

Music Intervention to Prevent Delirium among Older Patients Admitted to a
Trauma Intensive Care Unit and a Trauma Orthopedic Unit

by

Kari Elizabeth Johnson

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Graduate Supervisory Committee:

Julie M. Fleury, Chair
Nelma Shearer
Darya McClain

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ABSTRACT

Greater than half of older adults who are admitted to an acute care setting experience delirium with an estimated cost between four to twenty billion dollars annually in the United States. As a strategy to address the gap between research and practice, this feasibility study used the Roy Adaptation Model to provide a theoretical perspective for intervention design and evaluation, with a focus on modifying contextual stimuli in a Trauma Intensive Care and a Trauma Orthopedic Unit setting. The study sample included older hospitalized patients in a Trauma Intensive Care and a Trauma Orthopedic setting where there is a greater incidence for delirium. Study participants included two groups, with one group assigned to receive either a music intervention or usual care. The music intervention included pre-recorded music, delivered using an iPod player with soft headsets, with music self-selected from a collection of music compositions with musical elements of slow tempo and simple repetitive rhythm that influence delirium prevention. For the proposed study a music intervention dose included intervention delivery for 60 minutes, twice a day, over a three day period following admission. Physiologic variables measured included systolic blood pressure, diastolic blood pressure, heart rate, and respiratory rate, which were electronically monitored every four hours for the study. The Confusion Assessment Method was used as a screening tool to identify delirium in the admitted patients. Specific aims of this feasibility study were to (a) examine the feasibility of a music intervention designed to prevent delirium among older adults, and (b) evaluate the effects of a music intervention designed to prevent delirium among older adults. Findings indicate there was a

significant music group by time interaction effect which suggests that change over time was different for the music and usual care group.

DEDICATION

To my Mother who has followed my nursing career every step of the way and has been my cheerleader. It was my mother's dream to become a nurse as her grandmother was a nurse. When I started my nursing education, my mother and I both were in our first class together. My mother was unable to continue with her education, and continues to live her dream through my accomplishments. My son and daughter have been and continue to be a continuous beacon of encouragement for me as I pursue my education. They have since told me that I have been an example of what they can accomplish through dreams and aspirations.

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Chapter 1

INTRODUCTION

Delirium is a neurobehavioral syndrome characterized by alterations in consciousness, attention, cognition, and perception (Mattar, Chan, & Childs, 2013; Kalaria & Mukaetova-Ladinska, 2012). Recent theories addressing the pathophysiology of delirium propose different interacting biological factors disrupt neuronal networks in the brain resulting in cognitive dysfunction (Inouye, Westendorp & Saczynski, 2014). Leading mechanisms that contribute to delirium include neurotransmitter imbalance, inflammation, and physiological stressors (Inouye et al., 2014). The highest rate of delirium occurs in hospitalized older adults (Milisen, Lemiengre, Braes, & Foreman, 2009; Holroyd-Leduc, Khandwala & Sink, 2009; Halter et al., 2009; Witlox et al., 2010; Nouwen, Klijn, van den Broek, & Slooter, 2012; Inouye et al., 2014). This chapter provides an overview of the prevalence of delirium in older adults, clinical presentation of delirium, pathophysiology of delirium, risk factors, delirium prevention, pharmacological and non-pharmacological approaches, and neuroscience of music. The chapter will conclude with specific research aims that include testing a music intervention for delirium prevention among older adult patients who are admitted to a trauma intensive care unit and a trauma orthopedic unit.

Delirium in Older Adults

While delirium is often overlooked and under diagnosed in hospitalized adults over the age of 70, the prevalence of delirium in this population is estimated to be between 10%-40%, and new delirium during hospitalization from 6% to 56% (Pun & Boehm, 2011), with 15% to 62% postoperative delirium and 70% to 87%

delirium in intensive care units (ICU) (Mittal et al., 2011). In the United States alone, the population of adults age 65 years and older is projected to grow to 55 million in 2020, and 72.1 million by 2030 (Administration on Aging, 2008). The “oldest old” age group is projected to increase from 8.7 million in 2030 to 19 million in 2050, with adults aged 85 and older accounting for 4.3% of the United States population, compared to 2.3% in 2030 (Administration on Aging, 2008). Delirium prevention has recently been emphasized in national safety reports and as a health care quality indicator (Inouye et al., 2014; Field & Wall, 2013) and is clearly of significant importance when addressing the care of older adults.

Delirium increases ICU days, hospital length of stay (LOS), cognitive and functional decline, and most significant for family and caregivers, increased dependency, long term neuropsychological impairment, and institutionalization (Allen & Alexander, 2012; Girard, Jackson, et al., 2010; Pun & Boehm, 2011; Fong, Tulebaey, & Inouye, 2009; Inouye, 2006; Inouye et al., 2014; MacLulich, Beaglehole, Hall, & Meagher, 2009; Witlox et al., 2010; Field & Wall, 2013). A single occurrence of delirium may double the risk for dementia (Witlox et al., 2010). Delirium remains a direct indicator of morbidity and mortality in older adults following hospital discharge (Neufeld et al., 2011; Spronk, Riekerk, Hofhuis & Rommes, 2009; Mistraletti, Pelosi, Mantovani, Berardino, & Gregoretti, 2012; Devlin, Al-Qadhee & Skrobik, 2012; Inouye, 2006). Adults aged 65 years and older who are hospitalized for delirium cost U.S. hospitals \$164 billion per year, and greater than \$182 billion per year in 18 European countries combined (Inouye et al., 2014).

Witlox and colleagues (2010) conducted a meta-analysis examining the relationship between delirium in older patients and outcomes of mortality, long term dementia, and institutionalization. Delirium was associated with an increased risk of death compared with controls after an average follow-up of 22.7 months (seven studies; 271/714 patients [38.0%] with delirium, 616/2243 controls [27.5%]; HR, 1.95 [95% confidence interval {CI}, 1.51-2.52]; I^2 , 44.0%). Increased risk of institutionalization was noted among patients who had a history of delirium (seven studies; average follow-up, 14.6 months; 176/527 patients [33.4%] with delirium and 219/2052 controls [10.7%]; odds ratio [OR], 2.41 [95% CI, 1.77-3.29]; I^2 , 0%) and dementia (2 studies; average follow-up, 4.1 years; 35/56 patients [62.5%] with delirium and 15/185 controls [8.1%]; OR, 12.52 [95% CI, 1.86-84.21]; I^2 , 52.4). Delirium in older patients was associated with poor outcomes unrelated to age, sex, co morbid illness, illness severity, and baseline dementia (Witlox et al., 2010).

Samuelson (2011) conducted qualitative interviews with patients previously admitted to an ICU to explore their experience and recall. Two hundred fifty patients were interviewed with 81% recalling their ICU stay and 71% remembering unpleasant memories. Three themes of unpleasant memories included physical, emotional, perceptual, and environmental distress. Emotional distress included fear of dying, panic, anxiety, anger, frustration, terrifying dreams, unpleasant hallucinations, paranoid delusions, strange feelings, confusion, and hostile surroundings. Wanting to escape the constant fear was an impetus to climb out of bed. Concerns expressed included sadness, isolation, emptiness, and feeling trapped, locked up, powerless, and worrying about how to care for self if they survived. Perceptual distress included terrifying dreams of trying

to escape, death, violence, injured body parts and people trying to harm them. There was a fear of falling asleep to avoid terrible nightmares resulting in patients fighting sleep and attempting to climb out of bed. Hallucinations included black holes, animals or insects in the room, and strange figures (Samuelson, 2011). Environmental distress was caused by environmental factors, including noise, talking, and irritating tubes and lines. One patient noted, “You could feel them inside you; and the tube in my throat, I could not breathe” (Samuelson, 2011).

O’Malley and colleagues (2008) conducted a literature review evaluating patient, family, and staff perspectives related to the experience of delirium in an ICU. Patients were fearful, anxious, and felt threatened; the greater the fear and threat, the greater the anxiety and aggressive behavior by the patient, along with feelings of hopelessness, loneliness, and depression. Patients felt trapped with no control of the past or the present, were in a dream-like state, not making sense, unable to communicate with family or nursing (O’Malley, Leonard, Meagher, & O’Keefe, 2008). Among patients who recalled their delirious state, 54% felt remorse, embarrassment, relief, and fear of reoccurrence with future hospitalizations. Families and caregivers (76%) expressed concerns for post discharge care, especially among patients with hyperactive delirium and poor functional status (O’Malley et al., 2008).

Clinical Presentation

Clinical manifestations of delirium can be categorized into three subtypes; hyperactive delirium, hypoactive delirium, and mixed delirium (Maldonado, 2008). Patients with hyperactive delirium present with agitation, restlessness, attempting to remove devices, and emotional instability (Allen & Alexander, 2012; Lundstrom,

Stenvall, & Olofsson, 2012). Hyperactive delirium is the least frequent delirium subtype seen in ICU settings (Hipp & Ely, 2012). Consequences of hyperactive delirium include fractures due to falls (Yang et al., 2009) and increased medication use; especially antipsychotics compared to hypoactive and mixed delirium (Robinson, Raeburn, Tran, Brenner & Moss, 2011). Mixed delirium is a combination of hyperactive and hypoactive delirium and is the second most prevalent in ICU settings, with mixed and hyperactive subtypes of delirium more difficult to manage. Characteristics of hypoactive delirium include flat affect, withdrawal, apathy, lethargy, decreased level of responsiveness, and minimal psychomotor activity (Morandi & Jackson 2011; Allen & Alexander 2012; Vasilevskis, Han, Hughes, & Ely, 2011). Hypoactive delirium is seen most often (60%) in ICU settings; however, 65% to 75% of cases may go unrecognized and untreated (Hipp & Ely 2012; Allen & Alexander 2012; Lundstrom et al., 2012; Neufeld et al., 2011). Due to co morbid conditions, dementia, and delayed detection, hypoactive delirium has a poor prognosis and is less reversible in older adults (Han et al., 2009; Gonzalez et al., 2009; Meagher et al., 2011). Hypoactive delirium can result in complications including high rates of pressure sores and hypostatic pneumonia (Meagher et al., 2011; Leonard, Donnelly, Conroy, Trzepacz, & Meagher, 2011; Yang et al., 2009; Lundstrom et al., 2012).

Pathophysiology of Delirium

Delirium is a neurobehavioral expression of imbalances in neurotransmission in the brain that leads to cognitive dysfunction (Inouye et al., 2014). Main mechanisms that contribute to delirium include neurotransmitter imbalance, inflammation, and physiological stressors (Inouye et al., 2014).

Neurotransmitters are chemical messengers that can both activate and inhibit neuronal firing depending on the type of receptors present. Types of neurotransmitters include; amino acids (glutamate, Gamma Aminobutyric Acid (GABA), aspartic acid and glycine), neuropeptides (vasopressin, somatostatin, neurotensin), monoamines (epinephrine, norepinephrine (NE), dopamine (DA), histamine, and serotonin (5HT), and acetylcholine (ACh) (Gangrade, 2012). Neurotransmitters ACh, 5HT, DA, NE, glutamate, and GABA are involved in delirium (Lorenzo, Aldecoa, & Rico, 2013). The neurotransmitter GABA is a major inhibitor in the central nervous system (CNS) and a reduction in GABA can lead to delirium. The neurotransmitter ACh affects movement and is involved in learning, memory, and behavior (Krout, 2007). A reduction in the neurotransmitter ACh can result in impaired behavioral responses directly related to delirium (Inouye et al., 2014; Brown & Purdon, 2013). The neurotransmitter 5HT is the most plentiful monoaminergic neurotransmitter in the brainstem and is involved in mood, wakefulness, motor activity, and cognition (Hughes, Brummel, Vasilevskis, Girard, & Pandharipande, 2012). Elevated 5HT levels can cause impaired memory and learning with selective reuptake inhibitors associated with delirium (Hughes et al., 2012; Lorenzo et al., 2013). Glutamate is the most prevalent neurotransmitter in the brain, and is involved in learning and memory (Brown & Purdon, 2013). Certain drugs act on glutamate transmitters causing anxiety and psychosis which can lead to delirium. A reduction in glutamate can cause impaired behavioral responses (Inouye et al., 2014; Brown & Purdon, 2013). An imbalance of one or both neurotransmitters DA and ACh can cause unstable neurons and abnormal neurotransmission resulting in adverse effects from cholinergic deficiency and DA

excess, increasing the likelihood of delirium (Inouye et al., 2014; Girard, Pandharipande, & Ely, 2008; MacLulich, Ferguson, Miller, de Rooij, & Cunningham, 2008; Mora, Segovia, del Arco, de Blas, & Garrido, 2012). An increase in NE from the sympathetic nervous system (SNS) increases heart rate (HR) and can cause a fight-or-flight response along with epinephrine increasing HR, triggering the release of glucose from energy stores and increasing blood flow to skeletal muscle (Gangrade, 2012). An excess in NE and epinephrine can cause impaired attention, anxiety, mood, and hyperactive delirium through an increase in neuronal activity (Gangrade, 2012).

Central nervous system inflammation is prevalent in acute illness due to infection, trauma, cardiovascular disease or metabolic disorders, all prevalent in ICU settings (VanGool, Van de Beek & Eikelenboom, 2010; Sanders, 2011). Cytokines are proteins, peptides or glycoprotein's that mediate and regulates immunity, inflammation, and hematopoiesis and is necessary for maintenance of immune function and growth (Gangrade, 2012). Pro inflammatory cytokines are inflammatory mediators formed during critical illness that initiates a cascade of endothelial damage, thrombin formation, and microvascular compromise (Girard et al., 2008). The peripheral immune system affects brain function through pro inflammatory cytokines, especially interleukin 1 beta (IL-1 β), tumor necrosis factor α (TNF α), and interleukin-6 (IL-6), which are produced in the periphery and communicate with the brain to direct neural pathways and transport across the blood brain barrier (BBB) (Van Gool et al., 2010). A function of the BBB is to provide a secure setting for neuronal function. The BBB maintains a separation of neurotransmitters in the central and peripheral nervous systems (PNS)

necessary for normal brain function (Abbott, Patabendige, Dolman, Yusof, & Begley, 2010). Pro inflammatory cytokines play a role in the release of ACh, DA and NE all of which disrupt neurotransmission and increase the risk for delirium by increasing BBB permeability (Fong et al., 2009; Inouye, 2006; MacLulich, et al., 2013). When cytokines cross the BBB there is an increase in vascular permeability in the brain, causing changes on electroencephalography (EEG) consistent with those seen in patients with acute infection such as sepsis (Girard et al., 2008). With acute infection there is an increase in pro inflammatory cytokines; TNF α , IL-1 β , and IL-6, and can linger in the brain for months (Van Gool et al., 2010). Increased brain TNF α causes microglia activation and an increase in cytokines released in brain tissue, causing acute reversible behavioral changes and neuro inflammation, resulting in a neurotoxic response with degeneration of cholinergic neurons in the brain (Van Gool et al., 2010).

A physiological stressor is a brain-body reaction towards stimuli from the internal and or external environment (Mora et al., 2012). The main physiological mechanism in response to a stressor involves the interaction of the prefrontal cortex (PFC), amygdala, hippocampus, nucleus accumbens (NAc), and the hypothalamus of the brain through the release of certain neurotransmitters (Mora et al., 2012; Ulrich-Lai & Herman, 2009). The PFC undergoes neurochemical changes in response to a stressor. A stressor triggers the PFC to increase the release of neurotransmitters glutamate, NE, 5HT, ACh, DA, and GABA in the hippocampus (Mora et al., 2012; Hughes et al., 2012; Lorenzo et al., 2013). The hippocampus, amygdala, and NAc communicate with areas of the brain that release neurotransmitters NAc, 5HT, DA, ACh, GABA, and glutamate (Mora et al., 2012). The amygdala is the gatekeeper for processed sensory information that enters the brain. An

acute stressor increases concentrations of NE, 5HT, and DA in the amygdala and triggers the amygdala to release DA, ACh, NAc, and GABA (Mora et al., 2012). A stressor activates the hypothalamic pituitary adrenal (HPA) axis neurons in the hypothalamus. The HPA axis neurons releases a hormone called corticotropin releasing hormone (CRH) and arginine vasopressin (AVP). These hormones trigger the release of adrenocorticotropin (ACTH) from the pituitary gland, resulting in a production of glucocorticoids by the adrenal cortex (Lupien, Maheu, Tu, Fiocco, & Schramek, 2007).

Risk Factors

Delirium is a multi-factorial disorder; risk factors differ based on patient population, medical diagnosis, and postoperative stay in an ICU setting (Theuerkauf, Guenther, & Putensen, 2012; Fong et al., 2009). Risk factors include those potentially non modifiable and modifiable (Fong et al., 2009). Non modifiable risk factors include patient characteristics that influence susceptibility for delirium; age greater than 70 years, preexisting cognitive and functional impairment, alcohol abuse, sensory impairment, and multiple co-morbidities (Morandi & Jackson 2011; Banh, 2012; Theurekauf et. al., 2012; Fong et al., 2009; Sanders, 2011). Modifiable risk factors include neurotransmitter imbalance, inflammation, acute stressors, and medication (Allen & Alexander 2012; Banh 2012; Theurekauf et. al., 2012; Morandi, Jackson & Ely, 2009; Fong et al., 2009; Sanders, 2011).

Pro inflammatory cytokines increase with trauma, acute infection and surgery, cause inflammation and serve as a precursor for delirium (Fong et al., 2009). Preclinical data support inflammation as a possible pathogenic mechanism for post-operative

cognitive dysfunction (Cibelli et al., 2010; Terrando et al., 2010; Fidalgo et al., 2011). Vacas and colleagues (2013) conducted a search related to postoperative cognitive dysfunction (POCD) to examine whether neuro inflammation causes POCD. Postoperative cognitive dysfunction is defined as a later onset of postoperative delirium which occurs after surgery, causing inattention, disorganized thinking, and altered level of consciousness with an acute onset and fluctuating course (Vacas et al., 2013). An increase in pro inflammatory cytokines in both the CNS and systemic circulation in the hippocampus of mice post minor surgery was associated with cognitive decline, validating that surgery induced neuro inflammation can cause cognitive decline in mice (Vacas et al., 2013). An international multicenter study of POCD among adults aged 60 years and older found impaired memory in greater than 25% of patients one week after non-cardiac surgery, and after three months, 10% persisted with cognitive decline (Vacas et al., 2013). The potential mechanism proposed to cause POCD is postsurgical neuro inflammation. There is an increase in pro inflammatory cytokines in both the CNS and the systemic circulation, which disrupt neurotransmission and increase the risk for delirium (Fong et al., 2009; Inouye, 2006; MacLulich et al., 2013).

There is a disruption of a variety of situation-specific neurotransmitters that lead to delirium. Neurotransmitters ACh and 5HT play a role in medical and surgical delirium (Inouye et al., 2014). An imbalance of one or both neurotransmitters DA and ACh can cause unstable neurons resulting in adverse effects from cholinergic deficiency and DA excess, increasing the likelihood of delirium (Inouye et al., 2014; Girard et al., 2008; MacLulich et al., 2008; Mora et al., 2012; Brown & Purdon, 2013). An excess in the neurotransmitter NE can cause impaired attention, anxiety, and hyperactive delirium

(Hughes et al., 2012; Lorenzo et al., 2013). Elevated 5HT levels can cause impaired memory and learning with selective reuptake inhibitors associated with delirium (Hughes et al., 2012; Lorenzo et al., 2013).

With physiological stress increased levels of glucocorticoids act as a mediator between specific brain areas and the body (Mora et al., 2012). High levels of glucocorticoids elicit harmful effects to the brain and can cause glucocorticoid induced mood disturbances and psychiatric symptoms such as a steroid psychosis, impaired memory function, and acute fear (Colkesen, Giray, Ozenli, Sezgin, & Coskun, 2012). When released, glucocorticoids and catecholamines trigger a fight or flight response causing an increase in HR and blood pressure (BP) (Lupien et al., 2007). Stress hormones are released due to a stress response from surgery, pain, trauma, and systemic inflammation, and can cause and prolong delirium (Fong et al., 2009; MacLulich et al., 2008; MacLulich et al., 2013).

Medications that cause delirium interfere with GABA, DA, and cholinergic neurotransmission at areas of neuronal activity (Maldonado, 2008). Many psychoactive medications administered in ICU settings are drawn to GABA neurotransmitters, decreasing GABA levels, which is the major inhibitory neurotransmitter in the CNS, resulting in delirium. There is a decrease in ACh levels after administration of medications that have anticholinergic properties such as amitriptyline, clidinium, emepronium, hydroxyzine, levomepromazine, orphenadrine, oxybutynin, periciazine, furosemide, isosorbide nitrate, and digoxin (Luukkanen et al., 2011). Medication with anticholinergic properties deemed inappropriate for older adults include hydroxyzine, oxybutynin, doxepin, diazepam, and metoclopramide (Luukkanen et al., 2011).

Medications with anticholinergic properties cause a central cholinergic deficit resulting in perceptive and cognitive impairment in older adults (Lorenzo et al., 2013; Fong et al., 2009; Cerejeira, Nogueira, Luis, Vaz-Serra, & Mukaetova-Ladinska, 2012; Hughes et al., 2012).

The strongest risk factor for delirium is increasing age (Inouye et al., 2014; Kalaria et al., 2012). Age related changes in the brain alter neurotransmission, inflammation, and physiological stressors, predisposing older adults to delirium (Inouye et al., 2014). With aging, the brain has a reduced ability to preserve normal functional decline (Brown & Purdon, 2013). Older adults who have an inflammatory state due to age related changes elicit a more severe CNS response increasing pro-inflammatory cytokines at areas of existing inflammation in the brain (MacLulich et al., 2008; Fong et al., 2009). With normal aging the feedback regulation of cortisol can be impaired resulting in higher levels of baseline cortisol, placing older adults at a greater risk for delirium (Fong et al., 2009; Colkesen et al., 2012; MacLulich et al., 2008). Older adults with trauma requiring major abdominal, cardiovascular, and orthopedic surgery develop systemic inflammation from traumatized tissues in the body. The inflammatory cascade takes place immediately following the surgical insult and inflammation develops and peaks 24 hours or later. An increase in brain inflammation impairs brain capillary function to supply oxygen and nutrients to the brain, and systemic inflammation from surgical trauma causes diffuse microcirculatory impairment due to a reduction of ACh, significantly increasing postoperative delirium in older adults (Hala, 2007; Brown & Purdon, 2013). In older adults there is a structural change in the muscarinic binding site causing reduced muscarinic receptor sites and reduced activity of the pre-synaptic

enzyme choline acetyltransferase that decreases the amount of ACh in the CNS and an increase in the permeability of the BBB. Mechanisms that increase BBB permeability that are common in older adults include epithelial shrinkage, opening of tight junctions, and dilation of blood vessels, resulting in increased blood flow and leakage of larger molecules. Age related reductions in ACh release affects older adults by inhibiting cholinergic response known to be helpful in treating delirium (Inouye et al., 2014; Fong et al., 2009). Patients with Alzheimer's have severely impaired cholinergic neurotransmission due to neuronal degeneration and older adults with dementia have a greater sensitivity to central anticholinergic adverse effects than older adults without dementia (Kersten & Wyller, 2014).

Summary

In summary, delirium is an acute change in consciousness with an impaired ability to focus, sustain or shift attention, varies in degree, and can develop within hours or days (Godfrey et al., 2013). Hospitalized older adults are at a greater risk for delirium, with 70% to 83% of delirium in older adults found in ICU settings (Fong et al., 2009; Kostas, Zimmerman & Rudolph 2013). Risk factors for delirium are categorized as modifiable and non-modifiable (Fong et al., 2009). Modifiable risk factors influence the pathophysiological mechanisms (acute insult) that result in delirium (Mittal et al., 2011; Fong et al., 2009; Sanders, 2011). Non modifiable risk factors are characteristics that increase the likelihood for delirium (Morandi & Jackson 2011; Banh, 2012; Theuerkauf et al., 2012; Fong et al., 2009; Sanders, 2011). Three subtypes of delirium based on level of alertness include hyperactive, hypoactive, and mixed delirium (Maldonado, 2008). Main mechanisms that contribute to delirium include neurotransmitter imbalance,

inflammation, and physiological stressors (Inouye et al., 2014). Neurotransmitters are chemical substances that act as messengers regulating activation or inhibition of neurons by carrying signals from one cell to another (Gangrade, 2012). Activation of neurotransmitters chemically change an electrical message. Inflammation is caused from pro inflammatory cytokines that increase with trauma, acute infection and surgery, and increase the likelihood for delirium (Fong et al., 2009). With a physiological stressor the brain and body communicate with specific areas of the brain responding to information from the body's reaction to stress (Mora et al., 2012).

Delirium Prevention

Preventing delirium is considered standard of care, and the most effective course in decreasing frequency and adverse outcomes (Hipp & Ely 2012; Fong et al., 2009; Inouye et al., 2014; MacLulich et al., 2013; Khan et al., 2012). Current clinical approaches to prevention include pharmacologic and non-pharmacologic approaches (Fong et al., 2009; Hipp & Ely 2012).

Pharmacological approaches. Traditional pharmacologic approaches treat underlying causes of delirium, especially when non pharmacologic approaches are not successful. There are currently no medications approved by the Food and Drug Administration (FDA) to treat or prevent delirium (Hipp & Ely 2012; Devlin et al., 2012). Standard pharmacological treatment for delirium in the ICU is haloperidol (Hipp & Ely 2012; Ghandour, Saab, & Mehr 2011; Fong et al., 2009; Lorenzo et al., 2013) which is the drug of choice of the Society of Critical Care Medicine (SCCM) and the American Psychiatry Association (Hipp & Ely, 2012). Haloperidol is used by 75-85% of intensivists, and atypical antipsychotics including olanzapine, quetiapine and risperidone

(Grover, Kumar, & Chakrabarti, 2011) are used by 35-40% of intensivists as treatment for delirium in an ICU (Hipp & Ely, 2012). Despite recent delirium prevention guidelines that do not support long or short term antipsychotic use, antipsychotics including intravenous haloperidol, has increased in use from 4% to 50% over the past ten years (Devlin et al., 2012). Side effects from haloperidol include torsade's de pointes, prolongation of the QT interval, extra pyramidal effects (Jones & Pisani, 2012; Pisani et al., 2009; Skrobik et al., 2010), and an increased risk of stroke in older adults with dementia (Fong et al., 2009). Sedatives and hypnotics most frequently used in ICU settings have potential deliriogenic effects (Hipp & Ely, 2012). Medications associated with delirium include benzodiazepines, antihistamines, antibiotics, corticosteroids, metoclopramide, antipsychotics, cholinesterase inhibitors, and hypnotic sedatives (Lorenzo et al., 2013). Adverse effects from sedatives and analgesics administered for delirium include nausea, vomiting, hypotension, decreased gastro intestinal motility, urinary retention, and increased risk for infection (Davis & Jones, 2012).

Benzodiazepine is a sedative hypnotic frequently used to treat anxiety and agitation with patients in ICU settings (Berry & Zecca, 2012; Adams et al., 2012; Pisani et al., 2009; Riker et al., 2009; Vasilevskis et al., 2011) and can cause impaired sleep patterns by affecting rapid eye movement, with delirium as a consequence (Banh, 2012).

Benzodiazepines to treat sedation can increase episodes of iatrogenic coma, LOS, and mechanical ventilation days (Marik, 2015). Over sedation is a complication making it difficult to evaluate neurological status, resulting in undetected cases of delirium and delayed resolution of delirium in ICU patients. Over sedation can impair early mobilization and increase functional decline on discharge (Devlin et al., 2012). Greater

than 50% of patients who are mechanically ventilated are given a continuous infusion of sedatives (Wunsch, Kahn, Kramer & Rubenfeld, 2009). Precedex (dexmedetomidine) is an effective hypnotic sedative and analgesic, where daily arousal from a deep sedation is possible while maintaining deep levels of sedation, and is considered the sedative hypnotic of choice in an ICU due to a reduction in delirium, with recent trials supporting its use (Hipp & Ely, 2012). Dexmedetomidine was compared to midazolam in 375 mechanically ventilated patients in 68 ICUs; delirium was significantly lower within one day when using dexmedetomidine when compared to midazolam (54% vs. 76.6%, $p > 0.001$) (Riker et al., 2009). Dexmedetomidine and morphine sulfate were compared in 306 patients post-cardiac surgery; the duration of delirium was reduced by three days in patients who received dexmedetomidine when compared with patients receiving morphine ($p = .031$) (Shehabi et al., 2009). With medications considered quick, easy to administer, while non-pharmacologic interventions are not always known or available, medications are considered and used more frequently to prevent and treat delirium in hospitalized older adults (Devlin et al., 2012).

