (see Appendix A). An addendum required by the IRB of Billings discussed the participant's authorization to privacy (see Appendix B). Participants were encouraged to write down any questions, since they were not able to verbalize. The consent form and addendum was signed prior to the interview and the participants were given a copy.

There were no risks, costs, or payments provided to the participants who participated. The participants received no benefit from their participation in this study. The participants were assured they could withdraw consent to participate at any time during the study. All data was accessed only by the researcher and the researcher's thesis chairperson, who assisted with data analysis. No names or other personal identifying information were contained in printed or reported data.

Hypotheses

The hypotheses for this study were as follows:

- 1. Music will have a measurable effect on comfort of mechanically ventilated patients.
- 2. Music will have a measurable effect on anxiety of mechanically ventilated patients.

3. Music will have a measurable effect on pain of mechanically ventilated patients.

Instrumentation

<u>Tool Selection</u>. Three instruments were used for data collection in this study. These instruments were chosen because they have been standardized for direct assessment of comfort, pain, and anxiety in the adult population. A shortened, 23 question version of the Hospice Comfort Questionnaire (HCQ) was chosen to collect data related to comfort because it was derived from the General Comfort Questionnaire (GCQ) (Novak et al., 2001). The GCQ was developed from Kolcaba's theory of comfort, which was also the framework used for this study. Kolcaba (2003) provided the HCQ and GCQ in the textbook along with permission to adapt the tools as needed to best fit various populations. Written approval was also obtained by the investigator from Kolcaba prior to conducting the study. The HCQ was also chosen due to applicability of questions to the selected population. Question #24 "I've had a good life" was removed from the final version of the HCQ used for this study based on the recommendation from the MSU-Bozeman Human Subjects Committee that it implied the patient was soon to pass away.

Anxiety and pain were assessed in addition to comfort because the literature indicated anxiety and pain are often associated and used as indicators of comfort. As McKinley, Stein-Parbury et al. (2004) stated, "Obtaining valid and reliable measures of anxiety in ICU patients is important because of the effect of anxiety on patients' comfort and recovery" (p.147). Kolcaba (2003) stated, "The discomfort of pain is often a

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significant detractor from comfort" (p.240). The Faces Anxiety Scale was chosen to assess anxiety in mechanically ventilated patients because it has been demonstrated to be easier to respond for the ICU patient in comparison to a 6-item anxiety scale or numeric analog anxiety scale. Additionally, other assessment tools often cause limitations in responses by mechanically ventilated patients because they require more of a cognitive effort these patients may not be able to sustain and verbal responses they are unable to make (McKinley, Coote, et al., 2003). Written approval was obtained from the author to use the Faces Anxiety Scale. The Numerical Graphic Rating Pain Scale was chosen because it is easily administered and understood by a variety of patient populations, the validity and reliability is well established, and it is easy to score (Jensen & Karoly, 1992).

<u>Tool Description</u>. The HCQ was developed based on the definition of comfort as: "the experience of being strengthened by having needs for relief, ease, and transcendence met in four contexts (physical, psychospiritual, social, and environmental); much more than the absence of pain" (Kolcaba, 2003, p.251-252). The HCQ is a Likert-type selfreport instrument consisting of 49 statements related to the patient's comfort at the moment answering the questions. A shortened, 23 question version of the HCQ was used for this study. Negative items are reverse coded and added to the positive scores, with higher scores indicating higher comfort.

The Numerical Graphic Rating Pain Scale was developed to evaluate the effectiveness of a patient's pain treatment plan. It is a verbally administered or visually presented scale with the numbers 0-10 placed along a vertical line. The patient is asked to choose a number between 0-10 to rate their pain, with 0 equaling no pain and 10

equaling the worst possible pain. Scoring is done by documenting the number the patient chooses (McCaffery & Pasero, 1999).

The Faces Anxiety Scale was designed primarily to assess the anxiety of ICU patients unable to communicate their emotions because of impaired cognition and treatments such as mechanical ventilation. The single item scale uses five possible responses ranging from a neutral face to a face showing extreme fear. It is scored from one, indicating least amount of anxiety, to five, indicating extreme anxiety (McKinley, Coote et al., 2003).

<u>Tool Performance</u>. The term reliability is used to address the ability of the HCQ to consistently measure comfort. The six-item Likert response HCQ has been found to have a Cronbach's alpha of .98 in comparison to .83 with a four-item Likert response HCQ. This demonstrated the high internal consistency reliability with the six-response format of the HCQ (Novak et al., 2001).

The term reliability is used to address the ability of the Numerical Graphic Rating Pain Scale to consistently measure pain. Validity refers to the ability of the scale to accurately measure pain. A correlation of r=0.847 (p<0.001) was found between the visual analog scale (VAS) and the numeric (pain) rating scale (NRS), supporting the validity of the NRS since the VAS is widely accepted as a valid tool to measure pain intensity (Paice & Cohen, 1997).

