Abstract

NOTCHED ACOUSTIC STIMULUS AND TINNITUS: A TREATMENT INTERVENTION USING A RANDOMIZATION TEST APPROACH

by

Candice Amber Manning

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Co-Director of Dissertation: Deborah Culbertson, Ph. D.

Co-Director of Dissertation: Gregg Givens, Ph. D.

Major Department: Communication Sciences and Disorders

Musical training has considerable effects on human brain plasticity and music listening has been investigated as a means of treating tinnitus. In a laboratory setting, tailor-made notched music has been shown to reduce the annoyance and loudness of tinnitus. This study utilized at-home notched music sound therapy in conjunction with counseling. The current study explores counseling benefit prior to initiation of un-filtered music and then a randomly determined treatment start date for the notched music treatment. The study includes a more extensive self-report test battery and daily pitch matching, loudness scaling, and annoyance scaling to examine for changes in everyday life. In addition, this study differs in that participants were not required to undertake the treatment within a research facility but were able to complete the treatment in their daily lives.

Notched Acoustic Stimulus and Tinnitus: A Treatment Intervention Using a Randomization Test Approach

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By Candice Amber Manning

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Candice Amber Manning

APPROVED BY:

CO-DIRECTOR OF
DISSERTATION/THESIS: _____
Deborah Culbertson, Ph.D.

CO-DIRECTOR OF
DISSERTATION/THESIS: _____
Gregg Givens, Ph. D.

COMMITTEE MEMBER: _____
Kevin O'Brien, Ph.D.

COMMITTEE MEMBER: _____
Richard Bloch, Ph.D.

CHAIR OF THE DEPARTMENT
OF (Communication Sciences and Disorders): _____
Kathleen T. Cox, Ph.D.

DEAN OF THE
GRADUATE SCHOOL: _____
Paul Gemperline, Ph.D.

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CHAPTER 1

REVIEW OF THE LITERATURE

The origin of most tinnitus is within the auditory system itself. Therefore, consideration of the normal anatomy and physiology of the auditory system and possible neuroscience of tinnitus will be presented first. Then classifications of tinnitus, tinnitus evaluation and tinnitus management approaches will be discussed leading up to a rationale for the current study.

Peripheral and Central Auditory Pathways

The origins of subjective tinnitus are within the peripheral and central auditory nervous systems. Thus, a basic understanding of auditory anatomy and physiology is important for those seeking to study or treat subjective tinnitus. The following discussion offers information important to understanding the normal function of the auditory system before considering abnormal functions that may produce tinnitus. This discussion is primarily based on reviews of auditory anatomy and physiology offered by Pickles (2008) and Musiek and Baran (2007).

When a sound wave enters the ear, the sound energy is transferred through the outer, middle, and inner ear structures. That sound energy is transformed into mechanical energy by the tympanic membrane and middle ear ossicles and then sent to the inner ear structures where the process of sensory transduction (i.e., conversion to a neural impulse) occurs. Within the inner ear, motion of a moveable membrane, the basilar membrane, results in excitation of the outer and inner hair cells that then leads to stimulation of neurons within the auditory nerve.

Although briefly described above, the transduction process within the inner ear requires further elaboration. As stated, the sound energy that travels through the outer and middle ear moves the fluid within the inner ear and causes the basilar membrane of the cochlea to move.

This movement causes a shearing action of the outer hair cells' stereocilia against the tectorial membrane, depolarizing the outer hair cells and causing them to expand and contract. This expansion and contraction leads to increased motion of the basilar membrane that in turn causes bending of the stereocilia on the inner hair cells. The depolarization of the inner hair cells is critical because they release the neurotransmitters that stimulate the neurons of the auditory nerve.

Stimulation of both types of hair cells is related to the potassium channel tip-links located on the stereocilia that open when they are bent or sheared, causing depolarization of the hair cell. The depolarization of the hair cells causes voltage-gated calcium channels to allow an influx of calcium. Depolarization of the inner hair cells results in the release of a neurotransmitter, glutamate, leading to the firing of action potentials in the auditory nerve. The auditory nerve fibers extend to and transmit neural impulses to the three distinct cochlear nucleus divisions: the anterior and posterior ventral cochlear nuclei, and the dorsal cochlear nucleus. Continuing the pathway, fibers from the anterior and posterior ventral cochlear nuclei project to the superior olivary complex of the pons, whereas the dorsal cochlear nucleus projects directly to the inferior colliculus of the midbrain, with all projections decussating or crossing, to the opposite side of the auditory pathway. The nerve fibers from the superior olivary complex then project ipsilaterally to the lateral lemniscus and the inferior colliculus. Nerve fibers from the inferior colliculus ascend to the medial geniculate nucleus of the thalamus and project to the Heschl's gyrus of the auditory cortex (Emanuel & Letowski, 2009).

There are three key features of a normal functioning auditory system. First, spontaneous firing of neurons occurs throughout the peripheral and central auditory nervous systems. Even in the absence of sound within the environment, there is some level of nerve firing or spontaneous

firing within the auditory nervous system. Many studies have shown reduced spontaneous firing in central auditory nerve fibers with trauma, particularly after exposure to noise and ototoxic medications (Eggermont and Roberts, 2004). It is speculated by some that reduced spontaneous firing leads to the perception of tinnitus (Eggermont and Roberts, 2004). A second key feature of the auditory system relates to the fact that locations within the system are related to frequency response, otherwise known as tonotopicity. Tonotopicity is maintained from the level of the basilar membrane of the cochlea all the way to the central auditory structures and auditory cortex. There is some research that indicates changes in tonotopicity with auditory system damage might be associated with tinnitus (Eggermont, 2004). A third key feature, neural synchrony, or the balance of excitatory and inhibitory neural firing within the central auditory system, must be maintained in order to preserve the neural coding of auditory input (Norena and Farley, 2013). Excitation and inhibition are important neural functions within the auditory pathway (Pickles, 2008). When transduction occurs within the inner ear, all single fibers of the auditory nerve are excited showing no inhibition. Once the fibers reach the central auditory nervous system; however, different groups of neurons respond differently to stimulation. Some groups of neurons are primarily excitatory whereas others are primarily inhibitory. Current theories of the origin of tinnitus relate to abnormalities in spontaneous firing rate, tonotopicity, and/or neural synchrony.

Neuroscience of Tinnitus

Neuroscientific research has begun to expose the nature of tinnitus and how it is generated. Tinnitus researchers and neuroscientists are beginning to understand the link between the peripheral auditory system and the central auditory pathway and their roles in the generation of tinnitus. Several theories will be discussed; however, an exhaustive review of tinnitus

neuroscience and pathology will not be offered. Those interested may examine papers by leading researchers in the area, including Eggermont (2003, 2007, and 2010), Eggermont and Roberts (2004), Norena and Farley (2013), and Saunders (2007).

Researchers, such as Eggermont (2007), have suggested that damage or pathology within the peripheral auditory nervous system leads to the development of tinnitus, which is then generated and maintained through activity at another site within the central auditory system. Due to the many etiologies associated with tinnitus, it is difficult to identify the original peripheral pathology and the generation site of tinnitus within the auditory nervous system. In fact, it is possible that multiple pathology sites for auditory system damage and multiple sites for tinnitus generation exist (Saunders, 2007). The literature is divided between a peripheral or central site of tinnitus generation. Recent human and animal studies have focused on testing that indicates physiological functioning, including otoacoustic emissions, evoked potentials, and brain imaging. These studies have led to important discoveries regarding the neuroscience of tinnitus and changes that occur to the auditory system, both peripherally and centrally, when tinnitus occurs. The various possible etiologies of tinnitus have led researchers to hypothesize about the possible multiple causes of tinnitus, and these etiologies will be briefly discussed.

Tinnitus etiologies

The most common etiologies associated with tinnitus are aging (12.1%), hearing loss caused by noise exposure (18%), head and neck trauma (8%), and ear, nose, and throat infections and illnesses (8%) (Eggermont, 2007). When asked as to the likely cause of tinnitus, aging and noise exposure are two etiologies that are often reported together (Heller, 2003).

As individuals age, the outer and inner ear hair cells of the inner ear die, resulting in age-related hearing loss or presbycusis. Aging also causes changes within the central auditory

nervous system, which have been explored more extensively through animal research. For example, studies have shown that aging in rats significantly decreases the number of glycine receptor sites in the cochlear nucleus (Eggermont, 2007). In aging rats, the concentrations and release of the neurotransmitter Gamma-Aminobutyric Acid (GABA) are also significantly decreased in the inferior colliculus (IC) as well as Glutamic Acid Decarboxylase (GAD), an enzyme within the primary auditory cortex that is responsible for limiting the rate at which GABA is released (Eggermont, 2007).

Whereas tinnitus more commonly occurs in individuals with hearing loss, even individuals with normal hearing thresholds can experience tinnitus. This has led some investigators (Eggermont, 2004, 2007; Saunders, 2007) to propose that underlying auditory system damage may occur in some individuals with normal hearing sensitivity. For example, humans exposed to noise may show a hearing threshold shift and recovery of hearing sensitivity but continue to show reduced amplitude for distortion product otoacoustic emissions (Eggermont, 2007).

Noise exposure is the reported likely cause in 18% of those with tinnitus (Eggermont, 2007). Many individuals with noise exposure or noise trauma anecdotally describe the moment their tinnitus began and the event(s) that caused hair cell damage, which results in the hearing loss. Imaging studies in animals have shown that noise trauma causes degeneration of the auditory nerve, and axonal degeneration in the dorsal cochlear nucleus and ventral cochlear nucleus directly after exposure and for as long as eight months after exposure (Eggermont, 2007). Studies of noise exposure effects have also indicated changes at higher levels in the central auditory nervous system including a significant decline in cell density in the medial geniculate body and the layers of the primary auditory cortex (Muhlau et al., 2006). Another

important characteristic within the auditory nervous system that can be altered by noise exposure is the spontaneous firing rate (SFR) of neurons. Throughout the auditory nervous system, different groups of neurons fire without any sound stimulation (i.e., spontaneous firing), and researchers have determined different SFRs in different structures. The degeneration of synaptic endings during noise exposure and subsequent regrowth of these endings may also result in the reorganization of neural synapses that support excitation rather than inhibition (Muhlau et al., 2006). This is assumed to cause an increase in the spontaneous firing rate of neurons in the brainstem and primary auditory cortex.

Head and neck injuries as well as ear, nose, and throat pathologies account for 16% of tinnitus onset (Eggermont, 2007). Examples of such conditions include temporomandibular joint disorder and Meniere's disease. Many EEG and MEG studies of individuals suffering from these pathologies have found that the dorsal cochlear nucleus and inferior colliculus, areas associated with the extra-lemniscal pathway within the brainstem and auditory cortex, are key generation sites of tinnitus (Eggermont, 2007).

Ototoxic medications, such as quinine, lidocaine, and salicylate, all have the common side effects of tinnitus and hearing loss. According to Eggermont (2007), rats treated with high-dose salicylate, associated with tinnitus in humans, are found to have an increase in spontaneous firing rate within the inferior colliculus. Salicylate dosage in animals can produce effects in the peripheral and central auditory nervous system. According to Eggermont (2007), salicylate dosage eliminates the outer hair cell function in cochlear amplification, increases auditory nerve responses mediated by NMDA receptors and blocks L-type calcium (Ca2+) channels in the inferior colliculus.

Tinnitus is a symptom associated with many tumors including vestibular schwannomas, glomus jugulare, and acoustic neuromas. Tinnitus is a presenting symptom in 73% of patients with radiographically confirmed acoustic neuroma (Gombel et al., 2013). A significant correlation has been found between acoustic neuroma size and a patient's tinnitus severity score. After stereotactic radiosurgery and microsurgery, tinnitus perception and severity often decreases post-surgery. Patients who participate in any form of tumor treatment (i.e., translabyrinthine approach, retrosigmoid approach, middle fossa approach, stereotactic radiosurgery, or observation) experience an improvement in tinnitus severity score (10-point scale) from pre-operation to post-operation compared to those who do not receive treatment (Gompel et al., 2013).

Receptor Systems within the Auditory Nervous System

Receptor systems refer to the neurotransmitters and their associated synaptic uptake sites. As discussed in the previous section, many receptor systems are responsible for a normally functioning auditory system. Threats or damage to these receptor systems will most likely harm the function of the auditory pathway, both peripherally and centrally. Gamma amino butyric acid (GABA), a key neurotransmitter, plays an important role in the auditory system. Studies have found that age-related sensorineural hearing loss produces a decrease in GABA release, decrease in receptor binding, and a decreased number of presynaptic GABA releasing terminals (Eggermont, 2007). A decrease in Glycine receptor sites, a neurotransmitter located within the brainstem, in the ventral and anterior cochlear nuclei has also been observed in aging animals (Eggermont, 2007). Two other neurotransmitters, both Acetylcholine receptors, are found within the auditory nervous system: muscarinic (mAChR) and nicotinic (nAChR). Subunits of nAChR

receptors are located on cochlear hair cells and are responsible for the mediation of the medial efferent olivocochlear bundle responses, which are inhibitory in nature.

Pathophysiology: Neural Synchrony and Spontaneous Firing Rates

Both an imbalance of spontaneous firing rates and an increased neural (firing) synchrony are underlying physiological changes that appear to occur with tinnitus (Eggermont, 2004). Both have been considered a possible root cause of the tinnitus percept. Eggermont proposed that neural synchrony is the more likely cause because tinnitus pitch matches correspond to the re-organized auditory cortical areas showing increased neural synchrony. It is thought that peripheral damage and/or hearing loss leads to the hyperactivity of spontaneous firing rates within the central auditory nervous system. The spontaneous firing rate of neurons in the dorsal cochlear nucleus and the inferior colliculus is increased, which in turn, affects and increases the neural synchrony of the primary auditory cortex (Eggermont, 2004). fMRI studies in humans have evidenced an increase in spontaneous firing rate at the level of the inferior colliculus while evoked potential studies show an increase in neural synchrony at the level of the brainstem (Eggermont, 2004). Researchers are concluding that both conditions, spontaneous firing rates and neural synchrony, co-occur as a result of down-regulated inhibition or the increase in spontaneous activity of afferent neural fibers (Eggermont, 2004; Saunders 2007).

The potential roles of altered spontaneous neural activity and neural synchrony relative to the development of tinnitus have been considered when examining evoked potential animal studies that focus on the neuronal response to peripheral damage in the brainstem and auditory cortex. In a study by Saunders et al. (1972), mice of the BALB/c strain were exposed to a 104-106 Db SPL doorbell sound 21 days after birth. This stimulus previously had been found to reduce the amplitude of the cochlear microphonic and action potentials of the auditory nerve.

Two groups of mice were exposed to the loud noise, and a third control group was not exposed to the noise. At approximately 30 days after birth, the amplitude and latency of cochlear nucleus (CN) evoked responses were measured in one test group while the amplitude and latency of inferior colliculus (IC) evoked responses were measured in the other. The animals in the control group were split into two smaller subgroups, and one subgroup underwent the CN evoked measures and the other subgroup underwent the IC evoked measures. Results indicated that in mice with past exposure to intense sound, both CN and IC amplitudes were twice the size of the amplitudes in the control subgroups. Interestingly, while the hearing thresholds for the noise-exposed groups were found to be poorer for the click stimulus than those of the control group, the amplitudes of evoked responses were larger. The researchers suggested that the increased responses from the test groups correspond to the clinical representation of loudness recruitment, which is a common finding with tinnitus patients. The threshold shift and increased amplitude of evoked potentials are evidence that peripheral damage results in retrocochlear abnormalities of the brainstem, or central plasticity that occurs after peripheral damage.

Willot and Lu (1982) applied a single-neuron recording technique in C57BL/6 mice to examine the temporal pattern of neuronal discharges after noise exposure. The authors hypothesized that if a change occurred in discharge patterns of a neuron, the excitatory and inhibitory processes would be altered and therefore, impede normal coding patterns. The authors focused on responses from the IC and obtained frequency threshold curves (FTCs) before and after mice were exposed to 95-110 Db SPL white noise for 30 seconds. As previously demonstrated by Saunders et al., (1972), threshold elevation was observed after noise exposure as well as prolonged neuronal discharges to onset stimuli. The changes in discharge patterns resulted in an increase in excitatory effects of neurons, but decreased the inhibitory effects.

Again, this study shows that alteration of the periphery has a direct effect on auditory brainstem structures and causes significant changes in hyperactivity and neuron discharge patterns.

The effects of hearing loss extend beyond the periphery and auditory brainstem structures to the auditory cortex. There is evidence that the reorganization and plasticity of the auditory cortex contributes to the perception of tinnitus. Dominguez et al. (2006) developed a spiking neuron mathematical model in which five different conditions were tested. The model was used to generate excitatory and inhibitory postsynaptic action potentials and used lateral inhibition to decrease spontaneous firing in the impaired auditory region. The model was tested using spontaneous activity input and tonal input while altering the lateral inhibition of the system. The model exhibited an increase in spontaneous activity of the impaired auditory region when lateral inhibition was changed. Conversely, when lateral inhibition was unchanged, spontaneous activity declined. Tonal input near the edge of a simulated hearing loss also showed increased spontaneous activity when lateral inhibition was altered. The investigators stated that when the balance of excitation and inhibition of the lateral network were modified by a peripheral loss, elevated spontaneous activity, hyperexcitablity, and an increase in neural synchrony in spontaneous firing occurred within their mathematical model of auditory cortex function. These are all characteristics of cortical reorganization and its link to the perception of tinnitus.

In summary, research suggests that damage to the peripheral portions of the auditory system results in physiological changes within the central auditory system. Specifically, increased spontaneous firing rates of neurons and changes in neural synchrony have been observed within the central auditory system. These altered functions within the CANS are believed to be associated with the tinnitus percept. The exact relationship between these functions and the tinnitus percept is not yet known. However, the fact that events at the

periphery can produce tinnitus leads researchers to believe that some types of auditory stimulation might be used to change the patterns of response within the CANS in such a way that the tinnitus might be reduced**.**

Tinnitus Defined

There are a variety of definitions for tinnitus. The difficulty of offering any one simple definition for tinnitus is challenging due to its extensive variability in etiology, expression, and effects on individuals (Tyler, 2000). Two definitions capture the essential nature of the auditory phenomena itself. McFadden (1982) defined tinnitus as "a sound that originates in an involuntary manner in the head of its owner, or may appear to him to do so". Henry et al. (2010) define tinnitus as "the experience of perceiving sound that is not produced by a source outside of the body."

One important characteristic of tinnitus relates to whether it is transitory or persistent. Tinnitus may be experienced as a transient or occasional occurrence or may be chronic or long term in nature. Individuals with chronic tinnitus are more likely to report clinically significant tinnitus and seek treatment than individuals with transient tinnitus. Dauman and Tyler (1992) defined chronic tinnitus as "noise that lasts at least five minutes and occurs at least two times per week." The National Study of Hearing (Davis, 1995) only utilized the characteristic of duration to define clinically significant or clinically insignificant tinnitus. While chronic tinnitus is more likely to be clinically significant, other characteristics related to tinnitus severity such as tinnitus annoyance and effects on daily life are as important, if not more so, in determining whether tinnitus is clinically significant. Following further discussion, a definition for clinically significant tinnitus will be offered.

Tinnitus severity is an additional important characteristic in defining clinically significant tinnitus because it indicates the effects of tinnitus on an individual's quality of life (Tyler, 2000). Henry et al. (2012) define clinically significant tinnitus as "tinnitus that disrupts at least one important life activity and/or causes emotional reactions, resulting in a noticeable reduction in quality of life." As can be observed, that definition does not include the length or persistence of the tinnitus. Defining clinically significant tinnitus is essential with respect to determining which individuals need treatment. The definition used within this study for clinically significant tinnitus is a statement that the patient will confirm: "My tinnitus has affected one or more of my life situations, emotions, occupational goals and/or personal relationships for a period of at least one month" (i.e., based on Henry et al., 2010).

In addition to the time course descriptors (i.e., transient and chronic), various other classifications have been used in the description of tinnitus. Dauman and Tyler (1992) suggested that tinnitus be classified in three ways prior to treatment. First, the distinction between normal and pathological tinnitus should be distinguished. Normal tinnitus is experienced by most people without hearing loss, lasts less than five minutes, and occurs less than once a week while pathological tinnitus lasts more than five minutes, occurs more than once a week, and is experienced by those with hearing loss (Dauman and Tyler, 1992). Second, it should be determined as to whether the tinnitus severity and duration are acceptable or unacceptable to the individual. An individual with acceptable tinnitus has tinnitus that does not significantly impact quality of life while unacceptable tinnitus is disturbing and negatively impacts quality of life. Dauman and Tyler (1992) explain that the acceptability of an individual's tinnitus depends on the physiological mechanism and psychological factors related to the patient. Temporary tinnitus is a short-term experience, most likely due to a temporary dysfunction of the auditory system,

while permanent tinnitus may be either constant or intermittent. Third, the probable site of auditory system dysfunction and the etiology of the tinnitus are defined. The site of dysfunction, based on a complete hearing evaluation, can include the middle ear, the peripheral auditory system, or the central auditory system. Middle ear pathologies such as otitis media, cerumen impaction, cholesteatoma, otitis externa, tympanic membrane perforations, external auditory meatus tumors, atresia, otosclerosis, carcinoma, and ossicular chain discontinuity are all middle ear pathologies that can cause the perception of tinnitus (Henry et al., 2010). Peripheral auditory system dysfunction includes sensorineural hearing loss, perilymph fistulas, vestibular schwannomas, viral disease, bacterial infection, and meningioma, which often lead to a central auditory dysfunction (Henry et al., 2010). Tinnitus etiology may also be related to noise-induced hearing loss, Meniere's disease, ototoxicity, and presbycusis. The goal of Dauman and Tyler's (1992) classification system was to identify individuals with severe tinnitus characteristics in order to provide individualized treatment plans for those individuals.

The World Health Organization (WHO) in 2001 (Tye-Murray, 2009) classifies disorders such as tinnitus in a different manner. In the WHO (2001) classification scheme, the effects of tinnitus are described in terms of an individual's activity limitations and participation restrictions. An activity limitation is a change at the level of the patient, such as an inability to participate in a group conversation (Tye-Murray, 2009). A participation restriction is the effect of those limitations on the broader scope of life, such as the patient's tendency to avoid group interactions (Tye-Murray, 2009).

Tinnitus is often classified as either objective or subjective. Objective tinnitus is defined as tinnitus that is audible to the examiner (Dobie, 2004). This type of tinnitus is extremely rare and always has an internal acoustic source in the body related to an underlying condition. This

type of tinnitus is also called vibratory/extrinsic or pseudo-tinnitus and a physical examination should occur with an auscultation of the ear and surrounding structures (Heller, 2003). There is usually an identifiable acoustic source for objective tinnitus. Objective tinnitus requires medical evaluation by an otolaryngologist or otologist. In contrast, only the patient perceives subjective tinnitus. This type of tinnitus is the most common. Any description of the tinnitus is defined only by the patient due to the inability to directly measure the intensity or any other characteristic of the tinnitus (Tyler, 2000). Tinnitus matching (i.e., loudness and pitch) procedures can be performed by the audiologist to indirectly measure the patient's subjective tinnitus (Henry et al., 2004). Subjective tinnitus is caused by a neurophysiologic dysfunction; it is related to a sensorineural hearing loss or auditory system damage.

Prevalence of Tinnitus

The prevalence or number of individuals suffering from tinnitus at a given time is estimated to be from 10 to 15% of all adults in the United States (Hoffman and Reed, 2004). According to Brown (1990), 2.5 million Americans are debilitated by their tinnitus and seek medical intervention (Brown, 1990). In contrast, the American Tinnitus Association (ATA) approximates that 40 to 50 million Americans experience tinnitus as a chronic condition and of these individuals, 10 to 12 million seek some form of medical intervention (National Health and Nutrition Examination Survey, 1999-2004).

There are several factors that are related to the prevalence of tinnitus. Age is highly associated with tinnitus onset. The prevalence of hearing loss and tinnitus increases with age. A study by Brown (1990) found that the prevalence of tinnitus increases with age, from 1.6% for individuals eighteen to forty-four years of age to 4.9% for those individuals sixty-five to seventy-

four years of age. Brown concluded that there is an association between age and tinnitus because they are both related to hearing and health variables.

Gender is another consideration when studying medical conditions such as tinnitus. Gender can be associated with physiological and anatomical differences that may be linked to an individual's cause of tinnitus. Leske (1981) observed that 30% of males reported tinnitus in a clinic compared to 35% of females. Stouffer and Tyler (1990) reported that 44% of males and 49% of females with tinnitus did not know what had caused their tinnitus. However, when noise-induced hearing loss was the stated cause for tinnitus, it was reported by 30% of males compared to only 3% of females. Quaranta (1996) found no significant difference for tinnitus prevalence between males and females. Interestingly, many studies have shown that females are slightly more affected by tinnitus (Tyler, 2000). This could be due to the fact that women are more likely to identify medical symptoms than men.

Socioeconomic status is another factor that may be related to tinnitus prevalence. The National Study of Hearing (Davis, 1995) found an increase in the prevalence of tinnitus from the professional classes to the unskilled classes. This may have been due to the portion of the males that work in noise exposure in the unskilled classes (Tyler, 2000). Occupational groups are also a factor in tinnitus prevalence. Brown (1999) found that individuals not in the labor force are more likely to report tinnitus than those who are in the labor force. Brown concluded that this relationship does not signify that non-experience in the labor force causes tinnitus. He suggested that tinnitus may have prematurely forced the now elderly population out of the labor force earlier than they would have originally. This indicates an obvious economic implication (Tyler, 2000).

Excessive noise exposure is common among individuals with hearing loss, affects the auditory system, and can also cause tinnitus. Exposure to noise in everyday life has increased due to noise pollution such as traffic noise and recreational noise, and these have increased the likelihood of hearing loss at an earlier age (Tyler, 2000). When considering noise exposure it is important to consider the nature of the noise, its intensity, frequency spectrum, and duration and temporal characteristics. Noise can be intermittent, continuous, fluctuating, impulsive, or explosive (Tyler, 2000). Noise can be encountered in daily life activities, for example, through occupational work, shooting guns, and mowing the lawn. Noise causes hair cell damage, specifically outer hair cell damage, through metabolic exhaustion or through mechanical detachment from the basilar membrane (Pickles, 2008). The National Study of Hearing (Davis, 1995) found that 7.5% of individuals with tinnitus had little to no noise exposure, while 20.7% of individuals with tinnitus had experienced significant amounts of noise exposure over time.

According to both animal and human studies, smoking has been found to have an association with tinnitus. Nicotine has been shown to have degenerative effects on cochlear structures. Animal studies by Meffei and Miani (1962) show the degeneration of the neuroepithelium in the cochlea of chronically exposed to nicotine in guinea pigs. An increase in the incidence of hearing loss and tinnitus among smokers as compared to nonsmokers was found by Zelman (1962). Tyler (2000) suggests that more research is needed in a larger population to establish a direct relationship between tinnitus and smoking.