Prophylactic antipsychotic administration is considered a pharmacologic approach currently being studied in older adults to prevent and decrease the severity of delirium (Gilmore & Wolfe, 2013; Teslyar et al., 2013). Teslyar and colleagues (2013) conducted a systematic review to identify whether delirium prophylaxis using antipsychotic medication was effective in hospitalized older patients. Five out of 19 studies met inclusion criteria and were included in the review. All five studies were RCTs, totaling 1491 patients and covering five different countries (United States, China, Thailand, Netherland and Japan). All five studies examined older patients having surgery who

received haloperidol, risperidone, and olanzapine, with delirium prevention the primary outcome. Four of the five studies found that prophylaxis with antipsychotics resulted in a decrease in delirium, ranging from 4.0% to 12.6%. The overall effect as indexed with a relative risk ratio of (0.51 RR [95% CI]; 0.51 [0.33-0.79]), supported that patients using antipsychotic prophylaxis were 50% less likely to develop delirium compared with patients who did not use antipsychotic prophylaxis (Teslyar et al., 2013). Larsen and colleagues (2010) conducted a randomized, double-blind placebo-controlled trial where olanzapine 5 mg was administered prior to and immediately after joint replacement surgery in older patients; delirium rates were lower among patients receiving olanzapine compared with placebo (14.3% versus 40.2%, 95% CI 17.6 – 34.2, $p < .001$), however patients who received olanzapine and developed delirium had a longer and more severe period of delirium than patients who developed delirium in the placebo group. Wang and colleagues (2012) evaluated the efficacy of haloperidol in preventing delirium among patients over age 65 years who were admitted to the ICU after non-cardiac surgery. Two hundred twenty nine patients were randomized to receive 0.5 milligrams (mg) IV bolus of haloperidol followed by continuous infusion at a rate of 0.1 mg per hour for 12 hours, for a total dose of 1.7 mg postoperatively compared to 228 patients who received normal saline placebo. The primary outcome measured was incidence of delirium during the first seven postoperative days measured by the confusion assessment method ICU (CAM-ICU). Delirium in the haloperidol group was significantly lower with 35 out of 229 patients (15.3%) developing delirium compared to 53 out of 228 patients (23.2%) who did not receive haloperidol. Girard and colleagues (2010) conducted a randomized double-blind, placebo controlled trial from February 2005 to July 2007 to determine

whether antipsychotics haloperidol (5 mg), ziprasidone (40 mg), versus placebo as a treatment prophylaxis for ICU delirium would improve days alive without delirium or coma. Out of 3,297 patients who met inclusion criteria who were screened, 101 mechanically ventilated ICU patients were enrolled. Duration and volume of the study drug administered were similar among the three treatment groups. In the placebo group, 15 (42%) patients received an antipsychotic in addition to study drug compared with 7 (20%) patients in the haloperidol group and 10 (33%) patients in the ziprasidone group ($p = 0.14$). Neither haloperidol nor ziprasidone significantly increased the number of days patients were without delirium nor was coma compared to placebo, and the duration of both delirium and coma the same among all three treatment groups (Girard, Pandharipande et al., 2010). Girard and colleagues (2010) found no evidence that either haloperidol or ziprasidone effectively treated delirium in mechanically ventilated patients. Patients in all three groups had the same amount of days free from delirium and coma with no serious adverse events reported during the trial (Girard, Pandharipande et al., 2010). Ten (29%) patients in the haloperidol group reported symptoms consistent with akathisia, compared with 6 (20%) patients in the ziprasidone group and 7 (19%) patients in the placebo group ($p = 0.60$). Ten patients had QT prolongation > 500 mm while receiving the study drug, (two in the haloperidol group, five in the ziprasidone group, and three in the placebo group). Extra pyramidal symptoms were noted in all groups; 4 (11%) in the haloperidol group, 2 (7%) in the ziprasidone group and 6 (17%) in the placebo group (Girard, Pandharipande et al., 2010).

Inouye et al., (2014) reviewed 16 studies that utilized a pharmacologic approach for delirium prevention and treatment with a minimum of 25 patients in both the

treatment group and control group. There was no effective evidence reported for any pharmacologic approaches used for delirium prevention (Inouye et al., 2014). Rates of delirium did not differ significantly in six trials. In eight trials, the treatment group reduced rates with no effect on clinical outcomes (ICU admission, LOS, complications or mortality). Treatment groups in two studies had worse outcomes compared to the control group. Olanzapine decreased the incidence of delirium but increased the duration and severity of delirium, and rivastigmine increased the duration and mortality. There were different approaches with different patient populations involved with the 16 studies. Overall findings were pharmacologic approaches for delirium prevention and treatment was not recommended (Inouye et al., 2014).

Limitations of pharmacologic approaches. Pharmacologic approaches do not address risk factors of inflammation, acute physiological stressors and neurotransmitter imbalances for delirium (Devlin et al., 2012). Clinical guidelines do not support pharmacologic approaches for delirium prevention (Devlin et al., 2012). The majority of recent studies using pharmacologic approaches such as antipsychotics and sedatives to treat delirium do not study the underlying mechanism on the long and short term effects on delirium (Devlin et al., 2012). Traditional pharmacologic approaches are costly, have adverse side effects and worsen delirium in older adults. Medications that interfere with neurotransmitters GABA, DA, and ACh can cause delirium. Antipsychotic medications are drawn to GABA neurotransmitters, decreasing GABA levels, which is the major inhibitory neurotransmitter in the CNS, resulting in delirium. A reduction in ACh levels after administration of medications that have anticholinergic properties leads to delirium. An excess in the neurotransmitter NE can cause anxiety and hyperactive delirium.

Increased 5HT levels can cause impaired memory and learning with selective reuptake inhibitors associated with delirium (Hughes et al., 2012; Lorenzo et al., 2013). However, there have been some promising advances evaluating prophylactic antipsychotic medication for delirium prevention. Prophylactic antipsychotic administration is considered a pharmacologic approach currently studied in older adults to prevent and decrease the severity of delirium (Gilmore & Wolfe, 2013; Teslyar et al., 2013). Four out of five studies found that prophylaxis with antipsychotics resulted in a decrease in delirium, yet treatment groups in two studies had worse outcomes compared to the control group (Teslyar et al., 2013). Olanzapine decreased the incidence of delirium but increased the duration and severity of delirium, and rivastigmine increased mortality and the duration of delirium (Teslyar et al., 2013).

Non-pharmacological approaches. Non-pharmacological approaches for delirium prevention focus on optimizing cognition, early mobilization, and sleep promotion (Rossom et al., 2011; Michaud et al., 2007; Barr et al., 2013; Sendelbach & Guthrie 2009; Fong et al., 2009; Inouye et al., 2014, Khan et al., 2012). Mechanisms to manage cognitive impairment included appropriate lighting, signage, calendar, visible clock, and family visits. Mechanisms for immobility included early mobilization, mobility aids, and range of motion exercise. Mechanisms to promote sleep included avoiding noise and providing scheduled quiet time (Inouye et al., 2014).

The Hospital Elder Life Program (HELP) is a multicomponent delirium prevention protocol targeting five delirium risk factors, cognitive impairment, sleep deprivation, immobility, sensory impairment, and dehydration (Zaubler et al., 2013). Mechanisms used to address cognitive impairment included daily visits, reorienting,

answering questions, therapeutic activities, cognitive stimulation through games, reminiscence, reading the newspaper, and discussing current events. Mechanisms used to address sleep deprivation included minimizing and avoiding interruptions and noise reduction at night. Immobility was addressed with early mobilization, mobility aids, and range of motion exercise. Mechanisms used to address sensory impairment included ensuring patients had glasses and or hearing aids within reach that were fully functional. Mechanisms used to address dehydration included feeding assistance, unwrapping and arranging tray, encouraging patients to drink liquids, and ensuring liquids were readily available (Zaubler et al., 2013). Zaubler and colleagues (2013) conducted a quality improvement project in a community hospital on a 38 bed general medical floor. Patient's 70 years and older with a minimum of one risk factor for delirium other than age were enrolled, a total of 595 patients with 215 patients in the pre intervention group and 380 in the intervention group. Episodes of delirium were reduced from 42 patients (20%) in the pre intervention group (n = 215) to 47 patients (12%) in the intervention group (n = 380); a 40% reduction ($p = 0.019$). Duration of delirium episodes decreased from a median of 2.5 days in the pre intervention group to a median of 2 days in the intervention group with no statistical significance noted ($p = 0.22$) (Zaubler et al., 2013).

The Yale Delirium Prevention Trial evaluated the effectiveness of a multi component preventive intervention with patient's greater than 70 years of age who were admitted to a general medical floor (Khan et al., 2012). Interventions included orientation and therapeutic activities to target cognitive impairment, early mobilization to prevent functional decline, non-pharmacological approaches to decrease use of psychoactive medications, sleep promotion, communication methods, visual and hearing

devices, and early intervention for volume depletion. The incidence of delirium was 9.9% in the intervention group, compared with 15% in the usual care group (OR [odds ratio], 0.60; 95% CI, 0.39–0.92) .23 (Khan et al., 2012).

The Health Services Research and Development Service (HSR & D) Evidence Based Synthesis Program (ESP) developed clinical policies to improve patient outcomes and performance measures, and to direct research addressing gaps in clinical knowledge (Rossom et al., 2011). In 2011, the HSR & D and ESP conducted a delirium review evaluating the effectiveness of delirium screening, the effectiveness and harm of approaches to prevent delirium, and comparative diagnostic accuracy of tools used to detect delirium. Recommendations for delirium prevention included delirium screening, avoiding psychoactive medications, and use of pharmacologic interventions to decrease risk of delirium (Rossom et al., 2011). Promoting single or multi component interventions including music, mobilization, fluid and nutrition management, orientation and cognitive stimulation were also recommended (Rossom et al., 2011).

The American College of Critical Care Medicine (ACCM) convened an interdisciplinary task force with expertise in pain, agitation, and delirium to revise the 2002 “Clinical Practice Guidelines for the Sustained Use of Sedatives and Analgesics in The Critically Ill Adult” (Barr et al., 2013). Recommendations in the 2012 guidelines were developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology, a structure system for rating quality of evidence and grading strength of recommendations in clinical practice (Guyatt et al., 2008). Grade A recommendations for delirium prevention included early mobilization, sleep promotion

by controlling light, noise, clustering care activities, music listening, and decreasing stimuli at night (Guyatt et al., 2008).

The Acute Confusion/Delirium EBP guideline emphasized identification of risk factors, assessment for delirium, and implementing multi component interventions to prevent delirium (Sendelbach & Guthrie 2009). Orientation, pain management, early mobilization, visual and hearing aids, noise reduction, sleep promotion, and music therapy were multi component interventions used (Sendelbach & Guthrie 2009).

Summary

Other studies looked at risk factors that contributed to inflammation, neurotransmitter imbalance, and physiologic stressors. Focal stimuli foster changes in the internal and external environments (Roy and Andrews, 1999). Physiologic responses to focal stimuli include neuro, chemical, and endocrine factors (Roy & Andrews, 1999, p.46), which contribute to an adaptive response or an ineffective response. Focal stimuli can lead to delirium through inflammation, neurotransmitter imbalance, and physiological stressors. Acute illness, trauma, infection, and surgery can cause inflammation and result in delirium (Hipp & Ely, 2012). With infection, pro-inflammatory cytokines cause severe inflammation of the brain (Fong et al., 2009). With age, there is a low grade inflammation with chronic neurodegenerative changes in the brain, and decreases in DA, NE, ACh, and GABA neurotransmitters which increases the risk for delirium (Fong et al., 2009).

Iatrogenic factors such as medication can contribute to delirium through neurotransmitter imbalance. Sedatives, hypnotics, and anticholinergic medications used in the ICU have deliriogenic effects (Hipp and Ely, 2012). The primary inhibitory

neurotransmitter in the CNS, GABA exerts powerful effects across the brain (Fong et al, 2009). Several agents commonly prescribed in the ICU (benzodiazepines and propofol) are drawn to GABA receptors in key areas such as the brainstem, reducing CNS arousal, and resulting in changes in neurotransmission and disruptions in cerebral function (MacLulich et al., 2008). During stress, DA, ACh, NE and GABA are released. Stress hormones are released due to a stress response from surgery, pain, trauma, and systemic inflammation, and can cause and prolong delirium (Fong et al., 2009; MacLulich et al., 2008; MacLulich et al., 2013).

For adaptation to occur, an adaptive system needs to constantly grow and develop within a changing environment. Focal stimuli (neurotransmitter imbalance, inflammation, and physiological stressors) from the internal and external environment serve as inputs to the human adaptive system and are processed by the regulator subsystem causing a response (Roy & Andrews, 1999, p. 43). The goal of a nursing intervention in situations of health or illness is to maintain and enhance adaptive responses (Roy & Andrews, 1999, p.81).

Non-pharmacologic approaches are intended to reduce contributing factors for delirium prevention. There is a relationship between the various etiological factors of delirium (Fong et al., 2009). Inflammation can be the result of systemic infection, trauma or surgery. Neurotransmitters can be the result of medications that alter ACh, DA, NE, glutamate, and epinephrine. Diminished cognitive reserve, sensory deprivation, environmental triggers, pain, and immobilization, add to the mechanisms of inflammation, neurotransmitter imbalance and physiologic stressors, increasing the risk for delirium (Krishnan, Leung, & Caplan, 2014).

Khan et al., (2012) conducted a systematic review to provide evidence based recommendations for delirium care and identify gaps in delirium research. Khan et al., (2012) defined the problem of interest of delirium prevention through non-pharmacologic and pharmacologic interventions. Mechanisms or risk factors that influence delirium included sleep deprivation, immobilization, cognitive impairment, psychoactive drugs, sensory deprivation, and volume depletion. The primary outcome measured was delirium. Inouye et al; (2014) defined the problem of interest as delirium prevention with drug reduction for sedation and analgesia and non-pharmacologic approaches as interventions for delirium prevention. Inouye et al., (2014) suggested that different sets of interacting biological factors disrupt neuronal networks leading to acute cognitive dysfunction or delirium. Leading mechanisms felt to cause delirium included neurotransmitters, inflammation, physiologic stressor, metabolic derangements, electrolyte disorders and genetic factors (Inouye et al., 2014). Factors that interfered directly with neurotransmission included drugs, biological factors including hypercortisolism, electrolyte disturbances, hypoxia, and impaired glucose oxidation (Inouye et al., 2014). Factors that interfered with inflammation included acute infection (sepsis), peripheral inflammation, and acute head trauma. Physiologic stressors included previous history of dementia. Targeting risk factors for delirium were the mechanisms used to prevent delirium. Mechanisms that were targeted included reorientation, therapeutic activities, reduced use of psychoactive drugs, early mobilization, sleep promotion, and provision of hearing and visual aids.

Michaud and colleagues (2007) examined five guidelines and 19 systematic reviews for best practice in prevention, risk factors, screening, and management of

delirium in older adults. Grade A recommendations included delirium screening, education, drug toxicity mechanisms (withdrawal with benzodiazepines), and modifying stressors that elicited an acute stress response (low level lighting, noise reduction, normal sleep-wake cycle, visual and hearing aids, music listening, no physical restraints, early mobilization). Alteration of neurotransmitters included correcting electrolytic disturbances, dehydration, acute ethanol prevention, with the goal of restoring physiological conditions (Michaud et al., 2007). Identifying and modifying stressors, providing supportive care and following evidenced based practice (EBP) guidelines when administering pharmacological treatment are important in delirium management.

Fong and colleagues (2009) stated that delirium happened as a result of different pathogenic mechanisms. Pathogenic mechanism included disruption of neurotransmitters, inflammation, and acute stress responses. Delirium happened from an interaction of multiple risk factors; sensory impairment, medications, immobilization, acute illness, trauma, pain, metabolic disorders, emotional distress, and sleep deprivation. Inflammation included surgery, trauma, and infection. Acute stress included high levels of cortisol from normal age related changes, medications, and neurotransmitters from medications.

Non-pharmacologic approaches were considered first line treatment and included reorientation and behavioral interventions. No literature was found to support the physiological mechanisms of ACh, DA, glutamate, 5HT, and adrenergic pathways involved with early mobilization, sensory impairment, and noise reduction. A decrease in ACh which can occur with anticholinergic medications can cause a central cholinergic deficit and sleep disruption (Lorenzo et al., 2013). Metabolic imbalances, hypoxia and

hypoglycemia are mechanisms that can cause neurotransmitter imbalances and lead to delirium (Mittal et al., 2012). Trauma, surgery, and severe illness can cause physiological stressors increasing activity of the limbic hypothalamic pituitary adrenocortical axis and change BBB permeability, increasing cortisol level and causing delirium (Mittal et al., 2012). Music listening can reduce anxiety and reduce vital signs (Lorenzo et al., 2013). A physiologic reaction to music takes place in the brain through the neurotransmitter GABA where uncontrolled neuronal discharge often seen with stress is synchronized in response to a slow musical stimulus resulting in a calming effect (Hunter, Schellenberg, & Schimmack, 2010).

Music Listening for Delirium Prevention

A music intervention builds on non-pharmacologic approaches for delirium prevention by addressing the pathophysiologic mechanisms that contribute to delirium; neurotransmitter imbalance, inflammation, and acute physiological stressors (Inouye et al., 2014; Mora et al., 2012; Siritunga, Wijewardena, Ekanayaka, & Mudunkotuwa, 2013). They are measured through the CAM-ICU as the primary outcome being delirium.

Neuroscience of Music

Music has been researched over the last two decades as a stimulus that under controlled conditions can restore, maintain and improve patients physiological, psychological, and emotional health (Joanna Briggs Institute, 2011). The mechanism of action for processing music in the brain begins with acoustic information that is translated into neural activity inside the cochlea in the basilar membrane which triggers microscopic hair cells which signal the release of the first neurotransmitter glutamate.

Glutamate activates sensory neurons in the auditory nerve. The auditory nerve channels an electrical interpretation of the musical sound into neural responses which travel to the auditory brainstem where sound triggered motor neurons are located above each ear (Koelsch & Siebel, 2005). The auditory brainstem processes the neural responses which then travel to the hypothalamus and the auditory cortex (Koelsch & Siebel, 2005). Music activates the limbic system found in the temporal lobes of the brain near the auditory cortex where music and sound are processed (Lemonick, 2003). Interconnected neural structures located in the limbic system encircle the cerebral hemispheres situated on the brainstem (Schneck & Berger, 2006). The amygdala processes information from visual, auditory, and somato sensory areas of the brain and reacts to stimuli (Krout, 2007). The hippocampus is responsible for memory, which is important for recall of previous relaxed feelings with music listening (Schneck & Berger, 2006). The hypothalamus controls the autonomic and physiological response to emotional stimuli, influencing the Autonomic Nervous System (ANS) by responding to musical rhythms that promote relaxation. Brain activity during analysis of melodies takes place in the anterior and posterior superior temporal lobes bilaterally with greater activation of the right hemisphere (Warren, 2008). The anterior temporal lobe and insula of the auditory cortex are responsible for nonverbal sounds including familiar music (Warren, 2008). Emotional responses are mediated through the amygdale, hippocampus, subcortical and cortical connections of the limbic system (Schneck & Berger, 2006). The auditory cortex registers specific acoustic information including pitch, chroma, timbre, intensity, and roughness (Koelsch & Siebel, 2005; Warren, 2008). Physiological measures are mediated by tempo and slow music which can result in a decrease or increase in HR, respiratory rate (RR), and BP.

Brainstem neurons fire synchronously with tempo and rhythm altering cerebellum basal ganglia (Chanda & Levitin, 2013). Music changes brainstem mediated measures including HR, BP, body temperature, skin conduction, and muscle tension (Chanda & Levitin, 2013). With different musical elements, blood flow is increased in the frontal lobes of the brain within the NAc which stores the neurotransmitter DA. Music is channeled through the neurotransmitter DA influencing hormones, cells, and physiological measures of BP. Neurons carry messages through the brain and stimulate the release of neurotransmitters and hormones, activating the PNS causing HR to slow (Koelsch et al., 2011).

Gangrade (2012) conducted a review of literature examining the relationship between music and mechanisms of biologic response through stress hormones, cytokines, and neurotransmitters. The majority of studies reviewed examined the direct involvement of messengers including neurotransmitters, cytokines, stress hormones, and proteins, and how music causes biological responses to stress, emotion, and immune function, acting as a stimulator or inhibitor of messenger pathways in the body (Gangrade, 2012).

Okada and colleagues (2009) examined the effects of music therapy on the ANS, plasma cytokine, and catecholamine's (adrenaline and NE) levels in geriatric patients with cerebrovascular disease (CVD), congestive heart failure (CHF), and dementia. Patients were randomized to a music therapy (MT) group and a non-music therapy (non-MT) group. The MT group received music therapy once a week for 45 minutes

times 10 sessions at a scheduled time from 11:00 a.m. to 11:45 a.m. by two experienced and licensed music therapists. Music therapy included well known Japanese nursery rhymes, folk songs, hymns, and recent Japanese popular music. Cardiac autonomic activity was assessed by heart rate variability (HRV), plasma cytokines, and catecholamine levels which were measured in both the MT group and non-MT group. The incidence of both acute CHF and acute exacerbations of chronic CHF were significantly lower in the MT group compared with the non-MT group (10.9% versus 34.4%, $p < 0.05$). The HRV parameters indicating parasympathetic activity were significantly increased and sympathetic activity was decreased in the MT group. The MT group had significantly lower plasma cytokine, adrenaline, and NE levels compared to the non-MT group. These findings support that music therapy can enhance parasympathetic activity and reduce plasma cytokine and catecholamine levels in older patients with CVD, CHF, and dementia (Okada et al., 2009).

A randomized controlled trial (RCT) was conducted in ten critically ill patients to identify mechanisms of music-induced relaxation using a special selection of slow movements of Mozart's piano sonatas. Musical elements included duration, dynamic, and tempo. Cortisol, cytokine, and sedation levels were measured before and at the end of a one hour music intervention. A slow movement of Mozart's piano sonatas significantly reduced the amount of sedative drugs, plasma concentrations of growth hormone increased, and IL-6, and epinephrine decreased, causing a significantly lower BP, and HR (Conrad et al., 2007).

A systematic review was conducted on the psycho neuro immunological effects of music, with attention to neurotransmitters, hormones, cytokines, and vital signs (Fancourt, Ockelford, & Belai, 2014). Sixty three studies published between 1953 and 2013 were included in the review. Of the 63 studies, 56 examined the psycho neuro immunological effects of music to a stress response (Fancourt et al., 2014). Fifteen studies examined the neurological response to music. Neurotransmitters epinephrine and NE were tested in 12 studies, with seven studies reporting no change in neurotransmitters to recorded music, and three studies found that relaxing prerecorded music decreased epinephrine and NE. Twenty studies recorded physiological parameters of BP, HR, and RR. Sixteen of the 20 studies found relaxing music decreased BP, HR, and RR (Fancourt et al., 2014).

History of Music

The concept of music as “medicine” began as a healing modality as early as preindustrial and in tribal societies (Chanda & Levitin, 2013). Music as a therapeutic intervention was introduced in the mid-20th century and in most Cultures for many centuries were used to heal, strengthen, and restore harmony to the soul (Davis & Jones, 2012). In the 1800s, Florence Nightingale reported that soldiers who were injured healed faster with soft music continuously playing in the background (Davis & Jones, 2012). She noticed that wind instrument pieces emitting a continuous sound were beneficial to patients healing, while instruments that did not provide a continuous sound did not benefit the healing process (Nilsson, 2008). In the late 1800s hospitals introduced

recorded music with the invention of the phonograph, with a more consistent use in the 1900s, where music was played when anesthesia and analgesia was administered Nilsson, 2008). In 1914 intraoperative music was first provided during surgery for patients to provide distraction and a calm environment (Nilsson, 2008). In 1926, the National Association for Music in Hospitals was established by a nurse who believed that music prescriptions or treatment was therapeutic in patient healing, especially the musical element of rhythm (Nilsson, 2008). In the 1960's music interventions were frequently used in psychiatric care, palliative care, neurology, intensive care settings, and pain management (Guetin et al., 2012). Music listening was considered suitable in an ICU environment as music required minimal energy from the patient, no focused concentration on a stimulus, and patients were able to self-administer or request the music (Heiderscheit, Chlan & Donley, 2011).

Review of Music Interventions

Music has been the focus of research over the last two decades as a stimulus that interacts with the brain (Lin et al., 2011; Lupien, McEwen, Gunnar, & Heim, 2009). A music intervention is a controlled manner of listening to music utilizing physiological, psychological, and emotional influence as a treatment modality for an illness or trauma (Biley, 2000). Music may be delivered as a health treatment modality by a credentialed music therapist (Bruscia, 1998), for personal listening, and through allied professionals including therapists, nurses, music practitioners, and creative art therapists (Krout, 2007). Music used for health related goals may be described as music medicine, music listening, or music stimulation (To, Bertolo, Dinh, Jichici, & Hamielec, 2013). Music can be delivered in a controlled manner using specific musical elements including sound,

rhythm, harmony, dynamic, and tempo to facilitate movement, positive interactions, and improve emotional or cognitive states (Bernatzky, Presch, Anderson, & Panksepp, 2011). Musical elements perceived by participants as relaxing include a slow and stable tempo (pace or speed), low volume, soft dynamics, absence of percussive and accented rhythms, gentle timbre (sound or tone color), and simple harmonic or chord progressions (Briggs, 2011; Nilsson, 2008). Music can regulate stress and emotions through reflexive brainstem responses caused by soothing musical compositions that include predictable dynamics, slow tempo, low pitch, and simple repetitive rhythms. Reflexive brainstem responses have been found to alter physiological responses, decreasing HR, RR, and systolic blood pressure (SBP) (To et al., 2013; Chanda & Levitin, 2013; Lin et al., 2011; Nightingale, Rodriguez, & Carnaby, 2013). Noradrenergic neurons in the brain stem and mid brain regulate the autonomic responses of HR, BP, RR, and cholinergic and DA neurotransmission (Chanda & Levitin, 2013; Lin et al., 2011). Neurotransmission responsible for causing a calming effect with music comes from the cerebral cortex, hypothalamus, limbic system, and insula, through changing levels of cortisol and catecholamine's (Nilsson, 2009; Lin et al., 2011). Adrenaline and NE increase blood flow to the muscle and increase cortisol resulting in an adrenal cascade which can be initiated by stress and anxiety (Krout, 2007). Calming music can inhibit this adrenal cascade and release of adrenaline and NE (Krout, 2007). A physiological reaction to music takes place in the brain through the neurotransmitter GABA where uncontrolled neuronal discharge often seen with stress is synchronized in response to a slow musical stimulus, resulting in a calming effect (Hunter, Schellenberg, & Schimmack, 2010).

Music listening was evaluated in patients, specifically tempo, rhythm, melodic structure, duration, and individual preference, to assess the effect of music in modulating stress with a reduction in cardiovascular and respiratory variables as primary outcomes (Bernardi, Porta, & Sleight, 2006). Slower tempos caused relaxation, with raga music causing a significant decrease in HR (increase in RR interval, $p < 0.01$) compared to baseline (Bernardi et al., 2006). The ratio of tempo to RR was close to the music structure in the slowest (raga and classical slow, about one breath for four crotchets). All changes in physiologic outcomes were related to tempo, not to music preference. Speed of the music rather than style decreased cardio respiratory responses (Bernardi et al., 2006).

Chanda & Levitin (2013) conducted a systematic review to examine the extent to which music improved health and wellbeing through neurochemical transmitters including DA, opioids, cortisol, CRH, ACTH, 5HT, and oxytocin. Listening to music with a slow tempo, low pitch, and no lyrics reduced stress and anxiety in healthy adults (Chanda & Levitin, 2013). One study measured the effects of music using physiological markers of stress (HR, BP, electro dermal activity, serum cortisol, epinephrine, and NE) with no significant changes reported (Chanda & Levitin, 2013). One study measured the effects of music on cortisol levels in patients who were awake during cerebral angiography. Music prevented increases in cortisol levels compared to silence (Chanda & Levitin, 2013). Patients who were highly anxious prior to a music intervention did prevent cortisol levels from increasing with the music intervention. One study compared administration of a benzodiazepine to a music intervention by a licensed music therapist prior to surgery, measuring anxiety using the Spielberger State Trait

Anxiety Inventory (STAI), with both groups receiving the same attention and care (Chanda & Levitin, 2013). There was a significant reduction in baseline anxiety and HR with the music group compared to the group who received benzodiazepines. There was a greater reduction in SBP in the benzodiazepine group compared to the music group, with no difference in diastolic blood pressure (DBP) (Chanda & Levitin, 2013).

