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The Role of Entrainment on an Older Adult's Stress and Anxiety: A Mixed Methods Study

Francesca Brennan

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ENTRAINMENT ON AN OLDER ADULT'S STRESS AND ANXIETY.

The Role of Entrainment on an Older Adult's Stress and Anxiety: A Mixed Methods Study

A THESIS

Submitted in partial fulfillment of the requirements For the degree of Master of Science In Music Therapy

by

Francesca Brennan, MT-BC Molloy College Rockville Centre, NY 2018

MOLLOY COLLEGE

The Role of Entrainment on an elderly Adult's Stress and Anxiety:

A Mixed Methods Study

by

Francesca Brennan, MT-BC

A Master's Thesis Submitted to the Faculty of

Molloy College

In Partial Fulfillment of the Requirements

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2

2

Abstract

Elderly individuals diagnosed with dementia seem to exhibit similar characteristics; anxiety, depression, isolation, pain, and accumulated stress. it is the desire of this researcher to investigate the role of entrainment on an elderly individuals stress and anxiety. The researcher conducts a mixed method study that evaluates quantitative measures such as heart rate and blood pressure, and qualitative measures through interviews. Overall, the findings lead the researcher to believe that entrainment in music therapy can affect an elderly individuals stress and anxiety in a positive way. *Keywords:* elderly, dementia, Alzheimer's, anxiety, stress, pain, music, music therapy, and entrainment.

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It is with a great honor that I pay a special thanks and appreciation to the persons below who have assisted me at every point to achieve my research goal:

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My Mom and Dad, family members and friends, without whom I would not be where I am today. They remain my primary source of inspiration and example of unconditional love and support.

List of Tables and Figures

Table 1. Emergent Themes and subthemes based on analysis of open ended responses.

Theme and subtheme	Interview Response
T1: Uncertainty and Anxiousness1. Difficulty adapting to change.2. Changes in the environment trigger anxiety.	 "I can'twhatwhat are we doing? The door is closed there." "Can we go outside, can we go outside!?"
T2: Physical Pain1. Abdominal pain due to his prostate2. Restlessness and the need to keep moving.	 "I had some pain, I had some pain." "It is hard to sit still, but I keep myself to keep stillkeep still."
 T3: Need for Reassurance 1. Reliant on wife. 2. Paying compliments tends to proceed concerning statements. 3. Difficulty making choices. 	 "Well I dont know whats going on Carol. Uhhfirst of all, there is nothing coming out of this at all." (often yells for his wife when she is not around.) I like you and I think your beautiful. That's what gets youyou and you are beautiful ladies but could you get me out to there?
T4: Positivity 1. Verbal expression of moments of contentment.	1. "It's going very nice, I have to admit that."



Table 3. Blood Pressure Measures



TABLE OF CONTENTS

ABSTRACT	ii
i	
ACKNOWLEDGEMENTS	iv
LIST OF TABLES AND	
FIGURESv	
TABLE OF CONTENTS	7
ENTRAINMENT ON AN OLDER ADULTS STRESS AND	
ANXIETY8	
REVIEW OF	
LITERATURE	13
Dementia Anxiety and Stress Entrainment	
METHOD	29
RESULTS	
Participant Thematic Analysis Heart Rate and Blood Pressure Results	
DISCUSSION	45
CONCLUSIONS	5
3	
REFERENCES	56
APPENDICES	60

Appendix A: IRB Approval Letter Appendix B: Informed Consent for Participant Appendix C: Consent Form for Research Appendix D: Addendum for Research Appendix E: Affiliation Agreement

Entrainment on an Older Adults Stress and Anxiety

"You are lucky. You have visitors. I don't have anyone come and visit me, I wonder what that's like."

"I love you, I love you, I love you. Come here and hold my hand."

"Sacred heart of Jesus help me, help me to be a good old lady. I don't think I can do it, Oh lord please help me. I'm dying. I'm dying. Help me, I am dying."

These are quotes from residents on the dementia unit at my nursing and rehabilitation facility. These words have made an indelible impression on my work because they vividly depict these individuals' emotional states. These are direct quotes from specific individuals in my facility, and other residents express similar ideas and needs almost daily. I have come to believe that what they crave is a sense of stability and the need for comfort. This perception is in line with Skingley and Vella-Burrows' (2010) suggestion that promoting the health and wellbeing of older people in our society has become an issue of great urgency and must be reevaluated in our healthcare institutions.

Dementia is not a normal part of aging (Nogueras et al., 2016). Physiological aging of the brain typically begins around the age of 30. Normal aging includes a decline in memory or reasoning but dementia is a much more insidious condition. Individuals with dementia experience social isolation, drastic changes in behavior, anxiety, confusion, forgetfulness, stress, loss of purpose and depression. Since the aging process occurs at a very slow rate, the signs and symptoms of dementia can be hard to determine. As explained by Nogueras et al. (2016), approximately 47.7 million people in the world are presently diagnosed with dementia, with 7.7 million new cases each year. In addition, 27 million adults are currently living with dementia but remain undiagnosed. While many people may assume that dementia solely affects the individual, the disease also affects family members and caretakers. It can be hard for family members to suddenly find themselves caring for a parent who is no longer the independent person they once knew. Suddenly, the roles are reversed. That can be taxing on the family members or caretakers who may not know how to proceed.

Working with this population has made me aware of the existential concern that many of the residents in my facility seem to face. While all of my residents have similar diagnoses, they express themselves differently. It seems that these individuals deal with these "challenges" (i.e., change of environment, memory loss, confusion, fear of death) in various ways. Usually, when these problem areas are not worked through, they begin to manifest various behaviors. These behaviors tend to not only affect their quality of life but that of their peers. Having worked with the dementia population for the past 3 years, it seems that, for most of these individuals, anxiety remains at the root of their being.

Realizing that many individuals with dementia benefit from a consistent routine, crave contact with others, and benefit from a sense of comfort to relieve anxiety, I became curious to see how musical entrainment might affect individuals with dementia. I was inspired by the concept of musical entrainment in a medical setting after speaking with Dr. Joanne Loewy from the Louis Armstrong Center for Music and Medicine. It did not take long to realize that this intervention may have the potential to assist many of my residents in relieving their anxiety and stress, increasing duration of sleep at night, and providing comfort.

Musical entrainment is defined as the interaction and consequent synchronization of two or more rhythmic processes or oscillators (Clayton, Seger, & Will, 2004). Entrainment has the potential of allowing a person to relate to another physically, socially, and emotionally (Berger & Turow, 2011). This is why I am inspired to use this intervention in this study. I am interested in examining the use of entrainment as it affects an individual's physiological and emotional health. Specifically, my goal is to evaluate an individual's stress and anxiety levels before and after three individual music therapy sessions that utilizes entrainment.

In addition, while many healthcare professionals in nursing homes may see the need to incorporate music in their facilities, there is a need for current information and knowledge that involves more than a performer and an audience. Conducting a study and raising the awareness of current music therapy interventions has the potential to benefit the overall health of individuals with dementia, encourage diverse therapeutic interventions within clinical teams, and allow healthcare professionals to see the benefit of music therapy. Many clinical professionals acknowledge and are aware of the needs of this population are but not necessarily new types of therapies. When there is a need to reduce anxiety or stress in individuals with dementia, music therapy would be an ideal nonpharmacological intervention.

Proposed Study

In this proposed study, I am predicting that musical entrainment will have positive effects on the stress and anxiety levels for an older adult with dementia. I plan to

10

investigate this hypothesis by conducting a mixed-methods study to examine the impact of musical entrainment in a music therapy session with an elderly individual diagnosed with dementia. I will evaluate the effect of entrainment on the participant's level of anxiety and stress by collecting both qualitative and quantitative data before and after the music therapy session. The qualitative data will be collected through interviews and analyzed using thematic analysis. The quantitative data collected will include the participant's heart rate and blood pressure. The quantitative data collected will be analyzed through statistical analysis. It is my opinion that there is a great need for more music therapy interventions to be researched with this population, and I would feel honored to dedicate my thesis to a potential new discovery in this area.

Need for This Research

While the recognition of the value of participation in leisure activities and their desire for a "sense of purpose" among older adults is becoming more prominent, there is still a need for more current research with this population (Skingley & Vella-Burrows, 2010, p. 35). Although the literature on musical entrainment is scant, Dr. Loewy (2009) discusses the incorporation of musical entrainment with a focus on infants and preterm babies. After reading this research I began to see a connection between the needs of babies and the needs of some of my elderly residents. For example, music therapists have used the process of entraining to one's breath in an effort to lower heart rates. This in turn would lead to better sleep patterns and physiological function (Azoulay & Loewy, 2009). With some evidence that entrainment can affect heart rate and breathing patterns, provided by research at the Louis Armstrong Center for Music and Medicine, I became

curious about how utilizing the process of musical entrainment would affect my residents' physiological and emotional health.

Outside of music therapy, the topic of entrainment has been studied in the fields of anthropology, neuroscience, psychology, ethnomusicology, human health, and religious studies (Berger & Turow, 2011). Since entrainment is the synchronicity between two or more external rhythms, the topic of entrainment is broad and branches out to specific areas of interest. For example, some of the main areas of study include musical entrainment, brainwave entrainment, social entrainment, and entrainment of sediment (Clayton, Seger, & Will, 2004). I will be focusing this study around musical entrainment.

Review of Literature

This section will review literature on dementia, stress, anxiety, and entrainment, as it applies to music therapy. These topical areas were chosen due to the fact that they are necessary for the proper execution of this study.

Dementia

According to Amin and Holmes (2016), dementia is "a general term for a range of progressive organic brain diseases characterized by problems of short term memory and other cognitive deficits" (p. 687). This progressive decline affects one's cognitive functioning, memory, intellect, social skills, and ability to learn (Cooke et al., 2010).

Dementia is an irreversible and progressive degenerative disease that can be divided into two groups: primary and secondary dementia (Lamparero-Plokhotnikov, 2015). Primary dementia is not a result of any other condition, whereas secondary dementia usually occurs when another pathologic process is present. This could include infection, subcortical degenerative disorders, vascular problems, metabolic disorders, and so forth.

While progressive dementia is "the gradual loss of physical, emotional, and social abilities" (Clair & Memmott, 2008, p. 69), primary degenerative dementia has three distinct stages. Individuals in the mild (first) stage of dementia may exhibit forgetfulness, but usually interventions are not sought out right away because symptoms may not be prominent. Usually the onset of these symptoms is so subtle that they are overlooked or seen as characteristics of old age. Caregivers may see changes in behavior or character and regard it simply as a change in disposition.