Few studies have been completed to show the effect of caffeine on the auditory system and tinnitus. However, those studies have provided some evidence that has led some to consider caffeine as a risk factor for tinnitus. Brown and colleagues (1981) categorized caffeine as a central nervous system stimulant with the potential of causing tinnitus without affecting hearing

status. Findings from a Kemp and George (1992) study differ; however, in that they found no association between drinking coffee and a change in existing tinnitus. This study followed nine subjects as they kept diary entries about their experiences with tinnitus. Each participant was asked to record whether the sound quality, loudness, and annoyance changed, fluctuated, or remained the same throughout the day. They were also asked to rate on a scale from zero to nine (nine being "very difficult") to address their difficulty level with sleep, annoyance, experienced stress level, general health, and overall mood, particularly after taking medications and consuming alcohol and caffeine. After following these subjects for three months, it was found that caffeine had no effect on participant's experience and difficulty with tinnitus. Due to the differences of findings among studies, further research is needed to confirm caffeine as a factor in tinnitus severity.

Alcohol has been considered a contributing factor in tinnitus due to its ability to cause an increase in the intracellular concentration of glucose if ingested in excessive amounts (Tyler, 2000). Quick (1973) considered alcohol as a potentially ototoxic drug due to its ability to cause structural damage in the inner ear. Quaranta (1996) found that alcohol consumed on a daily basis is a statistically significant risk factor for tinnitus. Other studies, such as the Kemp and George (1992) study mentioned above, found that alcohol had no clinically significant effects on an individual's pre-existing tinnitus. As some of the other factors mentioned, further research is needed to show an association between alcohol and tinnitus.

Numerous factors have been associated with tinnitus onset or exacerbation. However, it is difficult to study such factors in humans who often have multiple possible factors that might produce and/or exacerbate tinnitus. It is standard practice, clinically, to question tinnitus patients about possible factors which may have caused or worsen existing tinnitus. This type of

information is routinely obtained during the tinnitus evaluation, which is the next topic of discussion.

Tinnitus Evaluation

There are several current protocols and guidelines that are accepted for use during a clinical tinnitus evaluation. The American Academy of Audiology (AAA) ("Audiologic Guidelines for the Diagnosis & Management of Tinnitus Patients," 2000) and the American Speech-Language and Hearing Association (ASHA) (Henry et al., 2005), and the Tinnitus Research Initiative Meeting (TRIM) (Langguth et al., 2007) are three published guidelines with recommendations for audiological evaluation, psychoacoustic measures of tinnitus, and self-reports related to the everyday impact of tinnitus. The following recommended audiological measures were included in each of these major guidelines: case history, otoscopy, tympanometry, pure tone air and bone conduction audiometry, high-frequency audiometry, and speech audiometry. Recommended psychoacoustic measures included tinnitus pitch and loudness matching, loudness discomfort levels, minimum masking levels, and residual inhibition measures. As stated, self-report measures are used to indicate the impact of tinnitus in the life of the individual and their use is also recommended. Other measurements that can be included in the clinical evaluation of tinnitus are otoacoustic emissions (OAEs) and auditory evoked potentials such as auditory brainstem responses (ABRs) and late evoked potentials (LEPs).

A tinnitus evaluation typically includes both an audiological evaluation and a psychoacoustical measurement to categorize and define an individual's tinnitus percept. Tyler and Dauman (1992) describe several reasons for the importance of evaluating the tinnitus percept itself. First, it provides a sense of reassurance to the patient that the perception of their tinnitus is real and that they actually perceive an internal noise. Secondly, evaluating the perceptual

characteristics of tinnitus helps to provide clinical information that may indicate a site of origin. This information on the acoustic characteristics of the tinnitus often results in a preliminary categorization of tinnitus as being related to either a medical condition of the head or neck or an auditory system abnormality. Thirdly, establishing baseline tinnitus perceptual measures allows one to gauge whether a tinnitus treatment has been effective. Tinnitus evaluation may also help to determine what type of treatment option will benefit a patient.

The AAA ("Audiologic Guidelines for the Diagnosis & Management of Tinnitus Patients," 2000), ASHA (Henry et al., 2005), and TRIM (Langguth et al., 2007) guidelines suggest the use of case history intake forms to establish the status and specific characteristics of the tinnitus experienced by the individual AAA guidelines (2000) specifically recommend a case history that includes tinnitus questions regarding time of onset, course of progression, description, location, perceived cause, extent to which the patient is bothered, exacerbating factors (such as food, stress, lack of sleep, etc.), history of noise exposure, medications, familial history of hearing loss or tinnitus, effect on sleep, and effect on personal relationships. Langguth et al. (2007) suggest that a case history should include a patient's tinnitus history, modifying influences, and related conditions in order to assess all characteristics of the tinnitus. The TRIM guidelines propose use of the Tinnitus Sample Case History Questionnaire (TSCHQ) to assess all characteristics mentioned above. The current study will utilize a modified version of the TSCHQ to obtain a participant's tinnitus background and history.

Tinnitus self-reports are also suggested in each of the aforementioned tinnitus guidelines. These self-reports can be used to document the everyday impact of tinnitus and can be used as outcome measures for observing change over time, especially when a treatment program has been implemented. Self-report measures are beneficial because they assess tinnitus related

disorders like depression, anxiety, and insomnia. These disorders can enhance an individual's perception of tinnitus annoyance and should be considered during treatment regimens. The international consensus, TRIM (Langguth et al., 2007), identified several self-report measures that are valid and reliable when evaluating tinnitus. The Tinnitus Handicap Inventory (THI; Newman et al., 1996), the Tinnitus Handicap Questionnaire (THQ; Kuk et al., 1990), the Tinnitus Reaction Questionnaire (TRQ; (Wilson et al., 1991), and the Tinnitus Questionnaire (TQ; Hallam et al., 1988) are all internationally accepted self-report measures acknowledged by TRIM. These self-report measures will be discussed in further detail in a later section.

The audiologic hearing evaluation begins with an otoscopic inspection, which consists of an examination of the external ear and tympanic membrane for signs of disease, malformations, or blockage from atresia, stenosis, foreign bodies, cerumen, or other debris (Diefendorf, 2005). Presence of some of the above-mentioned conditions may cause tinnitus and lead to medical diagnosis and treatment. Henry et al. (2005) suggest that clinicians should be aware of any external abnormality, such as cerumen impaction, which can cause the perception of tinnitus through a conductive hearing loss.

Tympanometry is an acoustic immittance measure that establishes middle ear function using measures of ear canal volume, tympanometric width, and peak-compensated static acoustic admittance. Like otoscopy, tympanometry assists in determining the site of origin of tinnitus stemming from a medical condition. For example, a middle ear infection, or otitis media, causes a conductive hearing loss that may result in the perception of tinnitus.

Pure tone air and bone conduction threshold measures are used to determine hearing sensitivity and the type of hearing loss present. Typically, it is recommended that pulsed tones (i.e., not steady tones) be used when evaluating tinnitus patients (Douek and Reid, 1968; Fulton

and Lloyd, 1975; Yantis, 1994). Pulsed tones help the patient distinguish between the test tones and the tinnitus, which is particularly helpful when the tinnitus pitch is close to the test frequency. Pure tone air conduction audiometry should include measures of thresholds from 250 Hz to 8000 Hz and pure tone bone conduction should assess the frequency thresholds from 500 Hz to 4000 Hz. Both are considered essential test measures within a tinnitus evaluation (Langguth et al., 2007).

High frequency audiometry has also been suggested in TRIM (Langguth et al., 2007). High frequency audiometry can diagnose cochlear damage in the early stages and can be used in the routine audiometric evaluation of individuals with a risk of hearing loss (Yildirim et al., 2010). It is also a beneficial test for those individuals with normal hearing and tinnitus. These individuals may have normal hearing by a regular audiometric evaluation testing up to 8000 Hz; however, exhibit signs of high-frequency hearing loss. High frequency audiometry has also been helpful in the diagnosis and follow-up for ototoxicity due to the negative effect of medications on the basal ciliary cells responsible for sensitivity to high frequencies (Yildirim et al., 2010).

In summary, pure tone audiometry indicates whether there is damage/disorder within the outer ear, middle ear, and/or inner ear that might be associated with tinnitus. It establishes whether there is hearing loss present and whether a patient may be a candidate for hearing intervention, such as amplification and/or tinnitus treatments like maskers, sound generators, and music therapy.

Speech audiometry typically involves the presentation of words and includes speech recognition thresholds (SRTs) and word recognition scores (WRS). According to the ASHA guidelines for determining the threshold level for speech (ASHA, 1988), the basic purpose of a speech threshold is to quantify an individual's hearing threshold level for speech. Clinically, the

primary purpose of a speech threshold is to serve as a validity check for the pure tone thresholds. Word recognition scores are percentage scores that represent an individual's ability to identify words at a designated presentation level. Word recognition scores can be determined to be either related to the degree of hearing loss or disproportionately poor (Dubno et al., 1995) and indicative of possible retrocochlear involvement.

The case history, otoscopy, tympanometry, pure tone thresholds and or speech audiometry results may indicate a possible medical condition. Medical referral should be made at this stage if the audiologist finds that the results suggest a medical condition. An otolaryngologist, for example, may check for symptoms related to vestibular schwannoma or retrocochlear pathologies, Meniere's Disease, vascular, muscular, skeletal, respiratory abnormalities, temporomandibular joint disorder (TMJ), vestibular symptoms, and asymmetric hearing loss (Henry et al., 2010).

Another major component of tinnitus evaluation is the psychoacoustic evaluation of the tinnitus percept. Psychoacoustic measures are performed to evaluate an individual's tinnitus pitch and loudness matches as well as the masking, residual inhibition, and loudness discomfort levels. Prior to testing, the clinician reviews the meanings of pitch and loudness to the patient so that s/he understands what is being matched. Those individuals with bilateral tinnitus are asked to use the ear that is most bothersome in order to match the pitch and loudness of their tinnitus to those of tones presented through the audiometer.

The first objective of tinnitus matching is to identify the frequency of a pure tone that is closest to a patient's perceived tinnitus pitch (Henry et al., 2005). Using an audiometer, a frequency is presented that is lower in pitch than the patient's perceived tinnitus pitch (Henry et al., 2005). Eggermont and Roberts (2004) stated that 90% of individuals choose a frequency

above 2000 Hz or higher as a pitch match. ASHA guidelines suggest starting the pitch match procedure at 1000 Hz. Once this mid-range frequency has been presented, different frequencies are presented at higher octaves to gradually approach the frequency identified as the tinnitus pitch. Each time a frequency is presented, the clinician asks: "Is the tinnitus higher pitched or lower pitched than the tone?" Once an octave frequency has been identified as being close to the tinnitus, adjacent inter-octave frequencies are presented to more closely specify the perceived pitch. The pitch-matched tone is then compared to octave frequencies above and below so that "octave confusion" has not occurred (Henry et al., 2005).

Once the pitch match has been obtained, the tinnitus loudness perception is evaluated (Henry et al., 2005). Using the intensity dial, the pitch matched tinnitus frequency is presented at various intensities in order to match the tinnitus loudness to the closest 1 Db step. After each presentation, the clinician asks, "Is the tinnitus louder or softer than the tone?" In order to assure that the patient understands the difference between pitch and loudness matching and that they are measuring their perceptions appropriately, pitch and loudness matches should be measured at an intensity 10-20 Db SL where the patient can comfortably perceive the presentations (Henry et al., 2005). Loudness matching can be a helpful measure for tinnitus evaluation and management, especially as an outcome measure in treatment trials (Langguth et al., 2007).

Another tinnitus characteristic that can be determined is whether the percept is that of a tone or noise. A comparison of a tone and a narrow band noise should be presented through the audiometer to show the patient the difference between the two stimuli. A tone at the pitch and loudness match should be presented to the patient for a few seconds and then compared to a narrow band noise at the relative pitch and loudness match for a few seconds. The clinician asks the patient, "Which of these sounds most like your tinnitus?" If the tinnitus is more tonal, no

further matching is needed. If the patient selects narrow band noise, a comparison between narrow band noise and broadband noise should be obtained using the same procedures described above.

Minimum Masking Levels (MMLs) are measured to determine the lowest level of broadband noise that render's a patient's tinnitus inaudible (Henry et al., 2005). The measurement of MMLs is important for providing a general indication of how a patient's tinnitus perception is affected by sound. It is also helpful in deciding if a patient would benefit from using a masker as a tinnitus treatment. First, a white noise threshold should be obtained. When the initial threshold is found, the Modified Hughson-Westlake approach is used until the patient matches the tinnitus intensity, or loudness of that individual's tinnitus percept. The matched white noise is presented binaurally for those individuals with bilateral tinnitus and monaurally for those individuals with unilateral tinnitus. Using the intensity dial of the audiometer, the clinician increases the intensity of the matched broadband noise in 1-Db steps until the patient cannot hear his tinnitus anymore.

Residual inhibition (RI) refers to the phenomenon whereby the tinnitus perception is reduced in intensity, or eliminated altogether, following auditory stimulation (Vernon, 1982; Vernon & Meikle, 1988). Measuring RI helps to further evaluate the characteristics of an individual's tinnitus and illustrate that a broadband noise stimulus can positively change and affect a tinnitus perception (Henry et al., 2005). The matched broadband noise used for MMLs is used for RI measurement. The patient receives instructions, such as the following: "There will be noise presented for exactly 1 minute. You do not need to respond in any way. The noise will then be shut off and you will be asked if there is any kind of change in your tinnitus." The noise is presented binaurally at MML plus 10 Db for one minute and then shut off immediately.

The patient is asked, "Does your tinnitus sound the same as before, or has it changed?" If there is no change, testing for the RI is negative. If positive, the inhibition can be timed until the tinnitus reappears or simply be measured by the patient's perception of change over time.

Loudness Discomfort Levels (LDLs) should be measured when a patient presents a problem with sensitivity to noises that are easily tolerated by the population at large. LDLs are defined as the threshold level for a sound at which there is discomfort. Lower than expected LDLs usually represent a symptom of cochlear or sensorineural hearing loss and are evidence for recruitment (Henry et al., 2005). Extremely low LDLs can offer evidence of hyperacusis. ASHA guidelines suggest that scripted instructions be read each time LDLs are measured in order to limit the variability in measurement. The instructions should state: "You will listen to different tones. Each tone will be made slightly louder in steps. Tell me when the loudness of the tone would be OK for 3 seconds, but would not be OK for more than 3 seconds." LDLs are obtained bilaterally at octave frequencies and should start with measures at 1000 Hz. A tone is presented at the patient's most comfortable level, presented for 1-2 seconds, and raised in 5-Db steps until the LDL is reported.

Other measures have been utilized in tinnitus evaluation but are not included in all tinnitus guidelines. The usefulness of otoacoustic emissions (OAEs) in tinnitus evaluation is a point of dispute among tinnitus researchers. OAEs are sounds that originate in the cochlea and propagate back through the middle ear and into the ear canal where they can be measured with a sensitive microphone (Prieve and Fitzgerald, 2009). OAEs indicate cochlear function, and specifically outer hair cell function. Three types of otoacoustic emissions have been considered for use in the evaluation of tinnitus: distortion product otoacoustic emissions (DPOAEs), transient evoked otoacoustic emissions (TEOAEs), and spontaneous evoked otoacoustic

emissions (SOAEs).

DPOAEs are measured following the presentation of pairs of pure tones (frequency 1 or f1 and frequency 2 or f2) close in frequency. While the exact mechanism is unknown, it is believed that the interaction between the two frequencies on the basilar membrane results in the output of energy from the cochlea (Prieve and Fitzgerald, 2009). The nonlinear distortion product emission frequency (DPOAE) originates along the basilar membrane and research suggests that its presence suggests that outer hair cells near the f2 frequency are functional (Shera and Guinan, 1999). Robust DPOAEs correspond to functional outer hair cells and normal or near normal hearing sensitivity. Husain (2013) measured DPOAEs twice in five groups of individuals including young adults with normal hearing, middle-aged adults with normal hearing, adults with high frequency hearing loss, age-matched adults with similar high-frequency hearing loss and chronic tinnitus, and adults with normal hearing and chronic tinnitus. Multivariate analysis showed that there was an effect between hearing loss and age but no effect of tinnitus with age or hearing status across all five groups. It was found that DPOAE signal to noise ratios (SNRs) in the group of adults with hearing loss and tinnitus were decreased while DPOAE SNRs in those adults with normal hearing and chronic tinnitus were enhanced (i.e., higher in amplitude). Husain concluded that due to the complex nature of tinnitus origin (i.e., origin within the auditory pathway) and the inconclusive results found between each group and their perception of tinnitus, there is no strong evidence for including DPOAE testing in tinnitus evaluation.

In order to measure TEOAEs, a broadband stimulus, click or tone burst, is delivered into the ear canal. The OAE response measured is an averaged waveform across the frequency range with data offered within defined frequency bands (e.g., cochlear responses, background noise).

Typically, TEOAEs are analyzed by examining the response amplitude, percent reproducibility, and signal-to-noise ratio within the frequency bands. Due to the high variability of TEOAE levels across individuals, TEOAE measurements have not been widely recommended in tinnitus evaluation and measurement.

SOAEs are measured in the absence of external stimulation (Strickland et al., 1985). SOAEs are found in approximately 50% of normal hearing children and adults (Prieve and Fitzgerald, 2009). Some researchers have suggested a direct link between SOAEs and tinnitus. Due to the theory that the cochlea "self-oscillates" and tinnitus is a spontaneous energy, it would make sense as to why SOAEs would be a perfect measurement for tinnitus evaluation (Moller, 1989). However, SOAEs can only be measured in ears having hearing loss no greater than 25 to 30 Db HL, and most tinnitus patients have sensorineural hearing loss greater than those levels (Bonfils, 1989). Few studies have supported a direct relationship between SOAEs and tinnitus. Because there is no evidence suggesting a link between SOAEs and tinnitus, SOAEs are not routinely included in tinnitus evaluation protocols.

Other audiological measures that might be considered in tinnitus evaluation are auditory evoked potentials (AEPs). AEPs are far-field measurements of synchronous neural activity that can be examined from the peripheral end organ of hearing up to the cortical structures responsible for audition (Ruth and Lambert, 1991). AEPs can be divided into early, middle, and late responses, which describe the neural activity latency, or the time after an auditory stimulation. Early responses include electrocochleography (EcochG) and auditory brainstem responses (ABRs), middle responses include middle latency responses (MLRs), and late responses, or long latency auditory evoked potentials (LLAEPs), include mismatch negativity

(MMN), the P300, and the N400. AEPs discussed in this section include an early response, the ABR, and LLAEPs.

Few studies using auditory evoked potentials in humans have found an association between tinnitus and these types of measures. Studies using auditory brainstem responses have shown some differences in wave amplitude, wave latency (i.e., the speed of transmission), interpeak latency (i.e., the time between peaks), and interaural latencies (i.e., the difference between wave V latency between ears) between those individuals with tinnitus and those without tinnitus. For example, a study by Gu and colleagues (2012) found a statistically significant difference between wave I amplitudes and wave V amplitudes when comparing individuals with tinnitus to those without tinnitus. Gu and colleagues proposed that the reduction of activity in the peripheral auditory system and the hyperactivity in the central auditory system was evident in the evoked responses for the individuals with tinnitus. However, the authors stated that though these results were statistically significant, the differences between the groups were minimal and detectable only because of the close matching of hearing threshold, age, and gender between tinnitus patients and non-tinnitus patients.

Late auditory evoked potentials have also been examined in individuals with tinnitus. LLAEPs are auditory evoked potentials that occur greater than 80 ms after a stimulus. These responses are cortical in origin and are larger and lower in frequency than early and middle-latency responses (Wible et al., 2002). One study demonstrated that LLAEPs in individuals with tinnitus are suggestive of dysfunction in the central auditory pathway at the level of the cortex (Filha and Matas, 2010). In this study, individuals with a history of occupational noise exposure were divided into two groups: individuals with tinnitus and individuals without tinnitus. Each group underwent LLAEP assessment and a statistically significant difference was found for the

mean latencies of N1 waves and P300 waves between the two groups. The authors concluded that it is relevant to study late evoked responses in individuals with tinnitus and a history of noise exposure. Nevertheless, it must be mentioned that the validity and reliability of late evoked responses is of concern. Similar to ABRs, few studies have been conducted on humans with tinnitus.

The current study will focus on diagnostic hearing evaluation measures, and psychoacoustic and self-report measures that might be expected to change over time during a treatment. The audiologic test battery will include otoscopic inspection, tympanometry, and pure tone air and bone conduction audiometry. The psychoacoustic test battery will include loudness scaling (i.e., an alternative to loudness matching) and pitch matching. Finally, self-reports will be used to gauge everyday impacts of tinnitus. These procedures, as described and suggested by AAA, ASHA, and TRIM guidelines, are the most efficient and valid measures to establish a participant's auditory functionality, tinnitus characteristics, and the effect of each on quality of life.

Tinnitus Treatments

The focus of tinnitus treatment research has been on addressing subjective tinnitus (i.e., rather than objective tinnitus which might be medically treated). Tinnitus treatments for subjective tinnitus are intended for individuals with "clinically significant tinnitus". Again, several definitions have been offered for what constitutes clinically significant tinnitus. Tyler (2000) focused on the everyday impact of tinnitus and suggested that clinically significant tinnitus is either severe, constant, or unrelieved or a primary complaint that causes the patient to seek treatment. Henry et al. (2012) define clinically significant tinnitus as "tinnitus that disrupts at least one important life activity and/or causes emotional reactions, resulting in a noticeable

reduction in quality of life (p. 1029)." Other researchers characterize clinically significant tinnitus in terms of duration. Caffier et al. (2006) define clinically significant tinnitus as "an etiologically insignificant, nosologically complex symptom lasting more than 6 months." In contrast, some suggest that the timeframe extends minimally over several weeks (Henry et al., 2005). For the purpose of the present study, an individual suffering from clinically significant tinnitus has tinnitus that disrupts at least one important life activity and/or causes emotional reactions, resulting in a noticeable reduction in quality of life for at least one month.

Though there is not yet a cure for tinnitus, there are several tinnitus management options that are based on current neuroscientific models and theories of tinnitus. Positive outcomes have been reported for treatment options, such as sound therapies, electrical stimulation, and pharmaceuticals (Tyler et al., 2007). Of these three main treatment options, electrical stimulation and pharmaceuticals are mainly experimental and are not routinely used with tinnitus patients. Electrical stimulation and pharmaceutical treatments will not be further discussed as they are not components of the proposed study. Those interested in these forms of treatment may seek further information by examining works such as Aran et al. (1983), Hazell (1989), Brummett (1989), and Dobie (2004).

Sound therapy treatment options have included hearing aids, personal listening devices, sound generators, maskers, and music. While many of these sound therapy treatment options include a counseling component, one treatment, Progressive Audiological Tinnitus Management (Henry et al., 2009), focuses equal attention on both sound generators and counseling. That treatment option will be separately discussed. The main sound therapy treatment options will be discussed along with the rationale for use of a notched-acoustic stimulus as a tinnitus treatment option in the current study.

Tinnitus Retraining Therapy (Jastreboff, 1990, 2004, 2007)

Tinnitus Retraining Therapy (TRT) is a clinical treatment founded on the neurophysiological model of tinnitus (Eggermont, 2004). This treatment is based on three assumptions, the main one stating that multiple systems in the brain, including the auditory structures, must be involved in an individual's perception of tinnitus. According to this treatment model, the limbic system and the sympathetic portion of the autonomic nervous system are responsible for the negative feelings and emotions that a tinnitus patient may experience. These feelings and emotions include annoyance, anger, stress, and discomfort. A second tenet of TRT, suggested by Jastreboff and colleagues (1990, 2007), is that tinnitus is an auditory phantom sensation, comparable to the phantom limb sensation commonly reported by amputees. With respect to tinnitus, an individual perceives sound without a related acoustic stimulus in the environment. The third assumption in TRT is that tinnitus arises due to damage within the peripheral auditory system, specifically to the hair cells. The input to the central auditory pathway structures is altered due to discordant damage to the outer hair cells (OHC) and the inner hair cells (IHC). Theoretically, an imbalance of hair cell activity occurs because the normal balance of functional OHCs and IHCs along the basilar membrane no longer exists. Along the basilar membrane, there may be areas where only OHCs are damaged resulting in decreased inhibitory input to the auditory nerve and cochlear nuclei, resulting in a change in neurophysiologic function (e.g., hyperactive neural firing, increased neural synchrony).

Jastreboff and colleagues discuss how systems other than the auditory structures within the brain contribute to the perception and annoyance of tinnitus. They proposed the existence of an abnormal conditioned reflex arc that includes all of the systems involved in the generation of the tinnitus percept. The abnormal reflex arc is created when altered auditory input from the

periphery is relayed to the auditory cortex and associated links to the limbic system and the autonomic nervous system. The individual recognizes that the sound perceived is not from the listening environment and cannot be avoided or eliminated, resulting in negative reactions that the individual begins to experience every time the arc is stimulated. Saunders (2007) stated that damage to the peripheral system is a trigger for tinnitus and that attentional and emotional aspects of the disorder are produced by the non-sensory areas of the brain, corresponding to the explanation from Jastreboff (1990, 2007). The goal of TRT is to reduce the negative feelings and emotions, arising from the limbic and autonomic nervous system involvement.

There are two main components to TRT: counseling and sound therapy. The purpose of counseling is to help the patient reclassify tinnitus as a neutral or non-threatening percept. Counseling is utilized to help the patient think of his/her tinnitus in a non-threatening way. The goal of sound therapy is to decrease the strength of the abnormal neural activity that causes the tinnitus. Sound therapy in TRT uses sound generators that are tailored to a patient's personal tinnitus "mixing point," the point at which the tinnitus and the noise are both heard (i.e., the noise is not used to mask the tinnitus). The patient is encouraged to adjust the sound generator over time so that the mixing point is reached and the process of habituation occurs. According to Jastreboff and colleagues, habituation refers to the brain's capability to reverse and retrain any kind of conditioned reflex through proper techniques and plasticity. The individual would continue to perceive the tinnitus; however, the negative emotions would be reduced or eliminated.

Jastreboff and Jastreboff (2002) reported data on TRT for 303 individuals that suffered from tinnitus and had an initial THI score of at least 36 (i.e., at least a mildly perceived tinnitus handicap). After one month of TRT, the participant group showed a statistically significant

improvement on overall THI scores. There have been several studies that have examined long-term use of TRT. Long-term TRT studies (Jastreboff, 2007; Bartnik et al., 1999; Lux-Wellenhof and Hellweg, 2002) have found that THI scores continued to show significant improvement when compared to initial scores in a large percentage of patients' evaluated following continuous TRT use over 3 months, 12 months, 18 months, and 5 years.

Hearing Aids

Hearing aids have been found to provide several benefits to tinnitus patients. Hearing aids amplify environmental sounds and make the patient less aware of the tinnitus and may even mask the tinnitus sensation altogether (Henry and Schecter, 2005). Hearing aids not only improve communication for tinnitus sufferers with hearing loss but can reduce the annoyance of the distracting effect that tinnitus has on sounds and voices. Del Bo and Ambrosetti (2007) stated that from epidemiological studies, 50% of patients using a hearing aid as a form of tinnitus treatment experience a relief from negative emotions and reactions to tinnitus.

Hearing aids are helpful because they can restore auditory input and stimulate neural plasticity. By increasing the intensity of surrounding, ambient noise in a patient's environment, amplification may reduce or completely eliminate the difference between internal sound (tinnitus) and the reduced everyday sound levels associated with an individual's hearing loss. The tinnitus patient hears their tinnitus along with other amplified sounds. Over time, the tinnitus may become less noticeable and annoying. Hearing aid amplification can be used alone or in some hearing aids (i.e., combination units) the tinnitus sufferer may choose to use amplification or choose to listen to calming Zen tones and/or masking noises. The Widex hearing aid company uses the Zen program that emits calming tones to address the emotional state of the patient experiencing tinnitus. A second hearing aid company, Resound, uses a sound generator

approach to mask the tinnitus that a patient is experiencing. Another company, Phonak, reportedly offers some hearing aids that offer masking noises and combines the methods of tinnitus masking, TRT, and Progressive Tinnitus Management in the patient's tinnitus program.

