



History of Tinnitus Research at the VA National Center for Rehabilitative Auditory Research (NCRAR), 1997–2021: Studies and Key Findings

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ABSTRACT

The Veterans Affairs (VA) Rehabilitation Research & Development (RR&D) National Center for Rehabilitative Auditory Research (NCRAR) was first funded by the RR&D Service in 1997 and has been funded continuously since that time. The overall purpose of the NCRAR is to “improve the quality of life of Veterans and others with hearing and balance problems through clinical research, technology development, and education that leads to better patient care” (*www.ncrar.research.va.gov*). An important component of the research conducted at the NCRAR has been a focus on clinical and rehabilitative aspects of tinnitus. Multiple investigators have received grants to conduct tinnitus research and the present article provides an overview of this research from the NCRAR’s inception through 2021.

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The National Center for Rehabilitative Auditory Research (NCRAR) was established in 1997 at the Veterans Affairs (VA) Portland Health Care System (VAPORHCS) in Portland, Oregon. The NCRAR is one of 13 research centers supported by the VA Rehabilitation Research & Development (RR&D) Service. Each of the RR&D centers focuses on a specific health condition that is of relevance to the U.S. military Veterans. The NCRAR is the only RR&D center that focuses on auditory and vestibular research. Most of the research has been of a clinical nature involving human participants. The NCRAR does not directly conduct animal research.

The purpose of this article is to summarize the tinnitus research that has been conducted by NCRAR investigators. The amount and scope of the research is substantial; descriptions of the different studies are accordingly brief, while key findings are highlighted.

The genesis of tinnitus research at the NCRAR traces back to James Henry being hired by John McDermott in 1987 as a research audiologist at the VAPORHCS. Being involved in research inspired Henry to return to school to earn a PhD, and he enrolled in the Behavioral Neuroscience doctoral program at Oregon Health & Science University (OHSU) in 1988. He spent the next 6 years in that program while working half-time for McDermott and Stephen Fausti. His doctoral training laboratory was the Oregon Hearing Research Center (OHRC). The OHRC, which is the research arm of the Department of Otolaryngology—Head and Neck Surgery at OHSU, housed the OHSU Tinnitus Clinic.¹ The director of the OHRC was Jack Vernon who pioneered tinnitus research and developed the masking technique for tinnitus intervention.² The OHRC had other tinnitus researchers, including Mary Meikle who was Henry's research advisor. Under Meikle's tutelage, Henry completed a master's degree in behavioral neuroscience, which involved a project to compare pulsed versus continuous tones for assessment of tinnitus loudness.³ His doctoral dissertation addressed the question of whether loudness

recruitment was responsible for the paradoxically small size of tinnitus loudness matches.⁴ These projects set the stage for Henry to further pursue tinnitus psychoacoustic assessment, resulting in his first research grant from RR&D in 1995. Hence, tinnitus research was already underway at the VAPORHCS when the NCRAR was first funded. Tinnitus research at the NCRAR has been ongoing since then, and numerous other NCRAR investigators have conducted their own studies, including (in alphabetical order) Kathleen Carlson, Robert Folmer, Erin Martz, Candice Quinn, Kelly Reavis, Sarah Theodoroff, and Tara Zaugg. Each of these investigators has received grant funding to conduct tinnitus research under the auspices of the NCRAR. Many more individuals, both internal and external to the NCRAR, have contributed to the different tinnitus studies. Their names appear as coauthors on the publications that are cited throughout this article.

TINNITUS ASSESSMENT

“Diagnosing” tinnitus relies entirely on a patient's self-report—objective detection of the tinnitus sensation (the sound itself) is not usually possible.^{5,6} Further, perceiving a phantom sound does not determine how a person's life may be affected by that perception. Chronic tinnitus is experienced by 10 to 15% of all adults.⁷ Only about one in five of those, however, will seek professional services.⁸ For the remainder, the sensation is most likely ignored most of the time.

For individuals with bothersome tinnitus, available interventions are intended to mitigate the *sensation* of tinnitus and/or the *effects* of tinnitus. The sensation of tinnitus is often assessed using rating scales and psychoacoustic testing methods.^{5,6} A number of questionnaires have been developed and validated for assessing effects of tinnitus (e.g., concentration difficulties, sleep disturbance, emotional distress, feelings of intrusiveness, and reduced sense of control).

Psychoacoustic Assessment

Tinnitus psychoacoustic research has been a mainstay at the NCRAR throughout its history. Henry and colleagues developed computer-automated methods to perform tinnitus psychoacoustic assessment.^{9,10} The idea of using computer automation to conduct this testing originated from Stephen Fausti, founder and previous director of the NCRAR. This line of research has been near-continuous since 1995, with seven successive grants funded by RR&D and 15 peer-reviewed articles published to date. In 2009, we received the Technology Innovation Award from OHSU for our work on the computer-automated Tinnitus Evaluation System (TES). In 2015, the TES was patented and the rights to its commercial production were licensed. TES research is currently funded by RR&D through 2024 to obtain normative tinnitus psychoacoustic data, which are essential for standardization of these measures.

The TES has been shown to (1) obtain measures of tinnitus loudness and pitch that are comparable to the same measures obtained by an audiologist using a clinical audiometer¹¹; (2) obtain reliable hearing thresholds with 1-dB resolution in normal-hearing and cochlear-impaired listeners^{12,13}; (3) obtain reliable tinnitus loudness matches with 1-dB resolution across the test-frequency range (0.25–16 kHz)¹⁴ (loudness matches were equally reliable at all frequencies, including at the tinnitus pitch-matched frequency); (4) obtain reliable measures of tinnitus noise-matching, minimum masking levels, and residual inhibition (RI; temporary suppression of tinnitus following certain sound stimulation)¹⁵; (5) enable efficient patient control of stimulus parameters during testing¹⁶; and (6) conduct tinnitus pitch matching using Bayesian methodology to improve precision of the measures.¹⁷ Other findings using the TES include the following: (1) psychoacoustic testing was not shown to be useful for detecting tinnitus malingering^{18–20}; (2) comparing measures of tinnitus loudness (loudness matching, constrained loudness scaling, and a numeric rating scale [NRS]) revealed only weak-to-moderate correlations²¹; and (3) psychoacoustic measures of tinnitus appear unrelated to the impact of tinnitus, as assessed by a subjective outcome instrument.²² These

latter two studies were published by Quinn (formerly Manning) who was a postdoctoral researcher at the NCRAR from 2015 to 2021.

A tinnitus assessment often includes testing loudness discomfort levels (LDLs) due to hyperacusis (decreased loudness tolerance) being commonly comorbid with tinnitus. Zaugg and colleagues conducted a study showing that LDLs show a low correlation with subjective reports of loudness tolerance problems in daily life.²³ Also pursuing this avenue of research, Theodoroff investigated an alternative approach to measuring loudness perception that does not require presenting high intensities with the risk of exacerbating hyperacusis.²⁴ Results of this pilot study demonstrated it was possible to characterize deviations in loudness perception using low-to-moderate intensity levels that represent the majority of sounds encountered in everyday life.

Tinnitus Questionnaires

For people seeking clinical care for tinnitus, one of the first steps is to complete a tinnitus questionnaire. The questionnaire provides an overall score (an “index score”) that indicates how much the tinnitus is responsible for causing negative reactions and adversely affecting patients’ quality of life.

TINNITUS FUNCTIONAL INDEX

Henry and Folmer collaborated with Meikle on an application to the Tinnitus Research Consortium (TRC—a funding agency for tinnitus research supported by private philanthropy). The application was made in response to the TRC’s request for proposals to develop a new tinnitus questionnaire, which they named the Tinnitus Functional Index (TFI). The TRC announcement explained that none of the existing questionnaires (at least nine at the time) adequately addressed the different dimensions for which tinnitus could affect a person. The announcement also noted that the existing questionnaires differed in many respects (such as formatting, scaling of responses, and wording). Also, none of the questionnaires was designed and tested specifically to maximize sensitivity to *changes in effects* of tinnitus that may result from therapy (i.e., “responsiveness”).