The Faces Anxiety Scale is a relatively new tool accessible by sick, nonverbal ICU patients. The Pearson correlation coefficient was used to assess the relationship between the Faces Anxiety Scale and patients' nonverbal responses to short questions from the Profile of Mood States anxiety subscale. The correlation was 0.64 (P<.001), within the range of 0.4 to 0.8 for criterion validity, indicating the Faces Anxiety Scale is a valid measure of state anxiety (McKinley, Stein-Parbury et al., 2004).

Data Collection

Data collection occurred between January 2005 and January 2006. Inservice presentations about the study were conducted for ICU nursing staff at each facility and posters were hung in both units with contact information. The researcher contacted the ICUs each week to see if there were any potential participants and nursing staff notified the researcher of potential participants.

Procedure. As required by Billings IRB, initial contact with each potential participant was made by healthcare workers within the ICUs familiar with the selection criteria. For each participant deemed eligible, the healthcare worker approached the participant about the study, explained why he/she was eligible to participate, and asked permission from the participant to be contacted by the investigator. If permission was granted, the investigator approached the participant, fully explained the study, and sought consent. Once eligibility was confirmed and consent to participate obtained, a time to begin data collection was arranged with the participant and staff. Data were collected for each participant using the HCQ (Appendix C), Numerical Graphic Rating Pain Scale (Appendix D), Faces Anxiety Scale (Appendix E), and data collection sheet with spaces provided for clinical and demographic data (Appendix F). Names and the identification number were known only to the investigator.

Prior to beginning data collection, the investigator compiled ten envelopes, five that contained the word 'Control' and five that contained the word 'Intervention'. The investigator randomly selected a sealed envelope prior to data collection for each participant. Once the envelope was selected, it determined if the participant received the intervention period of 30 minutes of therapeutic music first, or the control period of usual treatment (no music) for 30 minutes.

Prior to both the intervention and control periods, the participants completed a pre-test consisting of the HCQ, Numerical Graphic Rating Pain Scale, and the Faces Anxiety Scale. Following the pre-test, the participants received either the intervention or control period based on the envelope selected. After the 30 minute period, the participants completed a post-test consisting of the same three tools. If the participant received the intervention period first, a wash out period of one hour was given before the control period occurred (Figure 2). This was done to try to separate the effects of the music with the control of quiet time. However, if the participant received the control period first, the intervention period was conducted immediately following the control because the participant had not already listened to music (Figure 1). The same steps of pre-test, intervention or control period, and post-test were completed for each participant. The participant was asked to repeat this session two times over the course of one or two days, with at least eight hours provided between sessions.





Figure 2. Intervention First



Headphones were used during both the intervention and control periods to minimize unpleasant environmental noises or stimuli. Each participant was provided with a personal set of headphones. Unless contraindicated, the lights in the patient's room were dimmed, curtains closed, and the door partially shut to minimize unnecessary disturbance. The investigator stayed in the room during both intervention and control periods to collect physiologic data and to be available to adjust headphone volume if necessary.

As a consistent factor, during each intervention period, the participants listened to 30 minutes of the identical classical music CD provided by the researcher. The classical music selected was identified in a previous study using music as an intervention to reduce stress levels (Bonny, 1978). The seven classical music selections placed on the CD are listed in Appendix G. The control group (no music) undertook a 30-minute rest period with participants instructed to close their eyes and rest.

Physiological data gathered every five minutes during the intervention and control periods included heart rate, systolic and diastolic blood pressure, and respiratory rate. These measures were being continuously monitored for each participant per ICU protocol, so the investigator was able to easily collect this data with minimal disturbance to the patient. Additional clinical data gathered for each participant included respiratory status (ventilator settings, endotracheal or tracheal tube). Demographic data were collected primarily from participants' medical charts including primary diagnosis, age, sex, ethnic group, marital status, religious preference, number of days receiving mechanical ventilation, and drug therapy in the past 24 hours such as sedatives, opioids, corticosteroids, and anticonvulsants that could affect mental state. This demographic data was collected for the purposes of assessing comparability between subjects and to consider any other possible source of comfort.

Summary

The sample population used in this study consisted of two men and three women receiving mechanical ventilation for an acute period of time in the ICU. All participants were at least 18 years of age, alert enough to participate, able to sign a consent form, mentally competent, able to hear, able to understand and read English, and not receiving continuous intravenous sedation and/or analgesia.

The study was designed to protect the human rights of participants. The participants were given a copy of the consent form. The method of data collection assured participant anonymity and approval was obtained by both the Montana State University-Bozeman Human Subjects Committee and the Institutional Review Board (IRB) of Billings to complete this study. The researcher also obtained permission from both Deaconess Billings Clinic and St. Vincent Healthcare, hospitals in Billings, MT where participants were receiving care.