There are individuals who are not typically candidates for hearing aids due to the less severe nature of their hearing loss but who suffer from tinnitus. In place of hearing aids, ear-level combination instruments may provide benefit to a patient suffering from tinnitus with a mild loss or normal hearing. For these individuals, combination instruments offer low-gain amplification and the capability of constant broadband noise or calming tones, which can prove to be highly therapeutic (Henry et al., 2009).

A study by Parazzini et al. (2011) compared the use of open ear hearing aids to the use of sound generators in individuals suffering from tinnitus with high frequency hearing loss. Each subject had a complete audiological evaluation including pure tone air and bone audiometry, tympanometry, minimum masking level measures, and distortion product otoacoustic emissions (DPOAEs). Structured interviews using visual-analog scales (VAS) were completed at baseline testing. The VAS ratings were obtained for the following: effect on life, tinnitus loudness, annoyance, percent of daytime tinnitus awareness, and percent of daytime for tinnitus annoyance using a nine-point scale. On that 9-point scale, 0 corresponded to least discomfort/impact and 9 represented greatest discomfort/impact. In addition, all subjects completed the THI at baseline. All subjects underwent TRT that included educational counseling sessions and sound therapy. The subjects were randomly assigned into the sound generator group or open-ear hearing aid group. The sound generator devices produced a wide band sound with the capability of adjusting the spectrum for the individual. All subjects received counseling sessions at 3, 6, and 12-month visits and were instructed to use the sound therapy device (i.e., sound generator or hearing aid)

for at least 8 hours a day. After 12 months of therapy, it was concluded that a statistically significant improvement was observed for all outcome measures in both groups. It was also demonstrated that TRT is equally effective with either sound generators or open-ear hearing aids. Researchers concluded that both of these devices can be used for effective tinnitus treatment.

A study by Searchfield et al. (2010) compared the THQ scores of individuals with tinnitus receiving counseling only and of individuals with tinnitus receiving both counseling and a hearing aid. One to two hours of counseling was offered to each subject and covered the hearing evaluation results, auditory physiology, tinnitus, and tinnitus management options. At the completion of the study, it was found that both groups showed improvement or reduced tinnitus handicap. However, a difference in THQ scores was found to be statistically significant only in the group receiving counseling and the hearing aid ($p < 0.0001$). The researchers concluded that those individuals with hearing loss in combination with tinnitus should strongly consider the use of amplification during a tinnitus management program.

Both studies show that the use of sound therapy through hearing aids is a beneficial option for tinnitus sufferers. Theoretically, amplification reduces the contrast between tinnitus and background neuronal activity and indirectly reduces an individual's stress by improving communication (Searchfield, 2010). It is important to note; however, that amplification in combination with counseling was found to be the most effective in the Searchfield et al. (2010) study.

Personal Listening Devices

Personal listening devices can provide a tinnitus patient with helpful sound therapy. These devices offer an inexpensive way that a patient can stimulate the auditory pathway and reduce the perception of tinnitus. Personal devices include CD players, tape players, iPods, and

MP3 players. Tabletop sound-generating devices are also helpful for everyday use, especially in work and home environments. Tabletop devices include CD players, radios, wave machines, and televisions that can be placed in a room where a patient spends time. For example, a radio can be placed in an office during work hours or a wave machine can play during sleep. These devices offer auditory stimulation to help the patient re-focus his/her attention to an environmental sound rather than the tinnitus.

Music therapy with personal listening devices has been used in combination with other therapies to treat tinnitus. Different types of music tailored for the patient are used to decrease stress levels and reduce the tinnitus perception. The Heidelberg Model of Music Therapy (HMMT; Argstatter et al., 2012) protocol is one of the most structured and evaluated treatments of this kind; however, there is limited data indicating its effectiveness (Jastreboff, 2007). The HMMT is a short-term treatment option for tinnitus sufferers that have been proven to reduce tinnitus symptoms in the short run. The treatment lasts for nine consecutive 50-minute sessions. In each session, the subject receives cognitive therapy counseling, resonance training, and Neuroauditive Cortex Training, in which a subject vocally imitates a sequence of tones played on a piano. After completion of the therapy, an effect size of d' = 0.89 was found for the improvement of tinnitus distress through a decrease in Mini-TQ scores (Argstatter et al., 2012).

Masking Therapy

Masking therapy devices have been utilized since the 1970s by Vernon. Tinnitus masking devices aim to eliminate an individual's tinnitus percept through the use of external sound (Jastreboff, M., 2007; Vernon and Schleuning, 1978; Schleuning et al., 1980). Many sound therapies in the past have included using a piano to match tinnitus frequency and playing the pitch until the level masked the tinnitus perception (Spaulding, 1903), portable machines that

introduced noise to mask tinnitus (Jones, 1928), and hearing aid devices used as maskers and sound generators (Vernon, 1977). Currently, sound therapy masking devices have been developed to be worn in a hearing aid case. Depending on the therapy model used, these devices can output a broadband noise or a narrowband noise centered on a patient's tinnitus pitch match.

Over the past 30 years, hearing aid-like masking devices have become a popular technique in tinnitus management. "Complete masking" was introduced by Coles in 1997 where a masking noise in a device is raised in intensity until an individual's tinnitus is inaudible. Other sound devices have included white noise generators and combination hearing aids and noise generators. White noise generators have been shown to achieve down-regulation, or "habituation of the disordered auditory perception" (Hobson and Chisholm, 2012). This can be done by introducing a low level of white noise that masks an individual's tinnitus. Down-regulation occurs during white noise generation due to the patient's inability to hear their tinnitus over the noise.

Sound enrichment has been suggested to be a benefit from sound therapy because the white noise generation acts as a source of stimulation to the central auditory system (Hobson and Chisholm, 2012). In individuals with hearing loss, the white noise theoretically helps to compensate for the loss of auditory stimulation within the cochlea. Many sound therapies and management programs will include listening to low-level white noise, instead of complete masking, on a regular basis to establish a masker level that is comfortable (Vernon, 2003).

Music Therapy

It is well known in literature that musical training has considerable effects on functional and structural human brain plasticity (Pantev and Herholz, 2011). Studies of music perception have investigated how the human brain functions and the relationship between perception,

cognition, emotion, and learning (Pantev et al., 2012). Pantev and colleagues state that the positive effects that music has on the brain shows its potential in neuro-rehabilitative treatments. Due to the cortical map's ability to change and reorganize itself based on experiences, or plasticity, musical plasticity has been utilized in tinnitus treatment. The current discussion will focus on three main types of tinnitus music treatment: 1) un-altered music (Newman et al. (2012), 2) spectrally shaped and phase altered music, and 3) notch-filtered music.

Un-altered Music Listening Therapy

Music therapy has become an accepted form of treatment for tinnitus sufferers over the years. It has been observed in human studies that sound therapy, including music, reduces an individual's perceived tinnitus handicap and suppression of tinnitus characteristics (i.e., loudness) (Newman and Sandridge, 2012; Vanneste et al., 2013). Not only does music therapy reduce a tinnitus sufferer's perception of their tinnitus, but also it can reduce stress and anxiety levels by providing an enjoyable listening environment (Pantev et al., 2012).

A study by Wazen and colleagues (2011) utilized a music therapy for the treatment of tinnitus. Those included in the study were fifty-two individuals that had chronic non-pulsatile tinnitus that lasted at least 6 months and had a pure tone average $\leq$ 50 Db. The study was divided into two stages: Stage 1 used a customized broadband sound embedded into music and lasted 2 months, Stage 2 removed the broadband signal and used music-only as a treatment that also lasted at least 2 months and continued for 24 months. Participant's perception of tinnitus was tracked over time using the Tinnitus Reaction Questionnaire (TRQ) and the Tinnitus Handicap Inventory (THI). Scores for each of these measurements were taken at 2, 4, 6, 12, and 24 months throughout the study. Researchers also developed an individualized treatment plan for each participant that included relaxation techniques, counseling, and daily exercise. After

treatment was complete, it was found that there was a statistically significant improvement in TRQ and THI scores at 2 months of modified music (Stage 1). Scores continued to improve over time and were also found to be statistically significant. Researchers concluded that the customized acoustical stimulus improved quality of life measures for the participants, but continued to show improvement with the use of un-altered music as well. At a 1-year follow-up, participants who continued the music-only treatment reported significant improvement in both TRQ (82% of participants) and THI (77% of participants) scores.

A recent study by Pantev et al. (2012) compared the use of unmodified music to modified music in chronic tinnitus sufferers over the course of one year. Chronic tinnitus was defined as an individual who experienced tinnitus greater than 12 months. Study participants were individuals with unilateral, tonal tinnitus below 8000 Hz and no severe hearing impairment, psychiatric, or neurological disorders. Each participant was randomly assigned to one of three groups: 1) unmodified music group 2) music group using the notched music treatment centered on the participant's tinnitus frequency 3) placebo group with notched music treatment not centered on the participant's tinnitus frequency. Pitch matches were recorded regularly over the course of the year and loudness matches were performed weekly. Magnetic cortical fields were measured with a 275-channel MEG system at the baseline and every six months of treatment. It was found that the notched music treatment group had significant reductions in both behavioral and physiological measurements at six and twelve months. The unmodified music group had reductions of behavioral and physiological measurements at twelve months of treatment; however, they were not significant. The placebo group did not show any significant reduction in either measurement over the course of the year. The tailor-made notched music treatment was

the only treatment to provide significant improvement in the perception of an individual's tinnitus perception

Neuromonics (Davis et al., 2008; Hanley et al., 2008)

The development of the Neuromonics Tinnitus Treatment was undertaken to overcome the practical limitations of previous sound therapy approaches (Davis et al., 2008). The goal is to provide acoustic stimulation that desensitizes a tinnitus sufferer's perception in an easy, customizable way. An individualized custom acoustic stimulus is created for a patient to stimulate the auditory pathways that have been deprived by hearing loss. The stimulus also provides a comforting listening environment to positively engage the limbic system and it allows momentary tinnitus perception within a relaxing environment to facilitate desensitization to the tinnitus percept.

The customizable acoustic stimulus aims to stimulate auditory pathways across a broad frequency range through the use of a broadband stimulus that is "spectrally contoured" for an individual's hearing profile (Davis et al., 2007). The stimulus is a broad-spectrum signal that is delivered to the auditory system at low listening levels. The researchers note that this is different from other broadband noise generators in the fact that general broadband noise generators actually only provide a narrow band of effective acoustic stimulation centered around 500 Hz to 2000 Hz. Because the customizable signal is determined separately for each ear, the researchers state that Neuromonics controls the phase of the music between the right and left channels to promote stimulation across the auditory pathways. This approach is not possible in noise generators, maskers, or hearing aids that have independent phase relations between the ears (Davis et al., 2007). The stimulus is presented in the context of relaxing music in order to foster

a strong relaxation response and to make the therapy pleasant in order to foster high levels of treatment compliance.

Clinical studies (Davis et al., 2007, 2008) have shown that in early stages of the Neuromonics Tinnitus Treatment, patients experience a strong sense of relief and control because the stimulation allows the patient to experience their tinnitus percept along with a pleasant listening experience. By allowing an individual to intermittently experience their tinnitus percept within the customized musical environment, the patient experiences momentary exposure to their tinnitus in repeated therapy sessions. This, in combination with a collaborative counseling program facilitates "systematic desensitization" to the tinnitus (Davis et al., 2007).

Several clinical studies have been performed to show the effects of the Neuromonics Tinnitus Treatment. A clinical study by Hanley et al. (2008) used 552 patients suffering from tinnitus for more than 6 months. Responses to their tinnitus were primarily tracked through the TRQ self-report on which the mean pre-treatment scores were found to correspond to moderate to severe levels of tinnitus disturbance. Patients were instructed to listen to their tailored music for at least two hours a day, particularly when their tinnitus was most disturbing. A two-phase study was completed. For the first two months of treatment, the patient was instructed to place the acoustic stimulation at a volume level that would cover up a large portion of the tinnitus percept. After the first two months, the second phase had patients use the stimulus in a manner that allowed the tinnitus to be covered or masked only during intensity peaks in the stimulus so that the tinnitus was heard more often. After the complete treatment, TRQ scores were measured again and a reduction in tinnitus disturbance was found to be statistically significant. A treatment success rate, defined as the proportion of patients who reported an improvement in tinnitus disturbance, was found to be 40%.

Though several studies have shown positive changes in patient's tinnitus perception following Neuromonics Tinnitus Treatment, there are limitations to this treatment approach. In the previously discussed study, an absence of a control group makes it difficult to measure the degree to which the reported improvements could have been related to a placebo effect, intervention effect, or other non-treatment-specific effects (Davis, et al., 2007). In many clinical studies of Neuromonics, many patients were paid for treatment participation, which could result in positive reported outcomes due to financial investment.

Notch-filtered music (Okamoto et al., 2011 and 2012; Pantev et al, 1999 and 2012; Teismann et al., 2011)

Several studies have examined the impact of notch-filtered music as a treatment for tinnitus. A few of the studies have focused on long-term treatment (Okamoto and colleagues, 2010; Pantev et al.; 2012). In contrast, a few of the studies have focused on shorter-term treatments. The following discussion will address the long-term studies prior to addressing the short-term studies.

In studies by Okamoto and colleagues (2010) and Pantev and colleagues (2012), tailor-made notched music therapy has been shown to improve the perception and reduce loudness of patient's tinnitus. In studies by Okamoto and colleagues (2011, 2012), tailor-made notched music therapy has been shown to improve the perception and reduce loudness of patient's tinnitus. In a 2012 study, 39 tinnitus patients participated in a tailor-made music treatment. Each participant had chronic unilateral tonal tinnitus for at least 12 months, tinnitus frequency match less than 8000 Hz, and no severe hearing loss or neurological complications. Each participant was randomly assigned to one of three groups: non-modified (i.e., unfiltered) music, modified-music or notched noise music, and a placebo group that listened to music with a

placebo modification. The music was chosen by the participant. The notch filtering condition excluded a one-octave range around the individual's tinnitus frequency match. Each participant listened to their music daily for one to two hours through circumaural headphones and at a comfortable listening level over the course of one year.

Over the study (Okamato et al., 2012) time frame, the tinnitus pitch was matched regularly (i.e., at least four times on two different days) and tinnitus loudness was measured weekly using a continuous visual analog scale ranging from 0 (no tinnitus) to 100 (extremely loud tinnitus). All measurements were performed in a research facility. The Tinnitus Questionnaire (Goebel and Hiller, 1994) was also used to track changes pre- and post-treatment after the 12 months. Magnetic cortical fields were measured using a 275-channel MEG system and a baseline measurement was completed before treatment and again at 6 months and 12 months. Auditory steady-state responses (ASSRs) were also recorded with two different sound stimuli (duration of 1-s, 0.3-s pure tone; 0.7-s 40 Hz amplitude-modulated tone) and were delivered randomly to either the left or the right ear. The frequency of one stimulus corresponded to a patient's tinnitus frequency, while the other stimulus had a frequency of 500 Hz. Both stimuli were matched to 45 Db sensation level. After 6 and 12 months of exposure, participants whose tailor-made music notched around their tinnitus frequency showed a significant decrease in the physiological responses (i.e., MEG amplitudes and ASSRs), tinnitus annoyance and tinnitus handicap. The placebo and control groups did not experience any significant effects in the above-mentioned variables over time. The researchers speculate that the tailor-made music treatment has "reattracted lateral inhibition into the hyperactive tinnitus neurons, which in turn reverses their maladaptive hyperactivity and/or hypersynchrony" (p. 257). They hypothesize that due to the reductions in the physiological and self-report measurements, a long-term neuroplastic

effect within the auditory cortex has taken place. The researchers note that music is an advantageous stimulus to utilize in tinnitus treatment. Music is a pleasant experience for the participant and elicits positive emotions and attention throughout the treatment. Music has become a popular medium in tinnitus treatment and will be applied in the current project.

A shorter term notched music treatment plan was studied by Teismann et al. (2011) where the same notched treatment was issued to tinnitus participants for five days. Twenty-four adults suffering from chronic (i.e., $\geq$ 3 months), tonal tinnitus and no severe hearing impairment were recruited. Participants were divided into two groups based on their tinnitus frequency: 1) those with tinnitus frequency $\leq$ 8000 Hz and 2) those with tinnitus frequency > 8000 Hz. Participants were informed of the two treatments they could receive (target music training or alternative music training) but did not know which treatment they would randomly be assigned. However, all participants received the tailor-made notch music treatment. All participants received six hours of modified music from a CD audio recording. The music was modified as mentioned above in the previous study, with one octave notched out of the music centered on the patient's tinnitus frequency match. Over the course of five days, the patient would listen to the music for three hours on days one and five and six hours on days two, three, and four. Self-report measurements included the Tinnitus Questionnaire (Hallam et al., 1988) shortly before treatment onset, shortly after treatment completion, and three days, 17 days, and 31 days after treatment. The subjective tinnitus loudness was evaluated 14 days before treatment and continuing daily until 31 days after treatment. Auditory evoked fields were measured using a 275-channel MEG system and were measured during the same sessions as the Tinnitus Questionnaire. The two tinnitus groups were compared before treatment onset and no significant differences were seen regarding age, tinnitus duration, general distress, and hearing loss.

Tinnitus Questionnaire scores and loudness status were also not significantly different. It was found for the tinnitus group with frequencies $\leq$ 8000 Hz that tinnitus loudness and MEG measurements were significantly reduced after 5 days of treatment. In fact, these measurements were reduced after 3 days of treatment as well as 17 days after treatment. There were no significant differences in any measurement performed over the course of the treatment time frame for the tinnitus group with frequencies > 8000 Hz. It is promising that this study found that a short-term treatment can significantly improve an individual's perception of tinnitus. The current proposed study also will focus on a short-term treatment plan over the course of three months and use outcome measures to assess change over time.

Pantev and colleagues (1999) sought to determine whether frequency representation within the auditory cortex changes after a few hours of deprived sensory input (i.e., by notch filtering). Ten subjects between the ages of 25-50 years with normal hearing were observed. Each participant listened to music manipulated in such a way that a notch between 0.7 and 1.3 kHz, centered around 1 kHz, was produced using a band rejection filter. The participants listened to the music continuously for 3 hours. Magnetoencephalography (MEG) measurements were taken before and after the 3-hour music session and were repeated consecutively over the next 2 days. MEG results showed that listening to the 1 kHz notched music modified the frequency tuning of neurons in the auditory cortex. The decrease of neural activity to the 1 kHz test stimulus was more pronounced on the second and third day of listening suggesting that there is a cumulative effect of continuous notched music listening. Overall, reorganization of cortical representations of the human auditory cortex can occur within time periods as short as a few hours following notched music treatment.

The results of each of these key studies support the use of a notched music stimulus for the treatment of tinnitus. The researchers note that music is an advantageous stimulus to utilize in tinnitus treatment. Music is a pleasant experience for the participant and elicits positive emotions and attention throughout the treatment. Music has become a popular medium in tinnitus treatment and will be applied in the current project. These studies not only show that music is a viable stimulus, but it also illustrates that significant effects can be seen even in a short-term treatment timeline.

While various tinnitus treatments, such as the notched music approach focus heavily on therapeutic listening, one recent approach offers an integrated program of counseling and sound therapy. That approach, Progressive Audiological Tinnitus Management (Henry et al., 2009), will be further discussed.

Progressive Audiological Tinnitus Management

Progressive Audiological Tinnitus Management (PATM) combines the use of counseling and sound therapy through a hierarchical management program for individuals suffering from tinnitus (Henry et al., 2009). A hierarchical, or level, approach was taken due to the individualistic nature of tinnitus symptoms. Five levels were established so that the range of needs is met for each individual suffering from tinnitus. While PATM was developed through the Veterans Administration, components of the approach (manuals and related materials) are available for use as or in a modified form: (http://www.ncrar.research.va.gov/education/documents/tinnitusdocuments/index.asp).

Level 1 is described as Triage and offers established guidelines to properly refer patients who present tinnitus as a symptom. This includes a medical referral to a primary care physician or otolaryngologist to evaluate and assess the symptom of tinnitus. Once medical clearance has

been given in Level 1, Level 2 includes an audiological hearing evaluation. Management options for hearing loss are discussed at this level and hearing aids are implemented if needed. Once an individual understands their hearing loss and management options have been presented, Tinnitus Management begins at Level 3. Level 3 introduces Group Education sessions. Group education focuses on providing educational and psychological counseling to a group of individuals suffering from tinnitus. Counseling is a key step in the progressive approach because it provides self-management strategies. If an individual still requires further help, Level 4 offers a Tinnitus Evaluation that includes an in-depth interview to determine if an individualized plan should be implemented. The final stage, Level 5, is the Individualized Plan where the patient and the audiologist create a specific program customized for their needs, which includes an individualized psychological session with a cognitive behavioral therapist for tinnitus management.

PATM emphasizes several aspects in the intervention approach to manage an individual's tinnitus. The PATM approach is closely modeled after clinical methodologies that are used to manage chronic pain (Henry et al., 2009). Biomedical treatments are becoming less utilized in favor of educational approaches that focus more on long-term rehabilitation. Self-management is an important factor in PATM because the individual is highly involved in the decision-making process. A shift in the responsibility from the audiologist to the patient of their daily management helps them to understand their condition, self-manage the impact tinnitus has on their daily life, and track the success of the plan as well as revise areas that were not successful.

PATM also includes sound therapy. Studies have shown that those individuals who use sound therapy devices obtain better results in tinnitus management than those without a sound component; however, studies have not identified one therapy to be more successful than others

(Henry et al., 2006). The focus of PATM and the patient education is to provide individuals with the knowledge and skills to use sound in adaptive ways to manage their tinnitus in any life situation disrupted by tinnitus (Henry et al., 2009). The educational counseling is provided in Level 3 Group Counseling and addresses the different types of treatment sounds as well as their uses. A patient can utilize speech, environmental sounds, or music as a soothing, background, or interesting sound on which to focus listening.

Cognitive behavioral counseling is another unique component to PATM. Depending on the severity of an individual's tinnitus perception, some patient's require additional psychological intervention to help manage their maladaptive reactions to tinnitus. Cognitive behavioral counseling addresses emotional difficulties by teaching the patient to attend to their core beliefs and habitual thoughts, or "self-talk" (Henry et al., 2009). Both educational and cognitive behavioral counseling are used in conjunction with sound therapy in the management of tinnitus. The goal of PATM is to help the individual alter their negative perception of tinnitus and take control of their progress through a daily management plan.

Several randomized clinical trials have been completed to study different tinnitus treatment programs prior to finalizing the PATM program (Henry et al., 2005). One such study evaluated the treatment methods for clinically significant tinnitus within the veteran population. Participants were 123 veterans who required long-term, individualized treatment for their tinnitus. Participants were quasi-randomly assigned to either a tinnitus masking treatment group or a TRT group for an 18-month period. Each participant completed the THI, Tinnitus Handicap Questionnaire (THQ), and the Tinnitus Severity Index (TSI) at various intervals: baseline, 3, 6, 12, and 18 months. Results showed that both treatment groups experienced comparable improvement through 6 months of treatment. The TRT group, however, showed a significantly

greater improvement at the 12- and 18-month visits compared to the masking group. This study helped the development of the PATM by concluding that TRT treatment is most effective with those individuals who have more severe difficulty with their tinnitus and that long-term treatment of 1-2 years may be necessary to achieve maximum benefit of therapy.

A second study serving as a precursor to development of the PATM focused on a randomized clinical trial to assess the benefit of group therapy for tinnitus participants. This study included twenty-five veterans with "clinically significant" tinnitus. Each participant was randomized into one of three groups: educational counseling, traditional support group and usual care (no treatment). The study utilized group sessions that each lasted for 1.5 hours. The TSI was completed at baseline, 1, 6, and 12 months following the group counseling sessions. Results concluded that the mean TSI scores for all 3 groups decreased at each monthly session and showed that the decreases were statistically significant. However, group educational intervention provided statistically greater benefit to participants than the traditional support group or the usual care treatment group. This study helped to support the expected benefits that participants might receive from the group counseling designed in Level 3 of the PATM program. While counseling is integrated within PATM, it should be noted once again that many tinnitus management approaches incorporate counseling in their programs.

Counseling

As noted, in addition to sound therapy, many tinnitus treatment programs also include counseling. This counseling may address information related to tinnitus (i.e., informational counseling) and how the patient reacts to and manages their thoughts toward their tinnitus (i.e., cognitive behavioral counseling). Many tinnitus treatments include sound therapy in conjunction with both informational and cognitive-behavioral counseling. A study by Newman and

Sandridge (2012) supported the benefit of tinnitus programs that included sound therapy with counseling. This study used counseling in combination with one of two sound therapy devices: 1) Sound generator, and 2) Neuromonics device. The THI was used to track changes in handicap before treatment and at the end of the six month treatment program. Twenty three participants were fit with a sound generator and completed counseling sessions throughout the six month treatment program and 33 participants were fit with a Neuromonics device and completed counseling sessions throughout the six month treatment program. All participants had hearing levels not requiring amplification and were not under the care of a psychiatrist or psychologist. It was found that significant changes were seen in handicap after the six months of treatment (i.e., sound generator with counseling and Neuromonics device with counseling). However, the mean post-fitting handicap scores reflected residual tinnitus handicap even after six months of treatment. The authors concluded that the continued use of the sound therapy along with intensive and ongoing counseling might be necessary for optimum treatment benefit. The THI and other tinnitus self-reports can be used to gauge the impact of tinnitus on the individual and may be used before and after treatments as an outcome measure. The following section presents information on tinnitus self-reports.

Tinnitus Self-Report Measures

In a treatment study, such as the one described herein, reliable and valid outcome measures are essential. According to Tye-Murray (2009), an outcome measure indicates the amount or type of benefit experienced by either an individual or a group of individuals to a treatment or series of treatments. A common type of outcome measure is a self-report questionnaire. Tinnitus questionnaires may address an array of important impacts of tinnitus, including sleep disturbance, nature of tinnitus, irritability, reduced quality of life, cognitive

difficulty, mental confusion, difficulty relaxing, and decrease in social activities, depression, and hearing difficulties. Tinnitus outcome measures are an important component of tinnitus management and allow the patient to fully describe tinnitus before and after treatment.

Use of reliable, valid and evidence-based questionnaires are essential for outcome measurement. Data-based measures can be used to follow changes in the patient throughout tinnitus management. An international consensus statement for tinnitus assessment developed by Langguth and colleagues (2006) discussed the importance of selecting from a small set of questionnaires and outcome measurements that offer reliability and validity data. They argued that use of a small set of data-based measures "would facilitate more effective cooperation and more meaningful evaluations and comparisons of outcomes across research centers and countries (p. 526)."

