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# THE FEASIBILITY OF A MUSIC LISTENING INTERVENTION ON THE INCIDENCE, SEVERITY, AND DURATION OF DELIRIUM IN THE OLDER ACUTE CARE PATIENT. A FEASIBILITY TRIAL

A Dissertation

Submitted to the School of Nursing

Duquesne University

In partial fulfillment of the requirements for

the degree of Doctor of Philosophy

By

Mary Kitchura Kovaleski

May 2021

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Mary Kitchura Kovaleski

### THE FEASIBILITY OF A MUSIC LISTENING INTERVENTION ON THE INCIDENCE, SEVERITY, AND DURATION OF DELIRIUM IN THE OLDER ACUTE CARE PATIENT. A FEASIBILITY TRIAL

By

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Approved November 17, 2020

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#### ABSTRACT

# THE FEASIBILITY OF A MUSIC LISTENING INTERVENTION ON THE INCIDENCE, SEVERITY, AND DURATION OF DELIRIUM IN THE OLDER ACUTE CARE PATIENT. A FEASIBILITY TRIAL

By

Mary Kitchura Kovaleski

May 2021

Dissertation supervised by Dr. Patricia Watts Kelley

Delirium is an acute change in mental status that commonly occurs in the hospitalized elderly and if undetected, contributes to increased mortality and both functional and cognitive decline. Due to the high prevalence of delirium and its associated adverse health risks, it is critically important to prevent delirium among older adults admitted to the hospital. The purpose of this study was twofold: to test the feasibility of conducting an interdisciplinary music listening intervention in hospitalized older adults, and to assess the effect of a music listening intervention on the incidence, severity, and duration of delirium using standardized delirium assessments. A single setting, two-armed feasibility study with a music listening intervention group (n = 24) and a usual care control group (n = 20) was conducted on older adults admitted to the Progressive Care Unit of a 280-bed acute care hospital in the Mid-Atlantic region. This

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nurse-led music listening intervention was developed in collaboration with a music therapist who designed music playlists based upon individual patient preferences, experiences, and delirium subtypes. The music intervention was delivered by registered nurses following the twice daily Confusion Assessment Method (CAM) and Confusion Assessment Method-Severity (CAM-S) assessments of the patient's delirium, and delirium subtype in accordance with the protocol. Participants in both groups had a mean age of 77.75 years and 100% were Caucasian. There were no significant differences in the incidence, severity, and duration of delirium between the groups. The music listening intervention could not be delivered for the intended length of time as participants were transferred to units where the staff was not trained on the CAM and CAM-S.

#### DEDICATION

To my husband Jim for his unwavering love and support during this endeavor, and to my children, Kyle, Alicia and Marina for keeping me sane. To Eugene with love, you are the light of my life.

#### ACKNOWLEDGEMENT

To my family, especially my husband and children, your love, encouragement and support led me to have faith in myself and in my abilities. To Adele Spegman, I cannot thank you enough for your support, knowledge and kindness. You have left a lasting impression on me. To Marie Roke-Thomas, thank you for your statistical advice. To David Nolfi, thank you for your expertise with the literature review and obtaining hard to find articles. To Dr. Margarete Zalon, thank you for your patience, your friendship and for your expertise on the topic of delirium, the elderly and how to navigate a PhD program. To Dr. Noah Potvin, thank for the insight and expertise in understanding what music therapy is and how it can assist our patients. To Dr. Linda Garand, thank you for your guidance in advocating for the well-being of people with cognitive impairment. To Dr. Patricia Kelley, my committee chair, thank you for your guidance in my development as a novice researcher and for your assistance in guiding me through this process. Lastly, I would like to thank all my study participants for their enthusiasm, their invaluable information and wonderful, uplifting spirits.

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#### LIST OF ABBREVIATIONS

- CAM = Confusion Assessment Method
- CAM-S = Confusion Assessment Method Severity
- CNS = Clinical Nurse Specialist
- CVA = Cerebral Vascular Accident
- DST = Digit Span Test
- ICU = Intensive Care Unit
- IR = Integrative Review
- MMSE = Mini Mental State Exam
- NEECHAM = Neelon, Champagne Confusion Scale
- PCU = Progressive Care Unit
- PI = Principal Investigator
- RCT = Randomized Controlled Trial
- RN = Registered Nurse
- SPMSQ =Short Portable Mental State Exam
- TIA = Transient Ischemic Attack

#### **INTEGRATIVE REVIEW OF THE LITERATURE**

#### **Manuscript #1**

### The Effect of Music Interventions on Delirium in the Older Acute Care Patient: An Integrative Review of the Literature

#### Abstract

**Background.** Delirium is an acute change in cognition in response to some form of noxious insult which has been shown to last for up to one year post occurrence and may lead to permanent cognitive decline. As a non-pharmacological treatment, music may aid in improving patient engagement and attention. **Method.** An integrative review (IR) was used to synthesize current literature examining the effect of a music intervention on delirium in older acute care patients. **Results.** Systematic database searches (2000-2019) yielded four studies that included a music listening intervention. This IR found that collaborative music listening interventions (not music therapy), have been shown to decrease delirium in the older acute care patient, and that collaborative music interventions between nurses and music therapists are largely unexplored. **Conclusion.** Non-pharmacological music interventions have been used to reduce delirium incidence in older adults. Collaborative music listening interventions may help maintain cognitive function in this vulnerable population and requires further investigation.

### The Effect of Music Interventions on Delirium in the Older Acute Care Patient: An Integrative Review of the Literature

Although identified more than 2500 years ago, delirium remains underrecognized, underreported, and poorly understood. Delirium is a complex neuropsychiatric syndrome that is associated with functional decline, increased morbidity, hospital costs, and risk of institutionalization with prevalence rates of up to 80% in some hospital settings (Dasgupta & Brymer, 2014; Fuller, 2016; Young et al., 2015). Validated and reliable delirium assessment tools assist the nurse to identify and diagnose delirium. The National Institute for Health and Care Excellence (NICE, 2010) advises using a standardized assessment tool such as the Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV) or the Confusion assessment method (CAM) for screening. Despite having standardized detection tools, delirium detection remains poor. Nurses as front line providers detect delirium approximately 63.3% of the time, but document the presence of delirium only 43.6% of the time. (Ryan et al., 2010).

Delirium prevalence is widely variable across different clinical settings. General medical wards report delirium prevalence rates of 23.7%, orthopedic wards 28.5%, neurosurgical wards 22%, and geriatric wards 53% (Ryan et al., 2010). In critical care areas, sedation, analgesia and mechanical ventilation increase the occurrence of delirium which varies from 16% to 80% (Devlin et al., 2007). Palliative care units have delirium rates ranging from 13.3% to 42.3% that may climb upwards to 88% as death becomes imminent (Hosie et al., 2013). This IR was limited to studies of delirium on acute care inpatient wards, excluding articles on intensive care, palliative care or rehabilitation populations.

There is a need to examine the evidence for the non-pharmacological, clinical management of delirium in the acute care setting. Pharmacological management of delirium is not recommended, but the 2015 BEERS Criteria supports the use of a non-pharmacological approaches for delirium treatment (American Geriatrics Society, 2015). There is a need to examine the evidence for the non-pharmacological, clinical management of delirium in the acute care setting.

#### **Problem Identification and Significance**

Delirium is a preventable syndrome characterized by inattention, disorganized thinking, fluctuating levels of alertness and cognition, and is thought to be responsible for an 11% increase in mortality for every additional 48 hours spent delirious (Gonzalez et al., 2009). It is an acute change in cognition in response to some form of noxious insult such as surgery, a change in environment or medications. This may represent a series of insults and recovery that may lead to permanent cognitive decline such as dementia (Inouye et al., 2014). Delirium may last for up to one year post occurrence and is more likely to result in admission to a long-term facility, especially with hypoactive delirium (Dasgupta & Brymer, 2014; Siddigi et. al., 2007). The symptoms of delirium fluctuate; thus, it is difficult to detect and treat. This is evident in patients with hyperactive delirium who are treated inappropriately with psychotropic medications and physical restraints to control their distressing behavior (Cheong et al., 2016a; Marcantonio, 2012). This is in contrast to hypoactive delirium which remains underrecognized or mistaken as depression (Inouye et al., 2001; Marchington et al., 2012). Mixed delirium occurs when both types of delirium are present and wax and wane during hospitalization (Inouye, et al.).

**Exploring delirium and music.** Previous research on patients with dementia supports music therapy to improve both cognitive functioning and patient engagement (Blackburn & Bradshaw, 2014; Burgener, et al., 2015; Sarkamo et al., 2014; Vasionytė & Madison, 2013). This occurs through creating environments that are conducive to healing (Cheong et al., 2016a; McCaffrey, 2008; Skingley & Vella-Burrows, 2010) which may benefit delirious patients. Music listening, as a music therapy intervention under the direction of a music therapist (American Music Therapy Association, 2018 a), has been shown to improve orientation, attention and to a smaller extent, overall cognition in dementia patients (Sarkamo et al., 2014). In patients with traumatic brain injury, music therapy is used for rehabilitating basic and executive function, including cognition by promoting neurogenesis. This in turn leads to neuroplasticity as a response to stressors, such as a change in environment (O'Kelly & Magee, 2013; Hedge, 2014; Innes et al, 2017).

Music therapy has the ability to stimulate intricate cognitive, affective and sensorimotor processes in the brain that may then be generalized and applied to nonmusical, restorative applications (Hedge, 2014). Music therapy is a purposive, systematic process where the music therapist assists the patient to enrich, maintain or reinstate patient well-being, and is used as the main drive for change (Cheong et al., 2016; American Music Therapy Association [AMT], 2018 a). The music therapist's guidance is integral to support theraputic, individual music interventions. Without the guidance of a music thearpist the relationship is not therapeutic, client-centered, or infused with theory, assessment and evaluation (AMT, 2018 b,c).

#### **Purpose and Specific Aims**

The purpose of this IR was to examine, summarize, synthesize, and determine the extent and quality of literature regarding the effect of a music intervention upon delirium in the older, acute care patient to guide future research in this area. The use of music therapy has been studied in patients with severe dementia and traumatic brain injury (Sakamoto et al., 2013), in mechanically ventilated critical care patients (Almerud & Petersson, 2003; Mofredj et al., 2016) and in palliative care; but no studies have examined the effect of a music therapy intervention on delirium in the older, acute care patient. This IR examined the literature for music therapy interventions that examined the effect of a music intervention on delirium in the older, acute care patient. This IR examined the literature for music therapy interventions that examined the effect of a music intervention on delirium in the older, acute care patient. This specific aim guided the IR:

1. What effect does a music intervention have upon delirium in the older, acute care patient?

#### Method

The integrated literature review process outlined by Whittemore & Knafl (2005) was followed for this review to verify, support and/or oppose the quantitative and qualitative studies relating to the effect of a music intervention on delirium, to search and evaluate the evidence related to the effect of a music intervention on delirium, and to report the findings of the literature regarding the effects of a music intervention on delirium. The steps involved in this review method include: problem identification, conducting a literature search, evaluating the quality of the data, analyzing the data and synthesizing and presenting the findings (Whittemore & Knafl, 2005).

#### Literature Search

A thorough, methodological literature search outlined by Whittemore was conducted from January 2000 to January 2020, with the guidance of a health sciences librarian, on published studies from PubMed<sup>®</sup>, Cumulative Index of Nursing and Allied Health Literature (CINAHL<sup>®</sup>), PsychINFO<sup>®</sup>, Scopus<sup>®</sup>, Music Index<sup>®</sup>, Music Periodicals Database<sup>®</sup>, Répertoire International de Littérature Musicale (RILM<sup>®</sup>), Embase<sup>®</sup>, and JSTOR<sup>®</sup>. Although studies directly assessing music in relation to delirium in the acute care area were not published until 2004, the search years were extended to capture all published studies that might be pertinent to delirium and music interventions. Due to the number of synonyms for the term delirium, the search included the following key words and search terms: *delirium, acute confusion, agitation, confusion assessment method,* confusion, mental confusion, disorientation, disoriented, inattentiveness, poor historian and sundowning. The Boolean operators AND and OR were used to combine these terms with delirium<sup>\*</sup>, acute confusion and music therapy, music therapists, music therapies, *music therap*\*), "singing, or "*music*", to capture the appropriate studies. See Appendix A.Table for search terms used.

The search results were screened by this author and a review of the titles and abstracts (full text review if warranted) was performed to ascertain if an article met the inclusion criteria: a). the topic addressed a music intervention; b.) delirium or cognition was assessed; c). participants' were 65 years or older, admitted to an acute care ward, d). studies conducted between January 2000 – January 2020; and e). any research design was acceptable. The review excluded non-research publications and publications that did not address the inclusion criteria. Exclusion criteria: a). study did not address a music intervention; b). delirium or cognition were not assessed c). studies not reported in

English or conducted outside of 2000 – 2020 and d). participants younger than 65 years, and not admitted to an acute care ward. This IR was limited to studies of delirium on acute care inpatient wards, excluding articles on intensive care, palliative care or rehabilitation populations.

The search resulted in 1264 references for screening, 566 duplicates were removed, 698 studies screened against title and abstract, resulting in excluding 668 studies. Thirty studies were assessed for full-text eligibility, 26 studies were excluded (Figure 1 for the PRISMA flowchart of the study selection process). Four studies qualified for review: McCaffrey & Loscin (2004); McCaffrey & Loscin (2006); McCaffrey (2009) and Çetinkaya (2019). Included studies were all RCT's done between 2004- 2019, in a single hospital setting. (Table 1 Randomized Control Trials).

#### **Description of Sample**

Three RCT's (McCaffrey & Loscin, 2004; McCaffrey &Loscin, 2006; McCaffrey, 2009) were all conducted in a large tertiary care center in the Southeastern United States that examined music listening, without a music therapist's direction for the treatment or prevention of delirium from 2004-2009. One study was conducted in an orthopedic educational research hospital in Aksaray, Turkey from February 2018 through June 2018 that used a music listening, not music therapy intervention (Çetinkaya, 2019). Three studies reported convenience sampling (N = 66, McCaffrey & Loscin, 2006; N= 124, McCaffrey, 2009; N = 60, Çetinkaya, 2019) one used a non-probability convenience sample (N = 22, McCaffrey & Loscin, 2004) and one study reported a power analysis (Çetinkaya, 2019).

Inclusion criteria was the same for 3 studies: age > 65, undergoing elective hip or knee surgery, able to hear music, being alert and oriented to provide consent for surgery and to complete preoperative paperwork independently (McCaffrey & Loscin, 2004; McCaffrey & Loscin, 2006; & McCaffrey, 2009). Çetinkaya 2109, listed inclusion criteria as  $\geq$  65 years or older, no complications during the 3 postoperative period and willingness to participate. The exclusion criteria were mental retardation (that hinders communication), dementia (defined as a Mini-Mental State Examination [MMSE] score of < 23), age <65 years, hearing problem, the development of postoperative complications, and unable to speak Turkish (Çetinkaya, 2019).