CHAPTER 4

RESULTS

Introduction

The purpose of this study was to assess the effects of music therapy on comfort in acute mechanically ventilated patients in the ICU. Two men and three women who were mechanically ventilated for fourteen days or less completed the HCQ, Faces Anxiety Scale and the Numerical Graphic Rating Pain Scale using a pre-test and post-test design. The possible scores for the HCQ ranged from 23-138, the higher score indicating increased comfort. The range for the Faces Anxiety Scale was 1-5, one indicating the smallest amount of anxiety and five indicating the greatest amount of anxiety. The Numerical Graphic Rating Pain Scale ranged from 0-10, with zero indicating no pain and ten the worst pain possible. Respiratory rate, heart rate, systolic and diastolic blood pressure were recorded before, during, and after the intervention and control periods.

Description of Sample

The mean age of the sample was 70 (SD = 11.53) with the range of ages from 55-85 years old. All five participants were Caucasian and married. Two participants were Lutheran, one was Catholic, one was Protestant, and one had no religious preference. Participants were receiving mechanical ventilation for between two and fourteen days (mean = 6.78; SD = 4.55). All five were intubated with oral endotracheal tubes. The most common ventilator setting used was the pressure support mode (PS) along with synchronized intermittent mandatory ventilation (SIMV). The oxygen concentration given to the participants ranged from 30% to 60%. Primary diagnoses of participants included three with respiratory failure, one with pneumonia, and one following coronary artery bypass surgery.

Data Analysis

Upon completion of data collection, the test responses were scored according to the individual test directions. These results were entered into the Statistical Package for the Social Sciences (SPSS) data analysis program (version 14.0 for Windows). Descriptive analyses were used to summarize the data. Although the numbers were small, statistical comparisons were possible, and paired t-tests were used to detect any significant differences between pre-intervention and post-intervention and pre-control and post-control for all data sets.

<u>Scores</u>

The first hypothesis that music will have a measurable effect on comfort of mechanically ventilated patients was not supported. Paired t-tests were used to compare significance between pre-intervention to post-intervention and pre-control to post-control HCQ scores. Although neither value is significant, the intervention data approaches significance. There was no significant difference between the intervention pre-test and the control pre-test HCQ scores and the intervention post-test and control post-test HCQ

scores. The difference between the HCQ pre-test scores is nowhere near significant, but the difference in post-test HCQ scores nears significance.

The second hypothesis that music will have a measurable effect on anxiety of mechanically ventilated patients was not supported. There was no significant difference between pre-intervention to post-intervention and pre-control to post-control Faces Anxiety Scale scores. Pre-intervention and pre-control Faces Anxiety Scale scores were not significantly different. There were similar findings when comparing the significant difference between post-intervention and post-control scores.

The third hypothesis that music will have a measurable effect on pain of mechanically ventilated patients was not supported. There was no significant difference between pre-intervention to post-intervention and pre-control to post-control Numerical Graphic Pain Rating Scale scores. There was no significant difference between the intervention pre-test and the control pre-test Numerical Graphic Pain Rating Scale scores. There were similar findings when comparing the significant difference between postintervention and post-control scores (Table 1). No significant difference was found between post-intervention and post-control respiratory rate, heart rate, or blood pressure.

Mean comfort scores increased from pre-intervention to post-intervention periods, but decreased slightly from pre-control to post control periods. Anxiety scores decreased from pre-intervention to post-intervention, however scores did not fluctuate from precontrol and post control periods. Pain scores dropped following the intervention, but increased following the control period (Tables 2 and 3).

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Table 1	. Signifi	cance
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	Pre-intervention	Post-intervention
	and	and
	Pre-control	Post-control
	Significance	Significance
	(t)	(t)
Comfort	.879	.133
	(161)	(1.670)
Anxiety	.051	.695
	(2.294)	(406)
Pain	.214	.720
	(1.350)	(371)

 Table 2. Pre-Intervention and Post-Intervention Scores

	Pre-intervention	Post-intervention	Significance	t
	Mean (SD)	Mean (SD)	(2-tailed)	
Comfort	86.0 (29.12)	91.0 (27.43)	.206	-1.378
Anxiety	3.33 (1.58)	2.78 (1.56)	.247	1.250
Pain	5.33 (3.08)	4.44 (3.57)	.390	.909

Table 3. Pre-Control and Post-Control Scores

	Pre-control	Post-control	Significance	t
	Mean (SD)	Mean (SD)	(2-tailed)	
Comfort	86.56 (32.38)	85.67 (29.02)	.770	.302
Anxiety	2.78 (1.64)	2.78 (1.66)	.169	-1.512
Pain	3.33 (2.45)	4.78 (3.90)	.367	956

The mean systolic blood pressure increased from 130 to 136 mmHg during the intervention period and the diastolic blood pressure increased from 62 to 65 mmHg. The

mean systolic blood pressure increased from 137 to 140 mmHg during the control period, but the diastolic blood pressure decreased slightly from 66 to 64 mmHg. The mean heart rate increased during music therapy from 101 to 102, although the respiratory rate decreased slightly from 17 to 16. Heart rate and respiratory rate relatively stayed the same during the control period (Figure 3).