The consensus statement discussed above also emphasized several key factors in the development of standardized outcome measurements. A standardized measurement must take into account differences in culture, language, health care systems, existing databases and routines already established (Langguth et al., 2006). If a questionnaire is to be more universally applied, it must translate across cultures. The consensus team prioritized several key factors that should be assessed with each patient. Each factor was labeled as "essential," "highly recommended," or "might be of interest." One essential component to the agreed assessment standard was a validated outcome questionnaire for the description of areas of tinnitus handicap and indication of overall tinnitus severity. The consensus team listed the Tinnitus Handicap Inventory (THI; Newman et al., 1996), the Tinnitus Handicap Questionnaire (THQ; Kuk et al., 1990), the Tinnitus Retraining Questionnaire (TRQ; Wilson et al., 1991), and the Tinnitus Effects

Questionnaire (TEQ; Hallam et al., 1988) as the only validated assessments at the time of their review

Langguth et al. (2006) suggested the THI might be the preferred outcome tinnitus questionnaire because it is available and validated in most languages. According to Langguth et al., other important factors that may be assessed in individuals with tinnitus include depressive symptoms, anxiety, quality of life, insomnia, tinnitus loudness match, maskability, and an objective measure of brain function (e.g., MRI).

In an effort to foster the use of evidence-based questionnaires that reliably categorize the severity and negative impact of tinnitus, nine questionnaires have been identified as the most utilized among clinicians in the United States and represent features that differentiate the multifaceted perception of tinnitus (Meikle et al., 2007). These include the above mentioned TEQ, THQ, TRQ, and THI as well as the Tinnitus Severity Scale (TSS; Sweetow and Levy, 1990), the Subjective Tinnitus Severity Scale (STSS; Halford and Anderson, 1991), the Tinnitus Severity Grading (TSG; Coles et al., 1992), the Tinnitus Severity Index (TSI; Meikle, 1992; Meikle et al., 1995), and the Intake Interview for Tinnitus Retraining Therapy (IITRT; Jastreboff and Jastreboff, 1999). Though all of these questionnaires are considered to be widely used; only the *TEQ, THQ, TRQ*, and the *THI* will be discussed due to the fact that they offer reliability and validity data.

Tinnitus Effects Questionnaire (Hallam et al., 1988)

The Tinnitus Effects Questionnaire (TEQ) is a self-report measure that defines a patient's tinnitus-related distress. It should be noted that others in the literature refer to this questionnaire as the Tinnitus Questionnaire and not by the original name offered by Hallam et al. (1988). The TEQ was created through a two-phase study. Study one involved administration of a

questionnaire composed of 40 sentences that described the most commonly reported effects of tinnitus in the researchers' prior clinical interviews. A total of 79 subjects at a neuro-otology outpatient clinic were included in the study. The subjects all reported tinnitus unilaterally or bilaterally and had experienced tinnitus for over a year. Study participants responded by circling either "Yes," "Maybe/Sometimes," or "No" to questionnaire statements. Participant responses were examined using a factor analysis. The analysis of the first study's results produced three key factors. Emotional distress was a factor composed of items indicating anxious or depressed mood and associated thoughts. The second and third factors were sleep disturbance and auditory perceptual difficulties. The authors concluded from study one that items related to emotional distress are relatively independent of items indicating difficulties of a sensory and perceptual nature (i.e., auditory perceptual difficulties).

Study two replicated the first study using an improved questionnaire based on findings from study one. The response choices were changed to "True," "Partly true," and "Not true." The new questionnaire included 51 items that included all items related to the first three factors from study one. New items were added and included emotional responses such as resentment, irritability, and anger in order to broaden the category of emotional responses. A total of 100 patients complaining of unilateral or bilateral tinnitus for over a year were included in study two. The data was analyzed as it was in study one using a factor analysis. The same three factors were found in study two as in study one. One can consider these factors as representing three possible subscales within the TEQ. Upon inspection of the items within these factors or subscales, it appears that items within Factor 2 actually indicate difficulties with distraction and not simply items related to sleep.

The researchers concluded that there were three main aspects of complaint related to an individual's tinnitus, including emotional distress, sleep disturbance, and auditory perceptual difficulties. Emotional effects, particularly depression, anger, irritability, and anxiety, were found to have a relationship with how an individual "resents" the persistence of the noise, the inescapability, and the worry that it causes in relation to health and sanity. It was concluded that insomnia and auditory perceptual difficulties are not related to beliefs about tinnitus.

Hiller and Goebel (2004) created the Mini-TQ, which includes 12 items from the full TEQ. On the Mini-TQ, the three response categories are the same and there are 4 items related to sleep and distraction and 8 items related to emotional distress. The main purpose for the Mini-TQ is to allow for more rapid assessment of tinnitus effects.

Tinnitus Handicap Questionnaire (Kuk et al., 1990)

The Tinnitus Handicap Questionnaire (*THQ)* was developed to measure a tinnitus patient's perceived degree of tinnitus handicap. Kuk and colleagues (1990) created the questionnaire through a two-phase study. Phase one was used to generate an efficient tool with a limited number of items to be included in the final draft questionnaire, while phase two focused on the psychometric properties of the final questionnaire. During phase one, 87 items were selected from a report of difficulties that tinnitus sufferers experience (Tyler and Baker, 1983). The 87 items consisted of statements related to the effects of tinnitus on hearing, lifestyle, health, the emotion of the sufferers, and "other" miscellaneous topics. The respondents were asked to read each statement and rate their level of agreement with the statement by offering a number from "0" to "100" with "0" representing "strongly disagree" and "100" representing "strongly agree." The 87-item questionnaire was administered to 100 adult patients who stated they were experiencing tinnitus at the time of their evaluation at the Department of Otolaryngology of the

University of Iowa Hospitals and Clinics. Patients included those who reported that tinnitus was their primary complaint or a secondary complaint to hearing loss. Three criteria were used to select specific items from phase one for inclusion in the final questionnaire. Items were eliminated if they were insensitive to differences among participants. For example, a count of the proportion of times a rating was given to an item was performed and items that were assigned the same rating over 50% of the time were removed. Potentially redundant items were examined through use of correlation coefficients of items within subscales. Items that shared high inter-correlations were compared against one another and only one item was then selected for use on the final questionnaire. Examination of item-total correlation coefficients was utilized to further eliminate items. Only items with high item-total correlation coefficients were selected, resulting in a 27-item questionnaire. In order to determine the internal reliability of the 27-item scale, Cronbach's alpha was calculated and found to be .93.

In Phase two, the 27-item questionnaire was administered to 275 tinnitus patients who reported tinnitus during a hearing evaluation. These patients were sampled from otolaryngology offices in Iowa, the House Ear Institute, the Iowa City VA Medical Center, the UNC Hospitals and Clinics, and the University of Iowa Hospitals and Clinics. The participants used the same instructions and rating scale as during phase one.

Overall, results from the phase one and two studies indicated that the *THQ* has a high internal consistency reliability that was assessed through Cronbach's alpha and the item-total correlation coefficients. The questionnaire has good construct validity as evidenced by the moderately high correlation coefficients for items within the subsections of the THQ: i.e., life satisfaction, depression, general health status, and perceived tinnitus loudness.

Two versions of the THQ are available on line at: http://www.medicine.uiowa.edu/oto/research/tinnitus/questionnairres/ and each simply represents a different ordering of the items. The online description states that the THQ items fall within three designated subscales. The three subscales are 1) Physical, social, emotional, and behavioral effects of tinnitus, 2) Tinnitus and Hearing, and 3) Outlook on Tinnitus.

Tinnitus Reaction Questionnaire (Wilson et al., 1991)

The TRQ was designed to focus on psychological distress associated with tinnitus. The 26 items were chosen based on the clinical experience of the researchers, review of patient case histories, and the tinnitus difficulties included in the Tyler and Baker (1983) publication. Each item on the TRQ is a statement and respondents are asked to, "Please answer each question as you think it applied to you over the past week. Please ensure that you answer each question by circling the number that best reflects how your tinnitus has affected you over the past week." Response ratings for each item are made on a 5-point scale with the labels "not at all," "a little of the time," "some of the time," "a good deal of the time," and "almost all of the time." Scoring of the *TRQ* is based on addition of the ratings across items with total scores potentially ranging from 0 to 104. On the TRQ, a higher score represents a patient with greater distress.

The TRQ was administered to three population samples (Wilson et al., 1991). Sample one included 37 patients referred by the audiology department of a large hospital and who showed an interest in participating in a tinnitus therapy study. Sample two included 69 referrals for hearing assessment of the audiology department of a veteran's hospital. Sample three contained 50 subjects who responded to a radio advertisement on tinnitus and who volunteered for the study.

Each sample population completed the TRQ with different combinations of other self-report questionnaires. Sample one completed the TRQ along with the Bendig-Taylor version of the Taylor-Manifest Anxiety Scale (Bendig, 1956) and the Neuroticism subscale of the Eysenck Personality Questionnaire (Eysenck and Eysenck, 1975). Samples two and three completed the TRQ, the Beck Depression Inventory (Beck et al., 1961), and the Spielberger State-Trait Anxiety Inventory (Spielberger et al., 1970). Each sample population also had a different administration setting. Participants from samples one and two were administered the questionnaires in individual sessions with a psychologist. Participants in sample three were administered the TRQ twice as part of a hearing assessment through an audiology clinic. For sample three participants, the initial set of questionnaires was sent through the mail and a second administration of the questionnaire set was completed during the hearing evaluation in the clinic. Despite the combinations of different questionnaires and administration settings, it was found that the TRQ has a very high internal consistency reliability (Cronbach's alpha of .96) and a high test-retest reliability correlation of .88 with a retest period at 3 weeks. This data shows that the TRQ is a reliable instrument to use in the assessment of tinnitus. The TRQ, which includes sections on depression and anxiety, was also found to have moderately high correlations with the psychological measures of depression and anxiety. A factor analysis of TRQ results indicated four factors, which were labeled, general distress, interference (with work and leisure), severity (of distress), and avoidance (of activities). However, many items in the factor analysis loaded on more than one factor, making it difficult to argue for defining separate subscales. Thus, one could argue for only computing the total score when using this questionnaire. Though the TRQ questionnaire addresses a variety of areas, the impact of tinnitus on the patient's quality of life, hearing, and health are not addressed.

Tinnitus Handicap Inventory (Newman et al., 1996)

Newman and colleagues (1996) developed the Tinnitus Handicap Inventory (*THI)* through a standardization study with two investigation phases. The first investigation phase involved selection of 45 items based on review of tinnitus patient case histories and already-existing hearing and dizziness scales and symptom scales. The initial 45-item questionnaire was administered to 84 patients in audiology clinics in tertiary care centers at two locations. Each patient included in the study stated that tinnitus was either a primary complaint or a secondary complaint to hearing loss. The patient was instructed to circle "yes," "sometimes," or "no" when responding to each item. The scoring for the questionnaire awards four points to a "yes" response, two points to a "sometimes" response, and zero points to a "no" response. When examining the data from the study, questions that resulted in the same answer in the population sampled were eliminated due to the lack of discrimination among the sample population. Cronbach's alpha was used to determine the internal consistency reliability of the 45-item questionnaire and those items with an alpha coefficient of 0.50 or less were removed. Based on content validity, response distribution, and item correlations, the 25-item *THI* was created.

The 25-item THI contains statements within the following three subscales: 1) functional, 2) emotional, and 3) catastrophic. The functional subscale reflects role limitations in the areas of mental, social, occupational, and physical functioning. The emotional subscale items represent a broad range of affective responses to tinnitus, including anger, frustration, depression, and irritability. The catastrophic subscale defines a patient's desperation, inability to escape the tinnitus, perception of having a terrible disease, lack of control, and an inability to cope. Total scores on the THI range from 0 to 100 points, where higher scores represent a greater degree of

tinnitus handicap. The presence of subscales also may allow practitioners and researchers to examine tinnitus treatment effects in different areas.

The second investigation phase on the THI included 66 subjects at the same locations used in the first investigation. In the second investigation, the THI results were compared to results of several other questionnaires and scales. These other measures included the *THQ,* the Beck Depressive Inventory, Modified Somatic Perception Questionnaire (Main, 1983), and symptom severity rating scales (i.e., 0 to 100) of annoyance, sleep, depression, concentration, loudness and pitch. Convergent validity was evaluated between the THI and the THQ by correlating scores and a strong positive correlation of r = .78 was obtained. This suggests that the *THI* is comparable to the THQ in its measurement of the dimensions of an individual's perception of tinnitus handicap. An advantage of the *THI* is that it is brief, utilizes a simple response format, and has easy scoring and interpretation for clinical use. However, weak correlations were found when comparing scores on the THI and the Beck Depression Inventory, Modified Somatic Perception Questionnaire, and the pitch and loudness perception ratings. The researchers suggest that this may have been due in part to the fact that more of the population sample reported their tinnitus as a secondary complaint rather than a primary complaint.

Tinnitus Questionnaires Selected for Use in the Current Study

When examining the possible questionnaires for use in the current study, the THI was chosen for consideration. The THI is a widely used scale and offers subscales that allow one to examine the differential impact of tinnitus treatment in different areas. Two other non-traditional tinnitus self-reports were also selected for use and are discussed further.

Limitations of Traditional Tinnitus Questionnaires as Outcome Measures

There are two main limitations when using the THI and other traditional questionnaires when examining tinnitus treatment effects. First, the questionnaires were not developed to demonstrate treatment changes. Additionally, there is minimal data on treatment effect sizes for these questionnaires. For these reasons, a newer tool, the Tinnitus Functional Index (TFI) (Meikle et al., 2012), were included in the current study.

The Tinnitus Functional Index (TFI) (Meikle et al., 2012), was specifically designed and validated as a tool for measuring changes in tinnitus handicap and is sensitive to treatment changes. An Item Selection Panel made up of seventeen expert judges surveyed content of 9 widely used tinnitus questionnaires. The Panel identified thirteen domains of tinnitus distress and chose 70 items that would most likely be responsive to treatment effects. A second round of investigation eliminated redundant items but kept those that had good content validity. Other items were added to have 3 to 4 items per domain. After this round, 43 items were then used for the TFI Prototype 1. This Prototype was tested at 5 clinics and included 326 participants receiving tinnitus treatment. Content validity was measured by looking at the responsiveness of the overall scale and individual items after 3 and 6 months of treatment. The thirty best-functioning items were selected, creating TFI Prototype 2. This Prototype was tested at 4 clinics with 347 participants receiving treatment and was re-evaluated at 3 and 6 months. Finally, twenty-five items were selected for the final TFI. Both prototypes showed strong measurement properties, high validity for scaling of tinnitus severity, good test-retest reliability (0.78.), and strong convergent validity (r=0.86 with the THI). The final TFI focuses on 8 domains of tinnitus: intrusiveness, sense of control, cognitive factors, sleep, auditory ability, relaxation, quality of life, and emotional hindrances.

A second main limitation of standardized tinnitus self-reports is that they may not include the specific and individualized issues or goals of the individual with tinnitus. If that is true, then views on those issues most important to the patient may not be formally documented, addressed or measured pre or post tinnitus therapy (Cox et al., 2000). Tye-Murray (2009) suggests that a modified version of the Client Oriented Scale of Improvement (COSI; Dillon, James, and Ginis, 1997), typically used for hearing aid outcomes, might be used to obtain patient-specific issues/goals before and after aural rehabilitation programs. On a modified COSI, an individual is asked to generate up to 5 issues or problems that s/he would like to improve with treatment (e.g., sleep disturbance, distraction while communicating). Each of those issues/problems is individually rated following the treatment using two scales. The patient rates improvement by the degree of change. The response options available include: worse, no difference, slightly better, better, and much better. In addition, the patient rates his/her final (residual) ability related to the amount of time the difficulty is still experienced. Response options include: hardly ever, 10%; occasionally, 25%; half the time, 50%; most of the time, 75%; and almost always, 95%. The goal is to determine relative benefit by examining the degree of change and final ability. An example of the Modified COSI is found in Appendix C.

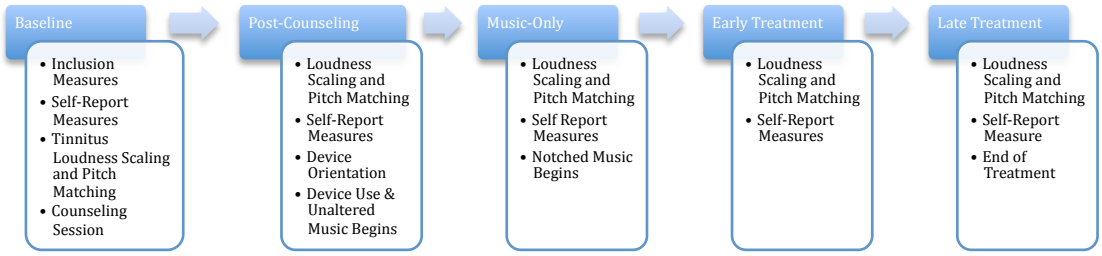
Rationale for Study and Research Questions

There is promising data on notched filtered music treatment for tinnitus (Okamoto et al., 2010; Pantev et al., 2011; Pantev et al., 2012; Teismann et al., 2011). The current study seeks to explore counseling benefit prior to initiation of notched music treatment, and a shorter timeframe for the notched filtered music treatment with a more extensive self-report test battery and daily pitch matching, loudness scaling and annoyance scaling to examine for changes in everyday life. In addition, this study differs in that participants were not required to undertake the treatment

within a research facility but were able to complete the treatment in their daily lives. Finally, the current study contrasts the notched filtered music treatment with unaltered music treatment, which has also been found to be of benefit (Newman et al., 2012).

The basic layout of the study includes two phases: unaltered music and notched music listening. The following schematic (Figure 1) overviews the time course of the evaluation sessions at the research center and the home treatments.

Figure 1.



After a preliminary session involving inclusionary measures (i.e., audiometric and tinnitus measures), participants were offered a counseling session on tinnitus. One week later, participants returned for tinnitus self-report measures, audiometric tinnitus pitch matching and loudness scaling, and orientation to the device and their treatment regimen. Following that session, the daily device pitch matching, loudness scaling, annoyance scaling and the unaltered music treatment was initiated. At session 3, loudness scaling, pitch patching and self-report measures were completed and the device was then switched to notched music. Participants were not advised in the change to the music. At sessions 4 and 5, participants returned to the research

center to complete audiometric pitch matching, loudness scaling and the self-report measures. The notched music treatment was discontinued after session 5.

The following research questions were posed:

1. Are there significant changes in self-reported tinnitus across the 5 research sessions (i.e., to gauge the effects of counseling, unaltered music, and notched music on total and subscale scores for each measure?
2. Are there significant changes in tinnitus loudness scaling, annoyance scaling, or tinnitus pitch matches over the course of treatment (as measured across research sessions and across daily at-home sessions)?
3. Are at-home device pitch matches (Hz) and clinic audiometric pitch matches (Hz) from corresponding weeks related?
4. Are at-home device and clinic loudness scaling ratings and annoyance scaling ratings from corresponding weeks related?

CHAPTER 2

METHODOLOGY

This study was approved by the East Carolina University Medical Institutional Review Board (#14-000265).

Recruitment

Twelve participants were recruited and enrolled in this study from the surrounding community through flyers, informational talks, newspaper, and word-of-mouth. All participants signed an informed consent as well as a HIPAA privacy notice document.

Inclusion Criteria

The following inclusion criteria were used in this study:

1. All participants must be between the ages of 18-65 years during the enrollment period.
2. All participants must report English as their first language.
3. All participants must have normal outer ear and middle ear function and a sensorineural hearing loss as determined using the measures stated below.
    a. Both ears were visually inspected by otoscopy to identify risk factors for outer and middle ear disease. Using a lighted hand-held otoscope, both ears were visually inspected to rule out "ear canal abnormalities such as obstructions, impacted cerumen or foreign objects, blood or other secretions, stenosis or atresia, otitis externa, and perforations or other abnormalities of the tympanic membrane" (ASHA, 1997, p. 344). Individuals were excluded from the study if abnormalities were observed and where appropriate, were referred to a medical professional. There is a high inter-examiner reliability for trained professionals in regards to

otoscopic examination with agreement ranging from 73% to 100% for identifying certain otoscopic signs including: drainage, tympanic membrane color, appearance, and position; presence of liquid; presence of perforation; collapsed ear canal; debris in ear canal; and vascularity (Nondahl, Cruickshanks, Wiley, Tweed, Klein, and Klein, 1996). In addition to the visual examination, the researcher listened to rule out audible tinnitus (i.e., objective tinnitus) during otoscopic inspection of each ear.

b. Using the Grason-Stadler Tympstar Middle Ear Analyzer (calibrated to ANSI S3.39, 2007), tympanometry was performed on both ears with a low frequency (226 Hz) probe tone. Tympanometric results, including static acoustic admittance, tympanometric width, and ear canal volume were analyzed. Participants were excluded if clinically significant tympanometry findings (Wiley et al., 1996) suggesting possible middle ear dysfunction were observed in either ear including:
    i. Static acoustic admittance <0.2 mmhos or >1.5 mmhos;
    ii. Tympanometric width <35 daPa or >125 daPa;
    iii. Ear canal volume <.9 cm^3 or >2.0 cm^3.
c. Air-conduction and bone conduction pure tone thresholds were measured using a GSI audiometer (either a GSI-61 or AudioStar Pro) calibrated to ANSI S3.6-2004 standards in a double-walled sound attenuated booth. Air-conduction pure tone thresholds were measured for the left and right ears with Etymotic 3A insert earphones. Audiological threshold measures were determined using the method as outlined in ASHA guidelines (2005). Octave frequencies from 250-8000 Hz

including the inter-octaves of 3000 and 6000 Hz were assessed. A 1000 Hz threshold reliability check was also completed to ensure the second threshold measure was within 10 Db of the original threshold measure at this frequency. Bone-conduction pure tone thresholds were obtained using a B-71 bone vibrator at the following frequencies: 500, 1000, 2000, and 4000 Hz. When needed (i.e., air bone gap >10 Db), contralateral masking was used to confirm the type of hearing loss. Participants with two or more unresolved air bone gaps of >10 Db in either ear were excluded from the study. Participants with asymmetric hearing loss (i.e., differences in air conduction thresholds between the ears of 15 Db or greater at two or more tested frequencies) were also excluded (ASHA Audiology Information Series, 2011). Those with conductive, mixed, and asymmetrical hearing losses were referred to an ear-nose-throat physician.

4. Participants must be non-hearing aid users at the time of enrollment.
5. Participants must not have objective tinnitus (i.e., tinnitus heard by the examiner during otoscopy) or somatic tinnitus (i.e., sounds that might be associated with vascular, muscular, skeletal, respiratory or TMJ as determined by case history questions in Appendix D and must have clinically significant tinnitus that is confirmed by the following statement:
    a. "My tinnitus has affected one or more of my life situations, emotions, occupational goals and/or personal relationships for a period of at least one month (i.e., based on Henry et al., 2010)."
6. Participants must not have any self-reported neurological or psychiatric problems as determined by case history questions in Appendix D.

7. Participants must not have participated in a formal tinnitus treatment program in the past. This would not exclude those who had previously tried hearing aids or those who use sound generators at home.

   Those excluded from the study were offered an informational sheet with professional care providers who might offer assistance with tinnitus.

Those meeting inclusionary criteria completed a modified tinnitus case history form (See Appendix D), tinnitus pitch matching and loudness scaling (See Appendices E for protocols), and tinnitus self-reports (See Appendices F, G, and C for the THI, TFI, Modified COSI, respectively). They were then offered a break of approximately 30 minutes followed by a counseling session. Each of these components will be described.

Modified Tinnitus Case History Form

An abbreviated version of a tinnitus intake form, the Tinnitus Sample Case History Questionnaire, described by Langguth et al. (2007) was be used. (See Appendix D). The intake was completed in a private and confidential room within the department of Communication Sciences and Disorders at East Carolina University.

Tinnitus Pitch Matching

Prior to pitch and loudness matching, the researcher reviewed the meanings of the terms "pitch" and "loudness" with the participant so that s/he understood what s/he was being asked to match. Pitch and loudness matching was completed on the GSI AudioStar Pro Two-Channel Clinical Audiometer because that audiometer allows for use of frequencies above 8000 Hz. Those individuals with bilateral tinnitus were asked to use the ear that was most bothersome when matching the pitch and loudness of their tinnitus.

The first objective of tinnitus matching is to identify the frequency of a pure tone that is

closest to a patient's perceived tinnitus pitch (Henry et al., 2005). A general description of pitch matching is offered while the specific protocol can be found in Appendix A. Using an audiometer; a frequency is presented that is lower in pitch than the patient's perceived tinnitus pitch. Once the initial frequency (i.e., 1000 Hz) has been presented, different frequencies are presented by octaves to gradually approach the frequency identified as the tinnitus pitch. Each time a frequency is presented, the clinician asks: "Is the tinnitus higher pitched or lower pitched than the tone?" Once an octave has been identified, inter-octave frequencies are presented above and below the chosen octave to specify the perceived pitch. The pitch-matched tone is then compared to octave frequencies above and below so that "octave confusion" has not occurred (Henry et al., 2005). Meikle et al., (2004) stated that 90% of individuals choose a frequency above 2000 Hz or higher as a final pitch match.

Loudness and Annoyance Scaling

Tinnitus loudness and annoyance scaling procedures offer two means for gauging an individual's tinnitus and how it affects quality of life. When tinnitus loudness is scaled an individual offers a number to express how he perceives the amplitude of his tinnitus (e.g., on a scale of 0 to 100). When annoyance is scaled, the respondent indicates how intrusive tinnitus is in daily life. Loudness and annoyance are commonly performed psychoacoustic outcome measurements to track changes in tinnitus perception over time. Typically, tinnitus scaling measures include the use of visual analog scales, or number scales that range from a low score (0) to a high number score (100). In the current study, a visual analog scale was used for tinnitus loudness and tinnitus annoyance.

Use of VAS

The current study will utilize visual analog scales housed on the iPad Tinnitus Player application to measure the loudness and annoyance of a participant's tinnitus. Each scale was the same, with a bar representing a number scale ranging from 0 ("None) to 100 ("Extreme"). The participant received these instructions:

"Look at the tinnitus loudness/annoyance scale and rate the loudness of the tinnitus in your tinnitus rating ear (i.e., ear with most bothersome tinnitus). Choose the place along the scale that best describes your tinnitus loudness/annoyance." (See Appendix E).

Each participant was asked to complete tinnitus loudness and annoyance ratings 5 days out of the week and at each face-to-face research session.

Self-Report Measures

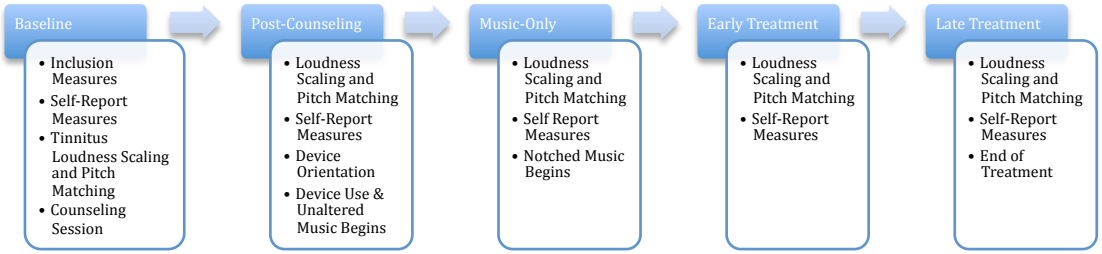
The following three self-report measures were used: 1) 25-item Tinnitus Handicap Inventory (Newman et al., 1996), 2) 25-item Tinnitus Functional Index (Henry et al., 2011) and 3) 5-item Modified Client-Oriented Scale of Improvement (Dillon, James, and Ginis, 1997). (See Appendices C, F, and G for Self-Report Measures). Each of the self-reports were administered face-to-face as a paper and pencil assessment in a private and confidential room within the department of Communication Sciences and Disorders. Prior to each self-report, the formal instructions were reviewed and the researcher was present throughout in case questions arose.

