VA/DoD CLINICAL PRACTICE GUIDELINE FOR TINNITUS

Department of Veterans Affairs
Department of Defense

QUALIFYING STATEMENTS

The Department of Veterans Affairs (VA) and the Department of Defense (DoD) guidelines are based on the best information available at the time of publication. The guidelines are designed to provide information and assist decision making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.

This clinical practice guideline (CPG) is based on a systematic review of both clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts, it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendation.

Variations in practice will inevitably and appropriately occur when providers consider the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Therefore, every health care professional using these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation with a patient-centered approach.

These guidelines are not intended to represent VA or DoD policies. Further, inclusion of recommendations for specific testing, therapeutic interventions, or both within these guidelines does not guarantee coverage of civilian sector care.

Version 1.0 – 2024

Prepared by

VA/DoD Tinnitus CPG Work Group

With support from

Office of Quality and Patient Safety, Veterans Health Administration

and

Clinical Quality Improvement Program, Defense Health Agency

Version 1.0 – 2024[a]

Based on evidence reviewed through April 7, 2023

[a] VA/DoD Clinical Practice Guideline. (2024). Tinnitus. Washington, DC: U.S. Government Printing Office.

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I. Introduction

The VA and DoD Evidence-Based Practice Work Group (EBPWG) was established and first chartered in 2004, with a mission to advise the VA/DoD Health Executive Committee "on the use of clinical and epidemiological evidence to improve the health of the population . . ." across the Veterans Health Administration (VHA) and Defense Health Agency (DHA), by facilitating the development of CPGs for the VA and DoD populations.(1) Development and update of VA/DoD CPGs is funded by VA Evidence Based Practice, Office of Quality and Patient Safety. The system-wide goal of evidence-based CPGs is to improve patient health and wellbeing.

VA/DoD EBPWG initiated the creation of the VA/DoD Tinnitus CPG in 2022. This CPG provides an evidence-based framework for evaluating and managing care for adults with bothersome tinnitus toward improving clinical outcomes. Successful implementation of this CPG will:

- Assess the patient's condition and collaborate with the patient, family, and caregivers to determine optimal management of patient care;
- Emphasize the use of patient-centered care and shared decision making;
- Minimize preventable complications and morbidity; and
- Optimize individual health outcomes and quality of life (QoL).

II. Background

A. Description of Tinnitus

a. Definitions

Tinnitus is the perception of sound that does not have an external source. It can be constant or intermittent and perceived as ringing, buzzing, hissing, sizzling, roaring, chirping, or other sounds in the ear or ears or the head.(2, 3) For definitions of types of tinnitus, see Table 1 or Appendix M.

Table 1. Types of Tinnitus

Type of Tinnitus	Definition
Brief/Transient Ear Noise	Transient ear noise is a tonal or ringing sound heard suddenly in one ear, sometimes accompanied by a sense of hearing loss and aural fullness. The sound usually goes away within five minutes. Transient ear noise does not generally require clinical management.
Acute	Acute tinnitus refers to recent onset (fewer than six months) and can last for a few minutes, hours, days, or weeks. Its onset might be associated with an ear infection, medications, head or neck injury, recent hazardous noise exposure, occluding cerumen, or changes in blood pressure or metabolism. With appropriate evaluation, such underlying conditions can be identified and treated, which might result in the resolution of tinnitus.(4)
Chronic/Persistent	Chronic tinnitus (persistence for six months or more) can also result from the conditions listed above in the "acute" definition and is more likely to occur in people who have hearing loss. Chronic tinnitus is experienced by millions of people in the United States and around the world.(5) Even though a true "cure" for most cases of chronic tinnitus is unavailable, patients can better manage the effects of tinnitus with assistance from providers who support their patients in learning and using effective strategies that improve quality of life (QoL) and functional status with tinnitus.(6)
Objective	Objective tinnitus, which can be heard by people in proximity to the patient's ear or head, can be associated with vascular abnormalities (e.g., congenital arteriovenous fistula, acquired arteriovenous shunt, glomus jugulare, high-riding carotid artery, carotid stenosis, persistent stapedial artery, dehiscent jugular bulb, vascular loop such as the anterior or posterior inferior cerebellar artery compressing the auditory nerve) or mechanical disorders (e.g., abnormally patent Eustachian tube, palatal myoclonus, temporomandibular disorder [TMD], stapedial muscle myoclonus). However, objective tinnitus is rare, accounting for fewer than 1% of all cases.(4)
Subjective	Heard only by the patient, subjective tinnitus accounts for most tinnitus cases.
Primary	Tunkel et al. (2014) define primary tinnitus as "tinnitus that is idiopathic and may or may not be associated with sensorineural hearing loss."(7)
Secondary	Tunkel et al. (2014) define secondary tinnitus as "tinnitus that is associated with a specific underlying cause (other than sensorineural hearing loss) or an identifiable organic condition."(7)
Bothersome	Bothersome tinnitus detracts from a person's enjoyment and QoL. This type of tinnitus often interferes with concentration, relaxation, sleep, work, leisure activities, or any combination of the aforementioned functions and is likely to be rated as a "severe" or "significant" problem by patients. People who experience bothersome tinnitus are more likely to seek medical care than people who consider it an insignificant or benign perception that can be ignored most of the time.