Lai, Liao, Huang, Chen, & Peng (2013) conducted a RCT to compare the effects of music on the levels of pro-inflammatory cytokines IL-6, TNF- α , interleukin-10 (IL-10), HR, and mean arterial pressure (MAP) among healthcare workers. A total of 60 nurses were randomized to listen to stimulating music, sedating music, or rest groups for 30 minutes. The sedating music included three sedating musical pieces (1) Beethoven Piano Sonata No. 14 Moonlight, (2) Beethoven Romance for Violin No. 2 in F major, and (3) Mozart Andante from Piano Concerto No. 21 in C Major (CM music Records Co., 1992, Taipei). The musical tempos ranged from 60 to 80 beats per minute (BPM), minor tonalities, smooth melodies, and no dramatic change in volume or rhythm. All sedative music used in this study were demonstrated in previous studies to have effects on stressors among adults undergoing surgical procedures (Lai, Hwang, et al., 2008) and test anxiety (Lai, Chen, et al., 2008). The stimulating music had fast tempos ranging from 100 to 130 BPM, major tonalities, percussive qualities, and fast rhythms (Lai et al., 2013). Participants from each group had psycho neuro immunological parameters measured using enzyme-linked immune-sorbent assays. There were statistically significant differences between the stimulating and sedating music groups

($p = 0.02$) in MAP, with the stimulating group having higher MAP levels than the sedative music group. The sedative music group had no detectable levels of IL-6, TNF- α , and IL-10 which are measures of pro inflammatory cytokines (Lai et al., 2013).

Chang, Peng, Wang, and Lai, (2011) conducted a RCT to examine the effect of music on psychophysiological indices in patients awaiting cardiac catheterization examination in 54 subjects aged 47 to 70 years. Subjects were randomized to a music group who listened to 30 minutes of sedative music including six different musical pieces (piano, harp, orchestra, jazz, Chinese orchestra, and synthesizer). Music rhythm ranged from 60 to 80 BPM with slow tempos, minor tonalities, smooth melody lines, and no dramatic changes in volume and rhythm. The control group received quiet rest without music. There was a statistically significant difference in anxiety scores between music listening and quiet rest ($p = .003$). Both music and quiet rest groups had decreased HR ($p < .001$).

Lai and Good, (2005) conducted a RCT to examine the effects of soft music on sleep quality in older adult community dwelling men and women in Taiwan. Sixty older adults aged 60-83 years of age who had difficulty sleeping were recruited. Participants were given a choice of five types of Western music and one type of Chinese music. Western music included synthesizer (new age), harp (eclectic), piano (popular oldies), orchestra (classical), and slow jazz (Good & Chin, 1998). Chinese music included an orchestra of folk music (Good & Chin, 1998). Participants were asked to choose the type of music and listened for 45 minutes at bedtime for three weeks. Music listening resulted in significantly better sleep quality in the music group; longer sleep duration, shorter sleep latency, less sleep disturbance, and less daytime dysfunction ($p = 0.04 - 0.001$),

with sleep improving weekly over a cumulative period (Lai & Good, 2005). In the music group, mean HR was 75.5 ± 5.0 BPM before listening to music and significantly lower at 74.7 ± 5.0 BPM after ($t = 6.6, p = 0.001$). Respiratory rate was 15.2 ± 1.8 breathes per minute before music and significantly lower, 14.7 ± 1.8 breathes per minute after ($t = 6.2, p < 0.001$), sedative music elicited effects on the ANS (Lai & Good, 2005).

Koelsch et al., (2011) examined the effect of an instrumental music intervention on serum cortisol, ACTH, immunoglobulin A, and sedation requirements during total hip surgery. Forty participants were randomized to either a music treatment group consisting of a selection of 15 joyful instrumental pieces or a control group who received noise of breaking waves. Blood samples were obtained at six different time points; two hours before surgery, immediately before spinal anesthesia, directly after skin incision (30 min after application of spinal anesthesia), before skin closure, three hours, and 24 hours at the end of surgery. Patients in the treatment group who listened to music received less sedation and had lower cortisol levels compared to the control group during three operative time points (spinal anesthesia, skin incision, skin closure). Two hours before surgery cortisol levels did not differ between groups ($p = 0.61$). At time point two to four hours during the intraoperative period, cortisol levels were lower in the music compared to the control group. The lower cortisol levels remained in the music group compared to the treatment group during the entire intraoperative period. At three hours and two hours after surgery there was no difference in cortisol levels between groups (Koelsch et al., 2011). The majority of studies reviewed reported a music intervention can decrease cortisol levels. Maintaining normal cortisol levels by modifying stressors elicits the PNS to respond resulting in decreased HR, RR and BP (Fong et al., 2009; Krout, 2007).

To and colleagues (2013) evaluated the effectiveness of music listening in facilitating sedation vacation. Inclusion criteria were patients who were mechanically ventilated, sedated, and clinically able to take part in a sedation vacation protocol. The music group received a four hour session of Mozart piano sonatas with headphones and the control group received a four hour session of no music (silence) with headphones. Soothing musical compositions that included predictable dynamics, slow tempo, low pitch, and simple repetitive rhythms altered physiological responses, decreased HR, RR, and lowered SBP. The music group had a greater decline in HR ($p = .042$), but not in RR ($p = .081$), or SBP ($p = .653$) compared to the control group (To et al., 2013).

Summary

Use of music for therapeutic purposes has been practiced dating back six centuries before Christ (Guetin et al., 2012). Current use of music interventions in healthcare settings have been shown to promote physical and psychological health (Chanda & Levitin, 2013). Neural pathways responsible for causing a calming effect with music come from the cerebral cortex, hypothalamus, limbic system, and insula changing levels of cortisol and catecholamine's (Nilsson, 2009). There is a disruption of neuronal networks that cause delirium; the three leading mechanisms include neurotransmitter imbalance, acute physiological stressors, and inflammation. Music modulates brainstem mediated measures, including HR, RR, and BP (Chanda & Levitin, 2013). Relaxing music causes a decrease in HR, RR, and BP through tempo and slow music when the brainstem neurons fire synchronously with tempo. Noradrenergic neurons in the brainstem and midbrain regulate the autonomic responses of HR, RR, BP, cholinergic, and DA neurotransmission (Chanda & Levitin, 2013). Brainstem activation mediates

sensory and motor function through epinephrine, NE, and 5HT. Music offers a noninvasive approach compared to medication.

Music Intervention to Prevent Delirium

The following review was designed to evaluate the efficacy of a music intervention for delirium prevention among hospitalized older adults, including an analysis of (a) sample, (b) setting, (c) mode of intervention delivery, (d) characteristics of music, (e) theoretical perspective, (f) evaluation of treatment fidelity, (g) study design, (h) training interventionist, (i) delivery of treatment, (j) receipt of treatment, (k) enactment of treatment skills, and (l) outcome measures.

Literature review methods. A review of literature evaluating music interventions to prevent delirium in hospitalized older adults was conducted to characterize strengths and limitations of this body of literature. Procedures included manual and computerized literature database searches of articles in the English-language literature from 2000 to present. The following databases were initially accessed: MEDLINE, PubMed, CINAHL, PsycINFO, and EBSCO host. Key search terms used included alternative, delirium, anxiety, older adults, elderly, intensive care unit, trauma intensive care unit, music intervention, HR, BP, RR, cortisol, acute confusion, inflammation, stress response, neurotransmitter, neurotransmission, and pathophysiology, with search terms narrowed over time. The search was conducted using terms both separately and in combination with each other. Inclusion criteria for review included, (a) data-based publications focusing on music interventions to prevent delirium in adults greater than 55 years, and (b) outcome variables that addressed delirium in older adults. A manual search with the same inclusion criteria was conducted accessing music therapy

journals. Characteristics for the music search included studies with outcome measures of physiological parameters, anxiety, delirium, inflammation, stress response, neurotransmitter, neurotransmission, and pathophysiology. Music interventions consisted of recorded music. Variables used in this analysis included sample and setting, mode of intervention delivery, dose, characteristics of music, theoretical perspective, evaluation of fidelity, outcome measures, and study results. Seven research articles met criteria and were included in the review (Appendix A).

Review results.

Sample and setting. Studies reviewed evaluated the effect of music interventions among older patients; four were conducted in ICU settings (Chlan et al., 2013; Twiss, Seaver & McCaffrey, 2006; Sendelbach, Halm, Doran, Miller & Gaillard, 2006; Nilsson, 2009) and three were conducted in orthopedic units located in a large tertiary medical center in Southeast Florida (McCaffrey & Locsin, 2004; McCaffrey & Locsin, 2006; McCaffrey, 2009). Manuscripts reviewed did not address participant ethnicity, education level, or socioeconomic status (SES) (McCaffrey & Locsin, 2004; McCaffrey & Locsin 2006; McCaffrey, 2009). Three studies evaluated the effect of a music intervention among older patients undergoing cardiovascular surgery (Twiss et al., 2006; Sendelbach et al., 2006; Nilsson, 2009). Three studies evaluated the effect of a music intervention among older patients undergoing hip and knee surgery (McCaffrey & Locsin, 2004; McCaffrey & Locsin, 2006; McCaffrey, 2009). One study evaluated a music intervention for patients who were mechanically ventilated (Chlan et al., 2013). Age of participants ranged from 55 years through 82 years. Sample size for intervention group and control groups ranged from 11 participants to 373 participants. There were more male

participants (69.8% - 80.6%) versus female participants in both intervention and control groups (Sendelbach et al., 2006). There were a greater percentage of female participants versus male participants in both intervention and control groups (McCaffrey & Locsin, 2006; Twiss et al., 2006; McCaffrey, 2009; Chlan et al., 2013). Gender was not reported (McCaffrey and Locsin, 2004; Nilsson 2009).

Mode of intervention delivery. All manuscripts reviewed tested music interventions, primarily passive music listening. Mechanisms for intervention delivery varied across studies reviewed. Patient selected music was used in five of the seven studies (McCaffrey & Locsin, 2006; Sendelbach et al., 2006; Twiss et al., 2006; McCaffrey, 2009; McCaffrey & Locsin, 2004), and researcher selected music in two studies (Chlan et al., 2013; Nilsson, 2009). Twiss and colleagues (2006) had participants in the treatment group select music from a collection of six musical compact discs (CD) s. Sendelbach and colleagues (2006) gave patients in the treatment group a choice of easy listening, classical, and jazz music. Patients in the noise cancelling headphone (NCH) group were encouraged to wear the headphones whenever they wanted to block out noise, with both the NCH and the patient directed music (PDM) group self-initiating headphone use (Chlan et al., 2013).

Intervention dose and delivery varied across studies reviewed. Dose was measured by frequency and length of a music intervention provided in a 24 hour period. Dose of scheduled passive music ranged from 20 minutes twice per day to one hour four times per day, (McCaffrey & Locsin, 2004; McCaffrey, 2009; McCaffrey & Locsin, 2006; Sendelbach et al., 2006; Chlan et al., 2013; Twiss et al., 2006; Nilsson, 2009) with patients self-initiating additional music listening during hospitalization with no dose

limitation (Twiss et al., 2006; McCaffrey & Locsin, 2006; McCaffrey, 2009; McCaffrey & Locsin, 2004).

Characteristics of music. Characteristics of relaxing music included predictable dynamics, slow tempo (60 BPM), low pitch, and simple repetitive rhythms, all found to calm physiological responses; slow HR, slow RR and lower BP (To et al., 2013). Nilsson (2009) provided music that was soft and relaxing, 60 to 80 BPM with different melodies in new-age style for 30 minutes with a volume of 50 to 60 decibel (dB). Chlan et al., (2013) provided music played on piano, harp, guitar, and Native American flute. A CD of soothing lullaby music was played to the treatment group on arrival to the orthopedic floor from the recovery room (McCaffrey, 2009; McCaffrey & Locsin, 2004; & McCaffrey & Locsin, 2006). Once the patient was awake, they could choose from a list of musical selections (relaxing classical music, nature sounds, meditative music, lullaby) provided by the nurse caring for the patient. Sendelbach et al. (2006) used taped music to elicit a relaxation response, which included no dramatic changes, slow tempo, with easy listening, classical, and jazz as music choices. Twiss and colleagues, (2006) implemented music purchased from “Prescriptive Music Inc.”, (Prescriptive Music, Woodland Hills, CA; Prescriptive Music, 2004) which included six CDs with different types of music to relax and calm hospitalized patients. Music was characterized as familiar melodies from classical motion pictures, heartfelt originals inspired by letters from individuals, spontaneous piano improvisations prompted by real life experiences, piano music by Mozart, synthesized compositions blending thought and sense, and original and traditional compositions with cello and piano (Twiss et al., 2006).

Theoretical perspective. Two of the seven studies reviewed reported a theoretical perspective guiding intervention implementation and evaluation. Twiss and colleagues, (2006) utilized a framework guided by the work of Florence Nightingale, who proposed that nurses provided a therapeutic environment to care for the person, not the disease (Nightingale, 1992). Intervention critical inputs to produce the expected outcome included a therapeutic environment of self-selected music listening that was consistently provided throughout surgery and in the surgical intensive care area. Once awake, the treatment group could request that the music selection be changed and family members were encouraged to bring in the participant's favorite music. Sendelbach and colleagues (2006) used the Gate Control Theory to guide the effects of music therapy to reduce the pain experience by closing the gating mechanism. According to the Gate Control theory, pain impulses are transmitted from nerve receptor to synapses in the gray matter of the dorsal horns of the spinal cord. Synapses act as gate keepers that close to keep impulses from reaching the brain or open to allow impulses to enter and reach higher levels of conscious awareness of pain. Other sensory impulses can alter the gates from opening and or closing. Sensory impulses from music therapy may cause impulses from the brainstem to close the gating mechanism, resulting in pain reduction (Guetin et al., 2012; Nilsson, 2009; Sendelbach et al., 2006). Intervention critical inputs to produce the expected outcome included a music intervention that was delivered on tape by headphones for 20 minutes twice per day, in the morning (between 8 a.m. and 10 a.m.), and in the evening (between 4 p.m. and 9 p.m.) on postoperative day (POD) one through POD three. For both groups, measures for pain intensity, anxiety, HR, and BP were

obtained immediately before and after each 20 minute intervention period in a consistent fashion (Sendelbach et al., 2006).

Evaluation of treatment fidelity. Evaluation of treatment fidelity was used to ensure the intervention was implemented and evaluated as planned (Bellg et al., 2004). Treatment fidelity can be evaluated linking theory and application in five areas; study design, training interventionists, delivery of treatment, receipt of treatment, and enactment of treatment skills (Bellg et al., 2004).

Study design. All studies were RCTs. Inclusion criteria included participants age 55 years and older (McCaffrey & Loscin, 2004; McCaffrey & Locsin, 2006; McCaffrey, 2009; Twiss et al., 2006), having elective hip or knee surgery, (McCaffrey & Loscin, 2004; McCaffrey & Locsin, 2006; McCaffrey, 2009), elective non-emergent coronary artery bypass (CABG), or valve replacement surgery (Sendelbach et al., 2006; Nilsson, 2009; Twiss et al., 2006). Patients who were alert and oriented to time and place on admission could provide consent, and complete preoperative paperwork or surveys independently (McCaffrey & Loscin, 2004; McCaffrey & Locsin, 2006; McCaffrey, 2009; Twiss et al., 2007; Chlan, 2013; Nilsson, 2009; Sendelbach et al., 2006), were able to hear music played from a CD player (McCaffrey & Loscin, 2004; McCaffrey & Locsin, 2006; Twiss et al., 2007; Nilsson, 2009), passed a hearing test (McCaffrey, 2009), and not currently using a music therapy intervention (Twiss et al., 2006; Nilsson, 2009) were enrolled. Study approval was obtained from Institutional Review Boards (IRBs) in the states where the research was conducted.

Training interventionist. Standardization of training ensures that all providers will be trained in the same manner to ensure the intervention is delivered systematically

across providers, decreases the incidence of provider treatment interactions, and prevents differential outcomes by providers (Bellg et al., 2004). The majority of studies reviewed used trained interventionists to deliver intervention components. All studies used registered nurses (RN)s to deliver the intervention (McCaffrey & Locsin, 2004; McCaffrey, 2009; McCaffrey & Locsin, 2006; Sendelbach et al., 2006; Chlan et al., 2013; Twiss et al., 2006; Nilsson, 2009). Twiss et al., (2006) utilized a trained RN researcher to deliver the intervention, and Sendelbach et al., (2006) used two research assistants, both credentialed in integrated therapies (certified message therapist and a certified occupational therapist) or one of three RNs trained in the intervention and involved in the protocol, who stayed and delivered the study intervention and collected data. Nilsson (2009) trained three research nurses to deliver the intervention. Limited detail was provided on interventionist training protocol, length of training or how interventionists were evaluated (McCaffrey & Locsin, 2004; McCaffrey, 2009; McCaffrey & Locsin, 2006; Sendelbach et al., 2006; Chlan et al., 2013; Twiss et al., 2006; Nilsson, 2009).

Delivery of treatment. To reduce the effect of potential confounding factors on outcomes measured, a sign was posted outside the door of all patient rooms for both the treatment group and the control group stating the patient was listening to music and to stop back at a later time (Sendelbach et al., 2006), and not to disturb the patient (Nilsson, 2009). Both the intervention and the control groups had daily assessment visits by the same research nurse (Chlan et al., 2013). The research nurse visited both the treatment groups and control groups daily so the attention the participants received was the same (McCaffrey & Locsin, 2004; McCaffrey, 2009; McCaffrey & Locsin, 2006). Patients in

both the treatment and control groups received standard post op care following protocols developed by cardiovascular surgeons and nurses and the same pain and sedation measures for the first three days after surgery (Twiss et al., 2006). The same research nurse delivered 30 minutes of uninterrupted bed rest with music to the treatment group and 30 minutes of uninterrupted bed rest to the control group (Nilsson, 2009). A research nurse remained in the room during the total 30 minutes for both the treatment group and the control group to discreetly obtain data on any interruptions (Nilsson, 2009). Overall, among manuscripts reviewed treatment groups received a music intervention and the control groups received standard care for that unit (Twiss et al., 2006; McCaffrey & Locsin, 2006; McCaffrey, 2009; McCaffrey & Locsin, 2004). Two studies had the treatment group receive a music intervention and the control groups receive uninterrupted bed rest (Nilsson, 2009; Sendelbach et al., 2006). Chlan et al., (2013) evaluated two treatment groups, one receiving a music intervention, one using noise cancelling headphones, and a control group who received standard care for that unit. Standard care was defined as standard of care for that ICU unit. In the majority of studies reviewed, a CD player and headphones were used to deliver the music intervention (Sendelbach, 2006; Chlan et al., 2013; Twiss et al., 2006; McCaffrey & Locsin, 2006; McCaffrey, 2009; McCaffrey & Locsin, 2004). Nilsson (2009) delivered music through a music pillow connected to a media player (MP3). In the majority of studies reviewed, intervention delivery was monitored by research assistants who were RNs who rounded daily to ensure the CD players were working, that times for automatic starting of the CD matched the patient's preference, and the CD music played was preferred by the patient (McCaffrey & Locsin, 2004; McCaffrey & Locsin, 2006; McCaffrey, 2009). Nilsson

(2009) monitored intervention delivery by closing the patient door and posting a sign to prevent the patient from being disturbed by visitors and health care providers. Chlan and colleagues (2013) utilized an environmental scan form to be completed by the RNs caring for the patients to monitor overall activity level in the patient room each shift during the intervention delivery. Sedative exposure was established for all patients as a daily sedative drug intensity score and sedative dose frequency to account for all medication administered to patients from nonequivalent disparate drug classes (Chlan et al., 2013).

Receipt of treatment. To ensure participants were able to hear the music intervention, inclusion criteria included the ability to hear music played from a CD player (McCaffrey & Loscin, 2004; McCaffrey & Loscin, 2006; Twiss et al., 2007; Nilsson, 2009; McCaffrey, 2009). To validate that patient's understood study risks, benefits, and procedures, patients had to answer seven "yes" or "no" questions correctly to the research nurse. All seven answers had to be correct or the participants were released from the intervention (Chlan et al., 2013). The questions were not included in the study for review. To ensure participants comprehension in using CD players, headphones, and a music pillow to deliver music, participants were observed during self-initiating music for proper application of headphones, use of CD player (Sendelbach et al., 2006; McCaffrey & Loscin, 2004; McCaffrey & Loscin, 2006; McCaffrey, 2009; Twiss et al., 2006; Chlan et al., 2013), and use of a music pillow (Nilsson, 2009). Research assistants who were RNs rounded on the orthopedic unit daily to observe that patients were using the CD players correctly (McCaffrey and Loscin, 2004; McCaffrey & Loscin, 2006; McCaffrey, 2009). Small sample sizes were reported (McCaffrey 2009; Twiss et al., 2006;

Chlan et al., 2013). Chlan and colleagues (2013) conducted a power analysis calculation based on their target sample size of 286. Nilsson (2009) based their sample size on a previous study with the following assumptions concerning a one-way analysis for the primary end point: serum cortisol, significance level of 5%, power 80%, and estimated medium effect size of .30. There was difficulty in recruiting and retaining larger sample sizes with patients who were critically ill; patients were not able to concentrate to answer questions during interviews or surveys or develop long term interest in the study due to fatigue, change in medical condition, and state of sedation (Chlan et al., 2013; McCaffrey, 2009; Twiss et al., 2006). A total of 59 patients who developed chest pain, surgical and cardiovascular complications including infection, stroke, and disseminated intravascular coagulation during the study withdrew prior to study completion (Nilsson, 2009; McCaffrey & Locsin, 2006; Chlan et al., 2013). Of the three groups participating in the study, participants who withdrew included two who were unable to wear the headphones, three who disliked the equipment, two per family request, and three who gave no reason (Chlan et al., 2013). A total of 241 patients were included in the anxiety analysis for the three groups (82 received music, 76 received noise cancelling headphones, and 83 received usual care). Of the 241 patients, 132 were excluded due to missing data (< 2 anxiety measurements) resulting from patients being too sedated, too tired, and unable to respond to questions (Chlan et al., 2013). A total of 266 patients were included in the sedation analysis for the three groups (87 received music, 90 received NCH, and 89 received usual care). Of the 266 patients, 98 were excluded due to missing data (< 48 hours in the study) resulting from complications noted earlier (Chlan et al., 2013). Those patients who withdrew or were removed after completing at least 48

hours in the study were included in the analysis. Twiss and colleagues (2006) excluded 26 patients, 14 in the treatment group and 12 in the control group due to postoperative complications from surgery (infection, disseminated intravascular coagulation and stroke), but additional participants were recruited until a total of 60 participants completed the study (Twiss et al., 2006).

Enactment of treatment skills. Among the studies reviewed, there was limited attention to intervention enactment. One study used a data-logger system on the headphones that recorded each PDM session and total daily music listening time (Chlan et al., 2013). To ascertain the number of episodes of acute confusion experienced by participants, the nurse researcher read the nurses narrative notes. Consistency was achieved in nurse identified signs and symptoms of delirium and confusion by the researchers by reviewing their findings with the nursing staff caring for the participants (McCaffrey & Locsin, 2006).

Outcome measures. Outcome measures varied across studies reviewed but focused mainly on outcomes related to acute confusion, cognition, anxiety, physiologic parameters, and serum cortisol levels. The Mini Mental Status Exam (MMSE) was used to measure cognition and the Neelon and Champagne (NEECHAM) Confusion Scale was used to measure acute confusion or episodes of delirium in older patients after hip and knee surgery (McCaffrey, 2009; McCaffrey & Locsin, 2006; McCaffrey & Locsin, 2004). Four anxiety scales were used to measure the effects of a music intervention on anxiety (Twiss et al., 2009; Sendelbach et al., 2006; Chlan et al., 2013) and postoperative stress response (Nilsson, 2009). Two studies used the State Trait Anxiety Scale of the STAI to evaluate the effect of a music intervention on state anxiety (Sendelbach et al.,

2006; Twiss et al., 2006). The 100-mm visual analog scale (VAS-A) scale measured anxiety in mechanically ventilated patients (Chlan et al., 2013). A numeric rating scale (NRS) was used to score anxiety (Chlan et al., 2013 & Nilsson 2009). Physiologic outcomes including HR, SBP, DBP, and MAP (Sendelbach et al., 2006; Nilsson 2009) and serum cortisol levels were used to measure anxiety (Nilsson 2009). Heart rate was recorded from the bedside monitor and was defined as BPM. Blood pressure was measured indirectly from a noninvasive BP module in the monitor or via cuff BP. Research assistants were trained in BP measurements before data collection (Sendelbach et al., 2006). Mean arterial pressure, HR, and RR were measured by the GE Carescape Datex-Ohmeda monitor (GE Healthcare Anandic Medical Systems AG/SA, Diessenhofen, Switzerland) (Nilsson, 2009).

Outcomes of intervention: Major findings. Three studies evaluated the effect of music on acute confusion or episodes of delirium among older patients (McCaffrey, 2009; McCaffrey & Locsin, 2006; McCaffrey & Locsin, 2004). All reported patients who received a music intervention group had significantly fewer episodes of acute confusion and delirium when compared with a control group who received usual care (McCaffrey & Locsin, 2006; McCaffrey, 2009; McCaffrey & Locsin, 2004). McCaffrey (2009) reported patients who received a music intervention had significantly less cognitive decline, measured by the NEECHAM Confusion Scale when compared with a control group on day one ($t = 64.2$; $df = 1, 22$; $p = .000$), day two ($F = 156.7$, $df = 2$, $p = .002$), and day three ($t = 98.5$; $df = 1, 22$ $p = .000$). The control group had a

significantly greater decline in cognition immediately after surgery with improvement noted day two and three, while the treatment group had a significantly smaller decline in cognition all three days, indicating higher levels of cognitive function in the music listening group on day one and two. By day three, both groups were similar in cognitive function (McCaffrey, 2009). Four studies evaluating the effect of music on anxiety among older patients reported less anxiety in the music intervention group compared with the control group overall (Twiss et al., 2006; Sendelbach et al., 2006; Nilsson, 2009; Chlan et al., 2013). Anxiety was significantly lower in the music group than the control group from day one a.m. thru day two a.m. ($p > .001$), though there was no differences between groups in SBP ($p = .17$), DBP, ($p = .11$) or HR ($p = .76$) (Sendelbach et al., 2006). Nilsson (2009) reported no differences in pre-intervention values of serum cortisol, MAP, HR, RR, and anxiety levels. After 30 minutes of bed rest there was a significant difference in serum cortisol levels between the two groups: 484.4 millimole per liter (mmol/L) in the music group and 618.8 mmol/L in the control group ($p < .02$). There was no difference after one hour of bed rest in both groups. A decrease over time compared with baseline levels was seen in RR ($p < .005$) and MAP ($p < .002$) in the music group but not in the control group. Anxiety levels decreased over time in the music group ($p < .004$) and the control group ($p < .037$) (Nilsson, 2009). As a result of reduced anxiety, less sedation was used in patients who received mechanical ventilation in both groups, making these findings the first RCT to test an integrative therapy for self-management of anxiety in mechanically ventilated patients (Chlan et al., 2013).

Summary of strengths and limitations. All studies reviewed were RCTs. All studies took place in acute care settings with older adults. Although this review included

a small number of studies, it is representative of current studies with a music intervention among older adults. Delirium is more prevalent in older adults, with the highest rate of delirium occurring in ICU settings. Thus, the ICU environment is relevant for intervention delivery with different approaches to preventing delirium (intervention efficacy) in a high risk environment. Delirium is a frequent post-operative risk in older patients undergoing surgery and is specifically related to poor outcomes in older patients having surgery (Twiss et al., 2006; Sendelbach et al., 2006; Nilsson, 2009; McCaffrey & Locsin, 2004; McCaffrey & Locsin, 2006; McCaffrey, 2009). To ensure fidelity delivery all music interventions were delivered by nurses at the bedside (McCaffrey & Locsin, 2004; McCaffrey, 2009; McCaffrey & Locsin, 2006; Sendelbach et al., 2006; Chlan et al., 2013; Twiss et al., 2006; Nilsson, 2009). The nurses who delivered the music interventions worked on the nursing units and were familiar with unit protocols, procedures and equipment. Fifteen minutes prior to a scheduled music intervention, the research nurses assisted patients into bed having them lie on their back in a relaxed position with the head of bed at 20 to 30 degrees (Nilsson, 2009). Patients who received music had the music distributed through a music pillow (Nilsson, 2009). It was the research nurses perception that acceptability of a music intervention was higher with self-selected music, assuring music that was familiar, pleasant, and calming to the patient (McCaffrey & Locsin, 2006; Sendelbach et al., 2006; Twiss et al., 2006; McCaffrey, 2009; McCaffrey & Locsin, 2004). Familiar music redirected the patient to soothing and comforting stimuli versus strange and unfamiliar noises in an ICU setting. With familiar music patients were able to reminisce about happy memories (Twiss et al., 2006;

McCaffrey & Locsin, 2004; McCaffrey & Locsin, 2006; Sendelbach et al., 2006; McCaffrey, 2009).

Compared to baseline levels, there was a statistically significant change in RR ($p < .005$) and MAP ($p < .002$) overtime in the treatment group who received a music intervention compared to the control group (Nilsson, 2009). Among studies reviewed, musical elements that promoted relaxation included music that was soft with a slow tempo (Nilsson, 2009; Chlan et al., 2013; McCaffrey, 2009; McCaffrey & Locsin, 2004; McCaffrey & Locsin, 2006; Sendelbach et al., 2006 & Twiss et al., 2006), and low volume, between 50 to 60 dB (Chlan et al., 2013).