Counseling Session

Those meeting inclusionary criteria and wishing to participate were offered a 30-minute break. After the break, they completed a 45-minute information session on tinnitus using a PowerPoint presentation. (See Appendix H for PowerPoint Presentation). The counseling session included information on the auditory system, types of hearing loss, medical causes of

tinnitus, theories behind tinnitus generation, and management options including stress management, hearing aids, sound generators, and music therapy. Following counseling, participants were scheduled to return in one week for a follow-up tinnitus session.

Follow-up Research Sessions



During the initial follow-up session, the test battery included readministration of the self-reports and the audiometric tinnitus loudness scaling and pitch matching. The estimated time for completing this second evaluation and orientation session was no more than two hours. Then participants were offered an orientation to the iPad device and treatment program (i.e., formal orientation document in Appendix I).

The music therapy was administered on Apple iPads (generation 1 or 2) that were offered to the participants for use during the study. A software application designed for the music therapy, "Tinnitus Player" (Hulsey, 200X), was uploaded by the researcher onto the iPad. Insert earphones were provided for each participant. The earphones used were Sony MDR-EX10LPs with a frequency response from 8 – 22,000 Hz to ensure that the music and notched-filter

reached the participant's tinnitus range. The participant was allowed to keep the earphones after the treatment was concluded.

The music application included a daily measurement of each participant's tinnitus pitch, loudness scaling, and annoyance scaling results that were recorded and sent through an encrypted email to a private database. Once these measurements were completed, the participant selected his iTunes player and a personal music playlist stored in the Apple device. During the notched-music treatment phase, the application automatically notched an octave centered at the participant's original pitch match (i.e., research session 1) out of the playlist music.

All participants were asked to listen to the music treatment for 1.5 hours a day for five days a week. The music session could be broken up into multiple sessions throughout the day to reach the total of 1.5 hours. The application housed a timer to allow participants to track their music session time each day. Participants were scheduled to return for the same follow-up test battery at sessions 3, 4, and 5. The study concluded at Session 5. At that time, participants were advised as to any future studies in which they might participate.

CHAPTER 3

RESULTS

In the sections below, demographic information on participants is first offered, followed by information addressing each of the research questions. The research questions were related to measures completed during five research sessions (i.e., self-reports, pitch matching, loudness scaling) at the university and at-home daily measures (i.e., pitch matching, loudness scaling, annoyance scaling). The five research sessions at the university were designated as Session 1 Baseline, Session 2 Post-Post-Counseling (i.e., session after the Post-Counseling program), Session 3 Music Only (i.e., session after unaltered music), Session 4 Early Notched Noise Treatment (session after early weeks of treatment), and Session 5 Late Notched Noise Treatment (session after final weeks of treatment). After Session 2, participants also completed daily at-home measures of pitch matching, loudness scaling and annoyance scaling with that data also presented below.

Demographics

Of the ten adult participants completing the study, 7 were male and 3 were female with an age range of 40-63 years. With regards to tinnitus perception, 4 reported tinnitus worse in the right ear, 2 worse in the left ear, 3 equal in both ears, and 1 reported "elsewhere" (i.e., above the head). All participants reported that English was their first language. All participants reported that the tinnitus manifests itself as a constant perception. None of the participants wore hearing aids or had ever participated in a formal tinnitus treatment program in the past. 5 participants reported that the tinnitus onset occurred after a loud blast of sound, 4 reported that the tinnitus

onset occurred due to another factor (i.e., "gradual onset of hearing loss" and "Unsure"), and 1 reported that the tinnitus onset occurred due to stress.

Research Question 1

Research question 1 addressed whether there were significant changes in self-reported tinnitus across research sessions for the total and subscale scores for the three self-reports. Both self-report total scores and subscale scores (i.e., for self-reports with subscales) were examined and analyzed. The following sections offer descriptive statistics for each of the self-reports and subscales along with repeated Measures ANOVAs to determine changes in scores across research sessions.

Tinnitus Handicap Index (THI)

On the THI, the total self-report score is obtained by adding the ratings for the 25 items. The total scores for the THI self-report were determined for each participant at each session. These scores can range from 0 to 100, with 0 representing the least amount of tinnitus handicap and 100 representing a catastrophic tinnitus handicap. Table 1 presents the group data with mean THI scores, minimum and maximum scores, and the standard deviations and variances for the scores at each session. The boxplot in Figure 2 below displays the mean scores, the 25th and 75th percentile, and the outliers.

Table 1: THI Mean Scores, Standard Deviations, Variances, and Range of Scores across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
Session 1	38.0	20.2	408.0	12	82
Session 2	33.8	18.3	334.6	10	66
Session 3	30.4	22.0	482.5	4	78
Session 4	25.0	22.7	516.7	2	80
Session 5	19.0	21.2	448.2	0	74

THI Total scores across Research Sessions

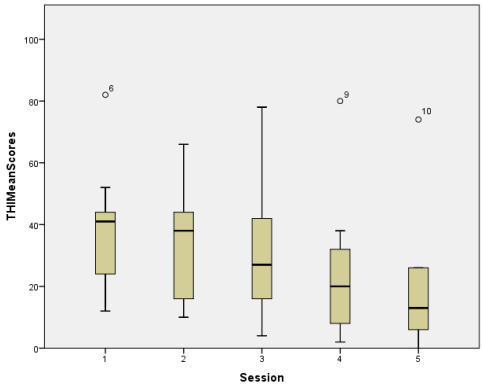


Figure 2: There was a significant difference in Mean THI total scores across research sessions (p = .001). Baseline session 1 and Post-Counseling session 2 had similar means. Music Only session 3, Early Treatment session 4, and Late Treatment session 5 had significantly different means.

Mauchly's test of sphericity (see Appendix J) was performed to analyze if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's Test indicated that the assumption of sphericity was violated; therefore, the df was corrected further using the Greenhouse-Geisser estimate of epsilon.

A repeated measures ANOVA was performed on the total scores for the THI across research sessions 1 through 5. There was a significant difference across sessions ($F = 22.6$, $df = 1$, $p = .001$). Follow-up pairwise comparison testing using the least-significant difference (LSD) method was used to determine which session scores were significantly different from one another. The Baseline THI scores were significantly different from those of the Music Only ($p = .017$), Early Notched Noise Treatment ($p = .006$), and Late Notched Noise Treatment ($p = .003$). The THI scores for Post-Counseling were significantly different from those of the Late Notched Noise Treatment session only ($p = .033$). The Music Only THI scores were significantly different from the THI scores of Baseline ($p = .017$) and the Late Notched Noise Treatment session ($p = .042$). The THI scores for the Early Notched Noise Treatment session were only

significantly different from the Baseline session (p = .006). Finally, the THI total scores for the Late Notched Noise Treatment session were significantly different from the Baseline (p = .003), Post-Counseling (p = .033), and Music Only sessions (p = .042).

Tinnitus Functional Index (TFI) Total Scores

The total score on the TFI is obtained by summing the participant ratings across the 25 items. Scores can range from 0 to 300 with 0 representing a low tinnitus severity perception and 300 representing a high tinnitus severity perception. Table 2 presents the mean of the total TFI scores for the group across research sessions as well as the minimum and maximum scores, standard deviations and variances of those scores for each session. Figure 3 presents the mean TFI scores across research sessions using a boxplot to display the mean scores, the 25th and 75th percentile, and the outliers.

Table 2: TFI Mean Scores, Standard Deviations, Variances, and Range of Scores across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
Session 1	119.5	52.8	2790.5	49	238
Session 2	121.2	53.0	2810.6	29	212
Session 3	108.2	52.0	2694.2	30	200
Session 4	92.1	59.5	3542.8	25	218
Session 5	77.3	56.5	3191.6	20	218

TFI Total scores across Research Sessions

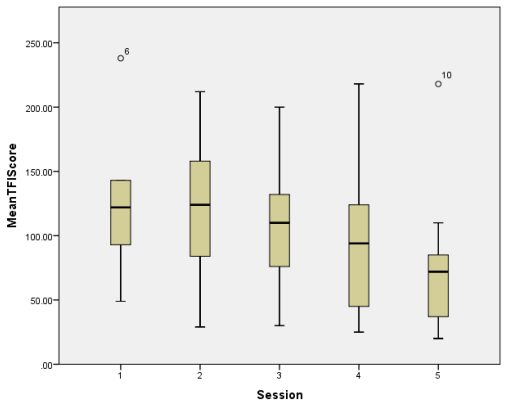


Figure 3: There was a significant difference between mean TFI total scores across Research Sessions ($p \leq .001$). Baseline session 1 and Post-Counseling session 2 had similar means. Early Treatment session 4, and Late Treatment session 5 had significantly different means from Baseline session1.

Mauchly's test of sphericity (see Appendix K) was performed to analyze if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's Test indicated that the assumption of sphericity was violated; therefore, the df was corrected further using the Greenhouse-Geisser estimate of epsilon.

A repeated measures ANOVA was performed on the total scores for the TFI across research sessions 1 through 5. There was a significant difference across sessions ($F = 40.3$, $df = 1$, $p \leq .001$). Follow-up pairwise comparison testing using the LSD method was used to determine which session scores were significantly different from one another. The Baseline session TFI scores were significantly different from those of both the Early Notched Noise Treatment ($p = .016$) and the Late Notched Noise Treatment sessions ($p = .002$). The TFI scores from the Post-Counseling session were significantly different from the Music Only session ($p = .038$), Early Notched Noise Treatment session ($p = .018$), and the Late Notched Noise Treatment session ($p = .006$). The TFI scores from the Music Only session was significantly different from the Post-Counseling session ($p = .038$) and the Late Notched Noise Treatment session ($p = .019$). The TFI scores from the Early Notched Noise Treatment session were significantly different from the Baseline ($p = .016$) and Post-Counseling sessions ($p = .018$). Finally, the TFI scores from the Late Notched Noise Treatment session were significantly different from the Baseline ($p = .002$), Post-Counseling ($p = .006$), and Music Only sessions ($p = .019$).

TFI Intrusiveness Subscale Score

The TFI Intrusiveness Subscale score is determined by summing the scaled responses of the 3 items on that subscale. Those scale ratings can range from 0 to 10 with 0 representing

"Never Aware" or "Not at All Strong or Loud" and 10 representing "Always Aware" or "Extremely Strong or Loud". The total score for the subscale items is then divided by the total number of questions and multiplied by 10 to make each score a percentage. Table 3 presents the mean TFI Intrusiveness subscale percentage scores across research sessions as well as the minimum and maximum subscale percentage scores and the standard deviation and variance of those scores for each session. Figure 4 presents the mean TFI Intrusiveness subscale scores over research sessions using a boxplot to display the mean scores, the 25th and 75th percentile, and the outliers.

Table 3: TFI Intrusiveness Mean Scores, Standard Deviations, Variances, and Range of Scores across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
Intrusiveness 1	68.6	18.8	353.7	30	90
Intrusiveness 2	71	17.2	296.4	46.7	100
Intrusiveness 3	59.7	19.6	383.5	30	93.3
Intrusiveness 4	53.3	25.4	646.8	13.3	93.3
Intrusiveness 5	44.7	25.1	632.4	6.7	93.3

TFI Intrusiveness subscale scores across Research Sessions

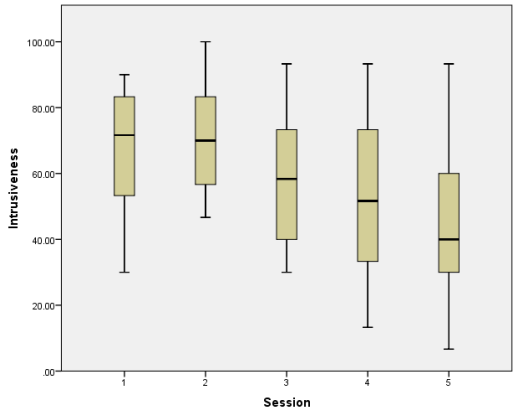


Figure 4: There was a significant difference between mean TFI Intrusiveness subscale scores across Research Sessions ($p \leq .001$). Baseline session 1 and Post-Counseling session 2 had similar means. Music Only session 3, Early Treatment session 4, and Late Treatment session 5 had significantly different means than the first 2 sessions.

Mauchly's test of sphericity (see Appendix L) was performed to analyze if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's Test indicated that the assumption of sphericity was violated; therefore, the df was corrected further using the Greenhouse-Geisser estimate of epsilon.

A repeated measures ANOVA was performed on the total subscale scores for the TFI Intrusiveness subscale across sessions 1 through 5. There was a significant difference across sessions ($F = 106.3$, $df = 1$, $p \leq .001$). Follow-up pairwise comparison testing using the LSD method was used to determine which session scores were significantly different from one another. The Baseline session TFI Intrusiveness subscale scores were significantly different from the Late Notched Noise Treatment session only ($p = .008$). The TFI Intrusiveness scores for the Post-Counseling session were significantly different from the Music Only session ($p = .016$), Early Notched Noise Treatment session ($p = .005$), and Late Notched Noise Treatment session ($p = .003$). The TFI Intrusiveness scores for the Music Only session were significantly different from the Post-Counseling session ($p = .016$) and the Late Notched Noise Treatment session ($p = .036$). The scores for the Early Notched Noise Treatment session were significantly different from the Post-Counseling session only ($p = 005$). Finally, the scores from the Late Notched Noise Treatment session were significantly different from the Baseline ($p = .008$), Post-Counseling ($p = .003$), and Music Only sessions ($p = .036$).

TFI Sense of Control Subscale Scores

The TFI Sense of Control subscale scores were obtained by summing the scaled responses from the 3 items on the subscale. These subscale ratings range from 0 to 10 with 0 representing "Very Much in Control" or "Very Easy to Cope" and 10 representing "Never in Control" or "Impossible to Cope." The total score for the subscale items is then divided by the

total number of questions and multiplied by 10 to make each score a percentage. Table 4 presents the mean TFI Sense of Control subscale percentage scores across research sessions as well as the minimum and maximum subscale percentage scores and standard deviation and variance of those scores for each session. Figure 5 presents the mean TFI Sense of Control (SC) subscale percentage scores over research sessions using a boxplot to display the mean scores, the 25th and 75th percentile, and the outliers.

Table 4: TFI Sense of Control Mean Subscale Scores, Standard Deviations, Variances, and Range of Scores across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
SC 1	59.7	20	401.4	30	90
SC 2	64.3	16	256.9	36.7	86.7
SC 3	57	21.9	477.7	16.7	83.3
SC 4	46.3	25.1	628.5	13.3	86.7
SC 5	44.3	22.1	489.2	10	86.7

TFI Sense of Control subscale scores across Research Sessions

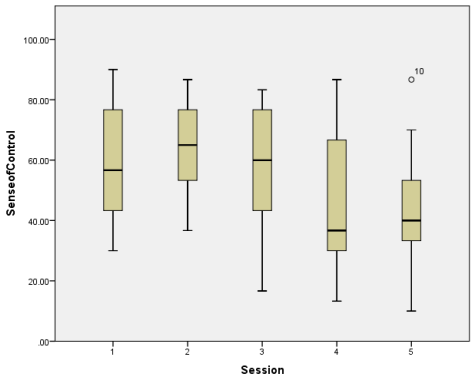


Figure 5: There was a significant difference between mean TFI Sense of Control subscale scores across Research Sessions ($p \leq .001$). Baseline session 1, Post-Counseling session 2, and Music Only session 3 had similar means. Early Treatment session 4 and Late Treatment session 5 had significantly different means than sessions 2 and 3.

Mauchly's test of sphericity (see Appendix M) was performed to analyze if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's

Test indicated that the assumption of sphericity was violated; therefore, the df was corrected further using the Greenhouse-Geisser estimate of epsilon.

A repeated measures ANOVA was performed on the total subscale scores for the TFI Sense of Control subscale across sessions 1 through 5. There was a significant difference across sessions ($F = 91.6$, $df = 1$, $p \leq .001$). Follow-up pairwise comparison testing using the LSD method was used to determine which session scores were significantly different from one another. The Baseline session TFI Sense of Control (SC) subscale scores were not significantly different from the scores of any of the other sessions. The SC subscale scores for the Post-Counseling session were significantly different from those of the Early Notched Noise Treatment session ($p = .008$) and Late Notched Noise Treatment session only ($p = .012$). The SC subscale scores for the Music Only session were significantly different from those of the Early Notched Noise Treatment session ($p = .05$) and the Late Notched Noise Treatment session ($p = .0043$). The SC subscale scores for the Early Notched Noise Treatment session were significantly different from those of the Post-Counseling session ($p = .008$) and the Music Only session ($p = .05$). Finally, the SC scores of the Late Notched Noise Treatment session were significantly different from those of the Post-Counseling ($p = .012$) and Music Only sessions ($p = .043$).

TFI Cognitive Subscale Scores

The TFI Cognitive Subscale scores were obtained by summing the 10 scaled responses from that subscale. The subscale ratings can range from 0 to 10 with 0 representing "Did Not Interfere" and 10 representing "Completely Interfered." The total score for the subscale items is then divided by the total number of questions and multiplied by 10 to make each score a percentage. Table 5 presents the mean TFI Cognitive I subscale percentage scores over research sessions as well as the minimum and maximum subscale percentage scores and the standard

deviations and variances of scores for each session. Figure 6 presents the mean TFI Cognitive subscale percentage scores over research sessions using a boxplot to display the mean scores, the 25th and 75th percentiles, and the outliers.

Table 5: TFI Cognitive Mean Subscale Scores, Standard Deviations, Variances, and Range of Scores across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
C1	33.3	26.9	725.2	0	93.3
C2	45	31.8	1013.1	0	100
C3	39.3	27.8	774.7	0	70
C4	29.3	28.5	811.9	0	90
C5	25.6	29.1	844.9	0	86.7

TFI Cognitive subscale scores across Research Sessions

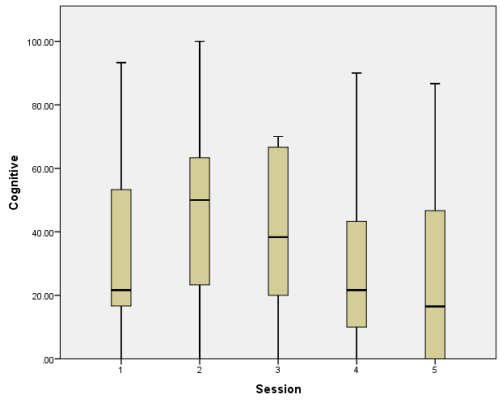


Figure 6: There was a significant difference between mean TFI Cognitive subscale scores across Research Sessions ($p \leq .001$). Baseline session 1 and Post-Counseling session 2 were significantly different with mean scores increasing after the Post-Counseling session. Early Treatment session 4 and Late Treatment session 5 had significantly different means from Post-Counseling session 2.

Mauchly's test of sphericity (see Appendix N) was performed to analyze if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's Test indicated that the assumption of sphericity was violated; therefore, the df was corrected further using the Greenhouse-Geisser estimate of epsilon.

A repeated measures ANOVA was performed on the total subscale scores for the TFI Cognitive subscale across sessions 1 through 5. There was a significant difference across sessions ($F = 16.9$, $df = 1$, $p \leq .001$). Follow-up pairwise comparison testing using the LSD method was used to determine which session scores were significantly different from one another. The Baseline session TFI Cognitive subscale scores were not significantly different from those of any of the other sessions. The TFI Cognitive scores for the Post-Counseling session were significantly different from the Early Notched Noise Treatment session ($p = .010$) and Late Notched Noise Treatment session only ($p = .016$). The Cognitive scores for the Music Only session were not significantly different from those of any of the other sessions. Finally, the TFI Cognitive scores of the Early Notched Noise Treatment ($p = .010$) and Late Notched Noise Treatment sessions ($p = .016$) were significantly different from those of the Post-Counseling session only.

TFI Sleep Subscale Scores

The TFI Sleep Subscale scores are determined by summing the scaled responses to the 3 items on that subscale. Ratings can range from 0 to 10 with 0 representing "Never had Diffculty" or "None of the Time" and 10 representing "Always had Difficulty" or "All of the Time." The total score for the subscale items is then divided by the total number of questions and multiplied by 10 to make each score a percentage. Table 6 presents the mean TFI Sleep subscale percentage scores over research sessions as well as the minimum and maximum subscale percentage scores and the standard deviations and variances of those scores for each session. Figure 7 presents the mean TFI Sleep (S) subscale percentage scores over research sessions using a boxplot to display the mean scores, the 25^{th} and 75^{th} percentiles, and the outliers

Table 6: TFI Sleep Mean Subscale Scores, Standard Deviations, Variances, and Range of Scores across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
S 1	45.3	28.1	790.9	0	90
S 2	52.7	30.2	910.3	0	100
S 3	41	24	573.2	6.7	76.7
S 4	35	30.1	948.1	0	93.3
S 5	35.3	33.5	1123.9	0	96.7

TFI Sleep subscale scores across Research Sessions

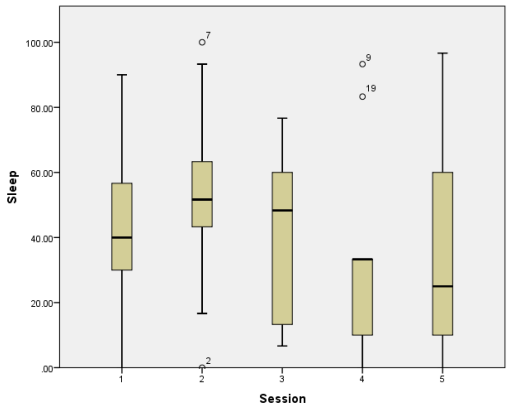


Figure 7: There was a significant difference between mean TFI Sleep percentage subscale scores across Research Sessions ($p = .001$). Baseline session 1 and Post-Counseling session 2 were significantly different with mean scores increasing after the Post-Counseling session. Music Only session 3 was not significantly different from Baseline Session 1 or Post-Counseling Session 3. Early Treatment session 4 and Late Treatment session 5 had significantly different means than the Post-Counseling session 2.

Mauchly's test of sphericity (see Appendix O) was performed to analyze if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's Test indicated that the assumption of sphericity was violated; therefore, the df was corrected further using the Greenhouse-Geisser estimate of epsilon.

A repeated measures ANOVA was performed on the total subscale scores for the TFI Sleep subscale across sessions 1 through 5. There was a significant difference across sessions ($F = 23.6$, $df = 1$, $p = .001$). Follow-up pairwise comparison testing using the LSD method was used

to determine which session scores were significantly different from one another. The Baseline session TFI Sleep subscale scores were significantly different from those of the Post-Counseling session only (p = .017). The TFI Sleep scores of the Post-Counseling session were significantly different from all sessions (p = .017, p = .044), p = .013, p = .023). The Sleep scores of the Music Only session (p = .044), Early (p = .013), and Late Notched Noise Treatment sessions (p = .023) were significantly different from only those of the Post-Counseling session.

TFI Auditory Subscale Scores

The TFI Auditory Subscale score is calculated by summing the scaled responses of the 3 items on this subcale. Ratings on this subscale range from 0 to 10 with 0 representing "Did Not Interfere" and 10 representin "Completely Interefered." The total score for the subscale items is then divided by the total number of questions and multiplied by 10 to make each score a percentage. Table 7 presents the mean TFI Auditory subscale percentage scores over research sessions as well as the minimum and maximum subscale percentage scores and standard deviation and variance of those scores for each session. Figure 8 presents the mean TFI Auditory (A) subscale percentage scores over research sessions using a boxplot to display the mean scores, the 25th and 75th percentiles, and the outliers.

Table 7: TFI Auditory Mean Subscale Scores, Standard Deviations, Variances, and Range of Scores across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
A 1	56.3	28.2	796.4	3.3	96.7
A 2	50	33	1086.1	0	100
A 3	49	36	1301	0	100
A 4	39.3	31.5	994.6	0	86.7
A 5	35	32.4	1047.6	0	100

TFI Auditory subscale scores across Research Sessions

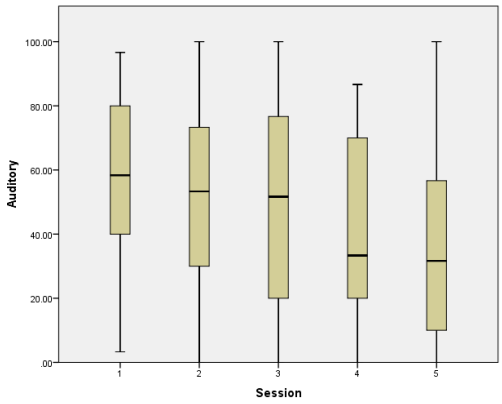


Figure 8: There was a significant difference between mean TFI Auditory percentage subscale scores across Research Sessions (p = .001). Baseline session 1, Post-Counseling session 2, and Music Only session 3 were not significantly different. Early Treatment session 4 and Late Treatment session 5 had significantly different means than the Baseline session1.

Mauchly's test of sphericity (see Appendix P) was performed to analyze if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's Test indicated that the assumption of sphericity was violated; therefore, the df was corrected further using the Greenhouse-Geisser estimate of epsilon.

A repeated measures ANOVA was performed on the total subscale scores for the TFI Auditory subscale across sessions 1 through 5. There was a significant difference across sessions (F =23.3, df = 1, p = .001). Follow-up pairwise comparison testing using the LSD method was used to determine which session scores were significantly different from one another. The Baseline session TFI Auditory subscale scores were significantly different from the TFI Auditory scores from the Early (p = .038) and Late Notched Noise Treatment sessions (p = .004). The TFI Auditory scores from the Post-Counseling session and the Music Only sessions were not significantly different from any other sessions (i.e., Baseline, Early and Late Notched Noise Treatment Sessions). The TFI Auditory scores from the Early (p = .038) and Late

Notched Noise Treatment sessions (p = .004) were significantly different from the Baseline session only.

TFI Relaxation Subscale Scores

The TFI Relaxation Subscale Scores were calculated by summing the scaled responses from the 3 items on this suscale. Ratings can range from 0 to 10 with 0 representing "Did Not Interfere" and 10 representing "Completely Interfered." The total score for the subscale items is then divided by the total number of questions and multiplied by 10 to make each score a percentage. Table 8 presents the mean TFI Relaxation subscale percentage scores across research sessions as well as the minimum and maximum subscale percentage scores and the standard deviation and variances of those scores for each session. Figure 9 presents the mean TFI Relaxation I subscale scores over research sessions using a boxplot to display the mean scores, the 25th and 75th percentiles, and the outliers.

Table 8: TFI Relaxation Mean Subscale Scores, Standard Deviations, Variances, and Range of Scores across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
R 1	60	27.5	754.5	13.3	100
R 2	65.6	31.2	973.1	13.3	100
R 3	53.3	25.3	642.2	10	86.7
R 4	48.8	34.8	1210.4	1.3	93.3
R 5	36.3	28.2	793.6	6.7	86.7

TFI Relaxation subscale scores across Research Sessions

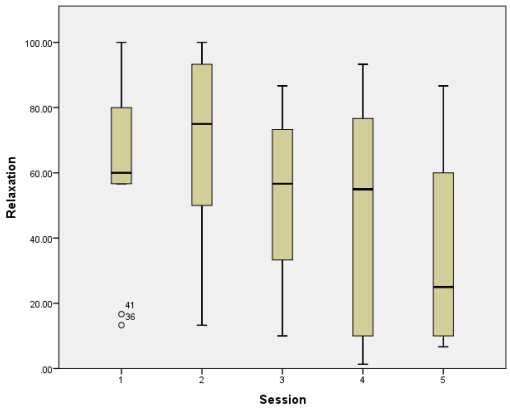


Figure 9: There was a significant difference between mean TFI Relaxation percentage subscale scores across Research Sessions ($p \leq .001$). Baseline session 1 and Post-Counseling session 2 were significantly different with Post-Counseling mean scores increasing after Baseline session 1. Music Only session 3 and Early Treatment session 4 were not significantly different. Late Treatment session 5 had significantly different means than Baseline session1, Post-Counseling session 2, and Music Only session 3.