In the moderate (middle) stage of dementia, one may demonstrate a loss of ADL skills, be unable to remember a spouse's name, display anxiety, become agitated, or even have delusional or obsessive behavior. In addition, the loss of short-term or long-term memory and loss of language in dementia make it difficult to express needs and feelings (Koo et al., 2017). Individuals in advanced stages of dementia (end stage) usually have severe loss of physical ambulation and verbal skills (Clair & Memmott, 2008). Individuals are typically withdrawn, become catatonic and unresponsive to stimuli. While there may be a lack of participation in regular activities or programming, quality of life goals are still highly important. Interventions used during this stage are typically catered to individual preference, and extra consideration is taken when integrating one's unique cultural background. This may include, but is not limited to, one's ethnic background, musical preferences, and family history.

Individuals with a diagnosis of dementia, when in a state of anxiety or stress, will most likely display certain behaviors such as repetitive movements, moans, or cries (Clair & Memmott, 2008). Dementia has also been known to affect a person's ability to speak and communicate verbally. When speech is lost, music is not only used to connect and/or reconnect with others, but to connect with the environment as well (Lamparero-Plokhotnikov, 2015). The most common type of dementia is Alzheimer's disease (Amin & Holmes, 2016). Other types of dementia include dementia with Lewy bodies, vascular dementia, and frontotemporal dementia. Ferrer (2012) defines Alzheimer's as "a human biological process which causes progressive degeneration of the brain and which is characterized clinically by cognitive impairment and dementia..." (p. 39). Neuropsychiatric symptoms such as disorders of thought, perception, behavior, and affect are common in individuals with dementia (Amin & Holmes, 2016). Since behavioral and psychological symptoms of dementia are common, many facilities attempt to prevent them by minimizing environmental changes, maintaining familiar staff, treating pain, providing psychoactive medications, and encouraging social interaction (Starr & Walesby, 2016). It is suggested that antipsychotic drugs should only be used in small doses and for short periods of time, as they lead to increased mortality rates. These medications are commonly used to treat symptoms but not dementia itself. It is often difficult to determine how much medication is needed and what the treatment response will be. Because of these difficulties with medication, nonpharmacological interventions that facilitate cognitive and stimulation are recommended and play an important role in healthcare facilities.

Sundowning is also common among individuals with dementia and typically occurs during the mid- to late afternoon, evening, and nighttime hours (Dunn & Linton, 2013). Sundowning is the term that is used to define behavioral symptoms that present themselves in individuals with dementia and the cognitively impaired. These behaviors could include agitation, aggression, wandering, resistance to care or redirection, screaming, and yelling. This condition can only present with individuals who have dementia, but not all individuals with dementia will experience sundowning.

Music therapy interventions. Bruscia (2014) provides a clear, working definition of music therapy:

Music Therapy is a reflexive process wherein the therapist helps the client to optimize the client's health, using various facets of music experience and the

relationships formed through them as the impetus for change. As defined here, music therapy is the professional practice component of the discipline, which informs and is informed by theory and research. (p. 152)

As infants, we all communicated musically (Gold, 2014). The elements of music that reside in our voices include pitch, tempo, volume, and rhythm. We used all of these elements to connect with others. Thus, an individual who has been affected by a neurological impairment such as dementia is able to revert back to primitive, musical modes of communication.

Common music therapy interventions with this population have previously included, but are not limited to: singing, dancing to music, using rhythm, talking about songs and their meanings, playing musical instruments and incorporating caregivers into the sessions (Lamparero-Plokhotnikov, 2015). While singing is the most common intervention used, it can be hard to engage someone in singing, even familiar songs, when they lose the capacity to use words (Gold, 2014). In these cases, singing chants and humming have been proven to be effective when encouraging musical connection.

Clinical improvisation is a free and flexible way of creating music (Wigram, 2014). Wigram defines musical improvisation as "any combination of sounds and sounds created within a framework of beginning and ending" (p. 37) and defines clinical improvisation as "the use of musical improvisation in an environment of trust and support established to meet the needs of clients" (p. 37). While it remains more common to use pre-composed music with the elderly population, clinical improvisation is the method that will be used in this research study. Within clinical improvisation the music therapist often uses musical techniques within the framework of various therapeutic methods. Musical

techniques could potentially involve pulsed or non-pulsed playing, arpeggios or broken chords, melodic improvisation, or the use of dissonance to name a few. Therapeutic methods are used intentionally and involve techniques such as holding, grounding, containing, mirroring, reflecting, matching, and/or dialoguing. All of these aspects make up the process of clinical improvisation and can be applied during the process of musical entrainment.

Several research studies have been conducted on music therapy and dementia. Gold (2014) conducted a study to evaluate the impact of music therapy on nine people with advanced dementia. The study took place in an in-patient unit where the impact of music therapy was measured by care notes provided by nursing and care staff members. These care notes contained information regarding the patient's mood, emotional state, and behaviors. Using published dementia scales, Gold (2014) devised a chart that listed four positive behaviors and four negative behaviors. The positive behaviors included showing pleasure, social interaction, creative/expressive engagement, and congruent emotion. The negative behaviors included agitation/restlessness, distress, verbal aggression, and physical aggression. She did not include her own care notes in the study. Information was taken on 2 days, one non-music therapy day and one music therapy day, over a period of 4 months. The results showed that eight out of the nine patients demonstrated more positive behaviors compared to the negative behaviors consistently.

While Gold (2014) found that there was a significant change in the mood and behaviors of individuals with dementia after music therapy, Graham et al. (2015) conducted a study to explore music therapists' strategies for creating musical experiences and communities in dementia care facilities and current needs of people who are affected

17

with dementia. The study consisted of focus groups and a comprehensive study of improvisational work. Participants were six experienced clinicians who have worked in dementia care facilities. These clinicians were trained in the Nordoff-Robbins Music Therapy model and met four times over an 18-month period. The data collected included their personal recordings and written narratives from sessions. The data was analyzed in two main cycles. The first consisted of the first two sessions, and the second consisted of the last two sessions. After analyzing their combined data, they defined their findings as the music therapy "ripple effect," which consisted of three distinct levels of improvisation with this population. The first level was defined as "micro" and involved person-to-person musicking. The micro level typically included spontaneous playing and vocalizing, which was said to reflect the agitation or disorientation that is typically present in people with dementia. The second level is defined as "meso" and was categorized as musicking beyond the session time. This meant that the family members or caregivers were integrated into the music therapy session, leading to a bridge between the individual's personal space and a more public and social space. The third level was defined as the "macro" level and involved the clinicians reporting their roles to the facility or organization so that a professional connection was made. This level is important for other professionals to better understand benefits of the field. Overall, they found that and that improvisational music therapy and music centered approaches help reveal and reflect the emotional state of an individual with dementia in the current moment. They also found that music therapists' work affects many aspects of dementia care facilities.

Although only anecdotal evidence, Habron (2013) shares a moving vignette of a woman with dementia who, after participating in a music therapy session, shares her experience by stating "It's like having a conversation without words" (p. 3) Habron (2013) explains that the rhythms within the group began to "overlap and intertwine" with one another and that they also began to reflect each other's movements resulting in a "supporting groove" (p. 3). He adds that the music therapy group met the constant challenge "to escape the medical confines of disease and to assemble a new humanity in the loss" (p. 3).

Takahashi and Matsushita (2006) conducted a study to measure the long-term effects music therapy would have on elderly individuals diagnosed with moderate to severe dementia. The study took place over a two year time period where there was an experimental music therapy group and a non-music group as the control group. Throughout the study they observed changes in cortisol levels in saliva, blood pressure measures, and an intelligence assessment. The music therapy sessions consisted of active reminiscence music therapy, singing, and playing instruments. The researchers noticed that there was more active engagement during the sessions when familiar music was played compared to unfamiliar music. The outcomes concluded that systolic blood pressure increased with aging but was still lower in the group that received music therapy as opposed to the group that did not. They also determined that the group that received music therapy maintained healthy physical and mental states more sufficiently during the two years than the non-music group. While they were not significant changes in cortisol or intelligence assessment responses, the overall the results showed that singing and playing instruments in a group are effective interventions to prevent cardiac and cerebral

diseases and maintain overall health for individuals diagnosed with moderate to severe dementia.

Anxiety and Stress

Anxiety is a symptom for many people who are diagnosed with dementia. It was determined by previous research that 56-96% of dementia patients in community settings such as hospitals and long-term care facilities exhibit significant distress and anxiety (Izumi et al., 2013). Koo et al. (2017) define anxiety as excess worry that is difficult to control and has at least three symptoms; such as irritability, excessive fears, muscle tension, restlessness, and/or respiratory distress. Defining and diagnosing anxiety with dementia can be difficult due to changes in behavior and decline in cognitive functions.

Erikson believed the human being to be a combination of body, soul, and spirit (as cited in Diessner, 2008). He also believed as humans, we are constantly in a state of change and therefore long for connections with other human beings and abstract beings such as "God" or the "Ultimate Other." When someone is in need of constant care, he or she is in a state of suffering. While Erikson believed that suffering and health are equally related because suffering is a natural part of life, he also believed that suffering prevents one from growing (Lamparero-Plokhotnikov, 2015). Erikson concluded that the root of this suffering is anxiety and fear of death (Diessner, 2008), so relieving one's anxiety would allow the individual to continue to develop and provide comfort.

Without intervention, anxiety will most likely lead to agitation and the compilation of agitated behaviors will lead to cumulative stress (Gerdner, 2012). Ironson et al. (2005) describe stress as the term used to represent the effects of any factor that threatens one's homeostasis. Homeostasis is one's internal state of being, and it remains

constant in the face of a changing environment. While a stressor is the threat to the person, the stress response is the person's response to the stressor. Ironson et al. (2005) also explains that as one's stress response increases it can lead to tissue damage as well as disease. In addition, high stress levels also have a tendency to lead to high blood pressure and increased heart rate.

People with dementia become less likely to connect with their environment as the disease progresses, making it more difficult for them to cope and manage. This leads to higher levels of stress (Lamparero-Plokhotnikov, 2015). In addition, physiological aging can change the way a person responds to stress, because, as one ages, there is typically reduced resilience (Lavretsky & Newhouse, 2013). Social support is one of the most important psychosocial resources that is required to mediate the impact of stress on a person and in turn can help prevent depression (Dunkle & Jeon, 2009). In this way, the forming and maintaining of relationships are imperative to reducing stress levels.

