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The Experience of Music Therapy During the Weaning Process of Patients Receiving Invasive Mechanical Ventilation

Stephanie M. Morris

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by

Stephanie M. Morris

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CERTIFICATE OF APPROVAL

This is to certify that the Thesis of

Stephanie M. Morris

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Annie Heiderscheit, Ph.D., MT-BC, LMFT

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Abstract

Mechanical ventilation (MV) is a medical intervention used to assist the respiratory function of someone who is medically compromised. Patients need to wean from the ventilator in order to resume breathing on their own. A spontaneous breathing trial (SBT) is used to determine one's readiness to be liberated from the ventilator. Music therapy is the use of music interventions, facilitated by a board-certified music therapist, to address patient-specific goals within a therapeutic relationship. Music therapists working in an intensive care unit (ICU) may focus their clinical work to address the stressors, fears, and medical complications associated with vent weaning. The goal of the present study was to determine if one 30-minute music therapy session during an SBT would decrease the patient's perceived level of anxiety and improve physiologic metrics related to the SBT, specifically, respiratory rate, blood pressure, oxygen saturation, and heart rate. In addition to evaluating the physiological response to music therapy, this study sought to understand the impact from the perspective of the patient. The research question was: What does the patient experience related to music therapy during their spontaneous breathing trial? Data collected from 20 patients revealed that measurements of heart rate and systolic and diastolic blood pressure significantly increased pre- to post-music therapy session. Data analyzed in the interviews suggested that music therapy may assist patients in coping with the physical, emotional, and spiritual stressors of weaning from MV.

Keywords: music therapy, mechanical ventilation, spontaneous breathing trial, vent weaning

Chapter 1

Introduction and Background

In the United States, it is estimated that 1 to 3 million patients receive mechanical ventilatory support annually (MacIntyre, 2016, p. 1761). Mechanical ventilation (MV) is a life-saving treatment that assists the respiratory function of someone who is medically compromised (American Thoracic Society, 2017, p. 3). The ventilator is connected to the person through an endotracheal tube which is placed in the mouth or nose and down into the windpipe (American Thoracic Society, 2017). A ventilator helps to support the work of breathing and gas exchange for patients until their existing disease process has improved enough to have the ventilator removed (American Thoracic Society, 2017, p. 3).

The patient must be weaned from the ventilator in order to resume breathing on their own. The weaning process comes with risks and potential complications such as ventilatory muscle overload and fatigue (MacIntyre, 2004, pp.831-832). Another common cause of weaning failure is cardiac dysfunction (Thille, Cortés-Puch, & Esteban, 2013, p. 58). In addition to the medical risks associated with weaning from MV, patients receiving care in an intensive care unit (ICU) may also experience the stress and fear that accompany the intense experience of being treated in this medical setting. The American Thoracic Society (2017) provides more insight into how a patient might feel while receiving MV:

> The ventilator itself does not cause pain. Some people don't like the feeling of having the tube in their mouth or nose. They cannot talk because the tube passes between the vocal cords into the windpipe. They also cannot eat by mouth when this tube is in place. (p. 3)

Music therapists working in an ICU may focus their clinical work to address these stressors, fears, and medical complications. While the medical literature explores the patient's experience during mechanical ventilation, there is little to no research that explores the patient's

experience of receiving music therapy while weaning from MV. Music listening studies focus on the patient's physiological responses while receiving a music listening intervention, facilitated by a medical professional during MV; however, very little literature exists involving music therapy, facilitated by a board-certified music therapist (MT-BC), and the MV population. This suggests the need to further explore the efficacy of music therapy interventions during the MV patient's weaning process.

Mechanical Ventilation Background

While MV involves established procedures and protocols to provide the most adequate respiratory support and promote safety for each patient, it is still nuanced and individualized to each patient. This section describes the crucial aspects of MV to help establish a better understanding of this medical intervention. Patients admitted to the ICU may be placed on MV if they have a condition that compromises their respiratory function. Respiratory failure is "a life-threatening impairment of oxygenation, carbon dioxide elimination, or both" (Porter, 2018, p. 559). Ventilatory assistance is usually deemed necessary when respiratory failure occurs. MV is defined as:

> The use of an apparatus designed to intermittently or continuously assist or control pulmonary ventilation. The use of a mechanical ventilator is indicated as a supportive measure in patients affected by respiratory paralysis and in those with ventilatory failure manifested by either alveolar hypoventilation, hypoxemia, or both. (O'Toole, 2017, p. 1103).

MV can be invasive or non-invasive depending on the respiratory needs of the patient. The process of providing a patient with an artificial airway is called intubation (Whitlock, 2019, p. 1).

Intubation is defined as "the passage of a tube into a body aperture, specifically the insertion of a breathing tube through the mouth or nose into the trachea" (O'Toole, 2017, p. 960). Invasive mechanical ventilation often involves the use of an endotracheal tube which is defined as "a large-bore catheter inserted through the mouth or nose and into the trachea to a point above the bifurcation of the trachea. It is used for delivering oxygen under pressure when ventilation must be totally controlled" (O'Toole, 2017, p. 621).

Complications and Risks of Mechanical Ventilation

The invasive nature of MV can involve several complications. Complications can result from either the endotracheal tube itself or from prolonged MV (PMV). Some of the complications brought on by the endotracheal tube may include "sinusitis, ventilator-associated pneumonia, tracheal stenosis, or tracheal-vascular fistula" (Porter, 2018, p. 563). Ongoing MV itself can cause complications including "pneumothorax, oxygen toxicity and hypotension" (Porter, 2018, p. 563). Additionally, the following risks can occur from MV: "infections, collapsed lung (pneumothorax), lung damage, side effects of medications, and inability to discontinue ventilator support" (Tobin & Manthous, 2017, p. 4).

These risks can cause additional complications because the endotracheal tube (ET) allows germs to get into the lungs more easily (Tobin & Manthous, 2017). Lung damage and collapsed lung can occur either because too much pressure has been put on the lungs from the ventilator or part of the lung that is weak becomes too full and begins to leak (Tobin & Manthous, 2017, p. 4). The National Heart, Lung, and Blood Institute names two additional risks including: risk for blood clots and serious skin infections (Ventilator/Ventilator Support, 2019).

While many hospitals have specific protocols and procedures in place to try and prevent these potential complications, it is suggested that limiting the duration of MV is the most effective way to reduce complications (Porter, 2018). While sedative medications are in place to assist the patient in the healing process, these medications can also cause side effects such as confusion or delirium which may continue to impact that person even after the medications have been discontinued (Tobin & Manthous, 2017). Thille et al. (2013) suggests that "the first weaning trial must be performed as soon as the patient meets the following criteria: resolution of disease for which the patient was intubated, cardiovascular stability, no continuous sedation, and adequate oxygenation" (p. 57).

Sedation

According to Sharma (2019) the study of spontaneous awakening trials (SAT) were first introduced in 2000 and showed that interruptions of sedative medications helped improve the time to extubation (p. 2). Evidence exists that prolonged use of sedative medications can lead to more complications for the patient and prolonged MV (Porter, 2018). This may also be due to the possibility of a cumulative effect from the sedative medications over time. The infusion of sedative medications should be stopped completely "until the patient is either awake and following commands or needs re-sedation for agitation, breathing asynchronously with the ventilator, or other physiologic derangements" (Porter, 2018, p. 569).

Tate, Dabbs, Hoffman, Milbrandt, & Happ (2012) discussed the perceptions of physicians and medical personnel caring for patients weaning from the ventilator. On the topic of sedation, one physician stated:

> There will be certain patients whose stress of spontaneous breathing is going to be so high that you need to regulate it. You need to regulate the (tachypneic) sensation that they're getting which is exceptionally real, not an inappropriate reaction to weaning (p. 13).

This study suggested that patient's perceptions of anxiety and agitation while weaning from the vent were not solely apparent in physiological responses but from a combination of observed behaviors, emotional experiences, and individual characteristics.

Weaning Assessment

The Merck Manual (2018) defines spontaneous ventilation, also known as spontaneous breathing as "normal, unassisted breathing in which the patient creates the pressure gradient through muscular movements that move air into and out of the lungs" (Porter, 2018, p. 1674). The process of re-establishing a patient's independent and spontaneous breathing or reduction of ventilatory support is referred to as weaning (Godard et al., 2016, p. 1). When the weaning process takes place, the medical team decides to perform a spontaneous awakening trial (SAT) which is also referred to as a sedation vacation (Sharma, 2019). The patient's sedative medication dosage is lowered so that the patient is alert and awake enough to allow them to more fully exercise their lungs (Sharma, 2019). If the patient passes the SAT then a spontaneous breathing trial (SBT) can be performed (Sharma, 2019). The SBT is the standard test that can determine a patient's readiness to be liberated from the ventilator (Thille et al., 2013, p. 59).

Inconsistencies exist regarding the weaning process. A study by Godard et al. (2016) reviewed current literature that suggested existing clinical practice guidelines vary when deciding on minimizing sedation and how much ventilatory support to provide a patient (p. 2).

Medical professionals agree that patients receiving minimal sedation are more likely to successfully wean from the ventilator; however, the literature provides limited standardized guidelines to be used across medical facilities. Godard et al. (2016) conducted a prospective observational study that analyzed SBT techniques that are used in eight different ICUs across North America. Data were analyzed from 680 patients and 931 SBTs. SBT's were performed for a mean duration of 38 plus or minus 18 minutes (Godard et al., 2016, p. 3). The Richmond Agitation and Sedation Scale (RASS) was an assessment used in this study. According to Sessler et al. (2002), RASS is defined as "a 10-point scale, with four levels of anxiety or agitation (+1 to +4 [combative), one level to denote a calm and alert state (0), and 5 levels of sedation (−1 to −5) culminating in unarousable (−5)" (p. 1338).

In the study conducted by Godard et al. (2016), "38% of the SBTs were performed in patients with a RASS of 0…and 22% were at a RASS of less than or equal to -2 indicating a sedated patient" (p. 3). According to the scale, patients with a RASS score of 0 are identified as alert and calm. Patients with a RASS of less than or equal to -2 are identified as either being drowsy or receiving light sedation. Drowsy was defined as "not fully alert but has sustained awakening (eye-opening/eye contact) to voice for ≥10 seconds" (Sessler et al., 2002, p. 1339). Light sedation was defined as "briefly awakens with eye contact to voice for <10 seconds" (Sessler et al., 2002, p. 1339).

According to the outcomes of this study, over-sedating a patient increased the risk of prolonged MV and also increased adverse outcomes such as suppressed heart rate and respiratory rate variability (Godard et al., 2016, p. 4). Researchers also found that the "trend of physiologic variables such as heart rate (HR), respiratory rate (RR), oxygen saturation (SpO_2), etc. did not change appreciably over the three time points of an SBT (2, 15, and 30 minutes)" (Godard et al.,

2016, pp. 3-4). This seems to indicate that judging a patient's readiness to wean is not based solely on physiologic parameters but instead on a variety of other indicators including anxiety, alertness, and individual personality characteristics, and emotional state.

Weaning: Spontaneous Breathing Trial & Spontaneous Awakening Trials

According to two studies reviewed in Rose (2015) the most important steps in the weaning process are readiness to wean and readiness to be extubated in order to prevent unnecessary prolongation of MV (p. 190). "Patients on prolonged mechanical ventilation (PMV) make up 5-10% of all mechanically ventilated patients in the United States" (MacIntyre, 2013, pp. 1075-1076). There are several factors associated with failed weaning including: "age, primary reason for intubation, neurological dysfunction, cough efficacy, and amount of secretions" (Thille et al., 2013, p. 60). Achieving successful ventilator independence can be challenging due to differing diagnoses and conditions that may impede weaning.

The literature provides recommendations regarding how an SBT and SAT should be implemented with MV patients weaning from the vent. "An SBT generally comprises 30-60 minutes on either low levels of pressure support or continuous positive airway pressure (CPAP) via the ventilator" (Rose, 2015, p. 190). Implementing the use of an SAT and SBT at the same time resulted in "a reduction in ventilator associated events as well as reductions in the duration of MV, ICU, and hospital length of stay" (Rose, 2015, p. 190).

While the weaning literature offers recommendations and protocols on how to successfully implement SBTs and SATs, the process is varied across each medical facility. The literature (Zein et al., 2016, p. 67) suggests the following criteria for successful weaning trials:

- A respiratory rate of < 35 breaths/minute
- Good tolerance to SBT
- Heart rate < 140/minute or heart rate variability of > 20%
- Arterial oxygen saturation >90% or PaO_2 > 60 mmHg on FiO_2<0.4
- Systolic blood pressure <80, < 180 mmHg, or <20% change from baseline
- No signs of increased work of breathing or distress

Literature also suggests that the SAT consist of a combination of scales and nursing observation including the RASS and the Confusion Assessment Method for ICU (CAM-ICU). Nurses assess the patient's mental status by the patient's ability to follow simple commands such as hand squeezing and eye opening and tracking (Sharma, 2019, p. 3). While the protocol may vary across medical facilities, the aforementioned was the protocol that was followed and implemented by medical professionals for the researched discussed in this paper.

Chapter 2

Literature Review

Mechanical Ventilation

A study conducted by Wunsch, et al. (2013) collected data from 97 ICUs in the United States. The purpose of this study was to understand how to better guide disaster planning in ICUs to accommodate unexpected increases in the need for rooms with ventilators (Wunsch, et al., 2013, p. 2). Out of the 226,942 patients from which data were collected, "the percentage of ICU occupied beds in any given hour ranged from 57.4% to 82.1%" (Wunsch, et al., 2013, p. 5). The percentage of beds filled with mechanically ventilated patients ranged from 20.7% to 38.9%. (p. 5). "Nationwide, the mean number of ventilator days is 5.6, but 5-20% of intubated patients require support for at least 21 days" (Hetland et al., 2015, p. 416). Given the varying and often prolonged lengths of stay for patients receiving MV, the hospitalizations are costly. "Patients who require MV for greater than 3 weeks account for more than 50% of total ICU costs" (Hetland et al., 2015, p. 416).

Hill et al. (2017) sought to determine the relationship between PMV and associated mortality, health care costs, and health care utilization. Data were collected between April 2002 and March 2013. Out of 213,680 ICU patients, 5.4% of them required PMV. Results showed that during the first six months after discharge, 36.1% of patients requiring PMV were readmitted to the hospital, compared to 28.7% of patients who were readmitted but had not received PMV. It was determined that patients who received PMV required health care that was significantly greater in cost the year after admission to the ICU. Hill et al. (2017) provides the following results description:

> In the year after hospital discharge, median (IQR) costs were Can $42,784 ($17,630–$95,888) among patients on PMV and Can $13,005 ($5,922–$35,705) among patients not on PMV, with higher costs for patients on PMV across all health care sectors. (p. 359)

The findings from the study suggest medical efforts should focus on preventing PMV which could result in improved patient outcomes with lower health care costs (Hill et al., 2017, p. 361).

Given the costly impact MV has on health care, it is important to understand the factors that may prolong a patient's ventilation experience. For example, when sedation is discontinued, patient's may be confused as they are waking up and try to pull out their tube (Sharma, 2019, p. 2). They may also feel anxious once the sedation is off, leading to increased HR or blood pressure (Sharma, 2019, p. 2). Medical professionals must assess a patient's ability to wean from the vent and learn to breathe on their own again. According to MacIntyre (2004), "Unnecessary delay in withdrawing mechanical ventilation increases the likelihood of complications such as pneumonia, discomfort, and ventilator-induced lung injury, and increases cost" (p. 830). It is important to assess the patient's ability to wean from the vent as soon as possible so as not to increase the likelihood of potential complications and prolonged MV.

In a recent review about weaning predictors and criteria, the following predictors were assessed including: "heart rate variability, sleep quality, hand grip strength, diaphragmatic dysfunction, and oxidative stress markers" (Zein et al., 2016, pp. 65-66). It was found that each of these factors could lead to weaning and extubation failures. Zein et al. (2016) also discussed an outline of criteria for weaning including subjective assessment of the patient's cough capabilities, no continuous sedation, adequate mental status as well as assessment of their vital signs. (p. 66). Patients are not required to meet all of the criteria because it was found that

patients were still successfully extubated despite not meeting one or more of the criteria (Zein et al., 2016, p. 66).

Given the complications that are possible with weaning from the ventilator, it is also important to consider the patient's experience of being on the vent and the rigorous weaning procedures. Tate et al. (2012) observed that patients attempting to wean from MV exhibited symptoms of anxiety and agitation. It was determined that these symptoms interfered with patient comfort and successful ventilator weaning (Tate et al., 2012, p. 2).