In two studies the demographics of participants were similar: McCaffrey & Loscin (2006) mean age, 77.33 (SD = 5.36) - 76.79 (SD= 5.12), and McCaffrey (2009) mean age 74.5 (SD = 4.8) & 75.9 (SD = 6.3). Gender was included in two studies (male: female) 4:7 (McCaffrey, 2009) and females 25 (SD = 83.3) and males 5(SD = 23.3) (Çetinkaya, 2109). The music listening intervention used in these studies was not under the direction of a music therapist, but three used lullaby music played initially upon awakening (McCaffrey & Loscin, 2004, McCaffrey & Loscin, 2006 and McCaffrey, 2009). Once awake, participants were able to choose from a select list of available music. One study used Acemasiran Turkish music throughout the three day study (Çetinkaya, 2109). One study reported post-operative ready for ambulation scores and episodes of acute confusion via post hoc nursing note review (McCaffrey & Loscin, 2004), one study used episodes of acute confusion determined by post hoc nursing note analysis (McCaffrey & Loscin, 2006) and two studies measured cognitive function via Mini Mental State Exam (MMSE) and Neelon and Champagne Confusion Scale (NEECHAM)

(Çetinkaya, 2109; McCaffrey, 2009). Two studies reported a significant decrease in the overall incidence of delirium in the music intervention group (F= 19.568, p = .001; McCaffrey & Loscin, 2004), (F= 29.56, p = .001, McCaffrey & Loscin 2006). Two studies reported higher NEECHAM scores in the music intervention group (F = 7.28, p = .014, McCaffrey 2009), while Çetinkaya, (2019) found significant differences between the intervention and control groups (p =.05) especially between post-operative day 2 (p= .006) and day 3 (p < .001).

#### **Data Evaluation**

A methodological approach was used to appraise the quality of each publication (Whitmore & Knafl, 2005). The data evaluation stage is essential to evaluate overall quality and reliability of the results and is dependent upon the consistency of the quality scores to accurately rate the quality of the evidence and the strength of the recommendations (Whittemore & Knafl, 2005). The GRADE approach will be used in this review to establish ratings on the quality of evidence and the grade strength of recommendations. According to Guyatt et al., (2008), the GRADE system's advantage in rating RCT's is in the separation between the quality of evidence and strength of recommendations, along with comprehensive criteria for downgrading or upgrading the quality of evidence ratings through recognition of the evidence's limitations. Two of the included studies received low grades (McCaffrey & Loscin 2004; McCaffrey and Loscin 2006) and two studies received a medium grade (Cetinkaya, 2019; McCaffrey 2009). These findings indicate that it is most likely that further research will have a significant impact on the confidence in the estimation of the magnitude of the intervention effect and is liable to change the estimation (Guyatt et al., 2008). A grid was created to track key

data extracted from each study using the following subheadings: author, publication year, design/methods, sample population, setting, purpose/aims, instruments, findings and quality appraisal. Table 1 summarizes applicable information for the three RCT's and provides the GRADE score for each (Melnyk & Fineout-Overholt, 2018).

#### **Data Analysis**

During data analysis, the studies were organized, categorized, summarized, and integrated into a conclusion about the research problem of each study based on the effect of a music intervention on delirium, in the older acute care patient. Results were synthesized using a consistent, correlative method to identify patterns and relationships, create themes, draw conclusions, and provide a comprehensive summary (Whittemore & Knafl, 2005).

#### Results

Data presentation is the final stage of the IR that presents detailed evidence from each selected study with a synthesis of the study based upon each study's purpose and aims (Whittemore & Knafl, 2005). During the data analysis review, the RCT's were organized, categorized, summarized, and integrated into a conclusion about the research problem of each study (Whittemore & Knafl, 2005). The results of this literature search indicated that "music therapy" has been used interchangeably with music listening, creating ambiguity surrounding the scientific findings. Articles meeting the criteria for this IR used music listening interventions without the guidance of a music therapist. Without this guidance, the therapeutic relationship is not client-centered or infused with

theory, assessment and evaluation (AMT, 2018 b, c). The RCT's were organized into two categories: the effect of a music intervention on delirium in the older, acute care patient on 1) acute confusion and 2) NEECHAM and MMSE scores. (Table 1)

The effect of a music intervention on acute confusion. To answer the question, what effect does a music intervention have upon delirium in the older, acute care, patient, two RCT's (McCaffrey & Loscin 2004; McCaffrey and Loscin 2006) were evaluated for the effect of music listening on acute confusion in older patients undergoing hip and knee surgery. Confusion is a descriptor used frequently by healthcare personnel in lieu of delirium (Zalon et al., 2017). Outcome measures included number of patients with more than one episode of acute confusion and readiness to ambulate scores.

McCaffrey & Locsin, (2004) conducted a non-probability RCT where room placement was randomized and treatment option was based upon room placement. Post hoc analysis of nurses' notes determined the number of episodes of confusion. Treatment group participants listened to lullaby music awakening from anesthesia, then a select list of individual music choice for at least one hour, three times a day. An ANOVA assessed the difference between groups and reported a significant decrease in the number of episodes of post-operative confusion in the treatment group (F= 19.568, p = 0.001). Readiness for ambulation scores were higher in the treatment group (F= 19.568, p= 0.001; F = 28.14, p = 0.001).

McCaffrey and Locsin (2006) conducted a convenience sample RCT to determine the number of episodes of post-operative confusion and readiness for ambulation scores. Lullaby music was played while awakening from anesthesia, after which preferred music from a select list was played for one hour four times a day. Research assistants conducted

daily visits in both the control and intervention groups. A post hoc analysis of the nurse's narrative notes ascertained the number of episodes of acute confusion. There was less post-operative episodes of acute confusion (F = 29.56, p = .001) and higher daily readiness to ambulate scores in the music listening group Day1: (F = 17.59, p = .001, Day 2: (F = 33.68, p = .001), Day 3: (F = 18.84, p = .001).

**NEECHAM and MMSE scores.** To answer the question, what effect does a music intervention have upon delirium in the older acute care patient McCaffrey (2009) and Çetinkaya (2019) conducted a convenience sample RCT to determine the effect of music listening on MMSE and NEECHAM scores. Participants in the McCaffrey (2009) intervention group listened to lullaby music until awake after which preferred music from a select list was played for one hour four times a day. Çetinkaya (2019) participants listened to Acemasiran type Turkish music for 20 minutes three times a day. The Mini Mental State Exam (MMSE) and the Neelon, Champagne, Carlson & Funk (NEECHAM) Acute Confusion Scale were used to determine the presence of acute confusion prior to the start of the study and then once, on each of the three postoperative days. An ANOVA was conducted to determine the differences in the groups over the three-day period (McCaffrey, 2009). Multiple-comparison post-hoc analysis was done to detect the greatest differences between the groups in both studies.

Prior to surgery, the MMSE scores between the groups (t = 0.94, df = 1, 22, p = .786) indicated similar levels of cognitive function (McCaffrey, 2009). The MMSE scores for all three post-operative days were higher for the intervention group (McCaffrey, 2009) while Çetinkaya, (2019) reported that the differences were not statistically significant between post-op days 1, 2, and 3 (p > .05). Group differences

(McCaffrey, 2009) were compared using the Greenhouse Geisser test for both Time (F=24.20, df=1, 22, p = .012) and Time x Group (F=5.00, df=1, 22, p = .012). The Scheffe test showed the greatest difference in scores between groups occurred between post-operative days 1 and 2 (mean difference = 2.64, p = .000) in the McCaffrey (2009) study.

For post-op episodes of acute confusion, McCaffrey (2009) conducted an ANOVA and repeated measures ANOVA to detect group changes (see Table 1). The control group had lower NEECHAM scores and more confusion over the three-day period than the intervention group (F= 7.28, df= 1, 22, p = .014). The Scheffe test confirmed that the greatest differences occurred between days 1 and 2 (mean difference = 1.87, p = .001). Cetinkaya (2019) found statistically significant differences between groups (p < .05), between pre-Op day 1 and post-Op day1 (p = .002) between post-Op day1 and post-Op day2: (p = .007) and for post-Op day1 and post-Op day 3: (p = 001). The Wald Test Statistic (WTS): group: WTS = 3.314; p = 0.69; time: WTS = 88.08; p =.000 an Group\*Time: WTS = p = .000. Both McCaffrey (2009) and Çetinkaya (2019) found that music listening increased the mean MMSE and NEECHAM scores in the intervention groups.

The four RCT studies included in this IR all provided a clear explanation of the purpose of the study, the sample size and used exploratory data analysis, to compare the means of the two samples. Two studies identified instruments that accurately measured the variable of interest, delirium or post-operative confusion (Çetinkaya, 2019; McCaffrey 2009). Without the direction of a music therapist the music intervention used in these studies did not meet the criteria for music therapy. These small positive findings

indicate that a music listening intervention guided by the expertise of a music therapist, in collaboration with nursing, should be more thoroughly explored.

#### Discussion

The purpose of this review was to examine the current literature related to the effect of a music intervention on delirium in the older acute care patient and to make suggestions for future research. These studies report that music listening has been recommended as a safe, feasible, useful and financially sound preventative measure and treatment method for delirium (Çetinkaya, 2019; McCaffrey, 2009; McCaffrey & Locsin, 2004; McCaffrey & Locsin, 2006). Research has indicated that music therapy as an intervention, under the direction of a music therapist is promising as a non-pharmacological intervention for delirious patients in the acute care setting (Cheong et al., 2016a). Findings of this IR manifest that delirium studies in the acute care area have not addressed music therapy, but casual music listening as a non-pharmacological delirium prevention or treatment method in this population.

Future research utilizing music therapist developed, nurse initiated music listening interventions, combined with formal delirium assessment tools is warranted. The collaboration between music therapists and nurses has the potential to instill the clientcentered theory, assessment and evaluation into the therapeutic process (American Music Therapy Association 2018 c). As an established clinical intervention, music therapy can be a strong source of cognitive stimulation in individuals with cognitive changes. Music therapists deftly modify musical patterns (instrumental or vocal) according to the patient; hence changes in heart rate or breathing lead to a modification of the musical tempo or rhythm to meet patient specific needs (Binzer et al., 2016). This allows patients to have

control over their environment when they have little to no control left during their hospital stay (Hsu, 2017).

#### **Implications for Practice, Policy and Research**

The findings of this IR support additional research on the use of a more theoretically based music intervention that is developed under the guidance of a music therapist and delivered in collaboration with nurses. It is imperative to investigate more thoroughly the use of non-pharmacological interventions for the prevention and/or treatment of delirium.

#### Limitations

Limitations of this review include the small number of studies, small sample sizes, only one study determined a power analysis (Çetinkaya, 2019), the use of a single hospital setting, multiple delirium descriptors (Çetinkaya, 2019; McCaffrey & Loscin 2004, McCaffrey & Loscin 2006, & McCaffrey, 2009) and in two studies, lack of a formal, standardized tool for delirium identification (McCaffrey & Loscin 2004, McCaffrey & Loscin 2006). Other limitations include convenience sampling, homogeneous populations, music listening without a music therapist's direction, and blinding that was not addressed which may lead to bias (McCaffrey & Loscin 2004, McCaffrey & Loscin 2006, & McCaffrey, 2009). Outcomes in all included studies were only reported to time of discharge, no studies reported medium or long-term effects and no studies assessed the severity and duration of delirium. Larger studies with random sampling, using a more heterogeneous population will provide a higher quality of evidence in support of music therapy as an intervention for delirium.

#### Conclusions

This review illuminates the limited research on the effect of a music intervention on delirium in the older, acute care patient. Going forward, researchers need to be clear and precise in their music interventions and conform to standardized music therapy definitions. Future studies on music therapy that are directed by a music therapist in collaboration with nurses, using valid and reliable delirium assessment tools to enhance methodological rigor, will produce research studies that confidently support music therapy interventions for the treatment of delirium. The implications of this research for nursing are significant for nurse-initiated interventions that promote improved cognition in the older, acute care patient. The results of this IR support further research on the use of a non-pharmacological intervention such as a music therapy intervention, for the treatment and/or prevention of delirium in the older acute care population.

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### Appendix A <del>1</del>

Database Search	Search Term Headings Used: Acute Confusion Delirium, Agitation, poor historian	No. of Titles and Abstracts
Pub Med	("Acute confusion"[tiab] OR "Agitation"[tiab] OR "Bonkers" [tiab] OR "Confusion Assessment Method" [tiab] OR Confusion* [tiab] OR "Confusion"[mesh] OR "Delirium"[Mesh] OR "Delirium"[tiab] OR Disorientat* [tiab] OR Hallucinations[mesh] OR Hallucination* [tiab] OR Hallucinations[mesh] OR Hallucination* [tiab] OR Hallucinations[mesh] OR "Inattentiveness" [tiab] OR "Poor Historian" [tiab] OR "Poor Historians" [tiab] OR "Psychomotor Agitation"[mesh] OR Sundown* [tiab] ) AND ("Music"[Mesh] OR "Music Therapy"[Mesh] OR "Music"[tiab] OR "Biomusicology"[tiab]) AND ("Aged"[Mesh] OR aged[tiab] OR elderly[tiab] OR geriatric*[tiab] OR gerontology[tiab]) ((DE "Delirium") OR Delirium OR "Acute Confusion" OR Agitation OR "Confusion Assessment Method" OR (DE "Mental Confusion") OR Confusion* OR "Disorient*" OR "Inattentiveness" OR "Poor Historian" OR "Sundowning") AND ((DE "Music Therapy") OR music)	252 344
CINAHL	((MH "Delirium") OR "Acute confusion" OR "Agitation" OR "Bonkers" OR "Confusion Assessment Method" OR "Confusion" OR "Confusion"[mesh] OR "Confusion*" OR "Delirium"[ot] OR "Delirium" OR "Disorient*" OR "Hallucination*" OR "Illusion*" "Inattentiveness" OR "Poor Historian" OR "Sundowning" OR "Change in mental status") AND ((MH "Music") OR (MH "Music Therapy") OR music* OR "Biomusicology") AND	181