Ayers et al. (2007) wrote about the evidence-based psychological treatments for late-life anxiety. This study conducted a review of literature involving psychotherapy treatments for anxiety disorders in older adults. The participants were 55 years of age and older, had subjective complaints of anxiety or a diagnosis of anxiety according to the American Psychiatric Association (1994). Two separate reviewers examined each study using the coding procedures. They concluded that anxiety is less researched compared to other forms of geriatric psychotherapy. They suggest further research should be conducted regarding various therapy models and examine various branches of anxiety disorders such as phobias and post-traumatic stress disorder. **Music therapy interventions.** Izumi et al. (2013) conducted a meta-analysis to investigate the effect music therapy has on behavioral and psychological symptoms of dementia with patients living with dementia by evaluating outcomes of previous articles and research. The study population included older individuals who were formally diagnosed with any type of dementia. This could include Alzheimer's disease, vascular dementia, frontotemporal dementia, and so forth. It was required that the intervention used was a single music-related experience or a combination of music-related experiences, such as singing, listening, performing, rhythmic exercise, or improvisation. Twenty studies were used in the analysis. After all their data was analyzed, it was determined that music therapy interventions that took place for more than three months had a higher effect in decreasing anxiety that shorter durations of music therapy interventions. It was also determined that music therapy had a greater effect than other nonpharmacological interventions.

While Izumi et al. (2013) examined the effect that music therapy had on anxiety; Chang et al. (2010) evaluated the effects that preferred music listening had on reducing anxiety with dementia patients in a nursing home. They utilized a quasi-experimental preand post-test design with 29 participants in the experimental group that received preferred music therapy and 23 in the control group that received no music therapy. They measured anxiety using the Rating Anxiety in Dementia scale. Thirty-minute sessions were conducted twice a week for 6 weeks. They found that participants who received the preferred music therapy intervention had a significantly lower anxiety score than the control group. Early intervention, taking place at the first and often subtle signs of stress, can help prevent anxiety (Gerdner, 2012). According to a study by Gerdner (2012), individualized music can make significant improvement in reducing anxiety and stress. Gerdner (2010) defines individualized music as "music that has been integrated into the person's life and is based on personal preference" (p. 9). She suggests that if the person is not able to independently make a selection, family or a caregiver can make it-(Gerdner, 2010). While many experience pleasure from musical experiences, if there is lack of a support system or a licensed music therapist who can employ interventions with clinical knowledge, it can be a challenge to employ. The idea that individual attention can prove to provide comfort to the individual, provides more probability that entrainment would be an effective intervention to reduce anxiety and stress.

Music therapy, and music in general, can have positive effects on people with stress and dementia as it provides opportunity for social interaction, alleviates pain and reduces stress, fear, and depression, common problem areas for those with dementia (Meeuwesen, 2010). Meeuwesen et al. (2010) investigated the effect of intimate live music performance on the quality of life and stress levels of patients in nursing homes diagnosed with dementia. Despite the fact that the music provided in the sessions was not facilitated by a music therapist, they found that there was a positive effect when live music was utilized. The patients seemed to demonstrate improved human contact, communication, and fewer negative emotions. They also suggested that the use of live music performance is an inexpensive and noninvasive way to improve quality of life and reduce stress for dementia patients. Bellelli et al. (2012) reviewed recent clinical control trials and randomized controlled trials as it relates to music, music therapy and dementia. They concluded that music therapy, along with the standard support of care, benefits the dementia population. In addition, they found changes in physiological aspects of health such as an increase in heart rate in depressed patients and improved cardiac function. These outcomes may in fact influence stress in dementia patients.

Entrainment

The fundamental principle of entrainment is the synchronicity of two external rhythms (Clayton, Seger, & Will, 2004). Berger and Turow (2011) depict the effects of musical rhythm entrainment and how it impacts the brain and nervous system. Research from professionals in the areas of musicology, anthropology, psychology, music therapy, and human health are utilized and examined. The main topical areas of this book include rhythmic entrainment in regards to theoretical research and clinical implications in such a way that it relates musical rhythms with biological rhythms.

Wellmann (2017) examines the importance of rhythm on a biological level, as she wrote about the epistemology of rhythm and its relation to life and the living process. She linked the history of rhythm in music theory with biology as it relates to development. She also exposed the role of rhythm with movement in the first systematic study of visualization in embryology.

Rhythm is considered an imperative musical element to use with the dementia population because it is easy to latch onto and entrain with as one attempts to connect with others musically (Clair & Memmott, 2008). In addition, research has shown that individuals will participate in experiences longer when vibrotactile stimulation or drumming is involved compared to any other involvement such as singing or moving to music. Research has also shown that individuals with dementia can distinguish the sounds much more easily when a drum is struck because each rhythm instrument has its own distinct sound. In addition, due to the fact that many drums or rhythm instruments are easy to play, those playing them can quickly adapt and entrain to another person's rhythm or rhythms that they hear. In this way, the person is immediately in a setting that is less isolating and able to connect with others.

Music therapy and entrainment. While entrainment is the primary music therapy intervention in this study, no literature was found regarding this intervention with the elderly population at this time. However, there is research regarding entrainment and music therapy with premature babies and infants and literature based in the areas of social entrainment that can help support the theme of this paper.

While Azoulay & Loewy (2009) explains the important influence that the breath has on emotional and physical health, vitality, and resilience, live music therapy sessions and entrainment involving the breath can assist in facilitating positive relationships and supporting interpersonal connection. Loewy, et al. (2013) conducted a study to examine the effects music therapy and entrainment might have on vital signs, feeding and sleep in premature infants. They conducted a randomized clinical multisite trial of 272 premature infants. Their aim was to test the live elements of music, such as breath, rhythm, and parent-preferred lullabies, to see how they would affect the infants' physiological and developmental functions. They found that live music and entrainment could influence cardiac and respiratory functions, sucking behavior, and enhance bonding with parents. Parent preferred lullabies also showed as a significant influence as it helped enhance bonding with parents and decrease stress levels in the parents.

In addition to musical entrainment, Stupacher et al. (2017) state that interpersonal synchronization of movements can strengthen social behavior. They explain that this type of social entrainment can lead to a state of pleasure or ecstasy. This could include the unintentional mirroring of one's movements. Furthermore, the synchronicity between musical rhythms not only helps to form socioemotional connections but also can help establish a sense of closeness and prosocial behavior. Stupacher et al. (2017) conducted an experimental study with the prediction that interpersonal synchrony while listening to music would reinforce social connection. The study included 40 university students, 20 male and 20 female. None of the participants had formal music training prior to the study. The participants were assigned to one of four groups and were evaluated to see if they moved with synchronicity or asynchronously to the music compared to just a metronome. The participants were given headphones and sat opposite the experimenter. Both used a midi pad to tap on. The results showed that the participants tapped in time with the music but did not synchronize as often with the metronome. They also found that there were pro-social changes occurring during these experiences.

In another study of synchronization with music, Dunbar et al. (2015) suggested that when synchronized music playing occurs, there is a blurring of the self and that the merging with others musically can cause the release of the hormone oxytocin and endorphins. The release of this hormone has been known to lead to increased trust. They studied and reviewed literature in an attempt to further research music in relation to social entrainment. Specifically they investigated two aspects of social bonding, the first being the self-other merging as a result of interpersonal synchrony, and the second being the release of endorphins while engaged in rhythmic activities, specifically, musical interaction. They found that the process of listening and synchronizing to music helps to reinforce social bonding which can lead to other positive effects such as change in mood, quality of life, reducing pain and psychological stress.

Grandjean, et al. (2017) found that metrical music contains qualities that the listener's bodily rhythms can adapt to. In addition, they have discovered that recent psychological frameworks featuring rhythmic entrainment can serve as an emotion induction principle. In their study, they reviewed theoretical and empirical literature on rhythmic entrainment and music as they influence brain processes and serve as an induction mechanism. Through evaluating previous literature they found that music interacts with one's internal body rhythms such as heart rate. These two rhythms eventually begin to synchronize together and the adjusted rhythm will potentially trigger an emotional response from the individual. This emotional response can vary depending on the individual. It is believed that adjusted rhythm in this way can trigger emotion in the same way a smile can potentially trigger amusement. In addition, they found a common link between rhythm and emotions to be the role of prediction and anticipation within the music. This response to the predictable nature of music entrainment can lead to dopamine release. Overall, they came to view entrainment as a phenomenon in music and remains capable of triggering synchronization behaviors in different biological rhythms therefore affecting one's emotional state.

In conclusion, the literature provides support for the idea that engaging individuals with dementia in an improvisation and music-centered approach can lead to forming stronger relationships. The process of listening and synchronizing rhythms has the potential to establish trust and assist in reducing anxiety and stress in individuals with

27

dementia. Entrainment provides an opportunity for the environment, such as the therapist or other group members to connect with the individual. This may in fact have the potential to reduce anxiety and stress.

Method

The purpose of this mixed methods study is to evaluate the impact entrainment may have on stress and anxiety in an individual music therapy setting with an elderly patient diagnosed with dementia. The researcher's philosophy behind this study is consistently pragmatic as she recognizes that there are different ways in which we interpret the world and that different viewpoints are needed to better understand the entire picture. Her philosophy remains determined to examine multiple realities and the importance of collecting and acknowledging various types of data.

There will be a total of three sessions in this study, one session per week for three weeks. They will take place between the hours of 3:00 pm and 4:00 pm and will be about 30 minutes in duration. The reason for this specific time is due to the fact that this is when sundowning typically takes place (Dunkle & Jeon, 2009). The patient's state of anxiety is especially heightened and as a result they are in the most need of comfort, support, and relaxation. Therefore, my research questions include:

- 1. Does entrainment in music therapy impact stress levels?
- 2. Does entrainment in music therapy impact anxiety levels?
- 3. Does entrainment in music therapy affect an individual's emotional well-being?

- 4. What are the key themes of qualitative data?
- 5. Is there a relationship between qualitative and quantitative data?

Both qualitative and quantitative data will be collected in order to determine the effects music therapy with entrainment has on the individual's stress and anxiety levels. The quantitative data collected will include heart rate and blood pressure in an effort to measure the participant's physical state. The qualitative data will be collected through an interview from the participant. The researcher will ask open-ended questions before and after each music therapy session and use thematic analysis to collect more qualitative data. It is important to also note that the participant would remain anonymous due to HIPPA laws and ethical research.

Participant

The participant will be a elderly individual, being the age of 65 or older, with a diagnosis of mild to moderate dementia, including individuals with Alzheimer's disease who are currently experiencing periods of anxiety and stress, which may be determined with an existing diagnosis of anxiety or from reports by nursing and other healthcare professionals. The participant has not had individual music therapy previously with the researcher. The participant will be a resident at Grace Plaza Nursing and Rehabilitation Center and will be individually recruited by the researcher. The researcher will choose the participant based on diagnosis, availability, and who has not spent time in individual music therapy previously. Criteria for inclusion and participation are not limited by gender, ethnicity, or sexual orientation. If they are willing to participate and meet the specific criteria mentioned regarding diagnosis and symptoms, they will be included in the study. The researcher will not discriminate against gender, ethnicity, or sexual

orientation. The participant must be able to express verbally basic needs and wants. Due to the participant's cognitive impairments, the researcher will require permission from their caregiver or guardian and will use a consent form to obtain permission.