The Patient Experience

A review of 43 qualitative studies analyzed interviews of patients after they were liberated from the vent. The interviews sought to understand the patients' experiences during MV and identified the overarching themes of these experiences. These themes included "fear, lack of control, realization of death and concepts of self (ie, the effect on a patient's sense of identity" (Rose, Dainty, Jordan, & Blackwood, 2014, p. e59). Thomas (2003) shared that anxiety was one of the four most frequently perceived stressors for a patient receiving MV.

Hetland et al. (2015) reviewed two studies that aimed to investigate patients' experiences after being extubated. Hetland et al. (2015) summarized that patients from these studies who received music intervention recalled "memories associated with pain, anxiety, discomfort and also shared dreams and delusions" (p. 423). These experiences can also be made worse because of the patients' inability to properly communicate. Thomas (2003) reported that "patient stressors specifically related to communication difficulties are among the most widespread stressors reported by patients receiving mechanical ventilation and have no relation to the medical or surgical condition of the patient" (p. 76). Patients described the inability to speak during MV

using the terms: “discomfort, distressful, a basic “need”, frustration, and stressor/stressful” (Thomas, 2003, p. 76). Fontaine (1994) also suggested that communication issues may negatively impact the MV patient’s experience. “Knowledge of the unique individual behind the endotracheal tube is essential if the anxiety associated with mechanical ventilation is to be limited” (Fontaine, 1994, pp. 696-697).

The literature refers to anxiety as a factor that negatively impacts a patient’s experience with MV. Chlan & Savik (1997) aimed to determine changes in anxiety ratings and if anxiety decreased over time in patients receiving MV. The study sample included 57 participants who had been in the ICU for a median of eight days and receiving MV for a median of six days. Using the Visual Analogue Scale for Anxiety (VAS-A), participants reported moderate but varying levels of anxiety over the course of treatment. It was also noted that sedative exposure did not significantly influence the participants’ ratings. Anxiety was found to be an individual experience that needs to be consistently monitored with ongoing assessments and individualized interventions.

Thomas (2003) suggested education or information sharing as a means of decreasing stress while receiving MV. Informative interventions helped “dyspnea symptom management, patient concerns about personal security during weaning, dealing with inability to speak, and dealing with stress and uncertainty during weaning” (Thomas, 2003, p. 79). Another study aimed to explore the relationships formed with MV patients in the ICU. “Perceptive communication and generation of trust are the hallmarks of presence as an intervention” (Fontaine, 1994, p. 699). A review of a study by Henneman (1989) reported that while there was “no documented change in physiologic stress parameters using hand holding and verbal interaction during the weaning process…the patients reported the capacity for a nurse to listen and anticipate their needs as most

important" (Fontaine, 1994, p. 699). In the book, *Music, Health, and Wellbeing* (MacDonald et al., 2012) music is discussed as a means of communication and emotional engagement as well as perceived control. "Related to the emotionally engaging aspects of music listening is the possibility that music provides a means for listeners to be distracted from other stimuli that may have negative effects" (MacDonald et al., 2012, p. 249).

Music Listening

Medical personnel have searched for supplementary ways to address the physiological and psychological obstacles patients must overcome. Existing literature discusses music and its relaxing characteristics. Robb et al. (1995), define these characteristics as follows:

> Tempo should be at or below a resting heart rate; 60 beats per minute (bpm)…with 72 bpm being cited as the upper limit. Rhythm should be regular, smooth, and flowing without sudden changes. Melodies that are slow, sustained, and progress by step are most desirable. Pitch, as determined by the frequency of sound waves, should be predominantly low to promote relaxation, as high-pitched sounds tend to elicit tension. Dynamics are to remain in the soft to moderately loud range (less than 65 dB) (p. 6).

Specific characteristics such as tempo, rhythm, pitch, melody, dynamics, harmony, and tone are important considerations when choosing relaxing music (Robb et al., 1995, p. 6).

The following is a review of fifteen music listening studies. The authors sought to understand the impact music listening may have on patients' receiving MV. Chlan (1995) conducted research using a two-arm parallel group design. Patients were enrolled for diagnoses necessitating MV such as pulmonary issues, cancer, transplants, etc. Patients were randomized to either a music group where patients could listen to patient-selected music through headphones or

a control group who wore headphones with no music playing. Patients could choose from researcher-selected classical music that had previously been tested and designated as relaxing (p. 235). Interventions occurred once for each patient, lasting 30 minutes. Researchers assessed changes from pre- to post- session of mood, HR, RR, SBP, respectively, arterial oxygen saturation (SaO_2), and airway pressure.

Researchers concluded there were significant decreases in HR and RR in the music group over the course of the 30-minute music listening intervention. The music group also showed a decrease in total mood disturbance using the Profile of Mood States questionnaire (POMS) scores which indicates decreased distress and improved mood (Chlan, 1995, p. 237). "No statistically significant results were found for SBP, DBP, airway pressure, or SaO_2" (p. 236). The decrease in HR and RR within the music group could indicate a relaxed state for those patients.

Chlan (1998) also conducted a two-arm parallel group design with repeated measures. Adults requiring MV due to pulmonary related, cancer, heart transplant, trauma and other miscellaneous diagnoses were enrolled into the study. The most common ventilator mode used was "the synchronized intermittent mandatory ventilation (SIMV); most subjects received both positive end-expiratory pressure and pressure support adjuncts" (p. 173). The experimental group consisted of patients receiving patient-selected music through headphones while the control group received quiet rest with no music or headphones. Patients in each group received one session for 30 minutes. Outcomes included state anxiety scored from the Spielberger State Anxiety Inventory. HR and RR were collected after the 30-minute intervention. Chlan (1998) concluded that the experimental group receiving music intervention had a "greater reduction in state anxiety" (p. 174). Chlan (1998) also found, that both mean HR and RR showed a reduction within the experimental group over the music intervention period (p. 174).

Wong (2001) used a cross-over trial design for adults with pulmonary disease who required MV in the ICU. Ventilator mode was set to pressure support (PS) (80%) and SIMV + PS (20%). The airway type was tracheostomy or oral endotracheal tube. Data from twenty patients were analyzed in both the experimental and control group. The experimental music group received patient selected music through headphones while the control group received uninterrupted rest. Music selections included: Chinese music, Chinese music played on Western instruments, and various Western music. Each participant received a 30-minute session in both the music group and control group; therefore, they served as their own controls. Outcomes included state anxiety (Spielberger State Anxiety Inventory), RR and mean BP. Both groups showed a significant reduction of state anxiety scores but those receiving music had less state anxiety than those in the control group.

A study conducted by Almerud and Petersson (2003) aimed to discover if a music listening intervention had a measurable relaxing effect on patients who were temporarily on a respirator in the ICU. Data from 20 subjects were researched for the quantitative portion of the data collection. Ten subjects were enrolled to each arm (music vs. non-music) of the study. The experimental group received classical music through headphones while the control group did not. Researchers discovered a statistically significant decrease of systolic blood pressure (SBP) and diastolic blood pressure (DBP) during music intervention. There were no significant differences between the two groups.

Lee (2005) used a two-arm parallel group design with adults on MV, diagnosed with respiratory problems and postoperative surgical problems. The ventilator mode was pressure support and the most common airways were the oral endotracheal tube, nasal, and tracheostomy. Data from 32 patients were analyzed in each group. The music group consisted of patients

listening to patient-selected music through headphones while the control group received quiet rest with headphones. Music selections provided were selected based on preferences of Chinese people since the study was conducted in China. The study used: Chinese classical music religious music (Buddhist and Christian), Western classical music and music with "natural sounds." Each participant received one 30-minute session. Outcomes included state anxiety using the Spielberger State Anxiety Inventory, HR, RR, SBP, and DBP. Researchers found a significant decrease in HR, RR, SBP and DBP after music intervention as well as an increase in observed resting behaviors.

Chlan, Engeland, Anthony, and Guttormson (2007) conducted a two-arm parallel group design study. The authors sought to explore the influence music listening had on serum biomarkers of stress response with adults receiving MV for varying diagnoses such as: pneumonia, respiratory failure, shortness of breath, ventricular tachycardia, and ischemic bowel. Of significance, patients were included in the study if they "were not receiving steroids or continuous intravenous infusions of a sedative" (Chlan et al., 2007, p.141). Sedative medications complicate the process of MV in critical care settings, as described in the previous chapter. Five participants were randomized to the music group compared to five participants who were randomized to the control group. The music group consisted of listening to patient-selected music through headphones. The control group rested quietly without headphones. Each participant received one session lasting 60 minutes.

Outcomes included blood samples obtained through central venous catheters, four different times throughout the session beginning at baseline, 15 minutes after baseline, 30 minutes from baseline, and 60 minutes after baseline. Blood samples looked at biomarkers such as: corticotropin, cortisol, epinephrine, and norepinephrine. HR was also collected at baseline

and then 15, 30, and 60 minutes after baseline. It was determined that levels of biomarkers did not differ significantly between intervention and control group. Levels of corticotropin and cortisol decreased over time in the music group, but this finding was not statistically significant. It is likely that significant outcomes were not found due to such a small sample size.

Conrad et al. (2007) conducted a two-arm parallel group design with critically ill patients on MV to identify whether a selection of Mozart's music impacted physiological markers of stress. Patients were intubated and required sedation with the short-acting narcotic agent Propofol (Conrad et al., 2007). Propofol is a sedative medication often used with patients who are receiving MV. Patients were randomized to two study groups including a music group in which patients listened to researcher-selected music through headphones or a control group with headphones but no music. A small sample size was used, with five patients randomized to the music group and another five patients randomized to the control group. Fifteen minutes after sedation had been discontinued, patients received music through the headphones. Patients received one session lasting 60 minutes in duration. The researcher-selected music chosen for the music group consisted of the slow movements of Mozart piano sonatas and played in chronological order. The selections were determined based on elements of relaxing music defined by the author. These musical elements included "duration, dynamic, tempo, and repetition of a theme" (Conrad et al., 2007).

Outcomes included sedative drug intake, HR variability, arterial pressure, serum level of dehydroepiandrosterone, serum concentrations of growth hormone, interleukin-6, prolactin, norepinephrine, adrenocorticotropic hormone cortisol, and prolactin monomer. Researchers found that music intervention significantly reduced the amount of sedative medication. There

was also a decrease in stress hormones found in the patients who received music which was also associated with a significantly lower blood pressure and HR.

Jaber et al. (2007) conducted a cross-over trial design study with adults on MV due to post-surgical ventilation, pancreatitis, respiratory issues, and sepsis. The types of airway included oral endotracheal tube and tracheostomy. Fifteen patients were randomized to both the experimental and control groups. The experimental music group listened to patient-selected music through headphones while the control group received uninterrupted rest without music. Patients either experienced 20 minutes of uninterrupted rest and then 20 minutes of the music listening intervention or vice versa. A music therapist created a compilation of patient-preferred music using the following guidelines: the music started at 90-100 beats per minute (bpm), slowed to 50-60 bpm and then increased to 70-80 bpm during the last five minutes to re-energize the patient. The music therapist was not involved in actually implementing the sessions. Each patient received one session which lasted 20 minutes. Outcomes included HR, RR, SBP, and DBP collected at 15-minute intervals because of the nature of the music increasing in tempo during the last five minutes of the session. Researchers found that music significantly decreased HR, SBP, and RR in both groups while no significant change was found during the rest period.

Wu (2008) used a two-arm parallel group design with adults needing MV. Diagnoses included lung-related disease and non-lung related diseases. The types of airway included oral endotracheal tube and tracheotomy tube. Thirty patients were randomized to both the music group and control group. The music group listened to music through headphones while the control group experienced quiet rest without music. Participants could choose from music selections such as: Chinese, religious, New Age, hymns, classical or orchestral music all with slow tempi. Patients received one session lasting 30 minutes. Outcomes included anxiety, HR,

RR, SBP, DBP, mean arterial pressure (MAP) and SpO_2. The experimental group showed improvement in anxiety based on VAS-A, DBP, MAP, and breathing rate compared to the control group. It was also found that anxiety and breathing rate decreased significantly following the music intervention.

A two-arm parallel group design study was conducted enrolling adults in ICU who were receiving MV (Dijkstra et al., 2010.) Participants were receiving MV for diagnoses such as: abdominal surgery, pneumonia, cardiovascular issues, sepsis, heart transplants, lung transplants, pancreatitis, respiratory distress, and trauma. The researchers hypothesized that patients who listened to music while sedated would have a reduction in physiological parameters and experienced deeper levels of sedation. This study reported that the ventilator mode was set for assisted spontaneous breathing. Ten participants were randomized to the music group with another ten participants randomized to the control group. The music listening group received patient-selected music through headphones while the control group experienced bed rest without headphones. This study used patient-selected music in the sense that patients chose from a pre-selected list of that was chosen by researchers to emulate the characteristics of relaxing music. Researchers offered four different classical music selections and easy-listening selections which had slow beats and were determined to be relaxing. Patients received three sessions over two days, lasting 30 minutes each.

Outcomes included HR, RR, arterial pressure, SBP, DBP, sedation scores, and mortality rate. Subjects in the music group were found to have higher sedation scores. The authors suggested, “The effects of sedative drugs seem to be augmented by listening to music” (Dijkstra, 2010, p. 1037). There were no significant changes in physiological parameters between groups.

Han et al. (2010) conducted a three-arm parallel design study for adults requiring MV due to cardiovascular disease, respiratory problems, and digestive system disease. Their aim was to examine the impact music listening had on physiological stress response and anxiety with MV patients. The ventilator mode reported in this study was the SIMV mode and types of airway included both oral endotracheal tube (ET) and tracheotomy tube. A larger sample size (n =137) was used compared to most of these studies with 44 subjects randomized to the music group, 44 subjects randomized to the placebo group, and 49 subjects randomized to the control group.

The music group participants listened to patient-selected music through headphones. The placebo group experienced quiet rest while wearing headphones without music. The control group received quiet rest without music or headphones. Patients selected music from the researcher's pre-selected offerings of 40 pieces of music. Music was chosen from four categories of relaxing music: Western classical music, Western light music, Chinese traditional music, and Chinese folk songs with lyrics. The research selected this music as it was familiar to Chinese people, the country in which this study took place. Each patient received one session for a duration of 30 minutes.

Outcomes included state anxiety (STAI-Chinese version) and physiological parameters including: HR, RR, SBP, DBP, and SpO_2. Significant differences were found in HR, RR, BP and anxiety among groups. There was a significant reduction of physiological stress response (HR and RR) over time in the music listening group. A significant reduction of anxiety was found in the music listening group as well as the headphone group. An increase of physiological stress was found in the control group over time.

Korhan, Korshid, and Uyar (2011) conducted a two-arm parallel group design study with adults in ICU receiving MV. Medical diagnoses necessitating MV included: pulmonary, heart

failure, chronic kidney failure, pancreatitis, and liver failure. These authors also sought to understand the impact music listening has on physiological signs of anxiety in the MV population. The ventilator mode used was positive end-expiratory pressure (PEEP). Thirty patients were randomized to the music group and another thirty patients were randomized to the control group. The music group listened to researcher-selected music through headphones while the control group received standard care. The researchers provided music selections which included Bach's 19 trio sonatas on flute with tempos of 60-66 bpm. Each patient received one session lasting 60 minutes. Outcomes included HR, RR, SBP, DBP, and oxygen saturation found in blood (SaO2). The music group showed a significant reduction in RR and blood pressures compared to the control group. The decrease progressed over the course of the intervention.

A study by Beaulieu-Boire et al. (2013) used a randomized controlled cross-over design, enrolling adults who needed at least three days of invasive MV. Patient diagnoses included respiratory, cardiovascular, and neurological issues, among others. The purpose of the study was to examine the impact of slow-tempo music listening on MV patients. Inclusion criteria consisted of patients who were receiving invasive MV for at least 3 days (p. 443). Patients were assigned to either an experimental group in which they listened to music through headphones or a control group in which they wore headphones connected to an MP3 player but with no music playing. This is one of the few circumstances where a music study can be properly blinded to the researchers. Music selections were chosen by the researchers and included popular classical music pieces by the following composers: Bach, Beethoven, Brahms, Chopin, Debussy, Pachelbel, Saint-Saens, and Tchaikovsky. Each arm of the study received two sessions lasting 60 minutes each time. Day 1 consisted of group A receiving music while group B did not. Day 2

consisted of only regular care for both groups. Day 3 provided music to group B and no music for group A.

Vital signs were assessed before and after each session. No significant change in vital signs was observed. Researchers expected to find a decrease in stress-related vital signs, which did not occur. However, a reduction in narcotic consumption did occur for the music listening group though it was not significant. It is important to note that sedative medications were not stopped entirely for the patients participating in the study which could potentially explain why vital signs did not show a significant change.