	((MH "Aged+")OR "In Old Age" OR elderly OR aged OR geriatric* OR gerontol*)	
Scopus		412
Music	(INDEXTERMS(Delirium) OR TITLE-ABS- KEY(Delirium) OR TITLE-ABS-KEY("Acute confusion") OR TITLE-ABS-KEY("Agitation") OR TITLE-ABS-KEY("Bonkers") OR TITLE-ABS- KEY("Confusion Assessment Method") OR TITLE- ABS-KEY("Confusion") OR TITLE-ABS- KEY("Confusional") OR TITLE-ABS- KEY("Delirium") OR TITLE-ABS- KEY("Delirium") OR TITLE-ABS- KEY("Disoriented") OR TITLE-ABS- KEY("Disoriented") OR TITLE-ABS- KEY("Hallucinations") OR TITLE-ABS- KEY("Hallucinations") OR TITLE-ABS- KEY("Inattentiveness") OR TITLE-ABS- KEY("Inattentiveness") OR TITLE-ABS- KEY("Inattentiveness") OR TITLE-ABS-KEY("Poor Historian") OR TITLE-ABS-KEY("Sundowning") OR TITLE-ABS-KEY("Change in mental status")) AND (TITLE-ABS-KEY("music") OR INDEXTERMS("music therap*") OR TITLE-ABS- KEY("Biomusicology")) AND (INDEXTERMS("Aged") OR TITLE-ABS- KEY("aged") OR TITLE-ABS-KEY("elderly") OR TITLE-ABS-KEY("geriatric*") OR TITLE-ABS- KEY("aged") OR TITLE-ABS-KEY("elderly") OR	412
Music Periodicals Database	<ul> <li>KET (gerontology ))</li> <li>("Acute confusion" OR "Agitation" OR "Bonkers" OR "Confusion Assessment Method" OR "Confusion" OR OR "Confusion*" OR "Delirium" OR "Disorient*" OR "Hallucination*" OR "Illusion*" "Inattentiveness" OR "Poor Historian" OR "Sundown*" OR "Change in mental status") AND</li> <li>(DE "MUSIC therapy" OR music* OR "Biomusicology") AND</li> <li>( DE "OLDER people" OR "In Old Age" OR elderly OR aged OR geriatric* OR gerontol*)</li> </ul>	12
	noft(("Acute confusion" OR "Agitation" OR "Bonkers" OR "Confusion Assessment Method" OR	

RILM	"Confusion" OR "Confusion*" OR "Delirium" OR "Disorient*" OR "Hallucination*" OR "Illusion*" "Inattentiveness" OR "Poor Historian" OR "Sundown*" OR "Change in mental status")) AND noft("MUSIC therapy" OR music* OR "Biomusicology") AND noft("OLDER people" OR "In Old Age" OR elderly OR aged OR geriatric* OR gerontol*)	24
Embase	("Acute confusion" OR "Agitation" OR "Bonkers" OR "Confusion Assessment Method" OR "Confusion" OR OR "Confusion*" OR "Delirium" OR "Disorient*" OR "Hallucination*" OR "Illusion*" "Inattentiveness" OR "Poor Historian" OR "Sundown*" OR "Change in mental status") AND (SW "therapy—music therapy" OR music* OR "Biomusicology") AND ( DE "OLDER people" OR "In Old Age" OR elderly OR aged OR geriatric* OR gerontol* OR "older adult*")	307
	('delirium'/exp OR 'acute delirium' OR 'chronic delirium' OR 'delier' OR 'delire' OR 'deliria' OR 'delirious state' OR 'delirious syndrome' OR 'delirium' OR 'delirium acutum' OR 'confusion'/exp OR 'confusion' OR 'confusion state' OR 'confusional state' OR 'agitation'/exp OR 'agitation' OR 'hallucination'/exp OR 'hallucination' OR 'hallucinations' OR 'Bonkers' OR 'Disorientat*' OR 'Illusion*' OR 'Inattentiveness' OR 'Poor Historian' OR 'Poor Historians' OR 'Sundown*') AND	
JSTOR	('music'/exp OR 'music' OR 'music preference' OR 'musical ability' OR 'musical test' OR 'orchestra' OR 'rock and roll music' OR 'music therapy'/exp OR 'music therapy' OR 'therapy, music' OR 'biomusicology') AND ('aged'/exp OR 'aged' OR 'aged patient' OR 'aged people' OR 'aged person' OR 'aged subject' OR 'elderly' OR 'elderly patient' OR 'elderly people' OR 'elderly person' OR 'elderly subject' OR 'geriatric' OR 'gerontology' OR 'senior citizen' OR 'senium')	281

(Delirium OR Confusion)
AND
(music OR "Biomusicology")
AND
("In Old Age" OR elderly OR aged OR geriatric OR
geriatrics OR gerontology OR "older adult" OR "older
adults"



**Figure 1**. Graphical representation of the flow citations reviewed. Adapted from "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement" Moher, Liberati, Tetzlaff, Altman, and Group (2009). *Public Library of Science Medicine*, 6, p.3. Copyright 2009 by Moher et al. Adapted with permission.
#### **Dissertation Proposal**

## THE IMPACT OF A MUSIC INTERVENTION ON THE INCIDENCE, SEVERITY AND DURATION OF DELIRIUM IN OLDER ACUTE CARE PATIENTS. A RANDOMIZED, CONTROLLED FEASIBILITY TRIAL Specific Aims

Delirium is a complex, neuropsychiatric syndrome (Leslie & Inouye, 2011; Maldonado, 2018). It is generally thought to be preventable (Inouye, 2000) occurring in response to some form of insult such as surgery or medications, or in response to an unfamiliar, stressful environment that inadvertently precipitates delirium in the-elderly population (Young et al., 2015). Delirium has adverse consequences, particularly for elderly hospitalized patients, such as higher mortality rates post discharge (14%-38%), increased hospital stays (21 days verses 9 days without delirium), a 63% increased risk for developing dementia within 48 months and a 62% increase in mortality (González, et. al., 2009; Leslie & Inouye, 2011). Delirium is often under-assessed, under-recognized, and the serious long term consequences of delirium are underestimated (Balas et al., 2012; Praditsuwan & Srinonprasert, 2016). Without a formal assessment, delirium is attributed to other causes and treated inappropriately (Balas et al., 2012).

Prevention and management of delirium remains complex due to the fluctuation in delirium symptoms which also makes identification difficult without a formal assessment (Maldonado, 2008). At present there is a lack of support for the pharmaceutical management or prevention of delirium which further supports the development of nonpharmacological measures to prevent or treat delirium in the acutely ill elderly patient (American Geriatrics Society, 2015).

Pharmacological management of delirium is not supported by the pain, agitation, and delirium guidelines of the American College of Critical Care Medicine, instead, it supports the use of nonpharmacological measures to prevent delirium (American Geriatrics Society, 2015; Rivosecchi et al., 2015). Geriatric and pharmacotherapy experts used an evidence based approach to develop lists of medications that are inappropriate for the older population. The resultant BEERS criteria identify medications that should be closely monitored for their risk of causing adverse events such as falls and delirium (American Geriatrics Society, 2015; Inouye et al., 2014; Stockl et al., 2010). Patients who receive seemingly benign, routine medications such as sedatives or anti-cholinergic agents, can be at an increased risk for delirium as these medications can be a catalyst for the development of delirium (American Geriatrics Society, 2015; Inouye et al., 2014; Stockl et al., 2010). Research on the pharmacological management of delirium has not produced sufficient evidence to support the use of medications, which may worsen patient outcomes and recommends limiting the use of pharmacologic agents (American Geriatrics Society, 2015; Inouye et al., 2014; Marcantonio, 2012; Rivosecchi et al., 2015). This lack of support for the pharmacological management of delirium should guide current treatment by limiting or omitting pharmacological interventions (Inouye et. al., 2014; Rivosecchi et al., 2015; Stockl et al., 2010).

Non-pharmacological, multicomponent interventions in both critically ill and noncritically ill older adults that have proven beneficial in limiting or preventing delirium include early mobilization, reorientation to time, cognitive stimulation, noise reduction and music therapy (Inouye et al., 1999; Vidan et al, 2009). As a single component intervention, music therapy has been shown to improve cognitive scores in patients who

had hip and knee surgery (McCaffrey, 2009). Music therapy is an "established health profession in which music is used within a therapeutic relationship to address physical, emotional, cognitive, and social needs of individuals" (American Music Therapy Association, 2018 a). Bruscia (2014) defines music therapy as a reflective process where the therapist assists the client to improve health with various aspects of music and its formed relationships as the catalyst for change. Under the direction of a music therapist, music therapy interventions are carefully selected to engage patients and meet their specific needs (Bruscia, 2014).

The purpose of this study was twofold: to test the feasibility of conducting an interdisciplinary music listening intervention in hospitalized older adults, and to assess the effect of a music listening intervention on the incidence, severity, and duration of delirium using standardized delirium assessments.

**Primary Outcome:** To test the feasibility of conducting an interdisciplinary music listening intervention in hospitalized, older adults.

<u>Specific Aim #1:</u> To assess the effect of a music listening intervention on the incidence of delirium as measured with the CAM. <u>Specific Aim #2</u>: To assess the effect of a music listening intervention on the severity of delirium as measured by the CAM-S. <u>Specific</u> <u>Aim #3:</u> To assess the effect of a music listening intervention on the duration of delirium as measured in the number of CAM positive hours.

#### **Background and Significance**

DSM-5 criteria define delirium as an acute disruption in awareness, attention and cognition that develops over a short period of time, and fluctuates in severity that is not explained by a preexisting or progressing neurocognitive disorder (American Psychiatric

Association, 2013). As a neuropsychiatric syndrome, delirium involves the dynamic interplay between a patient's vulnerability to precipitating factors (infection, surgery, medication reactions, restraints, bladder catheter) or predisposing factors (cognitive impairment, visual impairment, stressful environment) which may represent a series of insults and recovery leading to permanent cognitive decline, such as dementia (Inouye 1999; Inouye 2000). Delirium has been shown to last for up to one year post occurrence, especially for patients with hypoactive delirium (Marcantonio et al., 2000), increased likelihood of admission to a long-term facility, (Dasgupta & Brymer, 2014; Inouye et al., 1998), and an 11% increase in mortality for every 48 hours spent delirious (Gonzalez et al., 2009).

Approximately 37-74% of surgical patients (Holroyd-Leduc, et al., 2010) and 42%-50% of medical inpatients will develop delirium during their hospitalization (Inouye et al., 2014; Rivosecchi et al., 2015). Annually, more than 7 million older Americans develop delirium with spending projected to surpass the current annual cost of \$38- \$152 billion as our older population is expected to double from 46 million at present, to 98 million by the year 2060 (American Delirium Society 2015; Mather et al., 2015).

Under recognition of delirium is attributed to lack of formal assessments with validated tools (Cheong et al., 2016; Marcantonio, 2012; Siddiqi et al., 2007). Nurses, physicians and other members of the healthcare team do not identify and assess delirium in a systematic manner, but use casual words or phrases to describe, not identify delirium, and may mistakenly believe that delirium is a normal part of aging (Middle & Miklancie, 2015; Zalon et al., 2017). Patients with delirium, especially patients with hyperactive delirium, are often treated inappropriately with psychotropic medications and physical

restraints (American Geriatrics Society, 2015; Inouye et al., 2014; McCusker et al., 2001). Physical and chemical restraints increase delirium's risk and prevalence, and predispose the older patient to additional adverse effects such as increased mortality (Inouye et al., 2014; McCusker et al., 2001). Those with hypoactive delirium are often mistaken as depressed, are less likely to be treated, and have a greater likelihood of admission to a long term care facility with resultant deterioration of cognitive functioning (Cheong et al., 2016; Marcantonio, 2012; Marchington et al., 2012).

This study's focus on understanding the impact of an interdisciplinary music intervention on delirium in the older, hospitalized acutely ill patient supports the National Institute of Health (National Institute of Health, 2017) and the National Institute on Aging's (National Institute on Aging, 2018) mission to promote and improve the health of individuals and families and to enhance wellness in older populations. Ultimately the study findings might influence and guide the development of non-pharmacologic interventions for delirium management. A board certified music therapist, identifies the patient's goals and objectives to produce individual playlists for each patient that are cost effective, and that can be easily implemented by the nursing staff, depending upon the results of the CAM assessment. These individual playlists can be used to prevent delirium, to calm an agitated patient or stimulate a somnolent patient once delirious. These twice daily music listening interventions are safe and cost effective, and may prevent or minimize the incidence, severity and/or duration of delirium in the older patient who is acutely ill.

#### **Music Therapy Interventions**

Music therapy is an evidence-based, goal-directed treatment process where the music therapist and the patient maintain a state of well-being by matching the patients' current mood with appropriate music selections, effectively managing delirium symptoms to achieve individualized patient goals (Belgrave et al., 2011a; Palmer et al., 2016). In patients with dementia and disorders of consciousness such as vegetative states and minimally conscious states, music therapy has reduced the use of physical and chemical restraints, and improved cognitive functioning and patient engagement (Ceccato et al., 2012; Simmons-Stern et al., 2010). Exposure to music increases both grey and white matter in areas of the brain involved in cognitive processes, increases neurogenesis, enhances brain plasticity and regulates activity in regions implicated in regulating emotion and reward, behavioral responses, memory and attention (Innes, et al., Selfe, Khalsa & Kandati, 2017). Listening to music evokes widespread activity in the motor and pre-motor cortices that stimulate cognitive, sensorimotor and emotional brain structures and supports neuroplasticity (O'Kelly & Magee, 2013). Positive effects of music therapy support improved neurogenesis, increased grey and white matter volume in subcortical and cortical brain areas involved in cognitive processing and working memory, suggesting that music listening improves critical domains of cognitive functioning (Innes et al., 2017).

Music therapy and music listening may inhibit cognitive impairments in the dominant hemisphere through engagement of the non-dominant hemisphere of the brain to evade impairments in this hemisphere (Morgan, 2007). Music listening also promotes the development of executive neurocognitive processes and improves electrical activity in the frontal lobe, thus increasing cognitive functioning (Morgan, 2007). These changes in

the brain are a result of stimulation on altered brain structures to compensate for damaged adjoining areas which take on the functions of the damaged areas (Särkämö et al., 2008). Muaic listening supports long-term changes in plasticity thus improving cognitive skills and may be beneficial in preventing or limiting delirium (Särkämö et al., 2010). Music listening has the potential to enhance delirium prevention and management through promotion of care that is safe, efficient, has minimal side effects, facilitates improved cognition (Inneset al., 2017), and decreases both length of stay and resource utilization (Cheong et al., 2016).

#### **Interdisciplinary Music Interventions**

Music therapists are integral members of the interdisciplinary healthcare team who work collaboratively to support treatment goals by utilizing the appropriate knowledge and skills to address client specific needs across multiple disciplines (American Music Therapy Association, 2018 b). Interdisciplinary teams are a suitable and efficient way to manage healthcare for older acute care patients with complex problems. This is accomplished through a shared responsibility of all team members who represent their individual disciplines, are willing to learn from one another, integrate various viewpoints and are committed to improving patient safety (Zeiss, & Steffen, 1996). The "iso principle" was chosen as the method to conduct the patient intervention by matching the mood of a client and then gradually altering the mood with music to gradually attain the desired mood (Belgrave et al., 2011b). Music interventions developed by music therapists are defined as individualized music that is integrated into the patient's care routine to meet a specific need (Gerdner, 2012). In hypoactive delirium states, music listening would begin with slow, pensive music and slowly work up to

something more cheerful/upbeat using an individual patient playlist or start with something fast paced that transitioned to a slower tempo for hyperactive states (Belgrave, et al, 2011b; Heiderscheit & Madson, 2015). Nurses as front-line care providers are in an excellent position to identify delirium using validated tools. Working in conjunction with music therapists, nurses will administer individualized music interventions from music therapist designed patient playlists to reduce the incidence, severity and duration of delirium. (Heiderscheit & Madson, 2015). The environment is more than occupied space; it is circumstances, a state of being, or something that is perceived by our senses, that in times of illness can be manipulated in order to adapt to our surroundings to promote health (Hegge, 2013). Altering the hospital environment through music assists the patient in adapting to this new environment with minimal distress (Heiderscheit & Madson, 2015).