Procedures

Initially, the researcher will speak with the nurse about what medications the participant has taken and when. The researcher will also note potential side effects of the medication. The study will take place in the resident's room. If the resident has a roommate, it may be difficult to ensure privacy. If they have a private room, privacy should not be an issue. To ensure that staff members not included in this study will not interrupt the session, a sign will be placed on the resident's door. In a case where privacy cannot be guaranteed in the resident's room, the researcher will secure another location in the facility that will be made available for the music therapy session to facilitate a space where there is privacy and lack of interruption. The participant will be escorted to their room where the music therapy session will take place to ensure safety.

In private rooms there is a bed, clothing cabinet, night table, overnight table and chair. In rooms where individuals have a roommate, there is twice as much furniture and there is a curtain to separate each individual space. The participant will be situated in the room in such a way that they are facing the researcher. The overnight table may be placed in front of them so that playing the drum is more manageable and more accessible for them. The nursing staff will be notified of the time and place in which the study will be taking place so that there won't be any unnecessary interruptions or in the chance that they would be free to assist if there are any emergencies or safety concerns.

The participant will be presented with two hand drums, a pair of small conga drums, a djembe, and two maracas to play as desired. The instrument choices provided are due to the instruments available at the facility. The researcher will have an acoustic guitar and a heart rate/blood pressure monitor (a Tantan Lohas01 Smart Bracelet IP67). There will also be a digital voice recorder, an Evistr 8GB Digital Audio Sound Recorder Dictaphone, that will be used for the 30-minute session. The information recorded will remain confidential and will only be used for educational purposes by the researcher. Confidentiality will be ensured through a password protected computer and recording devices remaining in a locked safe when not in use.

After the participant has been escorted to the site of the music therapy session, the researcher will administer the pretest measures. The pretest measure includes the participant's heart rate, blood pressure, and open-ended interview questions. If the participant cannot retrieve answers due to extreme agitation, the researcher will attempt to notate what he or she is verbalizing and redirect to the session. If the participant becomes so severely agitated that there is no success in further incorporating the participant into the session, the researcher will arrange a new time to conduct the session. After the retrieving the interview questions, taking the participant's heart rate and blood pressure under the supervision of a Certified Nursing Assistant (CNA), the researcher will record these measures.

Before the interview questions are asked, the researcher will preface the questions by stating and asking the following:

 I am going to ask you some questions about how you have been feeling today, is this ok? If they decline, the researcher will ask the participant if they want to give a reason why. If they still refuse to provide a response, the researcher will write "NR" on the interview response page. If they say yes, I will proceed to question number 2.

- 1. Please try to answer the questions as openly and as honest as possible.
- 2. If you are uncomfortable answering a question, let me know and we can skip it.
- 3. Do you have any questions?

In an effort to obtain qualitative and consistent data about the resident's emotional state and initial anxiety level, the interview questions will be:

- 1. How is your day going?
- 2. Are you experiencing any pain?
- 3. Are you currently feeling tired?
- 4. Is it hard to sit still?
- 5. Do you find yourself worrying about anything?
- 6. How do you feel right now?

Once the questions have been answered and recorded, the researcher will begin the music therapy session..

Music Therapy Session

The music therapy method will be clinical improvisation. According to Bruscia (1998), improvisation is when the client makes up music through singing or playing an instrument, creating his or her own melody, rhythm, song, or instrumental piece. The researcher will have a guitar available to help guide the improvisation. The researcher will attempt to use her voice or guitar in whatever way best suits the entrainment process

with the participant. The clinical improvisation music therapy method will be employed via a sequence of procedures that include:

- 1. The participant will be provided with two hand drums, two small congas, and two maracas.
- 2. The participant will not be required to play each instrument, but rather have optional ways of engaging musically.
- 3. The session will begin with music improvisation.
- 4. The researcher will wait for a musical cue from the participant.
- 5. If the participant does not start playing then she will begin to improvise music that mirrors the participant's breath and/or spontaneous body rhythms.
- 6. If the participant initiates the music, the researcher will support his or her playing with an ostinati.
- As their music making continues the researcher will begin to adapt her music making to match the music making of the participant.
- If the participant begins to sing, the therapist will entrain to his or her singing, beginning with rhythm.
- 9. If the participant begins to sing his or her own lyrics, the researcher will entrain instrumentally only.
- 10. The researcher may also begin to entrain to vowels or words used by the participant.
- 11. If the researcher is in a situation where she is only playing guitar, the researcher will continue to entrain her guitar playing to the music created by the participant or his or her body rhythms.

- 12. The researcher will continue to adapt their tempo and time signature to the participants.
- 13. If, for any reason, the participant's state of anxiety is heightened to the point where music therapy is clearly not the best intervention at a certain point in time, the researcher will attempt to comfort them through discussion and may utilize the help of another healthcare professional (i.e. nurse, nursing assistant, etc.)

Following the conclusion of the music therapy session, the researcher will collect posttest data; this includes the participant's heart rate and blood pressure. In addition, she will ask the same series of open-ended questions in the closing interview as the pretest interview. Once these measurements have been recorded she will escort the participant back the main dining room.

Data Collection

The qualitative data will be collected through an interview, which will include the questions mentioned above. The researcher will look for patterns of meaning from the answers provided by the participant. The quantitative data will also be collected using a heart rate and blood pressure monitor, under the supervision of the CNA. Both the qualitative data and quantitative data will be taken and recorded during the pre-test and post-test data collection. In addition, the researcher will use a digital voice recorder for the entire session, including pretest and posttest measures to ensure accuracy when collecting qualitative and quantitative data.

Data Analysis

The qualitative data will be analyzed utilizing thematic analysis (Braun & Clarke, 2006) to evaluate the open-ended results. The researcher will employ peer debriefing for

34

accuracy, credibility and validity. The quantitative data will be analyzed using the t-test measure and will later be analyzed by a statistician to ensure accuracy. The reason for a mixed-methods design is to appropriately include both physical and psychological data.

The process of thematic analysis (Braun & Clarke, 2006) will involve the following steps:

- 1. The researcher will reevaluate the data provided by the participant by rereading and becoming familiar with it.
- 2. The researcher will transcribe all of the interview questions and answers verbatim.
- 3. The researcher will depict initial codes found in the data.
- 4. The researcher will search for similar themes in the answers using the codes extracted from data.
- 5. The researcher will review the themes depicted from the data.
- 6. The researcher will define and name the themes extracted from the data.
- 7. The researcher will attempt a member checking process for reliability.
- 8. The researcher will produce a report that includes a chart, displaying the results.
- 9. The researcher will write a interpretative analysis of the potential meaning behind the themes.

The process of analyzing the quantitative outcomes (Wilkinson, 1999) will involve:

1. The researcher will compose two graphs to show separate results of the participant's heart rate and blood pressure results from the three sessions.
- 2. The researcher will take the heart rate and blood pressure data outcomes and utilize a t-test to compare the findings from the heart rate and blood pressure and explore statistical significance.
- 3. In addition, the t-test will be used to analyze both the heart rate and blood pressure outcomes after each session to determine if the music therapy intervention is statistically significant. Using the t-test will also ensure that the outcomes, whether significant or not, are not solely due to chance but specifically from the music therapy intervention.
- 4. A statistician will be utilized to review the quantitative data and check for accuracy.
- 5. The results will then be displayed in an additional graph to show the statistical significance from all three sessions.

Once both quantitative data and qualitative data have been analyzed separately, they will then be compared and contrasted. The researcher will search for significant correlations between the two types of data and recorded in the discussion area of this paper.

Epoche

Due to the researcher's experience as a music therapist she thoroughly believes that music can have positive effects on individuals with many diagnoses and needs. In this way there is some bias to the intervention used in this study. The researcher assumes that music has the potential to benefit all individuals. To avoid bias in this study, the researcher will incorporate the process of peer-debriefing and supervision from supervisors and advisors to ensure that no steps taken are in the sole effort to sway the data a particular way.

Results

Participant

Analyses of the data involved thematic analysis of the responses to the participants' interview questions, and a t-test measuring heart rate and blood pressure. The data was collected over three consecutive sessions. Results were measured before and after each session. The sessions were 30 minutes in length. The analysis focused on the participant's physical and emotional state and how they relate to the participants

stress and anxiety levels. Because the participant seemed to have a significant attachment to his wife, it was decided at the beginning of the first session that the wife would be present in the room. Her attempt to leave lead to anxiousness, agitation, and yelling from the participant. However, there was an agreement on the wife's role as a passive observer.

Thematic Analysis

There were four significant themes and subthemes that the researcher found in this investigation. The four themes and their respective sub themes are illustrated in Table 1. While there were four distinct themes that seem to arise, there were some notable overlaps that occured that are presented in Table 2.

Table 1. Emergent Themes and subthemes based on analysis of open ended responses.

Theme and subtheme	Interview Response
T1: Uncertainty and Anxiousness3. Difficulty adapting to change.4. Changes in the environment trigger anxiety.	 3. "I can'twhatwhat are we doing? The door is closed there." 4. "Can we go outside, can we go outside!?"
T2: Physical Pain	3. "I had some pain, I had some pain."

 Abdominal pain due to his prostate Restlessness and the need to keep moving. 	 "It is hard to sit still, but I keep myself to keep stillkeep still."
 T3: Need for Reassurance 4. Reliant on wife. 5. Paying compliments tends to proceed concerning statements. 6. Difficulty making choices. 	 3. "Well I dont know whats going on Carol. Uhhfirst of all, there is nothing coming out of this at all." (often yells for his wife when she is not around.) 4. I like you and I think your beautiful. That's what gets youyou and you are beautiful ladies but could you get me out to there?
T4: Positivity 2. Verbal expression of moments of contentment.	2. "It's going very nice, I have to admit that."

Theme 1: Uncertainty and anxiousness. Throughout all three sessions,

difficulty with change and transitions remained difficult for the participant. In the first session, the participant displayed anxiousness and seemed uncertain about what was going on. He required step-by-step guidance and prompting. The moment the door to his room closed he became fixated on why it was closed and asked "can we go out there"? He would consistently ask "what are we doing?" and say "I don't know what's going on." It seemed that any moment of silence was a trigger for this anxiety. He seemed anxious to move on to the next task. This remained consistent throughout the following sessions, however he seem to adapt quicker in the last two sessions.