Mauchly's test of sphericity (see Appendix Q) was performed to if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's Test indicated that the assumption of sphericity was violated; therefore, the df was corrected further using the Greenhouse-Geisser estimate of epsilon.

A repeated measures ANOVA was performed on the total subscale scores for the TFI Relaxation subscale across sessions 1 through 5. There was a significant difference across sessions ($F = 38.8$, $df = 1$, $p \leq .001$). Follow-up pairwise comparison testing using the LSD method was used to determine which session scores were significantly different from one another. The Baseline session TFI Relaxation I subscale scores were significantly different from the Late Notched Noise Treatment session only ($p = .010$). The Relaxation scores from the Post-Counseling session were significantly different from the Music Only ($p = .032$), Early Notched Noise Treatment ($p = .004$), and Late Notched Noise Treatment sessions ($p = .004$). The

Relaxation scores from the Music Only session were significantly different from those of the Post-Counseling ($p = .032$) and the Late Notched Noise Treatment sessions ($p = .027$). The Relaxation scores of the Early Notched Noise Treatment session were significantly different from those of the Post-Counseling session only ($p = .004$). Finally, the Relaxation scores for the Late Notched Noise Treatment session were significantly different from the Baseline session ($p = .010$), Post-Counseling session ($p = .004$), and Music Only session ($p = .027$).

TFI Quality of Life Subscale Scores

The TFI Quality of Life subscale scores were calculated by summing the scaled responses for the 4 items on the subscale. Ratings can range from 0 to 10 with 0 representing "Did Not Interfere" or "Never had Difficulty" and 10 representing "Completely Interfered" or "Always had Difficulty." The total score for the subscale items is then divided by the total number of questions and multiplied by 10 to make each score a percentage. Table 9 presents the mean TFI Quality of Life subscale percentage scores across research sessions as well as the minimum and maximum subscale percentage scores and the standard deviation and variance for those scores for each session. Figure 10 presents the mean TFI Quality of Life (QL) subscale scores over research sessions using a boxplot to display the mean scores, the 25^{th} and 75^{th} percentiles, and the outliers.

Table 9: TFI Quality of Life Mean Subscale Scores, Standard Deviations, Variances, and Range of Scores across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
QL 1	32.2	28.5	809.7	0	100
QL 2	28.6	27	730.8	0	77.5
QL 3	30	24.8	716.7	0	65
QL 4	22.5	25.1	631.9	0	80
QL 5	16.5	23.9	569.7	0	80

TFI Quality of Life mean subscale scores across Research Sessions

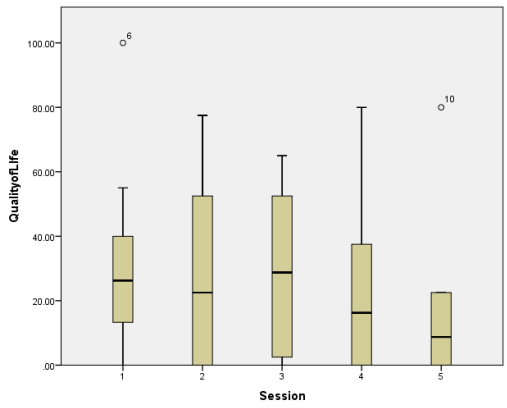


Figure 10: There was not a significant difference between mean TFI Quality of Life percentage subscale scores across Research Sessions. Baseline session 1, Post-Counseling session 2, and Music Only session 3, Early Treatment session 4, and Late Treatment session 5 were not significantly different.

Mauchly's test of sphericity (see Appendix R) was performed to analyze if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's Test indicated that the assumption of sphericity was violated; therefore, the df was corrected further using the Greenhouse-Geisser estimate of epsilon. The Greenhouse-Geisser estimate; however, was not significant because there were no between-subject factors and therefore, homogeneity tests or pairwise comparisons were not performed.

TFI Emotional Subscale Scores

The TFI Emotional Subscale score was calculated by summing the scaled responses of the 3 items on the subscale. Ratings range from 0 to 10 with 0 representing "Not at all Anxious or Worried," "Not at all Bothered or Upset," or "Not at all Depressed" and 10 representing "Extremely Anxious or Worried," Extremely Bothered or Upset," or "Extremely Depressed." The total score for the subscale items is then divided by the total number of questions and multiplied by 10 to make each score a percentage. Table 10 presents the mean TFI Emotional

subscale percentage scores across research sessions as well as the minimum and maximum subscale percentage scores and the standard deviation and variance of those scores for each session. Figure 11 presents the mean TFI Emotional I subscale percentage scores across research sessions using a boxplot to display the mean scores, the 25th and 75th percentiles, and the outliers.

Table 10: TFI Emotional Mean Subscale Scores, Standard Deviations, Variances, and Range of Scores across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
E 1	31.3	31.1	966.1	0	100
E 2	20.3	21.2	450	0	53.3
E 3	21.3	24.1	582.9	0	70
E 4	25	26.1	679.8	0	76.7
E 5	14.3	23.2	538.6	0	70

TFI Emotional subscale scores across Research Sessions

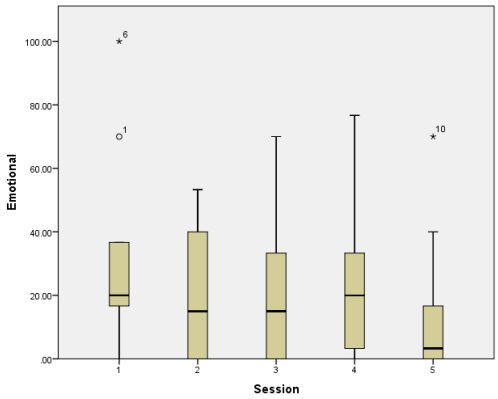


Figure 11: There was a significant difference between mean TFI Emotional percentage subscale scores across Research Sessions ($p \leq .001$). Baseline session 1 was significantly different from the Late Treatment session 5.

Mauchly's test of sphericity (see Appendix S) was performed to analyze if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's Test

indicated that the assumption of sphericity was violated; therefore, the df was corrected further using the Greenhouse-Geisser estimate of epsilon.

A repeated measures ANOVA was performed on the total subscale scores for the TFI Emotional subscale across sessions 1 through 5. There was a significant difference across sessions ($F = 11.3$, $df = 1$, $p \leq .001$). Follow-up pairwise comparison testing using the LSD method was used to determine which session scores were significantly different from one another. The Baseline session TFI Emotional subscale scores were significantly different from those of the Late Notched Noise Treatment session only ($p = 034$). The TFI Emotional scores from the Post-Counseling session were not significantly different from any other session (i.e., Baseline, Early Notched Noise Treatment or Late Notched Noise Treatment). The Emotional scores for the Music Only session were significantly different from those of the Late Notched Noise Treatment session only ($p = .016$). The Emotional scores for the Early Notched Noise Treatment session were not significantly different from those of any other sessions. Finally, the Emotional scores from the Late Notched Noise Treatment session were significantly different from the Baseline session ($p = .034$) and the Music Only session ($p = .016$).

Modified Client-Oriented Scale of Improvement (Modified COSI)

During the Baseline Session, each participant was asked to generate up to 5 tinnitus-related problems or concerns on the Modified COSI that s/he hoped would improve through the course of the study. Thus, each problem represents a goal for improvement. Table 11 below offers each of the 20 Modified COSI goals (i.e., problems that each participant wished to improve) that were generated across the entire group of ten participants and indicates how many participants offered each of these goals.

Table 11: Participant generated goals and the number of participants reporting each goal

Problem-Related Goals	Total Number of Participants Reporting
Reduce Tinnitus Loudness	4
Reduce of Awareness of Tinnitus	2
Reduce emotional stress	2
Reduce tinnitus to allow better hearing of conversations	5
Improve Concentration	2
Bring back my energy	1
Improve Sleep	8
Improve Quality of Life	1
Decrease fear of shooting/noise exposure	1
Reduce need for TV on high volume	1
Be able to work without background tinnitus	1
Eliminate tinnitus during regular daily activities	1
Hear "normal" outside noise during a walk instead of tinnitus	1
Reduce tinnitus while listening to music	1
Reduce tinnitus while lecturing	1
Eliminate the possibility of having to leave work	1
Reduce feeling of imbalance	1
Improve understanding of voices on TV	1
Understand conversations while on the phone	1
Reduce the annoyance of tinnitus	1
TOTAL	**37**

The most common goals generated by participants involved the reduction of tinnitus loudness, reduction of noise to assist in overall better hearing of conversations, and improvement in sleep. Again, each participant generated his/her problems during Session 1. Then s/he was asked to rate the degree of change in severity of each of these problems (i.e., "Worse" or 1," "No Difference" or 2, "Slightly Better" or 3, "Better" or 4, or "Much Better" or 5) and the occurrence of each problem (i.e., "Hardly Ever" or 1, "Occasionally" or 2," "Half the Time" or 3, "Most of the Time" or 4, or "Almost Always" or 5) during all other research sessions (i.e., 2-5).

For each session, the severity and occurrence ratings across all participants were averaged. Figure 12 below offers a cluster bar graph to show changes in the averaged change in

problem severity across sessions. The values on the X-Axis indicate the Research Sessions. The values on the Y-Axis indicate the mean Change in Severity with 1 indicating the problem is getting worse, 2 indicating the problem is no different, 3 indicating the problem is slightly better, 4 indicating the problem is better, and 5 indicating the problem is getting much better (i.e., relates to the scale indicators mentioned above). Each bar represents the generated goal of each participant.

Average Modified COSI Severity Ratings across Research Sessions

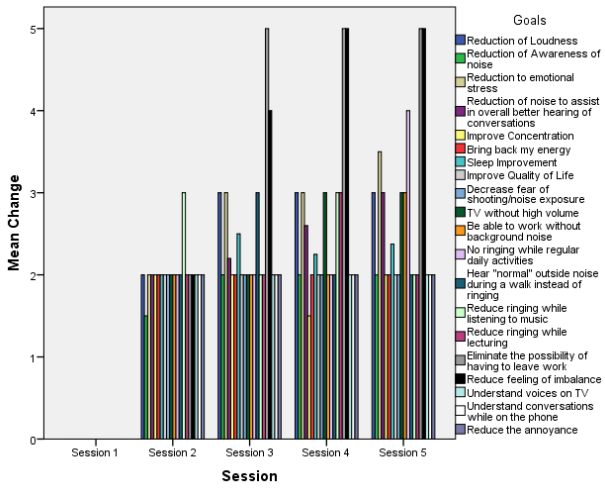


Figure 12: The bars representing "No Difference" (i.e., rating of 2) in the Change in Severity of goals were maintained across Research sessions for many participants. Several problems became "Slightly Better" across Research sessions and a few problems became "Better" and "Much Better" across research sessions.

Figure 13 below offers a cluster bar graph to show changes in the Occurrence of the problem across sessions. The values on the X-Axis indicate the Research Sessions. The values on the Y-Axis indicate the mean Occurrence with 1 representing the Occurrence of the problem hardly ever occurs and 5 representing the Occurrence of the problem is "Almost Always. Each bar represents the generated goal of each participant.

Average Modified COSI Occurrence Ratings across Research Sessions

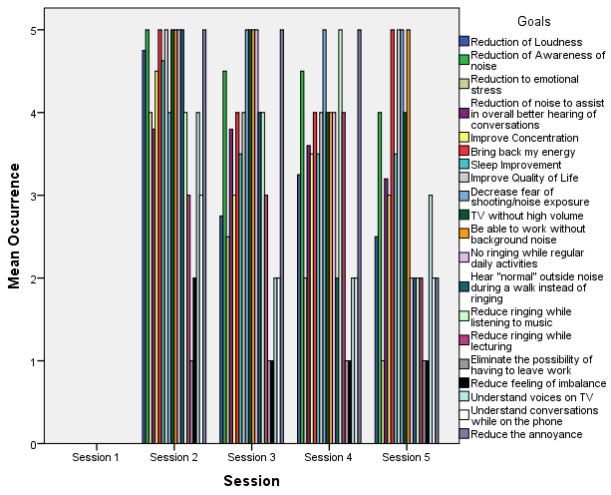


Figure 13: The bars representing "Almost Always" (rating 4) in the Occurrence of the problem were maintained across Research sessions for several participants. Many problem ratings changed to "Most of the Time," "Half of the Time" and "Occasionally" across Research sessions indicating a decrease in Occurrence.

Figure 13 illustrates that the occurrence of the problem reduced over time for many problems. The overall indication is that the decrease in occurrence was substantial for many participants. However, there were still participants that indicated the occurrence of the problem all of the time.

Research Question 2

Research question 2 addressed whether there were significant changes in tinnitus loudness scaling, annoyance scaling, or tinnitus pitch matches over the course of treatment (as measured at research sessions or daily at-home sessions). Changes in loudness scaling, annoyance scaling and pitch matches for daily at-home sessions were analyzed using the Randomizations Test Approach for a treatment intervention (Edgington and Onghena, 2007). Each participant had a random amount of days in the Music Only phase (i.e., Control Block) before the Notched Noise Treatment began (i.e., Experimental Block). During the Control and

Experimental Blocks, daily measurements (i.e., 5 days out of the week) were taken to analyze certain characteristics of the participant's tinnitus perception. The measurements for each participant are analyzed to create a p-value separately based on the mean scores under all possible control and treatment blocks for that subject. The individual p-values were then combined to create a group p-value based on the additive approach (Edgington and Onghena, 2007). Participant 5's data had to be omitted due to iPad failure to record daily measurements. The following sections offer an explanation of the randomization test approach performed and the group and individual p-values for each daily measurement across the study.

Tinnitus Loudness Visual Analog Scale (VAS)

The Randomization Test Approach was performed to measure the group change in tinnitus loudness across daily at-home sessions. Each participant's Experimental Block (Early and Late Notched Noise Treatment) ratings were subtracted from each participant's Control Block (daily sessions before treatment initiation) ratings to create a test-statistic. An Excel spreadsheet was used to calculate individual p-values, based on an algorithm presented in Edgington and Onghena, 2007. The equation for the additive approach to combining p-values is given below and was utilized within the specific Randomization Test software, provided in the text by the Edgington and Onghena, 2007. This test-statistic was then used in the following equation to create a group p-value:

$$\frac{C(n,0)(S-0)^n - C(n,1)(S-1)^n + C(n,2)(S-2)^n - \ldots}{n!}$$

where C(n,r) is the number of ways r items can be taken from n, and S is the sum of the p-values for all n subjects (Edgington and Onghena, 2007).

Individual p-values for loudness scaling ratings ($p = 0.13$, $p = 0.80$, $p = .73$, $p = .33$, $p = .20$, $p = .93$, $p = .20$, $p = .93$, $p = .53$) were entered into the above formula and a group p-value of

p = .62 was calculated. Loudness scaling ratings were not significantly different across research sessions for the group or for any of the individual participants. Figure 14 displays each participant's loudness ratings across the treatment time.

Participant Loudness VAS Ratings across Research Sessions

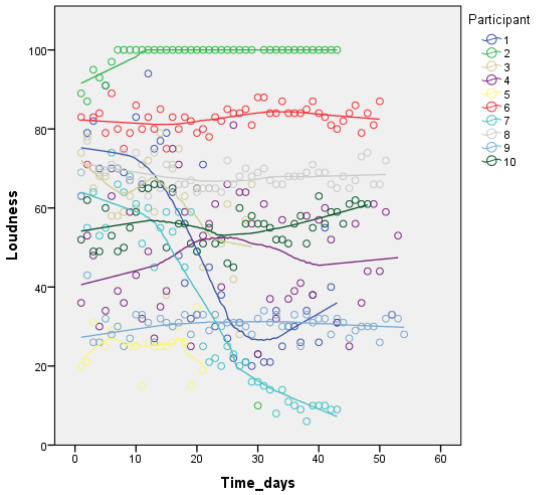


Figure 14: The Loudness VAS Ratings across research sessions was not significantly different when comparing Control Block measures (i.e., Baseline session 1, Post-Counseling session 2, and Music Only session 3) to Experimental Block measures (i.e., Early Treatment session 4 and Late Treatment session 5).

Tinnitus Annoyance Visual Analog Scale (VAS)

The Randomization Test Approach was performed to measure the group change in tinnitus annoyance across at-home daily sessions. Each participant's Experimental Block ratings were subtracted from each participant's Control Block ratings to create a test-statistic. An Excel spreadsheet was used to calculate individual p-values, based on an algorithm presented in Edgington and Onghena, 2007. The equation for the additive approach to combining p-values is given below and was utilized within the specific Randomization Test software, provided in the text by the Edgington and Onghena, 2007. This test-statistic was then used in the following equation to create a group p-value:

$$\frac{C(n,0)(S-0)^n - C(n,1)(S-1)^n + C(n,2)(S-2)^n - \ldots}{n!}$$

where C(n,r) is the number of ways r items can be taken from n, and S is the sum of the p-values for all n subjects (Edgington and Onghena, 2007).

Individual p-values for loudness scaling ratings (p = 0.47, p = 0.80, p = .80, p = .47, p = .60, p = .07, p = .40, p = .80, p = .53) were entered into the above formul and a group p-value of p = .70 was calculated. Annoyance scaling ratings were not significantly different across research sessions for the group. Only one participant, #7, had a significantly different annoyance rating (p = .07), indicating a significant decrease in annoyance. Figure 15 displays each participant's annoyance ratings across the treatment time.

Participant Annoyance VAS Ratings across Research Sessions

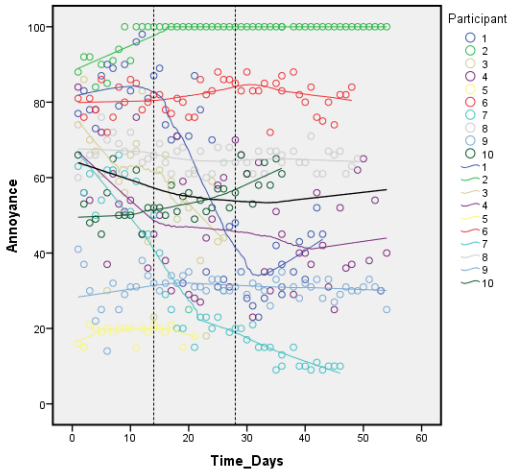


Figure 15: The Annoyance VAS Ratings across research sessions was not significantly different when comparing Control Block measures (i.e., Baseline session 1, Post-Counseling session 2, and Music Only session 3) to Experimental Block measures (i.e., Early Treatment session 4 and Late Treatment session 5).

Tinnitus iPad Pitch Matches

The Randomization Test Approach was performed to measure the group change in Tinnitus Pitch Matches on the iPad across research sessions. Each participant's Experimental Block ratings were subtracted from each participant's Control Block ratings to create a test-statistic. An Excel spreadsheet was used to calculate individual p-values, based on an algorithm

presented in Edgington and Onghena, 2007. The equation for the additive approach to combining p-values is given below and was utilized within the specific Randomization Test software, provided in the text by the Edgington and Onghena, 2007. This test-statistic was then used in the following equation to create a group p-value:

$$\frac{C(n,0)(S-0)^n - C(n,1)(S-1)^n + C(n,2)(S-2)^n - \ldots}{n!}$$

where C(n,r) is the number of ways r items can be taken from n, and S is the sum of the p-values for all n subjects (Edgington and Onghena, 2007).

Individual p-values for tinnitus iPad Pitch Matches (p = 0.20, p = 0.73, p = .13, p = .73, p = .80, p = .20, p = .13, p = .27, p = .33) were entered into the above formul and a group p-value of p = .13 was calculated. iPad Tinnitus Pitch Matches were not significantly different across daily sessions for the group and for individual participants. Figure 16 displays each participant's iPad Pitch Matches across the treatment time.

Participant Tinnitus iPad Pitch Matches across Research Sessions

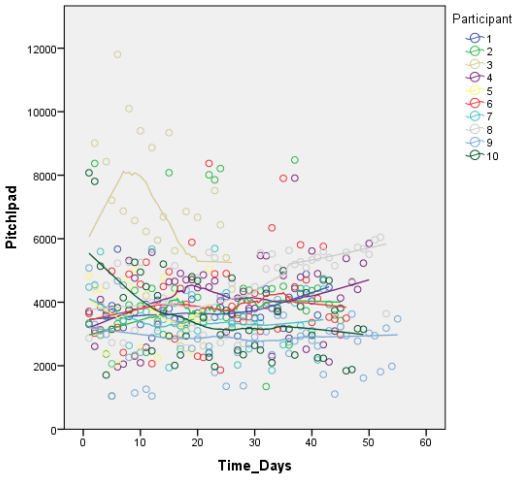


Figure 16: The iPad Tinnitus Pitch Matches across research sessions was not significantly different when comparing Control Block measures (i.e., Baseline session 1, Post-Counseling session 2, and Music Only session 3) to Experimental Block measures (i.e., Early Treatment session 4 and Late Treatment session 5).

Tinnitus Audiometric Booth Pitch Matches

Tinnitus pitch matches were established in the audiometric test suite during research sessions 1-5. Table 12 presents the mean Booth Pitch Matches (BPM) in Hz for the group across research sessions as well as the minimum and maximum subscale scores for each session and the standard deviation of those scores. Figure 17 presents the mean Booth Pitch Matches over research sessions using a boxplot to display the mean scores, the 25th and 75th percentiles, and the outliers.

Table 12: Audiometric Booth Pitch Match Mean Frequencies, Standard Deviations, Variances, and Range of Frequencies across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
BPM 1	2800	1378.4	1900000	1000	4000
BPM 2	2350	1313.4	1725000	500	4000
BPM 3	2425	1247.5	1556250	750	4000
BPM 4	2875	2199.3	4836805	250	6000
BPM 5	2850	1752.8	3072222	250	6000

Mean Booth Pitch Matches across Research Sessions

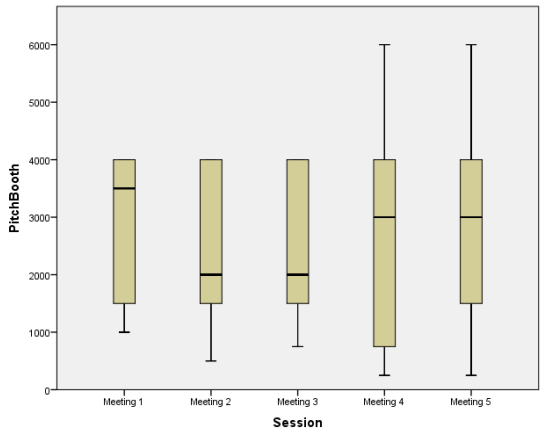


Figure 17: There was not a significant difference between mean Booth Pitch Matches across Research Sessions.

Mauchly's test of sphericity (see Appendix T) was performed to analyze if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's Test

indicated that the assumption of sphericity had not been violated and therefore, did not find significant differences between sessions. A repeated measures ANOVA was performed on the Booth Pitch Matches across sessions 1 through 5. There was not a significant difference across sessions.

Tinnitus Audiometric Booth Loudness VAS

Tinnitus Loudness VAS ratings were established in the audiometric test suite during research sessions 1-5 using the iPad application. Table 13 presents the mean Booth Loudness VAS (BLV) for the group across research sessions as well as the minimum and maximum subscale scores for each session and the standard deviation of those scores. Figure 18 presents the mean Booth Loudness VAS over research sessions using a boxplot to display the mean scores, the 25th and 75th percentiles, and the outliers.

Table 13: Audiometric Booth Loudness VAS Means, Standard Deviations, Variances, and Range of Ratings across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
BLV 1	59.6	23.5	550.3	23	79
BLV 2	59.5	14.9	220.9	36	74
BLV 3	60.6	25.4	646.8	20	100
BLV 4	51.7	28.6	28.6	14	100
BLV 5	50.4	31.0	31.1	9	100

Mean Booth Loudness VAS Ratings across Research Sessions

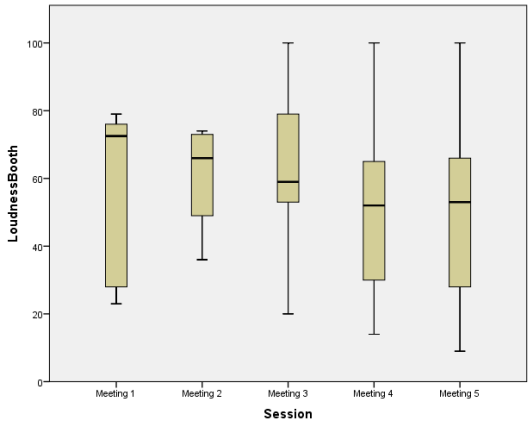


Figure 18: There was not a significant difference between mean Booth Loudness VAS ratings across Research Sessions.

Mauchly's test of sphericity (see Appendix U) was performed to analyze if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's Test indicated that the assumption of sphericity had not been violated and therefore, did not find significant differences between sessions. A repeated measures ANOVA was performed on the Booth Loudness VAS ratings across sessions 1 through 5. There was not a significant difference across sessions.

Tinnitus Audiometric Booth Annoyance VAS

Tinnitus Annoyance VAS ratings were established in the audiometric test suite during research sessions 1-5 using the iPad application. Table 14 presents the mean Booth Annoyance VAS (BAV) for the group across research sessions as well as the minimum and maximum subscale scores for each session and the standard deviation of those scores. Figure 19 presents the mean Booth Annoyance VAS over research sessions using a boxplot to display the mean scores, the 25th and 75th percentiles, and the outliers.

Table 14: Audiometric Booth Annoyance VAS Means, Standard Deviations, Variances, and Range of Ratings across Research Sessions

	Mean	SD	Variance	Minimum	Maximum
BAV 1	59.3	28.2	796.7	25	100
BAV 2	64.2	17.7	312.2	32	84
BAV 3	54.6	29.7	880	16	100
BAV 4	51	29.1	846.8	9	100
BAV 5	47.4	29.9	891	10	100

Mean Booth Annoyance VAS Ratings across Research Sessions

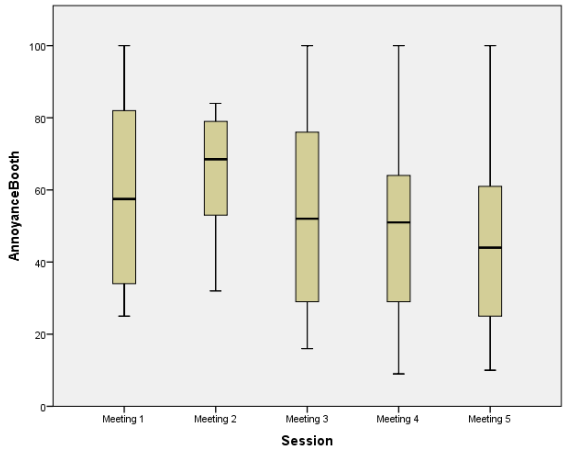


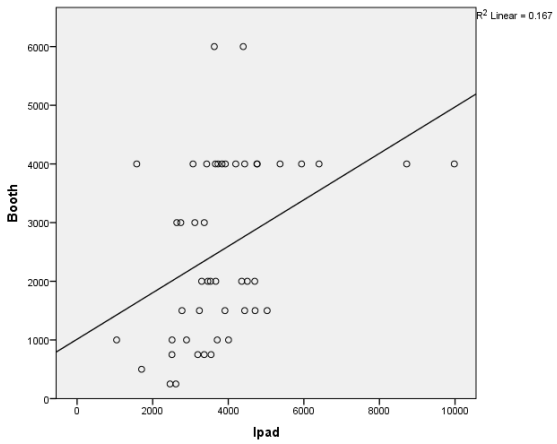
Figure 19: There was not a significant difference between mean Booth Annoyance VAS ratings across Research Sessions.