Music therapy has been shown to stimulate areas of the brain related to cognitive functioning, memory and emotion (Khan et al., 2017) and may assist with retaining cognitive function and improving the overall welbeing of our older population (Hsu et al., 2017). Delirium assessment and identification is now included in patient safety adgendas as a powerful indicator of patient safety, promting system wide process improvements and research funding to mitigate delirium and its consequences (Inouye et al., 2014).

There are several identified gaps in knowledge related to both delirium prevention and management. Previous research on music therapy and cognition examined patients with Alzheimer's dementia which showed significant improvement in cognition and memory (Gallego & García, 2017), low awareness states in long term care facilities that reported improved speech fluency and nonverbal dialogue (Binzer et al., 2016; Brotons &

Koger, 2000) or patients with anxiety and pain in the intensive care unit reporting less anxiety with music therapy (Lee et al., 2005). None of these studies directly address music therapy's impact on delirium in older patients in the acute care setting. Research directed at music therapy's impact on delirium in the acute care area is sparse, was conducted with small homogenous populations without the direction of a certified music therapist, and some did not directly assess for delirium. Instead, measures included readiness for ambulation scores and post hoc chart analysis of acute confusion (McCaffrey & Locsin, 2004) and pain and readiness for ambulation with post hoc chart analysis of acute confusion (McCaffrey & Loscin, 2006). McCaffrey (2009), using a direct measure in a quasi-experimental design, demonstrates that music listening resulted in a significant reduction in post-operative confusion. All three studies examined "acute confusion" a term often used synonymously for delirium (Slooter, 2017; Zalon, et al., Sandhaus, Kovaleski & Prior 2017) and reported a significant decrease in "acute confusion" in the music listening group as opposed to the care as usual group. To date, the evidence on the use of music therapy, specifically music listening, on delirium using validated assessment tools for the acute care patient remains limited to two studies, which does both report higher levels of cognitive functioning and less acute confusion in the music listening group (Cetinkaya, 2019; McCaffrey, 2009). There is a need to substantiate the limited research that has been conducted on the impact of music therapy interventions on delirium in the hospitalized older patient using validated delirium assessment tools, larger heterogeneous populations and music interventions directed by a certified music therapist.

This study is innovative for its use of validated, delirium assessment tools and an interdisciplinary music interventions admininstered under the direction of a music therapist. Board certified music therapists ensure that each patient has individualized music interventions that have been developed based upon patient needs and preferences (Belgrave et al., 2011a; Palmer et al., 2016). Music therapists provide a goal oriented process to assist the patient to restore or maintain wellbeing. It is this relationship with the music therapist that promotes patient responses using attention modulation, emotion modulation, cognition modulation, behavior modulation and communication modulation (Cheong, et al., 2016). Enlisting the expertise of a music therapist overcomes the limitations from previous studies that used generalized playlists which may induce sadness or memories that, without a therapist's processing, could lead to additional anxiety (Palmer, Lane 2016).

It is anticipated that this study will enrich our understanding of the impact of a music intervention on delirium. This feasibility study using computer generated 1:1 randomization assures that both populations (usual care and music intervention groups) are similar to limit or prevent bias (Suresh, 2011). The use of a board certified music therapist who develops individual goal based playlists to meet the specific needs of each patient, is consistent with the standards for music therapy (American Music Therapy Association, 2018 b) to promote safe patient care for older adults exposed to environmental stressors that predispose them to delirium (Inouye, 2000; McCaffrey, 2009). Participants in the treatment group will receive twice daily, 30-minute individual music listening playlists that are chosen based upon the most recent CAM assessment (playlist for CAM negative, hypoactive CAM or hyperactive CAM). Music therapists and

nurses work in conjunction to create theraputic environments and promote care that is safe, efficient and facilitates improved outcomes such as decreased lenghts of stay and resource utilization (Cheong et al., 2016). Understanding delirium and manipulating individaul environments to promote improved cognition may ensure that healthcare for the older patient is a realisitic expectation (Hegge, 2013).

#### **Theoretical Framework**

Earlier research on delirium supports an unfamiliar environment as a catalyst for the development of delirium which can be alleviated by making the environment more hospitable or familiar to the patient (Inouye, 2000; Hegge, 2013). Impaired hearing and vision, illness, admission to a strange hospital environment and routines that are unfamiliar to the older patient are speculated within an environmental framework for the development of delirium in the older patient (Holroyd-Leduc et al., 2010; Inouye et al., 2014). Nightingale believed that the environment could be changed or manipulated to improve conditions and support healing (Selanders, 1998). Furthermore, Nightingale's Environmental Theory supports the use of music therapy to change an unfamiliar environment into a familiar environment by redirecting the patient's attention away from confusing stimuli (Cheong et al., 2016; Hegge, 2013; Heiderscheit & Madson, 2015). Delirium, a potentially reversible alteration in attention, is best treated nonpharmacologically, such as with music listening interventions that alter the patient's environment to support cognition through enriched environments (Irwin et al., 2013; Medeiros et al., 2015).

Nightingale's Environmental Theory will provide the framework supporting initiatives that provide an organized system of care to bring environmental turbulence

under control, or for nursing to promote the ideal conditions "to restore or preserve health - to prevent or cure disease or injury" (Hegge, 2013, p. 213). Nightingale believed that the person and environment are inherently linked and that an alteration in the environment where nursing care is rendered, fosters health (Hegge, 2013; Heiderscheit & Madson, 2015; Selanders, 1998). As an evidence-based, goal directed treatment, a music intervention alters the patient environment by modifying their response to it through music matched to the patient's current mood and then changing both the music and the mood. When patients have little control over their environments, music interventions improved cognition and decreased sensory impairment allowing a feeling of control (Hsu et al., 2017). Furthermore, Nightingale's Environmental Theory supports the use of music therapy and individual music interventions to change an unfamiliar environment into a familiar environment by redirecting the patient's attention away from confusing stimuli and helps the patient focus their attention (Cheong et al., 2016; Hegge, 2013; Heiderscheit & Madson, 2015).

#### **Specific Aims/Research Questions**

The purpose of this study was twofold: to test the feasibility of conducting an interdisciplinary music listening intervention in hospitalized older adults, and to assess the effect of a music listening intervention on the incidence, severity, and duration of delirium using standardized delirium assessments.

**Primary Outcome:** To test the feasibility of conducting an interdisciplinary music listening intervention in hospitalized, older adults.

<u>Specific Aim #1:</u> To assess the effect of a music listening intervention on the incidence of delirium as measured with the CAM. <u>Specific Aim #2</u>: To assess the effect of a music listening intervention on the severity of delirium as measured by the CAM-S. <u>Specific</u> <u>Aim #3:</u> To assess the effect of a music listening intervention on the duration of delirium as measured in the number of CAM positive hours.

#### **Research Design and Methods**

The proposed two arm, randomized, controlled, feasibility study will test the effect of an interdisciplinary music intervention upon the incidence, severity and duration of delirium in 44 participants or 22 per arm. This number will be increased to 25 to allow for expected attrition and to control for moderating or mediating factors (Deke, Sama-Miller, & Hershey, 2015). Participants will be randomized into the control or usual care group based upon computer generated 1:1 randomization and all participants will be assessed twice daily with the CAM (Inouye et al., 1990). For delirium incidence, the participants in each group will receive daily CAM assessments. Once CAM positive, the severity of delirium will also be assessed twice daily using the CAM-S for up to a total of 14 days or until discharge, whichever comes first (Inouye et al., 2014). The duration of delirium will be the number of days the patient is CAM positive and the end date will be two days without delirium. Two independent *t*-tests will be conducted to compare the difference between the two groups on the independent variables of delirium severity and duration to see if the change in delirium is associated with the intervention. Chi square testing for independence will be conducted to analyze the incidence of delirium.

The primary outcome, the incidence of delirium will be assessed twice daily with the CAM to determine the presence or absence of delirium, either hyperactive or

hypoactive. The CAM assesses for evidence of acute onset or fluctuations in mental status, inattention, or either disorganized thinking or an altered level of consciousness to confirm the diagnosis of delirium. Secondly, the severity of delirium will be assessed with the CAM-S as ordinal data of the summative scores (0-7) by measuring acute onset, fluctuating course, inattention, disorganized thinking and altered level of consciousness. The third variable, the duration of delirium will be assessed as present: yes/no. The duration of delirium will be the number of days the patient is CAM positive and the end date will be two days without delirium.

Music listening interventions will be used to alter the patient's attention, affect or behavior by utilizing tempos that are either relaxing or stimulating which is dependent upon patient need (Belgrave et al., 2011a; Bruscia, 2014). Participants will be asked to self-report their musical preferences at the beginning of the study when meeting with the music therapist for the development of the music intervention: three individual, 30 minute playlists. The music intervention will be delivered via headphones in each participant's room using iTunes ® and initiated by the nursing staff dependent upon the latest CAM assessment: negative CAM, hypoactive CAM or hyperactive CAM. The CAM assessments will serve as a reminder to initiate the intervention for the nursing staff.

**Descriptive variables.** Additional data related to delirium occurrence that will be collected from the electronic medical record (EMR) based upon a delirium prediction model (Ryan et. al., 2013; Van den Boogaard et al., 2012) include: age, race, education, admitting diagnosis and medications, history of transient ischemic attack, ischemic stroke and intracranial hemorrhage. Additional values that will be included: albumin, glucose,

smoking history, alcohol consumption history and use of a urinary catheter or restraints (National Clinical Guideline Center 2010; Van den Boogaard et al., 2012). This will assist the researcher in comparing the intervention and control group's number of risk factors for delirium, preventing or limiting a rival hypothesis upon study completion if a music intervention is found to be effective (Yin, 2017).

#### **Population/Sample/Recruitment**

*Setting*. The setting for this study will be the Progressive Care Unit an 18-bed, acute care unit, of a 294-bed tertiary care, non-profit community hospital whose average length of stay is 4.5 days. This unit has a nurse/patient ratio of 1:4, where it is anticipated that 50% of the population will be eligible for participation in data collection over a four to eight month period (Neilsen, 2014). The four counties in this hospital's region have higher rates of individuals aged 65 or older (19.4%) than the state and national norms (16.6% and 14.2% respectively) (Neilsen, 2014) allowing for a robust sampling of patients meeting the eligibility criteria for the study.

*Sample Subjects*. Inclusion criteria will include: patients age 65 or older admitted to the PCU, English speaking, with a self- reported ability to hear music, no documented history of dementia or permanent cognitive impairment, are not delirious at study beginning (CAM negative) and are able to sign consent. Initial cognitive status will be assessed with the Short Portable Mental Status Questionnaire (SPMSQ) and Digit Span Test (DST) with the CAM assessment for inclusion in the study. The inclusion criterion of age 65 or greater is necessary for the recruitment of the target population as this group has an 11-42% possibility of developing delirium while hospitalized (Vidán et al., 2009). Exclusion criteria include: age < 65, not admitted to PCU, CAM positive, non-English speaking,

uncorrected hearing impairment, documented history of dementia or permanent decline (positive SPMSQ and Digit Span testing), expected death within 24 hours of enrollment, transferred off the floor and inability to sign consent. The principal investigator (PI) or the trained research assistant (RA) will read paper and pencil music questionnaire and instructions to all participants. The terms uncorrected hearing impairment, self-reported ability to hear and uncorrected or severe hearing impairment are commonly used criterion in music interventions (Khan et al., 2017; Mahendran et al., 2017). Fliers will be placed in public areas on the unit to alert and recruit study participants and their families. Once aware of participant interest, the PI will speak with and enroll eligible, willing participants (see Appendix B . Delirium and Music Study Flier).

*Sample size estimates*. Sample size estimates are based on the stage approach which begins with a pilot or feasibility study to investigate concerns or issues regarding treatment fidelity, recruitment, attrition and research assistant training (Bradt, 2012). G\* Power estimated the sample size with a statistical power of .80, medium effect size .30 and a significance level of 0.025 (corrects for doing multiple *t*-tests) (Faul et al., 2009).

*Recruitment Procedures*. Participants will be recruited from patients admitted to the Progressive Care Unit. The recruitment of potential participants will be done by the PI who will speak with patients, age 65 or greater, and their families about the study. The PI will develop and provide fliers for distribution by the staff to potential participants when the PI or trained RA are present to collect data and enroll patients. Potential participants or their representatives will be asked by the PCU staff if they are interested in participating in a study on the impact of a music intervention on delirium in the older hospitalized patient. The PI or trained research assistant will meet privately with PCU

patients interested in participation who will be assessed with the CAM and SPMSQ and Digit Span testing to determine cognitive status and eligibility requirements (Inouye, 2003). Once eligibility is established, participants will be informed about the details of the study by the PI or trained research assistant, and reminded that participation is voluntary and confidential and will not influence the healthcare that they will receive from the nurses and doctors at Geisinger Community Medical Center. The written consent form developed in English will be read to the participants by the PI.

The site has agreed to grant permission for the PI to access the participants' electronic medical record (EMR) after securing IRB approvals. The informed consent will include permission from participants to access the EMR records. Participants will receive a copy of the signed written informed consent to keep for their records, and the PI will keep a second copy of the signed written informed consent in a secure, locked location. The PI will provide documentation of IRB approval from Geisinger Health System and Duquesne University and supply the University of Scranton with a copy of the IRB approval. After IRB approval of study, participants who meet the inclusion criteria will be encouraged to ask questions related to the study before, during and after the completion of the study measures to clear up any misunderstandings. Participants will be fully informed of all study procedures, risks, benefits and time needed for completion of the study.

#### **Data Collection Procedures**

Once eligibility criteria have been met, the PI or RA will meet with participants in their private room while participants are resting comfortably to complete the study materials. Oral instructions regarding the study procedures will be provided to all study

participants. The music therapist or PI will complete the music therapy questionnaire relating to the individual music preferences for each participant to be used solely for the development of their individualized music playlists (see Appendix C . Music Therapy Questionnaire). The music therapist will review within 12 hours each participant's completed questionnaire to set goals, review the individual music selections for playlist development. The maximal anticipated time for completion of this form is 10 minutes.