It was therefore stipulated by the TRC how the TFI would be constructed, and that it would be validated for detecting responsiveness to change as a result of intervention for tinnitus.

Developing the TFI required 4 years of effort involving five clinical (audiology) sites and 20 investigators around the country, and almost 700 patients from the audiology clinics.²⁵ Its development involved iteratively selecting and refining items and outcomes. The final TFI version, which contains 8 dimensions and 25 items, was published in 2012 in the journal *Ear and Hearing*.²⁶ In 2013, the journal announced that the publication received its Editor's Award for Outstanding Research in Audiology and Hearing Science.

The TFI was copyrighted by OHSU, which has received numerous requests to use the instrument both for clinical and research purposes. As a result, the TFI received the Top Copyright License Award by OHSU in 2019. OHSU also receives requests to translate the TFI, with translations thus far into more than 20 languages.

Because of its responsiveness to treatment-related change, as well as its other properties, the TFI has the potential to become a standard for evaluating effects of tinnitus, both with clinical patients and in research studies. Most of the credit, of course, goes to Mary Meikle, the main author and driver of the project from start to finish.^{27,28}

TINNITUS AND HEARING SURVEY

A key concern when conducting a tinnitus evaluation is determining whether the tinnitus is bothersome.²⁹ It would seem that a tinnitus questionnaire such as the TFI would be sufficient to make such a determination. The concern, however, is that people who have both tinnitus and hearing difficulty often blame the tinnitus for the hearing problem.³⁰ When this occurs, responses to questions asking about effects of tinnitus can instead reflect primarily the hearing problem. Such a result then artificially elevates the tinnitus questionnaire's overall (index) score. This concern led to our development of the Tinnitus and Hearing Survey (THS).³¹

The THS is a one-page instrument containing 10 items. The first four items (Section

A) inquire about common tinnitus problems that would not be caused by a hearing problem (difficulty falling asleep, difficulty concentrating on reading in a quiet room, etc.). The second four items (Section B) address common hearing problems that would not be caused by tinnitus (e.g., understanding speech in noisy situations). Combined with results from an audiologic evaluation, responses to these eight items provide information that can be valuable in counseling patients regarding differences between hearing loss and tinnitus. The information helps the clinician and patient to collaboratively reach agreement on whether clinical services for tinnitus and/or hearing loss might be needed. The final two items on the THS (Section C) probe for a sound tolerance problem (which can be any combination of hyperacusis, misophonia, noise sensitivity, and phonophobia).³² Our continued use of the THS, and its use by clinicians and other researchers, has led to our recommendation to use this instrument as part of a standard audiologic assessment of patients who complain of tinnitus and to screen candidates for tinnitus intervention trials.³³

TINNITUS SCREENER

We also created the Tinnitus Screener, a six-item algorithm for categorizing tinnitus with respect to its temporal characteristics.³⁴ Such categorization is essential to promote standardization of tinnitus definitions and facilitate more precise estimates of the prevalence of tinnitus. This need became evident when starting our epidemiology study (described later) because it often was not clear what a person meant when stating they "have tinnitus."

With the Tinnitus Screener, individuals are categorized as having "constant" tinnitus (always or usually heard in a quiet room), "intermittent" tinnitus (lasting ≥ 3 minutes and occurring at least weekly), "occasional" tinnitus (lasting ≥ 3 minutes but experienced less than weekly), "temporary" tinnitus (caused by a recent event, then resolving), or "no" tinnitus (individuals experiencing only transient ear noise³⁵ or sudden brief unilateral tapering tinnitus³⁶ are included in the no-tinnitus category).³⁴ Table 1 shows, for each category, the frequency of tinnitus occurrence,

Table 1 Clinical recommendations for primary tinnitus according to temporal characteristics of tinnitus

Ear/Head noise	Frequency of occurrence	Symptoms and length of symptoms	Clinical implications
Transient ear noise (“no tinnitus”)	Random	Sudden tone in one ear, usually accompanied by sense of ear fullness and hearing loss. All symptoms resolve within 2–3 min	Normal physiological event experienced by almost everyone <i>Recommendation:</i> No referral indicated. Reassure patient this is normal and not a sign of pathology
Temporary tinnitus	Follows tinnitus-inducing event—usually noise exposure but also some medications and chemicals	May accompany temporary change in hearing—can be a warning sign that temporary hearing loss has occurred Can last 1 or more days	Indicates possible damage to inner ear <i>Recommendation:</i> Educate about hearing conservation (e.g., use hearing protection, reduce exposure to hazardous noise, get periodic hearing tests) and monitor symptoms
Occasional tinnitus	Less than weekly	Lasts at least 5 min	Referral not indicated unless there are otologic complaints <i>Recommendation:</i> Educate about hearing conservation and monitor symptoms
Intermittent tinnitus	At least daily or weekly	Lasts at least 5 min	Referral indicated due to persistence of tinnitus <i>Recommendation:</i> (1) Refer for clinical audiologic exam and brief tinnitus assessment; (2) counsel re: hearing conservation
Constant tinnitus	Always audible in quiet	Continuous sound	Referral indicated due to persistence of tinnitus <i>Recommendation:</i> Same as for intermittent tinnitus

Note: See text for description of the different types of primary tinnitus.

symptoms, length of symptoms, and clinical implications. The Tinnitus Screener also captures tinnitus duration (acute/recent-onset <6 months vs. chronic/persistent ≥6 months).²⁹ This instrument provides a method of standardizing categories of primary tinnitus, and can improve the quality and consistency of future tinnitus research by enabling direct comparison between studies and between clinics.

TINNITUS MAGNITUDE INDEX

As noted earlier, psychoacoustic measures of tinnitus appear unrelated to the impact of tinnitus as assessed by a subjective outcome instrument.²² We conducted a study to provide preliminary evidence of a unique “tinnitus magnitude” domain describing intensity of tinnitus perception that would be independent of

reactions to tinnitus.³⁷ Such a measure could enable researchers to study this magnitude domain of tinnitus separately from domains of psychological distress, cognitive impact, and quality of life. For this study, potential tinnitus magnitude items were selected from three items used for TFI development (percent of time aware of tinnitus, strength or loudness of tinnitus, and severity of tinnitus) that had the least overlap with tinnitus reactions. These items were analyzed retrospectively to assess discriminant validity, internal consistency, test-retest reliability, and between-group differences. Results of the analysis suggested that development of a Tinnitus Magnitude Index is feasible for obtaining reliable and valid measures of tinnitus magnitude that are not confounded by measures of cognitive, behavioral, and emotional tinnitus reactions.³⁷

Review of Tinnitus Questionnaires

Theodoroff joined the NCRAR in 2007. Her research is focused on the poorly understood perceptual consequences of noise exposure—specifically tinnitus, hyperacusis, and noise sensitivity. She reviewed factors that would be important to consider when selecting a tinnitus questionnaire for research purposes or for clinical care.³⁸ The review included suggestions for how to select among tinnitus questionnaires for intake assessment versus assessment of outcomes following an intervention. A checklist was provided to systematically evaluate and compare between instruments.

Ecological Momentary Assessment

When conducting tinnitus clinical trials, assessment of outcomes has historically been limited to the use of questionnaires that retrospectively assess emotional and functional effects of tinnitus. Through the use of ecological momentary assessment (EMA), recall biases are circumvented because individuals are asked about their current experiences in real time. Our group was the first to explore the feasibility of using EMA methods to assess within- and between-day effects of tinnitus by conducting a pilot study.³⁹ Personal digital assistants (PDAs) were programmed to perform the real-time assessments four times each day for 14 days, and were used by 24 participants. (At the time the study was conducted, smartphones were not available for this purpose.) Results of the study revealed high compliance with the protocol and positive feedback from participants. It was also shown that performing the EMA protocol did not increase participants' reactions to tinnitus relative to results of a pre- and post-protocol tinnitus outcome questionnaire. It was concluded that EMA methodology is a feasible method to obtain real-time tinnitus outcome data.