The dose and duration of music listening varied, confounding the causal link between intervention and outcomes. The majority of music interventions provided music from 20 to 30 minutes in length. The dose and the duration of music interventions varied, ranging from a minimum of 20 minutes twice per day (Sendelbach et al., 2006) to four hours daily (McCaffrey & Locsin, 2004), and self-initiated by the patient during their hospitalization (Twiss et al., 2006). Dose of passive music interventions included 20 minutes (Sendelbach et al., 2006), 30 minutes (Nilsson, 2009), 60 minutes, four times per day (McCaffrey & Locsin, 2006; McCaffrey, 2009; McCaffrey & Locsin, 2004), and continuous throughout the day per participants request (Twiss et al., 2006). Nilsson (2009) had the treatment group listen to music for 30 minutes during bed rest ($n = 20$) and the control group received bed rest only ($n = 20$). Sendelbach and colleagues (2006) randomized patients to one of two groups; with the treatment group receiving 20 minutes of music intervention twice per day in the morning between 8 a.m. and 10 a.m. and in the afternoon between 4 p.m. and 9 p.m. from POD one through POD three. The control

group received 20 minutes of rest in bed. The hours were chosen as the authors felt there would be less patient interruption at those times.

Attention is needed to determine the optimal intervention music dose for older adults in an ICU setting. There have been studies on dose and duration in young adult musicians and in outpatient settings, but not in older adults in an ICU setting. Nightingale and colleagues (2013) conducted a systematic review and meta-analysis of 13 RCTs of music interventions to reduce anxiety in adult cancer patients undergoing medical oncology treatment, with two in an inpatient setting, and the remaining 11 in an outpatient setting. Mean age ranged from 51 to 63 years. The majority of music interventions allowed patients to choose their music, four studies employed certified or trained music therapist to instruct the patients on the music exercise. Seven studies delivered a music intervention only during medical oncology treatment. Two studies delivered a music intervention while waiting and during the medical oncology treatment. The remaining four studies delivered music for patients while they were waiting for the oncology treatment, during their hospital stay, and over the course of the treatment (Nightingale et al., 2013). Six studies (85%) noted significantly less anxiety in the music intervention group compared to the control group post intervention. Duration of the music intervention varied depending on the course of the cancer treatment, with 10 studies ranging from five to forty minutes, one study having a four hour duration, and two not indicating duration (Nightingale et al., 2013). Dose of music interventions varied, eight studies delivered one session of a music intervention, one delivered eight sessions, and one delivered five sessions. Two studies delivered a music intervention any time over the course of the oncology treatment, and one did not specify. Nine studies

delivered music through headphones or earphones, three delivered live music, and one did not specify method of delivery. Of the two studies that took place in a hospital setting, both utilized a music therapist to deliver the music intervention, one twice a week for four weeks, each 45 minutes, and the other 20-30 minute sessions during the hospital stay with a median of five sessions during a median of 10 days. Both study results had a statistically significant decrease in anxiety with the treatment group who listened to music versus usual care. Of the seven who listened to music through headphones, five noted statistically less anxiety in the treatment group than the usual care group (Nightingale et al., 2013).

Nilsson (2008) conducted a systematic review of RCTs assessing effects of music interventions on perioperative patients' pain and anxiety. Forty two studies included a total of 3936 patients, number of patients in the study ranging from nine to 500, with a mean age from 34 to 76 years who met inclusion criteria. Of the studies reviewed, duration of preoperative or postoperative music listening lasted from five minutes to four hours; 17 studies had music doses ranging from 15 to 30 minutes, intra-operatively. Eleven studies played music during the entire surgical period; four did not report a music dose. In 12 of the 24 (50%) studies where music listening for anxiety was measured, a music intervention significantly decreased anxiety scores (Nilsson, 2008). There were several effective music doses ranging from 20 minutes to continuous, yet there was no established dose of a music intervention in the literature for young and older adults. There have been studies on dose and duration in young adult musicians in non-hospital settings with ages ranging from 23–25 years (Bernardi et al., 2006). Bernardi and

colleagues (2006) assessed for changes in stress through physiologic measures of BP, and HR induced by music, specifically tempo, rhythm, melodic structure, pause, and individual preference for a total of eight minutes with a random two minute pause with 12 practicing musicians and 12 age matching controls between ages 23-25 years. Bernardi and colleagues (2006) found that a musical pause decreased HR, BP, and minute ventilation, even below baseline and slow or meditative music caused a relaxing effect. Nilsson (2009) provided one music intervention for 30 minutes, with one type of music offered. The one time dose of the music intervention may have been a factor in not having any statistical differences on anxiety levels between the two groups during rest. Documentation of music's effects on patients related to correct dose (volume, time period, and elements of music) is also limited in research studies (Nilsson, 2008).

One study that used standardized monitoring devices to measure vital signs had their equipment calibrated and tested annually by the bioengineering departments at the hospital (Sendelbach et al., 2006). To ascertain the number of episodes of acute confusion experienced by participants, the nurse researcher audited the nurse's narrative notes. Consistency was achieved in nurse identified signs and symptoms of delirium and confusion by the researchers through reviewing their findings with the nursing staff caring for the patients (McCaffrey & Locsin, 2006). To decrease variability in intervention delivery, the majority of studies reviewed used trained interventionists to deliver intervention components.

To monitor delivery of the music intervention, Chlan et al. (2013) utilized an environmental scan form to be completed by the RNs caring for patients to monitor overall activity level in the patient room each shift during the intervention delivery.

Sedative exposure was established for all patients as a daily sedative drug intensity score and sedative dose frequency to account for all medication administered to patients from nonequivalent disparate drug classes (Chlan et al., 2013). To add clarity to the delivery of the music intervention a standardized protocol was used to provide standardized postoperative care developed by the cardiovascular surgeons and nurses for all participants in both the treatment and the control group (Twiss et al., 2006). To enhance reliability and validity of outcome measures all tools used had proven demonstrated reliability and validity in previous research. The MMSE was used to measure cognition, and the NEECHAM Acute Confusion Scale was used to measure acute confusion or episodes of delirium in older patients. The State Anxiety Scale of the STAI was used to evaluate the effect of a music intervention on state anxiety, The VAS-A scale was used to measure anxiety, and a numeric rating scale NRS was used to measure anxiety.

Physiologic outcomes included HR, SBP, DBP, MAP (Sendelbach et al., 2006; Nilsson, 2009), and serum cortisol levels to measure anxiety (Nilsson, 2009). An outcome measure consistently used in prior studies to detect delirium in ICU settings was the CAM-ICU, with an established reliability (Van den Boogaard et al., 2009; Guenther et al., 2010), and high sensitivity and validity in ventilated and non-ventilated patients (Barr et al, 2013: Van Eijk et al., 2009; Devlin et al., 2012). The CAM ICU is a tool that can be easily administered at the bedside with minimal training and can be used with patients encountering hearing and visual disturbances. Physiologic signs of anxiety including SBP, DBP, HR, and RR can also be measured at the bedside and is a procedure that nurses are already trained in and is relevant based on studies reviewed.

A limitation noted was that two studies used a theoretical perspective to guide program implementation and evaluation. Twiss and colleagues (2006) drew from the writings of Florence Nightingale, however there was not enough detail provided to determine how the theoretical framework guided operationalization of intervention. The purpose of a theory is to describe and explain how and why phenomena take place, and is used to organize and direct thought, observations, and actions (Sidani & Braden, 1998). For both studies, there was limited explanation of the processes that mediated the causal relationship between the intervention and the outcomes, though the studies did include specific interventions delivered to elicit the desired effects (Sidani & Braden, 1998).

A limitation noted that could explain why there were no differences between groups with SBP, DBP, and HR, was the physiological effects of beta-blockers and other cardiac medications (antihypertensive, digitalis) that alter SBP, DBP, and HR (Sendelbach et al., 2006). These medications were not collected during the study (Sendelbach et al., 2006). Beta blockers, digitalis, and anti-hypertensive medications can cause changes in HR and BP and can interact with music listening through medication induced physiological changes affecting study results.

Summary. Across studies reviewed, the incidence of delirium and acute confusion was a primary outcome. In studies measuring anxiety, acute confusion, or episodes of delirium, a music intervention significantly reduced anxiety scores (Twiss et al., 2006; Nilsson, 2009; Sendelbach et al., 2006; Chlan et al., 2013), acute confusion, and episodes of delirium compared with a control group (McCaffrey, 2009; McCaffrey & Locsin, 2006; McCaffrey & Locsin, 2004). In studies where mechanically ventilated patients received a music intervention, patients required mechanical ventilation for a

shorter period of time and less sedation (Chlan et al., 2013). A music intervention was effective in decreasing post-operative delirium in older patients undergoing hip and knee surgery, along with higher readiness to ambulate scores, and patients getting out of bed sooner (McCaffrey, 2009; McCaffrey & Locsin, 2006; McCaffrey & Locsin, 2004). Music interventions have been effective in healthcare settings to decrease pain perception (Vaajoki, Pietila, Kankkunen & Vehvilainen-Julkunen, 2013; Cole & LoBiondo-Wood, 2014; Phipps, Carroll & Tsiantoulas, 2010; Nilsson, 2008) and decrease use of pharmacological sedation (Chlan & Heiderscheidt, 2009; Chlan, Engeland, Anthony, & Guttormson, 2007; Lee, Chung, Chan, & Chan, 2005; To et al., 2013) Anxiety and depression have been decreased with a music intervention (Chlan et al., 2013; Korhan, Khorshid, & Uyar, 2011; Nilsson, 2008), as well as promoting relaxation (Krout, 2007; Azoulay, Chaize, & Kentish-Barnes, 2013). There are few studies evaluating music interventions in ICU settings to prevent delirium among older adults (McCaffrey & Locsin, 2004). The proposed research added to the strengths of previous research in this field by:

1. Conducting a RCT to add to the body of nursing research.
2. Providing a music intervention including music compositions with musical elements of slow tempo (60-80 BPM), smooth rhythm, and no dramatic change in volume and rhythm, designed to decrease SBP, DBP, HR, and RR and influence reminiscence of music that evoked comfort.

The proposed research addressed the limitation of research in this field by:

1. Examining use of a music intervention to measure physiological parameters for delirium prevention among older adults in a TICU and TOU environment which are

considered high risk environments due to increased noise stimuli, frequent interruptions for procedures, lab work, medication administration, and increased visual stimuli.

2. Providing a music intervention utilizing a theoretical framework to guide program implementation.

Purpose

The purpose of the proposed research was to (1) evaluate the feasibility of a music intervention for delirium prevention in a TICU and TOU setting and (2) evaluate the effects of a music intervention for delirium prevention.

Measurable Outcomes

Physiological signs measured included SBP, DBP, HR, and RR, which were electronically monitored every four hours for the study. The CAM-ICU was used to identify delirium in patients admitted to TICU and the TOU setting. Patients were assessed using the CAM-ICU on admission and at the beginning of every shift or every 12 hours as standard of care in a TICU and TOU setting.

Specific Research Aims

This feasibility study evaluated the acceptability, demand, implementation, and efficacy testing of a theory-based music intervention to prevent delirium among older patients in a TICU and TOU setting. Acceptability was evaluated based on survey feedback from the participants. Demand was evaluated based on participant attrition rates and dose of music intervention sessions. Implementation was evaluated based on the degree, likelihood, and manner in which an intervention is fully implemented as planned and proposed (Bowen et al., 2009). The Roy Adaptation Model provided a theoretical basis for the development and testing of a music intervention designed to

prevent delirium among older adults hospitalized in a TICU and TOU setting. The effects of this feasibility study in health promotion interventions guided evaluation of intervention implementation. Feasibility studies produce results that add to research to determine whether an intervention should be further tested for efficacy and to prepare for full scale research resulting in an intervention (Bowen et al., 2009).

Specific Aim 1. Examine the acceptability, demand, implementation, and efficacy testing of a music intervention among older adult patients in a TICU And TOU setting.

1a. What is the acceptability of a music intervention in older adults as measured by participant evaluation of the intervention protocol and delivery mechanisms?

1b. What is the demand of the intervention in older adults as evaluated by measurement of participant attrition rates and dose of music intervention sessions?

1c. What is the implementation of the music intervention as evaluated by the Index of Procedural Consistency?

Specific Aim 2. Evaluate the effects of the music intervention in decreasing physiologic variables (SBP, DBP, HR, RR), and the health outcome of delirium prevention among older patients.

2a. Intervention participants will demonstrate a significant decrease in physiologic variables (SBP, DBP, HR, and RR) compared with a usual care group.

2b. Intervention participants will demonstrate significantly less delirium post-admission (CAM-ICU) compared with a usual care group.

Significance of the research. With changes in hospital reimbursement for preventable conditions including falls, and a projected increase in older hospitalized patients, there is a need for interventions to promote patient safety and decrease incidence of injuries. The Center for Medicare and Medicaid Services (CMS) introduced the Hospital Quality Initiative (HQI), focusing on visible and accountable healthcare. The Medicare Inpatient Prospective Payment System (IPPS) ruling for fiscal year 2010 through CMS added new reportable measures to its Reporting Hospital Quality Data for Annual Payment Update Program (RHQDAPU), increasing from 10 measures to 43 measures in 2010. With 15 nursing sensitive care measures introduced in 2004 by the American Nurses Association (ANA), new nursing sensitive care measures include restraint prevalence, falls prevalence, falls with injury, and pressure ulcer prevalence (Montalvo, 2009). The 2010 National Institute for Health and Clinical Excellence (NICE) guidelines are EBP recommendations for treatment and care in acute and elective care settings in hospitals. A delirium guideline was developed in July 2010 for delirium prevention and management with priorities including risk factor assessment, presenting indicators of delirium, and interventions to prevent delirium. Interventions to prevent delirium included frequent reorientation, early mobilization, music therapy, non-verbal pain assessment, noise reduction, scheduled quiet time, sleep promotion, and hearing and visual aids to improve sensory impairment (Young, Murthy, Westby, Akunne, & O'Mahony, 2010).

Relevance to nursing science. As early as the 19th century Florence Nightingale identified the significance of the physical and social environment in individual health and wellbeing (Reed & Shearer, 2011). In the ontology of nursing science, human beings and their life experiences cannot be separated, and are in a continuous relationship with the environment, selves, thoughts, feelings, and choices. In chronic and acute illness and in life situations when adaptive processes are threatened, understanding ways that adaptation can be promoted is essential (Roy & Andrews, 1999).

According to Roy, nursing knowledge is based on understanding how individuals adapt within given life situations (Roy & Andrews, 1991). Assumptions underlying the Roy Adaptation Model are that individuals are capable of adaptation even when they are dependent on the nurse and their health is compromised (Roy & Andrews, 1991). Research is a scientific process that validates and refines existing knowledge, and generates new knowledge that directly and indirectly influences nursing practice. The proposed research will contribute to the body of nursing science in delirium prevention by operationalizing a theory-based intervention to guide practice. Utilizing theory is a method of validating a body of nursing knowledge and experiences, as well as generating new knowledge. The Roy Adaptation Model contributes to the body of nursing knowledge by focusing on the nature of change in individual or group adaptation using a holistic approach, as well as acknowledging a multifaceted response between physiological and psychological adaptive processes (Fawcett, 2005). The Roy Adaptation Model is congruent with the totality paradigm, which views human beings as bio-psycho-social-spiritual organisms who interact in a linear way with the environment.

Chapter 2

THEORETICAL FRAMEWORK

The Roy Adaptation Model was chosen as the theoretical framework guiding development and testing of a music intervention designed to prevent delirium among older adults hospitalized in an ICU setting. The Roy Adaptation Model proposed a general theory of an individual as an adaptive system with sub theories characterizing four adaptive modes: the theory of the physiological mode, the theory of the self-concept mode, the theory of the role function mode, and the theory of the interdependence mode (Roy & Roberts, 1981). The proposed research focused on the theory of the physiologic mode. Chapter Two will provide an overview of the Roy Adaptation Model, philosophic scientific assumptions, concepts central to the Roy Adaptation Model, theory of the problem, critical inputs, process variables, expected outcomes, extraneous factors, and implementation issues for use of the Roy Adaptation Model (Sidani & Braden, 1998, p.44).

Theoretical Framework

Theoretical models guide research, practice, and development of interventions that promote health (Fleury & Sidani, 2012). A theory can guide an intervention through conceptualizing the problem, specifying critical inputs and conditions that operationalize the theory, understanding the mechanisms or processes of behavior an intervention will target, and specifying relevant outcome variables (Fleury & Sidani, 2012). A theory provides a basis for the empirical, philosophical, and theoretical dimensions of nursing science (Reed and Shearer, 2011). Nursing knowledge continues to be developed by nurses who deliver hands on nursing. Nurse scientists collaboratively question and

challenge present nursing practice and strive to provide care that results in optimal health related outcomes. A theoretical framework provides a structure for the interpretation of behaviors, situations and events (Fawcett, 2005). Intervention theory specifies the problem of interest, and clarifies changes that take place as a result of the intervention, including achievement of desired outcomes (Sidani and Braden, 1998).

Roy adaptation model. The focus of the Roy Adaptation Model is the continuous interaction between the human adaptive system and the environment (Roy & Andrews, 1999). Adaptation is a process of promoting physiological, psychological, and social integrity leading to completeness or unity (Roy & Andrews, 1999). The concept of adaptation assumes people are open systems which respond to both internal and external stimuli (Roy and Andrews, 1999). Adaptation is influenced when the human adaptive system is unable to respond to stimuli from the internal and external environment in a manner that promotes health. The Roy Adaptation Model assumes the universal importance of promoting adaptation in both health and illness (Roy & Andrews, 1999).

Four meta-paradigm concepts of the Roy Adaptation Model include person, environment, health, and nursing. According to Roy (2009), “Person is defined as an adaptive system with cognator and regulator subsystems that act to maintain adaptation in four adaptive modes; role function; physiological/physical; self-concept/group identity; and interdependence” (p. 12). According to Roy (2009), “Environment is defined as all conditions, circumstances, and influences surrounding and affecting the development and behavior of persons and groups, with particular consideration of mutuality of person and earth resources” (p. 12). According to Roy (2009), “Health is defined as a state and process of being and becoming integrated and whole that reflects mutuality between

person and environment” (p. 12). Health can be viewed as a reflection of adaptation where health and illness coexist (Andrews & Roy, 1991a). According to Roy (2009), “Nursing is defined as a health care profession that focuses on human life processes and patterns of people, with a commitment to promote health and full life potential for individuals, families, groups, and global society” (p.3). An individual's health is not determined by the absence or presence of disease, it is determined by the use of processes that lead to patterns of integrity and the ability to move toward effective unity of the adaptive modes (Roy & Corliss, 1993).

Philosophical assumptions. Philosophical assumptions of the Roy Adaptation Model include values and beliefs congruent with the guiding principles of humanism, veritativity, and spirituality. Humanism proposes that humans (individuals and groups) share in creative power, behave purposefully, possess intrinsic holism, strive to maintain integrity and realize the need for relationships (Roy & Andrews, 1999). Promoting integrity of the system occurs through adaptation and interacting in a positive manner with the environment to promote health. Integrity is defined as the wholeness achieved by adapting to changes in the internal and external environment (Roy & Andrews, 1999). An ineffective response occurs when the human adaptive system responds to internal or external stimuli in a way that does not maintain integrity of the system (Roy, 1988; Roy and Andrews, 1999). Veritativity proposes that there is an absolute truth (Andrews & Roy, 1991a), agreement of the purpose of human kind, creativity for the common good, value, and meaning of life (Roy & Andrews, 1999). The philosophic principle of humanism recognizes individuals as striving to maintain integrity, behaving purposefully, and

possessing intrinsic wholeness (Roy & Andrews, 1999). Spirituality proposes that individuals and earth are one (Roy, 2009). In support of the philosophical assumption of spirituality, spiritual integrity is defined conceptually as “the need to know who one is so that one can be or exist with a sense of unity, meaning, and purposefulness in the universe” (Roy & Andrews, 1999, p. 101).

Scientific assumptions. The Roy Adaptation Model is a conceptual framework whose scientific assumptions are based on General Systems Theory and Adaptation Level Theory (Andrews & Roy, 1991a; Roy & Corliss, 1993). Roy (1976) stated that the scientific foundation for the Roy Adaptation Model initially came from the work of Helson (1964) and Von Bertalanffy (1968), with Helson remaining the parent theory for the origin of the Roy Adaptation Model concept of adaptation. Helson viewed adaptation as a dynamic state of equilibrium, including both heightened and lowered responses from autonomic and cognitive processes elicited by internal and external stimuli (Roy & Roberts, 1981). This concept involved a pooled effect of multiple influences termed focal, contextual, and residual stimuli (Roy, 1997). Roy revised her definition of the scientific assumptions underlying adaptation of the Roy Adaptation Model to broaden the view of person and environmental interactions which is the focus of nursing practice today (Roy, 1997). Roy further credits Nightingale’s beliefs on how to promote health existence and the proper use of the environment to aid in the natural reparative processes (Roy, 1997).

Concepts central to the model. The Roy Adaptation Model proposed a general theory of the individual as an adaptive system. Roy's metaparadigm includes concepts of human adaptive system, coping process, behavior, and adaptive modes (Fawcett, 2005).

Human adaptive system. The human adaptive system is defined as a whole with parts that function as a unity for some purpose (Roy & Andrew, 1999). Human adaptive systems can be an individual or a group who interact with the environment. The human adaptive system has thinking and feeling capacities rooted in consciousness and meaning by which they adjust effectively to changes in the environment (Roy & Andrew, 1999). The human adaptive system is in constant interaction with the internal and external environment whose purpose is to maintain integrity regardless of environmental stimuli (Roy, 2009). Stimuli represent the point of interaction between the human system and the internal or external environment (Roy & Andrews, 1999). A stimulus can emerge from the internal environment (internal stimulus) or the external environment (external stimulus) (Roy & Andrews, 1999). The Roy Adaptation Model promotes the ability of human adaptive systems to adjust effectively to changes in the environment and to create changes in the environment.

Coping process. Coping processes are defined as innate or acquired ways of interacting with a changing environment (Roy & Andrews, 1999). Innate coping processes have a genetic basis, and reflect autonomic processes (Roy & Andrews, 1999). Acquired coping processes are developed or learned through expected responses (Roy & Andrews, 1999). Life experiences and how individuals respond to stimuli influence expected responses (Roy & Andrews, 1999). Coping processes include four dimensions: regulator and cognator subsystems which are applied to individuals, and stabilizer and innovator subsystems which are applied to groups. The regulator subsystem processes internal and external stimuli through neural, chemical, and endocrine channels to produce a response (Roy & Andrews, 1999). Through the ANS, the regulator subsystem elicits

reflex actions that prepare an individual to respond and adapt to a stressful stimuli. This leads to psychomotor responses which activate a body response which is fed back as additional stimuli to the regulator (Roy & Andrews, 1999). The cognator coping subsystem includes emotional and cognitive channels that respond to a changing environment. Through an individual's emotions, defenses are used to obtain relief from anxiety by or through affective appraisal and attachments (Roy & Andrews, 1999).

Concept of behavior. The concept of behavior is defined as all responses of the human adaptive system including capacities, assets, knowledge, skills, abilities, and commitments (Roy & Andrews, 1999). The concept of behavior includes both adaptive response and ineffective response. Adaptive responses are behaviors that meet the goals of adaptation as it relates to the individual (Roy & Andrews, 1999). Ineffective responses are behaviors that in an immediate situation or if continued over time can threaten system survival (Roy & Andrews, 1999). The concept of adaptation levels includes integrated life process, compensatory life process, and compromised life process (Roy & Andrews, 1999). The integrated life process reflects structure and function, working as a whole to meet individual needs. The compensatory life process level reflects cognator and regulator subsystems that activate due to an insult or threat. The compromised life process reflects ineffective coping systems that lead to a negative response (Roy 2009).

Adaptive modes. Adaptive modes reflect ways of behaving and manifesting adaptive processes (Roy, 1988). Adaptive modes include four dimensions: physiological/physical mode, role function mode, self-concept/group identity mode, and interdependence mode (Roy, 1988). The physiological-physical mode includes two components; the physiological mode which is applied to individuals, and the physical

mode which is applied to groups. The physiological mode reflects how individuals interact as physical beings with the environment, with behavior manifesting the physiological activities of cells, tissues, organs, and systems, with the underlying goal of physiological integrity (Roy & Andrews, 1999). The physiological mode applies propositions from the regulator subsystem to address the needs of the individual (Roy and Roberts, 1981). The physiological mode includes sub dimensions: oxygenation, nutrition, elimination, activity, rest, protection, senses, fluid, electrolyte, acid-base balance, neurological function, and endocrine function (Roy and Andrews, 1999). Relevant to the proposed study are the physiological sub dimensions of neurological function and endocrine function. Neurological function is made up of the CNS including brain and spinal cord and the PNS including cranial and spinal nerves. The PNS has afferent and efferent components; the efferent components include the ANS (Roy and Andrews, 1999). Endocrine function involves the ANS to integrate and maintain physiologic processes for normal growth, development, and to maintain structure and function (Roy and Andrews, 1999).

The role function mode reflects roles in human systems (Roy & Andrews, 1999) including the roles that an individual has in society with a basic need to maintain social integrity. Roy & Andrews (1999), defines “role” as a set of expectations about how individuals behave with the basic need to maintain social integrity (p.49). The self-concept mode reflects feelings and beliefs about self at a given time, formed from internal perceptions and perceptions of others (Roy, 1988). The interdependence mode reflects interpersonal relationships and the giving and receiving of love, respect, and value achieved through effective relations and communication (Roy & Andrews, 1999).

Significant others and support systems are part of the interdependence mode (Roy & Andrews, 1999).

Roy & Andrews (1999), defines a stimulus as that which causes a response or the point of interaction of the human system and the internal or external environment (p. 32). A stimulus can emerge from the internal environment (internal stimulus) or the external environment (external stimulus) (Roy & Andrews, 1999). Three types of stimuli include: focal, contextual, and residual. Focal stimuli represent the internal and external stimulus immediately confronting a human adaptive system. Contextual stimuli represent environmental factors, both internal and external, that contribute to the effect of the focal stimulus (Roy & Andrews, 1999). Residual stimuli are internal and external environmental factors whose influence may be unclear in the current situation (Andrews & Roy & 1991a).

Figure 1 provides a diagram of the Roy Adaptation Model proposing a general theory of the individual as an adaptive system which is in constant interaction with the internal and external environment. Customizable elements include (a) environmental stimuli (focal), (b) coping processes (regulator and cognator), (c) adaptation mode (physiologic mode), and (d) management of stimuli.

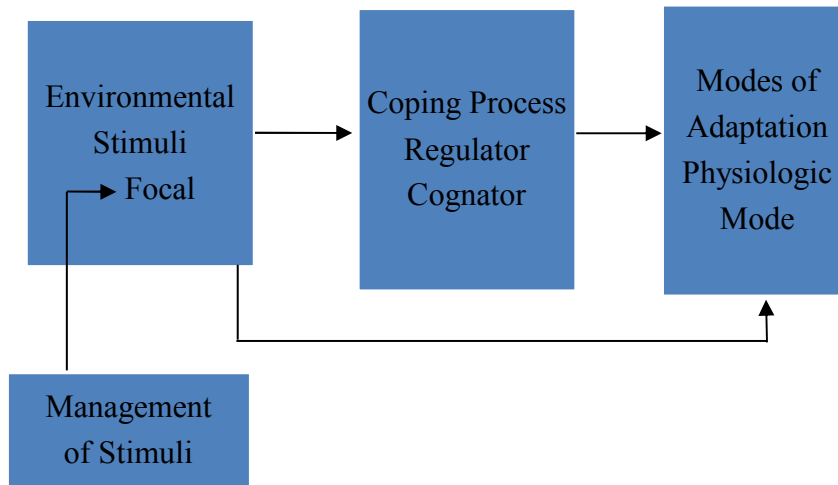


Figure 1. Roy Adaptation Model functional elements

Theory of the Problem

Focal stimuli foster changes in the internal and external environments (Roy & Andrews, 1999). A response to a focal stimuli involves physiologic changes including neuro, chemical and endocrine factors (Roy & Andrews, 1999) which contribute to an adaptive response or ineffective response. Focal stimuli can lead to delirium through inflammation, neurotransmitter imbalance, and physiologic stressors.

Acute illness, trauma, infection, and surgery can cause inflammation and result in delirium (Hipp & Ely, 2012). With infection, pro-inflammatory cytokines cause severe inflammation of the brain (Fong et al., 2009). With age, there is a low grade inflammation with chronic neurodegenerative changes in the brain, and decreases in DA, NE, ACH, and GABA neuro transmitters which increases the risk for delirium (Fong et al., 2009).