Anecdotal Findings

Although not originally planned to be included, clinical notes were kept to record subjective and objective qualitative notes before, during, and after the intervention and control periods to attempt to better understand the experiences of the participants, family members, and nurses in relation to music therapy.

A few days following the completion of data collection for one participant, who at this time was extubated, the family and participant offered their thanks for providing music therapy during the intubation period. The family said they had noticed a significant increase in the participant's "comfort" levels and suggested the music therapy had helped the participant to "cope" and divert attention away from the stimuli associated with the intubation.

Many nurses discussed their perceptions of the effects of music therapy on the participants. One nurse commented the participant appeared more relaxed following the music therapy period and was able to finally sleep following the intervention period. A few other nurses provided similar comments related to various participants and the effect of music, in a sense soothing and relaxing the participants.

Conversely, as I sat in the room during intervention and control periods gathering data, I noted various reactions of participants. For example, one participant tapped their hand against the bedrail while listening to music as if keeping rhythm. Other participants remained completely still during music, but appeared restless during the control period. One participant requested their family stay in the room during data collection, but appeared to remain calm during both intervention and control periods.

Summary

Descriptive analyses were used to summarize the data after results were entered into SPSS. Paired t-tests did not detect significance between pre-intervention and postintervention and pre-control and post-control periods for all data sets. The sample size makes generalization of these findings to the entire population of mechanically ventilated patients in Billings, Montana impossible. However, these findings provide important preliminary quantitative results for this pilot study.

CHAPTER 5

RESEARCH FINDINGS, CONCLUSIONS, LIMITATIONS AND

RECOMMENDATIONS

Introduction

In the following chapter, research findings are presented and discussed. Conclusions and comparisons to the review of literature are presented next, followed by a discussion of the limitations of the study along with recommendations for future research and practice. A summary of the research presented in this thesis concludes the chapter.

Research Findings

This study was based on the mid-range theory of holistic comfort developed by Kolcaba in 1994. The essentials of the theory are that needs, or tensions induced by obstructing forces, originate from some kind of stimulus. Obstructing, positive, and interacting forces exist within a stimulus situation. With the patients' help, nurses identify needs for comfort during these situations and apply appropriate interventions to increase comfort. Anxiety and pain are often associated and used as indicators of comfort, therefore they were measured in addition to comfort.

The research tools used for this study included the shortened version of the HCQ, the Faces Anxiety Scale, and the Numerical Graphic Pain Rating Scale. The HCQ was developed based on Kolcaba's mid-range theory of holistic comfort and has high reliability with a Cronbach's alpha of 0.98 (Kolcaba, 2003; Novak et al., 2001). The latter two tools were chosen because of their ease of administration, scoring and understandability. In addition, the validity and reliability of the Numerical Graphic Pain Rating Scale is well established (Jensen & Karoly, 1992).

The first part of data analysis consisted of calculating the participants' scores from the HCQ, Faces Anxiety Scale, and Numerical Graphic Pain Rating Scale completed during both pre and post intervention and pre and post control periods. The HCQ has a possible range of 23-138, the higher the number indicating increased comfort, providing a guide to the comfort level of the participant before and after the intervention and control periods. The range of possible scores for the Faces Anxiety Scale and Numerical Graphic Pain Rating Scale are 0-5 and 0-10, respectively, with the higher the number, the greater the pain or anxiety.

The mean, standard deviation, significance, and paired t-tests were compared for each tool to determine changes in scoring before and after the intervention and control. This was also completed for physiological data including systolic and diastolic blood pressure, respiratory rate, and heart rate. Paired t-tests showed no significant mean differences between two points of measurement on systolic, diastolic, heart rate, and respiratory rate in both the intervention and control groups. Comfort, anxiety, and pain scores before and after the intervention and control also did not demonstrate significance.

Discussion

The purpose of this study was to assess the effects of music therapy on comfort in acute mechanically ventilated patients in the Intensive Care Unit. Mechanical ventilation leads to decreased comfort. Pain and anxiety may increase during this treatment modality, and the literature suggests this may directly affect patient comfort levels. Music therapy as a nursing intervention within the context of comfort, pain, and anxiety of mechanically ventilated patients was investigated.