Standardizing Audiologic Assessment

In 2019, Quinn received a VA Innovators Network “Spark” Award for prototype development of a VA Tinnitus Care Plan. The objective was to promote standardization of VA audiologic tinnitus care by using a web-based application, housed on a tablet, to guide

procedures during an audiology appointment. The application provides tinnitus questionnaires (including the TFI, THS, and Tinnitus Screener) and educational materials for patients while in the waiting room, audiologic input sections for the clinician during the appointment, and a final summary screen that recommends an individualized Tinnitus Care Plan. Information collected from VA audiologists and Veteran participants provided preliminary evidence to support the feasibility of a tablet system in a clinical setting, and insight into Veteran satisfaction of system deliverables. Quinn is applying for the next level of VA Innovators Network funding, the “Seed” Award, to continue development of this versatile application within the clinical setting.

EPIDEMIOLOGY AND SURVEY STUDIES

Noise Outcomes in Service Members Epidemiology (NOISE) Study

Due to concerns about noise exposure in the military and its relationship with hearing loss and tinnitus, the U.S. Congress directed the national academies to investigate these issues as stipulated in the Veterans Benefits Act of 2002 (P.L. 107–330). The Institute of Medicine of the National Academies convened a committee, which was given the charge to review factors bearing on noise hazards in the military and their effects on tinnitus and hearing loss. The committee published its findings along with recommendations for needed research.⁴⁰ We assembled a team of audiology, epidemiology, and health services researchers to address the following committee recommendation: “*Establish cohorts of military veterans with various documented noise exposures, immediately on discharge, and survey them periodically for ototoxic exposures, subsequent nonmilitary noise exposures, and hearing function, as well as presence and severity of tinnitus, in order to determine whether there is a delay in the effects of military noise exposure. These cohorts will need to be followed through the remainder of members' lifetimes, but this longitudinal study will reveal elements of the natural history of noise-induced hearing loss and tinnitus that otherwise will not be determined*” (p.

10). Following up on this recommendation, the multisite Noise Outcomes in Service members Epidemiology (NOISE) study began in 2013 as a joint effort between the Department of Defense (DoD) and the VA.

The NOISE study design is to enroll a cross-sectional sample of Service members and Veterans and to follow them over time at regular intervals. This longitudinal panel design enables the following: (1) cross-sectional assessment of baseline associations between exposures and outcomes; (2) capturing exposures and changes in symptoms that occur between assessment intervals; and (3) analysis of why some participants experience changes in symptoms while others do not.

Data collection is comprehensive, including 15 questionnaires and an audiologic assessment (pure tone air and bone conduction thresholds 0.25–16 kHz, speech reception threshold, word recognition testing) at baseline.⁴¹ Questionnaires are completed every year thereafter, and audiologic testing is repeated every 5 years. The Tinnitus Screener is administered at baseline and at all follow-ups to determine if a participant should be placed in the “tinnitus” (constant or intermittent tinnitus) or “no tinnitus” (occasional, temporary, spontaneous/none) category (a participant’s category can change over time).³⁴ Participants who are placed in the “tinnitus” category complete tinnitus psychoacoustic testing in addition to the audiologic testing at 5-year intervals, and complete three additional questionnaires every year that they screen positive for tinnitus.

Participants are, on average, relatively young. For the first 1,022 participants (643 at the NCRAR and 379 at the Hearing Center of Excellence [HCE]), the mean ages of Veterans and Service members were 34.4 and 34.5 years, respectively.⁴² At their baseline assessment, the majority of participants had normal hearing thresholds (≤ 20 dB HL) in the conventional frequency range (0.25–8 kHz). Furthermore, 41% of Service members and 62% of Veterans were identified with the Tinnitus Screener as having intermittent or constant tinnitus—placing them in the “tinnitus” category.

The extensive amount of data collected with the NOISE study enables numerous comparisons and analyses between the different

measures. Tinnitus analyses that have been completed and published include: documenting predictive validity for the Tinnitus Screener,³⁴ reporting audiologic data and temporal characteristics of tinnitus,⁴¹ providing data revealing the adverse effects of tinnitus on active-duty Service members,⁴³ showing an association between blast exposure and decreased sound tolerance (hyperacusis),⁴⁴ providing definitions and assessment tools to promote standardization and data that are comparable between studies,⁸ and reporting notable findings from the first 690 participants enrolled in the NOISE study.⁴²

With continued effort for 20 years or more, the NOISE study will obtain data that will increasingly help explain the degree to which exposures in the military affect auditory functioning in Service members and Veterans—specifically risk factors for tinnitus onset and the longitudinal trajectory of tinnitus. These findings will inform prevention and management strategies for Service members and Veterans who are at risk for hearing loss and tinnitus, ultimately leading to improvements in their functioning and quality of life.

Characteristics of Patients with Tinnitus

Carlson is an NCRAR investigator as well as a core investigator for the Health Services Research & Development (HSR&D) Center of Innovation (COIN), the Center to Improve Veteran Involvement in Care (CIVIC) at the VAPORHCS. She was trained in injury epidemiology. In addition to her collaboration on the NOISE study, she has led her own studies related to traumatic brain injury (TBI), tinnitus, and auditory health. One of her studies examined associations between tinnitus severity and mental health symptoms.⁴⁵ This study was a population-based survey of 1,800 VA healthcare-using Veterans who were diagnosed with tinnitus. This stratified random sample of Veterans was assessed for tinnitus severity using the TFI, and for mental health symptoms using clinical screening instruments. Results of the analyses revealed a strong association between tinnitus severity and the likelihood of screening positive for

depression, anxiety, and posttraumatic stress disorder. In almost a dose–response fashion, the observed associations were robust even after using multivariable models that controlled for potentially confounding variables. This work suggests that VA clinical care for Veterans with functionally limiting tinnitus would be improved by greater collaboration between audiology and mental health services.

Another study conducted by Carlson and colleagues investigated Veterans with and without tinnitus who receive VA health care.⁴⁶ Ten percent of Veteran users of VA healthcare between 2011 and 2016 were randomly sampled, and 3.8% of the resulting sample (617,534 eligible Veterans) were found to have been diagnosed two or more times with tinnitus. Results of the analysis revealed the following: (1) Tinnitus diagnoses were associated with Veterans' age, race, sex, marital status, and status with respect to having a service-connected disability(s). (2) Hearing loss and TBI were often diagnosed along with tinnitus. (3) Veterans diagnosed with tinnitus used healthcare services more frequently than those not diagnosed with tinnitus. (4) Veterans with tinnitus were more often diagnosed with mental health disorders, including depression, anxiety, and substance use disorders, than those not diagnosed with tinnitus. These findings suggest the need for coordinated tinnitus services in the VA system of care that include behavioral healthcare.