Iatrogenic factors such as medication can contribute to delirium through neurotransmitter imbalance. Sedatives, hypnotics, and anticholinergic medications used

in the ICU have deliriogenic effects (Hipp and Ely, 2012). The primary inhibitory neurotransmitter in the CNS, GABA exerts powerful effects across the brain (Fong et al, 2009). Several agents commonly prescribed in the ICU (benzodiazepines and propofol) are drawn to GABA receptors in key areas such as the brainstem, reducing CNS arousal, resulting in changes in neurotransmission and disruptions in cerebral function (MacLulich et al., 2008).

During stress, DA, ACh, NA and GABA are released. Stress hormones are released due to a stress response from surgery, pain, trauma, and systemic inflammation, and can cause and prolong delirium (Fong et al., 2009; MacLulich et al., 2008; MacLulich et al., 2013).

For adaptation to occur, an adaptive system needs to constantly grow and develop within a changing environment. Health needs relate to use of processes (music intervention) that lead to integrity of the individual and the ability to move toward an adaptive response. Focal stimuli (neurotransmitter imbalance, inflammation, and physiological stressors) from the internal and external environment serve as inputs to the human adaptive system and are processed by the regulator subsystem causing a response (Roy & Andrews, 1999). The goal of a nursing intervention in situations of health or illness is to maintain and enhance adaptive responses (Roy & Andrews, 1999).

Critical inputs. Critical inputs address the nature of the intervention and what is needed to produce the expected outcomes (Sidani & Braden, 1998). Critical inputs define the components making up the intervention, mode of delivery, strength, and dose of the intervention required to bring about the desired changes (Sidani & Braden, 1998). It is theorized that a music intervention will promote adaptation through the cognator and

regulator subsystems through altering focal stimuli. The critical inputs needed to produce the expected outcome include music compositions with musical elements of a slow tempo (60-80 BPM), simple repetitive rhythm, and no dramatic changes in volume and mode of delivery (To et al., 2013). These characteristics of relaxing music are found to calm physiological responses; slow HR, RR, and lower SBP (To et al., 2013).

Critical inputs of a music intervention with self-selected music will mediate a physiological response through the cognator subsystem where memory promotes reminiscence of music that brings comfort and pleasure to the individual. The emotional channel of the cognator subsystem is used to obtain relief from anxiety through affective appraisal and attachments (Roy & Andrews, 1999, p.47). The critical input of self-selected individualized music can reduce stress and agitation by evoking positive emotions through recall of positive memories (Guetin et al., 2012). The Nursing Intervention Classification (NIC) defines reminiscence therapy as “using the recall of past events, feelings, and thoughts to facilitate pleasure, quality of life, or adaptation to present circumstances” (McCloskey & Bulechek, 2000). The physiological mode of the regulator subsystem can activate the ANS through music listening that is self-selected causing joy through release of the neurotransmitter DA (Salimpoor, Benovoy, Larcher, Dagher, & Zatorre, 2011).

Critical inputs of the intervention of music listening are intended to alter focal stimuli through the regulator subsystem which processes internal and external stimuli through neural, chemical and endocrine channels to produce responses for delirium prevention. The regulator subsystem will enhance adaptation by eliciting a response through the physiological mode. The physiological mode measures physiologic variables

of BP, HR, and RR. Existing research on the biological effects of music involve physiological parameters of BP, HR, and RR to explain the process whereby music causes a biological response to a stressor (Gangrade, 2012). Music stimuli processed through the brain has a positive effect on both neural function and hormonal activity, including emotional responses involved in these processes (Gangrade, 2012).

It is proposed that neurochemical effects of tempo may affect the central neurotransmission underlying cardiovascular and respiratory control, motor function, and higher order cognitive function (Chanda & Levitin, 2013). A slow tempo is associated with a decrease in BP, HR, and RR, where a fast tempo is associated with an increase in these parameters due to neurons firing at the same rate with tempo (Chanda & Levitin, 2013). Music studies where music was chosen with tempos between 60 - 80 BPM, which was similar to an adult HR elicited an effective response to stressors by decreasing BP and HR (Chang et al., 2011; Sendelbach et al., 2006). Sandstrom and Russo (2010) compared recorded music of four different tempos and reported a reduction in HR with low tempo music.

Rhythm is defined as a process of timing of musical sounds and silences found in music. Rhythmic properties differentiate music with rhythm that is regular, irregular, and non-rhythmic (Chanda & Levitin, 2013). Rhythmic perception of music occurs in the basal ganglia which are involved in the processing of pleasant emotion. Stimulation of the basal ganglia occurs through the rhythm of music (Levitin & Tirovolas, 2009; Grahn, 2009; Schwartz, Keller, Patel, & Kotz, 2011). Rhythm can trigger specific neural processes which contribute to certain emotional states. Simple repetitive rhythm is associated with a decrease in BP, HR, and RR (Chanda & Levitin, 2013). The

physiological response to relaxing music is due to a complex neurophysiological phenomenon that affects the entire nervous system and stress hormones (Siritunga et al., 2013). Siritunga and colleagues (2013) examined the effect of Indian classical music on SBP, DBP, HR, and RR in 252 community adults aged 45 to 65 years, with 127 who listened to Indian classical music and 125 with no music who were asked to sit quietly in silence. There was a statistically significant reduction in SBP (8.53 mmHg), DBP (5.8 mmHg), HR (5.15 BPM), and RR (2.55 breaths per minute, ($p < 0.01$). Fancourt and colleagues (2014) conducted a systematic review to examine the psycho neuro-immunological effects of music; relaxing music decreased BP, HR, and RR in 16 out of 20 studies.

Mode of delivery for this study will include a passive music intervention with patients in a resting position listening to music with an iPod and headphones. An iPod is a line of portable media players and multi-purpose pocket computers designed and marketed by Apple Inc., Cupertino, California. The majority of music studies who used a passive mode of delivery involved use of headphones (Tang & Vezeau, 2010).

Process variables. Process variables represent a series of changes that occur with delivery of the intervention that lead to expected outcomes (Fleury & Sidani, 2012). The intended effect of a music intervention on process variables includes physiological responses consistent with adaptation to focal stimuli to prevent delirium, which is reflected in physiological changes that take place during delivery of a music intervention.

Expected outcomes. The primary outcome of a music intervention in this study is prevention of delirium. The Roy Adaptation Model specified the nature of the expected outcomes through an adaptive response. Adaptation takes place when the

regulator and cognator subsystem elicits a response as measured in the physiological mode, including physiological parameters of BP, HR, and RR. A music intervention is designed to treat the leading mechanism for delirium resulting in an adaptive response.

Extraneous factors. Extraneous factors may influence intervention delivery or the achievement of specific outcomes. Extraneous factors can be patient characteristics that affects treatment processes and intervention effectiveness in achieving the expected outcomes (Sidani & Braden, 1998). In an ICU environment, factors identified that might influence receipt of the music intervention included noise stimuli, bright lights, and interruption with care activities.

Implementation issues. Implementation issues are resources necessary for delivering the intervention. Resources can include setting, equipment, and personal and professional characteristics of the intervener that facilitate intervention delivery. As outlined in Chapter Three, the principal investigator (PI) was well versed in the intervention protocol to maintain consistency in delivery of the music intervention and adherence to the intervention protocol.

The Intervention Model illustrated in Table 1 outlines the components of the Roy Adaptation Model which consists of the theory of the problem, critical inputs, process variables, expected outcomes, extraneous factors, and implementation issues.

Table 1
Intervention Model

| Intervention Components of the Roy Adaptation Model | | | | | |
|--|--|--|--|--|--|
| Theory of the problem | Critical Inputs | Process Variables | Expected Outcomes | Extraneous Factors | Implementation Issues |
| Neuro-transmitter Imbalance Inflammation Physiological Stressors | Regulator subsystem Music Intervention (1) Slow tempo (2) Simple repetitive rhythm Cognator subsystem (1) Self selected music | Adaptive Physiological Response to Focal Stimuli SBP DBP HR RR | Adaptive Response: Prevent Delirium | Noise stimuli Bright lights Interruption from care | ICU setting Intervention Delivery Intervener |

Chapter 3

RESEARCH DESIGN AND METHODS

The Roy Adaptation Model provided a theoretical framework guiding the development and testing of a music intervention to prevent delirium among older adults hospitalized in a TICU and TOU setting. The Roy Adaptation Model proposed a general theory of a person as an adaptive system within a changing environment. Focal stimuli (neurotransmitter imbalance, inflammation, and physiological stressors) serve as inputs to the adaptive system and are processed by the regulator and cognator subsystems (Roy & Andrews, 1999, p. 43). Music interventions have been effective in healthcare settings to decrease pain perception (Vaajoki et al., 2013; Cole & LoBiondo-Wood, 2014; Phipps et al., 2010; Nilsson, 2008); enhance pharmacological sedation (Chlan & Heiderscheidt, 2009; Chlan et al., 2007; Lee et al., 2005; To et al., 2013), decrease anxiety (Chlan et al., 2013; Korhan et al., 2011; Nilsson, 2009), and increase relaxation (Krout, 2007; Azoulay et al., 2013). There is few music interventions designed to prevent delirium among older adults in ICU settings (McCaffrey & Locsin, 2004). Delirium is more prevalent in older adults, with the highest rate of delirium occurring in ICU settings (Inouye et al., 2014). Three studies have evaluated the effect of a music intervention on acute confusion or episodes of delirium among older patients; significantly fewer episodes of acute confusion and delirium were noted in patients who received a music intervention when compared with a usual care group (McCaffrey & Locsin, 2006; McCaffrey, 2009; McCaffrey & Locsin, 2004). Key musical elements included soft music with a slow tempo (Nilsson, 2009; Chlan et al., 2013; McCaffrey, 2009; McCaffrey & Locsin, 2004; & McCaffrey & Locsin, 2006; Sendelbach et al. 2006 &

Twiss et al., 2006), and low volume, (50 to 60 dB) (Chlan et al., 2013). Chapter Three presents the design of a music intervention feasibility study, including methods proposed and evaluation of acceptability, demand, implementation, and efficacy testing in preventing delirium among older adult patients in a TICU and TOU setting.

Research Design

This feasibility study used a RCT design. Findings from a RCT can be used to test aspects of intervention feasibility prior to a full-scale clinical trial (Bowen et al., 2009).

The Roy Adaptation Model provided a theoretical perspective for intervention design and evaluation, focusing on managing focal stimuli in a TICU and TOU setting through regulator and cognator subsystems (Roy and Andrews, 1999). The proposed research was designed to examine the acceptability, demand, implementation, and efficacy testing of a music intervention among older adult patients in a TICU and TOU setting.

Acceptability was evaluated based on survey feedback from the participants. Demand was evaluated based on participant attrition rates and dose of music intervention sessions. Implementation was evaluated based on the degree, likelihood, and manner in which the intervention was implemented as planned and proposed (Bowen et al., 2009).

The music intervention was tested with the goal of extending nursing science in the area of a theory-driven intervention to prevent delirium in older adults admitted to a TICU and TOU setting. A feasibility study produces a set of findings that assist in determining whether an intervention should be recommended for continued efficacy testing (Bowen et al., 2009). Dimensions of feasibility include acceptability, demand, implementation, and efficacy testing (Bowen et al., 2009).

Research Methods

Sample. The sample size included forty adults age 55 and older who were hospitalized and admitted to a TICU and a TOU setting in a community hospital. Inclusion criteria included: (1) oriented to person, time and place using the admission assessment, (2) CAM-ICU negative score on admission, (3) able to hear music played from an iPod shuffle, as evaluated using the whisper test, and (4) able to provide consent for study participation. The age of 55 years and older was chosen as older adults experience the highest reported incidence of delirium among ICU patients (Inouye et al., 2014). Exclusion criteria included: (1) patients younger than age 55, (2) not able to pass the whisper test, (3) intubated patients, and (4) CAM-ICU positive on admission. Patients who were intubated were not included due to a higher acuity level, report of higher anxiety scores despite sedation, and medications administered at high doses for prolonged periods, which could introduce bias in response to intervention and interpretation of results (Chlan et al., 2013). The proposed sample was 40 patients, 20 receiving the music intervention and 20 receiving usual care. An attrition rate of 30% was anticipated based on previous research evaluating the effects of a music intervention among older adults in an ICU setting (Chlan et al., 2013). Power analysis was conducted using Statistical Solution, LLC (2014); 20 participants were assigned to each group to evaluate treatment differences using mixed methods Analysis of Variance (ANOVA) with a power of .80, level of significance at $p = .10$, and an effect size of .4502. A p of .10 was used as this is appropriate for a feasibility study (Lee, Whitehead, Jacques, & Julious, 2014).

Effect size for the proposed study was based on delirium or acute confusion as the primary outcome (McCaffrey, 2009). In a music intervention reported by McCaffrey (2009), participants who received a music intervention had significantly less acute confusion when compared with a control group on day one ($t = 64.2$; $df = 1, 22$, $p = .000$), day two 2 ($F = 156.7$, $df = 2$; $p = .002$), and day three ($t = 98.5$; $df = 1, 22$; $p = .000$). This effect size is appropriate for this feasibility study given the goal of estimating an effect size for a larger scale RCT (Bowen et al., 2009).

Setting. The study was conducted in a TICU and a TOU setting at a Level One Trauma Rural Hospital. Honor Health John C. Lincoln Medical Center (HH-JCLMC) is part of the Honor Health Network, a not-for-profit organization that consists of five hospitals, physician practices and a spectrum of charitable community service programs. Honor Health John C. Lincoln Medical Center is a 266 bed community hospital in the north central area of Phoenix, Arizona. The Level One Trauma Center provides service for much of the northern portion of the city, and extends to other regions of Arizona. The TICU is a 22 bed trauma intensive care unit that has a 98% census rate. The patient population includes motor vehicle accident involving multiple injuries, closed head injury, bone fractures, respiratory failure, gunshot wounds, falls, strokes, drug overdose, alcohol intoxication, altered level of consciousness, and self-inflicted stab wounds and gunshot wounds. The TOU is a 37 bed trauma orthopedic unit that has a 99% census rate. The patient population includes trauma patients who are transferred from the TICU, motor vehicle accidents that do not require admission to the TICU based on acuity, falls, chronic obstructive pulmonary disease, bone fractures, altered level of consciousness and elective bone fractures requiring surgery. The patient population for both units is

comprised of Non-Hispanic Whites (73%), with other races (African American, American Indian/Native American, Asian Pacific, Hispanics) representing 27 % of the population.

Recruitment and retention. Recruitment was conducted by the PI in collaboration with the nursing staff and charge nurses in the TICU and the TOU setting each shift. Random assignment was used to assign participants to the music intervention group or the usual care group.

Data Collection Procedures

Data collection was standardized across intervention and usual care conditions for each of the three days, and took place in the TICU and the TOU at HH-JCLMC. Data was collected and entered into an electronic medical record (EMR) data base by a trained TICU and TOU RN as part of standard care. Data from the EMR was then entered into SPSS 23 spreadsheet by the PI. Data was double entered and verified for accuracy using SPSS 23 Compare Certification Procedure.

Screening

Potential participants were screened for study inclusion during face-to-face interviews on admission to both the TICU and TOU settings. Orientation on admission to time, place, and person was evaluated using an Orientation Screening tool, asking the participants the following questions; (1) What is your name, (2) Where are you right now, and (3) What year is it; with a score of 100% needed to pass. The CAM-ICU is an adaptation of the CAM and is a tool used in an ICU setting to assess for delirium (Van den Boogaard et al., 2009; Guenther et al., 2010). Delirium was evaluated using four diagnostic features of the CAM-ICU including fluctuation in mental status,

inattention, altered level of consciousness, and disorganized thinking. Hearing impairment was assessed with the whisper test, which determines the accuracy of the whispered voice in detecting hearing impairment in older adults (Pirozzo, Papinczak & Glasziou, 2003). The ability to provide consent was met if the participant met all inclusion criteria.

Informed Consent and Enrollment

The PI who trained in the study protocol and completed the Human Subjects certification met with each potential participant on admission to review risks, benefits, and options of study participation. Patients who were interested in participating and met inclusion criteria were invited to participate. Each eligible patient was given a written copy of the consent form to review. Informed consent was signed by the patient and the PI who obtained consent. The original consent was double locked in a secured office and file cabinet and a copy was given to the participant. See Appendix B to view a copy of the consent form. Participants were withdrawn from the study in the event of: (1) no longer willing to participate, (2) positive score on the CAM-ICU, or (3) a critical health event leading to intubation.

Human Subjects

All policies, regulations, and guidelines set forth in the Code of Federal Regulations and by the IRB of Arizona State University (ASU) were adhered to by the PI. An application to conduct the research study was submitted and approved by the ASU Office of Research Integrity and Assurance IRB. Please see Appendix C for the IRB Approval Letter from ASU, and Appendix D for the IRB Modification Approval Letter from ASU. An application to conduct the research study was submitted and

approved by the IRB at Scottsdale Healthcare Research Institute in Scottsdale, Arizona. Please see Appendix E for the IRB Approval Letter and Appendix F for the IRB Modification Approval Letter from Scottsdale Healthcare Research Institute. The study protocol was determined to be exempt in accordance with Federal Regulations 45 CFR Part 46.101 (b) (1) (2).

Random Assignment

Participants were randomly assigned to the music intervention group or the usual care group following informed consent, using a table of blocked random numbers generated from SPSS. Two blocks included lists of random treatment assignments for 40 participants assigned to each of two groups (20 in each group). Random assignment of selected participants to the music intervention group or the usual care group was intended to increase the likelihood that participants in the two groups would be similar at baseline; the influence of potential extraneous factors, including participant characteristics would be equally distributed across the two groups (Sidani & Braden, 1998). Random assignment supports initial group equivalence on all measured and unmeasured variables, reducing selection bias or systematic between group differences that may have been missed by the intervention (Sidani & Braden, 1998).

Music Intervention

Dose of the intervention reflected the amount, frequency, and duration of music intervention needed to produce changes in process variables (Fleury & Sidani, 2012). Amount was defined as the quantity of the treatment given. Frequency was the number of times the treatment was given over a specified period of time. Duration was the total length of time the intervention was implemented for the expected outcomes to be

achieved (Fleury & Sidani, 2012). In this study, a music intervention dose included intervention delivery for 60 minutes, two times per day, at 2 p.m. and 8 p.m., over a three day period following admission. Dose and duration for the intervention was consistent with previous music intervention research with a primary outcome of delirium prevention or a decrease in the incidence of acute confusion (McCaffrey, 2009). The average LOS in the TICU and the TOU settings, from admission to discharge supported the feasibility of the proposed intervention dose. Timing for delivery of the music intervention was based on recommendations from a consulting group of nurses who work in the TICU and TOU settings. It was felt by the group of nurses that there would be minimal interruptions from physician rounding, family visits and procedures with music intervention sessions scheduled at 2 p.m. and 8 p.m. There was some flexibility around the time points. Sendelbach and colleagues (2006) delivered a music intervention twice per day, in the morning between 8 a.m. and 10 a.m. and in the afternoon between 4 p.m. and 9 p.m. from POD one through POD three; due to less patient interruption at those times.

A music intervention was proposed to promote adaptation through the cognator and regulator subsystems, altering focal stimuli. Critical inputs of the music intervention included: (a) simple repetitive rhythm, (b) self-selection, and (c) slow tempo (60-80 BPM), designed to alter physiological responses including SBP, DBP, HR, and RR (To et al., 2013). Self-selected music was thought to mediate a physiologic response through the cognator subsystem, where memory promotes comfort and pleasure. The physiological mode of the regulator subsystem activates the ANS through music listening that is self-selected through release of the neurotransmitter DA (Salimpoor et al., 2011).

Music compositions including these critical inputs have been shown to be effective in reducing pro-inflammatory cytokines (Lai et al., 2013).

Study protocol. The usual care group received standard of care for the unit. The music intervention group received headphones and a numbered iPod shuffle (1, 2, 3, 4, or 5; fourth generation, Apple Inc., Cupertino, California), preloaded with 60 minutes of music. Volume on each player was set at 50-60 dB; participants were asked if the music was loud enough to hear. Following the same protocol the usual care group received standard of care for the unit. The iPods were stored in a locked cabinet in the PI's office. The PI obtained the iPod for patient use for each three day period and returned the iPods after each music intervention. Examples of music selections including musical elements; tempo (60-80 BPM) without accented beats, percussive characteristics, or syncopation are outlined in Table 2 (Lai & Good, 2002).

Table 2

Music Selections

| Style | Selection | Tape or CD | Artist |
|-------------|----------------------------|------------------|---------------------|
| Synthesizer | Selection #1 | Comfort Zone | Steven Halpern |
| Harp | Gnossienne #2 | Fresh Impression | Georgia Kelly |
| Piano | Gigi #3 | Nadia's Theme | Roger Williams |
| Orchestra | Symphony #4 | Beethoven | Cleveland Orchestra |
| Jazz | When Joanna Loved Me #5 | Easy Living | Paul Desmond |

A Music Intervention Protocol to instruct on the delivery of the music equipment is outlined in Table 3.

Table 3

Music Intervention Protocol

Day 1, day 2, and day 3 at 2 p.m. and 8 p.m., have patient choose from a list of music selections.

Choose the iPod with the appropriate music.

The PI will obtain the iPod from the locked file cabinet in the nurse's station.

Attach the headphones to the iPod.

Set the appropriate volume and check for patient comfort.

Ensure surroundings are quiet, dim lights.

Monitor patient while music is playing.

The music intervention will be stopped at the patient's request.

Play music for 60 minutes.

After 60 minutes remove the iPod and patient labeled headphones.

Leave patient headphone at bedside, return iPod to locked cabinet.

Training for Intervention Delivery

Intervention training included review of the study protocol outlining Instruction's for both the music intervention group and the usual care group. The PI delivered the intervention. Registered Nurses working in the TICU and the TOU are oriented in the use of the bedside monitoring devices during hire, orientation, and annually through an orientation fair held at HHJCLMC. Two weeks prior to the intervention, the investigator reviewed the intervention protocol with each RN through walking rounds and during shift huddles at 7 a.m. and 7 p.m., to answer questions and clarify responsibilities. Shift huddles are five-minute group meetings led by the charge nurse at the beginning of each shift; at this time the latest information relevant to the unit is disseminated. The huddles provide a quick way to communicate information important to the daily function of the unit.

Intervention Fidelity

Fidelity in intervention delivery refers to the intervention being delivered as designed (Sidani & Braden, 1998). Lack of intervention fidelity increases the risk of analysis error or concluding that the intervention is not effective when it has not been implemented as designed (Sidani & Braden, 1998). Fidelity is evaluated and maintained through strategies used to monitor and enhance conceptualization, intervention delivery, and testing (Fleury & Sidani, 2012). The RNs in both the TICU and the TOU settings were introduced to the theory underlying the problem of delirium, the music intervention, the protocol for intervention delivery, and any procedures specific to participant contact or follow up (Fleury & Sidani, 2012).

The music intervention design was central to maintaining fidelity and correcting drift from the intended protocol. The dose, frequency, content, and length of each session was standardized for this study. To reduce differences in intervention delivery with the music intervention and usual care groups, the PI who delivered both the music and usual care stayed on the unit outside of the patient's room during the 60 minutes but did not interrupt their music listening. The music intervention was stopped if the patient requested.

Variables and Measurement

Variables categorized as demographic characteristics, acceptability, demand, implementation, and efficacy testing were measured using standardized questionnaires and procedures.

Demographic characteristics. Demographic variables were measured to describe the target population. Demographics included: (a) gender, (b) age, (c) race, (d) marital status, (e) admission diagnosis, (f) co-morbid conditions, and (g) medications ordered on admission. Gender, age, race and marital status were obtained from the admission assessment in the EMR. Admission diagnosis was obtained from the physician admission assessment. Co-morbid conditions were obtained from the EMR database based on patient self report and physician admission assessment. All medications ordered by the prescribing physician for cardiovascular, respiratory, sedation, pain, anxiety and sleep aides were collected from the patients chart and entered on a data collection sheet in Microsoft Excel database on the day of admission.

Acceptability. The Acceptability Questionnaire was administered post-intervention to the music intervention participants. Intervention acceptability is a reflection of participant views, expectations, and preferences. Interventions that are acceptable are more likely to be adhered to (Bowen et al., 2009). An investigator-developed Acceptability Questionnaire was used to evaluate acceptability targeting two major aspects of the intervention and its domains: (a) intervention components (utility, effectiveness, credibility, and satisfaction); and (b) mode of delivery (format and strength). Participants were asked to what extent they agreed with items representing these aspects of the intervention using a scale ranging from 1 (strongly disagree) to 5 (strongly agree). Participants were also invited to describe how the program could be improved and if they would recommend a music intervention to others. Examination and analyses of the resulting narrative data informed intervention acceptability evaluation.

Demand. Details about study attendance and attrition (intervention demand) in a feasibility study provide a basis for refining future studies (Bowen et al., 2009). In this study an attendance log was used to track participation. An attrition log was used to record date and rationale for participants leaving the study, allowing the PI to evaluate acceptable and unacceptable intervention attributes. Attrition rates were calculated as the percentage of persons volunteering for the study and providing consent, but withdrawing from the study.

Implementation. Implementation was evaluated by the Index of Procedural Consistency, to determine the degree to which the intervention was delivered as planned. The PI scored each content area from one (achieved very little) to three (achieved very well) and a mean score was calculated. Field notes were maintained and reviewed for each intervention session, which included the time in minutes the patient listened to the music, whether the patient refused to listen to music and reason, missed intervention time-points, and music selection.

Physiological variables. Physiological data collected in the clinical setting included SBP, DBP, HR, and RR. Systolic blood pressure, DBP, HR, and RR were recorded from noninvasive bedside monitors and collected on admission to the TICU and TOU with the first set of vital signs taken during the initial assessment of the patient, and every four hours over a three day period. The 22 bed monitoring system used in the TICU setting was a Fukuda Denshi modular patient monitor system including electrocardiogram (EKG), temperature, RR, noninvasive BP, invasive BP, and HR monitoring device. The 37 bed monitoring system in the TOU was a Fukuda Denshi modular patient monitor including EKG, temperature, RR, noninvasive BP, invasive BP,

and HR monitoring device. The TICU and TOU monitoring systems were calibrated quarterly by the bioengineering unit at the hospital to ensure accuracy.

Heart rate was defined as the number of heart beats per minute (Lippincott, 2009). Respiratory rate was defined as the number of respirations (breaths) per minute (Lippincott, 2009). Blood pressure was defined as the pressure of the blood in the circulatory system, often measured for diagnosis since it is closely related to the force and rate of the heartbeat and the diameter and elasticity of the arterial walls (Lippincott, 2009).

CAM Score. The CAM-ICU was used to measure delirium in patients admitted to the TICU and the TOU setting. The CAM-ICU was assessed every twelve hours at the beginning of each shift; the two shifts were from 7 a.m. to 7 p.m. and 7 p.m. to 7 a.m., and were documented in the EMR. The CAM-ICU has established reliability as an assessment tool for delirium in ICU settings (Van den Boogaard et al., 2009; Guenther et al., 2010). Tate and Happ (2008) supported interrater reliability of the CAM-ICU (Kappa = 0.79 - 0.96), noting the CAM-ICU provided rapid information for the tester to identify delirium. The CAM-ICU has established sensitivity (97 - 100%) and specificity (88% - 100%) in validation studies with ICU mixed patient populations (Van Eijk et al., 2009; Vreeswijk et al., 2007; Toro et al., 2009; Wong, 2010). The CAM-ICU scale has been useful in identifying delirium in trauma ICU patients (67%) and surgical ICU patients (73%) (Pandharipande et al., 2008). The CAM-ICU is easy to administer with minimal training, and can be used with patients encountering hearing and visual disturbances. The RNs in the TICU and TOU were trained in use and application of the CAM-ICU. Introduction of the CAM-ICU took place September, 2011. Education for CAM-ICU

included the CAM-ICU worksheet, training manual, and CAM-ICU tool. Each RN was enrolled in a mandatory education learning module which included a module on delirium and use of the CAM-ICU. After the education roll out, the TICU and TOU educator conducted walking rounds to answer any questions regarding use of the CAM-ICU and to review application of the CAM-ICU. In August 2013, the CAM-ICU was placed into the EMR for use which included a mandatory education learning module in the use and completion of the CAM-ICU in the EMR.

Data Management and Analysis

Data collected during the study period, including consent forms and coded information, were stored under double lock and key in the PI's office. Data entered on a computer were stored on a secured password protected system at HH-JCLNM. Study participants were assigned an identification number generated from SPSS 23 for use during data analysis. Data was double entered into SPSS 23 files and analyzed using (SPSS version 23.0; Chicago, IL). After data entry was completed, files were compared using compare datasets in SPSS 23, discrepancies were identified and compared to the excel data sheets. Please see Table 4. To prevent the accidental modification or deletion of the data sets, both files were marked as read-only. Access to study data was limited to the PI.