Chlan et al. (2013) conducted a study using a three-arm parallel group design with adults receiving MV due to respiratory failure or distress. The three arms of the study included a patient-directed music group (n=126), noise-cancelling headphones group (n=122), and usual care group (n=125). The patient-directed music group consisted of patients listening to their preferred music through headphones. Data were kept that tracked total daily music listening time. The noise-cancelling headphones group were encouraged to wear the headphones whenever they wanted to block out ICU noise or have quiet time. The usual care group received standard ICU care.

The patient directed music listening protocol was designed in collaboration with an MT-BC. This study is still classified as a music listening study because the music therapist assessed music preferences to provide appropriate music for each participant but did not facilitate a music therapy session. Participants were encouraged to self-initiate music listening or nurses offered it to the participants. A research nurse provided each participant in the music group a starter set of six CDs for immediate listening upon enrollment. The starter set included relaxing music played on piano, harp, guitar, and Native American flute. The music therapist completed a music

preference assessment within 24 hours of enrollment. Following the assessment, patients were provided with CDs based on their music preferences. Study outcomes included state anxiety, using the VAS-A, daily sedative drug intensity, daily sedative drug dose frequency, extubation rate at the end of study, mortality rate, and urinary free cortisol. Patients in the music listening group were found to have significantly lower anxiety scores and reduced measures of sedative exposure than patients in the usual care group.

Liang et al. (2016) used a cross-over repeated measures design with adults necessitating MV for four days or longer. Ventilator mode was not reported but type of airway required was a tracheostomy. This study is the only study that has focused on exploring the impact of a music listening intervention on patients while they were weaning from MV. Patients were randomized a music listening vs. non-music listening group on the first intervention day. The use of music listening was alternated for six days, allowing for three music listening and three non-music listening days. This allowed for each participant to serve as their own control. Patients' music preferences were assessed using a 13-item tool including questions such as: "identify your favorite type of music, favorite musician, preferred instruments, as well as music and/or instruments they disliked" (p. 73). Collaboration with a music therapist did not occur for this study.

Outcomes included HR, RR, SpO2, BP, VAS-A, Visual Analog Scale-Dyspnea (VAS-D) for 30 minutes at baseline. Headphones were applied to the patients after this 30-minute interval and data were collected again over a 60-minute listening period. Again, this data collection occurred during the patients' weaning trials. Data for 23 patients who completed the six-day intervention were analyzed. On music days, pre- and post-intervention, "there was a significant decrease in HR, RR, VAS-D, and VAS-A…there were no significant differences for these

variables on no-music days" (p. 74). Researchers also compared each patient to their own three music listening days vs. their three no-music listening days. They found "there were significant decreases in RR and VAS-D and a significant increase in daily weaning duration" (p. 74). Overall, the researchers concluded that "patient selected music intervention decreased dyspnea and anxiety and increased daily weaning duration for prolonged mechanically ventilated patients during daily weaning trials" (pp. 74-75).

A study published in 2017 by Hetland et al. sought to determine if music and anxiety had an influence on the time leading up to the initial weaning trial and the duration of the weaning trials. (p. 211). This was a secondary analysis of the parent study by Chlan et al. (2013) which was described above. The time to initial weaning trial was described as the hours from study enrollment to the time the first weaning trial was attempted. The duration of weaning trials was described as the duration in minutes from the start of each trial to the finish, each time the participant was being weaned. The results indicated that music and anxiety were not significant predictors of time to initial weaning trial or duration of the weaning trials. (Hetland et al., 2017, p. 217). Hetland et al. (2017) suggested:

> "…physiological measurement techniques and proxy assessment for anxiety are dated; future research should consider more precise biological measures in conjunction with direct reports from patients to evaluate anxiety to enhance our understanding of the exact mechanisms in which music affects the stress response" (p. 218).

Music Listening Summary

Of the fifteen music listening studies in this literature review, four of the studies used a randomized controlled cross-over design: Beaulieu-Boire et al. (2013); Jaber et al. (2007); Liang

et al. (2016); and Wong, Lopez-Nahas, & Molassiotis (2001); and 10 of the studies used a two or three arm parallel group design: Chlan (1995); Chlan (1997); Chlan, Engeland, Anthony, & Guttormson (2007a); Chlan et al. (2013); Conrad et al. (2007); Dijkstra, Gamel, Bijl, Bots, & Kesecioglu (2010); Han et al. (2010); Korhan, Khorshid, & Uyar (2011); Lee, Chung, MF. Chan, & WM. Chan (2005); and Wu & Chou (2008). Most studies contained small sample sizes ranging from 10 to 266 with participants randomly assigned one of two groups: music listening (experimental) or a control group. The control groups consisted of patients who wore headphones but received no music, experienced quiet rest without music, or were provided usual ICU care.

All participants recruited in these studies were receiving MV in critical care units. Diagnoses necessitating mechanical ventilation were reported in all fifteen of the articles presented in this review. A variety of diagnoses were reported including: respiratory/pulmonary illness, cardiovascular, neurological, cancer, transplants, trauma, sepsis, pancreatitis, and other various medical issues.

Six of the studies included information about the type of airway used for the subjects. Oral and endotracheal tube airways and a tracheostomy tube were reported in Han et al. (2010), Jaber et al. (2007), Lee et al. (2005), Liang et al. (2016), Wong et al. (2001) and Wu et al. (2008). A nasal airway was also reported in Lee et al. (2005). Ventilator mode was addressed in five of the studies. Dijkstra et al. (2010) reported that the ventilator mode was set for "assisted spontaneous breathing" while Han et al. (2010) reported the ventilation mode as SIMV. Korhan et al. (2011) reported use of PEEP only and Lee et al. (2005) used PS. Ventilator settings were reported in eight of the studies. Beaulieu-Boire et al. (2013) reported that inclusion criteria required patients who needed "at least 3 days of invasive MV with a self [patient]-triggering

mode on the ventilator" (p. 443). Chlan (1997) reported the most common ventilator mode in the study was "the synchronized intermittent mandatory ventilation (SIMV); most subjects received both positive end-expiratory pressure and pressure support (PS) adjuncts" (p. 173).

The most commonly used intervention duration was 30 minutes. This approach was used in six of the 14 studies assessed, while some of the studies used interventions that ranged in duration from 20 minutes to 60 minutes. Three of the studies involved more than one intervention. All fifteen studies included an experimental group that received music through headphones. Seven of these studies used a control group that received headphones without music while another seven used a control group that involved quiet or uninterrupted rest without headphones. Only two studies compared the experimental group to a control group consisting of usual care. Chlan et al. (2013) was the only study that used three groups including: headphones with patient directed music listening group, headphones with no music group, and a usual care group. This seems to be the design most worth replicating so that researchers can understand the music listening experience in comparison to headphones that cancel ICU noise, and patients receiving usual every day ICU care. Participants in the Chlan et al. (2013) study also had control over their music choices, when they wanted to listen to music, and for how long they wanted to listen.

A critical aspect to understanding the impact of music is assessing the type of music provided to the experimental group in each of these studies. Six of the fifteen studies used researcher-selected music that was offered to the patient. The patient then selected music from this list. The rationale provided by researchers for their music selections varied from study to study. Chlan (1995) provided the following reasoning, "Patients could choose from classical selections of music for relaxation which was previously tested with both critical care

and surgical patients and had been designated as relaxing" (p. 235). Dijkstra et al. (2010) also offered that music was chosen by researchers to emulate the characteristics of relaxing music. Their selections included classical and easy listening music which had slow-beats and were found to be relaxing by the researchers. Han et al. (2010) mentioned that all of their music selections included music that was familiar to Chinese people, the country in which the study took place.

Two of the fifteen studies involved a music therapist who assessed participant music preferences or created music playlists. Chlan et al. (2013) used a tool designed by an MT-BC to assess the music preferences of the patients. The MT-BC completed the music preference assessment and provided patients with CDs based on their music preferences. Patients were able to request as much music as they wanted. Jaber et al. (2007) collaborated with an MT-BC to create a compilation of researcher-selected music using the following guidelines: the music started with a tempo of 90-100 bpm, slowed to 50-60 bpm and then increased to 70-80 bpm to "re-energize" the patient. It is important to note the music therapist was reported as providing the equipment for the music listening intervention but left the room for the duration of the listening.

Outcomes

Outcomes for the music listening studies were focused in primarily two categories: physiological vital signs and anxiety. Eleven of the fifteen studies sought to understand the impact of a music listening intervention on physiological vital signs (including HR, RR, SBP, DBP, arterial oxygen saturation (SaO_2), and SpO_2, and five studies considered state anxiety. These studies used 3 different scales from which they obtained anxiety scores, including the Spielberger State Anxiety Inventory (STAI) (Chlan (1997), Lee et al. (2005), and Wong et al.

(2001), the Visual Analog Scale-Anxiety (VAS-A) (Chlan et al., 2013), and the STAI-Chinese Version (Han et al., 2010). Vital signs and anxiety outcomes are listed in Table 1.

Table 1

Outcomes for Music Listening Groups

Vitals/Anxiety	**Music listening group**
↓HR	Chlan (1995), 2 arm; Chlan (1998) 2 arm; Lee (2005), 2 arm; Conrad et al. (2007), 2 arm; Jaber et al. (2007), 2 arm; Han et al. (2010), 3 arm; Liang et al. (2016), 2 arm
↓RR	Chlan (1995), 2 arm; Chlan (1998) 2 arm; Lee (2005), 2 arm; Jaber et al. (2007), 2 arm; Han et al. (2010), 3 arm; Korhan et al. (2011), 2 arm; Liang et al. (2016), 2 arm
↑SpO_2	None
↓SBP	Almerud & Petersson (2003), 2 arm; Lee (2005), 2 arm; Conrad et al. (2007), 2 arm; Jaber et al. (2007), 2 arm; Korhan et al. (2011), 2 arm
↓DBP	Almerud & Petersson (2003), 2 arm; Lee (2005), 2 arm; Conrad et al. (2007), 2 arm; Wu (2008), 2 arm; Korhan et al. (2011), 2 arm
↓Anxiety	Wong (2001) 2 arm; Wu (2008), 2 arm; Han et al. (2010), 3 arm; Chlan et al. (2013), 3 arm; Liang et al. (2016), 2 arm

Sedative medications can cause many side effects for the patient. Sedative medications also impact each patient differently and their effects greatly depend on the amount and type. Conrad et al. (2007) enrolled patients who were intubated and receiving Propofol, a short-acting sedative medication (p. 2710). The music listening intervention was implemented 15 minutes after sedative medications had been discontinued and lasted 60 minutes after discontinuation of sedative medications. The researchers found that music intervention significantly reduced the amount of sedative medication needed (Conrad et al., 2007). Chlan et al. (2007) included patients

who did not receive steroids or continuous intravenous sedative infusions (p. 141). However, Beaulieu-Boire et al. (2013) noted that "sedative drugs were generally administered intermittently or titrated continuously but without daily interruption" (pp. 443-444). A reduction in narcotic consumption did occur in the music group, though it was not significant. The fact that sedative medications were not completely discontinued could explain why outcomes for vital signs did not show a significant change in that study (Beaulieu-Boire et al., 2013). Dijkstra et al. (2010) noted that subjects in the music group were found to have higher sedation scores. The author suggested that music listening enhanced the impact of sedative medications.

Overall, the music listening literature has shed light on the possibility that music listening has the capability of decreasing anxiety, reducing sedation exposure, and improving vital signs for patients receiving and/or weaning from MV. The literature has mostly explored music listening implemented by nurses or other medical professionals. There is limited literature involving music therapy which is facilitated by an MT-BC. The four nonpharmacologic interventions that have been reported in the literature for use with assisting MV patients with anxiety include: hypnosis, patient education, music therapy, and supportive touch (Thomas, 2003). Most studies may refer to a music listening intervention as music therapy despite the fact that the research did not involve a music therapist and the therapeutic relationship and process. There are only two known studies to this author's knowledge that have sought to understand the impact music therapy may have on the MV process.

Music Therapy and Mechanically Ventilated Patients

Bruscia (2014) defines music therapy as: "a reflexive process wherein the therapist helps the client to optimize the client's health, using various facets of music experience and the

relationships formed through them as the impetus for change (p. 36). The music therapist tailors music experiences to meet the unique needs a patient may present in the course of their treatment and fosters a client-therapist relationship in this process. The Certification Board for Music Therapists (CBMT) provides a comprehensive list of clinical domains that an MT-BC must be able to apply to their clinical practice. These domains include steps for referral, assessment, treatment planning, treatment implementation, termination and closure, and ongoing documentation and evaluation of treatment ("Board Certification Domains", 2015).

To date, two studies have been implemented using music therapy with MV patients in the ICU. Hunter et al. (2010) aimed to determine the feasibility of incorporating music therapy into the weaning process and to evaluate the efficacy of the interventions. The subjects were admitted to a pulmonary step-down unit and received MV through a trach-collar. Sixty-one subjects were enrolled and compared to historical controls. The music therapy intervention lasted 45-60 minutes, occurring three times per week during weaning trials.

During the first session, the MT-BC collected patients' music preferences by asking the patient, family members, and/or visitors. To facilitate a relaxation response, the MT-BC "adjusted music characteristics such as volume and tempo according to the participant's respirations and/or heart rate" (Hunter et al., 2010, p. 207). These researchers measured anxiety by using a patient and staff survey and collected vital signs before and after each music therapy session. They recorded the patients' days to wean and measured satisfaction by patient and nursing staff surveys. They concluded that both patient and nurse satisfaction with music therapy were high. They also determined that a significant difference in HR and RR occurred from beginning to the end of the music therapy session. Additionally, staff surveys showed that patients seemed to appear more relaxed after the music therapy session.

Phillips (2007) evaluated the impact of music therapy using the specific music therapy intervention of entrainment with mechanically ventilated patients. This study defined music entrainment as "the use and manipulation of musical tempo to modify respiration" (p. 11). In this randomized controlled trial, twenty patients were enrolled into an experimental group and compared to twenty patients in the control group. Each arm of the study was divided into two additional groups which included patients with medical diagnoses (n=10) and patients who had undergone cardiac surgery (n=10). This study used live music and applied the iso principle to match (entrain) music to the patients' respiratory rate. Patients in the music group received this music therapy intervention while patients in the control group received quiet rest only. The sessions lasted 25 minutes. The outcome measures included HR, RR, O_2sat, and rapid shallow breathing index (RSBI). The results indicated a significant difference in the RSBI readings of participants between medical diagnoses groups who received music therapy (Phillips, 2007).

Both the Hunter et al. (2010) and the Phillips (2007) studies focused on the physiological impact music therapy had on the patients. Phillips (2007) did not yield statistically significant data measures. According to Phillips (2007) the RSBI indicated one potentially positive outcome: "The rapid shallow breathing index decreased during music intervention which indicated that music tended to cause deeper and more productive breathing" (p. 24).

Literature Conclusion

The music listening literature indicate the need for more accurate measures of anxiety and readiness to wean. It seems important to truly understand the perceptions of patients' receiving MV and participating in the weaning process in order to more successfully liberate them from the ventilator with as little complications as possible.

Much of the literature reviewed in this chapter involves music listening interventions implemented by healthcare professionals, that in many cases did not involve the expertise of an MT-BC. If we are to fully understand the impact of music on patients' perceived anxiety and stress response during the weaning process, as suggested by Hetland et al. (2017), then we must design research studies that seek out those answers and include the professionals with the expertise to design and execute the research (Chlan et al., 2018). There is limited research involving music therapy during the weaning process of patients receiving invasive MV. Music therapists working in ICUs need evidence from which they can base their practice and develop best practices models. The purpose of this study was to evaluate the impact of music therapy on the physiological response of a patient weaning from MV as well as to examine the patients' experiences weaning from MV.

Operational Definitions

Anxiety: an emotion characterized by feelings of tension, worried thoughts and physical changes like increased blood pressure. (American Psychological Association, 2019)

BiPAP: refers to bilevel or two-level positive airway pressure (American Sleep Association, 2019). Respiratory support with respirations triggered by the patient, supports the work of breathing.

CPAP: Continuous positive airway pressure (CPAP). It uses air pressure generated by a machine delivered through a tube into a mask that fits over the nose or mouth (American Sleep Association, 2019).

Extubation: removal of a breathing tube that has been placed through the mouth or nose into the trachea

Intubation: the insertion of a breathing tube through the mouth or nose into the trachea

Invasive (mechanical ventilation): use of an endotracheal tube

Music relaxation: the use of music listening: to reduce stress and tension, to reduce or counter-condition anxiety, to induce body relaxation, or to facilitate entry into altered states of consciousness

Music entrainment: the use of vibrations, sounds, and music in various elemental and combined forms to establish synchronicity in autonomic or voluntary body responses

Music therapy: the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional

NIPPV: Noninvasive positive pressure ventilation: the delivery of positive pressure ventilation via a tight-fitting mask that covers the nose or both the nose and mouth.