Comorbidities of Tinnitus

NCRAR investigator Folmer was previously the OHSU Tinnitus Clinic's Chief of Clinical

Services. While there, he conducted numerous studies of tinnitus patients that identified comorbidities contributing to the negative impact of tinnitus on quality of life. For example, a study of 350 patients indicated that difficulty sleeping was positively correlated with tinnitus severity.⁴⁷ A study of 436 patients indicated that depression was positively correlated with tinnitus severity.⁴⁸ Reavis, another investigator at the NCRAR, similarly found that tinnitus was associated with depression symptoms and anxiety symptoms among community-dwelling adults.⁷ Because subsequent investigations revealed a similar relationship between anxiety and tinnitus severity, Folmer and colleagues published the “vicious circle” of symptoms diagram in 2001 (Fig. 1).⁴⁹ In this model, tinnitus that has been present for a year or more is likely to persist. For some patients, tinnitus can exacerbate co-symptoms of anxiety, depression, or insomnia. Conversely, these co-symptoms can affect the severity of tinnitus. Effective treatment of anxiety, depression, or insomnia should decrease the severity of tinnitus and improve the patient's quality of life. Effective management of tinnitus should reduce the impact of associated co-symptoms. Additional investigations described: (1) the characteristics of chronic tinnitus resulting from head or neck injuries⁵⁰; (2) chronic tinnitus resulting from cerumen removal procedures⁵¹; (3) associations between tinnitus and obsessive-compulsiveness⁵²; and (4) tinnitus that resulted from electroconvulsive therapy.⁵³

Further studies of Folmer's, both at OHSU and the NCRAR, focused on the epidemiology of tinnitus and hearing loss^{54,55} and

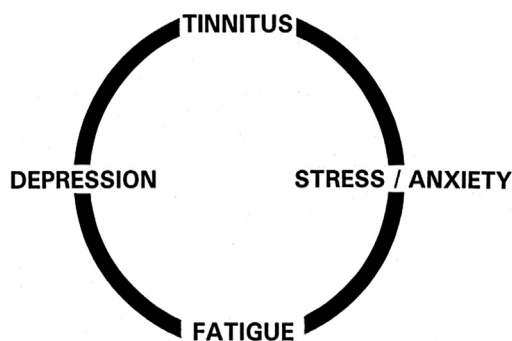


Figure 1 A “vicious circle” of symptoms that is often associated with severe cases of tinnitus.

descriptions of effective tinnitus evaluation and management strategies for primary care providers,^{56,57} audiologists, and otolaryngologists.^{58–62} The 2011 study⁵⁴ used National Health and Nutrition Examination Survey (NHANES) data to estimate the prevalence of hearing loss and tinnitus among 2,174 Veterans and 4,995 non-Veterans. Pure tone thresholds did not differ significantly between Veterans and non-Veterans for most audiometric frequencies tested (500–8,000 Hz). The overall prevalence of tinnitus was greater for Veterans (11.7%) than for non-Veterans (5.4%; $p < 0.001$), with statistically significant differences in the 50–59 and 60–69 age groups.

Patient Factors

Theodoroff and colleagues conducted a study to evaluate patient factors that may be associated with outcomes of tinnitus intervention, including demographics, audiometric data, tinnitus characteristics, psychoacoustic tinnitus measures, and physical and emotional health.⁶³ Veterans ($n = 89$) who completed outcome measures at baseline and 12 months, including the Tinnitus Handicap Inventory (THI),⁶⁴ were identified as either responders or nonresponders to intervention, that is, showing, respectively, a minimum 20-point reduction on the THI, or not achieving a 20-point improvement. In general, responders (1) were younger; (2) had better low-frequency hearing; (3) reported greater hearing difficulties; (4) had shorter-duration tinnitus; and (5) localized their tinnitus as “in the head” rather than “in the ears.” These findings revealed that relationships between characteristics of patients and outcomes of intervention they receive for tinnitus can be identified, which would contribute toward differentially predicting outcomes for individual patients and leading to more targeted and effective therapy.

Provider Surveys

Progressive tinnitus management (PTM) is a stepped-care, interdisciplinary method of providing tinnitus clinical services.⁶⁵ PTM was endorsed by national VA audiology leadership in 2009 and has been shown to

be effective in two randomized controlled trials (RCTs) described further below.^{66,67} Clinical implementation of PTM across the VA was assessed using an anonymous, web-based survey targeting audiology and behavioral health leaders at 144 major VA hospitals.^{68,69} The study addressed a gap in knowledge of PTM clinical implementation, focusing on factors that facilitated or hindered its implementation, and whether sites using PTM had developed adaptations to the methodology.

We explored PTM program implementation both quantitatively and qualitatively. The goal of the quantitative analysis was to estimate levels of PTM program implementation in VA audiology and behavioral health clinics.⁶⁹ Survey responses were received from 87 audiologists and 66 behavioral health clinicians. Data analysis revealed that the majority (44 audiologists and 60 behavioral health clinicians) did not offer PTM (categorized as “no PTM”) or they offered “partial PTM” (17 audiologists and one behavioral health clinician). “Full PTM” was offered by 26 audiologists and five behavioral health clinicians. In addition to the noted wide variation in tinnitus clinical services, results revealed the need for behavioral health providers to be more engaged in tinnitus care, and a clear interest by both audiologists and behavioral health providers in receiving tinnitus-related training.⁶⁹ Future research should address these barriers to PTM implementation in VA clinics.

The qualitative analysis focused on identifying facilitators and barriers to the implementation of PTM across VA sites.⁶⁸ To obtain these qualitative data, 21 audiology and behavioral health clinicians and service chiefs across a VA regional service network were interviewed. Prioritizing the implementation of PTM was found to be rare overall, with providers citing lack of capacity as well as other challenges. At sites where PTM was prioritized and delivered, providers noted its unique value, their personal experience of tinnitus, a good fit of PTM with their skills, and leadership support. PTM was frequently adapted by providing intervention to individuals rather than in group settings and reducing the number of intervention sessions. Important next steps are to identify and develop

clinician champions who can facilitate PTM implementation, and research the impact of adaptations to PTM on patient outcomes.

Tinnitus and Suicide

This project was conducted by NCRAR investigator Martz to explore the potential association between chronic tinnitus and suicide in Veterans and whether comorbid depression and anxiety strengthen this putative association.⁷⁰ Of 769,934 Veterans receiving VA healthcare between January 2002 and December 2011, 15% had a tinnitus diagnosis. In this retrospective study of VA data, suicide rates were observed to be lower for Veterans diagnosed with tinnitus than for those who had not been diagnosed with tinnitus. Furthermore, comorbid mental health conditions were not found to significantly increase the risk of suicide for Veterans diagnosed with tinnitus. Although the study did not confirm anecdotal reports from clinicians in the field that tinnitus is related to suicide in Veterans, it emphasized the need for healthcare providers to be aware that tinnitus and mental health conditions are often comorbid, and to be prepared to address the psychological needs of Veterans who experience bothersome tinnitus.

CLINICAL TRIALS

Repetitive Transcranial Magnetic Stimulation

Folmer and colleagues conducted the first trial in the United States using repetitive transcranial

magnetic stimulation (rTMS) to treat bothersome tinnitus.⁷¹ In this pilot study, a reduction in the perceived loudness of tinnitus was reported by the majority of participants after receiving a brief session of rTMS. A larger, placebo-controlled, double-blinded clinical trial of rTMS for tinnitus was then conducted by Folmer et al⁷² (Fig. 2). Results of the trial revealed 56% of the active-rTMS participants were considered to be responders to the treatment based on reductions in scores on the TFI, while only 19% of the placebo-rTMS participants were considered to be responders using the same criteria. Responders to treatment had sustained improvement at the 26-week follow-up assessment. This treatment method will require additional trials with larger numbers of participants before it can be implemented clinically. A follow-up imaging study revealed that, due to individual asymmetries and other systematic differences in anatomy, optimum TMS coil placement over the primary auditory cortex might necessitate using a method guided by magnetic resonance imaging (MRI).⁷³

Pharmaceutical Treatments

Enbrel (etanercept) is a Food and Drug Administration (FDA)-approved drug for the treatment of rheumatoid arthritis and psoriasis that is currently being studied in a clinical trial by Folmer and colleagues as an off-label treatment of tinnitus. In this DoD-funded trial (PI: Jinsheng Zhang for the multisite project), study participants will receive weekly injections for 12 consecutive weeks—half receive the Enbrel and

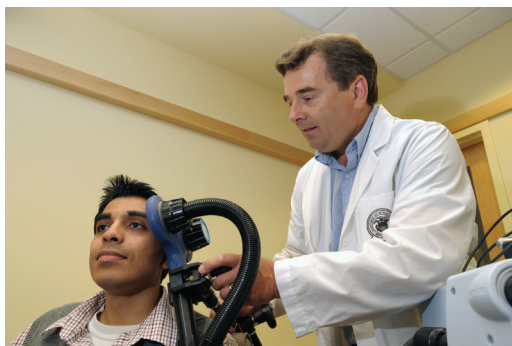


Figure 2 Dr. Robert Folmer administers repetitive transcranial magnetic stimulation (rTMS) to a study participant.

the other half (placebo group) receive saline. It is hypothesized that Enbrel's anti-inflammatory action will result in a significant reduction of tinnitus perception and/or severity for the treatment group but not for the placebo group.