Mauchly's test of sphericity (see Appendix V) was performed to analyze if the correlation problem is sufficiently severe as to require an epsilon factor adjustment. Mauchly's Test indicated that the assumption of sphericity had not been violated and therefore, did not find significant differences between sessions. A repeated measures ANOVA was performed on the Booth Annoyance VAS ratings across sessions 1 through 5. There was not a significant difference across sessions.

Research Question 3

Research question 3 addressed whether at-home device pitch matches (Hz) from the iPad software application and booth pitch matches (Hz) from corresponding weeks were related. A correlation was measured to test the strength of the linear association between the averaged at-home pitch matches from the week prior (i.e., to the corresponding booth pitch match) and the booth audiometric pitch match. Figure 20 presents a scatterplot and regression line to show the relationship of the two different pitch matches.

Figure 20: Correlation of tinnitus pitch matches on the iPad vs. tinnitus pitch matches in the audiometric booth



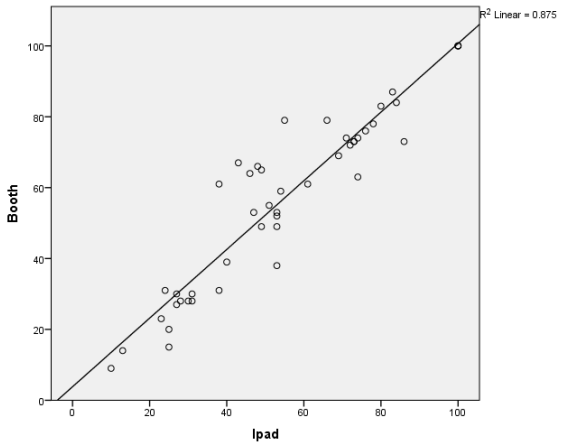
The correlation test confirms a statistically significant association between the iPad pitch matches and audiometric booth pitch matches ($p < .001$). Figure 20 shows a linear form and a positive, but weak, association between the two variables. The Pearson correlation is equal to 0.41, a weak, positive correlation.

Research Question 4

Research question 4 addressed whether at-home device and research session loudness scaling ratings and annoyance scaling ratings from corresponding weeks were related. All at-

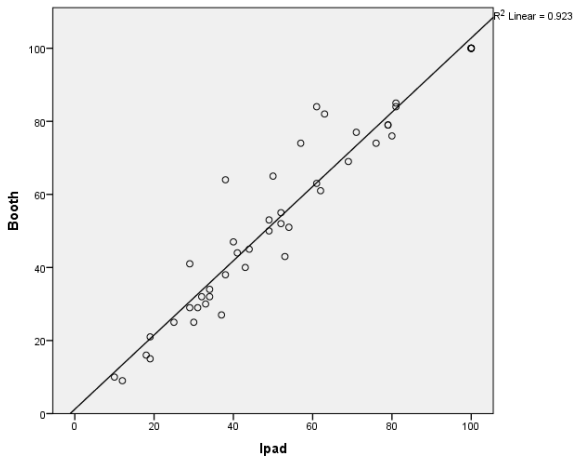
home and research scaling measures were completed using the iPad software application. A correlation was measured to test the strength of the linear association between the averaged at-home loudness and annoyance scaling ratings for the week prior to the research sessions and the research session loudness and annoyance scaling ratings. Figure 21 presents a scatterplot and regression line to show the relationship of the loudness ratings and Figure 22 presents a scatterplot and regression line to show the relationship of the annoyance ratings.

Figure 21: Correlation of tinnitus loudness VAS scores on the iPad vs. iPad tinnitus loudness VAS scores in the audiometric booth



The correlation test confirms a statistically significant association between the iPad loudness VAS scores and audiometric booth iPad loudness VAS scores ($p < .001$). The Pearson correlation coefficient is equal to .935, a strong, positive correlation.

Figure 22: Correlation of tinnitus annoyance VAS scores on the iPad vs. tinnitus annoyance VAS scores in the audiometric booth



The correlation test confirms a statistically significant association between the iPad annoyance VAS ratings and audiometric booth iPad annoyance VAS ratings ($p < .001$). Figure 22 shows a linear form and a positive association between the two variables. The Pearson correlation coefficient is equal to 0.961, a strong, positive correlation.

CHAPTER 4

DISCUSSION

The current study examined changes in the perception of tinnitus and the everyday impact on 10 adults with clinically significant tinnitus and sensorineural hearing loss who completed a notched-noise music treatment. As confirmed by the inclusionary measures, all participants had bilateral sensorineural hearing loss and clinically significant tinnitus. The entire study timeline included an initial baseline visit that was comprised of audiometric testing, educational counseling, self-report measures, and 4 follow-up research sessions that consisted of self-report measures, annoyance and loudness scaling, and pitch matching. The at-home components of the study included annoyance and loudness scaling, pitch matching and music listening delivered through loaned iPads that housed the participant's favorite music and the application that offered the measures and notched filtering (i.e., during that phase of the study). Based on the Randomization Test design, the termination of the unaltered music control listening and initiation of the notched-noise music listening phase was based on a randomly selected start date for each participant. The following sections first present information related to participant compliance followed by a review and discussion of the research questions.

Participant Compliance

Compliance is a major factor when using Randomization Tests and daily measurements of a treatment. Each participant's measurement adds to the significance of the individual p-value and ultimately affects the group p-value. In the current study, the compliance in participant daily sessions and research sessions was extremely high. All 10 participants completed the entire study including the required daily ratings (loudness, annoyance, and pitch matches) and

1.5 hour listening sessions. Technical difficulties in iPad function did prevent logging of data for several participants; however, daily compliance worksheets indicated task completion. A portion of one participant's data had to be thrown out due to the encrypted database error in saving data (i.e., data for Participant 5). In contrast to compliance with these study requirements, the compliance rate for individuals completing a computer-based AR program (i.e., LACE) has been found to be approximately 30% (Sweetow, 2010).

Research Question 1

The first research question addressed whether there were significant changes in self-reported tinnitus across the 5 research sessions (i.e., to gauge the effects of counseling, unaltered music, and notched music on total and subscale scores for each measure). First, the results for the standardized self-report measures, THI and TFI, will be reviewed and discussed. The Modified COSI represents a very different type of assessment and it will be discussed separately.

THI and TFI Data

One could consider the counseling, music only and notched-noise treatment components within the study as a tinnitus program. In the literature, there are studies examining the improvement in self-reported tinnitus handicap following tinnitus programs (Henry et al., 2009; Newman & Sandridge, 2012). It was expected that improvement would be observed on some of the self-report measures in the current study from the Baseline session to the End session.

Before addressing changes possibly related to counseling, unaltered music and notched music, changes in self-reports across the timespan of the entire study will be reviewed and discussed. The total scores on the Tinnitus Handicap Index (THI) and total scores on the Tinnitus Functional Index (TFI) showed significant decreases (i.e., improvements) between Baseline scores and End of Treatment (session 5). In addition, all subscale scores on the TFI

(i.e., Intrusiveness, Sense of Control, Cognition, Sleep, Relaxation, Auditory, and Emotions) significantly decreased from baseline to session 5 measures with the exception of the Quality of Life subscale. Overall, self-report measures showed a significant difference in tinnitus perception when comparing baseline scores to end of treatment scores.

It was highly unexpected that there would be significant improvement on both of the formal self-reports (THI and TFI) and all but one of the subscales on the TFI (i.e., Quality of Life). Surprisingly, all but one of the participants was unaware that their self-reported tinnitus handicap was improving. It is possible that participants were focused on their everyday tinnitus, its overall loudness and its overall annoyance rather than on the specific detailed issues presented in the self-report measures. The daily ratings may have focused their attention on the negative aspects of their tinnitus rather than the everyday improvements they were receiving. To the researcher's knowledge, no one else has examined or compared these types of daily ratings with standardized self-reports. It may be that daily ratings are detrimental and should not be used.

Post-Counseling Effect on THI and TFI

Changes from the Baseline Session 1 to Post-Counseling Session 2 self-reports may suggest changes related to the educational counseling session offered at the end of Session 1. It was expected that educational counseling might reduce tinnitus handicap. Anecdotally, many audiologists assume that this is true. Following a brief review of findings related to session 1 and session 2 self-reports, the discussion will focus on possible reasons for these findings.

Analysis of the THI data demonstrated that there was no change from Baseline scores to Post-Counseling session 2 scores. In fact, several participants' scores increased, or worsened in handicap. As observed for the THI, TFI overall total scores did not show a significant difference when the Baseline session and the Post-Counseling sessions were compared. Only the TFI

Sleep subscale scores were significantly different from Baseline to Post- Counseling, and they were significantly worse after counseling.

Overall, findings indicated no significant differences in self-report scores from Baseline Session 1 to Post-Counseling Session 2. This suggests that the counseling component was not effective in reducing tinnitus handicap in this sample of adults with clinically significant tinnitus. Many participants stated that the counseling forced them to think about their tinnitus more than they usually do and instead of coping or managing, they were analyzing certain characteristics that were discussed in the counseling sections. This is important information because educational counseling is necessary but may not be sufficient to help tinnitus patients cope with clinically significant tinnitus (Henry et al., 2010). For patients with tinnitus that is not clinically significant this level of educational counseling might suffice and be beneficial. Perhaps, this highlights the importance of measuring self-reported tinnitus handicap before and after counseling, as some counseling can actually worsen tinnitus handicap and necessitate further counseling or intervention. Further counseling may include cognitive behavioral therapy, for instance.

Music Only Effect on THI and TFI

Changes from Sessions 2 to 3 may suggest changes related to the music only listening phase. Based on the findings of no music treatment effect offered by Okamoto et al. (2011), it was hypothesized that the music only phase in the current study would produce no significant changes in self-reported tinnitus. First, differences in self-report measures from Session 2 to Session 3 will be presented, followed by an interpretation of those results.

The total scores on the THI did not significantly differ from Session 2 to Session 3. In contrast, the total score on the TFI and a few selected subscale scores on the TFI (i.e.,

Intrusiveness, Sleep, and Relaxation) did show improvement from Session 2 to Session 3. The expectations for no improvement with the Music Only treatment were based on the Okamoto et al. (2010) study. In that study, pitch matches, loudness scaling, and auditory evoked potentials were used to evidence change rather than self-reports. In the current study, improvements were not expected following unaltered music listening. However, it is perhaps not surprising that these were found only on the newest measure, the TFI, which was designed to be most sensitive to tinnitus treatment changes. Perhaps, the TFI subscales were able to show differences that were not indicated by the very different measures used in the Okamoto et al. (2010) study.

As stated, the Music Only phase resulted in selected improvements in self-reported tinnitus handicap (i.e., Intrusiveness, Sleep, and Relaxation subscales of the TFI). According to the Jastreboff (1990), the limbic system is highly involved in an individual's perception of tinnitus. Negative feelings like anger, sadness, depression, anxiety can all have a negative impact on an individual's tinnitus. It has been theorized that negative emotion enhances tinnitus perception due to the link between the auditory cortex and the limbic system. Using music as a treatment stimulus provides a more positive experience to a negative perception. Each participant chose personal music selections that they enjoyed listening to in everyday life. Many participants reported that by using personal and enjoyable stimuli, the tinnitus treatment became more of a stress-relief activity rather than a negative task.

Notched Noise Music Treatment Effect on THI and TFI

Changes from Sessions 3 to 4 and 5 may suggest changes related to the early and later stages of the notched-noise music treatment. It was expected that there would be significant improvements in some of the self-report scores from Session 3 to Session 4 (early weeks of notched noise treatment) to Session 5 (late weeks of notched noise treatment). Based on data

from Teismann et al. (2011), it was also expected that participants might need 24 hours of notched noise listening prior to receiving benefit. Thus, it was considered possible that significant improvements might not be found for the early treatment phase. Before Session 4, participants had completed two weeks or 15 hours of notched noise treatment and by Session 5 participants had completed four weeks or a total of 30 hours of notched noise treatment.

Overall, there were no significant changes in self-reports when comparing Session 3 (i.e., before notched noise treatment) to Session 4 (i.e., after 2 weeks of notched noise treatment), with the exception of the Sense of Control subscale on the TFI which significantly improved. Thus, no significant changes were found on the total scores for the THI, the total scores on the TFI, or any of the other 7 subscales of the TFI. Based on these findings, there was minimal improvement from early notched noise treatment (i.e., only in the area of sense of control). This finding was considered a distinct possibility based on the prior research of Teismann et al. (2011). The theory behind notched-noise treatment is that long-term notched noise listening produces changes in auditory cortical reorganization, which requires a certain amount of exposure time.

In contrast, there were significant improvements observed when comparing Session 3 (i.e., before notched noise treatment) to Session 5 (four weeks of notched noise treatment). Both the total scores for the THI and the TFI significantly improved, as well as 4 of the TFI subscales (i.e., Intrusiveness, Sense of Control, Relaxation, and Emotional). The TFI subscales of Cognitive, Sleep, Auditory and Quality of Life; however, did not show improvements. It should be noted that each of the TFI subscales has only 3 items apiece with the exception of the Quality of Life subscale which has 4 items. With these small subscales, there is a very small range of possible scores making it more difficult to show significant differences. As stated,

improvements were expected for the later phase of the notched noise treatment. The overall interpretation here of long-term benefit is based on the improvement in the total scores of the THI and TFI. These results are promising and they represent the first extensive self-report results confirming the benefits of one month of notched noise treatment.

Modified Client-Oriented Scale of Improvement (COSI)

The Modified COSI was a beneficial measure because it allowed the participant to generate personal goals that they would like to have change over the course of the treatment timeline. It was expected that improvement would be observed on some of the modified COSI ratings in the current study from the Baseline session to the End session. Some individuals generated the same goals. Of interest is the fact that sleep disturbance, conversation difficulty due to tinnitus, and tinnitus annoyance were 3 goals that were duplicated across the 10 subjects. The change in severity and the occurrence of the tinnitus problems on the Modified COSI were tracked at each Research Session. Tinnitus problem occurrence appeared to demonstrate a decrease in the majority of participants across research sessions. Many individuals showed a decrease in the amount of time they experienced their problem compared to when they started at the Baseline session. Results indicated that though participants felt that the change in severity may not have decreased with treatment sessions, the occurrence of the tinnitus problem decreased in their daily lives.

It was expected that there would be an improvement on the Modified COSI ratings over the course of the research sessions. It is unclear as to why the severity rating did not improve for most participants whereas the occurrence did.

Post-Counseling Effect on Modified COSI Ratings

Changes from the Baseline Session 1 to Post-Counseling Session 2 Modified COSI ratings may suggest changes related to the educational counseling session offered at the end of Session 1. It was expected that the educational counseling session would improve the participants' goals formed at Baseline Session 1 to Post-Counseling Session 2. Similar to the THI and TFI, the modified COSI did not show any apparent change in severity or problem occurrence for the group when comparing Baseline ratings to Post-Counseling ratings. This suggests that the counseling component was not effective in improving the goals' severity or occurrence in this sample of adults with clinically significant tinnitus. As seen with the self-report measures, counseling may have only emphasized the negative aspects of their tinnitus rather than provide relief.

Music Only Effect on Modified COSI Ratings

Changes from Sessions 2 to 3 may suggest changes related to the Music Only listening phase. It was postulated that the Music Only phase in the current study would produce no significant changes in self-reported tinnitus. Examining the change in severity and occurrence of all participants' goals, there were no apparent changes in either COSI rating from Session 2 to Session 3. One exception to the group, Participant 7, showed improvement on both change in severity and occurrence of the problem from the Post-Counseling session to the Music Only session. The perception of change and occurrence were overall, maintained for majority of participants' goals once the Music Only session began. Again, the reasoning behind this observation may be due to the participants' inability to realize change in daily goals and the focus of attention on the negative aspects of their tinnitus perception.

Notched Noise Music Treatment Effect on Modified COSI Ratings

Changes from Sessions 3 to 4 and 5 may suggest changes related to the early and later stages of the notched-noise music treatment. It was expected that there would be significant improvements in some of the modified COSI goals from Session 3 to Session 4 (early weeks of notched noise treatment) to Session 5 (late weeks of notched noise treatment). The Modified COSI showed that there was not a significant difference in change in severity or occurrence of problem from the Music Only session 3 to Early and Late sessions 4 and 5; however, there were goals that did improve at the Late Treatment session only. The decreases from the Music Only session 3 were, for the most part, maintained after treatment was introduced. A few goals that improved in severity included reduction emotional stress, elimination of tinnitus during everyday activities, and the improvement of feeling imbalanced. The change in occurrence saw many improvements from Music Only to Late Treatment session ratings including the reduction of tinnitus during daily activities, the ability to understand voices on the television, and the reduction of the annoyance of tinnitus. As observed in the self-report findings, the Late Treatment session showed improvements in goals compared to the Music-Only session. However, these improvements in both severity and occurrence were not as noticeable for the modified COSI ratings as they were for the standardized self-reports. Again, the reasons for these findings are uncertain.

Research Question 2

Research question 2 addressed whether there were significant changes in tinnitus loudness scaling, annoyance scaling, or tinnitus pitch matches across research sessions and across daily at-home sessions. The following discussion will address possible changes across the research sessions, followed by examining possible changes across the daily at-home sessions.

Audiometric Booth Loudness, Annoyance and Pitch Match Measures across Research Sessions

The Repeated Measures analysis results did not show significant differences for audiometric booth loudness, annoyance, or pitch match measures throughout the study. Baseline session 1 loudness, annoyance, and pitch match measures were not significantly different from Post-Counseling session 2. Session 2 Post-Counseling measures were not significantly different from those of session 3 Music Only. Music Only session 3 measures were not significantly different from Early and Late Treatment sessions 4 and 5. In contrast, Teismann et al. (2011) found a decrease in perceived loudness over time using a tinnitus loudness diary log after 24 hours of notched noise listening. The findings in the current study could be due to the fact that tinnitus loudness, annoyance, and pitch did not change over the course of the at-home listening program (i.e., 6-8 weeks of at-home listening sessions depending on randomly determined notched noise treatment start dates), but the capability of the participant to cope and manage with these tinnitus characteristics did (i.e., as indicated by the self-reports).

*Daily Loudness, Annoyance, and Pitch Match Measure*s *across Daily Sessions*

The Randomization Test Approach analysis results did not show significant differences for daily at-home loudness, annoyance, or pitch match measures (i.e., group or individual data or p-values) throughout the study with one exception. Participant 7 showed a significant improvement in the annoyance rating. In fact, that participant has requested the notched noise treatment software because his annoyance has worsened lately and he wishes to resume the treatment. The Randomized Test Approach offers a unique way to examine possible treatment effects for individuals and groups. There is no known prior data related to daily tracking of changes in tinnitus pitch, loudness, or annoyance either for untreated or treated tinnitus patients. In fact, a major tinnitus researcher has proposed a study to investigate changes in untreated

patients (Henry, 2014, personal communication). Perhaps, pitch, loudness, and annoyance do not change. In the Progressive Tinnitus Management approach, patients are advised to learn to manage tinnitus despite the fact that its loudness and annoyance may never change. Again, the researcher noticed that participants tended to focus on the lack of apparent changes in daily tinnitus pitch, loudness, and annoyance rather than the significant improvements in self-report.

Research Question 3

Research question 3 addressed whether at-home device pitch matches (Hz) and research session audiometric pitch matches (Hz) from corresponding weeks were related. It should be noted that the at-home pitch matches were conducted through the iPad application with 1 Hz resolution and the research session audiometric pitch matches were completed using an audiometer with no more than ½ octave frequency resolution.

iPad Tinnitus Pitch Match vs. Audiometric Booth Pitch Matches

A correlation test was performed and a positive linear association was found between the averaged at-home pitch matches from the week prior (i.e., to the corresponding booth pitch match) and the booth audiometric pitch match. Though positive, this correlation is not strong (i.e., Pearson correlation = .41). One possible reason for this weak correlation is that participants' pitch matches measured in the audiometric booth were extremely limited in range compared to the pitches presented on the personal iPads. Audiometric booth pitches included only 10 frequencies in the range that corresponded to the participant matches (i.e., 125 Hz, 250 Hz, 500 Hz, 750 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, and 8000 Hz). iPad pitch matching allowed the participant to choose amongst a much wider range of individual frequencies (e.g., 4352 Hz vs. 4000 Hz). It is not possible to know whether the iPad pitch match or booth pitch match is a better reflection of the actual tinnitus pitch. However, the fact that the

notched noise treatment (i.e., based on notch filtering one octave around the iPad pitch) showed benefit would suggest that the iPad match may better reflect the tinnitus pitch.

Research Question 4

Research question 4 addressed whether at-home device and research session loudness scaling ratings and annoyance scaling ratings from corresponding weeks were related. In order to evaluate this question, the scaled at-home ratings from the week prior to session 3 were averaged and compared to the session 3 measures, the scaled at-home ratings from the week prior to session 4 were averaged and compared to the session 4 measures, and the scaled at-home ratings from the week prior to session 5 were averaged and compared to the session 5 measures.

iPad Tinnitus Loudness and Annoyance VAS Ratings vs. Audiometric Booth Tinnitus Loudness and Annoyance VAS Ratings

A correlation test was performed and a positive linear association was found between iPad tinnitus loudness and annoyance VAS ratings at-home and in the audiometric booth during research sessions. The correlations were very strong between at-home and booth loudness ratings (Pearson correlation = .935) and between at-home and booth annoyance ratings (Pearson correlation = .961). These strong correlations may be related to the reliability of these VAS ratings.

Study Limitations

One limitation with the study measures was related to difficulties with pitch matching and the reliability of tinnitus pitch matches (Henry et al., 1999). Pitch matching is a difficult task for both the participant and the clinician/researcher. The participant must understand the definition of pitch and be able to apply the definition to the tinnitus. Often, tinnitus is not a tonal sound and it may have several frequencies, not just a single frequency. Precautions were taken

to ensure that pitch and loudness concepts were understood before measurements were performed. However, it is unknown as to whether the participant experienced "octave confusion," or confusing the actual tinnitus pitch with the octave above or below. It would be beneficial to develop a more defined protocol for pitch matching. The pitch match directly affects the notched octave that is centered on the pitch-matched frequency in this treatment approach; therefore, the pitch match directly affects treatment.

In the current study, tinnitus etiology and characteristics were not controlled. Heller (2003) suggested that different treatments might benefit different populations and so this is a serious consideration.

Future Directions

This study has led to many future research questions related to the treatment of tinnitus. One such question is the notch width and its effects on the neuroplasticity of the auditory cortex and perception of tinnitus. In the current study, a one-octave notch filter was used because of key studies finding benefits from the one-octave notched filter (Okamoto et al., 2010). The effect of notch width is; however, unknown. A future research question could entail the use of several different notch widths over the course of a treatment program.

Another question arises as to the potential for day-long use of notch noise treatment. In the current study, participants only listened through the notched filter for 1.5-hour daily segments. Ear-level devices, such as a hearing aid device, could offer longer periods of notched noise listening and possibly speed up the treatment effects. Ear-level devices could also be beneficial in that the user might control his/her own treatment.

Finally, this study included a sample of individual's whose tinnitus was associated with a variety of etiologies and characteristics (i.e., sensorineural hearing loss, noise exposure, stress,

etc.). Another possibility is studying tinnitus treatment in designated populations, such as military personnel, a group in which there is usually noise exposure as a cause of tinnitus.

In conclusion, notched acoustic stimulus treatment had a significant and positive effect on participants in this study as measured by standardized self-reports. While daily at-home listening sessions were beneficial, the daily measurements of loudness, pitch and annoyance may not be ideal. Those daily ratings appeared to focus extra attention on the most annoying aspects of the tinnitus. Perhaps, alternatively abbreviated at-home self-reports would help patients focus more on areas of possible improvement and demonstrate the benefits of treatment.

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APPENDIX A: IRB APPROVAL

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board Office
4N-70 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834

Office **252-744-2914** · Fax **252-744-2284** · **www.ecu.edu/irb**

Notification of Initial Approval: Expedited

From:	Social/Behavioral IRB
To:	Candice Manning
CC:	Deborah Culbertson
Date:	2/14/2014
Re:	UMCIRB 14-000265 Notched Acoustic Stimulus and Tinnitus

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) is for the period of 2/13/2014 to 2/12/2015. The research study is eligible for review under expedited category #4, 7. The Chairperson (or designee) deemed this study no more than minimal risk.

Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The Investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

Name	Description
Counseling Presentation	Interview/Focus Group Scripts/Questions
Data Collection Sheet	Data Collection Sheet
Dissertation Proposal	Study Protocol or Grant Application
Informed Consent	Consent Forms
Modified Client-Oriented Scale of Improvement	Surveys and Questionnaires
Tinnitus Flyer	Recruitment Documents/Scripts
Tinnitus Functional Index	Surveys and Questionnaires
Tinnitus Handicap Inventory	Surveys and Questionnaires

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418
IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418

APPENDIX B: IRB INFORMED CONSENT

East Carolina University

Informed Consent to Participate in Research

Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: Notched Acoustic Stimulus and Tinnitus
Principal Investigator: Candice Manning
Institution/Department or Division: East Carolina University/CSDI
Address: College of Allied Health Sciences, Department of Communication Sciences and Disorders, Allied Health Sciences Building, Greenville, NC 27858
Telephone #: 252-744-6088

Researchers at East Carolina University (ECU), Department of Communication Sciences and Disorders, study problems in society, health problems, environmental problems, behavior problems and the human condition. Our goal is to try to find ways to improve the lives of you and others. To do this, we need the help of volunteers who are willing to take part in research.

Why is this research being done?
The purpose of this research is to determine if specifically notched music can change the loudness and annoyance of tinnitus perception. The decision to take part in this research is yours to make. By doing this research, we hope to learn how effective this treatment approach is towards the treatment of tinnitus and the emotions in which it evokes.

Why am I being invited to take part in this research?
You are being invited to take part in this research you are an adult who has clinically significant tinnitus that has lasted at least one month and has disrupted at least one important life activity and/or causes emotionally reactions that affects quality of life. If you volunteer to take part in this research, you will be one of about 10 people to do so.

Are there reasons I should not take part in this research?
You should not participate in this research if you are under the age of 18, if you do not have tinnitus, if you have not had tinnitus for at least one month, if you have reported psychological or neurological problems in your case history, if you have participated in a tinnitus study in the past, or if you wear a hearing aid(s).

What other choices do I have if I do not take part in this research?
You can choose not to participate.

Where is the research going to take place and how long will it last?
The research procedures will be conducted at the Health Sciences Building on the Allied Health Sciences Campus. You will need to come to the East Carolina University Speech-Language-Hearing Clinic 6 times during the study. The total amount of time you will be asked to volunteer for this study is 1.5 hours for 5 days a week over the next 12 weeks.