Prolonged (MV): greater than 7 days before liberation from ventilator

SAT: Spontaneous awakening trial; sedation interruption or vacation

SBT: Spontaneous breathing trial-normal, unassisted breathing that moves air in and out of the lungs

Weaning: The process of re-establishing a patient's independent and spontaneous breathing

Chapter 3

Methodology

Introduction

This study was conducted as a feasibility study; therefore, a small sample size of 20 was targeted and no control group was used for comparison. This study used an embedded mixed method study design within a larger design (phenomenology). The quantitative and qualitative data collection and analysis processes will be discussed in further detail in this chapter.

Research Hypothesis 1: Quantitative

One 30-minute music therapy session during an SBT will decrease the patient's perceived level of anxiety and improve physiologic metrics related to the SBT, specifically, RR, blood pressure (BP), SpO_2, and HR.

Research Question 1: Qualitative

In addition to evaluating the physiological response to music therapy on the patient during an SBT, this study sought to understand the impact from the perspective of the patient. The research question was: What does the patient experience related to music therapy during their spontaneous breathing trial?

Clinical Research Context

This study was conducted in a 600-bed hospital in the Midwest region of the United States. The research was conducted in the medical ICU, a 24-bed general medical ICU that provides care for patients with a variety of critical illnesses. The ICU medical team consists of an

attending physician (intensivist), nurse manager, critical care bedside nurses, pharmacist, respiratory therapists, nurse case managers, social workers, clinical nurse specialists, physical and occupational therapists, and music therapists. Data collection for this research study occurred from April 2018 through January 2019.

Study Participants

The researcher sought to enroll 20 participants as a target sample size. Screening for enrollment into the study occurred upon the patient's admission to the ICU. Screening was accomplished by completing the screening form (Appendix A). Patients who were eligible for the study needed to meet the following inclusion criteria:

- medical or cardiac diagnosis
- admitted to the medical/surgical ICU
- at least 18 years or older
- invasive mechanical ventilation for greater than 24 hours

Patients could not be enrolled if they had received music therapy sessions previously as evidenced through a medical chart review. Patients were excluded from study enrollment if they were less than 18 years old, unable to speak, read, or write in English, received noninvasive mechanical ventilation, had a tracheostomy, were hard of hearing, or received prior music therapy. A list was created in the electronic medical record system, EPIC, identifying eligible and enrolled patients. Only the participating investigators listed on the IRB application had access to this list in EPIC. These investigators included: the principal investigator (music therapist not facilitating the sessions), the study coordinator, a clinical nurse specialist (CNS), a music therapist (facilitating the sessions), and a nurse manager.

After screening for enrollment, either the CNS, study coordinator, or music therapist (facilitating the sessions) explained the study to patients. Eligible participants or their family were presented with both the recruitment letter and consent form, allowing sufficient time for them to review it and ask questions before enrollment in the study. The patient or patient's Power of Attorney (POA) signed consent, since patients were not always alert enough to sign their own consent. If a POA was not designated, the closest next of kin (i.e. spouse, parent, or child) had the authority to provide consent. If there was more than one family present, and no one identified as closest next of kin, the decision about whether or not to participate was based on a vote held by the family members present, with the majority vote making the decision. This study was reviewed by the Institutional Review Board (IRB) of both the Cleveland Clinic Foundation and Augsburg University.

The Written Informed Consent Form (Appendix B) was signed and completed by those participants and/or family members agreeing to participate in the study. The signature and date the consent was obtained was documented on the form with a copy provided to the participant and/or family. A second copy was placed in a research binder which was stored in a locked cabinet of the principal investigator's (PI) locked office. The co-investigator obtaining consent provided clear documentation of this process in the participant's EPIC record.

No participant identifiers were used on the data collection forms. A study code number, used to identify the participant, was assigned to each participant who consented to the study. All identifiable participant information was de-identified and the proper steps taken to prevent disclosure of identifiable participant information which included keeping all forms for each participant in a binder in a locked cabinet in the PI's locked office.

Participants could be removed from the study (Appendix C) for events including: discharge from the hospital, deceased, refusal to participate, lack of completion, change in code status, patient self-extubation, interruption due to testing/procedure, deterioration of medical status, and family request to be removed from the study. Participants were removed from the study for the following reasons: participant declined participation (n=3), participant deceased (n=2), participant was palliatively extubated (n=1), participant had tracheostomy placed (n=2), participant placed on CPAP trial (n=1), participant failed SBT prior to 30-minute completion (n=1).

Quantitative Measures

Several assessment instruments were used to collect data regarding pain, anxiety, assessments, and vital signs before and after each music therapy session including: RASS, CAM-ICU, the Nonverbal Pain Assessment (NPAT), and numerical scales for pain and anxiety. All data collection instruments are tools that are part of standard patient care at this facility. Participants were initially assessed for appropriate awake states by using the RASS and CAM-ICU scales. RASS "is a 10-point scale, with four levels of anxiety or agitation (+1 to +4 [combative), one level to denote a calm and alert state (0), and 5 levels of sedation (−1 to −5) culminating in unarousable (−5)" (Sessler et al., 2002, p. 1338). Patients with a RASS score of 0 are identified as alert and calm. Patients with a RASS of less than or equal to -2 are identified as either being drowsy or receiving light sedation. Drowsy is defined as "not fully alert but has sustained awakening (eye-opening/eye contact) to voice for ≥10 seconds" (*RASS Scale*, 2019). Light sedation is defined as "briefly awakens with eye contact to voice for <10 seconds" (*RASS Scale*, 2019).

CAM-ICU is "a delirium assessment tool recommended by the Society of Critical Care Medicine's Clinical Practice Guidelines for the Management of Pain, Agitation, and Delirium in Adults Patients in the ICU" (Tate & Balas, 2019, p. 1). The assessment can be completed in less than one minute by a bedside nurse and is not validated for use outside of the ICU (Tate & Balas, 2019, p. 1). These assessments were completed by the nurse manager or CNS prior to the SBT and music therapy session. Participants' ability to follow simple commands such as making eye contact, shaking head, and squeezing hands were documented prior to the SAT and SBT by the bedside nurse as this is done for each patient per nursing protocol at this medical facility.

Pain was assessed with a number (0-10) on the numerical pain scale with zero being no pain at all or ten being the most pain they had experienced. This was assessed immediately before and after the SBT and music therapy session by either the CNS or the nurse manager. When participants were unable to report a numerical value for their own pain, the NPAT scale was used instead. The NPAT scale consists of a series of observable behaviors in 5 domains including: emotion, movement, verbal cues, facial cues, and positioning/guarding (Stites, 2013, p. 70). These behaviors are interpreted by the bedside nurse or appropriate medical personnel. NPAT is accepted for use at the medical facility in which the research took place.

Participants' anxiety level was assessed using numeric ratings of 0-10, with zero indicating no anxiety at all and ten indicating the most anxiety the participant had ever experienced. This assessment was facilitated immediately before and after the SBT and music therapy session by either the CNS or nurse manager. A nonverbal anxiety assessment does not exist at this medical facility; therefore, when participants were unable to provide a numeric value, anxiety was assessed by nursing perception and observation. This is considered standard nursing protocol at this medical institution.

Vital signs including HR, RR, SBP, DBP, O_2 sat were collected by the nurse manager or CNS before and after each SBT and music therapy session. Sedation type and amount were documented immediately prior to the sedation vacation, after the music therapy session, and when weaning was completed. Information from the RASS and CAM-ICU scales were documented immediately prior to sedation vacation. Time of sedation vacation, time weaning began, and time of music therapy implementation were also documented. These data were placed on the Data Collection Form (Appendix E). The study coordinator input the data collection forms into the REDCap database. According to its website, REDCap is a secure web application designed to support data capture for research studies. It provides user-friendly web-based care report forms, real-time data entry validation, audit trails, and de-identified data export mechanism to common statistical packages. ("REDCap", 2019).

Qualitative Measures

Participants were eligible for an interview if they met the following inclusion criteria (Appendix D): hemodynamic stability, defined as a systolic blood pressure >80; a negative score on the CAM-ICU scale; pulse oxygenation (>92 bpm); no evidence of expressive aphasia; and alert and oriented to self, place, and time. These criteria were created based on recommendations from critical care nurses and nursing practice in the ICU. All participants who received a music therapy session were screened for eligibility into the interview group. The PI conducted interviews after successful extubation for nine of the participants as only nine met the interview criteria.

Study Procedures

All participants received one, 30-minute music therapy session concurrent with the start of their SBT. Music therapy documentation was completed after each session as is standard for every music therapy session facilitated at this hospital. Music therapists documented in a flowsheet that can be accessed by the rest of the medical team. The flowsheet consists of ratings of pain, anxiety, and mood before and after each session if the participant was able to report those answers. The flowsheet also reports music therapy goals and interventions as well as the genre of music and names of songs used in the session. The flowsheet automatically populates into the music therapy note which includes a narrative of the session written objectively from the standpoint of the music therapist. The music therapist facilitating sessions for the study omitted the pre- and post-session pain and anxiety ratings from study participants' flowsheet documentation as that data was already being collected for study purposes.

A screening test (wean screen), facilitated by a respiratory therapist to every ventilated participant once every 24 hours, was used to determine the earliest point in time that a participant might tolerate an SBT. Criteria assessed to determine suitability for an SBT must be present as well as physician discretion to pass the wean screen. The wean screen criteria for this hospital were as follows:

- Patient off all paralytics
- Patient sedative medication level no higher than 10mcg/kg/min
- Norepinephrine (or equivalent) < 5 mcg/min
- PEEP ≤ 8 cm H_2O
- Substantial reversal of underlying needs for mechanical ventilation
- Patient triggered breath at rate < 35 breaths/min

- $FiO_2 \leq 0.50$ with $SpO_2 > 90\%$
- No metabolic acidosis
- Not in shock
    - MAP > 65 mm Hg
    - Norepinephrine < 5mcg/min o
- Hemodynamic stability: absence of chest pain
    - Arrhythmias
    - Uncontrolled hypertension

It is important to note that other factors like physician, respiratory, and nursing discretion exist when screening a participant for weaning suitability. The music therapist facilitating sessions was required to abide to the standard protocols specific to the ICU. Timing of the SBT and amount of sedation was determined by the nurse's discretion per the ICU protocol.

Once the participant passed the wean screen, the participant's sedative medication was decreased at the nurse's discretion for at least 10 minutes before an SBT was immediately applied by the respiratory therapist. The bedside nurse documented the passing of a Sedation Awakening Trial (SAT). The duration of the SBT lasts approximately 30-60 minutes depending on the participant's needs. The preferred ventilator mode is: pressure support set at 5-8 cm H_2O above PEEP. Successful passing of the SBT requires the following:

- $SpO_2 > 90\%$
- Respiratory rate < 40/min for at least 30 minutes
- Systolic blood pressure > 80 mm Hg

If the participant or family member on the participant's behalf, declined to participate in a music therapy session, they were offered a session on another day. This process continued until the participant received a music therapy session during the SBT.

Music Therapy Sessions

Music therapy sessions included an assessment and music therapy intervention(s) facilitated by an MT-BC. Music therapy sessions are not comprised of a specific set of interventions. The music therapist had a guitar and piano keyboard available, as well as an iPad to search for patient-preferred sheet music as needed. The music therapist determined the most appropriate music experience based on the needs of the participant in the moment; therefore, a specific protocol for music therapy intervention was not described or implemented in this study.

Music preferences were assessed for each participant prior to receiving the music therapy session. If the participant was unable to indicate their own preferences, the music therapist asked family to help identify music preferences. If family was not present to assist with music therapy assessment, then the MT-BC used their own judgment and discretion in choosing appropriate music for the session. When this occurred, music considerations included the participant's age, religion, and anecdotal evidence from bedside nurses that may have been passed on by family members.

Although specific protocols were not implemented, consistent with the MT- BC's clinical practice, one or both music therapy interventions including music-assisted relaxation and musical entrainment were used in each music therapy session. Music relaxation is defined as "the use of music listening: to reduce stress and tension, to reduce or counter-condition anxiety, to induce body relaxation, or to facilitate entry into altered states of consciousness" (Bruscia, 2014, p.

136). The music therapist offered verbal guidance in addition to music to support a relaxation experience. Verbal guidance included cues for deep breathing and validation of the participant's observed expressions and feelings. The music therapist also provided ongoing education about what was happening to the participant in the moment. This education included reminders about the medical intervention taking place, identifying the medical personnel who were in and out of the room, and indications of what to expect throughout the music therapy session.

Music entrainment is defined as, "the use of vibrations, sounds, and music in various elemental and combined forms to establish synchronicity in autonomic or voluntary body responses" (Bruscia, 2014, p. 135). The music was created by the MT-BC using guitar, piano, and voice or a combination of two. Relaxing characteristics of music were incorporated including use of a slow, steady beat to promote deep breathing. Both patient-preferred and improvised, non-familiar music was used based on the participants' needs. The music included improvised, predictable chord progressions on guitar or piano as well as improvised humming or singing. The improvised singing included phrases created by the therapist that served as reminders or cues to breathe or sustained vowel sounds ("oo"). All of this music was provided in a sedative style which included an appropriate volume and tempo entrained to the RR of the participant.

Statistical Analysis

Continuous measures were summarized with Median [Q1, Q3], and categorical measures were summarized with frequency (percentage). Differences in continuous measures (after music therapy – before music therapy) were summarized with Mean ± Standard Deviation and analyzed with paired *t*-tests. ANOVA procedures were used to analyze differences in vitals between

groups. Pearson correlation coefficients were used to summarize the linear relationship between continuous measures. For this analysis, $p < 0.05$ were considered statistically significant. The analysis was done in SAS software (version 9.4; Cary, NC).

Analysis of Interviews

The structure for qualitative analysis proposed by Braun and Clarke (2013) was used as a guideline for analysis in this study. The interviews were conducted as experiential qualitative research. Braun and Clarke (2013) define this type of research as "validating the meanings, views, perspectives, experiences and/or practices expressed in the data" (p. 21). The aim was to understand the experience of the participant receiving music therapy while weaning from MV. It was therefore, imperative to hear about the experiences directly from the participants themselves rather than only learning about their experience through numerical data.

Interviews.

Qualitative data focused on the participants' lived experiences was collected in their hospital room during an open-ended, semi-structured interview once they were liberated from the vent and met inclusion criteria. The PI conducted interviews consisting of several open-ended questions:

- How would you describe your mechanically ventilated experience?
- What do you remember from the mechanial ventilation experience?
- What were your limitations?
- Describe your experience in music therapy during the weaning process.
- What was the music therapy experience like?

The interviewer asked additional follow-up questions to clarify and better understand each participant's experience. It was important to ask open-ended questions in order to obtain a full description of the participant's experience and not just "yes" or "no" responses. Follow-up questions were necessary in order to better understand an individual participant's experience as all medical treatment and music therapy sessions could vastly differ between participants. Interviews were recorded using the Sony UX560 Digital Voice Recorder with a built-in USB drive provided by the Cleveland Clinic Foundation. After recording, the interviews were uploaded to and transcribed from the approved network drive on the researcher's secure, approved computer at the medical facility.

Epoché.

Qualitative research involves a subjective process on the part of the researcher. The researcher for this qualitative portion currently works as a music therapist in a medical setting treating MV patients who are weaning from the vent. The researcher acknowledged their biases in the research process including their beliefs of the power of music to positively impact one's physical, emotional, and mental health. As stated above, literature has already identified the use of music to promote relaxation. This researcher believes that one's response to music is dependent upon their current health circumstance and the method and timing in which the music is received.

Each person has their own music preferences as well as memories, past experiences, and social standards that impact their musical experiences. These past experiences can illicit emotional responses when listening to certain genres of music. Familiar music can also be "too close" to an individual and elicit emotional responses. While emotional responses are not meant

to be defined as “positive” or “negative” they can still elicit emotional behaviors such as crying. Crying can be contraindicated for a patient attempting to breathe on their own. This understanding of the impact music may have on an individual weaning from the vent was taken into consideration when analyzing interviews. It was also this researcher’s understanding, prior to conducting this study, that MV can be extremely uncomfortable, like “breathing through a straw,” confusing, painful, anxiety-provoking, and something one would not want to remember. The researcher took these biases and beliefs into great consideration when conducting interviews and analyzing the data. These biases and beliefs are integrated into the researcher’s interpretations of the data set and will be explored in further detail throughout the results and discussion.