Folmer and colleagues are also collaborating with a research group at Columbia University to conduct a clinical trial of the drug ketamine for the treatment of tinnitus. Ketamine is an NMDA receptor antagonist in the brain and is used clinically as a surgical anesthetic. It is also used to treat severe depression in patients who do not respond to other medications or behavioral therapy. MRI is performed on all participants at baseline and posttreatment. It is hypothesized that the ketamine will reduce tinnitus perception and/or reduce its negative functional and emotional effects for participants in the treatment group.

Tinnitus Retraining Therapy and Tinnitus Masking

Tinnitus masking is an intervention that uses sound for the purpose of providing immediate relief from tinnitus.⁷⁴ Patients treated with tinnitus masking are fit with ear-level devices—"maskers" or hearing aids with built-in maskers (or streaming capability). Sound from the device is adjusted to the level that induces a sense of relief. With tinnitus retraining therapy (TRT), the goal is to achieve habituation from both the awareness of, and reactions to, the tinnitus.^{75,76} Intervention with TRT involves a combination of structured counseling and sound therapy, with the counseling being the most important component. For sound therapy, patients are advised to "enrich their sound environment 24/7." Those with more severe tinnitus often use ear-level sound generators with instructions to use the devices in a very specific fashion—unlike masking, which allows patients flexibility in adjusting the output level.

TRT VERSUS MASKING

The comparative efficacy of masking versus TRT for Veterans with bothersome tinnitus was evaluated in a controlled clinical study.^{77,78} Participants ($n = 123$) were allocated by alternating assignment to masking or TRT and followed up for 18 months. Both groups showed

significant improvement overall, with masking showing improvement that leveled off at 6 months, while TRT effects continued to improve (mostly with participants who reported a "very big" tinnitus problem at baseline). This trial demonstrated that sound can be used in different ways to achieve the same therapeutic objectives for tinnitus management. It also demonstrated the importance of counseling. It cannot be known how much of the observed benefit for each method was due to the sound therapy versus the counseling that was employed.

GROUP TRT COUNSELING

The essential component of intervention with TRT is its structured counseling. We hypothesized that administering TRT counseling to groups of Veterans with bothersome tinnitus would be an effective and efficient intervention. An RCT with three groups (TRT counseling: [$n = 94$]; traditional tinnitus support group [$n = 84$]; and wait-list control [$n = 91$]) was conducted to test the hypothesis.⁷⁹ TRT and support-group participants attended four weekly sessions. Outcome questionnaires, including the tinnitus severity index (TSI)⁸⁰ were administered at baseline and at 1, 6, and 12 months. TSI results revealed the TRT counseling group showed significantly more benefit than the other two groups, presumably because the TRT group followed the recommendation to "enrich their sound environment 24/7" to facilitate habituation to tinnitus. This was a counseling-only study, and it was evident that outcomes would have been improved if participants had received a hearing evaluation, and hearing aids as necessary, prior to receiving the counseling. Hence, lessons learned from this study include the importance of audiologic care as the *first stage* of tinnitus management, and more broadly to use a stepped-care approach to provide only the services required for each individual.

TRT VERSUS MASKING VERSUS TINNITUS EDUCATION

This multisite (four VA medical centers) RCT was conducted to assess the effectiveness of masking and TRT when performed by VA audiologists.⁸¹ At each site, participants were

randomized into one of four groups, TRT, masking, or one of two control groups: one that received tinnitus educational counseling on using sound to reduce the impact of tinnitus (and hearing aids if needed for a hearing problem) (referred to as “TED”) and a wait-list control group. A total of 148 Veterans were enrolled across the four sites. Tinnitus severity was measured using the THI.⁸² All three of the active interventions (masking, TRT, and TED) provided effectiveness that was relatively similar through 6 months and beyond.

Implications for tinnitus clinical management derived from this study include the following: (1) Educational counseling on using sound for tinnitus can be as effective as sound-based therapy for which ear-level devices are issued. (2) It is important to provide comprehensive training to clinicians. (3) Individuals who do not benefit from initial intervention should receive more intensive services. Further, the educational counseling protocol created for the TED group led to the development of numerous concepts, techniques, and tools for using therapeutic sound that are described as part of the PTM educational counseling.^{83–85}

Development of PTM

Conducting these early trials first led to our development of Audiologic Tinnitus Management (ATM), which was a structured protocol of both assessment and intervention to be conducted by audiologists.^{86,87} The idea of a stepped-care (progressive) method of tinnitus management was first introduced by our group in 2005.⁸⁸ That led to ATM being modified to become *Progressive Audiologic Tinnitus Management* (PATM).^{85,89–91} We soon realized that the intervention level (Level 3) of PATM should include cognitive behavioral therapy (CBT) because CBT had the strongest scientific evidence for tinnitus intervention.⁹² Adding CBT to the protocol made the method multidisciplinary (audiology and behavioral health). The method was renamed PTM so that the title would not suggest the method was conducted only by audiologists.⁶⁵

PTM was endorsed for VA-wide use by the VA Audiology and Speech Pathology (ASP) Program Office in 2009. Numerous materials

were developed to support PTM in the clinic, including books, videos, brochures, and online training.^{65,83,93}

PTM Multisite RCT

We completed an RCT with 300 Veterans who were randomized into either PTM or wait-list control across two VA sites (a “clinically embedded” study).⁶⁷ Participants in the PTM group attended Level 3 Skills Education, which involved two sessions of sound therapy self-care education and three sessions of CBT (Fig. 3). Analyses of this first RCT for PTM revealed significant improvement for the PTM group for all outcome measures, including the TFI. The improvement was significantly better for the PTM group versus the wait-list control group, though observed effect sizes were small ($d = 0.36$ for the TFI).⁹⁴

Tele-PTM

We developed and pilot tested a protocol for providing tinnitus services to Veterans who had experienced a TBI.⁹⁵ PTM counseling was adapted to create an individualized, telephone-based intervention, and administered to Veterans with and without symptoms of TBI located throughout the United States. This telephone version of PTM is now referred to as Tele-PTM, which has expanded to include other telehealth modalities. All groups in this pilot study showed similar improvement in outcomes, with moderate to large effect sizes. This study demonstrated feasibility and efficacy of providing tinnitus counseling by telephone to Veterans both with and without a history of TBI.

Tele-PTM, as developed for patients with TBI in the pilot study (earlier), was further refined, and an RCT was completed with 205 participants to evaluate its efficacy relative to wait-list control.⁶⁶ Recruitment took place nationwide at primarily VA and military hospitals. Analyses showed a significant change from baseline to 6 months for the Tele-PTM group compared with waitlisted controls, with large effect sizes⁹⁴ observed for the primary outcomes ($d = 1.06$ at 3 months, and 1.20 at 6 months for the TFI).