Theme 2: Physical pain. The participant at times stated "I had some pain, I had some pain." He pointed to his abdomen and said that was where he had his pain. His wife mentioned that he has occasional pain there from his prostate. Nursing was made aware of his pain and confirmed his medical history. He also stated "It is hard to sit still, but I

keep myself to keep still...keep still" and "Occasionally, I feel tired". He seemed to exert his energy in spurts. Physically he appeared still, but as his anxiety and restlessness manifested in his voice, he had a burst of physical energy that displayed abruptly. He waved, lifted his hands, raised his voice, and at times threw himself back into his chair. It became apparent that there was a pattern of him verbalizing that he was tired, that it was hard for him to sit still, and that sometimes he had pain.

Theme 3: Need for reassurance. Throughout the sessions he displayed a constant need for guidance and reassurance. During the interview he had a pattern of paying a compliment and then asking questions about what was next or making a demand for guidance. For example, in the moment when he realized the door was closed and the environment changed, He stated "I like you and I think your beautiful. That's what gets you...you and you are beautiful ladies but could you get me out to there"? This was a consistent pattern throughout all three sessions.

Positivity. The occurrence of positivity was rare, however, it remains significant. While he was paying compliments throughout the sessions, there were only a few moments where he seemed to demonstrate genuine contentment and make a positive statement without being followed by a demand. For example, when he said "Ok because I'm right here! This was a lot of fun right here" and "It's going very nice, I have to admit that". These statements not only show contentment but they demonstrate the participant is in the present moment instead of worrying about the next task and show a certain level of awareness of self.

Heart Rate and Blood Pressure Results

The t-test results. After consultation with a statistician, I utilized a paired t-test, since I was examining the before and after result. The paired t-test showed that the results are not significant. For SBP, the results showed a p-value of 0.742, and since 0.742 > 0.05, it rejects the null hypothesis. Similarly, for DBP the results show a p-value of 0.1655, which is larger than 0.05, and for heart rate the results showed a p-value of 0.6134. Since this study only explores three pairs of data points in one participant, a limitation in the study is that there is not enough data to find significance or generalize the results. However, while the t-test results were insignificant, the results did show a decrease in blood pressure and heart rate. This could warrant future research involving more participants.





Heart rate results. As demonstrated in Table 2., there was a large decrease in heart rate measure. The pre-test measure showed 88 bpm and the post test showed 70 bpm. The second session showed an opposite direction, where the participants heart rate

increased from 54 bpm to 61 bpm. The third and final session demonstrated results similar to the preliminary session. The pre-test measure showed 56 bpm and the post-test with 54 bpm. While there seemed to be no statistically significant outcomes with these measure, there is significance in the decrease in heart rate from two of the three sessions.



Table 3. Blood Pressure Measures

Blood pressure measure. Although there were changes in blood pressure, they remained in the healthy range. Similar to the heart rate measures, two out of three of the session showed a decrease in blood pressure measures, as demonstrated in Table 3. However, In session one, when the increase was noted, it only occured with the SBP measure which increased from 103 to 105 and the DPB decreased from 69 to 53. The second and third session were similar in that both the DBP and SBP decreased compared to the pre-test measures. In session two, SBP measures went from 136 to 103 and the

DBP measures decreased from 91 to 66. In session three, the SBP decreased from 120 to 113 and the DBP decreased from 80 to 78. The second session consisted of the largest difference between pre-test and post-test measures.

Discussion

Thematic analysis

While the music therapy session was not part of the qualitative data collected, it is important to note significant moments that relate to the interview data set. Much of what was said during the interview was repeated during the music therapy session. Importantly, the themes that were revealed during the interview were also expressed in the music, in a seemingly unconscious way. In this investigation the main themes were uncertainty and anxiousness, pain, the need for reassurance, and positivity. Gold (2014) mentions that when we are infants we all communicate musically. We interact with others using pitch, tempo, volume, and rhythm. Although he showed resistance in the music, the participant seemed to communicate more effectively when immersed in the music.

Uncertainty and anxiousness. While there was resistance in the music therapy session, the music seemed to assist in reducing anxiety and stress levels. The participant appeared very anxious during the transitional moments of the session. Any pause, moment of silence, or moment of uncertainty seemed to trigger anxiousness and would cause him to ask "what are we doing"? When the harmonica was introduced in the session, he was resistant. He took the harmonica and said "It's heavy! It's too heavy, I can't!" With some encouragement, he began to blow into the harmonica. At that time, I was actively entraining to his rhythm and breathing patterns. As we played together, I

noticed the tempo change and slow down. I saw his chest move as he took in deep breaths. In these moments, not only were we breathing together, but his breath was becoming regulated.

I found that he showed resistance when introducing new instruments. In fact, his resistance to playing instruments and singing was so strong in the first session I was only able to entrain to his breathing patterns. I sang on the vowel "ah" in an effort to continue to matching his breath and breathing pattern. In fact, his statement "It's too heavy" was consistent throughout all three sessions. He said this regardless of the size and weight of the instrument. This begs the question if it was truly the weight of the instrument that was heavy or the stress and the emotional "weight" of the task itself.

In the midst of co-operative music-making and entrainment interventions, although at times short lived, he appeared less anxious and seemingly less stressed. In fact, the moments when we entrained together, whether singing or playing, his breathing patterns became consistently regulated as we decreased the tempo. Similar results were found in an experimental study conducted by Chang et al. (2010). The study investigated the impact receptive music therapy would have on anxiety levels of patients diagnosed with dementia. The results showed that the group that received music intervention had lower levels of anxiety compared to the control group. This further supports music as an effective intervention to lower anxiety levels.

Pain. When we played the glockenspiel together, not only did he seem focused for a long duration of time, but we entrained to each other for the majority of the time. He was resistant at first but with some verbal encouragement and modeling how to play, he began to play. I listened to him for a moment and then began to entrain to the rhythm of

44

his playing, though not in a synchronized fashion. In the beginning, he would only hit one pitch over and over, so I played an ostinato underneath him to reflect his playing and create a tonal center. He played continuous eighth notes the entire time, sped up the tempo, then stopped abruptly and said he couldn't do it. When he stopped playing, I whispered a phrase as a verbal prompt by saying "one, two, three" while slowly lifting the mallet into a ready position. He mirrored my gestures and then we would begin to play together again. As we kept playing, he would play other notes by moving up and down keys in the style of a scale. Finally, the session ended when he said he was tired and asked if we could stop. It is also important to note that once the music therapy session ended, he began to focus his attention to the door and "getting out".

Not only was there a pattern in his verbal responses in regards to the theme of physical pain, but in the music you could see the similar pattern of a gradual build of energy followed by an abrupt stop. This was similar to his physical movements outside of the music when he would gradually raise his voice, move energetically and then stop. His physical behaviors came through in the musical phrasing and in the style in which he was playing. However, it is important to note that within the musical context, his attention span and breathing patterns seemed to be regulated.

Need for reassurance. This theme was also carried out within the music therapy session. It seemed that the participant was looking for something familiar in the music and looking for something he could "hold onto," so to speak. Many times, it seemed like he was trying to entrain and follow me. During the second music therapy session, he refused to play any instruments. I began to sing to him, trying to entrain to his breathing pattern. I immediately noticed him making direct eye contact with me and attempting to

45

sing what I was singing. At this point, I began to repeat one vocal phrase. Once I did this, we began to sing together with me and entrain with my breathing and the melodies.

In addition, when he sang he would match my vocal inflections, melody, and dynamics. For example, when I ended with a descending cadence, he would also end with a descending cadence. If I ended on a high pitch he would attempt to sing that same pitch. He even matched my dynamics. There were other moments when we were not singing in unison, however, he finished the musical phrases when I made space in the musical rhythm. I also noticed that he was moving his feet to the same strumming pattern on the guitar. It seemed that he was, again, entraining to me. This participant seemed to demonstrate the constant need for reassurance, not only during the interviews, but within the musical experiences. While, I was actively entraining to him, he seemed to also be looking for something familiar within the music.

Similar to Meeuwesen et al. (2010) when they examined the impact that live music had on the quality of life and stress levels of patients in nursing homes diagnosed with dementia, they found that music intervention did reduce stress and improve quality of life. This investigation also relates to Meeuwesen et al. (2010) in that it seemed to reinforce positive relationships. Both the results of their investigation and the results of this investigation show that there was additional improved human contact and communication. There were also fewer negative behaviors noted during the interventions.

This proves to be an important intervention for this population as there is much need to facilitate situations where people with dementia can connect to their environments as the disease progresses (Lamparero-Plokhotnikov, 2015). This is due to the fact that individuals with a diagnosis of dementia are often isolated and find it difficult to cope and adjust to new environments. The inability for one to connect to their environment in a positive way can lead to high stress levels and agitation. Social support and forming positive relations remains imperative aspects to the health and well-being of these individuals.

Positivity. While he showed resistance to playing music at times, he continued to try new things with some prompting. This was significant for him because his resistance was so strong. For instance, in the first session, he refused most of what was offered. By session three, he required less verbal prompting and responded to musical prompting and modeling. The openness to new experiences was a great success for this participant. During the sessions he would make positive statements during the interviews such as "It's going very nice, I have to admit that," "Ok because I'm right here! This was a lot of fun right here," and "The best that I can."

The fact that he would make these positive statements most likely indicate that he is content in that particular moment and not living in a state of uncertainty. It could also indicate that positive relationships are either being formed or reinforced. In this case, since I was familiar with the participant in group settings, we had formed a prior relationship.

Overlapping themes. After defining the themes of the qualitative data, it became apparent that some of the themes were related and overlapped. For instance, the participant seemed uncomfortable with what was unfamiliar and uncertain. This seems to relate to his constant need for his wife, whom he would constantly call for before and after the sessions. This happened not only during the interviews but within the musical experiences. In this way, there seems to be connection between his need for reassurance

to his anxiety. Also, there seemed to be an overlap of his physical pain to his restlessness and anxiousness. Many times when he would say he feels tired or that he has some pain, it is often after he has exerted himself or made statements in an anxious state. Although he would follow these statements with compliments or positive statements. However, there seems to be a need to separate the compliments and positive statements. While throughout the sessions he would pay compliments and make positive statements, one may confused the two themes as the same. However, there were very few moments where he made purely positive statements. Many times when he would pay compliments, it would be followed by a command, or followed by a statement where he seemed to be trying to convince me that he is a good man.

Heart Rate and Blood Pressure Measures

Heart rate. While there seemed to be no statistically significant outcomes with these measures, there is significance in the decrease in heart rate from two of the three sessions. This could indicate that music therapy can relieve stress and anxiety through entrainment. It could also lead one to believe that he was taking slower, deeper breaths, and more regulated breathing patterns. This could have been from the impact of entrainment, although it is hard to say definitively.