b. Tinnitus Generators/Risk Factors

Any condition or exposure that results in hearing loss or damages the auditory system can contribute to the generation of subjective tinnitus. These conditions include presbycusis (hearing loss caused by aging), prolonged exposure to loud sounds (noise-induced hearing loss), acoustic trauma (brief exposures to very high intensity sounds), otosclerosis (abnormal remodeling of the bone of the middle ear ossicles or cochlea),

infections (bacterial, viral, fungal), autoimmune hearing loss, Meniere's disease, or endolymphatic hydrops (abnormally high inner ear pressure). Tinnitus can also result from neoplasms (for example, vestibular schwannoma or cholesteatoma); head or neck trauma/injury; genetic predisposition; or ototoxicity (e.g., caused by medications such as aminoglycoside antibiotics, valproate, cisplatin, loop diuretics or by heavy metals such as lead). Cardiovascular conditions such as hypertension, arteriosclerosis, cerebral aneurysm, or cerebrovascular accident; metabolic conditions such as anemia, hypothyroidism, hyperthyroidism, or diabetes mellitus; musculoskeletal abnormalities such as temporomandibular disorder (TMD) can also give rise to the perception of tinnitus.(6)

Acute tinnitus that occurs immediately after exposure to loud sounds—such as gunfire, explosions, or very loud music—results from mechanical damage to stereocilia on the tops of hair cells within the cochlea. Figure 1 and Figure 2 display images of hair cells before and after exposure to loud sounds, respectively.[b] If the stereocilia and hair cells can recover from the effects of intense sound exposure, the tinnitus might subside within a brief period. However, repeated exposures to loud sounds without the proper use of protective devices (e.g., earplugs, earmuffs) can cause permanent damage to cochlear structures or permanent hearing loss and can contribute to the onset and persistence of chronic tinnitus.(8)

Figure 1. Hair Cell before Loud Sound Exposure (9)

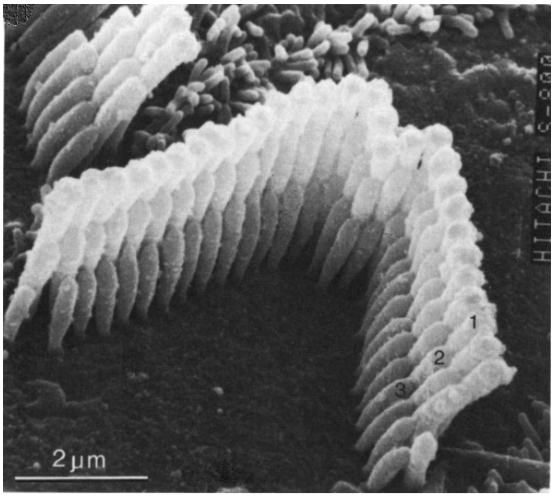
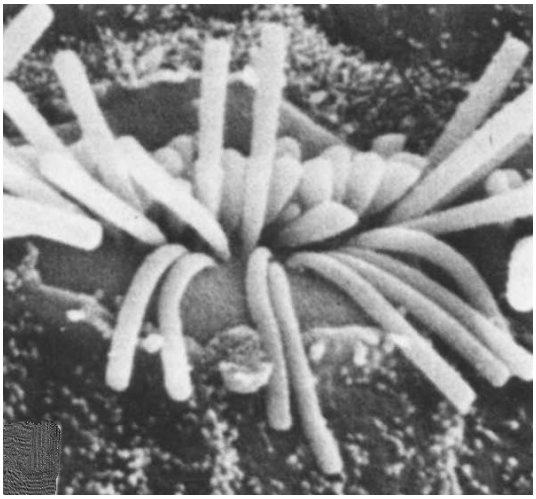