Once consent is obtained for each participant, they will be randomized into either the control group (usual care) or into the intervention group (music therapist consultation and twice daily music interventions) based upon computer generated 1:1 randomization (Urbaniak & Plous, 1997). The PI will retain the signed consent form and completed study materials together in a folder with a corresponding de-identified patient number and place it in a secure location, such as a locked office once data collection is complete. The signed consent forms will be separated and placed in a locked cabinet each day after data collection is completed. Electronic data will stored on a password protected hard drive. There is no financial incentive to participate in this study.

### Variables/Instruments

**Delirium definition.** Delirium is defined using the three domains based upon the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as: (a) disturbance in attention, (b) change in cognition, or (c) fluctuation from baseline (American Psychiatric Association., 2013). Delirium identification is complex due to the fluctuating nature and subtypes of delirium (i.e., hyperactive, hypoactive, or mixed) (American Delirium Society, 2015; American Psychiatric Association, 2013). Patients with hyperactive delirium exhibit behaviors such as restlessness, agitation, mood changes with motor

behaviors such as pulling at lines and tubes (Neufeld & Thomas, 2013). Hypoactive delirium is defined as a disruption of arousal with difficulty staying awake, diminished cognition, alertness, and verbal responses and is often mistaken for depression (Maldonado, 2008). The mixed subtype of delirium includes periods of both hypo and hyper active delirium where both may occur within minutes to hours (Neufeld & Thomas, 2013). Delirium is present when a positive CAM score is obtained.

**Music Therapy Definition.** Music Therapy is the use of evidence based music interventions to enable the attainment of individual goals inside a therapeutic relationship developed by a credentialed professional from an approved music therapy program. (American Music Therapy Association, 2018 a). Once randomized into groups, a music therapist will meet with the treatment participants to develop individual playlists; one each for no delirium, hypoactive delirium and hyperactive delirium. Participants in the intervention group will listen to the appropriate playlist which is selected by the nurse based upon the previous CAM assessment, for thirty minutes twice daily (AM and PM), using mp 3 players and headphones, while the control group will receive care as usual.

**Music Intervention Definition.** Music interventions are defined as individualized music that is integrated into the patient's care routine to meet a specific need (Gerdner, 2012). In hypoactive delirium states, music therapy would begin with slow, pensive music and slowly work up to something more cheerful/upbeat using an individual patient playlist or start with something fast paced that transitioned to a slower tempo for hyperactive states and preferred music playlist will used in patients who are CAM negative (Belgrave, et al., 2011b; Heiderscheit & Madson, 2015).

**Music Therapy Variables Questionnaire.**-The music therapy questionnaire will be administered to all participants in the intervention group upon admission to the study to obtain their music likes and dislikes (religious, rock, blues, country, jazz, classical, pop, folk, rap, hip-hop, Latin, Broadway, show tunes or ethnic) whether they have played an instrument (guitar, piano, drums, bass, flute violin, other) or performed in an ensemble (orchestra, band, choir, etc.). This questionnaire will also address the types of music participants do not enjoy to provide the participant with music that is specific to their preferences and life experiences. This information will only be used to compile an individualized playlist for use as warranted by participant need, should take approximately 10 minutes to complete and will not be used for data analysis. (See Appendix C . Music Therapy Questionnaire).

**Confusion Assessment Method (CAM).** Hypothesis 1: For the older hospitalized acute care patient delirium incidence will be lower in the music intervention group as opposed to the care as usual group. Initially, the CAM (see Appendix D . CAM) will be used to determine if the patient is delirious (CAM positive) which would prevent inclusion in this study (Inouye, 2003; Pfeiffer, 1975). Once inclusion criteria have been met, the (CAM) will be administered every 12 hours while on the unit for 14 days or until discharge, whichever comes first. The CAM is a reliable and validated tool to diagnose the presence of delirium in the older population (age 65 or >) that can be administered in under five minutes and has a high inter-rater reliability (kappa > 8) (Inouye et al., 1990). The CAM is intended for use in populations at high risk for the development of delirium (Inouye et al., 1990.) The CAM measures the presence or absence of four features: acute onset and fluctuating course (feature 1), inattention (feature 2), disorganized thinking

(feature 3), and an altered level of consciousness (feature 4). Delirium is present if features 1 and 2 are present and either feature 3 or 4 is present (Holroyd-Leduc et al., Khandwala, & Sink, 2010; Inouye et al., 1990). Some formal cognitive assessment is recommended, such as the Short Portable Mental Status Questionnaire and the Digit Span) since the validity of using CAM for unstandardized observations (e.g., routine clinical care) is poor (Inouye, Foreman et al., 2001).

Short Portable Mental Status Questionnaire (SPMSQ). The Short Portable Mental Status Questionnaire (SPMSQ) will be used to determine whether the patient has dementia which would prevent inclusion in this study, participants with 3 or more errors on the SPMSQ will be excluded from the study (Inouye, 2003). The SPMSQ is a short, reliable, 10 item instrument that identifies intellectual impairment (see Appendix E . SPMSQ Form) and is the cognitive test required prior to inclusion in the study (Inouye, (2003). It tests short and long term memory, orientation to surroundings, current event knowledge and the ability to complete serial mathematical tasks. The SPMSQ is reported to have high validity (88%) and reliability (83%), a score of 3 or more errors indicates cognitive impairment. (Inouye, 2003; Pfeiffer, 1975).

**Digit Span Test (DST).** The Digit Span test is a screening tool for the detection of mild cognitive impairment, can be administered in under five minutes and is recommended as a component of cognitive testing (Appendix F . Digit Span). When administered forward, it assesses attention and short term memory, when administered backwards it measures working memory. Participants are asked to listen carefully to a series of numbers and will be asked to repeat them back in the same order they are said. A score of less than five indicates cognitive impairment and exclusion from the study.

The results of the SPMSQ and the DST will be used for admission criteria only and not for statistical analysis.

CAM- S. Hypothesis 2: For the older hospitalized acute care patient delirium severity will be lower in the music therapy group as opposed to the care as usual group. To determine the severity of delirium, once the participant becomes CAM positive, each participant will then be assessed with the CAM-S every 12 hours while on the unit until to discharge or 14 days, whichever comes first. The CAM-S is a more in-depth exploration of a change in cognition (for age 65 or >) by assessing for delirium severity and is recommended for use in any research study due to its strong psychometric properties and robust associations with important clinical outcomes (Inouye, et al., 2014). The CAM-S does not replace the CAM, but is used in conjunction with the CAM to quantify the intensity or severity of delirium and is useful to ascertain the response to delirium management interventions in the older population (Inouye, et al., 2014) (See Appendix G. CAM-S). The CAM-S rates delirium symptoms as absent (0), mild (1) or marked (2). Fluctuation is rated as either absent (0) or present (1) and acute onset is also rated as absent (0) or present (1), yielding a score that ranges from 0 to 7 with 7 being most severe. The CAM-S is used by trained personnel to reliably conduct the assessments, can be completed in under 5 minutes and is easier to use than other severity measures while being relatively unbiased in respect to rating the severity of both the hypoactive and hyperactive forms of delirium (Inouye, et al., 2014). The CAM-S has an excellent intraclass correlation coefficient of 0.92, indicating a high level of agreement (Inouye, et al., 2014).

**Delirium Duration**. Hypothesis 3: For the older hospitalized acute care patient delirium duration will be lower in the music therapy group as opposed to the care as usual group. The duration of delirium will be determined by the number of days the patient remains delirious as determined by a positive CAM (start date) and the ongoing CAM and CAM-S assessments, until discharge from the unit or up until 14 days, whichever comes first. Due to the fluctuating nature of delirium, ascertaining the duration of delirium is difficult, so a cautious definition of delirium recovery will be defined as two subsequent days without delirium according to the CAM and CAM-S assessments (end date) (Slor et al., 2013).

Research assistants (RA) receive extensive training on the utilization of the Confusion Assessment Method (CAM), the Confusion Assessment Method-S (CAM-S), SPMSQ and Digit Span Test prior to the start of the study. Inter-rater reliability will be established as follows: Masters prepared nurses with prior training on the CAM, CAM-S, SPMSQ and Digit Span Test will conduct training sessions for the RA's and staff members that will be assessing for delirium. This setting requires that the CAM is completed each shift on older patients. The instruments will be discussed, items on the four instruments will be reviewed and practice sessions utilizing the four instruments will be conducted followed by a group discussion with question and answer sessions. Staff members and RA's will assess the same patients: as one RA asks questions, each of the nurses write down their evaluation of the patient responses and each nurse will assess patients. Training will continue until both trained researchers and novice researchers' findings are in complete agreement.

#### Intervention

The PI will notify the music therapist to meet with assigned participants upon inclusion to the study to utilize the information obtained from the completed music questionnaires to ensure that all music selections and interventions are safe and specific to each patient and congruent with the treatment plan.

The daily music therapy intervention used in this study will be two, thirty-minute music therapy sessions conducted in the morning and again in the evening. The unblinded Music Therapist programs the music devices based on each individual participant randomized into the intervention group. Playlists will be created with iTunes ® based upon the individual music preference questionnaire and music will be delivered via mp 3 players and headphones. Prior to delivering mp 3 players to participants, all devices will be checked to ensure that all identifying characteristics (name, genre, artists) are removed, the volume is set to a comfortable volume and it is clean and in working order. Each participant in the intervention group will be assessed by the music therapist upon consent to participate. It is the hope that individual music intervention will prevent and reduce episodes of delirium per patient, thereby promoting faster overall recovery and preventing further cognitive decline.

Each participant in the intervention group will get twice daily (AM and PM), 30 minute music listening sessions using mp 3 players and headphones, while the control group will receive care as usual. The times and frequency of the intervention were chosen as they are the least disruptive to the care routine on the PCU, and because a therapeutic dosage of music therapy has not been clearly established (Tang & Vezeau, 2010) but earlier research reports success with similar session times and intervals (Cheong et al., 2016).

### **Data Analysis**

**Data organization and management.** All participants will be assigned an individual, unique ID when obtaining raw data such as the hardcopy completed music survey and electronic medical record demographics. Participant survey data, CAM, CAM-S data and EMR information will be entered into SPSS (IBM SPSS Statistics for Windows, version 25) by the PI. Electronically entered data will be evaluated for dataentry errors, missing data, outliers, linearity and for required statistical assumptions and comparison of raw survey data by the PI. Simple computer based 1:1 randomization program will be used to ensure that participant assignments are truly random, to control for covariates in the analysis for unbiased results (Suresh, 2011). All Excel data will be imported into SPSS 25 transforming variables into their final format. Generated (recoded) variables will then be assessed for coding errors by cross-tabulating raw variables with the recoded variables.

#### Key variable creation.

**Primary Outcome:** To test the feasibility of conducting an interdisciplinary music listening intervention in hospitalized, older adults.

<u>Specific Aim #1:</u> To assess the effect of a music listening intervention on the incidence of delirium as measured with the CAM. Utilizing the CAM, these variables will be assessed using a non-parametric Chi-Square analysis to determine if delirium incidence rates differ across the two groups (Munro, 2005). This will be assessed as nominal, or categorical data as follows: delirium yes/no. For playlist development, the CAM will be used to determine whether the patient has no delirium, hyperactive yes/no or hypoactive yes/no delirium. <u>Specific Aim #2</u>: To assess the effect of a music listening intervention on the severity of delirium as measured by the CAM-S. Utilizing the CAM-S, this ordinal data: Acute onset/fluctuating course: no = 0, yes = 1, Inattention: no = 0, yes (mild) = 1, yes (marked) = 2, Disorganized thinking: no = 0, yes (mild) =1, yes (marked) =2, and Altered level of consciousness: normal = 0, vigilant/lethargic (mild) = 1, stupor/coma (marked) = 2 will be analyzed. For data analysis, an independent *t*-test will use the highest summative score for delirium severity.

# <u>Specific Aim #3:</u> To assess the effect of a music listening intervention on the duration of delirium as measured in the number of CAM positive hours.

The duration of delirium will be analyzed with an independent *t*-test to determine the duration of delirium (Polit & Beck, 2016).

#### **Strengths and Limitations**

Limitations. This study will be conducted on one acute care unit in a community hospital in Northeastern Pennsylvania, thus limiting generalizability. Future studies would be needed to replicate this study in different settings, such as other acute care areas in different states, with different patient populations, such as intensive care units, post-operative units and/or long-term care units. Bias will be difficult to control for, as researchers and staff will be aware of those participants that will be undergoing music therapy. Other concerns/barriers with recruitment and retention include: older people are less likely to participate in research, time constraints for recruitment, study design and timing of interventions, and utilizing a single site may also be a barrier to recruitment if enough older patients are not admitted (Chittester, 2013).

Confounding delirium factors that may influence the outcome of this study that may require further analysis include age, gender, race, education, diagnosis, past medical history, medications, use of a urinary catheter or restraints, low albumin, smoking and alcohol history. Randomization in the music therapy group or care as usual group will help to limit these biases by creating groups that are relatively comparable in regard to known and unknown confounding variables (Pourhoseingholi et al., 2012).

**Strengths.** Delirium recognition is difficult secondary to the fluctuating nature of the syndrome and the multiple symptoms patients' exhibit. Therefore, to produce reliable delirium assessments, all participating staff members and RA's must have formal training in both the CAM, CAM-S, and SPMSQ and Digit Span Test (cognitive testing required together with administration of the CAM) and be able to demonstrate proficiency in assessment (Inouye et al., 2014). This will be accomplished through comparison of results between RA's and the PI to confirm inter-rater reliability. If the study is prolonged (greater than 6 months) repeated CAM training sessions are required to maintain accurate results and intervention fidelity (Inouye, 2003; Horneret al., 2006).

#### **Conclusions and Recommendations**

This is a feasibility study for providing older hospitalized acute care patients with individualized music interventions. This study also allows an estimation on the preliminary impact of music interventions for decreasing delirium incidence and severity and builds on previous research that has demonstrated music does have an impact on the incidence of delirium (McCaffrey & Locsin 2004, 2006; McCaffrey 2009). The literature supports using nonpharmacological measures to prevent and or manage delirium in the hospitalized older patient to enhance wellness, and to minimize the functional and

cognitive decline while preserving patient safety (Inouye et al., 2014, Rivosecchi et al., 2015). Listening to music increases both white and grey matter and supports neuroplasticity which aids in improving cognitive skills, thus reducing or limiting delirium (Innes et al., 2017; Särkämö et al., 2010). Music therapy enhances delirium care by promoting care that is safe and efficient, while decreasing both length of stay and resource utilization. The results of this study will guide future studies on the care that delirious patients receive and will aid in developing protocols for future research.

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## Figure 2. Study Protocol

## **Music Intervention Study Protocol**

Staff Education on CAM, CAM-S, SPMSQ, Digit Span, MTB & study protocol. Post Fliers

Enroll patients

Screen with CAM and SPMSQ and Digit Span for study inclusion

Obtain consent

Randomize to control group or intervention group

Control Group Randomized to control group. Care as usual B.I.D. CAM assessments If CAM +: B.I.D. CAM & CAM-S Assessments Intervention Group Usual care B.I.D. CAM Assessments If CAM +: B.I.D. CAM & CAM-S Assessments Music Therapist session and development of individualized Music Interventions: Track 1. General preferred music Track 2. Slow tempo transitions to more upbeat tempo. (Hypoactive delirium) Track 3. Fast tempo that transitions to a slower tempo. (Hyperactive delirium) Twice daily music intervention is dependent upon if patient is delirious or not (see track 1, 2, or 3).