The predominant results of heart rate in this study relates to the study conducted by Loewy, et al. (2013). They also found that during the music intervention of entrainment, the babies heart rates slowed down. However, in this study the heart rate was taken before and after the session. In the study conducted by Loewy, et al. (2013) they evaluated the heart rate during the music intervention. The second session showed an opposite direction, where the participants heart rate increased from 54 bpm to 61 bpm. The increase in heart rate in the second session could indicate that the musical intervention was stimulating or that there was a potential trigger for anxiety either during the session or in the transition after the session. It is hard to determine the potential trigger for the increase in heart rate. However, this increase could indicate that the participants breath was stimulated and a possible increase in airflow.

While this study was not looking to investigate depression, Bellelli et al. (2012) found that music increased the heart rates of their participants with depression which led to improved cardiac function. Therefore one should potentially analyze increased heart rate not only as possible evidence for anxiety, but potential evidence of excitement as well.

Blood pressure. Since the blood pressure measures were mostly consistent, this could lead one to believe that it was positively relieving anxiety and stress levels. However, in session one, the SBP measure was the only measure noted with an increase. Interestingly, in a study conducted by Gabin, Tambs, Saltvedt, Sund, & Holmen (2017), SBP proved to be an indicator for Alzheimer's before diagnosis has been made. They conducted a longitudinal study lasting 27 years which concluded that not only high blood pressure, but high systolic blood pressure, are associated with eventual Alzheimer's disease. This is potentially not only beneficial to understanding Alzheimer's in the future, but also understanding the role of SBP in an Alzheimer's patient.

In fact, in Takahashi and Matsushita's (2006) study where they looked to measure the long-term effects music therapy would have on elderly individuals diagnosed with moderate to severe dementia, also showed an increase of SBP. Their music therapy sessions utilized active reminiscence music therapy, singing, and playing instruments. The similarities in this study and the study by Takahashi and Matsushita (2006) provide further evidence that support music has an impact on blood pressure measures.

Conclusion

Summary

This study investigated the impact entrainment would have on an older adult's stress and anxiety. Overall, the results seemed to show consistent evidence that the music therapy intervention of entrainment does in fact impact anxiety and stress levels. However, the results proved to be statistically insignificant due to the small data set. Due to the results of the qualitative data, it appears that entrainment in music therapy does affect an individual's well-being. Other research supports the notion that music therapy can have positive influences on an individual diagnosed with dementia, however, it is important to note that each individual is unique and therefore perceive experiences differently. The qualitative data consisted of four main themes; uncertainty and anxiousness, pain, the need for reassurance, and positivity. Additionally, there seemed to be consistent overlap and similarities between the quantitative data and the qualitative data. As there was an increase in connectedness and support through entrainment, there was decreased heart rate and blood pressure. Social support and positive relationships remain significant aspects within the intervention utilized. The decrease in heart rate and blood pressure demonstrate the physiological measures to support the impact of entrainment had on this participant and could potentially have on other individuals in the future.

Reflection

There were moments in the sessions where I began to wonder if the music was a trigger for anxiety. This caused some slight hesitation on my part as I became uncertain if my countertransference would potentially interfere with the sessions in a negative way. I sought out peer-supervision after the first session and remembered the words of my former professors saying "trust the music." I continued to rely on listening to the client and trusting the music itself. During the music experiences moving forward, the participant was focused and engaged. This was remarkable to see after seeming so anxious and agitated. It became apparent as the sessions continued that it was more

51

clearly the space in between musical experiences that were the main triggers. During those moments, he became anxious about what we were doing and what was next.

In addition, I had worked with the participant of this study in a group setting prior to this series of individual sessions. Fortunately, all the guidelines were set beforehand and any anticipated biases were addressed with my advisor. Although we have formed a relationship prior to the sessions, a different and unique relationship was formed within this intimate musical setting. I began to notice certain patterns of behavior that I did not notice as strikingly when he was in a group, but they became much more apparent in the individual session. After conducting this study, I felt rejuvenated and refreshed. I felt that I was doing something of great importance. To witness the way music therapy can impact not only the client but the support system of that client is extremely rewarding.

Implications For Music Therapy

Understanding the way in which music can impact physiological measures appears to be an opportunity to have music therapy observed from a different vantage point. Much research and funding in our westernized society is based around numbers and quantitative information. If we can communicate our findings in this fashion, we may find more opportunity for funding.

It will also benefit the music therapy field to understand how music affects physiological measures because it can help us understand how music is truly affecting an individual, not just emotionally. It seems to be important in understanding how music affects vital signs, areas of the brain, etc. In therapy it seems that these aspects would be important to investigate and understand. While much of the musical experience is a phenomenon, there are still many areas to be explored.

Implications for Further Research

It would benefit the music therapy field to have future researchers to study entrainment in music therapy further. Before now, entrainment has only been studied in the field of music therapy as it relates to infants and premature babies in the NICU. Entrainment should be studied further with a larger data set in order to find statistical significance. Loewy, et al. (2013) also found that the decreased heart rate during music intervention of entrainment also improved their sleep patterns. Since this is another area of concern for the dementia population, it would behoove further researchers to investigate how music therapy effects their sleep patterns.

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Molloy College

HUMAN SUBJECT RESEARCH PROPOSAL – FORM A GENERAL STUDENT APPLICATION FOR RESEARCH INVOLVING HUMAN SUBJECTS (FULL APPLICATION FOR STUDENT WHEN INDIVIDUAL IRB APPROVAL NEEDED BUT SUPERVISED BY FACULTY)*

I. IDENTIFYING DATA Graduate_ X

Undergraduate

Principal Investigator Name: <u>Francesca Brennan</u> Department/Division: <u>Music/ Humanities</u> Email: <u>fwelhous@lions.molloy.ed</u> <u>u</u>

I accept responsibility for conducting the proposed research in accordance with the policy regarding protection of human subjects as specified by the Molloy College Institutional Review Board, including the supervision of faculty and student co-

investigators.



Signature:

Other Investigator(s)

Name: ___Dr. Sangeeta Swamy _____ Department/Division: ___Mu Email: ____sswamy@molloy.edu

I accept responsibility for conducting the proposed research in accordance with the policy regarding protection of human subjects as specified by the Molloy College Institutional Review Board, including the supervision of faculty and student coinvestigators.

Signature:

Title of the Research: The Role of Entrainment on an Older Adult's Stress and Anxiety: A Mixed Methods Study

Date submitted:

Reason for Study:

<u>X</u> Degree Requirement.	School affiliation: Molloy College, Rockville Centre, NY
Independent Study	Committee Chairperson:
Other (Specify):	

Purpose of study: To investigate the impact musical entrainment might have on an elderly individuals stress and anxiety levels.

- 1. Does entrainment in music therapy impact stress levels?
- 2. Does entrainment in music therapy impact anxiety levels?

Have y	ou submitted	this to an	y other	IRBs?	Yes	X No
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If yes, to which IRB?

What was the outcome of that review?

*Class/Course projects when student desires publication; class study applications that cannot be considered exempt or expedited; student individual projects beyond course requirements: student is the PI for the study with faculty supervision.

In the judgment of the Principal Investigator, this research qualifies for which of the following (see Molloy College Institutional Review Board Policy for criteria):

____Exempt ____X_Expedited ____Full

Board Review Faculty Supervisor

______I have carefully read the Molloy College IRB Policy and I approve this proposal as satisfying the stipulations of the IRB. I accept responsibility for overseeing the proposed research in accordance with the protections of human subjects as specified by the IRB, including the supervision of all co-investigators.

_____I cannot approve this proposal as written; it will be returned to the researcher.

Signature:

In the judgment of the Faculty Supervisor, this research qualifies for which of the following:

Exempt	Expedited	X	Full Board Review

(SEE ATTACHED FOR DEFINITIONS)

Research Category Check all categories that apply:

Education Research	Gene Transfer Research
_X_Survey/Interview	Medical Records
X Audio/Video Recording	Stem
<u>Cell Research Oral History</u>	_
	_Medical
Imaging	
Internet-based	Human/Animal Tissue
Analysis of Existing Data	Animal Research
International Research	Pathogens
X_ Other (specify)Heart rate and blood	Hazardous
Substances pressure measures and Improvisat	ional Music
Controlled Substances Therapy	

I. DESCRIPTION OF HUMAN SUBJECT SAFEGUARDS AND RIGHTS

A. Risks/Benefits to Participants

- 1. Among the potential risks in this study, there is a possibility that the privacy of the session may be compromised due to the unpredictable environment of the medical facility. The likelihood of this happening is small since the researcher is taking precautions to ensure it remains private. She will make sure that the study is conducted during a time when the participant has no prior engagements with therapies or recreation activities, etc. In addition she will discuss with staff the times that no one is in the area where the study will be conducted. This study is noninvasive and does not involve any intense medical procedures. There are minimal psychological risks to the participant in this study, however, it is possible that the primary participant may encounter feelings, thoughts, or physical sensations that may be unpleasant while participating in music therapy or when reflecting on the experience. If this were to occur, the principal investigator will provide him or her with emotional support by taking a break and allowing him or her to share his or her feelings. The principal investigator will also remind the primary participant that he or she has the option to withdraw from the study or reschedule the interview to another time that is convenient to her or him.
- 2. Participating in this study allows the participant to be a part of a private music therapy session. Residents at this facility are offered group music therapy on a weekly basis and do not receive individual music therapy as standard care in this facility. There is potential that the primary participant may gain a deeper understanding of his or her experience in music therapy, which may or may not be beneficial to him or her. The participant will also be contributing to a research study that has not been published, thus helping to further educate current researchers and healthcare professionals about the regarding the importance of examining entrainment in music therapy. In addition, participation in this study is free.
- 3. Do benefits outweigh risks in your opinion? __x__Yes ___No
- 4. Are there potential legal risks to the Principal Investigator or to the College? ___Yes __x_No

B. Collection of data

The study will take place at Grace Plaza Nursing and Rehabilitation Center in Great Neck, New York on the Dementia Unit, where the principal investigator, who is the clinician in the study, provides weekly music therapy services for individuals in various units of the nursing home. The principal investigator will take audio recordings of three 30-minute sessions, in which the primary participant will partake in a music therapy session involving entrainment (the synchronicity of two external rhythms [Clayton, Seger, & Will, 2004]). The participant will be encouraged to play musical instruments provided and sing in the session. As the participant expresses himself or herself musically, the principal researcher will then entrain to their rhythm. The principal researcher may also

entrain to their breath and body movements. The sessions will also contain a brief interview before and after each session to gain more information about the participant's emotional state. The Tantan Lohas01 Smart Bracelet IP67 will be used to take heart rate and blood pressure before and after each session. Tantan Lohas01 Smart Bracelet IP67 is not a medical device but is used and marketed as a simple fitness tracker bracelet. This bracelet is similar to a fitbit and does not have any known risks for the wearer. While we do not have a biomedical department at our facility, the administrator has approved the use of this bracelet for the music therapy research study as the researcher is merely looking for significant differences in the before and after outcome measures. You will also find additional photos and brochure attached to this document.