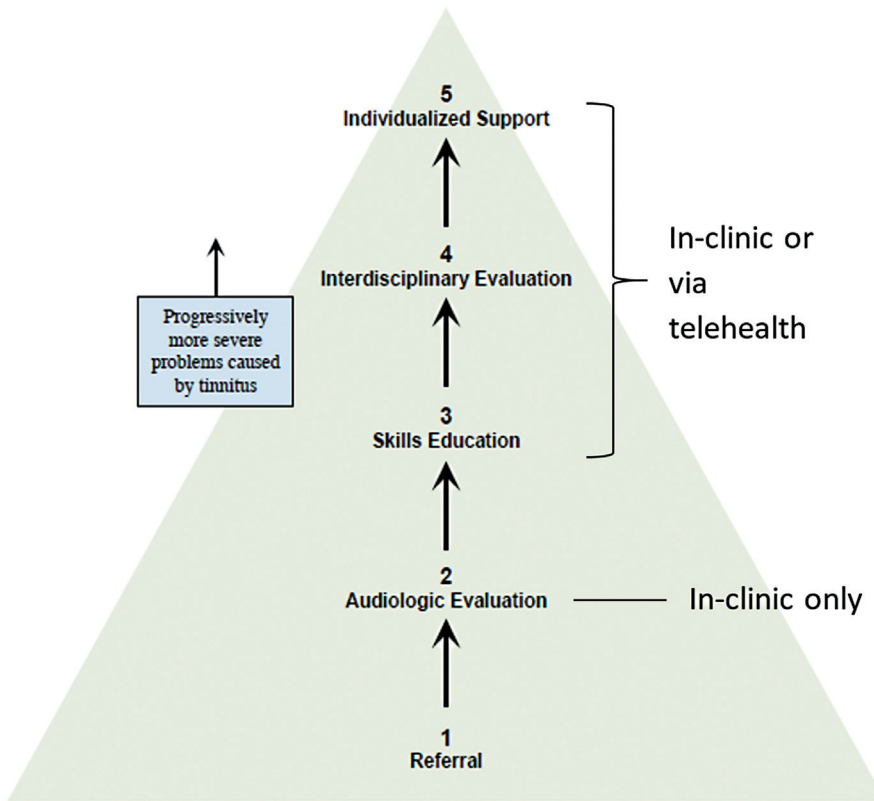


Figure 3 Five stepped-care levels of PTM. Level 1: Referral is for properly routing patients who complain of tinnitus. Level 2: Audiologic evaluation is the basic assessment level conducted by audiologists for any patient with chronic/persistent tinnitus. Level 3: Skills education is the first intervention level, and normally addresses the needs of patients requiring intervention for their bothersome tinnitus. If Level 3 is insufficient, then Level 4: Interdisciplinary evaluation is recommended, involving in-depth assessment by both an audiologist and a psychologist. Level 5: Individualized support provides options for intervention, including extending the Level 3 intervention, focusing just on sound therapy or cognitive behavioral therapy, or providing a completely different form of intervention.

Hearing Aids for Tinnitus Management

Hearing aids have often been reported to provide secondary benefit for tinnitus management.⁹⁶⁻¹⁰¹ The first hearing aids to incorporate built-in sound generators intended to provide relief from tinnitus were called “combination instruments,” though most hearing aids now employ Bluetooth streaming of sound files from mobile phones. Studies had failed to demonstrate combination instruments were more effective than hearing aids alone for tinnitus management.¹⁰² We conducted a small RCT to address this question.¹⁰³ Thirty qualified hearing aid candidates who also had bothersome tinnitus were enrolled and randomized to receive either hearing aids or combination instruments

(all devices supplied by Starkey Hearing Technologies). Participants, who were all new users of hearing aids, wore the devices for 3 months and completed the TFI before and after the intervention period. Both groups showed significant improvement, as indicated by reductions in their TFI scores. Neither outperformed the other, suggesting that both hearing aids and combination instruments are effective in managing reactions to tinnitus.

We conducted another RCT to evaluate the relative efficacy of ear-level devices provided by Phonak, LLC: conventional hearing aids, combination instruments, and extended-wear, deep fit hearing aids (Lyric), to provide relief from tinnitus.¹⁰⁴ Fifty-five hearing aid

candidates with bothersome tinnitus who were not already using hearing aids were randomized to use one of these three types of devices (bilaterally) for 4 months. Nearly all participants had a reduction in tinnitus symptoms during the study. Significant improvement on the TFI was observed for all three groups, but there were no significant differences between groups.

Both the Starkey and Phonak studies concluded that although all of the devices provided improvement in the functional effects of tinnitus, there was no evidence that any of these devices offered greater relief from tinnitus than any other one tested.

We were aware of numerous reports from audiologists successfully providing hearing aids with low-gain amplification on patients with bothersome tinnitus who were not otherwise hearing aid candidates. This nontraditional fitting practice had not been formally evaluated, and Zaugg (principal investigator) and Quinn (co-investigator) were funded to conduct a pilot study designed to lay the groundwork for a future full RCT to study this approach. For the pilot study, which is currently underway, 20 Veterans with normal hearing thresholds and bothersome tinnitus will be fit with hearing aids programmed to provide a low level of amplification. Outcomes will be assessed with the TFI, Hearing Handicap Inventory for Adults (HHIA),⁶⁴ and the Quick Speech in Noise (QuickSIN) test¹⁰⁵ following 3 months of hearing aid use. Participants will also be interviewed at the last visit to determine their self-perceived benefit and potential barriers from using the hearing aids.

This pilot study will also involve interviews of VA clinical audiologists who will be identified via an email survey as providing low-gain amplification for bothersome tinnitus to their patients with normal hearing. The interviews will determine, for this nontraditional practice, these audiologists' rationale, fitting procedures, and criteria for identifying suitable candidates. Outcomes from this pilot study will determine if a full RCT is warranted to assess the efficacy of this practice.

Sound Therapy

COMMERCIAL DEVICE FOR USE DURING SLEEP

An RCT was conducted to determine if an acoustic stimulus that was customized and delivered from the Otoharmonics in-ear Levo System during sleep is beneficial for reducing the impact of tinnitus.¹⁰⁶ Sixty participants ($N=60$) with bothersome tinnitus were enrolled and randomized to one of three groups: (1) Levo programmed according to manufacturer instructions to produce a tinnitus-matched sound; (2) Levo programmed to serve as a control stimulus by being programmed to play a broadband noise that was not chosen by the participant; and (3) a bedside sound generator. Outcomes were assessed with the TFI, a NRS of tinnitus loudness, and a tinnitus loudness match. All groups showed improvements after 3 months and all appeared to offer promise for reducing the impact of bothersome tinnitus. The bedside sound generator group showed a mean reduction on the TFI of ~ 15 points. Both Levo groups showed approximately 5 points greater reduction on the TFI compared with the bedside sound generator group.

ACOUSTIC COORDINATED RESET NEUROMODULATION

Acoustic coordinated reset (CR) neuromodulation is a sound-based therapy intended to disrupt pathological neural synchrony thought to underlie primary tonal tinnitus.¹⁰⁷ The Desyncra device was created to use the acoustic CR neuromodulation computational algorithm to deliver sequences of tones centered around the tinnitus pitch-matched frequency. It was theorized that any increased synchronized neuronal activity associated with the tinnitus would become desynchronized, thus reducing tinnitus symptoms.¹⁰⁸ An RCT was conducted to test this premise.¹⁰⁹ Participants ($N=61$) were stratified based on whether or not they were hearing aid users at baseline, and randomized to receive either Desyncra or CBT. Participants attended 7 to 12 intervention visits, based on their randomization. Outcomes were assessed with the Tinnitus Questionnaire (TQ).¹¹⁰ Mean TQ scores decreased from 5 to 15 points across treatment arms and strata. In the

no-hearing-aid stratum, model-based results revealed that the difference between using Desyncra and CBT showed, on average, greater improvement by 2 to 3 TQ points using the Desyncra device. These findings suggested Desyncra is at least as effective as CBT in reducing tinnitus distress.