The ultimate goal of a nursing intervention is that the patient's comfort is enhanced from a previous baseline (Kolcaba, 1994, 2003) and can be demonstrated by an increased HCQ score following the intervention period. The mean comfort scores increased from baseline following music therapy, indicating increased comfort levels. Conversely, comfort scores slightly decreased following the control period of rest only. The first hypothesis was not supported, however, because pre-intervention and postintervention comfort scores were not significant.

Hypotheses two and three were developed to examine if music would have a measurable effect on anxiety and pain of mechanically ventilated patients. The literature suggests the subjective sensation of pain and anxiety are often interrelated in critical care settings (Frazier, Moser, Riegal et al., 2002) and that the alleviation of anxiety leads to the promotion of comfort in patients in the intensive care setting (McKinley, Stein-Parbury et al., 2004). Similarly, the literature indicates that pain is directly correlated to patient discomfort (Stanik-Hutt, 2003; Aslan et al., 2003). Wong et al. (2001) found that

mean state anxiety scores significantly decreased following music therapy. Although this study used a different tool to measure anxiety, mean scores decreased following the intervention period, indicating a decrease in anxiety after listening to music. Following the control period, mean anxiety scores stayed the same. Differences between pre-intervention and post-intervention anxiety scores and pain scores were not significant therefore the second and third hypotheses were not supported.

Physiologic measures of anxiety including mean heart rate, respiratory rate, and blood pressure with mechanically ventilated patients have been studied in relation to relaxing music (Wong et al., 2001; Chlan, 1995). Although Wong et al. (2001) found that subjects listening to music had a greater reduction in blood pressure and respiratory rate compared to the control group, Chlan (1995) found no statistically significant results for systolic blood pressure and diastolic blood pressure. Mean heart rate decreased following the music listening period, however. In comparison to the literature, this study found no statistically significant results for mean heart rate, respiratory rate, and blood pressure. The mean systolic blood pressure increased following both intervention and control periods, whereas the mean heart rate and respiratory rate relatively stayed the same.

Post-hoc Analysis

The question of sample size affecting the results of this study arose following data analysis. For theoretical purposes only, the sample number was doubled to examine how this would affect significance. Paired t-tests between pre-intervention and post-intervention (Sig.=.033) and pre-control and post-control (Sig.=.279) were compared,

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revealing significance post-intervention. Similarly, by increasing the sample size by a factor of two, the difference between group means after treatment (Sig.=.026) versus control conditions (Sig.=.818) is significant.

Conclusions

A small sample of 5 mechanically ventilated patients with 9 sets of data is not representative of all acute mechanically ventilated patients in Billings, Montana. Therefore, the results cannot be generalized. The results also were not statistically significant. However, the mean comfort scores increased following music therapy and difference between the pre-intervention to post-intervention HCQ scores approached significance, something that should not be overlooked. The anecdotal findings indicate some participants relaxed and were able to sleep better after music therapy.

The literature review suggests that comfort is seldom defined as an outcome variable (Morse et al., 1994) although several researchers have demonstrated the value of comfort as a patient outcome (Bottorf, 1991; Morse, 1992; Gropper, 1992; Walters, 1994; Ferrell & Ferrell, 1990; Kolcaba, 2003). At this time, health care providers in Billings, Montana do not formally assess the comfort levels of mechanically ventilated patients using a specific comfort tool. It is uncertain how often pain and anxiety are formally assessed.

When the sample size was increased by a factor of two, the difference between the group means after treatment versus control conditions was significant. Therefore, theoretically, as sample size increases, the effect of music on comfort becomes significant. This study points to the need for a more in-depth examination with a larger sample size. This study provides useful preliminary data for future research.

Limitations

A small convenience sample of 5 participants cannot be generalized to all mechanically ventilated patients. As previously discussed, the sample was drawn from Deaconess Billings Clinic and St. Vincent Healthcare, two hospitals in Billings, MT. Patients who were receiving continuous intravenous sedation and/or analgesia and were not alert enough to answer questions were not included in this study, limiting the population base. There were more patients than expected who required mechanical ventilation for greater than 14 days. Conversely, many patients were on the ventilator for such a short time (1-1 ¹/₂ days), not allowing enough time for data collection.

Using classical music rather than allowing the patient to choose their favorite music may also have limited the sample size. One patient declined to participate because classical music was not a preferred choice of music. Three other patients declined to participate for unknown reasons.

The types of tools used to gather data may also have led to limitations. Although the tools, including the questions for the HCQ, were enlarged for increased ease of reading, it still appeared that subjects experienced difficulty seeing, regardless if they were wearing eyeglasses. Because of this difficulty, the researcher read the HCQ questions out loud for each patient. Each patient was able to point with their finger to their level of pain and anxiety using the Faces Anxiety Scale and the Numerical Graphic Rating Pain Scale. Several limitations specifically address the HCQ. It is questionable as to the ease of use with this patient population. The number of questions may be too many, as most patients were exhausted, and some patients had difficulty staying awake to complete the questionnaire each time. The amount of time needed to complete the questionnaire was longer than initially anticipated, usually taking 15 minutes. The patient was asked to complete the questionnaire several times throughout the study, further compounding the time issue. Some patients were too weak to physically circle the selection of one through six and many patients indicated their choice using their fingers.