Braun and Clarke (2013) believe that trustworthiness in qualitative research may include one or more of the following: validity, generalizability, transferability, member checking, and triangulation. Each concept involves literature with opposing beliefs depending on the researcher and their interpretation of how to do qualitative research (Braun & Clarke, 2013, pp. 280-286). Validity is described as whether reality is being accurately captured (Braun & Clarke, 2013, p. 280). This researcher aligned with the concepts of internal validity (“the effects identified are in fact being caused by the variable(s) under study”) and external validity (“whether the results from the study can be generalized from the sample to the wider population”) (Braun & Clarke, 2013, p. 280).

Braun and Clarke (2013) refer to triangulation as a research process that refers to two or more methods of data collection. The researcher collected journal entry data from the music therapist facilitating the sessions. The music therapist facilitating the sessions described their theoretical approach as:

> A humanistic, person-first approach where I presume competence in all patients and view them first as the person they are with the many abilities they possess. I strive to build a strong and genuine rapport with patients rooted in trust. I aim to foster growth in individuals through personalized, innovative musical experiences while assessing in the moment. (E. Guthe, personal communication, August 18, 2019)

The music therapist wrote down a description of their observations, thoughts, and experiences after each session they facilitated. This was done as an effort to provide a greater understanding of the experience of each music therapy session from the MT-BC's point of view. These data were not included in this paper as it was not the main focus of the research question and was also not included due to researcher time constraints.

Analysis.

Open-ended, semi-structured interviews were conducted and transcribed verbatim by this researcher. Transcriptions were completed in an ongoing process after each interview was obtained. Each interview was read thoroughly as many times as needed. The researcher kept a log of free-associated thoughts that arose while reading the interviews and highlighted pertinent information. Relevant data were coded and placed in a table. The table consisted of three columns with the headings: emergent themes, original data, and comments.

The researcher commented on each selection of original data that were broken into three categories: descriptive, linguistic, and conceptual (Braun & Clarke, 2019). Descriptive comments involved the researcher's overall summary of the original data. Linguistic comments focused on the specific language the participant used in their statement(s) and any of the researcher's thoughts or interpretations of this language. The conceptual comments involved higher level

interpretation of what the participant was really saying in their original data extract (Braun & Clarke, 2019).

After comments were completed for each original data extract, the researcher created emergent themes. According to Braun and Clarke (2013), emergent themes are "developed from the original data item *and* the exploratory comments…and they reflect a mix of staying *close* to the participant's experience, and the analyst's developing interpretation" (p. 237). The researcher produced emergent themes with this idea in mind and produced as many emergent themes as needed to best encompass the original data and researcher comments.

These emergent themes were abstracted, which is described as "many similar emergent themes clustered together to form a similarly oriented but slightly more abstracted superordinate theme, closely related to the core issue" (Braun and Clarke, 2013, p. 237). The emergent themes were placed into these new categories called superordinate themes. Superordinate themes are "developed through searching for patterns of connection across emergent themes" (Braun and Clarke, 2013, p. 237). The emergent themes were cross-referenced with the original data repeatedly until the researcher extracted all valuable information needed. Superordinate themes were changed several times to best reflect the patterns in emergent themes and the original data set.

The superordinate themes were individually defined by the researcher and correctly categorized with appropriate emergent themes and the connected original data piece. Therefore, the superordinate themes reflect both the essence of the original data combined with the researchers ongoing interpretation of the data and the researcher's own biases and beliefs.

Further analysis was continued through the writing process. The researcher attempted an illustrative approach to analyzing the data. Braun and Clarke (2013) describe this approach

stating that the “analytic narrative provides a rich and detailed description and interpretation of the theme, and data quotations inserted throughout are used as examples of the analytic points you are claiming” (p. 252). The following analysis aims to provide the researchers interpretation of the data while “staying close” to the story of the original data.

Chapter 4

Results

Quantitative Results

Patients weaning from MV are likely to experience a physical, physiological, psychological, and/or emotional impact from the medical process. Previous research has attempted to study this phenomenon by assessing a participant's vital signs in response to music intervention and MV. This study sought to determine if one 30-minute music therapy session during an SBT will decrease the participant's perceived level of anxiety and improve metrics comprising the SBT, specifically, HR, RR, SBP, DBP, and O_2sat. The data collected for anxiety was not included in analysis because of lack of consistency within the data collection process. Protocol at this facility suggests that nurse's use their own discretion to determine a patient's level of anxiety (0-10) if the patient is unable to verbalize the number themselves. Participants in this study were often not awake and alert enough at the beginning of the session to rate their own anxiety level but were awake and alert enough at the end of the session and rated a numeric value at that time. It was determined that the numerical values for anxiety were assessed using two different perceptions and could not be analyzed.

The following tables provide the final results of the analyzed quantitative data in this study. Table 2 provides a summary of the participant data including: age range and median age, gender, race, and participants' history of anxiety. It provides the range and median of vital signs before and after music therapy including HR, RR, SBP, DBP, O_2 saturation. The CAM and RASS scores were collected before and after the music therapy session. Sedation type was collected only before starting the music therapy session and subsequent weaning trial. The overall sample size is 20, and there are missing values in three different variables.

Table 2

Participant Data Summary

	Total (N=20)	
Factor	**n**	**Statistics**
Age	**20**	**Median [Q1, Q3]**
	20	70.0[63.5,76.0]
Gender	**20**	**Percentage**
Female	12	60.0%
Male	8	40.0%
Race	**20**	**Percentage**
Black/African American	5	25.0%
White/Caucasian	15	75.0%
History of Anxiety	**8**	**Percentage**
	8	40.0%
Vitals Before Music Therapy	**20**	**Median [Q1, Q3]**
Heart Rate	20	76.5 [69.5, 88.5]
Respiratory Rate	20	21.0 [17.0, 26.5]
Systolic BP	20	128.0 [102.0, 145.0]
Diastolic BP	20	64.0 [55.0, 69.0]
Oxygen Saturation	20	99.0 [96.5, 100.0]
Vitals After Music Therapy	**20**	**Median [Q1, Q3]**
Heart Rate	20	82.5 [68.5, 96.0]
Respiratory Rate	20	23.0 [16.0, 28.5]
Systolic BP	20	144.5 [117.0, 155.5]
Diastolic BP	20	66.0 [59.0, 72.0]
Oxygen Saturation	20	98.0 [96.0, 100.0]
Sedation Type Before Music Therapy	**20**	**Percentage**
Fentanyl and Precedex	1	5.0%
Fentanyl, Precedex, Propofol	1	5.0%
N/A	1	5.0%
None	1	5.0%
Precedex	4	20.0%
Precedex and One-time dose of Fentanyl	1	5.0%
Propofol	11	55.0%

Table 2

Participant Data Summary

	Total (N=20)	
Factor	**n**	**Statistics**
RASS Before Music Therapy	**20**	**Percentage**
-1	9	45.0%
-2	7	35.0%
-3	1	5.0%
-4	1	5.0%
0	1	5.0%
0 to -2	1	5.0%
RASS After Music Therapy	**19**	**Percentage**
-1	5	26.3%
-2	3	15.8%
0	9	47.4%
0 to +1	1	5.3%
1	1	5.3%
CAM Before Music Therapy	**19**	**Percentage**
Negative	17	89.5%
Positive	2	10.5%
CAM After Music Therapy	**19**	**Percentage**
Negative	17	89.5%
Positive	2	10.5%
Extubation After SBT	**4**	**Percentage**
	4	20.0%

Table 3 shows the differences in vital signs before and after music therapy. As the difference is calculated as "value after SBT" – "value before SBT", positive differences indicate an increase from before music therapy to after. Heart Rate, systolic & diastolic blood pressure all significantly increased after SBT.

Table 3

Difference in Vitals Before/After Music Therapy

Factor	**Time**	**Mean**	**SD**	**p-value**
Heart Rate	Before	79.4	12.4	*0.032*
	After	83.5	13.9	
	Change	4.1	7.8	
Respiratory Rate	Before	21.8	5.9	0.352
	After	23.3	7.5	
	Change	1.5	6.8	
Systolic BP	Before	125.1	24.6	*0.002*
	After	140.1	28.6	
	Change	15.0	18.6	
Diastolic BP	Before	64.1	9.1	*0.039*
	After	67.8	12.3	
	Change	3.7	7.5	
Oxygen Saturation	Before	98.1	2.0	0.384
	After	97.7	2.1	
	Change	-0.35	1.8	

Note. p-values: Paired t-test.

Figure 1 depicts the change in vital signs pre-music therapy session to post-music therapy session. The solid lines indicate vital signs that changed significantly while a dotted line deptics those that did not show a significant change.

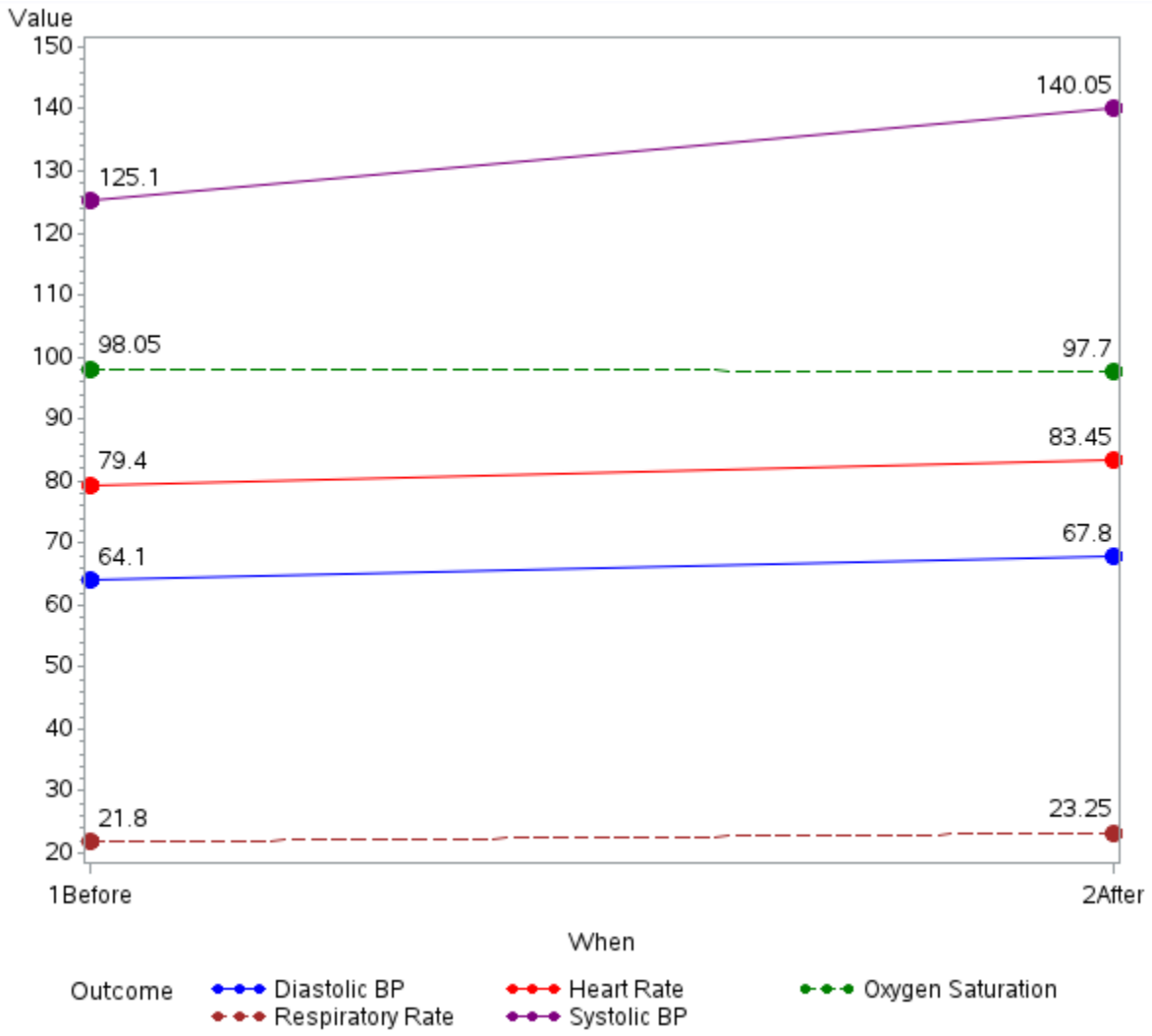

Figure 1. Change in Vitals

Table 4 shows the changes in vitals by gender. There were no significant differences between male and female participants.

Table 4

Difference in Vitals by Gender

	Total (N=20)		Male (N=8)		Female (N=12)		
Factor	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**p-value**
Heart Rate Change	4.1	7.8	1.5	7.4	5.8	8.0	0.25
Respiratory Rate Change	1.5	6.8	-1.5	5.9	3.4	6.9	0.11
Systolic BP Change	15.0	18.6	11.1	13.7	17.5	21.5	0.47
Diastolic BP Change	3.7	7.5	1.8	4.5	5.0	8.9	0.35
Oxygen Saturation Change	-0.35	1.8	-0.13	2.0	-0.50	1.7	0.65

Note. p-values: ANOVA

Table 5 shows analyses for difference in vital changes by race. Change in oxygen saturation, the only variable to show a decrease from before to after SBT, was significantly different for white and black people in this study. White participants saw a decrease, while black participants saw an increase in oxygen saturation.

Table 5.

Difference in Vitals by Race

	Total (N=20)		Black (N=5)		White (N=15)		
Factor	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**p-value**
Heart Rate Change	4.1	7.8	2.6	5.3	4.5	8.6	0.65
Respiratory Rate Change	1.5	6.8	1.2	7.3	1.5	6.9	0.93
Systolic BP Change	15.0	18.6	26.0	19.0	11.3	17.6	0.13
Diastolic BP Change	3.7	7.5	7.2	9.1	2.5	6.8	0.24
Oxygen Saturation Change	-0.35	1.8	1.00	1.4	-0.80	*1.7*	*0.044*

Note. p-values: ANOVA

Table 6 includes analyses for the relationship between age and change in vitals. Correlations measure strength of a linear relationship, and range from 0 to 1, (positive or negative). The largest value (0.42), indicated a weak to moderate positive relationship between age and change in oxygen saturation. The p-values, however, are > 0.05, meaning that there is not enough evidence to conclude that there is a relationship between change in vitals and age.

Table 6. *Difference in Vitals by Age*

Factor	Mean	SD	Pearson Correlation Coefficient	p-value
Heart Rate Change	4.1	7.8	-0.22	0.347
Respiratory Rate Change	1.5	6.8	0.15	0.518
Systolic BP Change	15.0	18.6	0.17	0.484
Diastolic BP Change	3.7	7.5	0.15	0.516
Oxygen Saturation Change	-0.35	1.8	0.42	0.068

Note. p-values: H_0: Correlation = 0.

The results indicated findings which opposed the suggested hypothesis. Instead of the music therapy intervention improving vital sign indicators from pre- to post-music therapy session, data showed that vital signs including HR, RR, DBP, and SBP all significantly increased. It also indicated that O_2 saturation was the only value to decrease from before to after music therapy session. It would not be considered an improvement for O_2 saturation to decrease for participants because a higher value of O_2 saturation indicates better outcomes for the participant. A more detailed summary and discussion of these findings are presented in the next chapter.

Qualitative Results

The second aim of this study was to assess the participants' experience of receiving music therapy while weaning from MV. The following results were derived from nine of the 20 study participants' interviews. The three overarching themes that were analyzed from the original interview data are: the feeling and experience of MV, the power of music to promote change, and the therapeutic relationship and process. Each overarching theme consists of subthemes with specific data relating to those findings.

Overarching theme 1: the feeling and experience of MV.

Participants discussed at length their experiences receiving MV. These experiences were analyzed into four different subthemes including: physical or emotional manifestation of MV, spiritual manifestation, sense of agency, and lack of reality orientation. The subtheme of *physical or emotional manifestation* describes the participants' account of MV as feeling unpleasant and painful. MV also elicits complex emotions including vulnerability, fear, shame, frustration and abandonment.

The subtheme of *spiritual manifestation* explores the participants' thoughts and feelings surrounding mortality and spiritual inquiry as brought about by experiencing MV. *Sense of agency* explores the participants' description of decreased sense of control and agency over their own physical and emotional functioning. MV also seemed to create a confusing and disorienting experience for participants therefore generating the subtheme *lack of reality orientation.*

The endotracheal tube is placed to assist with one's breathing ability until they are able to do so on their own; however, the participant's ability to breathe often feels stressed or even more difficult despite the fact that the tube is providing the opposite experience. The tube becomes a

separate entity or intrusion to the body. Participant 118 described this idea stating, "I woke up with that thing in my mouth and I was scared to death." They also stated:

"**118:** "It made it hurt worse.