Table 4

Matched Summary

| <i>Datasets Results</i> | <i>Statistics</i> | <i>Active</i> | <i>Comparison</i> |
|-------------------------|-------------------|---------------|-------------------|
| Cases | Count | 40 | 40 |
| Cases Compared | Count | 40 | 40 |
| | Percent | 100.0% | 100.0% |
| Cases Not Compared | Count | 0 | 0 |
| | Percent | 0.0% | 0.0% |

Data entry took place daily to monitor documentation of the CAM-ICU every 12 hours, and SBP, DBP, RR, and HR every four hours via the EMR used in the TICU and the TOU settings. Data input was reviewed weekly by the IT department at HH-JCLMC, with weekly feedback to the unit director and individually to the nurses who document in the EMR.

Specific Aim 1. Examine the acceptability, demand, and implementation of a music intervention among older patients in a TICU and TOU setting. Analysis was descriptive. Summary measures of means and standard deviation (SD) for continuous variables were examined and described. Acceptability intervention dose rate, missed intervention time sessions, and reasons for missed intervention sessions were described for the music intervention group. Evaluation of feasibility was summarized using frequencies and percentages. Means, standard deviations, and medians were used for continuous variables. Music dose was characterized in minutes, with dose and duration

for the intervention consistent with previous music intervention research with a primary outcome of delirium prevention or acute confusion (McCaffrey, 2009).

Specific Aim 2. Evaluate the effects of a music intervention in decreasing physiologic variables (SBP, DBP, HR, RR), and health outcome of delirium prevention among older patients. Analysis included:

1. Descriptive statistics to summarize demographic characteristics and major variables of interest.

2. Data were examined to evaluate normal distribution. If not normally distributed, data were examined for outliers. Missing data were examined for systematic patterns using SPSS 23 missing value analysis procedures. The missing values analysis procedure describes the pattern of missing data, location of missing values, how extensive, and are the values missing random.

3. A Chi Square test was conducted to examine for systematic differences on key baseline demographics (age, race, gender, and marital status), frequency, amount and type with both the music intervention group and the usual care group.

4. Frequencies were run on all medications that patients were prescribed in the music intervention group and the usual care group. Medication categories included cardiovascular, anti-anxiety, analgesics, sleep aid, and respiratory medications. A Chi Square test was conducted to examine for differences in the music group and the usual care group by medication categories.

5. A Pearson Product Correlation was computed to assess the relationship between age and SBP, DBP, HR, and RR at T1 (pre-test), T2 (day1, post-test), T3 (day2, post-test), and T4 (day 3, post-test), and anti-anxiety medication and

SBP, DBP, HR, and RR at T1, T2, T3, T4. Age is considered a non-modifiable risk factor that influences susceptibility for delirium (Banh, 2012; Theurekauf et al., 2012; Fong et al., 2009; Sanders, 2011). Age related changes in the brain alter neurotransmission, inflammation, and physiological stressors, predisposing older adults to delirium (Inouye et al., 2014). Anti-anxiety medication is considered a modifiable risk factor for delirium (Allen & Alexander 2012; Fong et al., 2009; Sanders, 2011). Sedatives and hypnotics most frequently used in ICU settings have potential deliriogenic effects that can impact delirium (Hipp & Ely, 2012)

6. Using multiple imputation, a mixed design ANOVA (repeated measures with a between subject factor) was completed to determine differences in the music intervention group and the usual care group across time. The within subjects factor were four different time points; T1, T2, T3, and T4, including SBP, DBP, HR, RR. Between subjects factor were two levels (1) music intervention group and (2) usual care group. Forty patients took part in the intervention. Of the 40 participants, 20 were randomly assigned to the music intervention group and 20 were assigned to the usual care group. Significance was set at ($p < .10$) for this analysis.

7. Measures were calculated on differences between T1, T2, T3, and T4. Paired sample *t*-tests were performed to assess differences between the music intervention group and usual care group overtime.

8. A *t*-test was calculated to determine the mean scores of the CAM-ICU between the music intervention group and the usual care group.

9. Cohen's d effect sizes for the covariates of age and anti-anxiety medication and SBP, DBP, HR, and RR and the physiologic variable RR for T1, T2, T3, and T4 were calculated by subtracting the mean of the music intervention group from mean of the usual care group and divided by the pooled standard deviation.

10. The effect size η^2 (Eta Squared) was calculated for between groups ANOVA by dividing the Treatment Sum of Squares by the Total Sum of Squares for the music intervention group and the usual care group. The effect size for a within subjects ANOVA was calculated by adding the Treatment Sum of Squares, plus the Error Sum of Squares, to equal the Total Sum of Squares, followed by dividing the Treatment Sum of Squares into the Total Sum of Squares.

Summary

As the population of older adults increase, risk for delirium in hospitalized older adults will also increase. A leading complication in a hospitalized older adult is delirium. This study evaluated the feasibility of music listening for delirium prevention among older patients in a critical care setting using a randomized controlled trial. Research design and methods allow for evaluation of the acceptability, demand, implementation, and efficacy testing of a music intervention among older adult patients admitted in a TICU and TOU setting and the effects of a music intervention for delirium prevention.

Chapter 4

RESULTS

The purpose of this study was to evaluate the feasibility of a music intervention (acceptability, demand, implementation, and efficacy testing) among older patients admitted in a TICU and TOU setting. Acceptability and implementation were evaluated among participants in the music intervention group. Demand and efficacy were evaluated among participants in both the music intervention group and the usual care group. The intended effect on process variables and outcomes within and between the treatment and usual care groups over time were analyzed. Study results are presented according to the specific aims and prefaced by a brief description of the sample and properties of measures used.

Sample Description

Figure 2 outlines the flowchart for the study consistent with the Consolidated Standards of Reporting Trials (CONSORT) Statement (Boutron et al.,). A total of 234 patients were interested in participating and were screened for eligibility. One hundred sixteen did not meet inclusion criteria; one hundred eighteen met inclusion criteria. Seventy eight patients declined. Consent was signed by 40 patients who were randomized to music intervention and usual care conditions.

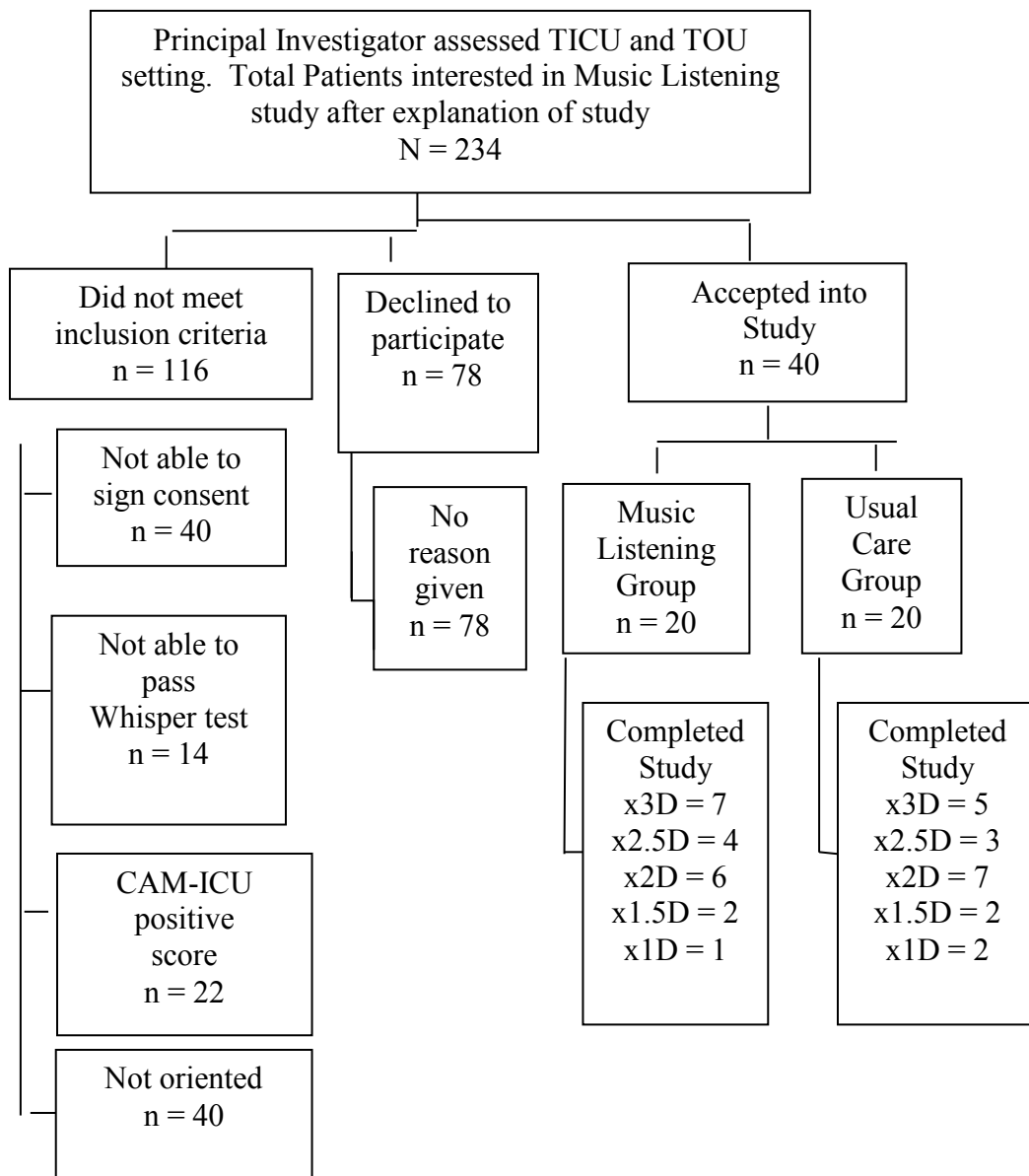


Figure 2. Recruitment flowchart.

Demographic Characteristics

Demographic characteristics for study participants are presented in Table 5. Participants ranged in age from 58 to 87 years, with a mean and standard deviation of 71.85 (9.23) years. The majority of participants were female 34(85%) with male 6(15%). The majority of participants were White Caucasian 34(85%), with Hispanic Non Caucasian 4(10%), Asian 1(.025), and Black 1(.025%). Seventeen (42.5%) were widowed, 10(25%) were single, and 13(32.5%) were married. Ordered medications obtained from the initial medication sheet on admission included cardiovascular, anti-anxiety, analgesics, sleep aides, and respiratory medications. The majority of the participants fell into the category of “yes” for cardiovascular medications and “yes” for analgesic medication for both the music group and the usual care group. The majority of patients in both the music intervention group and the usual care group reported cardiac, gastrointestinal, and endocrine co-morbid conditions. Admitting diagnosis was obtained from the physician admission data base in the EMR. The majority of patients in both the music intervention group and the usual care group fell into the admitting diagnosis category of respiratory and gastrointestinal conditions. Co-morbid conditions for both the music intervention group and the usual care group were obtained from the history and admission assessment found in the EMR.

Table 5

Demographic Characteristics of Study Participants.

| | Usual Care Group (n=20) | Intervention Group (n=20) | Total |
|----------------------------|----------------------------|------------------------------|--------------|
| Age | | | |
| Range | 58-87 | 58-86 | 58-87 |
| Mean (SD) | 73.50 (9.45) | 70.20 (8.93) | 71.85 (9.23) |
| Race | | | |
| White Caucasian | 16 (80%) | 18 (90%) | 34 (85%) |
| Black | 1(.05%) | 0(00%) | 1(.025%) |
| Asian | 1(.05%) | 0(00%) | 1(.025%) |
| Hispanic Non Caucasian | 2 (10%) | 2(10%) | 4(10%) |
| Gender | | | |
| Female | 17 (85%) | 17(85%) | 34(85%) |
| Male | 3(07%) | 3(07%) | 6(15%) |
| Marital Status | | | |
| Married | 6(30%) | 7(35%) | 13(32.5%) |
| Widowed | 8(40%) | 9(45%) | 17(42.5%) |
| Single | 6(30%) | 4(20%) | 10(25 %) |
| Admitting Diagnosis | | | |
| Cardiovascular | 4(20%) | 4(20%) | 8(20%) |
| Respiratory | 5(25%) | 5(25%) | 10(25%) |
| Gastrointestinal | 4(20%) | 6(30%) | 10(25%) |
| Bone | 5(25%) | 3(15%) | 8(20%) |
| Acute Infection | 1(5%) | 1(5%) | 2(5%) |
| Injury | 1(5%) | 1(5%) | 2(5%) |
| Co Morbid Conditions | | | |
| Cardiovascular | 16(80%) | 15(75%) | 31(77.5%) |
| Respiratory | 9(45%) | 9(45%) | 18(45%) |
| Endocrine | 12(60%) | 9(45%) | 21(52.5%) |
| Gastrointestinal | 14(70%) | 12(60%) | 26(65%) |
| Joint/Connective Tissue | 6(30%) | 4(20%) | 10(25%) |
| Mental Health | 3(15%) | 4(20%) | 7(17.5%) |
| Neuro Vascular | 7(35%) | 6(30%) | 13(32.5%) |
| Bone | 3(15%) | 3(15%) | 6(15%) |
| Medication | | | |
| Cardiovascular | | | |
| No | 9(45%) | 8(40%) | 17(42.5%) |
| Yes | 11(55%) | 12(60%) | 23(57.5%) |
| Anti-anxiety | | | |
| No | 12(60%) | 16(80%) | 28(70%) |
| Yes | 8(40%) | 4(20%) | 12(30%) |
| Analgesic | | | |
| No | 6(30%) | 5(25%) | 11(27.5%) |
| Yes | 14(70%) | 15(75%) | 29(72.5%) |
| Sleep Aid | | | |
| No | 17(42.5%) | 18(90%) | 35(87.5%) |
| Yes | 3(15%) | 2(10%) | 5(12.5%) |
| Respiratory | | | |
| No | 11(55%) | 13(65%) | 24(60%) |
| Yes | 9(45%) | 7(35%) | 16(40%) |

Table 6 outlines the results of a Chi Square test conducted to examine differences on key baseline demographics (gender, age, race, and, marital status), for both the music intervention group and the usual care group. There were no significant differences in gender, age, race, and marital status between the music intervention participants and the usual care participants.

Table 6
Mean and Standard Deviation for Demographic Variables

| <i>Variable</i> | Music (N=20) | | | Usual care (N=20) | | |
|-----------------|--------------|----------|-----------|-------------------|----------|-----------|
| | <i>n</i> | <i>M</i> | <i>SD</i> | <i>n</i> | <i>M</i> | <i>SD</i> |
| Gender | 20 | 1.85 | .366 | 20 | 1.85 | .366 |
| Age | 20 | 70.00 | 8.76 | 20 | 73.70 | 9.53 |
| Race | 20 | 1.05 | .224 | 20 | 1.15 | .366 |
| Marital Status | 20 | 1.85 | .745 | 20 | 2.00 | .795 |

Ordered medications on admission included cardiovascular, anti-anxiety, analgesics, sleep aides, and respiratory medications. Table 7 outlines results of a Chi Square test conducted to examine differences in the music group and the usual care group by medication categories. There were no significant differences between the music group and usual care group for medications ordered on admission.

Table 7
Group Statistics for Demographic Variables of Medication

| <i>Variable</i> | Music (n=20) | | | Usual care (n=20) | | |
|-----------------|--------------|----------|-----------|-------------------|----------|-----------|
| | <i>n</i> | <i>M</i> | <i>SD</i> | <i>n</i> | <i>M</i> | <i>SD</i> |
| Cardiac | 20 | 1.400 | .5026 | 20 | 1.450 | .5104 |
| Anti-Anxiety | 20 | 1.800 | .4104 | 20 | 1.600 | .5026 |
| Analgesic | 20 | 1.200 | .4104 | 20 | 1.350 | .4894 |
| Sleep Aid | 20 | 1.950 | .2236 | 20 | 1.800 | .4104 |
| Respiratory | 20 | 1.650 | .4894 | 20 | 1.550 | .5104 |

Properties of Measures

Descriptive analyses included means, standard deviations, skewness, kurtosis, and when appropriate, correlation of item to scale. Evaluation of the Evaluation of Intervention Acceptability Questionnaire had normal distributions with normal skewness and kurtosis. Items in the Index of Procedural Consistency, where the music intervention was rated with “achieved very little”, “achieved” and “achieved very well” had normal distribution and normal skewness and kurtosis. All physiologic vital signs (SBP, DBP, HR, and RR) were normally distributed with normal skewness and kurtosis. The CAM-ICU scores for both the usual care group and music intervention group were not normally distributed; all CAM-ICU scores were negative for both groups.

Multiple imputation procedure was conducted using SPSS version 22 to provide analysis of 20 patterns of missing data. When statistical analysis is performed, the parameter estimates for all of the imputed datasets are pooled, which provides estimates that are considered more accurate than only one imputation (Sterne et al., 2009). The purpose of multiple imputation is to generate possible values for missing values, creating several “complete” data sets (Stern et al., 2009).

Specific Aim. 1. Examine the feasibility of a music intervention among hospitalized older adults evaluated as acceptability, demand (attrition and attendance rates), and implementation.

Acceptability. Acceptability of the music intervention was measured by participant evaluation of the intervention protocol and delivery mechanisms (intervention components, mode of delivery).

Evaluation of the intervention acceptability. Seventy four percent of participants reported they would recommend music listening to others while in the hospital. Suggestions to improve the music intervention included; allowing the participants to choose the time they wanted to listen to the music 7(35%), shortening the music sessions as they were too long 6(30%), and offering another listening device instead of head phones 4(20%). While a variety of music selections were offered, participants shared they would have liked to listen to music they were familiar with that they listen to at home; specific songs and albums 5(25%). Twelve (20%) of participants felt the headphones were comfortable. The majority of participants 11(55%) disagreed with the statement, “I was satisfied with the number and length of music listening sessions.” Overall 14(74%) agreed they would recommend music listening to others while in the

hospital. Music selection varied with participants. Five participants who listened to music selected Jazz, five selected Beethoven, five selected Comfort Zone, three selected Piano, and two selected Synthesizer. The majority of participants agreed or strongly agreed with indicators measuring helpfulness and satisfaction of music listening while in the hospital.

Narrative response to the survey and field notes suggested that music listening helped with anxious thoughts. There was varied responses to, “Music listening helped me with anxious thoughts while in the hospital.” Narrative responses to this statement included; “I am not sure if I was anxious, the music did help me relax,” “I was not thinking of anxious thoughts, but I did feel nervous not knowing,” and “It was a nice distraction and overall I found it to be very calming.”

Similar responses were noted with the statement, “Music listening helped me feel more like myself while in the hospital.” Narrative comments reflecting this statement included, “How can I feel like myself when I am in pain,” “How can I feel like me when I am in the hospital and not at home,” and “When I am home I will feel more like myself.”

Responses were noted with “Wearing music listening headphones was comfortable.” Narrative responses included; “The headsets did not completely block outside noise, I could hear my neighbor talking on the phone,” “I would have liked ear buds, these headphones are not comfortable lying down,” “The head sets are not blocking out extra noise,” and “I don’t like the headsets on with my oxygen.” One woman shared, “I was still able to hear outside sounds as the earmuffs (headsets) were not tight enough,” “I might suggest ear buds for long term use.”

Narrative responses for the number and length of music listening sessions included, “I had enough listening half way through,” “I don’t see how you can decide on a good time with patients who are in a hospital,” “I remember you told me that I could take the headsets off any time I felt and I did when my family came or my phone rang.”

Narrative responses for choice of music included; “I would like a music player at the bedside,” “I would like to choose my own music, you gave me a choice but it was not my favorite,” “I listen to music at my nursing home and I like it,” and “I like Beethoven, but I did not like the album you had.” Another shared, “This was a great transition while in the hospital, when ideal is not available.” Another patient shared, “I like my choice of music from your selection but I usually listen to country western at home and would have liked that as a choice.” Another patient shared; “I would have preferred to put the music on myself and listen when I wanted to, company or the doctor may be here with scheduled times.” One participant shared that she liked someone to bring the music in at scheduled times as you can always find excuses not to listen.

Table 8 outlines frequencies and percentages for ordinal variables from the Evaluation of Intervention Acceptability Questionnaire.

Table 8

Evaluation of Intervention Acceptability for Music Listening (ML)

| Variables | n | % |
|--|----|----|
| Overall ML was helpful | | |
| Strongly agree | 3 | 15 |
| Agree | 17 | 85 |
| ML helped me relax in hospital | | |
| Strongly agree | 2 | 10 |
| Agree | 18 | 90 |
| ML helped with anxious thoughts | | |
| Strongly agree | 2 | 10 |
| Agree | 8 | 40 |
| Neutral | 7 | 35 |
| Disagree | 2 | 10 |
| Does not know | 1 | 5 |
| ML helped me feel more like myself | | |
| Agree | 7 | 35 |
| Neutral | 7 | 35 |
| Disagree | 3 | 15 |
| Does not know | 3 | 15 |
| I was satisfied with ML in hospital | | |
| Strongly agree | 2 | 10 |
| Agree | 18 | 90 |
| Using ML equipment was easy | | |
| Agree | 10 | 50 |
| Neutral | 5 | 25 |
| Disagree | 5 | 25 |
| Wearing headphones was comfortable | | |
| Agree | 12 | 60 |
| Neutral | 1 | 5 |
| Disagree | 7 | 35 |
| I was satisfied with number and length of sessions | | |
| Agree | 7 | 35 |
| Neutral | 2 | 10 |
| Disagree | 11 | 55 |
| I would recommend ML to others in hospital | | |
| Agree | 14 | 74 |
| Neutral | 5 | 26 |

Demand. Demand for the intervention in older adults was evaluated by participant attrition and attendance at music intervention session and minutes engaged in the music intervention. Attrition rates were evaluated as indicated by withdrawal from the study.

Minutes engaged in music intervention. There were a total of 79 music intervention sessions delivered over three days of music listening. Table 9 outlines means and standard deviations for music listening in minutes by intervention sessions for day1 intervention 1 (Day1I1), day 1 intervention 2 (Day1I2), day 2 intervention 1 (Day2I1), day 2 intervention 2, (Day2I2), Day 3 intervention 1 (Day3I1), and day 3 intervention 2 (Day3I2).

Table 9

Means and Standard Deviations for Music Listening in Minutes by Intervention Session

| | <i>n</i> | <i>Minimum</i> | <i>Maximum</i> | <i>M</i> | <i>SD</i> |
|--------|----------|----------------|----------------|----------|-----------|
| Day1I1 | 20 | 53.00 | 60.00 | 1.400 | .8826 |
| Day1I2 | 18 | 35.00 | 60.00 | 1.056 | .2357 |
| Day2I1 | 17 | 60.00 | 60.00 | 1.000 | .0000 |
| Day2I2 | 14 | 30.00 | 60.00 | 1.286 | 1.069 |
| Day3I1 | 6 | 45.00 | 60.00 | 1.333 | .8165 |
| Day3I2 | 4 | 40.00 | 60.00 | 2.250 | 2.500 |

Intervention session overview of minutes. Overview of minutes note that time spent listening to music decreased over time. Field note documentation indicates participants missed intervention sessions due to pain, family visits, medication request, procedures, transfers, and discharge planning. Patients who missed due to family visits had either family present in the room, or were anticipating family arrival, and did not want to appear involved in a procedure which might turn family away. Missed intervention sessions due to procedures included patients who either were anticipating a procedure that day. or who

were actively involved in a procedure. Patients who were anticipating a procedure felt if they were involved with the music intervention the procedure may not take place. Missed intervention sessions included patients who were planning their discharge, or transfer to another nursing unit. One participant shared, “I would like to stop now, I am going home tomorrow and it will be a busy day.” One participant shared, “I need to get ready for my discharge tomorrow, and I think this is enough.” Table 10 outlines reasons for missed intervention time points of music listening.

Table 10

Reasons for Missed Intervention Sessions

| Reason | Day1I1 | Day1I2 | Day2I1 | Day2I2 | Day3I1 | Day3I2 |
|--------------------|--------|--------|--------|--------|--------|--------|
| Family Visit | 0 | 0 | 1 | 0 | 1 | 1 |
| Medication Request | 0 | 0 | 0 | 0 | 1 | 3 |
| Procedures | 0 | 0 | 0 | 2 | 1 | 1 |
| Transfers | 0 | 1 | 1 | 0 | 8 | 2 |
| Discharge Planning | 0 | 1 | 1 | 4 | 3 | 9 |

Withdrawal from study. There were no participants who withdrew from the music intervention group or usual care group.

Implementation. Implementation of a music intervention was evaluated by the Index of Procedural Consistency, to determine the degree to which the intervention was delivered as planned. The PI scored each content area from one (achieved very little) to three (achieved very well), with a mean score calculated. Table 11 outlines participant's responses to how well the intervention was delivered as planned.

Table 11

Participants Response to Intervention Delivery

| <i>Variables</i> | <i>n</i> | <i>%</i> |
|----------------------|----------|----------|
| Day1I1 | | |
| Achieved Very Well | 12 | 60% |
| Achieved | 4 | 20% |
| Achieved Very Little | 4 | 20% |
| Day1I2 | | |
| Achieved Very Well | 13 | 72% |
| Achieved | 1 | 06% |
| Achieved Very Little | 4 | 22% |
| Day2I1 | | |
| Achieved Very Well | 12 | 70% |
| Achieved | 4 | 24% |
| Achieved Very Little | 1 | 06% |
| Day2I2 | | |
| Achieved Very Well | 6 | 43% |
| Achieved | 5 | 36% |
| Achieved Very Little | 3 | 21% |
| Day3I1 | | |
| Achieved Very Well | 3 | 50% |
| Achieved | 2 | 33% |
| Achieved Very Little | 1 | 17% |
| Day3I2 | | |
| Achieved Very Well | 3 | 75% |
| Achieved | 1 | 25% |
| Achieved Very Little | 0 | 00% |

Specific Aim 2

The second aim in this study was to evaluate the effects of a music intervention in decreasing physiologic parameters of (SBP, DBP, HR, RR), and the health outcome of delirium prevention among older patients. The following sections present the results of analyzing differences in the physiologic variables of SBP, DBP, HR, and RR over time and CAM-ICU scores.

Processes of Change

Physiologic Variables. Adaptive physiologic responses to change included SBP, DBP, HR, and RR. Physiologic changes were measured using SBP, DBP, HR, and RR over time. Physiologic data collected in the clinical setting included SBP, DBP, HR, and RR. Blood pressure, HR, and RR were recorded from noninvasive bedside monitors and collected on admission to the TICU and the TOU setting, with the first set of vital signs taken during initial assessment and every four hours over a three day period.

Using multiple imputation, a mixed design ANOVA (repeated measures with a between subject factor) was conducted to examine differences between the music intervention group and usual care group across time on variables of SBP, DBP, HR, and RR. Between subjects factor were two levels, the music intervention group and the usual care group. Forty patients took part in the intervention. Of the 40 participants, 20 were randomly assigned to the music group and 20 were assigned to the usual care group. Significance was set at ($p < .10$) for this analysis (Lee et al., 2014).

Covariates of interest in this study were age and anti-anxiety medication as both are considered risk factors for delirium (Inouye et al., 2014). Using a multiple imputation dataset, a Pearson Product Correlation was computed to assess the relationship between

age and SBP, DBP, HR, and RR, at T2, T3, and T4, and anti-anxiety medication and SBP, DBP, HR, and RR at T2, T3, and T4. There was a positive correlation between age and HR at T4, ($r = .343$, $n = 40$, $p = .057$, $d = .73$.), thus age was entered as a covariate for the HR model. Cohen's effect ($d = .73$) suggested a moderate to large practical significance of age and HR. There was a negative correlation between anti-anxiety medications and HR at T2 ($r = -.320$, $n = 40$, $p = 0.45$, $d = .67$). Cohen's effect ($d = .67$) suggested a moderate practical significance of anti-anxiety and HR. Table 12 outlines differences between the music intervention group and the usual care group on physiologic parameters of interest analyzed using ANOVA. There were no statistically significant differences between groups for SBP ($p = .480$), DBP ($p = .469$), or HR ($p = .154$). There were statistically significant differences between groups for RR ($p = .073$), consistent with a decrease in mean RR over time from T1 to T3 for the usual care group, and from T1 to T3 for the music intervention group.

Table 12

Differences Between Groups for the Variables SBP, DBP, HR, RR

| Variable | <i>F</i> | <i>df</i> | <i>Sig.</i> |
|----------|----------|-----------|-------------|
| SBP | 1.065 | 3.000 | .480 |
| DBP | 1.104 | 3.000 | .469 |
| RR | 6.964 | 3.000 | .073 |
| HR | .644 | 3.000 | .592 |

Table 13 outlines mean and SD for T1, T2, T3, and T4 for the variable RR. There was a decrease in mean RR over time from T1 to T3 for the usual care group, and from T1 to T3 for the music intervention group. These results indicate that participants in both the music intervention group and the usual care group had a decrease in RR over time. Cohen's effect ($r = 0.94$) for T1 between the usual care group and the music intervention group suggest a large practical significance between groups on the physiologic variable of RR at T1. Cohen's effect ($r = .84$) for T2 between the usual care group and the music intervention group suggest a large practical significance between groups on physiologic variable of RR at T2. Cohen's effect ($r = .56$) for T3 between the usual care group and the music intervention group suggests a moderate practical significance between groups on the physiologic variable of RR at T3. Cohen's effect ($r = .57$) also suggests a moderate practical significance between groups on the physiologic variable of RR.