Another limitation is that resistance was met by one participant's spouse when he arrived at the participant's room and realized she was participating in the study. Although the participant had fully agreed to participate and had already completed one session of listening to music, the spouse did not agree with the study and insisted the participant stop immediately. The spouse appeared irritated and said the music was bothering the participant, although the participant vehemently disagreed. The researcher asked the participant if indeed the study should be stopped, and upon looking at her spouse, the participant declined further participation.

The researcher also found it difficult to work around the healthcare providers schedules. Although the researcher would collect data during the most convenient times for the participant and staff, this still did not eliminate frequent distractions from healthcare personnel. It is important to allow the healthcare providers to perform care as necessary therefore distractions will never be completely avoided. However, the researcher received permission from both organizations to proceed with the study and it was indicated full support would be provided as necessary. In order for future nursing research to proceed with fewer roadblocks within the organizations, support must be communicated through actions and not only with words.

The effects of medications such as analgesics, sedatives, or cardiovascular drugs administered before intervention and/or control periods may have influenced results of the study. The action of these medications may affect the participant's heart rate, blood pressure, respiratory rate, and even the perception of comfort, anxiety, and pain.

The presence of other unknown variables that may have influenced outcomes must also be considered such as the time of day and other illness factors. These may represent extraneous variables that may influence the study outcome.

Recommendations

<u>Research</u>. Future research should include a replication of this study using a larger sample size from a more diverse population base. Research should also be done to compare patients who require acute ventilation versus ventilation for extended periods of time. It would be interesting to research whether or not patients' comfort, anxiety, and pain scores differ from those requiring short and long term ventilation. I also recommend the replication of this study using a different tool for comfort that is shorter and may be easier for the participant to complete. For example, Kolcaba (2003) developed the Comfort Line, a visual analog scale for measuring comfort.

Qualitative studies looking at participants' lived experience of mechanical ventilation and music therapy in comparison to no music therapy would also be an interesting research topic. This may help to further understand what patients requiring
mechanical ventilation go through and how healthcare professionals can make the experience more bearable.

Future research should also examine whether the choice of music directly affects participants' comfort, anxiety, and pain. It would be interesting to compare different types of music in relation to comfort, anxiety, and pain. Future studies may benefit by assessing participant preferences of music prior to conducting a similar study.

Health care providers should be surveyed to determine their beliefs and utilization of alternative therapies such as music with critically ill patients, particularly those requiring mechanical ventilation. Researchers may then understand the frequency of use and possible road blocks related to the use of music and alternative therapies in the critical care environment.

<u>Clinical Practice</u>. Health care professionals, particularly nurses, need to assess comfort of mechanically ventilated patients. Comfort, pain, and anxiety are interrelated (McKinely, Stein-Parbury et al., 2004) and may be assessed in combination. Utilizing formal screening tools with all mechanically ventilated patients to assess comfort, anxiety, and pain may facilitate appropriate nursing interventions. Health care providers need to be made aware that mechanically ventilated patients may experience a decrease in comfort along with an increase in anxiety and pain, adversely affecting their treatment course. Alternative therapies such as music therapy can easily be applied within this population and may reverse the discomfort, anxiety, and pain associated with mechanical ventilation. Of the screening tools used in this study, the Faces Anxiety Scale and Numerical Graphic Pain Rating Scale appeared easiest to complete by participants and each tool took a few seconds to complete. The literature suggests similar findings, as several researchers have demonstrated each tools ease of administration and understandability (McKinley, Coote et al., 2003; Jensen & Karoly, 1992). The Numerical Graphic Rating Pain Scale gives heath care providers information about the level of pain patients experience and evaluates the effectiveness of pain treatment plans (Jensen & Karoly, 1992). The Faces Anxiety Scale assists health care providers with assessing anxiety of patients unable to communicate such as during mechanical ventilation (McKinley, Coote et al., 2003).

Prior to this study, the HCQ had not been used with the population of mechanically ventilated patients to assess comfort level. In comparison to the other tools, the HCQ required a minimum of 5-10 minutes and appeared difficult for participants to complete. Since comfort is an important outcome to assess, it is recommended an alternative comfort screening tool be investigated with this population that requires less cognitive thinking skills and time to complete.

Summary

The purpose of this study was to assess the effects of music therapy on comfort in mechanically ventilated patients in the ICU. Analysis of the data revealed no significance between pre-intervention and post-intervention and pre-control and postcontrol periods for anxiety and pain and the physiologic measurements of respiratory

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rate, heart rate, and blood pressure. The mean comfort scores increased following music therapy and the difference between the pre-intervention to post-intervention HCQ scores approached significance.