Researcher (R): When you tried to talk?

118: Yeah. It just seemed like I was having such trouble it was cutting deep, ya know?"

These descriptions of the tube, especially referring to it as "that thing" and that it "made it hurt worse" suggest this idea that the tube is an intrusion and causing more harm than good. Participant 118 also went on to say, "It was just…like taking up my whole throat. I could barely get any air." The entire point of receiving the placement of an endotracheal tube is to assist with one's respirations. The feeling this participant experienced versus the reality of what the tube assisted with is starkly different. Participant 110 described it stating, "It was pretty horrific and…I didn't enjoy it much […] but it was gobs and gobs of tubing. It was disgusting." This suggests that participants have an awareness of the foreign object inside their bodies. The description of "disgust" could lend itself to an emotional manifestation of how one is feeling about the state of their own body at that point in time.

The physical manifestations seem to be directly connected to the emotional manifestations. Participant 118 described feeling "scared to death" while Participant 120 shared that MV was like "diving into hell and getting pulled right back out." One must then ask themselves, what does Hell feel like? If we think about spiritual and religious conceptualizations of Hell, one could assume this experience is extremely unpleasant because Hell could be associated with evil, fire, death, suffering, etc. The description of "hell-like" came up for several participants and one of the overarching mindsets of this hell-like experience was the fear of death.

This spiritual inquiry alone could elicit feelings and emotions which would also impact their physical experience. Participant 113 shared more about this fear stating, "Scary. Afraid you're going to not die not wake up. Yeah it was very scary." This excerpt suggests that participants were uncertain as to whether they would live through the experience of MV. Participants seemed to contemplate or be faced with their own mortality in these moments. Participant 118 shared, "I just…I thought I went to hell…Yeah, I felt so bad I thought I went to hell…but I don't know. It was a sign they didn't want me, so I got one more chance." Additionally, Participant 111 offered:

111: …Um I pretty much I think detached from my body and left my soul. I happen to believe in that. And um…to protect my body.

R: How did you protect your body?

111: By leaving my soul behind.

Again, this spiritual manifestation of mortality could be linked to the emotional manifestation of fear which could then be linked back to the physical manifestation of discomfort from the tube. While it appears that the physical, emotional, and spiritual manifestations of MV were all related, these experiences were further complicated by the participants' reported inability to communicate these feelings or thoughts in real-time.

Their *sense of agency* is hampered by the tube, medications, and overall experience of receiving MV. According to the *Sage Dictionary of Cultural* Studies, agency is "associated with notions of freedom, free will, action, creativity, originality and the possibility of change brought about through the actions of sovereign individuals" (Barker, 2004, p. 4). This ability is stripped away when one is receiving MV. Participant 112 described it as "Very…prison. Confined…like being in prison. And I felt confined. I couldn't do certain things without getting frustrated." This

participant also described the feeling of frustration which relates to the emotional manifestation that is occurring during this process. Participants had thoughts and feelings they were unable to cope with because they lacked the agency to do so**.** Their ability to openly express these feelings had been taken away, often without them understanding why. The lack of agency may also contribute to confusion that naturally manifests as a result of being confined to one place and enduring one kind of experience for an extended period of time.

Participants discussed their lack of awareness of their own self, place, time, and other understanding necessary for orientation. This *lack of reality orientation* further complicates the participants' abilities to process, understand, and properly express their physical, emotional, and spiritual manifestations. Participant 116 provided a rich description of their hallucinations in the following excerpt:

R: Where did you think you were?

116: I thought I was abducted by aliens. It was creepy. I really thought I was abducted by aliens.

(Moments later in the interview)

116: I thought my daughter um…

R: What about your daughter?

116: Um…was an alien.

(Later in the interview after describing another hallucination or "dream.")

R: What did the people look like in your dream?

116: Oranges.

This participant used the word "abducted" which means to be taken away by force which could be associated with one being placed in a position of harm ("Abduct", 2019). The hallucinations

could further complicate the emotional experiences of these participants, leading to more fear and uncertainty as well as more anxiety and stress, causing difficulty in weaning from the ventilator.

Overarching theme 2: the power of music to promote change.

The participants in this study were provided with music intervention, facilitated by an MT-BC to assist in the physically, emotionally, and spiritually distressing experience of weaning from MV. It seems that the experience of music elicited its own physical, emotional, and spiritual manifestations in the participants. Music therapists widely base their practice on the use of familiar music though some approaches to music therapy use unfamiliar, improvised music. All the music used in music therapy sessions has a meaning and thought process behind why it was chosen, based on the music therapist's training, theoretical orientations, and knowledge of the participants' preferences and needs. The MT-BC providing sessions in this study determined familiar music based on anecdotal reports from family members or participants' own indication of preferred music if they were able to answer. If neither of these resources were available, the music therapist used discretion in choosing age appropriate music or improvised music to suit the participant's observable physical and emotional needs in the moment.

Participants discussed the impact of familiar on their physical, emotional, and spiritual experiences while weaning from MV. Participant 110 stated,

110: "So she sang Rod Stewart for me as they were taking all this out…It was just gobs and gobs and gobs of tubing…And she kind eased it."

R: What was that music therapy experience like for you?

110: Very soothing. 'Cause I love Rod Stewart like I said…She sang a couple Rod Stewart songs and it was very soothing and relaxing. And like I said she was just peaceful. So, she helped make it all very peaceful."

The experience of familiar music (Rod Stewart) prompted a physical response from the participant (soothing and relaxing) while having the tube removed. This physical manifestation of music led to an emotional manifestation of "peace."

Other participants also described the experience of the music while weaning from MV using words such as beautiful, soothing, relaxing, peaceful, and emotional. One could argue that an emotional response to music also has an impact on one's physical response. Participant 113 described this idea saying, "It was very beautiful. Very emotional. And I guess put me to relax." The aesthetics of the music experience promoted a relaxation response in this participant. Music can elicit memories, or the feelings associated with these specific memories. Sometimes, feelings and emotions are directly linked to a specific song as the song reflects our life experiences. Bruscia (1998) eloquently captured the power of songs stating:

> "Songs are the ways that human beings explore emotions. They express who we are and how we feel, they bring us closer to others, they keep us company when we are alone. They articulate our beliefs and values. As the years pass, songs bear witness to our lives. They allow us to relive the past, to examine the present, and to voice our dreams for the future. Songs weave tales of our joys and sorrows, they reveal our innermost secrets, and they express our hopes and disappointments, our fears and triumphs. They are our musical diaries, our life stories" (p. 25)

If songs are telling the stories of our lives, once can assume that not all of those stories are going to be "positive." These emotional responses are not always pleasant to feel. Songs can remind us

of painful past experiences or a place in time where we would rather be than in the present. One participant described this experience stating, “It just triggered. I don’t know this song just triggered memories and emotions that were too close I guess at that time.” This excerpt highlights the possibility that if music is not used carefully and facilitated purposefully, one could actually cause harm to the person receiving the music.

Another way the music reflected the experiences of MV was by providing reality orientation for the participants. Music can ground us in reality and help us find meaning in our experiences. One of the clinical domains listed in the “Board Certification Domains” provided by CBMT states that music therapists are able (but not limited) to “Provide music therapy experiences to address client’s: reality orientation” ("Board Certification Domains", 2015, p. 2). Participant 120 reflected, “Actually that’s the only thing I do remember is the music.” Participant 113 seemed to also be able to mark time or make sense of the situation by the timing of the music. They stated, “Calmed me down. Long enough where they could pull that tube out.” It seems like the presence of the music acted as a signal to the participant or prompted the understanding that something new was occurring in their plan of treatment.

Participant 120 had also recalled that MV felt like “diving into hell and being pulled back out” and “the only thing I do remember is the music.” These statements might reflect the participant using music as a resource for coping with a traumatic experience such as MV. Participant 112 reflected this sentiment as well stating, “I was in pain and just trying to concentrate on what she was singing.” It seemed like the music was a means of coping with the pain and experiences associated with weaning from MV but was also used as a way to mark time and ground this person in the reality of what was happening in that very moment. It is possible the music encouraged the participants to be present with MV but in a more tolerable way.

The experience of music also reflected the experience of MV through spiritual manifestations. It did not seem surprising that while participants were having thoughts about mortality that they might also relate the music to events or experiences that involve death. Participant 113 elaborated on this stating, "Yeah when [she] played the music it reminded me of a funeral […] except I didn't die." Music is often a common thread in the rituals of funerals, memorial services, and celebrations of life. This excerpt lends itself to the idea that receiving music during a time when mortality is so present in someone's mind that they might assume their death is impending. Participant 110 interpreted the therapist herself as an "angel" figure stating, "The little girl who sang to me was just an angel." This participant also identified one of the songs in the session as "Angels in Heaven." One might suggest that mortality and the symbols associated with death become more present when a participant is faced with a traumatic experience like weaning from MV.

Overarching theme 3: the therapeutic relationship and process

The familiarity of the music and the overall experience of hearing the music might be impactful on its own. Music is a connecting experience and people can often relate to one another's cultural, emotional, physical, or overall life experiences when hearing and sharing music with another person. The component that really makes this idea a reality is the sharing of these experiences between human beings. Music can break down barriers, decrease isolation, and connect us with the world around us.

For example, Participant 120 further described his emotional response to the music:

> It just triggered. I don't know this song just triggered memories and emotions that were too close I guess at that time. And so, it was just probably the wrong choice

> of music for me to have playing at that time…She recognized that I was emotional and said, "you know…I'm just gonna slip into a little medley here because it looks too emotional for you" and I was like "yeah." She was right. She was dead on."

The excerpt provides us with the idea that not all music is "safe" or "good" for us. While the music might be familiar and meaningful, it might not be warranted at a specific time. This participant was weaning from the vent which we know is a distressing experience. The participant provides an example of connecting with the therapist and knowing that their emotions were observed by the therapist and validated in the change of music intervention. Bruscia (2014) describes how we can empathize with another person through the use of music. He states:

> When we sing the same song together, we live in the same melody, we share the same tonal center, we articulate the same lyrics, we move ahead according to the same rhythm—moment by moment, sound by sound, through an ongoing awareness of the other, and through continuing efforts to stay together and thereby become one within the experience. (Bruscia, 2014, pp. 77-78)

Participant 120 also offered the following statement, "I would've freaked out had she not been there. Bottom…end of story." This excerpt provides information that the participant and the therapist were engaging in an empathic therapeutic relationship while sharing in music during this distressing event. The music united them and allowed them to communicate despite the barriers that MV presents.

It is also important to acknowledge the individualization that music can require. Music preferences and experiences are all unique to an individual. It has already been established in previous chapters that weaning from MV is not often a standardized medical intervention. All

participants respond to weaning differently based on their medical, emotional, and psychological needs. Music therapy becomes part of that individualized process when assisting them with the weaning experience. For example, Participant 112 stated, “Well she sung about something in the contents of Jesus and the Lord. What I’m very into.” This participant added, “And I appreciate it. The fact that she took the time to perform personally to me.” These excerpts highlight the importance of each person feeling like they are an individual who is receiving treatment that serves them uniquely based on their individual experience and needs within that specific moment.

The participants did not only discuss meaningful human interactions with the music therapist but with other caregivers, friends, and family members. This further implicates the need for human interaction in these confusing and distressing moments. Participant 111 did not recall the music therapy experience but did offer memories of support they received from others. They stated, “But I remember a lot of people coming in and praying with me because I’m a firm believer in prayer.” They continued with “Plus the preacher here. Cause I knew I needed help. I couldn’t do it by myself at that moment.” This statement begins to encompass the enormity of feelings associated with MV. There seems to be isolation present in their experience but also the acknowledgement of needing support and receiving support.

It is safe to say that the experience of receiving MV and also weaning from MV is complex. We know that the experience of MV manifests itself in one’s physical, emotional, and mental capacities. Live music intervention seems to parallel those experiences in ways that may not have been expected. Participants felt the calming or relaxing impact of the music but also the reality of their situation and reminder of their potential mortality. Those thoughts might have brought about fear but at the same time they could also feel comforted and supported.

It seems that the presence of other humans with whom the participants could make connections offered some of the greatest means of support. While the music harnessed power to impact the physical, emotional, and mental capacities of the participants, the therapist could guide that power to be better applied in the moment.

Chapter 5

Discussion

Introduction

This chapter further summarizes, discusses, and explores the implications of the findings from this study. Explanations of unanticipated findings are also discussed, as well as the implications of these results on clinical practice. Lastly, recommendations for future research are explored based on the outcomes of this study and related research completed to date.

Statement of the Problem and Review of the Methodology

This study used an embedded, mixed-methods design to further explore the experience of music therapy during the weaning process of patients receiving invasive mechanical ventilation. The quantitative hypothesis: One 30-minute music therapy session during a spontaneous breathing trial (SBT) will decrease the participant's perceived level of anxiety and improve metrics comprising the SBT, specifically, RR, SBP, DBP, O_2sat, and HR. These metrics were collected at the start and finish of the 30-minute music therapy session by a co-investigator on the study and analyzed by a statistician.

While the researcher sought to understand the participants' physiological responses to music intervention and the weaning process, the researcher also wanted to understand the participants' experiences in their own words. Qualitative research question: What does the mechanically ventilated patient experience in music therapy during their SBT? Participants who met the inclusion criteria were interviewed after having been extubated from the ventilator. They were asked questions open-ended questions that assessed what they remember from their experience receiving and weaning from MV as well as receiving music therapy during the

weaning process. The interviewer asked additional follow-up questions to clarify and better understand each participant's experience.

Results Summary

Overall, the vital signs increased from pre- to post-session which did not support the proposed hypothesis. As discussed in the quantitative results, HR, SBP, and DBP all showed a statistically significant increase. Change in oxygen saturation was the only variable to show a decrease from before to after SBT; however, oxygen saturation would be expected to increase from before to after session.

The qualitative results provided more insight into individual participant experiences. Open-ended, semi-structured interviews were conducted and transcribed verbatim by the researcher. The three overarching themes that were analyzed from the original interview data are: how we feel and experience mechanical ventilation, the power of music to promote change, and the therapeutic relationship and process. Each overarching theme consisted of subthemes with specific data relating to these findings.

The first overarching theme called "how we feel and experience MV" involved sub-themes including: physical or emotional manifestation of MV, spiritual manifestation of MV, sense of agency, and lack of reality orientation. The second overarching theme called "the power of music to promote change" explored sub-themes such as familiarity of music, emotional responses to music, reality orientation of music, music as a spiritual experience, and music for relaxation (or the physical manifestation of music). The third and final overarching theme was "the therapeutic relationship and process," which was comprised of the sub-themes: human connection, the therapist, the music therapy process, and coping resources.

Discussion of the Quantitative Results

Weaning literature suggests that the weaning process consists of about 40% of the duration of MV (Zein et al., 2016, p. 65). Complications such as pneumonia, discomfort, and increased costs may arise if the weaning process is prolonged (MacIntyre, 2004, p. 830). Thille et al. (2013) elaborates that extubation failure may also be caused by "hidden factors such as delirium, prolonged sedation or ICU-acquired weakness" (p. 60). Weaning assessment criteria are guidelines and not strict rules set forth for each participant. It was important for this feasibility study to first understand how the specific medical facility in which this study took place approached the weaning process and what data it collected to determine successful vent weaning and eventual vent liberation.

Due to the fact that this was a feasibility study with a small sample size, no control group, and lack of numerical ratings of anxiety, it is not possible to discern whether the quantitative results fully reflected the participants' experiences as reported in the interviews. The average measures for HR, SBP, and DBP significantly increased from the start of weaning and music therapy to the end of the half hour music therapy session which might suggest an increase in anxiety. The average measure of oxygen saturation among participants decreased. It is uncertain whether these results had any significant clinical impact on the participants' weaning process. It is likely that participants were not all in the same awake and alert state at the start of the music therapy session and SBT. Each participant's sedative medication was not treated the same way depending on the bedside nurse's discretion, what medications the participant was receiving, and the comorbidities of the participant themselves. Nurses also consider the participant's observed behaviors such as restlessness and agitation. Zein et al. (2016) reported that "excessive sedation can result in poor performance of SBTs and prolong the duration of mechanical ventilation" (p.