**B** . Delirium and Music Intervention Flier

Delirium and Music Intervention Study



• Would you like to take part in a research study that has the potential to improve

care for our elderly population?

- Do you want to make a difference in someone's life?
- Please ask your nurse to participate in a research study regarding the experience

of the impact of music therapy on delirium in the hospitalized elderly patient.



Please contact your nurse to speak with a representative to be included in this study

## Appendix C.

## Music Therapist Questionnaire

DELIRIUM and MUSIC INTERVENTION QUESTIONNAIRE		
Patient:	Date of Admission:	
Name of person filling out form:	Relationship to patient:	
Primary language of Patient:	English (please circle):	
Yes No		
Caretaker Name/Emergency Contact:	English (please circle):	
Yes No		
Caretaker Phone Number:	Permission to call?	
Yes No		
Diagnosis of Patient/Reason for Hospitalization:		

Has Patient participated in any of the following musical activities: (Please circle all that apply).

Played instrument/sang in music ensemble (e.g. orchestra, band, choir, etc.)

Performed in musical theater Attended concerts for fun Listened to radio Other:

\_\_\_\_

Has Patient played any instruments? (Please circle all that apply.)

Guitar Piano Drums Bass Singing Flute Violin Other:

Does the Patient have a religious affiliation? Yes No If so,

name\_\_\_\_\_ What type of music does Patient enjoy? (Please circle all that apply.) Religious Rock Blues Country Jazz Classical Pop Folk Rap Hiphop Latin Broadway/Show tunes Ethnic (please specify): \_\_\_\_\_ Other: \_\_\_\_\_

Please name any musical artists, songs, or styles of music that the Patient especially enjoys:

Please name any musical artists, songs, or styles of music that Patient especially does

**NOT** enjoy or that evoke unpleasant memories (artists/songs/genres):

Please provide any additional information that will aid us in providing the Patient with music that is specific to their preferences and life experiences:

# Appendix D.

# CAM Form

Acute Onset of Changes or Fluctuations in the Course of Mental Status (Feature 1). AND

Inattention (Feature 2).

# AND EITHER

Disorganized Thinking OR Altered Level of Consciousness (Feature 3). (Feature 4).

# EQUALS DELIRIUM

"Confusion Assessment Method. Copyright 2003, Hospital Elder Life Program, LLC. Not to be reproduced without permission."

"Thank you for your interest in the CAM. You have the Hospital Elder life Program's permission to use the CAM for clinical, educational, or training purposes in a non-profit setting."

(Inouye et al., 1990)

# Appendix E . SPMSQ Form

Question	Response	Incorrect Responses
1. What are the date, month and year?		
2. What is the day of the week?		
3. What is the name of this place?		
4. What is your phone number?		
5. When were you born?		
6. Who is the current president?		
7. Who is the current president?		
8. Who was the president before him?		
9. What was your mother's maiden		
name?		
10. Can you count backward from 20 by		
3's?		

# The Short Portable Mental Status Questionnaire (SPMSQ).

## Scoring:

0-2 Errors: normal mental functioning.

3-4 Errors: Mild Cognitive Impairment.

5-7 Errors: Moderate Cognitive Impairment.

8 or more Errors: Severe Cognitive Impairment

\*One more error is allowed in the scoring if a patient has had a grade school education or less.

\*One less error is allowed if the patient has had education beyond the high school level. *Pfeiffer, E.* (1975). A short portable mental status questionnaire for the assessment of organic brain deficit in elderly patients. *Journal of American Geriatrics Society. 23*, 433-41.

## Appendix F

## THE DIGIT SPAN

A subtest of the WMS-III consists of two parts: Digits Forward and Digits Backward. For each part, the test administrator says a series of numbers at the rate of about one per second.

Following the presentation, the examinee either repeats the numbers in the order they were presented (Digits Forward) or in reverse order (Digits Backward).

For both Digits Forward and Digits Backward, the test begins with a series of two numbers. For Digits Forward, the test continues to a maximum of **eight numbers**, and for Digits Backward, the test continues to a maximum of **seven numbers**.

Examinees are given two trials at each series length, and the test continues until both trials of a series length are failed.

One point is awarded for each trial that the examinee answers correctly.

The total raw score for Digit Span is the sum of the trails answered correctly for both Digits Forward and Digits Backward. The maximum possible score for the Digit Span subtest is 30 (16 points for Digits Forward and 14 points for Digits Backward).

https://www.verywellhealth.com/what-is-the-digit-span-test-98627

# Appendix G. CAM-S Form

# CAM-S SHORT FORM SCORING WORKSHEET

Note: This worksheet should be used for assessing delirium severity. At a minimum,

testing of orientation and sustained attention is recommended, such as digit spans, days of

week, or months of year backwards.

EVALUATOR:	DATE:
------------	-------

Feature	Severity Score
I. ACUTE ONSET AND FLUCTUATING COURSE	I. Either present:
a) Is there evidence of an acute change in mental	
status from the patient's baseline?	No
OR	0
b) Did the (abnormal) behavior fluctuate during the	
day, that is tend to come and go or increase and	Yes:
decrease in severity?	1
II. INATTENTION	II.
Did the patient have difficulty focusing attention, for	No
example, being easily distractible or having difficulty	0
keeping track of what was being said?	
	Yes (mild)
	1
	Yes (marked)
	2

III. DISORGANIZED THINKING	III.	
Was the patient's thinking disorganized or incoherent,	No	
such as rambling or irrelevant conversation, unclear	0	
or illogical flow of ideas, or unpredictable switching		
from subject to subject?	Yes (mild)	
	1	
	Yes (marked)	
	2	
IV. ALTERED LEVEL OF CONSCIOUSNESS	IV.	
Overall, how would you rate the patient's level of consciousness? Alert (normal)	Normal:	
- Vigilant (hyperalert)	0	
Lethargic (drowsy, easily aroused)	Mild: vigilant	
- Stupor (difficult to arouse)	or lethargic:	
	1	
	Marked:	
	stupor or coma:	
	2	
V. SEVERITY SCORE: Add the scores in rows I-IV	Severity Score:	
Scoring the CAM-S: Rate each symptom of delirium listed in the short CAM		
instrument as absent (0), mild (1), marked (2). Acute onset or fluctuation is rated as		
absent or present. Summarize these scores into a composite that ranges from 0-7		
(higher scores indicate more severe delirium) (Inouye	et al., 2104)	

## Appendix H

## **Informed Consent**

## **Research Consent / Authorization Form**

RB NUMBER: 2019-0319IRB Approved: 06/11/2019

IRB #

Study Name: Delirium and Music Therapy

Full Title: Delirium and the effect of Music Therapy in the elderly hospitalized

patient.

Dr. Vendetti /Mimi Kovaleski

Site(s): Geisinger Community Medical Center

Study Phone Number: 570-XXX-XXXX

Funded by: N/A

We are asking you to be in a health research study. You do not have to be in this study. Your care at Geisinger will not change if you say no. If you join this study, you can stop at any time.

This form tells you about the study. You can ask someone to read it to you. You can ask questions at any time.

A description of this clinical trial will be available on <u>www.clinicaltrials.gov</u>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

During the study, we will tell you if there is new information or changes to the study that could affect you, your health or your desire to stay in the study.

# What Should I do?

- Read this form or have it read to you.
- Make sure we explain the study to you.

• Make sure we explain what is done for research and what is done as part of your routine care.

• Ask questions.

• Take time to think about this, and talk to your family and friends. A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. During the study, we will tell you if there is new information or changes to the study that could affect you, your health or your desire to stay in the study.

#### Why is this study being done?

We are asking you to join this study because you may develop delirium. We want to learn more about delirium. We hope that by using Music Therapy, patients who are admitted to the hospital will have less delirium than those patients admitted to the hospital who do not listen to Music Therapy.

#### Who will be in the study?

About 60 people will join at Geisinger Community Medical Center.

How long will I be in the study? You will be in the research study for 14 days or until discharge from the Progressive Care Unit, whichever comes first.

### What will I be asked to do?

First, you will be assessed to find out if you can be in the study. This involves talking with a study team member and answering questions. It will take about 10-15 minutes. Next, you will be "randomized" into one of two study groups. Randomization means that you are put into a group by chance, like flipping a coin. A computer program will place

you in one of the study groups. You will have an equal chance of being placed in either group. Neither you or your doctor can choose the group you will be in. If you are in the music therapy group, you will use headphones to listen to music twice a day or more often. If you are in the standard care group, you will receive standard care. If you are assigned to the music therapy group, you will meet with a Music Therapist to determine what type of music you like. Then the Music Therapist will develop playlists for you.

#### Will I be paid?

There is no payment for participating in this study. There is no cost to you for participating in this study. You or your insurance company will be charged for the costs of your medical care.

### Can being in this study help me?

This study might or might not help you. We hope that what is learned from this study will help others in the future. Music Therapy may offer therapeutic benefits with little to no risk and does not use medication. If you are in the standard care group, you will receive care that is the normal care for delirium.

#### What are the risks?

There are no physical risks expected with this study. There is a risk that your information could be seen by someone other than the study staff. However, we will take steps to protect your information. Completing the music questionnaire prevents using music that may bring to mind any unpleasant memories.

### How will Geisinger use and share my information?

The Geisinger study staff will view and collect information that is in your medical record. We will also collect information about you during this study. Some of this information will be kept in a research record at Geisinger, and may be used in future research studies. Any information placed in your medical record will be a permanent part of your medical record.

The information collected and shared in this study include factors that may influence the occurrence of delirium:

• Age, race, education

- Admitting diagnosis, medications, smoking and alcohol history
- Lab study that had been ordered by your doctor: albumin, glucose
- Medical history about strokes
- Information about the care you receive during the course of the study

Your primary care doctor or specialist may receive information about your participation in this study. By signing this form, you are giving Geisinger permission to use and share your health information. It can be shared indefinitely for purposes of this study. If you change your mind, tell us in writing to stop using and sharing your information. Information already collected will still be used. We will only use and share new information if it is needed to protect your safety or follow with the law.

Write to: Dr. Adele Spegman, Music Therapy and Delirium Study, 100 N. Academy Avenue, Danville PA 19722

Your research and medical record could be reviewed for quality and to make sure rules are followed. This review could be done by:

Geisinger Institutional Review Board

- Geisinger staff
- Department of Health and Human Services (DHHS)
- Office for Human Research Protections (OHRP)If information from this research study

is included in an article published in a medical journal or presented at a medical or

scientific meeting, it will be done in a way that does not identify you.

Information from this study might be used for other, future research projects. Those

projects can focus on any topic and might be unrelated to the goals of this study.

Information we share with researchers at Geisinger research institutions or companies

around the world, will not identify you directly.

IRB NUMBER: 2019-0319IRB

Approved: 06/11/2019GIRB

Template 08.28.2018IRB # 2019-0319, Music therapy, Consent v1.2, 5.27.2019

research institutions or companies around the world, will not identify you directly.

## What if I have questions or problems?

For questions about the research study, call the study team. Call: Mimi Kovaleski XXX-XXX

Geisinger has a group of people who are not part of this study that review research to protect your safety, rights, and welfare. If you would like to obtain more information, offer input or discuss problems or concerns about your rights as a research participant, you can call Geisinger Institutional Review Board (IRB) at:

- 844-542-3299 or 570-271-8663 (Danville, PA)
- 609-449-4395 (Atlantic City, NJ) [Only add for AtlantiCare studies]

Signature\_\_\_

I agree to take part in this research study and allow my health information to be used for this

research study. My questions have been answered. I will get a signed copy of this form.

Research Participant's Printed Name\_\_\_

Research Participant's Signature	
Date	
l confirm that the research study was thoroughly explained to the participant. I reviewed the	
consent form and answered all questions. The participant appeared to have understood the	
nformation.	
Person Obtaining Consent	
SignatureDateDate	

Appendix I. Protection of Human Subjects and Data Management

Protection of Human Subject and Data Management Medical record data on participants will be collected by the PI or research assistant(s) who have undergone HIPPA training to maintain participant's confidentiality. De-identified data will be stored in a password protected computer after being numerically coded by the PI at the time of collection and de-identified paper data will be kept in a secure locked cabinet in the PI's office or on a password protected hard drive. Consent forms and numeric codes will be locked in a separate, secure, locked cabinet. Institutional Review Board (IRB) approval of all study operations and materials will be obtained prior to data collection as per the IRB protocols of Duquesne University, University of Scranton and Geisinger together with completed HIPPA forms. Informed consent will be obtained prior to conducting any research. Informants will be treated with respect according to the ethical guidelines for the conduct of research. Voluntary informed consent will be obtained before beginning the study. Participants will be informed that taking part in this study is voluntary and participants can choose to stop participating at any time without fear of retribution. If a participant notifies the principal investigator of the desire to withdraw from the ministudy, all data from the participant will be destroyed. There are no anticipated risks greater than those encountered in everyday life. Participants will be provided with the contact information of the researcher and the Duquesne University IRB in case they deem it necessary to contact them.

### Appendix J. Research Assistant Training Manual

Research assistants (RA) will receive extensive training on the utilization of the Confusion Assessment Method (CAM), the Confusion Assessment Method-S (CAM-S), SPMSQ, Digit Span and the month of the year backwards (MTB), prior to the start of the study.

1. Masters prepared nurses with prior training on the CAM, CAM-S, SPMSQ, Digit Span and MTB will conduct training sessions for the RA's that will be assessing for delirium. The instruments will be discussed, items on the four instruments will be reviewed and practice sessions utilizing the four instruments will be conducted followed by a group discussion with question and answer sessions.

**2.** Trained RA's will independently assess four patients, independent of the reviewers with the CAM, CAM-S, SPMSQ, Digit Span, then the same four patients will be assessed by the nurses with prior training (assessors are blind to each other's findings) to ascertain agreement.

**3.** Training will continue until both trained researchers and novice researchers' findings are in complete agreement. These trained researchers will begin utilizing these four instruments with each older (age 65 or older) patient assessment until they are in complete agreement.

**4.** If the research continues after six months, this training will be repeated to maintain inter-rater reliability.

## RESULTS Manuscript #2

#### Abstract

**Background**: Delirium is an acute change in mental status that commonly occurs in the hospitalized elderly and if undetected, contributes to increased mortality and both functional and cognitive decline. Due to the high prevalence of delirium and its associated adverse health risks, it is critically important to prevent delirium among older adults admitted to the hospital. **Purpose:** The purpose of this study was twofold: to test the feasibility of conducting an interdisciplinary music listening intervention in hospitalized older adults, and to assess the effect of a music listening intervention on the incidence, severity, and duration of delirium using standardized delirium assessments.