NOTCHED NOISE THERAPY

In 2020, Quinn was awarded a VA RR&D Career Development Award-2 (CDA-2) to continue her dissertation findings focused on notched noise therapy (NNT) for suppression of tinnitus. For NNT, broadband noise is presented with the individual's tinnitus frequency region notched out of the stimulus. It is theorized that by eliminating (notching) acoustic energy in the tinnitus frequency region, lateral inhibition is distributed into the associated tonotopic region in the auditory pathways, suppressing neural activity thought to cause the tinnitus percept.¹¹¹ The study will involve an RCT to systematically evaluate the utility of functional, psychoacoustic, and electrophysiologic measures to reveal the whole-health impact of NNT in Veterans with bothersome tinnitus. At the completion of this CDA-2 program, the expected outcome is to demonstrate if NNT is a viable therapy for tinnitus and the contributions that it may have on tinnitus perception.

PILOT STUDIES

Commercial Tinnitus Relief Sounds

Sound therapy is often limited to the use of broadband noise. For this pilot study, it was hypothesized that the effectiveness of sound therapy can be improved by expanding the auditory-stimulus options available to patients.¹¹² Commercially available sounds that were designed to promote tinnitus relief were evaluated to that end by 21 participants who compared the customized sounds to white noise. In a sound booth, participants listened to white noise and to custom sounds that were available commercially and intended to provide tinnitus relief. The different sounds included three from the Dynamic Tinnitus Mitigation (DTM-6a) system (Petroff Audio Technolo-

gies, Inc.) and seven from the Moses/Lang CD7 system (OHRC at OHSU). Across participants, all of the sounds resulted in a significant reduction in tinnitus annoyance. Also, two of the sounds from the DTM-6a system were judged significantly more effective than the other sounds. These findings suggested that specially designed "dynamic" tinnitus-relief sounds may be more effective than the use of broadband or filtered bands of noise.

Notched versus Matched Noise

A small RCT was conducted to evaluate two types of sound therapy theorized to suppress the tinnitus percept.¹¹³ The sound therapies included broadband noise (1–12 kHz) that was notched over a 1-octave range centered around the tinnitus pitch match frequency, and a 1-octave-wide band of noise centered around the pitch match frequency. A control group listened to a band of low-frequency noise (250–700 Hz). Thirty participants (10 per group) with bothersome tinnitus listened to the acoustic stimulus for 2 weeks (6 hours per day). This study showed improvement on the TFI for all of the groups, providing further support that many types of sound therapy are beneficial for relieving effects of tinnitus. Suppressing the tinnitus percept was not conclusively demonstrated, and these results can serve as preliminary evidence for a larger study to more fully investigate that theory.

Smartphone App for Tinnitus Management

A study was conducted to develop and evaluate a smartphone app that would teach coping skills that are used with PTM Level 3 Skills Education.¹¹⁴ A prototype app was developed and usability testing was conducted. The prototype app was evaluated by two focus groups containing members who represented potential users of the app. Lastly, a field study was conducted with three successive groups of participants to evaluate the app. Participants in the focus groups and field studies responded favorably to the app content. Some features, however, were deemed too complex for routine use. The use of smartphone apps has the potential to

increase access to coping skills education for people with bothersome tinnitus.

Pilot Study of Group Interventions

This pilot study was a small RCT led by Martz to compare outcomes from three brief group interventions and a wait-list control group.¹¹⁵ The interventions were based on CBT, acceptance and commitment therapy (ACT), and coping effectiveness training (CET). Although ACT and CBT focus primarily on managing unwanted thoughts and emotions, CET teaches skills not explicitly taught by ACT or CBT, including a range of coping strategies to more effectively manage stressors that both can and cannot be changed. Coping factors were assessed with the brief COPE scale¹¹⁶ pre- and post-intervention, and 4 weeks following intervention. Forty participants were randomized into one of the four groups. Significant group differences were observed on the social support coping factor, with the CET group scores being significantly higher than the wait-list group. Future research should involve a larger sample and outcome instruments that measure the impact of tinnitus. Different delivery formats should also be evaluated for the interventions.

Residual Inhibition

The NCRAR provided seed funding to Quinn to investigate the effects of an acoustic stimulus customized to maximize RI (the temporary suppression or elimination of tinnitus that is usually observed following appropriate auditory stimulation).¹¹⁷ The study adapted a new method to induce RI that involves presenting repeated 3-second bursts of sound separated by short intervals of silence (1 second) to determine the minimum residual inhibition level (MRIL).¹¹⁸ This technique was adapted by assessing and delivering noise at the MRIL through hearing aids. Fifteen participants with bothersome tinnitus completed the protocol. Results were promising and the plan is to use these pilot data to support a fully powered RCT of the technique.

NARRATIVE PUBLICATIONS

Coping with Tinnitus

A narrative article was published addressing coping with tinnitus.¹¹⁹ Perspectives about defining and categorizing coping were discussed. A summary of the empirical research on coping with tinnitus was provided, with a focus on how coping with tinnitus has been measured and trends that had been discovered in relevant research on coping with tinnitus. The problems relating to this type of research were highlighted. Suggestions were offered on how to improve research on coping with tinnitus.

Tinnitus Mechanisms

NCRAR investigators have published articles addressing theorized underlying neural mechanisms of tinnitus. Henry and Theodoroff collaborated with others to write an article reviewing neurophysiological changes in the auditory system that were thought to be responsible for tinnitus.¹²⁰ Henry has also addressed tinnitus mechanisms elsewhere,^{121,122} while Theodoroff has written about the role of the brainstem in generating and modulating tinnitus.¹²³ Folmer and colleagues conducted a functional MRI (fMRI) study of tinnitus patients to elucidate the neural mechanisms associated with tinnitus perception and severity.¹²⁴ Results indicated that neural activity in auditory cortex was associated with tinnitus perception, while activity in the putamen and posterior cingulate regions was associated with differences in tinnitus severity.

Sound Therapy

Henry and Quinn reviewed the NCRAR's RCTs that showed benefit for different methods of sound therapy, including hearing aids (both with and without a sound generator), masking, TRT, PTM, and specialized sound therapy devices.² In addition to these trials, many studies over the past 50 years support the effectiveness of sound therapy in general.¹²⁵ For example, Folmer and Carroll⁶¹ conducted a retrospective study of 150 tinnitus patients: 50 patients purchased and used hearing aids; 50 patients purchased and used in-the-ear

sound generators for an average of 18 months after their initial tinnitus clinic appointment; 50 patients did not use ear-level devices. At follow-up, all three groups of patients exhibited significant reductions in TSI¹²⁶ scores and self-rated tinnitus loudness. Patients who used ear-level devices reported greater improvement than patients who did not use hearing aids or sound generators.

Although systematic reviews have not recommended sound therapy, it is known that sound has been used to obtain relief from tinnitus for hundreds of years.^{60,127} These articles emphasize that considerable evidence, from both clinical and research studies, supports the effectiveness of sound therapy for tinnitus management.

Cognitive Behavioral Therapy

In 2014, the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) published “the first evidence-based clinical guideline developed for the evaluation and treatment of chronic tinnitus” (p. S3).²⁹ Following a systematic review, the only intervention the AAO-HNSF recommended for bothersome tinnitus was CBT. Similarly, between 2007 and 2016, four separate tinnitus clinical guidelines were published in Europe, which, together with the AAO-HNSF guideline, were summarized by Fuller et al.¹²⁸ All of these guidelines agreed that CBT had the strongest evidence of benefit and was therefore the only method recommended for tinnitus intervention.