67). It seems likely that participants were still waking up throughout the music therapy session and SBT and that their vital signs reflected this more awake and alert state in which they are working harder to wean from the vent because they were becoming more aware of the presence of the tube. If over sedated, their ability to be oriented to their surroundings can be compromised. This may impact their ability to respond to their surroundings which includes the invasive nature of the endotracheal tube and the experience of participants' perceived pain and anxiety. Measures for pain and anxiety were not analyzed though they were included in data collection. Due to the participants awake and alert state at the beginning of the session compared to an improved awake and alert state at the end of the session, the perceived levels of pain and anxiety were determined using two different scales from pre- to post- MT session. Pain was typically assessed using the NPAT scale pre-MT session vs. a numerical rating scale post-MT session. Anxiety was assessed using a numerical value determined by nursing discretion for the pre-MT session measurement versus the participant's own perceived numerical rating post-MT session.

This brings into question how important a participant's awake and alert state is in relation to the impact music therapy may have on their weaning process. The medical facility in which this study took place does follow a protocol for sedation and participates in daily sedation interruption, but the protocol is loosely followed. The quantitative results of this study do not provide us with enough information about sedative medications. The qualitative results suggest that participants are confused and in pain during MV but, one cannot infer that sedative medications are causing these issues based on the qualitative results.

Discussion of Qualitative Results

The significant increase of HR, SBP, and DBP might appear to indicate that the participants' anxiety did not decrease and therefore was not positively impacted by the music therapy session. On the contrary, the participant interview data provide different insight into the overall experience of weaning from MV. In the interviews, participants describe their experience of weaning from the vent from physical, psychological, emotional, and spiritual manifestations. A review of literature by Thomas (2003) found that patients often identify dyspnea (air hunger), tension/anxiety/stress, fear, and pain/discomfort as stressful symptoms felt during MV (p. 77). These stressors were identified the most often across literature and were also discussed in the participant interviews during this study.

Medical professionals, including music therapists, can take away three ideas from the experiences shared in the participant interviews including:

- The physical experience of MV connects to one's emotional experience which also connects to one's spiritual experience. These are all fluid experiences that may influence one another concurrently.
- Participants seemed unable to cope with the experiences of weaning from MV because they lacked the agency to do so in the first place.
- The presence of others helps the participants to make connections and decrease isolation which could improve their overall experience.

Participants discussed the *physical* manifestation of MV, using words and phrases such as "disgusting, hurt, couldn't breathe, and horrific." These feelings also related to their *emotional* manifestations as they described feeling fear about death and lack of understanding what was

happening to them. These emotional manifestations connected to their *spiritual* manifestations as they believed they were coming face to face with their own mortality.

Participants also identified the ways in which music impacted their physical, emotional, and spiritual experiences, using words such as "relaxing, beautiful, soothing, emotional, calming", etc. In their interviews, participants often described hearing preferred music and the experience of that music was described as having a positive impact on their weaning process. Paraphrasing Aldridge (1991), the authors suggest that "interventions involving creative forms of expression are applicable to individuals with chronic illness because they can help them regain a sense of control and autonomy" (MacDonald et al., 2012, p. 250). Music is a creative form of expression whether it is being created or just received, like in the experience of participants weaning from MV. The familiarity of the music facilitated by a therapist who is providing one-on-one patient communication is providing participants the opportunity to engage with the environment, participate in their own care, express emotion, and experience a relaxation response. It seems that the experience of MV caused physical discomfort and difficulty breathing which can be connected to emotional experiences of fear, anxiety, and confinement. These emotional experiences were heightened by spiritual concerns about death and mortality which have also been described in previous literature (Rose et al., 2014). All the while, these experiences are distorted due to hallucinations and lack of agency or control over one's situation.

When one lacks agency, it is likely they will have difficulty coping with the situation at hand. The experience of music therapy was an opportunity for the participants to exercise some control over their situation. With the therapist asking questions and providing opportunities for choice, the participants could determine the music used. The therapist could also be available to provide information that might otherwise have been left out or communicate the participants'

needs to the bedside nurse. Once the participants had a better understanding of what was happening to them, they could focus on the music as a source of expression or coping. An example of this can be found with Participant 120 who suggested that while expressed an emotional response to the music, the therapist's reflection and acknowledgement of this response allowed him to cope with that feeling in the moment. The emotional expression could have negatively impacted their weaning process as well. The interaction with the music therapist impacted their ability to cope with this experience.

The presence of the music therapist, other medical team members, or family and friends seemed to alleviate fear and stress. The participants are often waking up and becoming aware of their surroundings during the SBT and may feel confused or afraid. The presence of another person in the room to communicate with them can address those feelings of fear and isolation and help them make connections. To again refer to the quote about songs by Bruscia (1998) "Songs are the ways that human beings explore emotions. They express who we are and how we feel, they bring us closer to others, they keep us company when we are alone" (p. 25). The combination of music experiences facilitated by the MT-BC provides a combination of expression, coping opportunities, and therapeutic presence which positively impacts the participants' physical, emotional, and spiritual needs during the distressing experience of weaning from MV.

Limitations

The sample size for this study is small and would need to be expanded and also compared to a control group for baseline comparisons to participants who are not receiving music therapy. Music therapy began concurrently with the start of the SBT, oftentimes when sedative

medications had not been fully reduced or the participant did not receive an adequate amount of time to become more awake and alert before participating in the SBT and music therapy session. Accurate depictions of participant's perceived pain and anxiety could not be determined due to the inconsistency of pain and anxiety scales used pre- and post- MT sessions. Several adjustments to the study's design would need to be made including: timing of sedation vacation, SBT, and music therapy session; careful collection of sedative medication data for each participant; a control group for comparison; and consistency in pre and post pain and anxiety scales.

Recommendations for Future Research

There is significant research regarding the benefits of music listening during MV and how it helps to reduce anxiety and sedation, while there is limited research on music therapy during the weaning process. While this study explored the impact of a single music therapy session during the weaning process, the findings from this study suggest the following recommendations for future research: a randomized controlled trial based on power analysis is needed to determine the appropriate number of participants who should be enrolled to gain statistically significant data and to provide comparison data between a music therapy groups and a usual care group. Since there is strong evidence supporting the use of music listening during MV, it would be beneficial to compare music listening, music therapy, and usual care. Ideally, the music listening intervention would occur using headphones, with patient preferred music determined by assessment from an MT-BC, the other control group receives usual ICU care, and the music therapy session is conducted by the MT-BC based on the participant assessment. It would be valuable to gather data on whether or not the participant passed the individual SBT in

which the music therapy and music listening session took place. This may indicate whether or not music therapy helped to achieve successful weaning trials.

Sedative medications take different amounts of time to act in the body. Propofol is classified as an anesthetic agent or hypnotic and was used on participants in this study. According to a sedation guide provided by Allina Health, Propofol has an onset of 30 seconds, a peak effect in 1-3 minutes, and a duration of 5-10 minutes ("Care of the Patient Receiving Sedation", 2019). It would therefore be important to track the frequency of Propofol infusion and document the time at which the medication was decreased or turned off. Based on the duration as reported above, it would be expected that the effects of Propofol would begin to "wear off" after about 10 minutes.

Fentanyl was another drug that some study participants received and is classified as an opiate agonist or depressant. This drug's onset is 1-2 minutes with a peak effect at about 3-5 minutes; however, it's effects may be felt for 30-60 minutes. Precedex was the third sedative medication used with participants in this study. Side effects of Precedex may include bradycardia and sinus arrest ("Precedex", 2019). "It's onset of action is less than 5 minutes and the peak effect occur within 15 minutes…it provides a titratable option of hypnotic sedation that can be readily reversed" (Kaur & Singh, 2011, p. 7). The effects of Fentanyl seem to have the longest duration in comparison to the other two drugs used in this study. This information highlights the differences in how medication may impact each participant and how music therapy sessions might need to be implemented once the effects of these medications have fully dissipated.

Type and amount of sedative medication as well as time of sedation vacation were all collected *before* the music therapy session began. There was variability regarding type of medication used for each participant and one must also consider how the specific type of

medication impacts each individual participant. It would have been helpful to collect sedative medication data in the following manner:

- Sedative type and amount before session (including the amount of time passed since medication had last been given.)
- Sedative type and amount immediately prior to music therapy session.
- Any change in sedative medication *during* the session including type and amount added or decreased/stopped completely.
- Sedative type and amount immediately upon the end of the session.

It could also be helpful at the end of the music therapy session to determine how much time passed before the participant needed to receive more sedative medication. This might provide more insight to the lasting impact music therapy has on the weaning process and participant's anxiety. Given the effects of sedative medications, it seems that one of two options would be most appropriate for future research. The participant should not be receiving any sedative medication before beginning the SBT and subsequent music therapy session or the type of sedative medication should be controlled for in the participant group. This means that participants receiving only one specific sedative medication can be enrolled and studied.

Further exploration is indicated to fully understand music therapy's impact on the weaning process of patients receiving MV as well as potential for impacting healthcare costs. While there is recent research demonstrating the cost effectiveness of patient directed music listening in reducing the costs associated with MV (Chlan et al., 2018), additional research is needed to explore the use of music therapy in decreasing costs associated with MV and weaning. Music listening alone may have some impact on the physiological parameters of a patient's weaning process. The combined efforts of live music intervention facilitated by an MT-BC are

warranted for MV patients because, as the qualitative results indicate, music is a means of expression and coping and the presence of the therapist can help the participant to make connections with their physical, emotional, and spiritual experiences while weaning from MV. Further assessment of the music therapy session and patient's experiences and perceptions help clinicians to better understand the relationship in which the music, therapist, and patient work together to improve cost and health outcomes.

References

Abduct. (2019). Retrieved from https://www.merriam-webster.com/dictionary/abduct

Agency. (2004). In C. Barker, *The SAGE dictionary of cultural studies*. London, UK: Sage UK. Retrieved from https://ezproxy.augsburg.edu/login?url=https://search.credoreference.com/content/entry/ageukcult/agency/0?institutionId=2251

Allina Health. (2017). Care of the patient receiving sedation. Retrieved from https://www.allinahealth.org/-/media/allina-health/files/for-medical professionals/sedation-self-learning-packet.pdf

American Thoracic Society. (2017). Mechanical ventilation. *American Journal of Respiratory and Critical Care Medicine, 196*(2), 3-4. doi:10.1164/rccm.1962p3

Barker, C. (2004). *The Sage dictionary of cultural studies*. London: Sage Publications.

Beaulieu-Boire, G., Bourque, S., Chagnon, F., Chouinard, L., Gallo-Payet, N., & Lesur, O. (2013). Music and biological stress dampening in mechanically-ventilated patients at the intensive care unit ward—a prospective interventional randomized crossover trial. *Journal Of Critical Care*, *28*(4), 442-450. doi: 10.1016/j.jcrc.2013.01.007

Board Certification Domains [PDF]. (2015). Downington, PA: The Certification Board for Music Therapists.

Bradt, J., & Dileo, C. (2015). Cochrane review: music interventions for mechanically ventilated patients. *Journal Of Evidence-Based Medicine*, *8*(1), 56-56. doi: 10.1111/jebm.12143

Braun, V., & Clarke, V. (2013). *Successful qualitative research*. Sage.

Bruscia, K. E. (1998). *The Dynamics of Music Psychotherapy*. Barcelona Publishers.

Bruscia, K. E. (2014). *Defining music therapy* (3rd ed.). University Park, PA: Barcelona

Publishers.

Chlan, L. (1995). Psychophysiologic responses of mechanically ventilated patients to music: a pilot study. *American Journal Of Critical Care*, *4*(3), 233-238.

Chlan, L. (1998). Effectiveness of a music therapy intervention on relaxation and anxiety for patients receiving ventilatory assistance. *Heart & Lung*, *27*(3), 169-176.

Chlan, L., Engeland, W., Anthony, A., & Guttormson, J. (2007). Influence of music on the stress response in patients receiving mechanical ventilation support: a pilot study. *American Journal Of Critical Care*, *16*(2), 141-145.

Chlan, L., & Savik, K. (2011). Patterns of anxiety in critically ill patients receiving mechanical ventilatory support. *Nursing Research, 60*(Supplement). doi:10.1097/nnr.0b013e318216009c

Chlan, L., Weinert, C., Heiderscheit, A., Tracy, M., Skaar, D., Guttormson, J., & Savik, K. (2013). effects of patient-directed music intervention on anxiety and sedative exposure in critically ill patients receiving mechanical ventilatory support. *JAMA*, *309*(22), 2335. doi: 10.1001/jama.2013.5670

Chlan, L., Heiderscheit, A., Skaar, D., Neidecker, M**.** (2018). Economic evaluation of patient directed music intervention compared to usual care on costs in ICU patients receiving mechanically ventilatory support. *Critical Care Medicine, 46*(9), 14301-1435. DOI: 10.1097/CCM.0000000000003199

Conrad, C., Niess, H., Jauch, K., Bruns, C. J., Hartl, W. H., & Welker, L. (2007). Overture for growth hormone: requiem for interleukin-6?*. *Critical Care Medicine, 35*(12), 2709 2713. doi:10.1097/00003246-200712000-00005

Davis, T., & Jones, P. (2012). Music therapy: decreasing anxiety in the ventilated

patient. *Dimensions Of Critical Care Nursing*, *31*(3), 159-166. doi: 10.1097/dcc.0b013e31824dffc6

Dijkstra, B., Gamel, C., van der Bijl, J., Bots, M., & Kesecioglu, J. (2010). The effects of music on physiological responses and sedation scores in sedated, mechanically ventilated patients. *Journal Of Clinical Nursing*, *19*(7-8), 1030-1039. doi: 10.1111/j.1365-2702.2009.02968.x

Fontaine, D. K. (1994). nonpharmacologic management of patient distress during mechanical ventilation. *Critical Care Clinics, 10*(4), 695-708. doi:10.1016/s0749-0704(18)30101-5

Godard, S., Herry, C., Westergaard, P., Scales, N., Brown, S., & Burns, K. (2016). Practice Variation in Spontaneous Breathing Trial Performance and Reporting. *Canadian Respiratory Journal*, *2016*, 1-10. doi: 10.1155/2016/9848942

Han, L., Li, J. P., Sit, J. W., Chung, L., Jiao, Z. Y., & Ma, W. G. (2010). Effects of music intervention on physiological stress response and anxiety level of mechanically ventilated patients in China: A randomised controlled trial. *Journal of Clinical Nursing, 19*(7-8), 978-987. doi:10.1111/j.1365-2702.2009.02845.x

Heiderscheit, A., Breckenridge, S., Chlan, L., & Savik, K. (2014). Music preferences of mechanically ventilated patients participating in a randomized controlled trial. *Music & Medicine*, *6*(2), 29-38.

Heiderscheit, A., Chlan, L., & Donley, K. (2011). instituting a music listening intervention for critically ill patients receiving mechanical ventilation: exemplars from two patient cases. *Music And Medicine*, *3*(4), 239-245. doi: 10.1177/1943862111410981

Hetland, B., Lindquist, R., & Chlan, L. (2015). The influence of music during mechanical ventilation and weaning from mechanical ventilation: A review. *Heart & Lung*, *44*(5), 416-425. doi: 10.1016/j.hrtlng.2015.06.010

Hetland, B., Lindquist, R., Weinert, C., Peden-McAlpine, C., Savik, K., & Chlan, L. (2017). Predictive associations of music, anxiety, and sedative exposure on mechanical ventilation weaning trials. *American Journal Of Critical Care*, *26*(3), 210-220. doi: 10.4037/ajcc2017468

Hill, A. D., Fowler, R. A., Burns, K. E., Rose, L., Pinto, R. L., & Scales, D. C. (2017). Long term outcomes and health care utilization after prolonged mechanical ventilation. *Annals of the American Thoracic Society, 14*(3), 355-362. doi:10.1513/annalsats.201610-792oc

Hunter, B., Oliva, R., Sahler, O., Gaisser, D., Salipante, D., & Arezina, C. (2010). Music therapy as an adjunctive treatment in the management of stress for patients being weaned from mechanical ventilation. *Journal Of Music Therapy*, *47*(3), 198-219. doi: 10.1093/jmt/47.3.198

Jaber, S., Bahloul, H., Guétin, S., Chanques, G., Sebbane, M., & Eledjam, J. (2007). Effets de la musicothérapie en réanimation hors sédation chez des patients en cours de sevrage ventilatoire versus des patients non ventilés. *Annales Françaises DAnesthésie Et De Réanimation, 26*(1), 30-38. doi:10.1016/j.annfar.2006.09.002

Kaur, M., & Singh, P. M. (2011). Current role of dexmedetomidine in clinical anesthesia and intensive care. *Anesthesia, essays and researches*, *5*(2), 128–133. doi:10.4103/0259-1162.94750

Khan, S., Wang, S., Harrawood, A., Martinez, S., Heiderscheit, A., & Chlan, L. et al. (2017). Decreasing delirium through music (DDM) in critically ill, mechanically ventilated patients in the intensive care unit: study protocol for a pilot randomized controlled trial. *Trials*, *18*(1). doi: 10.1186/s13063-017-2324-6

Korhan, E. A., Khorshid, L., & Uyar, M. (2011). The effect of music therapy on physiological signs of anxiety in patients receiving mechanical ventilatory support. *Journal of Clinical Nursing, 20*(7-8), 1026-1034. doi:10.1111/j.1365-2702.2010.03434.x

Lee, O. K., Chung, Y. F., Chan, M. F., & Chan, W. M. (2005). Music and its effect on the physiological responses and anxiety levels of patients receiving mechanical ventilation: A pilot study. *Journal of Clinical Nursing, 14*(5), 609-620. doi:10.1111/j.1365 2702.2004.01103.x

Liang, Z., Ren, D., Choi, J., Happ, M., Hravnak, M., & Hoffman, L. (2016). Music intervention during daily weaning trials—A 6 day prospective randomized crossover trial. *Complementary Therapies In Medicine*, *29*, 72-77. doi: 10.1016/j.ctim.2016.09.003

MacDonald, R., Kreutz, G., & Mitchell, L. (Eds.). (2012). *Music, Health, & Wellbeing*. Oxford, UK: Oxford University Press.