- 1. The questions that will be used during the interview will include: *How is your day going? Are you experiencing any pain? Are you currently feeling tired? Is it hard to sit still? Do you find yourself worrying about anything? And how do you feel right now?*
- 2. When will it take place? January 2018 February 2018
 - a. Period of time needed: Two months
 - b. Length of time needed: 45 minutes to 1 hour per session.
- 3. Name of Instrument to be used (if standardized): Tantan Lohas01 Smart Bracelet IP67 and Evistr 8GB Digital Audio Sound Recorder Dictaphone.
 - a. Where available: Supplied by the researcher.
 - b. If not standardized instrument, attach instrument.
- 4. Describe methodology to be used: (Please see attached copy of the detailed methodology.)
 - a. A mixed methods design will be used in this study. Thematic analysis, adapted from Braun and Clarke's (2006) steps for analyzing data, will be used to induce themes from the interviews. Heart rate and blood pressure measure will be taken before and after each session and displayed in two separate graphs, which will later be compared through statistical analysis and results displayed in an additional graph. The primary participant will be an individual with a diagnosis of dementia who also displays anxiety, is of the age 65 years old and over, and has never received individual music therapy.
- 5. Population, including number of subjects: One person with a diagnosis of dementia, who displays anxiety and is the age of 65 years or over.

The study population may include (check all categories which may be included, by design or incidentally):

____Minors

___Pregnant women

____Women of Childbearing Age __x_Institutionalized Persons (Includes prisoners) __x_Other (specify)_Elderly individuals in nursing home. ____Students __x_Low Income Persons __x_Minorities __x_Incompetent Persons (or those with diminished capacity

[NOTE: IF ANY STUDY SUBJECTS ARE CONSIDERED VULNERABLE BY THE FEDERAL GOVERNMENT, PLEASE EXPLAIN ADDITIONAL MEASURES YOU ARE TAKING TO PROTECT THEIR RIGHTS.]

How are subjects recruited and selected?

The participant will be selected via purposeful sampling of an individual residing at the nursing home who has never previously participated in individual music therapy. Because of cognitive deficits due to diagnosis, informed consent will need to be given by the caretaker/ guardian of the participant. All recording materials and data will be password protected and stored in a locked safe.

What incentives will be offered, if any? None

Are you associated with the subjects (e.g., your students, employees, patients)? Yes _x___ No ____

If yes, please explain the nature of the association and what measures you are taking to

protect subjects' rights, including safeguards against any coercion.

I currently work as a Recreation Therapist at Grace Plaza Nursing and Rehabilitation Center. In an effort to protect the participant from coercion I will reiterate that participation in this study is not mandatory and that participating in this study is completely their choice. Since individual music therapy sessions are not standard care in this facility and there is additional risk for coercion, I will offer individual music therapy sessions free of charge at the facility for those who do not want to participate or are not selected to participate in this research study. The consent form provided to the participant and the caregiver will clearly state that there will not be any negative consequences should they refuse to participate in the study. In addition, the principal investigator will ensure the participant and/or caregiver that the services provided to the individual that are provided at the nursing home will not be affected by consent for participation.

 Will subjects be minors (under 18) or otherwise not fully competent to consent?

 Yes _____
 No _x____

 If yes, explain:

Will this research be conducted with subjects who reside in another country,

or who reside in the U.S. but in a cultural/ethnic context different from traditional U.S. society/culture (including non-English language speakers)? Yes x No

If yes, explain.

If yes, will there be any corresponding complications in your ability to minimize risks to subjects, maintain their confidentiality and/or assure their right to voluntary informed consent?

___Yes x_No

If yes, what are these complications and how will you resolve them?

C. Informed Consent

Describe briefly how and to what extent participants will be informed about the research before they give their consent. Please attach a copy of the informed consent letter you will use. (It should be at the 8th grade reading level, or lower as dictated by the needs of the subjects.)

The consent form will include information about the purpose of the study, information about confidentiality and securing data, as well as permission to have the music therapy session and interview audio recorded (see Appendix A). The principal investigator will also explain the general process of the music session.

The participant and caregiver will be provided a copy of the consent form and the principal investigator will read out loud and clarify each section. The principal investigator will ask if they have any questions about the consent form. There will be another healthcare professional present when this takes place to ensure that the participant and/or caregiver understand and feels comfortable with the information provided.

2. Does your investigation involve incomplete disclosure of the research purpose or

deception of subjects? ___Yes x_No

[NOTE: DESCRIBE ANY DECEPTION, IF ANY, TO BE USED WITH HUMAN SUBJECTS.]

If yes, be sure to include copies of your debriefing procedures for subjects.

2. Indicate how subjects can, if they wish, withdraw from the study. *[IF PROCEDURES ARE POTENTIALLY HARMFUL, DESCRIBE*]

ARRANGEMENTS FOR MEDICAL REFERRAL OR OTHER ASSISTANCE. IF EXPECTED CULTURAL OR LANGUAGE PROBLEMS, DESCRIBE PROVISIONS TO BE MADE FOR CONSENT.]

If at anytime the participant wishes to withdraw from the study, the researcher will escort the participant to the dining room and ensure them that no judgment will be made against him or her. Participants will be informed in the consent form found in Appendix A that their participation is voluntary and they are free to withdraw from the study at any time. Their withdrawal will have no negative consequences and will not affect the services provided by the facility. Should they choose to withdraw from the study, they or their caregivers can contact me in person, by phone, or by email. If participants wish to withdraw prior to the data collection day, all of the participants is to withdraw during or after the music therapy session and/or interview, all of the participants' data and records collected thus far will be erased and discarded immediately.

D. Privacy/Confidentiality

- 1. Does the project involve protected health information as defined by HIPAA? Yes.
- 1. Describe whether the research will involve observation or intrusion in situations where subjects have a reasonable expectation of privacy.
 - a. The participant will be taken to their room for privacy. If for any reason that environment is compromised the researcher will seek out another room for privacy with the assistance of her supervisor and/or nurse on staff.
- 3. If records are to be examined, has appropriate permission been sought? Yes.
- 2. Specify how subjects' anonymity will be achieved and/or how confidentiality will be

maintained.

a. The participant's name will be changed for the purpose of anonymity and recordings will not be released outside of the parameters mentioned in the consent form. The recorded music therapy session and interview, and transcriptions will be audio recorded and kept in a locked safe and guarded with a password known only by the principal researcher. All data will be stored on the principal investigator's personal computer, which is secured and locked with double passwords- one for the computer, and one for the files. Printed copies the data will be stored in a locked safe in the investigator's home, if necessary. All written and video data will be stored in these secured locations at all times. Access to all raw data will only be granted to the principal investigator.

- b. The principal researcher will not share the data collected and outcomes outside of the educational setting. If published, the researcher will maintain participants' confidentiality and anonymity. Information that is discussed will be discussed in the educational setting will be expressed through general themes presented in the interview or interactions during the music therapy session. Meetings or conversations with the thesis committee will remain strictly confidential.
- c. To ensure that this research activity is being conducted properly, Molloy College's Institutional Review Board (IRB), whose members are responsible for the protection of human subjects' rights for all Molloy-approved research protocols, have the right to review study records, but confidentiality will be maintained as allowed by law.

E. Use of data

- d. Describe how data will be used.
 - The quantitative data will be used to investigate the physiological effects of the music therapy intervention.
 - The qualitative data will be used to investigate the impact the music therapy intervention had on their emotional state.
- e. Will subjects be given research results if they so request? Yes_x_ No_____

[ANY FINANCIAL INTEREST IN THE RESEARCH? IF SO, BRIEFLY EXPLAIN AND ATTACH A STATEMENT TO BE DISTRIBUTED]

- I. Please submit one electronic document with all components of:
- A. Proposal form (application)
- B. Proposal Executive Summary (abstract with specific protocol details)

[The Executive Summary is a proposal abstract that includes specifics about the research protocol such as how the applicant will recruit and enroll subjects such as contact letters, the data collection procedures such as location, and assurances of human subject protection]

- C. Research tool(s)
- D. Consent form and/or letter

All applications must be submitted as one hard copy and one e-copy, submitted to the email addresses of the Co-Chairpersons of the IRB, or directly to the Molloy College IRB email address (irb@molloy.edu).

Signature(s) of investigator(s)

Date: (Electronic signature with email accept



<u>ATTACHMENT:</u> CATEGORY DEFINITIONS (NIH) AND MOLLOY IRB IMPLEMENTATION

Exempt Categories

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB review. Researchers should submit their applications to the IRB and self-identify the proposal as Exempt, which must be confirmed by the Co-Chairpersons.

- a. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
- b. Research involving survey or interview procedures, except where any of the following conditions exist:
 - (1) Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.
 - (2) The subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and
 - (3) The research deals with sensitive aspects of the subject's own behavior, such as, illegal conduct, drug use, sexual behavior, or use of alcohol.
- c. Research involving the observation (including observation by participants) of public behavior, except where any of the following conditions exits:
 - (1) Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.
 - (2) The observations recorded about the individual, if they became known outside

the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and

- (3) The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
- d. Research involving the collection or study of existing data, documents, records, pathological specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that the subject cannot be identified, directly or through identifiers linked to the subjects.

Expedited

Research, which involves no more than minimal risk and falls within the categories listed below, will be reviewed by expedited review. 'Minimal risk' means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than in those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Researchers should submit their applications to the IRB and self-identify the proposal as Expedited, which is confirmed by the Co-Chairpersons. The researcher should ensure that the project is scientifically sound and that the procedures and likely risks are adequately described.

Expedited review will be carried out by at least three members of IRB that may include the Co-Chairpersons and one member or a combination of 3 members that represent:

- 1. a member from the related discipline;
- 2. a scientific member;
- 3. a non-scientific member.

Researchers will be notified if the IRB approves; such approval is valid for a period of 12 months, unless otherwise specified.

Expedited Categories

a. Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

- b. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
- c. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing, sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography.
- d. Collection of both supra and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic and aseptic techniques and using "universal precautions".
- e. Voice recordings made for research purposes such as investigations of speech defects
- f. Moderate exercise by healthy volunteers.
- g. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
- i. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

Full Review

All other research, i.e., non-exempt, non-expedited, will be reviewed by all members of the Committee. Following determination of approval by unanimous agreement, researchers may collect data. Any dissent or need for clarification from the researchers requires the full committee to meet within a month that the application was received for discussion. Dates of meetings will be arranged by the Co-Chairpersons and conclude with a vote of members to approve or disapprove the proposal.