Table 13

Means and Standard Deviations for T1, T2, T3, and T4 for the Variable RR

| | T1 | | T2 | | T3 | | T4 | |
|------------|----------|-----------|----------|-----------|----------|-----------|----------|-----------|
| | <i>M</i> | <i>SD</i> | <i>M</i> | <i>SD</i> | <i>M</i> | <i>SD</i> | <i>M</i> | <i>SD</i> |
| Usual Care | 19.350 | 0.00 | 19.960 | 0.377 | 17.946 | 0.638 | 18.546 | 0.415 |
| Music | 18.067 | .301 | 18.238 | 0.673 | 17.881 | 1.160 | 19.122 | 0.402 |

Comparing the means between the usual care group and the music intervention group for T2 through T3, Cohen's effect ($d = .68$) suggests a medium practical significance with RR over time. Comparing the means between the usual care group and the music intervention group for T3 through T4, Cohen's effect ($d = -.57$) suggests a medium practical significance with RR over time.

Comparing means for the music intervention group from T2 through T3, Cohen's effect ($d = .37$) suggests a small practical significance with RR; a decrease in RR over time. Comparing the means for the music intervention group from T3 through T4, Cohen's effect ($d = -1.4$) suggests a large practical significance with RR; an increase in RR over time. Comparing the means for the music intervention group for T1 through T2, Cohen's effect ($d = .32$) is consistent with a small practical significance with RR; an increase in RR over time.

Comparing the means for the usual care group from T2 through T3, Cohen's effect ($d = 3.8$) is consistent with a large practical significance with RR; a decrease in RR over overtime. Comparing the means for the usual care group from T3 through T4, Cohen's effect ($d = -1.1$) is consistent with a large practical significance with RR; an increase in RR overtime. Comparing the means for the usual care group for T1 through T2, Cohen's effect ($d = -2.2$) is consistent with a large practical significance with RR; an increase in RR over time.

To follow up the significant music group by time interaction for RR, paired sample t-tests were performed to assess differences between the intervention music group and usual care group over time as seen in Table 14. When examining the between group differences, RR was statistically lower in the music intervention group throughout the

time period T2 through T3 ($p = .038$) and T3 and T4 ($p = .081$). In the usual care group, RR was significantly lower from T2 through T3 ($p = .038$) and T3 through T4 ($p = .081$).

Table 14

Paired Sample T-tests for the Variable RR for Music and Usual Care

| Pair | <i>t</i> | <i>df</i> | Sig. (2-tailed) |
|------------|----------|-----------|--------------------|
| Music | | | |
| T2 – T3 | 2.143 | 39 | .038 |
| T3 – T4 | -1.793 | 39 | .081 |
| Usual Care | | | |
| T2 – T3 | 2.143 | 39 | .038 |
| T3 – T4 | -1.793 | 39 | .081 |

To determine if a music intervention prevented delirium among older adults in a TICU and TOU setting, *t*-tests were calculated to determine whether the mean scores of the CAM-ICU between the music group and the usual care group were statistically significantly different from T2 throughout T4. The CAM-ICU for both conditions remained CAM-ICU negative at each data collection time point. Table 15 outlines the mean scores and SD between the music group and usual care group in CAM-ICU. A *t* value was not computed because the standard deviations of both groups were .0000.

Table 15

Means and Standard Deviation for CAM-ICU Scores for T2, T3, and T4 for the Music Intervention Group and Usual Care Group

| Music = 1 Usual Care = 0 | <i>n</i> | <i>M</i> | <i>SD</i> |
|--------------------------------|----------|----------|-----------|
| CAM Negative Music | | | |
| T2 | 19 | 2.000 | .0000 |
| T3 | 17 | 2.000 | .0000 |
| T4 | 4 | 2.000 | .0000 |
| CAM Negative Usual Care | | | |
| T2 | 19 | 2.000 | .0000 |
| T3 | 14 | 2.000 | .0000 |
| T4 | 7 | 2.000 | .0000 |

Summary

Study findings supported the feasibility (acceptability, demand, implementation, and effects) of a music intervention among older adult patients admitted to a TICU and TOU setting. Acceptability of the intervention was supported with suggestions for modification in intervention delivery. Demand of the intervention was variable due to the constraints of medical procedures, physician consultation, and family visits. Intervention effects were variable but provide direction for further study. Implementation of a music intervention was successful in that delivery was consistent with protocol.

Chapter 5

DISCUSSION

This study supports the feasibility and acceptability of a music intervention to prevent delirium among older adult patients admitted in a TICU and TOU setting. Results lend support for the conceptual theory of the Roy Adaptation Model, and the relevance of the research for delirium prevention and nursing practice. Chapter Five discusses findings specific to delirium prevention among older adult patients in an acute care setting, according to the specific aims of this study. Strengths, limitations, suggestions to support the conceptual theory of the Roy Adaptation Model, relevance to nursing science, significance of the research for delirium prevention and nursing practice will be discussed.

Specific Aim 1

Acceptability. The music intervention was evaluated as acceptable to participants randomized to the music intervention group.

Music intervention acceptability. The music intervention was acceptable to the majority of participants. Some of the participants noted that if they had their music at their bedside they could listen to the music throughout the day when they felt anxious. These findings were consistent with McCaffrey & Locsin, (2004), who reported that nurses working with patients who received a music intervention noticed a calming effect on patients and family members, as well as the nurses feeling calm themselves when they went into a room where music was playing.

Demand. Demand for the intervention in older adults was evaluated by measurement of participant attrition rates and dose of music intervention sessions in minutes. Previous studies have also reported disruption during the music intervention

despite efforts to maintain a quiet environment (Sendelbach et al., 2006). Based on the field notes from this study, there was noise from roommates where the rooms were semi private. Interruptions from physicians, medications administered, procedures and patient phone calls occurred in both the TICU and TOU settings. Both the TICU and the TOU settings are trauma intensive care units where procedures are based on a patient's acuity and any change in their acuity may result in an emergent unscheduled procedure.

Understanding challenges in decreasing excess stimuli in an ICU setting can provide support for further research and improve expected outcomes. Understanding differences in physiological parameters over time will facilitate music intervention replication in future research and provide a basis for integration of music among patients in a critical care setting.

Demand for Music Intervention. There was a total of 79 sessions delivered over three days of music listening with 71(89.8%) participants listening to music for 60 minutes each intervention session over three days. Reasons for participants missing intervention sessions included family visits, medication request, procedures, transfers, and discharge planning. Reasons for stopping music listening early included family visits, phone calls, medication request, a noisy environment, or they had enough music listening. Extraneous factors including unnecessary noise, lights, patient interruptions, and alarms could be considered barriers to demand. Noise from roommates, including television and visitors in the TOU due to no private rooms was a factor that may have influenced demand. Both the TICU and the TOU settings had interruptions from physicians, medications administered, procedures and patient phone calls that may have influenced intervention delivery. In both TICU and the TOU settings, procedures are

based on a patient's acuity and any change in their acuity may result in an emergent unscheduled procedure. Sendelbach et al., (2006) reported occasional disruption during a music intervention despite efforts to maintain a quiet environment. Understanding challenges in decreasing excess stimuli in an ICU setting can provide support for further research and improve expected outcomes.

Implementation. Implementation of the music intervention was evaluated to determine if the intervention was delivered as planned. Sendelbach (2006) reported missing intervention sessions were prevalent for the afternoon sessions on postoperative day two and both music sessions on postoperative day three. Reasons for missing music intervention time points included patients who refused. The authors did not provide a reason for the refusals.

Index of procedural consistency. There was some difficulty in delivering the intervention at the scheduled times. Chlan and colleagues (2013) used a data-logger system on headphones to record a patient directed music session. Because the music intervention was initiated by the patient, not all the patients randomized to the music interventions listened twice a day. However, implementation was consistent with protocol in a TICU and TOU setting with older adults.

Specific Aim 2

Physiologic variables. A music intervention was designed to treat the leading mechanisms for delirium by promoting an adaptive response. The study was designed to prevent delirium among patients admitted to a critical care unit who were CAM-ICU negative on admission through an adaptive response that took place when the regulator and cognator subsystem elicited a response as measured in the physiologic mode. The

effects of an adaptive response measured by physiologic variables of SBP, DBP, HR, and RR within and between the music group and usual care group over time were analyzed.

Although the mean difference was significant in both groups for the variable RR, the usual care group showed a greater decrease over time. There was a significant music intervention group by time interaction effect which suggests that the change over time was different for the music intervention group and the usual care group. Both groups showed the same pattern of change (decreasing from T1 to T3) but the usual care group showed greater change, hence the significant interaction. Sendelbach and colleagues (2006) reported no significant differences between the two groups with SBP, DBP and HR. Their rationale for this included physiologic effects that cardiac medications can cause with BP and HR. Nilsson (2009) reported significant decreases in RR over time in the music group. The authors noted that over time patients became more relaxed which could cause a decrease in RR. Understanding differences in physiologic variables over time will facilitate music intervention replication in future research and provide a basis for integration of music among patients in a critical care setting.

Music has been researched over the last two decades as a stimulus that under controlled conditions can maintain and improve patient's physiological, psychological, and emotional health (Joanna Briggs Institute, 2009). Music interventions effective in healthcare settings include pain management (Vaajoki et al., 2013; Cole & LoBiondo-Wood, 2012; Phipps et al., 2010; Nilsson, 2008), decrease in pharmacological sedation (Chlan & Heiderscheidt, 2009; Chlan et al., 2007; Lee et al., 2005; To et al., 2013), decrease anxiety and depression (Chlan et al., 2013; Korhan et al., 2011; Nilsson, 2008), and increase relaxation (Krout, 2007; Azoulay et al., 2013). A population at risk

that would benefit from a music intervention are hospitalized older adults found in ICU settings who are at risk for delirium (Fong et al., 2009; Kostas et al., 2013).

There are a multitude of studies proposing management of delirium and delirium prevention through pharmacologic approaches. The feasibility and acceptability of this study builds on non-pharmacologic approaches for delirium prevention by addressing the pathophysiologic mechanisms that contribute to delirium; neurotransmitter imbalance, inflammation, and acute physiological stressors (Inouye et al., 2014; Mora et al., 2012, Siritunga et al., 2013).

Implications for Theory/Nursing Science

To guide this intervention study a theory was used to provide for understanding of the intervention effects, characteristics of the intervention, causal processes underlying the effects, the extent and effect of time of the anticipated changes and the conditions under which it was successful (Sidani & Braden, 1998). Continued research of assumptions, values, and beliefs which underpin different theoretical approaches will add to nursing knowledge. Nursing theory contributes to the relevance of nursing knowledge and research to improve health outcomes. Research can be defined as a scientific process that validates and refines existing knowledge and generates new knowledge that directly and indirectly influences nursing practice. Applying existing knowledge and evidence based practice will define a broader concept in which nurses utilize the best available clinical evidence (research) along with individual clinical expertise and the patient's values and expectations to guide nursing practice.

For adaptation to occur, an adaptive system needs to constantly grow and develop within a changing environment. Health needs related to use of a music intervention can

foster the patient moving toward an adaptive response. The goal of a nursing intervention in situations of health or illness is to maintain and enhance adaptive responses (Roy & Andrews, 1999, p.81). The Roy Adaptation Model used critical inputs of the intervention of music listening to alter focal stimuli through the regulator subsystem which processes internal and external stimuli through neural, chemical and endocrine channels to produce responses for delirium prevention.

Findings from this study provide support for using the Roy Adaptation Model as an innovative framework for a non-pharmacologic intervention among older patients admitted to an ICU setting who are at risk for delirium.

Fawcett (1984) believed nursing knowledge was the avenue where the discipline of nursing would advance. She further identified central concepts and themes and formalized them as nursing's metaparadigm. Three themes mentioned by Fawcett (1984) included the relationship between the concepts of "person" and "health"; "person", "environment", "health"; and "health" and "nursing". Theories addressing "person" and "health" described, or predicted individual's behavior during periods of wellness and illness. Theories addressing relationships among the concepts of "person," "environment," and "health" described, or predicted individuals' behavioral patterns as they were influenced by environmental factors during periods of wellness and illness. Such theories placed individuals within the context of their surrounding environment rather than considering them in isolation, as in the first theme. Concepts of "health," and "nursing" described nursing processes or predicted the effects of nursing actions.

This feasibility study supports the application of a theory that focuses on the continuous interaction between the human adaptive system and the environment (Roy & Andrews, 1999). The concept of adaptation assumed people are open systems which respond to both internal and external stimuli (Roy and Andrews, 1999). Adaptation is influenced when the human adaptive system is unable to respond to stimuli from the internal and external environment in a manner that promotes health. The Roy Adaptation Model assumes the universal importance of promoting adaptation in both health and illness (Roy & Andrews, 1999).

Implications for Future Research and Practice

Ongoing research is needed which addresses (1) setting implications, (2) dose and delivery, (3) sensitivity of outcomes measures, (4) emerging characteristics of delirium, and (5) patient acuity.

Additional research is needed to further evaluate intervention effects in acute trauma units where the incidence of delirium remains high. Delirium has been noted as a growing critical care burden in critical care settings (Pauley et al., 2015). Current literature about delirium includes studies conducted with patient populations who are admitted to medical and surgical settings (Pauley et al., 2015). Older adults present to a hospital setting with a higher disease severity, many co-morbidities, and higher acuity which results in admission to a critical care setting. The prevalence of delirium among critically ill older adults demonstrates an urgency for additional studies to develop and implement non-pharmacologic approaches for delirium prevention.

Attention is needed to determine the optimal intervention music dose for older adults in an ICU setting. There have been studies on dose and duration in young adult musicians and in outpatient settings, but not in older adults in an ICU setting. Across studies, dose of scheduled passive music ranged from 20 minutes twice per day to one hour four times per day, (McCaffrey & Locsin, 2004; McCaffrey, 2009; McCaffrey & Locsin, 2006; Sendelbach et al., 2006; Chlan et al., 2013; Twiss et al., 2006; Nilsson, 2009). In this study, the majority of participants listened for the full 60 minutes, but some stopped the music intervention session early due to family visits, phone calls, medication request, a noisy environment, not liking their music selection, or they had enough music listening. Participants in this study reported they would have liked their music at the bedside to listen to when they wanted to, and the ability to work around interruptions and still benefit from the music. In other studies, participants who had their music at the bedside could turn music on and listen for additional periods of time when they chose to (Twiss et al., 2006; McCaffrey & Locsin, 2006; McCaffrey, 2009; McCaffrey & Locsin, 2004). Throughout their hospital stay, patients were able to self-initiate music to manage their anxiety (Twiss et al., 2006). When patients felt anxious they were able to reach for their music on their bedside table and play the music as often as they liked (McCaffrey & Locsin, 2006; McCaffrey, 2009; McCaffrey & Locsin, 2004)

The CAM-ICU screening tool for delirium is sensitive as a clinical measure, but may not be a research sensitive tool for studies involving a music intervention. Relevant studies included outcome measures such as the NEECHAM Acute Confusion Scale, McCaffrey, (2009), the State Anxiety Scale of the STAI (Twiss et al., 2006, Sendelbach et al., 2006), the VAS-A scale (Chlan et al., 2013), and a numeric rating scale, NRS

(Nilsson, 2009). All studies that used these screening tools to measure anxiety noted significant decreases in the anxiety of participants who listened to a music intervention compared to usual care. Outcome measures varied across studies reviewed but focused mainly on outcomes related to acute confusion, cognition, anxiety, physiologic parameters, and serum cortisol levels. The MMSE measured cognition, the NEECHAM Confusion Scale measured acute confusion in older patients after hip and knee surgery (McCaffrey, 2009; McCaffrey & Locsin, 2006; McCaffrey & Locsin, 2004), two studies used the State Trait Anxiety Scale of the STAI to evaluate the effect of a music intervention on state anxiety (Sendelbach et al., 2006; Twiss et al., 2006). The VAS-A scale was used to measure anxiety daily with patients who were mechanically ventilated as patients were unable to verbalize (Chlan et al., 2013). Chlan et al., (2013), and Nilsson (2009) used a NRS scored from zero representing no anxiety to 10 representing maximal anxiety. Physiologic outcomes including HR, SBP, DBP, and MAP (Sendelbach et al., 2006; Nilsson 2009) and serum cortisol levels were also used to measure anxiety (Nilsson 2009).

Wei and Colleagues (2008) examined psychometric properties, adaptations, translations and applications of the CAM to identify delirium with a reported overall sensitivity of 94% (95% CI = 91-97%) and specificity of 89% (95% CI= 85-94%). Recommendations to optimize performance of the CAM-ICU included scoring the CAM-ICU based on observations made during formal cognitive testing and training.

Van Rompaey and colleagues (2008) compared the CAM-ICU and the NEECHAM confusion scale in an intensive care unit to screen for delirium; NEECHAM (20.3%), CAM-ICU (19.8%). In addition to screening for delirium the NEECHAM also assesses

for acute confusion, early to mild confusion, at risk for confusion, or normal. Five patients who scored “mildly confused” were negative using the CAM-ICU; the same patients were positive for delirium using the NEECHAM scale.

Emerging characteristics of delirium emphasize the need to screen more comprehensively for cognition as a marker of hypoactive delirium. Historically delirium has been categorized mainly as a disorder of arousal; recent advances now deem delirium as mainly a disorder of cognition (Inouye et al., 2014). Recent recommendations include screening patients using a simple cognitive screening tool and the CAM-ICU screening tool (Inouye et al., 2014, Peritogiannis et al., 2015). There is difficulty in screening for hypoactive delirium in ICUs, as the results are not usually accurate (Inouye et al., 2014). The NEECHAM may have a greater tendency to identify hypoactive delirium, which has the highest incidence in ICU settings, and is the most frequently missed due to its presentation (Van Rompaey et al., 2008, Peritogiannis et al., 2015). Characteristics of hypoactive delirium include flat affect, withdrawal, apathy, lethargy, decreased level of responsiveness, and minimal psychomotor activity (Morandi & Jackson, 2011; Allen & Alexander, 2012; Vasilevskis, Han, Hughes, & Ely, 2011). The NEECHAM screening tool is useful in nursing-based studies as it consists of a behavioral checklist for delirium symptoms (Inouye et al., 2014). Delirium is a syndrome that is characterized by anxiety. Anxiety is a common symptom among older adults who are hospitalized (Twiss et al., 2006). There is strong evidence that identification of symptoms for delirium like anxiety can aid in identifying delirium (Twiss et al., 2006).

All patients for both conditions remained CAM-ICU negative at each data collection time point. The exclusion criteria and patient population for this study may

have influenced why patients remained CAM-ICU negative for both conditions. A risk factor for delirium is patients who are mechanically ventilated. Patients who were mechanically ventilated were excluded from this study due to a higher acuity level, report of higher anxiety scores despite sedation, and medications administered at high doses for prolonged periods, which could introduce bias in response to intervention and interpretation of results (Chlan et al., 2013). Duceppe and colleagues (2015) conducted a prospective observational study of 150 trauma patients; 40% were from falls, 28.7% from motor vehicle accidents with 69.3% requiring mechanical ventilation; delirium developed in 58 (38.7%) patients. Pauley and colleagues (2015) reported 80% of patients who are mechanically ventilated develop delirium.

Another risk factor for delirium is patients who are admitted with an acute infection. For this study one patient (5%) had an admitting diagnosis of an acute infection for the music intervention group and one (5%) patient had an admitting diagnosis of an acute infection for the usual care group. A univariate analysis revealed that delirium was significantly associated with patients who were mechanically ventilated, with an active acute infection, presence of traumatic brain injury, and pre-existing diabetes. There were no patients in this study for both conditions with a traumatic head injury. Three patients had pre-existing diabetes; two in the usual care group and one in the music intervention group. There was one patient in the usual care group who had sustained a fall and no patients in the music intervention group. All patients in this study were cognitively intact for both conditions.

Summary

A music intervention based on the Roy Adaptation Model is feasible among older hospitalized patients who are risk for delirium. A feasibility study can pave the way for conducting similar interventions in clinical practice. This study adds to the body of nursing research and the ability to implement a music intervention in a practice setting, furthers knowledge of the critical inputs and mediating processes of a music intervention, the related dose and strength of the intervention that underlie the intervention effects, the intended and unintended outcomes of the intervention, the patient population that would most benefit, and the context in which the intervention is useful (Sidani and Braden, 1998).

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APPENDIX A
STUDY DETAILS

Study Details

| Author Purpose | Sample Setting | Design, Duration Intervention Critical Inputs, Fidelity Evaluation | Outcome Variables Measures | Major Findings |
|---|--|---|---|--|
| <p>Chlan et al. (2013). Determine whether listening to self-initiated pt. directed music (PDM) can reduce anxiety and sedative exposure during MV in critically ill patients.</p> | <p>N= 373. Cauc= 86% Female=52% Male = 48% Age= 59 (14) PDM= 126 NCH= 122 UC= 125 12 intensive care units.</p> | <p>Design: RCT Duration: Mean (SD), 79.8 (126) (median [range], 12 [0-796]) minutes per day of PDM. Mean (SD) of 34.0 (89.6) (median [range], 0 [0-916]) minutes/day of NCH. Intervention Critical Inputs: Self-initiated PDM, Music choice by music therapist, self-initiated use of NCH or usual care. Fidelity Evaluation: Trained research nurse as interventionist. Daily sedative drug score & sedative dose frequency ICU, 24 hours prior to enrollment and daily. Research nurse oriented patient to CD, player, & headphone.</p> | <p>Outcomes: Daily assessment of anxiety (100-mm visual analog scale) Two aggregate measures of sedative exposure (intensity & frequency)</p> | <p>PDM: Anxiety score 19.5 points lower (95% CI, -32.2 to -6.8) than UC group ($p = .003$). Fifth study day: Anxiety reduced by 36.5% in PDM pts. PDM: Reduced sedation intensity by -0.18 (95% CI, -0.36 to -0.004) points/day ($p = .05$) reduced frequency by -0.21 (95% CI, -0.37 to -0.05) points/day ($p = .01$). PDM: reduced sedation frequency by -0.18 (95%CI, -0.36 to -0.04) points/day vs. NCH group ($p = .04$).</p> |
| <p>McCaffrey & Loosin (2004). Determine effects of music on acute confusion in older patients with elective hip & knee surgery</p> | <p>N = 66. IG = 33 Age => 65 years CG = 33 Age => 65 years</p> | <p>Design: RCT Duration: Adm - discharge Intervention Critical Inputs: CG: Standard post-op care. IG: Standard post-op care. Bedside CD player. Music choice. 3x day x 1 hr. Pt. self-initiation. Fidelity Evaluation: Standardized signs, symptoms of delirium, confusion tool reviewed with nursing. Discharge: Pt's computerized nurse's notes, checklists reviewed to verify episodes of confusion, signs, symptoms of delirium.</p> | <p>Outcomes: Episodes of confusion Delirium entered numerically. Post-op scores for ability to ambulate x1 POD</p> | <p>IG: fewer episodes of confusion & delirium vs CG without ML. ($F = 19.568, p = 0.001$). CG: Lower scores for readiness to ambulate scale vs IG who had higher scores, ambulating day of surgery ($F = 19.568, p = 0.001$; $F = 28.14, p = 0.001$).</p> |

| Authors Purpose | Sample Setting | Design, Duration Intervention Critical Inputs Fidelity Evaluation | Outcome Variables Measures | Major Findings |
|---|---|---|---|---|
| McCaffrey & Loesin (2006). Examine whether music therapy decreases acute confusion (AC), pain, & early ambulation in older patients having hip & knee surgery in an orthopedic unit | N=124 IG= 62, Mean age= 77.33 Male= 22 Female= 40 Hip OR= 19 Knee OR= 41. CG= 62. Mean, age=76.79 Male= 22 Female= 40 Hip OR= 21 Knee OR= 39. | Design: RCT Duration: 4 x day x 3 PODs Intervention Critical Inputs, : Pain, cognition, ability to ambulate after hip or knee OR, patient satisfaction. IG: post op care plus music (patient's choice) played x1 hour, QID CG: usual post-op care no music Fidelity Evaluation: Standard signs/symptoms of delirium & confusion reviewed with nursing Review of computerized nurse's notes & checklists to verify episodes of confusion & delirium. | Outcome: Incidence of Delirium | IG: Less episodes of AC vs. CG, ($f = 29.56, p = .001$). 84% (124): No episodes of AC. 32 = 1 episode of AC (28 CG & 2 IG) 6 = CG had ≥ 2 episodes of AC. IG: 2 with AC CG: 36 with AC |
| McCaffrey (2009) Determine effects of music listening with acute confusion in older adults post hip or knee surgery. | N = 22 IG 11 Mean age 74.5 Male 7 Female 4 CG 11 Mean age 75.9 Male 7 Female 4 | Design: RCT Duration: Post recovery - POD 3 Intervention Critical Inputs: CG: standard care (pain & ambulation) IG: standard care (pain & ambulation) with CD player at bedside played on arrival to unit from recovery. Lullaby music Self-select music, dose/freq. 4xday x1 hour, and as requested. Fidelity Evaluation: Utilized standardized protocol for postoperative pain, medication, and ambulation. | Outcome: NEECHAM Acute Confusion Scale MMSE | No difference in MMSE scores in CG and IG prior to OR. IG: POD1/2 higher MMSE scores than CG POD1: ($t = 110.5; df = 1, 22; p = .001$) POD2: ($t = 54.9, df = 1, 22; p = .001$) POD3 IG: ($t = 121.6; df = 1, 22; p = .000$). |

| Authors Purpose | Sample Setting | Design, Duration Intervention Critical Inputs Fidelity Evaluation | Outcome Variables Measures | Major Findings |
|---|--|--|--|---|
| Nilsson, (2009). The effect of music intervention in stress response to cardiac surgery. | N= 58 IG = 28 Age = 64 ± 11.5 CG = 30 Age = 69 ±7.5. Cardiothoracic unit. | Design: RCT Duration: 30 minutes Intervention Critical Inputs: ML: 60-80 bpm, different melodies new-age x30 min. volume (50-60dB). Fidelity Evaluation: Three RNs conducted interventions & outcome assessments. Both IG & CG had scheduled rest. IG: ML distributed through music pillow. CG: rest usual care without ML. RNs controlled noise by closing doors & placing sign to prevent interruptions. | Primary Outcomes: Stress response determined by serum cortisol, HR, RR, MAP, arterial oxygen saturation, subjective pain, anxiety levels. | IG: Serum-cortisol between groups; 484.4 mol/L in IG vs 618.8 mol/L in CG ($p < .02$) after 30 min. No difference in HR, RR, MAP, arterial oxygen tension, arterial oxygen saturation, subjective pain, anxiety levels between groups. |
| Sendelbach et al., (2006). Examine effects of music therapy and rest on pain intensity, anxiety, physiologic parameters & opioid consumption after cardiac surgery. | N= 86 IG= 50. Male = 62% Female = 38% Mean age = 62.3 Previous ML to relax: Yes = 24%, No = 76%. CG = 36. Male = 80.6% Female = 19.4%. Mean age = 64.7 Previous ML to relax: Yes= 11.4%, No = 88.6%. | Design: RCT Duration: 20 minutes Intervention Critical Inputs: IG 20 min ML 2x day a.m. & p.m. POD 1 -POD 3. CG: 20 min bedrest. Both groups: Pain intensity, HR, BP pre/post 20 min. intervention. Fidelity Evaluation: Interventionist trained, involved in protocol, stayed & delivered intervention, collected data, delivered brief session of relaxation (preprinted script) before music started with IG, Signed placed outside of room don't interrupt | Outcomes: anxiety, pain, physiologic parameters, opioid consumption measured pre/post 20 minute period. | IG Reduction in anxiety ($p \leq 0.001$) Pain ($p = 0.009$) CG. No difference in SBP ($p = 0.17$), DBP ($p = 0.11$), or HR ($p = 0.76$). No reduction in opioid use in 2 groups. |

| Authors Purpose | Sample Setting | Design, Duration Intervention Critical Inputs Fidelity Evaluation | Outcome Variables Measures | Major Findings |
|---|---|--|--|---|
| Twiss et al., (2006). Determine effect of music listening on postop anxiety and intubation time in pt.'s undergoing cardiovascular surgery. | N = 86 IG = 42. Mean age = 72.6 yrs., CG =44. Mean age = 75.1 yrs. Female = 67% Male = 33% both IG and CG. | Design: RCT Duration: IG: Pre OR - POD 3. Intervention Critical Inputs: Continuous through surgery & surgical ICU. Once awake request music of choice CG: received postop care without music. Pre OR - POD 3 both groups completed STAI. Fidelity Evaluation: Night before surgery, RN delivered STAI, participants chose one CD out of a set of six music CDs | Outcome Variables: STAI, to measure anxiety. Pre/post intervention. Differences in mean intubation times | IG: lower scores on STAI (f = 5.57, p = .022). Fewer min. of postop intubations (F = 5.45, p = .031) post cardiac surgery. IG: less anxiety, reduced intubation time. |

APPENDIX B

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

| RESEARCH SUBJECT INFORMATION AND CONSENT FORM | |
|---|---|
| TITLE: | Music Intervention to Prevent Delirium Among Older Patients Admitted to a Trauma Intensive Care Unit (TICU) |

This consent form contains important information to help you decide whether to participate in a research study.