What will I be asked to do?
You are being asked to do the following:

You will start (week 1) by coming to the Health Sciences Building and ECU Speech-Language-Hearing Clinic for a standard clinic hearing evaluation, consisting of otoscopy (looking in the ears for any obstructions or trauma), tympanometry (measuring ear drum function), and air conduction and bone conduction testing (find out how soft some tones can be and still heard). A case history and three tinnitus questionnaires (TFI, THI, and modified COSI) will be given to you to find out information about you and your tinnitus. We will use a smart phone application and an audiometer to find the pitch of your tinnitus each time you come in to the clinic and each time you use the application at home. Tinnitus visual analog scales will be used to measure the loudness and annoyance of your tinnitus perception. Once initial measures have been completed, a 45-minute counseling session will take place to give you information about tinnitus.

After one week (week 2), you will return to the clinic to repeat the tinnitus pitch matching and tinnitus loudness and annoyance scales as well as the tinnitus questionnaires. You will receive an iPad with your tinnitus treatment application and a set of earbuds. You will complete an orientation session on how to use your iPad and the tinnitus application. You will also receive an informational packet with instructions to take home.

Each day, you will open you tinnitus application and measure your tinnitus pitch and rate your tinnitus loudness and annoyance. Next, you will select your favorite music playlist in iTunes through the application. You will listen to the music for 1.5 hours a day for five days a week. Each time you open the application, you will repeat these steps.

You will return to the ECU Speech-Language-Hearing Clinic on three other occasions for tinnitus pitch matching, loudness and annoyance ratings, and questionnaires.

What possible harms or discomforts might I experience if I take part in the research?
It has been determined that the risks associated with this research are no more than what you would experience in everyday life.

What are the possible benefits I may experience from taking part in this research?
We do not know if you will get any benefits by taking part in this study. This research might help us learn more about changes that can occur in tinnitus over certain lengths of time and if music filters are useful treatments for people with tinnitus. There may be no personal benefit from your participation but the information gained by doing this research may help others in the future. Other people who have participated in this type of research have experienced reduced awareness of their tinnitus, including lower volume and less stress or anxiety about tinnitus. By participating in this research study, you may also experience these benefits.

Will I be paid for taking part in this research?
We will not be able to pay you for the time you volunteer while being in this study.

What will it cost me to take part in this research?
It will not cost you any money to be part of the research. The sponsor of this research will pay the costs of: filtering the music, providing the live acoustic filter, downloading the smart phone application, and hearing evaluations.

Who will know that I took part in this research and learn personal information about me?
To do this research, ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- Any agency of the federal, state, or local government that regulates human research. This includes the Department of Health and Human Services (DHHS), the North Carolina Department of Health, and the Office for Human Research Protections;
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff, who have responsibility for overseeing your welfare during this research, and other ECU staff who oversee this research;

How will you keep the information you collect about me secure? How long will you keep it?
Any information you provide is protected and kept confidential unless the law requires that the information be reported (such as cases of child abuse). Identifying information will be kept separate from the data collected during the study; the data will be given a code and not reported using your name, so your personal information will be protected. Personal information and the data collected will be stored under lock and key in separate locations only accessible by the researchers of this study. Identifying information will be kept until data can be analyzed, then all data will be normalized so any published information will be based on groups and not individuals.

What if I decide I do not want to continue in this research?
If you decide you no longer want to be in this research after it has already started, you may stop at any time. You will not be penalized or criticized for stopping. You will not lose any benefits that you should normally receive.

Who should I contact if I have questions?
The people conducting this study will be available to answer any questions concerning this research, now or in the future. You may contact the Principal Investigator at TINNITUS@ecu.edu.

If you have questions about your rights as someone taking part in research, you may call the Office for Human Research Integrity (OHRI) at phone number 252-744-2914 (days, 8:00 am-5:00 pm). If you would like to report a complaint or concern about this research study, you may call the Director of the OHRI, at 252-744-1971.

I have decided I want to take part in this research. What should I do now?
The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
    - I know that I can stop taking part in this study at any time.
    - By signing this informed consent form, I am not giving up any of my rights.
    - I have been given a copy of this consent document, and it is mine to keep.

_____ _____

Participant's Name (PRINT) **Signature** **Date**

Person Obtaining Informed Consent: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person's questions about the research.

_____

Person Obtaining Consent (PRINT) **Signature** **Date**

APPENDIX C: MODIFIED CLIENT-ORIENTED SCALE OF IMPROVEMENT (COSI)

MODIFIED CLIENT ORIENTED SCALE OF IMPROVEMENT

Describe up to five tinnitus problems that you hope this treatment will improve. Rank the problems numerically in order of most importance.

SPECIFIC NEEDS:

☐ _____

_____

_____

☐ _____

_____

_____

☐ _____

_____

_____

☐ _____

_____

_____

☐ _____

_____

_____

Worse	No Difference	Slightly Better	Better	Much Better	Hardly Ever	Occasionally	Half the Time	Most of Time	Almost Always

APPENDIX D: MODIFIED CASE HISTORY

Modified Tinnitus Sample Case History Questionnaire

Code #: _____ **Date:** _____

1. Age:

2. Gender:

3. Is English your first language?
    a. Yes
    b. No

4. Was the initial onset of your tinnitus related to:
    a. Loud blast of sound
    b. Head trauma
    c. Whiplash
    d. Change in hearing
    e. Stress
    f. Other

5. Where do you perceive your tinnitus?
    a. Right ear
    b. Left ear
    c. Both ears, worse in the left
    d. Both ears, worse in the right
    e. Both ears, equally
    f. Inside the head
    g. Elsewhere _____

6. How does your tinnitus manifest itself over time?
    a. Intermittent
    b. Constant

7. Does the loudness of your tinnitus vary from day to day?
    a. Yes
    b. No

8. Please describe in your own words what your tinnitus sounds like:
    a. Clear tone
    b. Buzzing
    c. Humming
    d. Ringing

e. Roaring
f. Clicking
g. Other _____

9. How many different formal treatment programs have you undergone because of your tinnitus?
    a. None
    b. One
    c. Several
    d. Many

10. Do you have any of the following tinnitus characteristics:
    a. Heard by others
    b. Pulsatile sensation
    c. Tinnitus associated with head or neck movement or pain
    d. Tinnitus associated with Temporomandibular Joint Syndrome (TMJ)
    e. Other_____

11. Do you wear hearing aids at this time?
    a. Yes
    b. No

12. Do you have any neurological or psychiatric problems?
    a. Yes
    b. No

13. Circle all that apply:
    a. My tinnitus has affected one or more of my life situations
    b. My tinnitus has affected my emotions
    c. My tinnitus has affected my occupational goals and/or personal relationships
    d. My tinnitus has lasted for a period of at least one month

APPENDIX E: TINNITUS PITCH AND LOUDNESS/ANNOYANCE MATCHING

Tinnitus Pitch And Loudness/Annoyance Matching Procedure

1. Identify the "Tinnitus Rating Ear"

Prior to the beginning of testing, the "tinnitus rating ear" should be identified by the participant in order to distinguish between the tinnitus perception and the external auditory stimulus presented by the investigator. These designations of "tinnitus rating ear" will be maintained throughout the study.

a. Ask the participant: "Which ear has the loudest or most prominent tinnitus?" (Henry et al., 2010)
b. Circle the participant's selection, right or left, on the accompanied worksheet. (See Appendix X)
c. If the participant states that the tinnitus is symmetrical, or similar in both ears, the participant is to select the "tinnitus rating ear".

2. Ensure the participant understands "pitch" and "loudness"

Individuals may not understand the definitions of pitch and loudness (Vernon & Fenwick, 1984). Before the psychoacoustic assessment, the investigator should review these terms and provide examples.

a. Provide the explanation of pitch: "Pitch is a characteristic of sound that can be ordered on a musical scale from bass to treble." (Moore, 2003)
b. Provide an example of pitch: demonstrate low and high pitches using a xylophone located in the audiometric booth.
c. Provide the explanation of loudness: "Loudness is a characteristic of sound that can be ordered on a scale extending from quiet to loud." (Moore, 2003)
d. Provide an example of loudness: demonstrate quiet and loud sounds using a xylophone located in the audiometric booth.
e. Pitch and loudness confirmation:
    i. Present key 1 and key 8 (low, high)
    ii. Present key 4 and key 1 (high, low)
    iii. Present key 1 and key 2 (low, low)
    iv. Present key 1 soft stroke and key 1 loud stroke (quiet, loud)
    v. Present key 1 loud stroke and key 1 soft stroke (loud, soft)
    vi. Present key 1 loud stroke and key 1 loud stroke (loud, loud)

3. Testing strategy for tinnitus matching using an audiometer

The first objective of the psychoacoustic assessment is to determine the frequency of a pure tone that participants perceive to be closest to the pitch of their tinnitus.

a. Remind the participant of the tinnitus rating ear.

b. Present a 1000 Hz pulsed pure tone at 20 dB SL relative to the air conduction threshold in the tinnitus rating ear. That level of pulsed tone will be presented to both ears for 20 seconds.
    i. If the participant reports loudness discomfort the dB SL will be reduced in 5 dB steps until comfortable.

c. Ask the participant:
    i. "Is that pulsing tone comfortably loud?"
        i. If not, raise or lower the pulsing tone in 10 dB steps until comfortably loud.
    ii. "Should the pulsing tone be adjusted higher or lower to match your tinnitus pitch in your _____, tinnitus rating ear?"

d. Pulsed pure tones of different frequencies are presented in octave intervals to gradually approach and identify the octave frequency that is closest to the participant's perceived tinnitus pitch. Frequencies include 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, and 12,000, 16,000 Hz. For example:
    i. If the participant responds "higher," increase the tone to 1500 Hz with the same intensity rules as stated above. If "lower," decrease to 750 Hz.
    ii. Repeat the question: "Should the pulsing tone be adjusted to a higher or lower pitch to match your tinnitus pitch in your ___, tinnitus rating ear?"
        i. If the patient responds "higher," increase the pitch to 2000 Hz with the same intensity adjustments and comfortable loudness inquiry.
        ii. If the patient responds "lower," decrease the pitch to 1000 Hz.
    iii. Repeat the sequence of presentations until the participant has selected two adjacent frequencies with the lower frequency having a report "higher" (e.g., 2000 Hz) and the next adjacent frequency having a report of "lower" (e.g., 3000 Hz).
    iv. Ask the participant: "Which tone is closest to your tinnitus pitch in your _ _____, tinnitus rating ear?"

b. Each step should be recorded on the investigators worksheet. Once a pitch has been matched, it should be recorded on the participant's worksheet and audiogram.

<u>Tinnitus Loudness and Annoyance Scale</u>

a. The participant will be asked:
    i. "Look at the tinnitus loudness scale and rate the loudness of the tinnitus in your _____, tinnitus rating ear at this moment."

b. The tinnitus loudness scale is ranked from:
    i. 0 – None
    ii. 100 – Extreme

c. The participant will be asked:
    i. "Look at the tinnitus annoyance scale and rate the annoyance of the tinnitus in your _____, tinnitus rating ear at that moment."

d. The tinnitus annoyance VAS is ranked from:
    i. 0 – None
    ii. 100 – Extreme

APPENDIX F: TINNITUS HANDICAP INDEX (THI)

Tinnitus Handicap Inventory (THI)

Name: _____ Date: _____

The purpose of this scale is to identify the problems your tinnitus may be causing you. Check 'Yes', 'Sometimes', or 'No' for each question. Do not skip any questions.

1. Because of your tinnitus is it difficult for you to concentrate?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
2. Does the loudness of your tinnitus make it difficult for you to hear people?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
3. Does your tinnitus make you angry?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
4. Does your tinnitus make you confused?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
5. Because of your tinnitus are you desperate?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
6. Do you complain a great deal about your tinnitus?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)
7. Because of your tinnitus do you have trouble falling asleep at night?	☐ Yes (4)	☐ Sometimes (2)	☐ No (0)

8. Do you feel as though you cannot escape from your tinnitus?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
9. Does your tinnitus interfere with your ability to enjoy social activities (such as going out to dinner or to the cinema)?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
10. Because of your tinnitus do you feel frustrated?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
11. Because of your tinnitus do you feel that you have a terrible disease?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
12. Does your tinnitus make it difficult to enjoy life?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
13. Does your tinnitus interfere with your job or household responsibilities?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
14. Because of your tinnitus do you find that you are often irritable?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
15. Because of your tinnitus is it difficult for you to read?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
16. Does your tinnitus make you upset?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)

17. Do you feel that your tinnitus has placed stress on your relationships with members of your family and/or friends?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
18. Do you find it difficult to focus your attention away from your tinnitus and on to other things?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
19. Do you feel that you have no control over your tinnitus?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
20. Because of your tinnitus do you often feel tired?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
21. Because of your tinnitus do you feel depressed?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
22. Does your tinnitus make you feel anxious?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
23. Do you feel you can no longer cope with your tinnitus?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
24. Does your tinnitus get worse when you are under stress?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)
25. Does your tinnitus make you feel insecure?	☐ Yes (4) ☐ Sometimes (2) ☐ No (0)

APPENDIX G: TINNITUS FUNCTIONAL INDEX (TFI)

TINNITUS FUNCTIONAL INDEX

Today's Date _____ Your Name _____
Month / Day / Year *Please Print*

Please read each question below carefully. To answer a question, select *ONE* of the numbers that is listed for that question, and draw a *CIRCLE* around it like this: (10%) or (1).

I **Over the PAST WEEK...**

1. What percentage of your time awake were you consciously **AWARE OF** your tinnitus?

Never aware ► 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ◄ *Always aware*

2. How **STRONG** or **LOUD** was your tinnitus?

Not at all strong or loud ►0 1 2 3 4 5 6 7 8 9 10 ◄ *Extremely strong or loud*

3. What percentage of your time awake were you **ANNOYED** by your tinnitus?

None of the time ► 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ◄ *All of the time*

SC **Over the PAST WEEK...**

4. Did you feel **IN CONTROL** in regard to your tinnitus?

Very much in control ►0 1 2 3 4 5 6 7 8 9 10 ◄ *Never in control*

5. How easy was it for you to **COPE** with your tinnitus?

Very easy to cope ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Impossible to cope*

6. How easy was it for you to **IGNORE** your tinnitus?

Very easy to ignore ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Impossible to ignore*

C **Over the PAST WEEK, how much did your tinnitus interfere with...**

7. Your ability to **CONCENTRATE**?

Did not interfere ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Completely interfered*

8. Your ability to **THINK CLEARLY**?

Did not interfere ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Completely interfered*

9. Your ability to **FOCUS ATTENTION** on other things besides your tinnitus?

Did not interfere ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Completely interfered*

SL **Over the PAST WEEK...**

10. How often did your tinnitus make it difficult to **FALL ASLEEP** or **STAY ASLEEP**?

Never had difficulty ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Always had difficulty*

11. How often did your tinnitus cause you difficulty in getting **AS MUCH SLEEP** as you needed?

Never had difficulty ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Always had difficulty*

12. How much of the time did your tinnitus keep you from **SLEEPING** as **DEEPLY** or as **PEACEFULLY** as you would have liked?

None of the time ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *All of the time*

Please read each question below carefully. To answer a question, select *ONE* of the numbers that is listed for that question, and draw a *CIRCLE* around it like this: (10%) or (1).

A	**Over the PAST WEEK, how much has your tinnitus interfered with...**	*Did not interfere*									*Completely interfered*
13.	Your ability to **HEAR CLEARLY?**	0	1	2	3	4	5	6	7	8	9	10
14.	Your ability to **UNDERSTAND PEOPLE** who are talking?	0	1	2	3	4	5	6	7	8	9	10
15.	Your ability to **FOLLOW CONVERSATIONS** in a group or at meetings?	0	1	2	3	4	5	6	7	8	9	10
R	**Over the PAST WEEK, how much has your tinnitus interfered with...**	*Did not interfere*									*Completely interfered*
16.	Your **QUIET RESTING ACTIVITIES?**	0	1	2	3	4	5	6	7	8	9	10
17.	Your ability to **RELAX?**	0	1	2	3	4	5	6	7	8	9	10
18.	Your ability to enjoy "**PEACE AND QUIET**"?	0	1	2	3	4	5	6	7	8	9	10
Q	**Over the PAST WEEK, how much has your tinnitus interfered with...**	*Did not interfere*									*Completely interfered*
19.	Your enjoyment of **SOCIAL ACTIVITIES?**	0	1	2	3	4	5	6	7	8	9	10
20.	Your **ENJOYMENT OF LIFE?**	0	1	2	3	4	5	6	7	8	9	10
21.	Your **RELATIONSHIPS** with family, friends and other people?	0	1	2	3	4	5	6	7	8	9	10

22. How often did your tinnitus cause you to have difficulty performing your **WORK OR OTHER TASKS**, such as home maintenance, school work, or caring for children or others?

Never had difficulty ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Always had difficulty*

E **Over the PAST WEEK...**

23. How **ANXIOUS** or **WORRIED** has your tinnitus made you feel?

Not at all anxious or worried ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Extremely anxious or worried*

24. How **BOTHERED** or **UPSET** have you been because of your tinnitus?

Not at all bothered or upset ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Extremely bothered or upset*

25. How **DEPRESSED** were you because of your tinnitus?

Not at all depressed ► 0 1 2 3 4 5 6 7 8 9 10 ◄ *Extremely depressed*

Understanding Tinnitus

Presented by Candice Manning

Overview

- What is tinnitus?
- Why is it caused?
- What can I do if I have tinnitus?

What is Tinnitus?

- The experience of perceiving sound that is produced within the ears/head.
- May be described as:
  - Ringing
  - Whistling
  - Buzzing
  - Chirping

Tinnitus Characteristics

- Tinnitus Annoyance
- Tinnitus Impacts in Everyday Life
  - Psychological
  - Emotional
  - Restricting Activities (e.g., concentration, sleep, social)

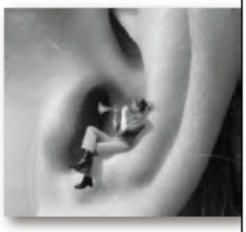
Prevalence of those Seeking Treatment

- 10 to 12 million seek some form of medical intervention (National Health and Nutrition Examination Survey, 1999-2004)

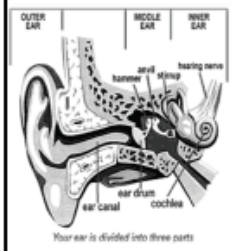
Possible Causes

Tinnitus Causes

- Most common:
  - Hearing loss caused by noise (18%)
  - Aging (12.1%)
  - Head & neck trauma (8%)
  - Ear, nose, throat infections & illnesses (8%)



Parts of the Ear

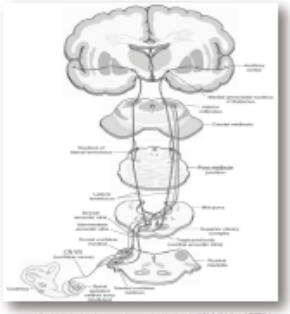


Your ear is divided into three parts

- Outer Ear
- Middle Ear
- Inner Ear

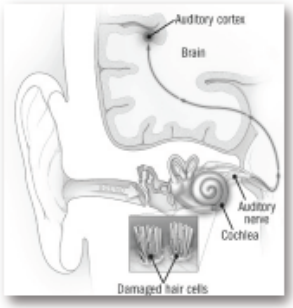
Central Auditory System

- Carries information to brain
- Auditory cortex



Theory of Tinnitus

- Damage occurs within ear
- Abnormal information from damaged ear is sent to brain

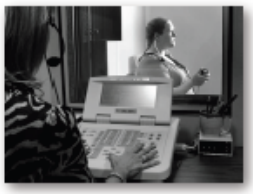


Theory of Tinnitus

- The abnormal information within brain is perceived as tinnitus sound
- Parts of brain that create tinnitus are connected to emotional response areas

Tinnitus Evaluation

How is Tinnitus Evaluated?



- Audiologic Evaluation:
  - Case history
  - Otoscopy
  - Tympanometry
  - Pure tone air and bone conduction thresholds

Tinnitus Evaluation

- Tinnitus pitch and loudness matching
  - Commonly measured
- Loudness discomfort levels
  - Measured for masker treatments, sound generators, or hyperacusis
- Minimum masking levels
  - Measured for masker treatments
- Residual inhibition
  - Measured for masker treatments or sound generators

Tinnitus Treatment

Can Tinnitus be Cured?

- "Cure" = eliminating tinnitus
- No cure yet – research underway
- Sound therapies with counseling used together to reduce tinnitus annoyance

Sounds Used

- Hearing aid amplified sounds, if hearing loss is present
- Masking noises
- Music
- Environmental Sounds

Counseling Used

- Many tinnitus treatments include informational counseling

Summary Points

- Tinnitus is an internal head noise
- Tinnitus can be caused by hearing loss
- Tinnitus is evaluated by an audiologist
- There is not a cure for tinnitus yet
- Tinnitus treatments are available:
  - Music
  - Hearing aids
  - Counseling

Thank you!

QUESTIONS?

References

- Henry, J. A., & Schechter, M. A. (2005). Clinical Guide for Tinnitus Management II: Treatment, *14*(June), 49–70.
- Henry, J., & Schechter, M. (2005). Clinical management of tinnitus using a" progressive intervention" approach. *Journal Of Rehabilitation Research And Development*, *42*(4), 95–115. doi 10.1682/JRRD.2005.01.0005
- Henry, J.A., Zaugg, T.L., Myers, P.J., Kendall, C.J. (2010). "Progressive Tinnitus Management: Clinical Handbook for Audiologists." San Diego: Plural Publishing, Inc.

APPENDIX I: iPAD ORIENTATION

Daily Use of Your Tinnitus Player Application

My Rating Ear: _____

- Turn on your iPad and insert your earphones.

Tinnitus Player Menu

- You should see seven options on your home screen:

    - **Measure: You will measure your tinnitus pitch once a day.** Press the measure icon. You will see the directions posted on the first screen. Use the up and down arrows to match your tinnitus pitch. Once you have found the pitch that best matches your tinnitus perception, press the "Pitch Matches" button. This will return you to the main menu.

    - **Rate Tinnitus Loudness: You will rate your tinnitus loudness once a day.** Press the "Rate Tinnitus Loudness" icon. You will see the directions posted on the first screen. Use the slider scale with your finger to rate the loudness of your tinnitus at that moment. Press continue – this will return you to the main menu.

    - **Rate Tinnitus Annoyance: You will rate your tinnitus annoyance once a day.** Press the "Rate Your Annoyance" icon. You will see the directions posted on the first screen. Use the slider scale with your finger to rate the annoyance of your tinnitus at that moment. Press continue – this will return you to the main menu.

    - **Player: This is your music player – only select this once you have measured your pitch, loudness, and annoyance for the day.** Press the "Player" icon. You will see the directions posted on the first screen. Remember to use your provided earphones while listening to your music. Press "Continue." Pick your music by selecting "Pick Music" on the second screen. You can also just press "Play" and listen to your full library. You will see the artist, title of song, duration of song, and a timer at the bottom of the screen. This timer helps you track the amount of time you have listened to music. Remember: **you will listen to your music 1.5 hours, 5 days a week.**

    - **Upload Stats: Press this button daily to upload your measures for the researcher.**

    - **Stats:** This icon is only used by the researcher.

    - **Settings:** This icon is only used by the researcher.

*** You may choose to break up your listening time throughout the day (e.g., 45 minutes in the morning, 45 minutes at night). You do not have to re-measure your pitch, loudness, and annoyance.**

*** If you have any questions, PLEASE email TINNITUS@ecu.edu at any time.**

APPENDIX J: THI TOTAL SCORES MAUCHLY'S TEST OF SPHERICITY

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
treatments	Sphericity Assumed	2217.120	4	554.280	7.471	.000
	Greenhouse-Geisser	2217.120	1.681	1318.820	7.471	.007
	Huynh-Feldt	2217.120	2.024	1095.562	7.471	.004
	Lower-bound	2217.120	1.000	2217.120	7.471	.023
Error(treatments)	Sphericity Assumed	2670.880	36	74.191		
	Greenhouse-Geisser	2670.880	15.130	176.526		
	Huynh-Feldt	2670.880	18.214	146.642		
	Lower-bound	2670.880	9.000	296.764		

APPENDIX K: TFI TOTAL SCORES MAUCHLY'S TEST OF SPHERICITY

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
factor1	Sphericity Assumed	14076.520	4	3519.130	8.343	.000
	Greenhouse-Geisser	14076.520	2.526	5572.794	8.343	.001
	Huynh-Feldt	14076.520	3.593	3918.092	8.343	.000
	Lower-bound	14076.520	1.000	14076.520	8.343	.018
Error(factor1)	Sphericity Assumed	15185.880	36	421.830		
	Greenhouse-Geisser	15185.880	22.733	667.998		
	Huynh-Feldt	15185.880	32.334	469.653		
	Lower-bound	15185.880	9.000	1687.320		

APPENDIX L: TFI INTRUSIVENESS SUBSCALE SCORES MAUCHLY'S TEST OF SPHERICITY

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Intensity	.211	11.542	9	.251	.620	.874	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept

Within Subjects Design: Intensity

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

APPENDIX M: TFI SENSE OF CONTROL SUBSCALE SCORES MAUCHLY'S TEST OF SPHERICITY

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
SC	.392	6.947	9	.652	.690	1.000	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept

Within Subjects Design: SC

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

APPENDIX N: TFI COGNITIVE SUBSCALE SCORES MAUCHLY'S TEST OF SPHERICITY

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Cognitive	.348	7.821	9	.562	.662	.963	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept

Within Subjects Design: Cognitive

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

APPENDIX O: TFI SLEEP SUBSCALE SCORES MAUCHLY'S TEST OF SPHERICITY

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Sleep	.243	10.488	9	.324	.663	.966	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept

Within Subjects Design: Sleep

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

APPENDIX P: TFI AUDITORY SUBSCALE SCORES MAUCHLY'S TEST OF SPHERICITY

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Auditory	.308	8.735	9	.473	.690	1.000	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept

Within Subjects Design: Auditory

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

APPENDIX Q: TFI RELAXATION SUBSCALE SCORES MAUCHLY'S TEST OF SPHERICITY

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Relaxation	.179	12.762	9	.184	.657	.953	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept

Within Subjects Design: Relaxation

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

APPENDIX R: TFI QUALITY OF LIFE SUBSCALE SCORES MAUCHLY'S TEST OF SPHERICITY

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
QL	.305	8.796	9	.468	.673	.988	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept

Within Subjects Design: QL

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

APPENDIX S: TFI EMOTIONAL SUBSCALE SCORES MAUCHLY'S TEST OF SPHERICITY

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Emotional	.098	17.204	9	.050	.539	.715	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept

Within Subjects Design: Emotional

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

APPENDIX T: TINNITUS AUDIOMETRIC BOOTH PITCH MATCHES MAUCHLY'S TEST OF SPHERICITY

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
PM	.061	20.724	9	.016	.590	.814	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept

Within Subjects Design: PM

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

APPENDIX U: TINNITUS AUDIOMETRIC BOOTH LOUDNESS VAS RATINGS MAUCHLY'S TEST OF SPHERICITY

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Loudness	.020	25.063	9	.004	.440	.555	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept

Within Subjects Design: Loudness

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

APPENDIX V: TINNITUS AUDIOMETRIC BOOTH ANNOYANCE VAS RATINGS MAUCHLY'S TEST OF SPHERICITY

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Annoyance	.068	17.291	9	.051	.579	.830	.250

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept

Within Subjects Design: Annoyance

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.