Comfort is an important outcome to assess with mechanically ventilated patients. Clinical implications of this study are that music therapy could increase comfort of acute mechanically ventilated patients. A further clinical implication is that by using a tool to assess the comfort of this patient population, nurses could design specific interventions to improve comfort outcomes for mechanically ventilated patients.

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APPENDICES

APPENDIX A

CONSENT FORM

CONSENT FORM

STUDY TITLE: The Effects of Music Therapy on Comfort in Mechanically Ventilated Patients in the Intensive Care Unit.

PARTICIPATION: You are being asked to participate in a study of comfort using music as a nursing intervention. You are being asked to take part in this study because you require a breathing machine for your illness.

PURPOSE: This study is being done because little is known about the effects of music therapy on comfort in patients who need a breathing machine. This study may help us better understand whether or not music affects patient comfort while on a breathing machine. The study is part of the work being done by the investigator as part of a Masters in Nursing program and will be conducted in the intensive care units of Deaconess Billings Clinic and St. Vincent Healthcare, in Billings, Montana..

PROCEDURES: You were identified as a potential participant by your nurse or doctor. After your nurse or doctor told you about this study and asked if you were interested in learning more about it, you gave permission for the research investigator to tell you more about participation in this study. If you agree to take part in the study, you will need to sign a consent form informing you about study procedures.

It is not known if using music is better than not using music. The order in which you receive the intervention (music) or no intervention (no music) will be decided randomly so neither you nor the investigator will choose which comes first. You will be asked to repeat this session two times over the course of one or two days, with at least 8 hours provided between sessions. The times when you listen to music or have a quiet time will take one-half hour and the questionnaire should take about fifteen minutes to finish. You will listen to a classical music CD provided by the investigator. During the times of listening to music and quiet time, you will wear a personal pair of headphones to help decrease any background noise. You may ask that the music be turned off or you may chose not to answer questions at any time.

Additionally, the investigator will record measures including your blood pressure, respiratory rate, heart rate, and information about your breathing machine. The investigator will ask you or access your medical chart to record your marital status, religious preference, prior relaxation techniques, number of days needing the breathing machine, medications in the past 24 hours, age and your diagnosis.

RISKS: No risks have been identified as part of this study.

BENEFITS: While no medical benefit is expected from participation, this study could help other patients in the future.

COST: Your participation is voluntary. Taking part in this study will not cost you anything and you will not receive any payment for taking part in this study.

CONFIDENTIALITY OF RECORDS: Every effort will be made to maintain confidentiality of your personal information. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. The signed consent form(s) may be reviewed by qualified representatives from your healthcare provider (either St. Vincent Healthcare or Deaconess Billings Clinic) and by agencies that oversee the rights and welfare of human subjects in research, such as the Institutional Review Board (IRB) of Billings or the Institutional Review Board at Montana State University at Bozeman, Montana. These agencies might review your records to check the information collected in this study, to check how the study was conducted or for other uses allowed by law. The information obtained in this study may be published in nursing journals, but your identity will not be revealed. Signed consent forms will be kept in a locked file cabinet at Montana State University-Bozeman College of Nursing for five years and destroyed after that time.

ADDITIONAL QUESTIONS: Additional questions about the study can be answered by the investigator, Jamie Besel (406) 657-1773 or the committee chair, Jane Scharff (406) 657-2912. For questions about your rights as a research participant, contact the Institutional Review Board (IRB) of Billings at (406) 245-8528, which is a volunteer group that acts as a patient advocate. Additional questions about the rights of human subjects can also be answered by the Montana State University-Bozeman Chairman of the IRB, Mark Quinn at (406) 994-5721.

AUTHORIZATION: I have read the above and/or have had this study explained to me and my questions answered to my satisfaction at this time. Study. I, _______, (printed name of participant) agree to participate in this study and I understand that by signing this form, I have not given up any of my legal rights. I understand that I may later refuse to participate, and that I may withdraw from the study at any time without it affecting any relationship I might have

I have received a copy of this consent form for my own records _____ Yes _____ No

with my healthcare provider.

Signature of Participant	Date
Witness	Date

Date

Principal Investigator/Graduate nursing student signature

APPENDIX B

ADDENDUM TO CONSENT FORM: PRIVACY AUTHORIZATION

Addendum to Consent Form: Privacy Authorization

The Effects of Music Therapy on Comfort in the Mechanically Ventilated Patient in the Intensive Care Unit

Explanation and Background

<u>Records – Use and Disclosure</u> This attachment to the information and consent form provides additional information about how your health information will be used and disclosed for this study. If you agree, your name will be provided to a researcher and you will be asked to sign a consent form and this authorization form.