The NCRAR has collaborated on numerous publications focusing on CBT for tinnitus management.^{109,129,130} CBT is normally delivered by behavioral health providers (counselors, social workers, psychologists). Unfortunately, relatively few behavioral health providers offer CBT specifically for tinnitus, and it can be difficult if not impossible to find one in any given geographical area. Audiologists typically provide tinnitus services, and recent studies have suggested that audiologists can provide CBT, or at least support internet-based CBT.^{131–134} This has been a controversial topic, and we recently published an article addressing this controversy.¹³⁵

DISCUSSION

Since 2007, tinnitus has been the most commonly awarded service-connected disability for Veterans.⁴⁶ The tinnitus services that Veterans receive in VA clinics are mostly delivered by audiologists, behavioral/mental health providers (usually psychologists), and otolaryngologists. Results of a survey targeting audiology and behavioral health leaders at the majority of VA medical centers suggested “wide variation in services provided, a need for greater engagement of mental health providers in tinnitus care, and an interest among both audiologists and mental health providers in receiving tinnitus-related training” (p. 2).⁶⁹ Considering the existing scientific literature covering tinnitus research, it is reasonable to conjecture that these same conclusions would apply in non-VA settings.

NCRAR investigators have a long history of conducting research projects focusing on understanding the distribution and determinants of tinnitus as well as the clinical management of tinnitus. This line of research has its origin in the world-renowned OHSU Tinnitus Clinic that was founded and directed by Jack Vernon. The tinnitus research at the NCRAR is specifically targeted to improving tinnitus care for Veterans, but anything accomplished has wider application to individuals everywhere who must cope with chronic intrusive tinnitus.

Since 1995, our group has had continuous funding of projects that investigated various aspects of tinnitus epidemiology and clinical management. The NCRAR is the VA's only research field center that is dedicated to supporting clinical research pertaining to hearing loss, tinnitus, and balance problems.

Overall, NCRAR investigators have been funded to conduct more than 40 tinnitus projects, including 20 controlled trials that have focused on intervention and rehabilitation for bothersome tinnitus. These trials have identified procedures that are the most efficacious, and efficient, for clinical application. Many of these efforts led to the development of PTM, an interdisciplinary, stepped-care program that combines elements of sound therapy and CBT.

By disseminating research findings and offering training seminars, NCRAR investigators are fulfilling the mission of the NCRAR,

which is “to improve the quality of life of Veterans and others with hearing and balance problems through clinical research, technology development, and education that leads to better patient care.” As mentioned, NCRAR investigators focus mostly on clinical methodologies and only have ancillary involvement in basic science, wet laboratory, and mechanisms studies.

Perspectives on Tinnitus Intervention Trials

As reviewed earlier, clinical trials at the NCRAR that evaluated methods of tinnitus intervention showed similar positive outcomes. Every intervention studied showed improvement on most outcome measures. These results are typical of tinnitus intervention studies that almost universally produce positive results. Some comment is warranted to properly interpret this body of literature.

The “best scientific evidence” for interventions addressing any health disorder comes from systematic reviews, which critically analyze pertinent clinical trials that meet certain criteria to be included in the review.^{136,137} Each trial is assessed for risk of bias, which refers to “risk of error in the study data, analysis, or conclusions” compared with a “perfectly controlled trial.”¹³⁸

The Cochrane Collaboration produces systematic reviews with what many consider to be the highest scientific integrity.¹³⁹ The Cochrane Handbook for Systematic Reviews of Interventions (<https://training.cochrane.org/handbook>) describes the assessment of risk of bias criteria for the various forms of bias. One of those risk of bias criteria that is pertinent to tinnitus clinical trials is blinding. Blinding is done to ensure that both study clinicians and participants (double blinding) remain unaware of the intervention being implemented to avoid creating expectations of potential outcomes, leading to biased results. With drug trials, blinding and placebo control (inert treatment) are straightforward as long as side effects do not cue participants that an active drug is being taken. (An “active placebo” can be used that mimics the side effects of the active drug. Inducing side effects, however, raises ethical

concerns.) TMS for tinnitus also enables blinding and placebo control by using a sham stimulation protocol for a control group.^{72,140,141}

Most controlled trials that have been conducted for tinnitus involve some form of counseling and/or sound therapy. In these cases, it is usually impossible either to blind researchers and participants to study group assignment or to conceive of a true placebo control intervention.¹³⁸ Counseling, including CBT, cannot be administered in a blinded fashion, as both clinician and participant are aware that counseling is being administered. Participants could, however, be blinded (single blinding) if comparing different methods of counseling and participants do not know the difference. Additionally, researchers administering outcome assessments may be kept blinded to group assignments (if staffing allows). A true placebo control would require making the placebo similar in all respects to the counseling method being studied, which is not feasible.

With respect to psychotherapy in general (of which CBT is one form), there are hundreds of methods that each have their own theory and working hypothesis.¹⁴² Numerous reviews of the different methods have concluded they all work fairly well with little differences between them. It was even observed that random assignment did not make any difference in effectiveness.¹⁴³ Furthermore, one study showed that inexperienced therapists obtained the same results as professional therapists.¹⁴⁴ Tinnitus is still an emergent field and not enough studies have been done to reach these same kinds of conclusions.

With sound therapy, double blinding can be accomplished if the experimental sound therapy is compared with a sham treatment (using an identical device that delivers a sound that is completely different from the experimental sound, to have no chance of creating a similar therapeutic effect). Or, as for counseling, different methods of sound therapy can be compared in a double-blinded protocol. The only way to create a placebo control for sound therapy is to devise a procedure whereby the participant thinks that sound therapy is being delivered but it really is not. Possibly the only study that has attempted such an approach

involved fitting the placebo-control participants with ear-level devices that initially produced sound when first turned on, but then the sound gradually faded to silence within the first 40 minutes.¹⁴⁵

Because of the inability to create a true placebo control group (for either sound therapy or counseling), tinnitus clinical trials can at best be double blinded to compare the effectiveness of different forms of therapy rather than a placebo, which is an inactive treatment meant to have no effect. Any variation of sound therapy or counseling, however, has the potential to produce beneficial effects, and no single method has been proven to be more effective than any other.^{2,138} Any form of sound therapy or counseling used as a control could produce effects that are as effective as the investigational therapy. These concerns should be considered when interpreting the results of clinical trials and how reviewing the scientific evidence factors into the decision-making process about clinical care for patients with tinnitus.

Future Directions

Future directions for tinnitus research at the NCRAR will continue to focus on validating and improving existing methodologies, developing new methodologies for clinical tinnitus management, and documenting the natural history and progression of tinnitus. Some areas of particular interest include (1) sound therapy studies, such as notched noise, matched noise, and RI that have potential for suppressing the tinnitus percept beyond the stimulation period; (2) more efficient methods for clinical assessment of tinnitus; (3) developing special treatments for tinnitus that can be somatically modulated, i.e., “somatosensory” tinnitus; (4) further research on rTMS as a treatment method; and (5) risk factors leading to tinnitus percept onset, tinnitus changes over time, and the role of tinnitus in multimorbidity. Accessibility and efficacy of these methods for various population subgroups will also be a focus (e.g., gender, race, and ethnicity subgroups that are minorities in the Veteran population; people with other impairments such as vision and mobility limitations), as these groups may have been underrepresented and underexami-

ned in study samples and analyses in the past. Future research on PTM has moved into the realm of implementation science. There is still much to be learned about adaptations made to PTM in the field, and barriers to more widespread implementation of PTM within the VA. Analysis of clinical data will be essential to address these questions.

CONCLUSION

Although other researchers are focusing on finding a cure for tinnitus (permanent elimination or reduction of the tinnitus sensation), the NCRAR's focus has been on developing and testing different methods of tinnitus clinical management with the overall purpose of validating clinical methodologies for routine application. Much more has been accomplished than has been described here, including the development of numerous materials for both clinicians and patients to be used as part of clinical care. An online training course, consisting of six separate training modules, has been developed and efforts are underway to update all of our materials and to develop new ones. We are part of the DoD/VA Tinnitus Working Group, which develops clinical tools for tinnitus management at both the DoD and VA. This summary and review should leave no doubt that the VA and DoD have substantially supported tinnitus research for many years, and continue to do so. These efforts have benefitted Veterans, Service members, and civilians who suffer from chronic tinnitus, as well as clinicians who strive to help them.

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CONFLICT OF INTEREST

None declared.

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