**Methods:** A single setting, two-armed feasibility study with a music listening intervention group (n = 24) and a usual care control group (n = 20) was conducted on older adults admitted to the Progressive Care Unit of a 280-bed acute care hospital in the Mid-Atlantic region. This nurse-led music listening intervention was developed in collaboration with a music therapist who designed music playlists based upon individual patient preferences, experiences, and delirium subtypes. The music intervention was delivered by registered nurses following the twice daily Confusion Assessment Method (CAM) and Confusion Assessment Method-Severity (CAM-S) assessments of the patient's delirium, and delirium subtype in accordance with the protocol.

**Results:** Participants in both groups had a mean age of 77.75 years and 100% were Caucasian. There were no significant differences in the incidence, severity, and duration of delirium between the groups. The music listening intervention could not be delivered for the intended length of time as participants were transferred to units where the staff was not trained on the CAM and CAM-S.

**Conclusions:** The study was not feasible as designed. It was possible to (a) recruit participants for this study, (b) implement the CAM and CAM-S assessments, and (c) deliver the music listening intervention. The study was underpowered, and retention was an issue due to unforeseen organizational and structural changes within the hospital. Implications for clinical practice, and suggestions for further research are included.

Keywords: Music, music listening, delirium, older adults.

Delirium is a serious syndrome experienced by some older adults admitted to the acute care setting (American Delirium Society, 2015; Balas et al., 2012). As an acute disruption in awareness, attention, and cognition that develops over minutes to hours, delirium fluctuates in severity that is not explained by a preexisting or progressing neurocognitive disorder (American Psychiatric Association [APA], 2013). Delirium is characterized by (a) disturbance in attention, (b) change in cognition, and/or (c) fluctuation in cognition from baseline (APA, 2013). Annually, more than seven million hospitalized older adults will develop delirium with costs that will surpass the current amount of \$38-\$152 billion as the older population is expected to double from 52 million at present, to 95 million by the year 2060 (Mather et al., 2019). Globally, the estimated costs associated with delirium in U.S. dollars were reported to range from \$806 to \$24,509 per occurrence in the hospital setting to \$1,529 - \$14,462 in the intensive care unit (ICU) setting (Kinchin et. al., 2021).

Delirium occurs in roughly one-third of non- ICU hospitalized older adults, where 50% are admitted with delirium and the other 50% will develop delirium during their hospitalization (Marcantonio, 2017). Delirium has a robust, independent correlation with negative patient outcomes such as the increased risk of death, prolonged hospitalizations and may persist for up to two years post-hospital discharge requiring admission to a long-term care facility (Andrews et al., 2020; Marcantonio, 2011).

Three delirium subtypes have been identified in the literature, hyperactive, hypoactive, or the mixed type. Hyperactive delirium is characterized as restlessness, agitation, rapid mood changes or hallucination, and refusal to cooperate with care (Neufeld & Thomas, 2013). Hypoactive delirium is characterized as a disruption of arousal with difficulty staying awake,

diminished cognition, alertness, and verbal responses, and is often mistaken for sleepiness or depression (Jin et al., 2020; Marchington et al., 2012; Neufeld & Thomas, 2013). The mixed type of delirium exhibits features of both types, fluctuating within minutes to hours (Neufeld & Thomas, 2013).

Delirium may represent a series of insults and recovery, which may lead to permanent cognitive decline, such as dementia (Inouye, 1999; Inouye, 2000). As a neuropsychiatric syndrome, delirium development is a multifactorial process involving the dynamic interplay between a patient's vulnerability to precipitating factors (e.g., infection, surgery, medication reactions, restraints, and bladder catheter) and/or potential predisposing factors (e.g., cognitive impairment, visual impairment, and stressful environment) (Inouye, 1999; Inouye, 2000).

Delirium is frequently not identified or assessed systematically in hospital settings, but described with casual words or phrases, and may mistakenly be considered to be a normal part of aging (Middle & Miklancie, 2015). Identification, prevention, and management of delirium remain complex due to the fluctuation in delirium symptoms (Maldonado, 2008). Under-recognition of delirium is attributed to lack of formal assessments with validated tools (Balas et al., 2012; Cheong et al., 2016; Marcantonio, 2012; Siddiqi et al., 2007). Inouye (2003) developed the CAM, a reliable and validated tool to detect delirium, and in 2014, developed the CAM-S tool to assess the severity of delirium (Inouye et al., 2014).

Earlier research found delirium has been shown to last for up to one-year post occurrence, especially for patients with hypoactive delirium (Saczynski et al., 2012). The clinical significance of this finding is that recent research suggests that increased delirium severity and duration increases the mortality risk for up to two years post-discharge (Andrews et al., 2020) and should be explored.

Routine medications such as sedatives or anticholinergic agents can be a catalyst for the development of delirium (American Geriatric Society [AGS], 2015; Inouye et al., 2014). Research does not support the pharmacological management of delirium but recommends limiting its use to prevent worsening patient outcomes (AGS, 2015; Inouye et al., 2014; Marcantonio, 2012; Rivosecchi et al., 2015). Music listening as a non-pharmacological intervention has improved patient engagement and agitated behaviors in institutionalized individuals with dementia and may improve cognition in patients hospitalized with delirium (Cheong et al., 2016). Since the relationship between music listening and delirium has not been fully explored, the purpose of this study was twofold: to test the feasibility of conducting an interdisciplinary music listening intervention in hospitalized older adults, and to assess the effect of a music listening intervention on the incidence, severity, and duration of delirium using standardized delirium assessments.

#### Background

In hospitalized, severely demented patients with agitation, music listening as a single component intervention has been shown to restore residual cognitive and emotional functioning (Sakamoto et al., 2013). Music listening was used to improve acute confusion, a term used synonymously for delirium (Slooter, 2017; Zalon et al., 2017), in hospitalized postoperative adults (Çetinkaya, 2019; McCaffrey, 2009; McCaffrey & Locsin, 2004; McCaffrey & Locsin 2006), and to reduce anxiety and agitation (Goodall & Etters, 2005; Hicks-Moore, 2005). The positive effects of music listening support improved neurogenesis, increased grey and white matter volume in subcortical and cortical brain areas involved in cognitive processing and working memory; suggesting that music listening improves critical domains of both cognitive and memory functioning (Innes et al., 2017). These improvements in cognitive and memory

functioning are a result of stimulation on altered brain structures to compensate for the damaged adjoining areas, which take on the functions of the damaged brain structures (Särkämö et al., 2008). These compensatory cognitive and memory changes support long-term changes in plasticity thus improving cognitive skills and may be beneficial in preventing or limiting delirium (Särkämö et al., 2010).

There are several shortcomings in studies related to delirium management. First, research directed at music's effect on delirium in the acute care area is sparse. Second, there is a lack of conceptual clarity in the literature with some studies using the term, "acute confusion." Third, research was conducted with small homogenous samples without including the expertise of a certified music therapist and did not directly assess for the presence of delirium (Çetinkaya, 2019; McCaffrey 2009; McCaffrey & Locsin, 2004; McCaffrey & Locsin, 2006). Two published studies did address the effect of music listening on acute confusion (Çetinkaya, 2019; McCaffrey, 2009). Overall, music listening has been recommended as a safe, feasible, and financially sound preventative measure and treatment method for acute confusion (Çetinkaya, 2019; McCaffrey, 2009; McCaffrey & Locsin, 2004; McCaffrey & Locsin, 2006).

The purpose of this study was twofold: to test the feasibility of conducting an interdisciplinary music listening intervention in hospitalized older adults, and to assess the effect of a music listening intervention on the incidence, severity, and duration of delirium using standardized delirium assessments.

**Primary Outcome:** To test the feasibility of conducting an interdisciplinary music listening intervention in hospitalized, older adults.

**Secondary Outcome 1**: To assess the effect of a music listening intervention on the incidence of delirium as measured with the CAM.

**Secondary Outcome 2**. To assess the effect of a music listening intervention on the severity of delirium as measured by the CAM-S.

**Secondary Outcome 3**: To assess the effect of a music listening intervention on the duration of delirium as measured in the number of CAM positive hours.

#### Method

This feasibility study was implemented at a regional medical center's Progressive Care Unit (PCU) from June through September 2019. The study assessed the feasibility of (a) recruiting and retaining participants and, (b) of assessing the effect of a music listening intervention on the incidence, severity, and duration of delirium in hospitalized older adults. Human Subjects Institutional Review Board approval was obtained, and the study was registered as a clinical trial (NCT03980782, www.clinicaltrials.gov), in accord with the CONSORT recommendations. (Figure 3 Abstract 2).

### Sample and Setting

Eligibility criteria included patients with (a) medical, surgical and trauma diagnoses, (b) age 65 or older, (c) admitted to the PCU, (d) English speaking, (e) with a self-reported ability to hear music through headphones, (f) who were cognitively intact, and (g) able to sign an informed consent. Exclusion criteria included (a) positive CAM, (b) greater than three errors on the Short Portable Mental Status Questionnaire (SPMSQ), and (c) three or more errors on the Digit Span Test (DST) (Figure 2). Sample size justification for feasibility or pilot studies may not be appropriate, but recommendations range anywhere from 24 to 50 participants (Billingham et. al., 2013; Julious, 2005). The study setting was a 280-bed, acute-care hospital in the Mid-Atlantic region.

#### Procedure

*Preparation for intervention.* To ensure the fidelity of the CAM and CAM-S assessments six months before initiating data collection, all PCU registered nurses (RNs) received training on the utilization of the CAM (Inouye et al., 1990) and the CAM-S tools (Inouye et al., 2014). Clinical Nurse Specialists (CNS) with prior training on the CAM and CAM-S (Appendix G) conducted 60-minute training sessions for RNs who assessed participants. The instruments were explained, including assessment, and scoring. All items on the two instruments were reviewed and practice sessions using the two instruments were conducted followed by a group debrief with question and answer sessions. The RNs and CNSs assessed the same patients: as one PCU RN asked questions, each of the RNs evaluated the participant responses. Training continued over the next six months until the CNSs assessments and PCU RNs assessments were identical.

One month before data collection the music therapist and principal investigator (PI) conducted training sessions for PIs who assessed participants' music preferences using the music therapist developed questionnaire (Appendix C ). Instructions on how to complete the questionnaire were explained, and the PI or music therapist completed the questionnaire. All items on the instrument were reviewed and practice sessions utilizing the questionnaire were conducted followed by a discussion with question and answer sessions.

RNs on the unit posted fliers and notified the PI of participant interest. PCU RNs approached patients and their family members about inclusion in the study. Once aware of participant interest, the PI spoke with eligible and willing participants to obtain consent and enroll participants. Participants were randomized into the music listening group or usual care group based upon computer-generated 1:1 randomization (using blocks of eight). Upon

acceptance of a patient, the appropriate, serially numbered, opaque envelope was opened to determine the participant's study group. Usual care was defined as hourly rounding, taking every four-hour vital signs, every 12-hour CAM assessments, with CAM-S if positive, and the placement of clocks and whiteboards in all participant rooms. Participants in both groups were assessed every 12 hours for delirium with the CAM. Once CAM positive, all participants were assessed with the CAM-S to determine delirium severity.

Participants in the music intervention group met with the music therapist or PI to answer the structured music listening questionnaire. The initial music listening session was instituted within 12 hours of enrollment into the study. Participants in the music listening group received a twice-daily, 30-minute, individualized music listening intervention (Figure 4) that was implemented by the nursing staff between 7-9 AM and 7-9 PM. The rationale for using an individualized, pertinent music intervention was to increase participant engagement in the music listening activity to reduce the incidence, severity, and duration of delirium.

Participants in the music listening group listened to the individual playlist that corresponded with their most recent CAM assessment (no delirium, hypoactive delirium, or hyperactive delirium). These playlist constructions align with Nightingale's environmental theory where nurses alter the environment through internal and external factors to promote health or to overcome an unfamiliar, turbulent environment (Hegge, 2013; Nightingale, 1969). Altering the hospital environment through music assists the patient in adapting to this new environment with minimal distress (Heiderscheit & Madson, 2015). For hypoactive delirium, the music listening playlist began with slow, pensive music and slowly transitioned to tempos that were more upbeat. For hyperactive delirium, the playlist would start with selections with faster tempos

before transitioning to selections with slower tempos. CAM negative participants listened to a preferred music playlist.

#### **Data Collection**

Initial cognitive screening and delirium screening on all participants was conducted by the PI before randomization to the treatment group using the Short Portable Mental Status Questionnaire (SPMSQ), Digit Span Test (DST), the CAM, and CAM-S.

Once inclusion criteria were met, data were collected at enrollment into the study by the PI and included demographics (age, gender, race, number of medications, glucose, albumin levels), and information about potentially predisposing or confounding factors (transient ischemic attack, cerebral vascular accident, indwelling catheter, alcohol and smoking histories) (Inouye, 1999; Inouye, 2000). CAM, CAM-S scores, and delirium duration in hours were collected by RNs. Once CAM positive, the CAM-S assessments were completed on all participants to more accurately determine delirium severity and participant response.

The CAM and CAM-S assessment scores were extracted from the study participant's medical record between 7-9 am daily and 7-9 pm daily. The primary outcome, the incidence of delirium, was assessed with the CAM to determine the presence or absence of delirium, classified as either hypoactive or hyperactive. The severity of delirium was assessed with the CAM-S to quantify the intensity of delirium as ordinal data of the summative scores by measuring acute onset, fluctuating course, inattention, disorganized thinking, and altered level of consciousness. The duration of delirium was measured in hours from the time between the initial CAM positive results to the next CAM negative results. The severity and duration of delirium in the control and the music listening groups were analyzed using independent *t*-tests. To measure

the incidence of delirium in the control and music listening groups, a chi-square analysis was conducted. Data were analyzed using IBM SPSS Statistics for Windows, version 25 (2017).

#### Results

Forty-four participants were enrolled in this study. The music-listening group had 24 participants, (n = 24), and the control group had 20 participants, (n = 20). The two groups were compared using *t*-tests, chi-square, and Fisher Exact tests to analyze whether the groups were significantly different concerning history of transient ischemic attack (TIA), cerebral vascular accident (CVA), alcohol use, smoking, age, number of medications, albumin, and glucose levels. There were no significant differences in any of the above characteristics between the groups. The sample had a mean age of 77.75 years and no study participants were physically or chemically restrained. (Table 2 )

**Primary Outcome:** To test the feasibility of conducting an interdisciplinary music listening intervention in hospitalized, older adults.