MacIntyre, N. (2013). The ventilator discontinuation process: an expanding evidence base. *Respiratory Care*, *58*(6), 1074-1086. http://dx.doi.org/10.4187/respcare.02284

MacIntyre, N. R. (2016). Mechanical ventilation. In *Murray and Nadel's Textbook of Respiratory Medicine* (6th ed., Vol. 2, pp. 1761-1777). Elsevier. doi:https://doi.org/10.1016/C2011-1-08123-7

O'Toole, M. T. (Ed.). (2017). *Mosby's Medical Dictionary* (10th ed.). St. Louis, MO: Elsevier.

Paiz, J., Angeli, E., Wagner, J., Lawrick, E., Moore, K., Anderson, M.,…Keck, R. (2010, May

5). *APA formatting and style guide*. Retrieved from http://owl.english.purdue.edu/owl/resource/560/01/

Phillips, S. (2007). *The effect of music entrainment on respiration of patients on mechanical ventilation in the intensive care unit* (Master's thesis). Florida State University, Florida.

Porter, R. S. (2018). *The Merck manual: Of diagnosis and therapy* (20th ed.). Rahway: Merck Sharp & Dohme.

Precedex. (2019). Retrieved from https://www.pfizerpro.com/product/precedex/hcp

REDCap. (2019). Retrieved from https://www.project-redcap.org/software/

Robb, S. L., Nichols, R. J., Rutan, R. L., Bishop, B. L., & Parker, J. C. (1995). The effects of music assisted relaxation on preoperative anxiety. *Journal of Music Therapy*, *32*(1), 2 21. doi: 10.1093/jmt/32.1.2

Rose, L. (2015). Strategies for weaning from mechanical ventilation: A state of the art review. *Intensive And Critical Care Nursing*, *31*(4), 189-195. doi10.1016/j.iccn.2015.07.003

Rose, L., Dainty, K., Jordan, J., & Blackwood, B. (2014). Weaning from mechanical ventilation: a scoping review of qualitative studies. *American Journal Of Critical Care*, *23*(5), e54-e70. doi: 10.4037/ajcc2014539

Sessler, C. N., Gosnell, M. S., Grap, M. J., Brophy, G. M., Oneal, P. V., Keane, K. A., Elswick, R. K. (2002). The richmond agitation–sedation scale. *American Journal of Respiratory and Critical Care Medicine, 166*(10), 1338-1344. doi:10.1164/rccm.2107138

Sharma, S. (2019). *Sedation Vacation in the ICU*. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK513327/

Stacy, K. (2012). Withdrawal of life-sustaining treatment: A Case Study. *Critical Care Nurse*, *32*(3), 14-24. doi: 10.4037/ccn2012152

Stites, M. (2013). Observational pain scales in critically ill adults. *Critical Care Nurse, 33*(3), 68-78. doi:10.4037/ccn2013804

Tate, J. A., & Balas, M. (2019). The confusion assessment method for the ICU (CAM ICU). *Best Practices in Nursing Care to Older Adults,*(25), 1-2. Retrieved from https://consultgeri.org/try-this/general-assessment/issue-25.pdf.

Tate, J., Devito Dabbs, A., Hoffman, L., Milbrandt, E., & Happ, M. (2011). Anxiety and agitation in mechanically ventilated patients. *Qualitative Health Research*, *22*(2), 157-173. doi: 10.1177/1049732311421616

The Glasgow structured approach to assessment of the Glasgow Coma Scale. (2019). Retrieved from https://www.glasgowcomascale.org/what-is-gcs/

Thille, A., Cortés-Puch, I., & Esteban, A. (2013). Weaning from the ventilator and extubation in ICU. *Current Opinion In Critical Care*, *19*(1), 57-64. doi: 10.1097/mcc.0b013e32835c5095

Thomas, L. A. (2003). Clinical management of stressors perceived by patients on mechanical ventilation. *AACN Clinical Issues: Advanced Practice in Acute and Critical Care, 14*(1), 73-81. doi:10.1097/00044067-200302000-00009

Tobin, M., & Manthous, C. (2017). A primer on critical care for patients and their families. *Am J Respir Crit Care Med, 196*(2), 3-4. doi:doi:10.1164/rccm.1962p3

Tracy, M., Staugaitis, A., Chlan, L., & Heiderscheit, A. (2015). Perceptions of patients and families who received a music intervention during mechanical ventilation. *Music & Medicine*, *7*(3), 54-58.

Ventilator/Ventilator Support. (n.d.). Retrieved July 20, 2019, from https://www.nhlbi.nih.gov/health-topics/ventilatorventilator-support

Whitlock, J. (2019). Why Intubation Is Required for Most Surgeries. Retrieved

from https://www.verywellhealth.com/what-is-intubation-and-why-is-it-done-3157102

Wong, H., Lopez-Nahas, V., & Molassiotis, A. (2001). Effects of music therapy on anxiety in ventilator-dependent patients. *Heart & Lung*, *30*(5), 376-387. doi: 10.1067/mhl.2001.118302

Wu, S., Lopez-Nahas, V., & Molassiotis, A. (2008). The effectiveness of music therapy in reducing physiological and psychological anxiety in mechanically ventilated patients. *Hu Li Za Zhi, 55*(5), 35-44.

Wunsch, H., Wagner, J., Herlim, M., Chong, D. H., Kramer, A. A., & Halpern, S. D. (2013). ICU occupancy and mechanical ventilator use in the united states. *Critical Care Medicine, 41*(12), 2712-2719. doi:10.1097/ccm.0b013e318298a139

Zein, H., Baratloo, A., Negida, A., & Safari, S. (2016). Ventilator weaning and spontaneous breathing trials; an educational review. *Emergency, 4*(2), 65-71. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4893753/pdf/emerg-4-065.pdf.

Appendix A: Screening Form

(complete entry) Protocol Title:	*(complete entry)* Hillcrest Tracking No:
(complete entry) Principal Investigator:	*(complete entry)* IRB Tracking No:
(complete entry) **Pt Name**:	*(complete entry)* **CCF #**:

GENERIC SCRIPT OF INTRODUCTION

We would like you to participate in a research study. This study may or may not benefit you at the present time, but it will help us understand more your condition and will help us treat or deal with it better in the future. We will provide you with a document that has all the information you will need to help you decide whether to participate in this research study. Consent must be based on an understanding of the nature and risks of the treatment, device, or procedure. Please ask questions if there is anything you do not understand. Your participation is voluntary and will have no effect on the quality of your medical care if you choose not to participate

Thank you for your attention!

Screening Questions (Circle one answer for each question):

1) Patient has medical or cardiac diagnosis? Yes No

2) Patient admitted to critical care unit (Medical/Surgical Intensive Care Unit, Cardiovascular Surgical Intensive Care Unit at Cleveland Clinic's Hillcrest Hospital? Yes No

3) On invasive mechanical ventilation (MV)? Yes No

4) Age requirement of 18+ has been met? Yes No

5) > 24 hours of MV prior to study? Yes No

6) No previous music therapy experience? Yes No

7) Patient or family representative cognitively able to consent to participate? Yes
No

8) Patient or family representative speaks, reads, & writes English? Yes
No

9) Patient or family representative agreed to participation in study? Yes
No

Patient has been excluded for the following (check as many answers as apply):

☐ Patient or family representative cognitively unable to consent to participate
☐ Patient or family representative is unwilling to participate
☐ Patient or family representative is unable to meet language requirement

Appendix B: Consent Form

The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: The Experience of Music Therapy During the Weaning Process of Patients Receiving Invasive Mechanical Ventilation
PI: Stephanie Morris, MT-BC; phone: 440-312-1294
Study Coordinator: Lisa Gallagher, MA, MT-BC; phone: 216-448-8334

Please note:

- You are being asked to participate in a research study to help us learn about your experience with music therapy.
- Ask as many questions as needed so you can make an informed decision.
- Carefully consider the risks, benefits, and alternatives of the research.
- Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at any time.

1. INFORMATION ON THE RESEARCH

Background for the study

- The purpose of this study is to learn how music therapy affects patients during the mechanical ventilation weaning process.
- Patients will receive music therapy services.
- These sessions may have an effect on patients.
- A research assistant will track your vital signs as evidenced on the monitor before and after each session.
- Patients may be asked to participate in an interview after being successfully removed from mechanical ventilation.
- We hope that this information will help us learn how patients may or may not benefit from music therapy during the mechanical ventilation weaning process so that music therapists can provide the best care possible.

What if I decide to take part in this research study?

- You will be enrolled to receive music therapy.
- You will receive one 30 minute music therapy session. We will observe your vital signs and medical responses, and we may ask you a few questions before and after each session. Other information, such as amounts and types of medications used, will be collected from your medical chart.
- It may be determined that you will participate in an open-ended, audio-recorded interview after you have been removed from the vent. All information recorded in this interview will be kept confidential.
- Once your one music therapy session is completed you will be eligible to receive future music therapy sessions if desired. Your participation will increase our knowledge about music therapy so that future patients will have the best possible experience with it.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

- You will receive standard medical care.

3. RISKS

What are the risks of participating in the research study?

- This is a minimum risk study as there are no foreseeable physical, psychological, financial, or social risks that can be expected.
- Participants may experience anxiety, sadness, tearfulness, agitation, and/or restlessness; however, these reactions may be more situational than study induced.
- There is a small risk to the confidentiality of your data; however, there are safeguards in place to minimize this risk.
- The data file with your data will contain a study number, which will not be linked to your patient medical record, and answers to questions will be entered into an electronic database for analysis. This is all done in accordance with Cleveland Clinic directives. All data will be kept on a password protected, encrypted computer.
- All data will be kept 15 years after study completion or upon discontinuation of the study (2031 at the latest). Study results will be published in a professional journal as group results with no possibility for identification of participants. The results will also be disseminated in a final Master's thesis, and a copy of it will be placed in the Lindell Library at Augsburg College.

4. BENEFITS

What are possible benefits of participating in the research?

- While participation in the research may or may not provide you with any direct benefit, the knowledge to be gained may likely benefit future patients.

5. COSTS

Are there any costs to you if you participate in this study?

- There is no cost to you if you participate in this study.

6. COMPENSATION

Are there any payments to you if you participate in this study?

- Participation in this study is voluntary and unpaid.

7. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

- Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

- The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

- Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

- People outside Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

- You do not have to give this permission to use and give out your information; however, you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

- You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing***, Stephanie Morris, MT-BC, Hillcrest Hospital, Music Therapist, 6780 Mayfield Rd., Mayfield Heights, OH 44124.*** If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

8. CONFLICT OF INTEREST

Do the researchers or institution have any conflicts of interest relating to this study?

- Neither the researchers, nor the institution, have any conflicts of interest related to this study.

9. QUESTIONS

Who do you call if you have any questions or problems?

- Principal Investigator: Stephanie Morris, 440-312-1294 ***or*** Study Coordinator: Lisa Gallagher, 216-448-8334.
- This study has been approved by the IRB. Should you have any questions or problems please call 216-444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

- Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to

which you are entitled. If you decide to withdraw from the study, you should discuss with your study doctor your decision to ensure a safe withdrawal.

12. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Legally Authorized Representative (LAR)

You have had the above research study explained to you and as an individual likely to understand the subject's situation and acting in their best interest, you give your permission (or authorize) for participation in this research

_____
Printed Name of Subject

_____ _____
LAR Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date

Appendix C: Removal from Study Form

(complete entry) Protocol Title:	*(complete entry)* Hillcrest Tracking No:
(complete entry) Principal Investigator:	*(complete entry)* IRB Tracking No:
(complete entry) **Pt Name**:	*(complete entry)* **CCF #**:

Patient has been removed from study for the following:
(complete entries below)

- ☐ Patient is discharged
- ☐ Patient is deceased
- ☐ Patient or family member refuses to participate
- ☐ Change in code status/deterioration in medical status
- ☐ Patient self-extubates
- ☐ Testing/procedures needed
- ☐ Lack of 30 minute completion

☐ Other (describe clearly):

_____
_____
_____
_____
_____
_____

Recorded by / Date:

_____
_____

Appendix D: Interview Selection Criteria

Inclusion Criteria
▪ Hemodynamic Stability: defined as a systolic blood pressure >80. ▪ CAM negative **(Appendix 9)** ▪ Pulse oxygenation (>92 bpm) ▪ No evidence of expressive aphasia ▪ Alert and oriented x 3

Appendix E: Data Collection Form

BEFORE MUSIC THERAPY IMPLEMENTATION

SEDATION TYPE AND AMOUNT	RASS/CAM	ABILITY TO FOLLOW SIMPLE COMMANDS	VITAL SIGNS Before starting Music Therapy Session
		EYE CONTACT: Y / N SHAKE HEAD: Y / N SQUEEZE HANDS: Y / N	HR: RR: BP: SpO2:

Time of Sedation Vacation: _____ Time Weaning Began: _____

Time of Music Therapy Implementation: _____

Pre Music Therapy Implementation Questions:

What is your anxiety level on a scale of 0-10, with 10 being the most anxious? _____

What is your pain level on a scale of 0-10, with 10 being the most pain? _____

AFTER MUSIC THERAPY IMPLEMENTATION

VITAL SIGNS (immediately after Music Therapy Session)	RASS/CAM
HR: RR: BP: SpO2:	

Post Music Therapy Implementation Questions:

What is your anxiety level on a scale of 0-10, with 10 being the most anxious? _____

What is your pain level on a scale of 0-10, with 10 being the most pain? _____

Time Weaning Ended: _____

Was the Patient Able to be Extubated: Yes/No

Appendix F: Selection Criteria

Inclusion Criteria	Exclusion Criteria
▪ Medical or cardiac diagnosis ▪ Admitted to the critical care unit Medical/Surgical Intensive or Cardiac Surgical Intensive Care Unit at Cleveland Clinic's Hillcrest Hospital ▪ On invasive mechanical ventilation ▪ At least 18 years old ▪ > 24 hours of mechanical ventilation prior to study ▪ No previous music therapy experience ▪ Patient, and/or family representative (Power of Attorney, closest next of kin, or majority), cognitively able to consent to participate ▪ Patient, and/or family representative, speaks, reads, and writes English ▪ Patient, and/or family representative, consents to participate ▪ Passed Wean Screen performed by Respiratory Therapy	▪ Less than 18 years old ▪ Patient and/or family representative does not speak, read, or write in English ▪ Patient and/or family representative is cognitively unable to consent to participate ▪ Patient receiving noninvasive mechanical ventilation ▪ Patient has a tracheostomy ▪ Patient is hard of hearing ▪ Patient has received prior music therapy

Appendix G: Demographic Data Collection Form

Patient Age: _____ Gender: _____ Race/Ethnicity: _____

Diagnosis Causing Patient to be Intubated: _____

_____

History of Anxiety: Yes _____ No _____

Comments:_____

_____

_____

_____

_____

_____

_____

AUGSBURG UNIVERSITY

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Work (s) to be deposited

Title: The Experience of Music Therapy During the Weaning Process of Patients Receiving Invasive Mechanical Ventilation

Author(s) of Work(s): Stephanie M. Morris

Depositor's Name (Please Print): Stephanie M. Morris

Author's Signature: Stephanie Morris Date: 5/11/2021

If the Deposit Agreement is executed by the Author's Representative, the Representative shall separately execute the Following representation.

I represent that I am authorized by the Author to execute this Deposit Agreement on the behalf of the Author.

Author's Representative Signature: _____ Date: _____