The signed consent form(s) and this form also might be reviewed by qualified representatives from your healthcare provider (either St. Vincent Healthcare or Deaconess Billings Clinic) and by agencies that oversee the rights and welfare of human subjects in research, such as the Institutional Review Board (IRB) of Billings or the Institutional Review Board at Montana State University at Bozeman, Montana. These agencies might review your records to check the information collected in this study, to check how the study was conducted or for other uses allowed by law.

<u>Authorization Requirement for Participation</u> If you do not sign this authorization, you cannot participate in the study. You can cancel this authorization at any time by giving a written notice to the study researcher. If you cancel this authorization, then you no longer will be able to participate in the study. If you cancel this authorization, then the researcher will no longer use your records.

<u>Duration of Authorization</u> This authorization does not have an expiration date. If you do not cancel this authorization, then it will remain in effect indefinitely.

Privacy Authorization

I have read all two pages of this Privacy Authorization and have had my questions answered to my satisfaction at this time.

I authorize the release of my name and my signed consent form and this addendum, to the researcher and to my healthcare provider, St. Vincent Healthcare or Deaconess Billings Clinic, the IRB of Billings, and the IRB at Montana State University-Bozeman.

By signing this form, I have not given up any of my legal rights as a research participant. I understand that I will receive a signed copy of this authorization for my records.

Printed Name of Participant

Signature of Participant

APPENDIX C

HOSPICE COMFORT QUESTIONNAIRE

(MODIFIED)

HOSPICE COMFORT QUESTIONNAIRE (MODIFIED)

Date _____ Code # _____

Below are statements that relate to your comfort right now. Six numbers are provided for each question. Please circle the number you think most closely matches your feeling. Relate these questions to your comfort *at the moment you are answering the questions*.

		Strongly Agree		·			Strongly Disagree	
1.	My body is relaxed right now	6	5	4	3	2	1	
2.	My breathing is difficult	6	5	4	3	2	1	
3.	There are those I can depend on when I need help	6	5	4	3	2	1	
4.	I worry about my family	6	5	4	3	2	1	
5.	I know I am loved	6	5	4	3	2	1	
6.	These surroundings are pleasant	6	5	4	3	2	1	
7.	I have difficulty resting	6	5	4	3	2	1	
8.	I feel peaceful	6	5	4	3	2	1	
9.	I sleep soundly	6	5	4	3	2	1	
10	. I like being here	6	5	4	3	2	1	
11	. I am nauseated	6	5	4	3	2	1	

12. I am able to communicate with my loved ones	6	5	4	3	2	1
13. I am afraid of what is next	6	5	4	3	2	1
14. I have experienced changes that make me feel uneasy	6	5	4	3	2	1
15. My mouth and skin feel very dry	6	5	4	3	2	1
16. I am okay with my personal relationships	6	5	4	3	2	1
17. I can rise above my pain	6	5	4	3	2	1
18. The mood around here is depressing	6	5	4	3	2	1
19. This bed makes me hurt	6	5	4	3	2	1
20. I feel confident spiritually	6	5	4	3	2	1
21. I feel good enough to do some things for myself	6	5	4	3	2	1
22. I feel hopeless	6	5	4	3	2	1
23. I feel lonely	6	5	4	3	2	1

APPENDIX D

NUMERICAL GRAPHIC PAIN RATING SCALE

NUMERICAL GRAPHIC PAIN RATING SCALE



<u>APPENDIX E</u>

FACES ANXIETY SCALE

FACES ANXIETY SCALE



(McKinley, S., Coote, K., Stein-Parbury, J. (2003). Development and testing of a Faces Scale for the assessment of anxiety in critically ill patients. *Journal of Advanced Nursing*, *41*(1), 73-79.)

APPENDIX F

DATA COLLECTION SHEET

DATA COLLECTION SHEET

Date		
Code #		
Age:		
Sex:		
Primary Diagnosis:		
Marital status:		
Religious preference:		
Ethnic group:		
Relaxation techniques prev used:	iously	
Number of days receiving N	MV:	
Drug therapy in past 24 hou	ırs:	
Respiratory Status: Vent Se ET Tub	ettings:e or Trach:	
Baseline	During Intervention/Control	Post
RR:		
HR:		
BP:		

APPENDIX G

CLASSICAL MUSIC SELECTED FOR MUSIC CD

CLASSICAL MUSIC SELECTED FOR MUSIC CD

- 1. Respighi: "The Birds, The Dove"
- 2. Bach: "Suite No. 3 in D-Air for the G String"
- 3. Pachelbel: "Canon in D String"
- 4. Debussy: "Claire de Lune"
- 5. Respighi: "Pines of Rome-The Pine of Giancolo"
- 6. Vaughan-Williams: "Fantasia on Greensleaves"
- 7. Bizet: "Adagietto from L'arlesienne Suite"