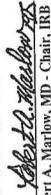
The study staff will explain this study to you. Ask questions about anything that is not clear at any time.

- **Being in a study is voluntary – your choice.**
- **If you join this study, you can still stop at any time.**
- **No one can promise that a study will help you.**
- **Do not join this study unless all of your questions are answered.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done
- What will happen during the study
- Any possible benefits to you
- The possible risks to you
- Other options you could choose instead of being in this study
- How your personal health information will be treated during the study and after the study is over
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

Please read this consent form carefully.

SHC IRB #2014-052
Effective: 8/1/2014 - 7/30/2014

Robert A. Marlow, MD - Chair, IRB

SCOTTSDALE HEALTHCARE
INSTITUTIONAL REVIEW BOARD

Consent to Participate in Research

Protocol Name: Music Intervention to Prevent Delirium Among Older Patients
Admitted to a Trauma Intensive Care Unit (TICU)

Sponsor: NA

Principal Investigator: Kari Johnson RN, MSN, ACNS-BC, PhDc, Hartford
Scholar

Contact Name and Telephone: Kari Johnson (602)380-1034

Introduction

You are invited to consider taking part in this research study because hospitalized older adults are at a greater risk for delirium, especially in acute care settings. We will be testing to determine if a music intervention will prevent delirium among older patients admitted to a trauma intensive care unit. This form will describe the purpose and nature of the study, its possible risks and benefits, other options available to you, and your rights as a participant in the study. Please take whatever time you need to discuss the study with your physicians, hospital personnel and your family and friends. The decision to take part or not is yours. If you decide to take part please initial each page and sign and date the last line of this form.

Background and Purpose of the Study

Delirium is an acute change in consciousness with an impaired ability to focus, sustain or shift attention and can develop within hours or days. Hospitalized older adults are at a greater risk for delirium, with 70% to 83% of delirium in older adults found in ICU settings. Preventing delirium is considered standard of care, and the most effective course in decreasing frequency and adverse outcomes. Current approaches to prevent delirium include approaches that do not have any adverse effects. Music listening can provide distraction and a calm environment. Music listening can be offered in a hospital setting, there are no adverse events with music, requires minimal energy from the patient, patients are able to self-administer or request the music. Our purpose is to prevent delirium through music listening with self-selected music with musical elements proven to relax patients.

Total Number of Participants

Version date: 7/14/14

Initials: _____

About 40 people will take part in this study. People in this study are referred to as "participants." Forty participants will be enrolled at this site.

General Plan of This Study

If you want to be in this research on admission you may be randomized to a "usual care plus music" or a "usual care with no music" group. Both groups will receive "usual care" which is standard of care for the trauma intensive care unit. One group will receive music in addition to "usual care". The no music group will receive a quiet room with dim lights. If randomized to the music group you will ask to self-select from a sample of music selections. Your choice of music to select includes slow tempo (60-80 bpm) and simple repetitive rhythm that has characteristics of relaxing music found to calm physiological responses. You can change your music at any time during the music listening. You will on day 1, day 2, and day 3 at 2 p.m. and 8 pm have an iPod with your choice of music attached to headphones. The iPod will be set so you can hear and you will be checked to see if the headphones are comfortable for you. We will ensure the surroundings are quiet; lights are dim for both the music group and the no music group. You will be monitored by your nurse while the music is playing to make sure you are tolerating the music. The music will play for 60 minutes. After 60 minutes the iPod and headphones will be removed. You are free to decide whether you wish to participate in this study. You can request to have the music stopped at any time.

The choices include the following:

| Style | Selection | Music | Artist |
|-------------|----------------------------|------------------|---------------------|
| Synthesizer | Selection #1 | Comfort Zone | Steven Halpern |
| Harp | Gnossienne #2 | Fresh Impression | Georgia Kelly |
| Piano | Gigi #3 | Nadia's Theme | Roger Williams |
| Orchestra | Symphony #4 | Beethoven | Cleveland Orchestra |
| Jazz | When Joanna Loved Me #5 | Easy Living | Paul Desmond |

To evaluate acceptability of the music intervention, you will be surveyed following the music protocol. You will be asked if you found the music to be helpful, if you would use music listening again during hospitalization, and if you would recommend a music intervention to others.

During the music intervention we will monitor your blood pressure, heart rate, and respiratory rate with noninvasive bedside monitors on admission to the TICU with the first set of vital signs taken during your initial assessment and every four hours over a three day period. Heart rate is defined as the number of heart beats per minute. Respiratory rate is defined as the number of respirations (breaths) per minute. Blood pressure is defined as the pressure of the blood in the circulatory system, often measured for diagnosis since it is closely related to the force and rate of the heartbeat and the diameter and elasticity of the arterial walls.

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Robert A. Marlow
Robert A. Marlow, MD - Chair, IRB

The Confusion Assessment Method will be assessed every twelve hours at the beginning of each shift, the two shifts are from 7 a.m. to 7 p.m. and 7 p.m. to 7 a.m., and will be documented in your electronic medical record. This assessment is a standard assessment that every patient has done while you are a patient in the trauma intensive care unit. Registered nurses in the trauma intensive care unit have been trained in use and application of the Confusion Assessment Method.

How your Treatment will be Determined in This Study

You will be assigned to one of two research treatment groups. A computer will determine which group you will be in through a process that is much like picking a number out of a hat. Neither the researcher nor any of the participants will know who is in which group until the study ends. Your chance of being in any group is 50%. In the event of an emergency, Kari Johnson who is the primary investigator can obtain information about which group you are in and the treatment you are receiving. This process is called randomization.

Length of the Study for Each Participant

We expect that you will spend 60 minutes twice a day for three days participating in the proposed activities, as long as you are patient in the trauma intensive care unit.

Possible Benefits of Participating in the Study

You might not experience delirium while hospitalized; however, we cannot guarantee that you will experience medical benefits from participating in this study. Others may benefit in the future from the information we obtain while you are in this study.

Possible Risks or discomforts

There are no known risks from taking part in this study, but in any research, there is some possibility that you may be subject to risks that have not yet been identified. If at any time you feel uncomfortable, you may exit the study.

Who Can Participate?

This study is designed for patients who are admitted to the Trauma Intensive Care Unit. On admission, you will be screened for eligibility. You will be screened for orientation to person, time, and place on admission, 2) assessed for Delirium using the Confusion Assessment Method (CAM-ICU) which you need to be negative on admission, 3) able to hear 4) able to provide consent for the music intervention and 5) able to speak and understand English. Hearing impairment will be assessed with the whisper test.

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Robert A. Marlow
Robert A. Marlow, MD - Chair, IRB

Who Cannot Participate

You will not be considered for enrollment if you are younger than age 55, not able to pass the whisper test, intubated, or are CAM-ICU positive on admission. If you are interested in participating and meet the inclusion criteria you will be invited to participate.

Confidentiality of the Data Collected During the Study

Every effort will be made to keep your medical records confidential, as well as other personal information that we gather during this study. Please see the attached "Authorization to Share Protected (personal) Health Information (PHI) in Research."

Whenever data from this study are published, your name will not be used.

Individuals from the Scottsdale Healthcare IRB, Scottsdale Healthcare, the U.S. Food and Drug Administration, and John C Lincoln North Mountain Hospital may look at medical and research records related to this study, both to assure quality control and to analyze data. We will disclose personal information about you to others as required by law.


Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

All consent forms will be stored under double lock and key in the Principal Investigators (PI) office. Research data collected during and after the study period and coded information will be stored under double lock and key in the PI's office. Computerized data will be located on a secured password protected John C. Lincoln Network. Study participants will be assigned a research number generated from SPSS for use during data analysis. Access to study data will be limited to the PI. No study data with identifiers will be released to any outside agencies. Research data will be kept until completion of data analysis and publication of results in accordance with the Scottsdale Lincoln Health Network IRB. Data will be entered into a Microsoft Excel database. Data will be analyzed using a commercial software package (SPSS version 16.0; Chicago, IL). Data will be double entered as independent SPSS 16 files. After data entry is completed, files will be compared, with discrepancies identified and reconciled

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Robert A. Marlow, MD - Chair, IRB

with raw data forms. Data will be secured on a password protected personal computer at work where the PI only operates the computer. The computer is in an office that is locked.

New Findings

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

Costs to You for Participating

You will not be charged for any costs related to this study.

Payments to the Principal Investigator, Institution/Hospital

The principal investigator for this trial is not receiving payment for the time spent completing study related duties.

Payments to You for Participating

Study participants will not be paid for participating in this study.

Compensation in Case of Injury

We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive emergency medical care. The costs of this care will be charged to you or to your health insurer. No funds are available from John C. Lincoln North Mountain Hospital, Scottsdale Healthcare or the federal government to compensate you for a study-related injury or illness. This does not mean that you are giving up any of your legal rights.


Your Rights as a Participant in the Study

Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Should you decide to leave the study, you can notify your registered nurse who is caring for you or the primary investigator. Should you decide not to participate or to withdraw, your medical care will not be affected nor will your relations with your physicians, other personnel, and the hospital.

Problems and Questions

Version date: 7/14/14

Initials: _____

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Effective: 8/1/2014 - 7/30/2014

Robert A. Martow, MD - Chair, IRB

Contact Kari Johnson at (602 870-6060 ext. 2592) day or night if you have questions about the study, any problems, unexpected physical or psychological discomforts, any injuries, or think that something unusual or unexpected is happening.

Regulatory or Ethical Issues

The Scottsdale Healthcare Institutional Review Board (IRB) has reviewed this document for compliance with federal guidelines, and ethics. *Please note the IRB staff will NOT have information regarding appointment times. You will need to contact the investigator at the number above.* If you have questions about your rights as a research participant, you may call or write: IRB Coordinator or Robert Marlow, MD, Chair, IRB, 9003 E. Shea Blvd., Scottsdale, AZ 85260, 480-323-3071.

Withdrawal by Investigator

The investigators may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

Participant's Consent

You have read the information provided in this Informed Consent Form (or it was read to you by Kari Johnson. All of your questions were answered to your satisfaction. You voluntarily agree to participate in this study in this study.

Upon signing, you will receive a copy of this form, and the original will become part of your medical record.

Your signature _____ Date _____

Investigator's Statement

I have fully explained this study to the participant. I have discussed the procedures and treatments, the possible risks and benefits, the standard and research aspects of the study, and have answered all of the questions that the participant and the participant's family members have asked.

Signature of Investigator or Investigator's Designee _____

Date _____

SHC IRB #2014-052
Effective: 8/1/2014 - 7/30/2014
Robert A. Marlow MD
Robert A. Marlow, MD - Chair, IRB

APPENDIX C
IRB APPROVAL EXPEDITED
REVIEW LETTER ASU



APPROVAL: EXPEDITED REVIEW

Julie Fleury
CONHI - PhD
602/496-0773
Julie.Fleury@asu.edu

Dear Julie Fleury:

On 6/2/2014 the ASU IRB reviewed the following protocol:

| | |
|---------------------|--|
| Type of Review: | Initial Study |
| Title: | Music Intervention To Prevent Delirium Among Older Patients Admitted To A Trauma Intensive Care Unit (TICU). |
| Investigator: | Julie Fleury |
| IRB ID: | STUDY00000910 |
| Category of review: | (5) Data, documents, records, or specimens, (7)(a) Behavioral research |
| Funding: | None |
| Grant Title: | None |
| Grant ID: | None |
| Documents Reviewed: | <ul style="list-style-type: none">• Consent FORM, Category: Consent Form;• CAM-ICU1.pdf, Category: IRB Protocol;• HRP-503a - TEMPLATE PROTOCOLSOCIAL BEHAVIORALfinal523 (3).docx, Category: IRB Protocol;• Music Protocol[3].pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);• Index of Procedural ConsistencyMusic (3).pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);• Spotchecking.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);• Music Interview Survey, Category: Measures |

| | |
|--|---|
| | <p>(Survey questions/Interview questions /interview guides/focus group questions);</p> <ul style="list-style-type: none"> • HIPPA Policy, Category: Other (to reflect anything not captured above); • Recruitmentmaterial2014final[1].pdf, Category: Recruitment Materials; • Recruitment Script, Category: Recruitment materials/advertisements /verbal scripts/phone scripts; • Orientation Screening, Category: Screening forms; • Screening ToolASUIRB (1).pdf, Category: Screening forms; • Screening ToolWhispered Test (1).pdf, Category: Screening forms; |
|--|---|

The IRB approved the protocol from 6/2/2014 to 6/1/2015 inclusive. Three weeks before 6/1/2015 you are to submit a completed "FORM: Continuing Review (HRP-212)" and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 6/1/2015 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Kari Johnson
 Nelma Shearer
 Kari Johnson
 Darya McClain
 Julie Fleury

APPENDIX D

IRB APPROVAL MODIFICATION LETTER ASU



APPROVAL: MODIFICATION

Julie Fleury
CONHI - PhD
602/496-0773
Julie.Fleury@asu.edu

Dear Julie Fleury:

On 9/12/2014 the ASU IRB reviewed the following protocol:

| | |
|---------------------|---|
| Type of Review: | Modification |
| Title: | Music Intervention To Prevent Delirium Among Older Patients Admitted To A Trauma Intensive Care Unit (TICU). |
| Investigator: | Julie Fleury |
| IRB ID: | STUDY00000910 |
| Funding: | None |
| Grant Title: | None |
| Grant ID: | None |
| Documents Reviewed: | <ul style="list-style-type: none">• Consent FORMmodified2014- no highlight.pdf, Category: Consent Form;• Consent FORM, Category: Consent Form;• HRP-503a-TEMPLATE PROTOCOLSOCIAL BEHAVIORALfinal, Category: IRB Protocol;• CAM-ICU1.pdf, Category: IRB Protocol;• Index of Procedural ConsistencyMusic (3).pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);• Music Interview Survey, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);• Music Protocolmodification2014.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);• Spotchecking.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); |

| | |
|--|---|
| | <ul style="list-style-type: none"> • Scottsdale IRB approvalMusic2014.pdf, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc); • HIPPA Policy, Category: Other (to reflect anything not captured above); • Music Protocoltalkingpointsstaffmodified2014.pdf, Category: Recruitment Materials; • Recruitment Script, Category: Recruitment materials/advertisements /verbal scripts/phone scripts; • Screening ToolASUIRB (1).pdf, Category: Screening forms; • Screening ToolWhispered Test (1).pdf, Category: Screening forms; • Orientation Screening, Category: Screening forms; |
|--|---|

The IRB approved the modification.

When consent is appropriate, you must use final, watermarked versions available under the “Documents” tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc:

APPENDIX E

IRB APPROVAL LETTER SCOTTSDALE

HEALTHCARE RESEARCH INSTITUTE



FWA00001751

August 6, 2014

Kari Johnson, RN, MSN, ACNS-BC, PhDc
John C Lincoln-North Mountain
250 East Dunlap Ave
Phoenix, AZ 85020

RE: SLHN IRB #2014-052: Your new submission received on 6/13/2014 regarding Music Intervention to Prevent Delirium Among Older Patients Admitted To A Trauma Intensive Care Unit (TICU) (None)

Dear Ms Johnson:

I have reviewed your request for expedited approval of the new study listed above. Your study is eligible for expedited review under FDA and DHHS (OHRP) Category 5. Materials collected for non research purposes designation.

This is to confirm that as of 7/31/2014 I have approved your application. The current protocol as written, is approved. Consent form version dated 7/14/2014 has been approved at this time.

You are granted permission to conduct your study as described in your application effective immediately. The study is subject to continuing review before the expiration date of 7/30/2015, unless closed before that date.

Only the enclosed official SHC consent form with the approval stamp may be used to consent your subjects.

Please note that any changes to the study as approved must be promptly reported and approved. Some changes may be approved by expedited review; others require full board review. Contact Kituria V. Gaines (480-323-3071; fax 480-323-3208; email: Kgaines@SHC.org) if you have any questions or require further information.

Sincerely,

A handwritten signature in black ink that reads "Robert A. Marlow MD". The signature is written in a cursive style with a large, stylized "R" and "M".

Robert Marlow, MD-IRB Chair

10510 N. 92nd Street, Suite 300, Scottsdale, AZ 85258 / Tel 480-323-3011 / shc.org

APPENDIX F

IRB APPROVAL MODIFICATION LETTER SCOTTSDALE

HEALTHCARE RESEARCH INSTITUTE



October 17, 2014

Kari Johnson, RN, MSN, ACNS-BC, PhDc
John C Lincoln-North Mountain
250 East Dunlap Ave
Phoenix, AZ 85020

RE: **SHC IRB #2014-052**: Your modification form received on 9/17/2014 regarding Music Intervention to Prevent Delirium Among Older Patients Admitted To A Trauma Intensive Care Unit (TICU) (None)

Dear Ms. Johnson:

I have reviewed your application for revision or modification of the study listed above. The requested revision involves changes to the protocol. Your request is eligible for expedited review under 21 CFR 56.110(b) and 45 CFR 46.110(b) regulations.

This is to confirm that I have approved your request for revision on 10/16/2014. The protocol is approved through 9/10/2014 Addition of Trauma Orthopedic Unit to capture more subjects that meet inclusion criteria.

The following was approved at this time:

Revision Request 9/10/2014 Addition of Trauma Orthopedic Unit to capture more subjects that meet inclusion criteria

You are granted permission to conduct your study as revised effective immediately. The date for continuing review remains unchanged at **7/30/2015**, unless closed before that date.

Please note that any further changes to the study must be promptly reported and approved. Contact Kituria V. Gaines (480-323-3071; fax 480-323-3208; email: kgaines@SHC.org) if you have any questions or require further information.

Sincerely,

A handwritten signature in black ink that reads "Robert D. Marlow MD".

Robert Marlow, MD-IRB Chair

APPENDIX G
DATA COLLECTION PACKET

Whispered Test

Conducting the Whispered Voice Test

The examiner stands arm's length (0.6 m) behind the seated patient and whispers a combination of numbers and letters (for example, 4-K-2) and then asks the patient to repeat the sequence. The examiner should quietly exhale before whispering to ensure as quiet a voice as possible. If the patient responds correctly, hearing is considered normal; if the patient responds incorrectly, the test is repeated using a different number/letter combination. The patient is considered to have passed the screening test if they repeat at least three out of a possible six numbers or letters correctly. The examiner always stands behind the patient to prevent lip reading. Each ear is tested individually, starting with the ear with better hearing, and during testing the non-test ear is masked by gently occluding the auditory canal with a finger and rubbing the tragus in a circular motion. The other ear is assessed similarly with a different combination of numbers and letters.

Orientation Screening

Each participant will be asked:

1. What is your name?
2. Where are you right now?
3. What year is it?

Evaluation of Intervention Acceptability

I am a graduate student under the direction of Dr. Julie Fleury at Arizona State University College of Nursing and Health Innovation. I am conducting a research study to evaluate whether a music intervention can prevent delirium among older patients admitted to a trauma intensive care unit. As part of my research study I would like to ask you what you think about your experience with the music listening that you participated in. These questions that I ask will help me evaluate acceptability of the music intervention.

| | Strongly Agree | Agree | Neutral | Disagree | Strongly Disagree | Refused | Doesn't know | Missing |
|--|----------------|-------|---------|----------|-------------------|---------|--------------|---------|
| 1. Overall, music listening was helpful to me while in hospital | 1 | 2 | 3 | 4 | 5 | 666 | 777 | 999 |
| 2. Music listening helped me to relax while in hospital | 1 | 2 | 3 | 4 | 5 | 666 | 777 | 999 |
| 3. Music listening helped me with anxious thoughts while in hospital | 1 | 2 | 3 | 4 | 5 | 666 | 777 | 999 |
| 4. Music listening helped me feel more like myself while in the hospital | 1 | 2 | 3 | 4 | 5 | 666 | 777 | 999 |
| 5. I was satisfied with the music listening while in the hospital | 1 | 2 | 3 | 4 | 5 | 666 | 777 | 999 |
| 6. Using the music listening equipment was easy | 1 | 2 | 3 | 4 | 5 | 666 | 777 | 999 |
| 7. Wearing the music listening headphones was comfortable | 1 | 2 | 3 | 4 | 5 | 666 | 777 | 888 |
| 8. I was satisfied with the number and length of the music listening intervention sessions | 1 | 2 | 3 | 4 | 5 | 666 | 777 | 888 |
| 9. I would recommend the music listening intervention to others while in the hospital | 1 | 2 | 3 | 4 | 5 | 666 | 777 | 999 |

Index of Procedural Consistency

Pt. Identification number _____ Date _____

Time Music Started _____ Time Music Ended _____

Music Monitoring: Please write down patient study Id#, time music started and ended, and date. Please check appropriate box after each music intervention.

____ Patient listened to music full 60 minutes

____ Patient listened to music _____ minutes

____ Patient refused music listening.

Reason _____

____ Music Selection

Please rate music intervention after each occurrence by an Index of Procedural Consistency to determine the degree to which the intervention was delivered as planned. The Interventionist will score each music intervention from 1 (achieved very little) to three (achieved very well) and a mean score will be calculated. Please rate the degree to which the intervention was delivered as planned after each intervention.

Achieved very little Achieved Achieved very well

1

2

3

Field Notes:

Music Interview Survey

I am a graduate student under the direction of Dr. Julie Fleury at Arizona State University College of Nursing and Health Innovation. I am conducting a research study to evaluate whether a music intervention can prevent delirium among older patients admitted to a trauma intensive care unit. As part of my research study I would like to ask you three questions about your experience with the music listening that you participated in. These questions that I ask will help me evaluate acceptability of the music intervention.

- 1) Did you find the music to be helpful during your hospital stay?
- 2) Would you use music listening again during your hospitalization?
- 3) Would you recommend music listening to others?

The Confusion Assessment Method for the ICU (CAM-ICU)

By: Judith A. Tate, PhD, RN and Mary Beth Happ, PhD, RN
Department of Acute & Tertiary Care, University of Pittsburgh School of Nursing

WHY: The reported incidence of delirium among intensive care unit (ICU) patients ranges from 40-87%, with highest occurrence among older adults and those who receive mechanical ventilation in the ICU. Delirium can be classified as either hypoactive (calm, less movement) or hyperactive (agitated, combative). Delirium is associated with negative clinical outcomes (i.e., increased hospital length of stay, medical complications, physical restraint use, and prolonged neurocognitive deficits). Assessment of delirium using a clinically valid and reliable tool provides neurocognitive data necessary for the development of an appropriate treatment plan.

BEST TOOL: Accurate delirium assessment cannot be obtained by informal bedside nurse-patient interaction. The CAM-ICU is an adaptation of the Confusion Assessment Method by Inouye (1990), the most widely used instrument for diagnosing delirium by internists and non-psychiatric clinicians. The CAM-ICU is the only delirium assessment tool constructed with yes/no questions for use with nonspeaking, mechanically ventilated ICU patients.

TARGET POPULATION: The CAM-ICU should be used on all older adults admitted to the ICU in order to promptly identify any potential delirium and prevent negative outcomes.

VALIDITY AND RELIABILITY: The CAM-ICU is valid, and shows high interrater reliability ($\kappa=0.79-0.96$). Compared with a reference standard (psychiatrist) diagnosis of delirium, the CAM-ICU used by study nurses had sensitivities of 93-100% and specificities of 89-100%.

The CAM-ICU has not been validated for use in other clinical settings. A brief version for screening delirium is being tested for use in the Emergency Department. Other instruments that have been validated for screening for delirium in settings outside the ICU include the original CAM, the Delirium Rating Scale, the Memorial Delirium Assessment Scale, and the Nursing Delirium Screening Scale.

STRENGTHS AND LIMITATIONS: The CAM-ICU is rapid (2 minutes), easy to administer with minimal training, and has been translated into 10 different languages. It can be adapted for use with patients with hearing and visual disturbances and is easily reproducible. Staff training should include methods to assure reliability of assessment and to maintain performance after initial training. Although the CAM-ICU requires the use of special pictures, particularly for hearing impaired patients, materials and training manual can be downloaded from <http://www.mc.vanderbilt.edu/icudelirium/index.html>.

FOLLOW-UP: Because delirium can occur at any time during critical illness, ICU patients should be monitored every shift, or at minimum each day, for delirium onset and/or resolution of these symptoms.

MORE ON THE TOPIC:

Best practice information on care of older adults: www.ConsultGerRN.org.

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Table 1. The Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)

| FEATURES AND DESCRIPTIONS | ABSENT | PRESENT |
|---|----------------|---------------|
| I. Acute onset or fluctuating course* | | |
| A. Is there evidence of an acute change in mental status from the baseline? B. Or, did the (abnormal) behavior fluctuate during the past 24 hours, that is, tend to come and go or increase and decrease in severity as evidenced by fluctuations on the Richmond Agitation Sedation Scale (RASS) or the Glasgow Coma Scale? | | |
| II. Inattention† | | |
| Did the patient have difficulty focusing attention as evidenced by a score of less than 8 correct answers on either the visual or auditory components of the Attention Screening Examination (ASE)? | | |
| III. Disorganized thinking | | |
| Is there evidence of disorganized or incoherent thinking as evidenced by incorrect answers to three or more of the 4 questions and inability to follow the commands? Questions 1. Will a stone float on water? 2. Are there fish in the sea? 3. Does 1 pound weigh more than 2 pounds? 4. Can you use a hammer to pound a nail? Commands 1. Are you having unclear thinking? 2. Hold up this many fingers. (Examiner holds 2 fingers in front of the patient.) 3. Now do the same thing with the other hand (without holding the 2 fingers in front of the patient). (If the patient is already extubated from the ventilator, determine whether the patient's thinking is disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject.) | | |
| IV. Altered level of consciousness | | |
| Is the patient's level of consciousness anything other than alert, such as being vigilant or lethargic or in a stupor or coma? ALERT: spontaneously fully aware of environment and interacts appropriately VIGILANT: hyperalert LETHARGIC: drowsy but easily aroused, unaware of some elements in the environment or not spontaneously interacting with the interviewer; becomes fully aware and appropriately interactive when prodded minimally STUPOR: difficult to arouse, unaware of some or all elements in the environment or not spontaneously interacting with the interviewer; becomes incompletely aware when prodded strongly; can be aroused only by vigorous and repeated stimuli and as soon as the stimulus ceases, stuporous subject lapses back into unresponsive state COMA: unarousable, unaware of all elements in the environment with no spontaneous interaction or awareness of the interviewer so that the interview is impossible even with maximal prodding | | |
| Overall CAM-ICU Assessment (Features 1 and 2 and either Feature 3 or 4): | Yes ___ | No ___ |

* The scores included in the 10-point RASS range from a high of 4 (combative) to a low of -5 (deeply comatose and unresponsive). Under the RASS system, patients who were spontaneously alert, calm, and not agitated were scored at 0 (neutral zone). Anxious or agitated patients received a range of scores depending on their level of anxiety: 1 for anxious, 2 for agitated (fighting ventilator), 3 for very agitated (pulling on or removing catheters), or 4 for combative (violent and a danger to staff). The scores -1 to -5 were assigned for patients with varying degrees of sedation based on their ability to maintain eye contact: -1 for more than 10 seconds, -2 for less than 10 seconds, and -3 for eye opening but no eye contact. If physical stimulation was required, then the patients were scored as either -4 for eye opening or movement with physical or painful stimulation or -5 for no response to physical or painful stimulation. The RASS has excellent interrater reliability and intraclass correlation coefficients of 0.95 and 0.97, respectively, and has been validated against visual analog scale and geropsychiatric diagnoses in 2 ICU studies.

† In completing the visual ASE, the patients were shown 5 simple pictures (previously published) at 3-second intervals and asked to remember them. They were then immediately shown 10 subsequent pictures and asked to nod "yes" or "no" to indicate whether they had or had not just seen each of the picture. Since 5 pictures had been shown to them already, for which the correct response was to nod "yes," and 5 others were new, for which the correct response was to nod "no," patients scored perfectly if they achieved 10 correct responses. Scoring accounted for either errors of omission (indicating "no" for a previously shown picture) or for errors of commission (indicating "yes" for a picture not previously shown). In completing the auditory ASE, patients were asked to squeeze the rater's hand whenever they heard the letter A during the recitation of a series of 10 letters. The rater then read 10 letters from the following list in a normal tone at a rate of 1 letter per second: S, A, H, E, V, A, A, R, A, T. A scoring method similar to that of the visual ASE was used for the auditory ASE testing.

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