The study was not feasible as designed. However, it was possible to (a) recruit participants for this study, (b) implement the Confusion Assessment Method (CAM) and Confusion Assessment Method-Severity (CAM-S) assessments, and (c) deliver the music listening intervention. Overall study recruitment rate was 92%. Study retention was not met as participants were transferred to other units, rendering them lost to follow up. Given the extensive training on the instruments (CAM and CAM-S), it was not feasible to continue the study on alternate units without this education. This limitation led the study to be underpowered. The final sample consisted of five participants in each group (25% control group and 20.8% music listening group) with complete data, therefore the study did not obtain 44 complete data points. The CAM and CAM-S assessments had a 100% completion rate when participants remained on

the PCU. It is feasible to recruit participants, but retention may be improved by educating all units on the use of the CAM and CAM-S.

**Secondary Outcome 1**: To assess the effect of a music listening intervention on the incidence of delirium as measured with the CAM.

It was feasible to measure the incidence of delirium using the CAM after staff education. Of the 24 patients in the music listening group, 5 (20.8%) had a CAM score that reflected the incidence of delirium. Of the 20 patients in the control group, 5 (25.0%) had a CAM score that reflected the incidence of delirium. A chi-square showed there was no significant difference in the incidence of delirium between the music listening and control groups: (1)  $\chi 2$ = .108, *p* = .74. **Secondary Outcome 2**: To assess the effect of a music listening intervention on the severity of delirium as measured by the CAM-S.

It was feasible to measure the severity of delirium with the CAM-S after staff education. An independent *t*-test was performed to determine significant differences in the music listening group vs. the control group's severity of delirium. The mean CAM-S score in the music listening group was not significantly different (M = .31, SD = .656) from the mean CAM-S in the control group (M = .55, SD = .999). There was no significant difference in the delirium severity (CAM-S) score between the music listening group and control groups as the study was underpowered (t(42) = .946, p = .349).

**Secondary Outcome 3** To assess the effect of a music listening intervention on the duration of delirium as measured in the number of CAM positive hours.

It was feasible to measure the duration of delirium. An independent *t*-test was performed to determine significant differences in the music listening group vs. the control group's duration of delirium. The mean duration of delirium as measured in hours in the music listening group
was not significantly different (M = 1.08, SD = 2.685) from the mean duration of delirium in the control group (M = 5.05, SD = 14.923). There was no significant difference in the duration of delirium between the music listening and control groups (t(42) = 1.280, p = .255).

### Discussion

As an individual music listening intervention has not been fully explored in participants with delirium, it was necessary to see if and how the intervention worked. It was important to see if it was possible to recruit, assess and retain participants before conducting a larger randomized clinical trial of an individual music listening intervention. Additionally, the research team assessed if it was feasible to measure the variables of interest.

When this unit was being considered for this study, the average length of stay was five to seven days. The major confounding factor in this study was the frequent transfers of participants to other units which interfered with obtaining complete cases (receiving at least two sessions of the music listening intervention) in accordance with the approved protocol. Participants were transferred to other units within the facility. The staff on other units were not trained in the use of the CAM and CAM-S, therefore, it was not possible to retain the participants in the study.

This study could be strengthened by adding an advanced practice nurse (APRN) as the research project director (PD). The APRN has the necessary expertise to provide resources, train RNs on the study protocols, and oversee the transfer of participants throughout their hospital stay. A PD would ensure adequate monitoring and delivery of the interventions (Durning, et. al., 2010). The study would benefit from institutional support for the PD before starting the study. Such support is necessary for both the education of nursing staff, the smooth transition (to another clinical unit), and the retention of participants in this study. Due to participants being

transferred off the unit, following the effect of the music listening intervention longitudinally was not possible.

The researcher intended to make the control and the music listening groups as equal as possible to negate any confounding variables that may affect participant delirium. As conducted, the study did not maintain a sufficient sample to determine if the music listening intervention influenced patient delirium outcomes due to the high attrition rate. The incidence of delirium was similar in both the music listening and control groups. Although underpowered, the findings of this study might support consideration of further research on the effect of a music listening intervention on delirium in the acute care population.

Early recognition of increasing delirium severity may prompt clinicians to treat delirium earlier and to follow each participant's response to delirium treatment to preserve cognitive function (Inouye et al., 2014). There are fewer resources allocated for clinical care and research in persons affected by delirium and the significance of the debilitating effects of delirium may remain underestimated until the associated societal and economic impacts are recognized (Andrews, 2020; Leslie & Inouye, 2011; O'Hanlon & Inouye, 2020; Slooter 2017).

Future research on the effect of a music listening intervention on delirium should include studies comparing individualized music listening with general music listening (the music channel). This will assist clinicians in measuring multiple variables of interest to produce results that inform clinicians on music listening intervention's effect on delirium.

A nurse-led music listening intervention might be a cost-effective, non-pharmacological intervention for delirium treatment or prevention. Music listening interventions may lessen delirium's impact as the individual, personalized music selections are relevant and familiar to each participant's life experiences and are designed to support the individualized needs of the

listener (AMTA, 2020). Enlisting the expertise of a board-certified music therapist supports the evaluation of participant response to their individual music selections and adaptation of the music selections to protect the participant from negative outcomes. The music therapist uses the individually tailored music listening playlists to match and alter the participant's present mood, supporting the individual's change in mood, thus supporting the full spectrum of emotions and feelings (AMTA, 2020).

Considering restricted visiting due to the COVID-19 pandemic, hospital patients have limited contact with families and hospital staff, leading older adults to experience social isolation. This isolation has led to fear and agitation which may result in increased usage of both chemical and physical restraints (O'Hanlon & Inouye, 2020). These measures may not only increase the risk for older patients developing delirium but may prolong the duration and severity of delirium, thus increasing the associated healthcare costs and disability (O'Hanlon & Inouye, 2020). Individual music interventions may assist COVID-19 patients during hospitalization by minimizing the distress of an unfamiliar environment.

One incidental benefit of this study is that all PCU staff were trained on the CAM and CAM-S assessments and these assessments were embedded in their care routine. This education allowed staff to identify and promptly treat delirium in all PCU patients. Retention rates for this study could be improved if more personnel on alternate units were educated on the study protocol and assessment tools.

A serendipitous finding was the staff's use of the music channel for delirious patients both in the study's control group and for patients not enrolled in the study after observing the participants who received the music listening intervention. Future studies should measure the

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control group's music exposure (music channel) as it is likely that this may occur again in future studies.

### Limitations

Limitations of this study include an underpowered sample and convenience sampling from a single institution. Such organizational factors limit the generalizability of the study findings. Although participants were appropriately randomized, the intervention was not blinded which may have influenced findings. The inability to follow participants throughout multiple hospital units limited data collection and hindered the sample size of this study.

Several confounding variables could have affected the results. Patients may have had a change of medication due to being diagnosed once in the hospital or they may have received medications after surgery, both having the possibility to alter, precipitate or resolve delirium symptoms. For future researchers, once participants are identified as having delirium, the music listening should be started immediately following the pre-severity score, followed by the post-severity score. The CAM-S should be administered both before and after each music session to capture delirium incidence and severity more accurately. This would allow for better control of potentially confounding variables.

There was also contamination of the study protocol in the current study. Once the PCU staff observed the music listening group's enjoyment of the music intervention, the PCU staff recognized the potential role of music and utilized the music channel for participants in the control group, which may have affected their CAM and CAM-S scores. These findings inform clinicians that music listening may be a viable option for delirium prevention and may be used to co-treat delirium in collaboration with a Music Therapist's expertise.

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#### Conclusions

Future feasibility studies are recommended before undertaking a larger study to determine sufficient recruitment and retention strategies, to check the feasibility of the study design, and to determine the performance of the instruments. It is recommended that training on delirium assessment with the CAM and CAM-S be provided more broadly to the staff on all clinical units where study participants may be located. This may improve retention, as participants can transfer throughout the system and still be included in the study. Assess for delirium immediately after each music listening intervention to capture the effect of the music listening.

Future studies should address the cost-effectiveness of a music listening intervention as a preventative measure for delirium. The true effect of a music listening intervention in reducing the incidence, severity, and duration of delirium remains uncertain. Further studies with larger sample sizes drawn from more diverse older hospitalized patient populations are needed to evaluate the effect of a music listening intervention on the incidence, severity, and duration of delirium in the older patient in acute care settings.

Music interventions might be a safe, low-cost, stand-alone intervention to help prevent delirium and assist patients to maintain cognitive functioning. In conclusion, music listening could be a promising intervention in the acute care setting that may affect delirium's incidence, severity, and duration.

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Figure 3. Consort diagram of enrollment, intervention, and follow-up of study participants.

Appendix K . Cognitive Assessment Instruments.



Appendix L L. Delirium Assessment Instruments.

# Delirium Assessment

**Confusion Assessment Method (CAM):** The CAM is a reliable, validated tool used to diagnose the presence of delirium in the older population (age 65 or greater), can be administered in under five minutes, has a high inter-rater reliability (kappa >8), excellent reliability between clinician raters with a high (94%) sensitivity and (90%) specificity (Inouye et al., 1990). The CAM is intended for use in populations at high risk for the development of delirium (Inouye et al., 1990), by measuring the presence or absence of four features: 1. acute onset and fluctuating course), 2. inattention, 3. disorganized thinking and 4. an altered level of consciousness. Delirium is present if features 1 and 2 are present and either feature 3 or 4 is present (Holroyd-Leduc et al., 2010; Inouye et al., 1990).

### Confusion Assessment Method (Severity) (CAM-S short form): Once CAM positive, the CAM-S is a more in-depth exploration of cognitive change and used to measure the severity of delirium. Participants were screened by staff members with the CAM while on the unit until positive. Once CAM positive, the CAM-S was completed. The CAM-S has an intraclass correlation coefficient of 0.92, and rates both hyperactive and hypoactive delirium symptoms with scores that ranged from 0-7 with seven being the most severe (Inouye et al., 2014). Delirium symptoms (inattention, disorganized thinking and altered level of consciousness) are listed in the short CAM instrument as absent (0), mild (1), marked (2). Acute onset or fluctuation is rated as absent or present. These scores are summarized into a composite ranging from 0-7 with higher scores indicating greater delirium severity.

# Appendix M Music Listening Intervention Protocol MUSIC LISTENING INTERVENTION PROTOCOL

- A pre-composed music listening questionnaire was developed by a board-certified music therapist.
- Prior to conducting the study, the music therapist conducted training sessions with the PI who assessed participants. Instructions on how to complete the questionnaire were explained, and the PI and music therapist completed the questionnaire. All items on the two instruments were reviewed and practice sessions utilizing the questionnaire were conducted followed by a group debrief with question and answer sessions.
- Participants in the **music listening group** met with the PI to complete the self-reported music listening questionnaire (Figure 4). The PI read the questions aloud to participants and recorded their responses. The music listening questionnaire was able to be completed in approximately 15 minutes by the PI in each participant's room.
- Using the individual music selections from the **music listening group** participant's questionnaires, the music therapist developed three separate, individual, 30-minute playlists, designed to match the participant's delirium assessment with music. These playlists are tailored by the must therapist based upon the last Confusion Assessment Method (CAM) score, delirium subtype, and patient's music preferences:

Playlist 1. (No delirium) Tempos were random across the playlist.
Playlist 2. (Hypoactive delirium) Tempos progressed from slow to fast across the playlist.
Playlist 3. (Hyperactive delirium) The tempo progressed from fast to slow across the playlist.

- The music listening intervention was delivered between 7-9 am and 7-9 pm post-CAM assessment while on the unit, in the privacy of the participant's room where ambient noise was kept to a minimum during the intervention and within twelve hours of obtaining consent. The timing of the music listening intervention was designed to occur right after the CAM assessments.
- Participant care was structured around the timing of the music listening interventions to promote adherence to the intervention, treatment fidelity, and limit interruptions in the treatment.
- The music was delivered via SanDisk® MP3 players using TITAN Bass Jaxx soft external headphones.
- The PI initiates the initial music listening session. The PI or the RN begins the music listening intervention as follows: headphones are applied and checked for wearer comfort and volume prior to initiating the music listening intervention. The PI instructs each participant on how to adjust the volume and fit of the headphones. If able, participants set the volume for their 30-minute music listening intervention and if unable, the, PI or RN will adjust the volume to the patient-reported level of comfort.
- Headphones and MP3 players were left at the bedside for participants and staff with written stepby-step instructions and images showing where to turn on the MP3 player, how to adjust volume, how to access the appropriate playlist and how to turn on/off the MP3 player. Participants all had call bells within reach during the music listening intervention in the event they needed assistance. Unit RN's rounded as usual.
- Data were collected between 7-9 am and 7-9 pm by the PI on participants in both groups while on the PCU.

- Family/visitor/nurse presence was allowed during the music listening intervention. a. Family/visitors/nurses were asked not to interrupt the music listening intervention unless the participant required assistance/comfort.
- If the participant wished to listen to the music longer than the 30-minute playlist, they were allowed to do so.
- PI meets daily with all participants in both control and music listening groups to check on each participant and address any study concerns.
- The PI conducted daily assessments about the music listening group's self-report of any adverse effects to the music. If necessary, adjustments (different selections from the artists/genres already selected and recorded in the music listening questionnaire) were made to the playlist selections by the music therapist while maintaining music tempos per CAM assessments. The support of the music therapist assists participants who may be at risk for negative outcomes and promotes a healthy solution, supports the individual's change in mood, thus supporting the full spectrum of emotions and feelings (AMTA, 2020).

## Table 2 . Participant characteristics

	Control Group			Music Group					
(n =20)	(n = 24)								
	n	%		n	%	Chi-Square	Fish	er's Exact	<u>p</u>
Education									
High school or less	9	45		11	46				
College/Trade	11	55		14	58				
Ethnicity									
Caucasian	20	100		24	100				
Gender									
Male	12	60		18	75				
Medications	20	100		22	92				
Anticholinergic		3	15		3	13			
Benzodiazepines	2	1		5	21				
Opioids		17	85		14	58			
Antibiotics	7	35		8	33				
TIA History	1	5		1	4			*.708	
CVA History	0	0		1	4			*.545	
Indwelling Catheter	5	25		7	29	.095		.757	
EtOH History		11	55		11	46 .	367	.545	
Smoking History	11	55		14	58	.049		.824	
	(M ±SD) range			(M ±SD) range					
Age	(77.75, 7.738) (68-91 years old)			(77.7	75, 8.97	75)			
				(65-91 years old)					
Number of Medications	(13.25, 4.58)			(13.88, 4.34)					
Albumin Level	(3.45, .680)			(3.09, .607)					
<b>Glucose Level</b>	(172.3, 83.97)			(164.04, 67.30)					

**TIA:** Transient Ischemic Attack. **CVA:** Cerebral Vascular Accident. **EtOH:** Alcohol history. **Smoking History:** If they ever smoked. **Precipitating/predisposing medications:** medications that have been associated with an increased risk of delirium and include but not limited to: antihistamines, antidepressants, antimuscarinics, antiparkinson's agents, antipsychotics, antispasmodics, skeletal muscle relaxants, antiarrhythmic and antispasmodics. **\*\* Fischer's Exact** test indicated