Applications that are not EXEMPT or EXPEDITED should be submitted to the IRB Co- Chairpersons by the first of the month so that if a meeting is required, it will occur during that month. Applications requiring full board approval submitted after this time will be reviewed at the following meeting. If the research is externally funded, or external funding is being sought, IRB applications should be submitted early enough so that the Federal Wide Assurance can be submitted with the grant application. Researchers will be sent a copy of the IRB approval and any Institutional Assurance submitted. IRB approval is valid for one year, unless otherwise specified.

Attachment I: Proposal Executive Summary

Francesca Brennan, MT-BC

Grace Plaza Nursing and Rehabilitation Center 15 St. Pauls Place Great Neck, NY 11021 Tel: (516) 466-3001 x.219 Email: fwelhous@lions.molloy.edu

ABSTRACT

I am proposing a study to explore the impact of musical entrainment on an older adult with dementia and anxiety. Entrainment is the synchronicity of two external rhythms (Clayton, Seger, & Will, 2004). In other words, entrainment involves matching rhythms together.

These rhythms can be from improvising and creating music or it can be through matching bodily rhythms and breathing patterns. Through the process of entraining or matching rhythms, a person may feel comforted and supported in their environment.

I will be employing Improvisational Music Therapy (IMT) in an effort to match the participant's music making, breathing, and body movements. Currently, there is no published literature that explores entrainment with older adults in a music therapy session. This mixed-methods study will evaluate the participant's heart rate and blood pressure before and after each session. Interviews will be conducted to further investigate the participant's anxiety and stress levels. The following research questions will guide this study: Does entrainment in music therapy impact stress levels? Does entrainment in music therapy impact anxiety levels? Does entrainment in music therapy affect an individual's emotional wellbeing? What are the key themes in the qualitative data? Is there a relationship between qualitative and quantitative data?

Data will be obtained from three 30-minute music therapy sessions with one participant, aged 65 or over, with a diagnosis of dementia and display of anxiety on a regular basis. Data will be collected through quantitative measures of heart rate and blood pressure using the Tantan Lohas01 Smart Bracelet IP67; and through qualitative measures in a brief interview before and after each session. The Tantan Lohas01 Smart Bracelet IP67 is a simple bracelet that will be placed on the participant's wrist for a few moments to gather heart rate and blood pressure. The participant will not experience any pain with the bracelet on. It will feel as though they are wearing a piece of jewelry or a watch.

The primary participant will be recruited by utilizing a purposeful sampling method, in which the participant would have never previously had individual music therapy. The interviews will consist of brief open-ended questions before and after each session. Each interview should last no more than 5 minutes in length. This consent form is being provided to the guardian and/or caretaker and will include the purpose, method of the study, possible risks and benefits, methods
of confidentiality, and permission to take audio recording of the music therapy sessions and interviews.

A Copy of the Informed Consent Form is attached.

Additional Information and Product Information regarding the Tantan Lohas01 Smart Bracelet IP67

Information taken from Amazon.com:

https://www.amazon.com/Bracelet-Waterproof-Pressure-Bluetooth-Activity/dp/B0718VQNRV/ref=cm_cr_arp_d_product top?ie=UTF8



Heart Rate Monitor Blood Pressure Monitor

Double 3D sensor give you most real-time and accurate heart rate&blood pressure monitor. Please keep in mind that It will be more accurate if you wear the tracker higher on your wrist and stay still during Monitoring.

The results for reference only, not for medical use.

- Multifunctional Sports Smart Band: Time & calendar, steps taken, distance, calories burned, blood pressure monitor, heart rate monitor, sleep monitor, running mode, message notifications, sedentary reminder, remote camera control, social media sharing, vibrate alarm clock, compatible with Android 4.3 above and IOS 8.0 above.
- Automatic Heart Rate Monitor: Lohas will detect you heart rate automatically every half-hour; You can review your heart record anytime on the "H Band" dashboard; Blood Pressure Monitor: there are two modes of BP monitor, Normal and Personal. Please follow the operation instructions in the user manual. (Note: The result is for reference only, not for medical use)
- Sleep Monitor & Vibrate Timer: track your status and quality of your sleep, light sleep time, deep sleep time and awake hours. Lohas01 gives you a best decent reading of whether you're sleeping well and wakes you (not your partner) with a silent wake alarm.
- Silicone & Metal Button Band: Silicone is the top environmental protection

material with good elasticity and soft, which makes it very comfortable to wear; Metal Button design makes the band perfect for sporting#MustHave, you will never loose your device again!

 What You Get: Tantan Lohas01 * 1, Micro Charging Cable * 1, User Manual * 1, Worry-Free 12-month warranty and 7¡Á24 hrs friendly customer service.

Technical Details

Color	DI
Itom Woight	0.06
Dackage	1 12 v 2 7/ v 2 7/
Shinning	0.33
9i70	omali largo v

Product description

Tantan Lohas Smart Bracelet - committed to redefining your life in a healthy and sustainable way. #Must Have

Easy to Charge

Super Convenient USB plug, easy to get charged on USB block or computer.

Easy to Awake Screen

You can easily see the time by turning over your wrist instead of tapping the screen.

Note: Please do not turn over your wrist very fast or continuously to test the function; Please allow a second to the sensor to give instruction:-)

Easy to Get Notifications

Support Call, SMS, WhatsApp, Facebook, Twitter, Wechat, and other social network site alert (When phone is nearby).

Sleep Monitor

Tracks how long and how well you sleep and wake you up with a silent vibrating alarm. Please note that the sleep monitor function only actived betwwen 6:00 PM and 10:00 AM.

Remote Camera

Take selfie with whole family and friends without tapping the phone or selfie sticker, just use "remote camera" function and shake your tracker.

Extended Warranty

At Tantan, we always stand behind our products and back them all with an 12month warranty and provide friendly, easy-to-reach support.

Specification

CPU: Nordic N51822 Bluetooth Version: 4.0 Sensor: 3D Gravity Sensor Trap Material: Silicone Stand By: 5-7 days Battery Capacity: 90mAh Dust-proof &Waterproof: IP67

Storage

Temperature: -20jæ-

70jæ

Battery: Built-in rechargeable lithium battery

System Requirement: Android 4.3 And Above, IOS8.0 And Above

App Download : Search "H Band" on App store, Google Play, or Scan the QR code on the User Manual and install it.

Note: Bluetooth is a #must have condition when connecting the smart bracelet with "H Band".

Attachment I: Proposal Executive Summary

Francesca Brennan, MT-BC Grace Plaza Nursing and Rehabilitation Center 15 St. Pauls Place Great Neck, NY 11021 Tel: (516) 466-3001 x.219 Email: fwelhous@lions.molloy.edu

ABSTRACT

I am proposing a study to explore the impact of musical entrainment on an older adult with dementia and anxiety. Entrainment is the synchronicity of two external rhythms (Clayton, Seger, & Will, 2004). In other words, entrainment involves matching rhythms together.

These rhythms can be from improvising and creating music or it can be through matching bodily rhythms and breathing patterns. Through the process of entraining or matching rhythms, a person may feel comforted and supported in their environment.

I will be employing Improvisational Music Therapy (IMT) in an effort to match the participant's music making, breathing, and body movements. Currently, there is no published literature that explores entrainment with older adults in a music therapy session. This mixed-methods study will evaluate the participant's heart rate and blood pressure before and after each session. Interviews will be conducted to further investigate the participant's anxiety and stress levels. The following research questions will guide this study: Does entrainment in music therapy impact stress levels? Does entrainment in music therapy impact anxiety levels? Does entrainment in music therapy affect an individual's emotional wellbeing? What are the key themes in the qualitative data? Is there a relationship between qualitative and quantitative data?

Data will be obtained from three 30-minute music therapy sessions with one participant, aged 65 or over, with a diagnosis of dementia and display of anxiety on a regular basis. Data will be collected through quantitative measures of heart rate and blood pressure using the Tantan Lohas01 Smart Bracelet IP67; and through qualitative measures in a brief interview before and after each session. The Tantan Lohas01 Smart Bracelet IP67 is a simple bracelet that will be placed on the participant's wrist for a few moments to gather heart rate and blood pressure. The participant will not experience any pain with the bracelet on. It will feel as though they are wearing a piece of jewelry or a watch.

The primary participant will be recruited by utilizing a purposeful sampling method, in which the participant would have never previously had individual music therapy. The interviews will consist of brief open-ended questions before and after each session. Each interview should last no more than 5 minutes in length. This consent form is being provided to the guardian and/or caretaker and will include the purpose, method of the study, possible risks and benefits, methods of confidentiality, and permission to take audio recording of the music therapy sessions and interviews.

A Copy of the Informed Consent Form is attached.



1000 Hempstead Avenue Rockville Centre, NY 11571 www.molloy.edu

> Tel. 516.323.3801 Tel. 516.323.3711

Date:	February 7, 2018	
To:	Professor Swamy for Student Francesca Brennan	
From:	Kathleen Maurer Smith, Ph.D.	
	Co-Chair, Molloy College Institutional Review Board	
	Patricia Eckardt, Ph.D., RN	
	Co-Chair, Molloy College Institutional Review Board	
SUBJECT:	MOLLOY IRB REVIEW AND DETERMINATION OF FULL BOARD APPROVAL	
Study Title:	The Role of Entrainment on an Older Adult's Stress and Anxiety: A Mixed Methods	
	Study	
Approved:	February7, 2018	
Approval No.:	06021805-0207	

Dear Professor Swamy for Student Francesca Brennan:

The Institutional Review Board (IRB) of Molloy College has reviewed the above-mentioned research proposal and determined that this proposal is approved by the committee. It is considered a FULL BOARD review per the requirements of Department of Health and Human Services (DHHS) regulations for the protection of human subjects as defined in 45CFR46.101(b) and has met the conditions for conducting the research. Please note that as Principal Investigator (PI), it is your responsibility to be CITI Certified and submit the evidence in order to conduct your research.

You may proceed with your research. Please submit a report to the committee at the conclusion of your project.

<u>Changes to the Research</u>: It is the responsibility of the Principal Investigator to inform the Molloy College IRB of any changes to this research.

Sincerely,

Kathleen Maurer Smith

Kathleen Maurer Smith, Ph.D.

Jaurno

Patricia Eckardt, Ph.D., RN

Grace Haza

Nursing and Rehabilitation Center

October 17, 2017

Re: Francesca Brennan Research Study

Dear Members of the Molloy College Institutional Review Board,

This letter is to confirm that student Francesca Brennan has permission to conduct her research on the impact of music therapy on Dementia at Grace Plaza Nursing & Rehabilitation Center.

If you need anything further, please feel free to contact me at 516-466-3001 extension 235.

Sincerely yours,

K Sodem.

Kim Sodano, LNHA, LCSW Administrator

KS:mvf

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