Figure 2. Hair Cell after Exposure to Very Loud Sounds (10)



Imaging studies using functional magnetic resonance imaging (fMRI) or positron-emission tomography have demonstrated that the perception of chronic tinnitus usually occurs as a result of abnormal hyperactivity within central auditory areas of the human brain, especially the auditory cortex.(11, 12)

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Figure 3 and Figure 4 illustrate an fMRI of brain activity associated with tinnitus in an individual who perceives tinnitus on the right side only.[c](12) White areas indicate masking sounds ("white noise") played through a headphone to the left ear, activating the auditory cortex primarily on the right side of the brain. The black area is this brain region (secondary auditory cortex) that is active when the patient hears tinnitus (and the masking sound is off).

Figure 3. Functional MRI of Brain Activity (Sagittal View)

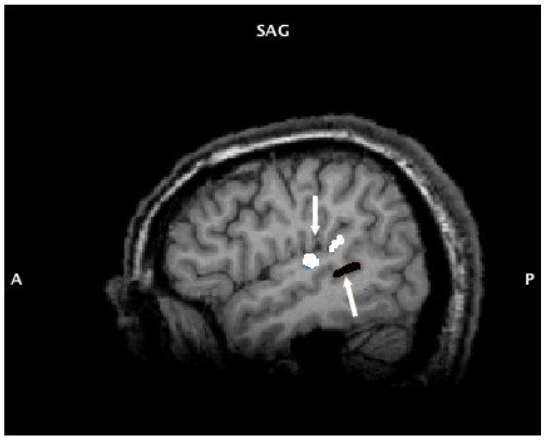
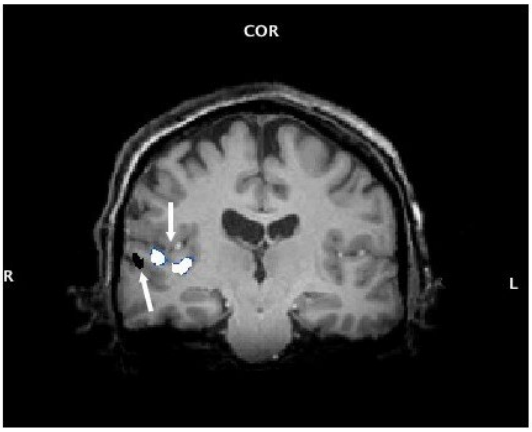


Figure 4. Functional MRI of Brain Activity (Coronal View)



Abbreviations: A: anterior; COR: coronal view; L: left MRI: magnetic resonance imaging, P: posterior R: right; SAG: sagittal view

As portions of the auditory system degenerate during the aging process or from noise exposure, disease, or accidents, the natural balance of central auditory excitation versus inhibition is disrupted.(13, 14) In patients who perceive tinnitus, excitatory pathways within the auditory system are active when they should not be (e.g., in quiet environments). This might give patients the perception of phantom sounds known as tinnitus.

Figure 5 illustrates the central auditory system, showing neural pathways from the cochlea (inner ear) to the auditory cortex.(15) Sound entering an ear on one side tends to activate the auditory cortex more on the contralateral side compared with ipsilateral activation.

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Figure 5. Diagram of the Central Auditory System

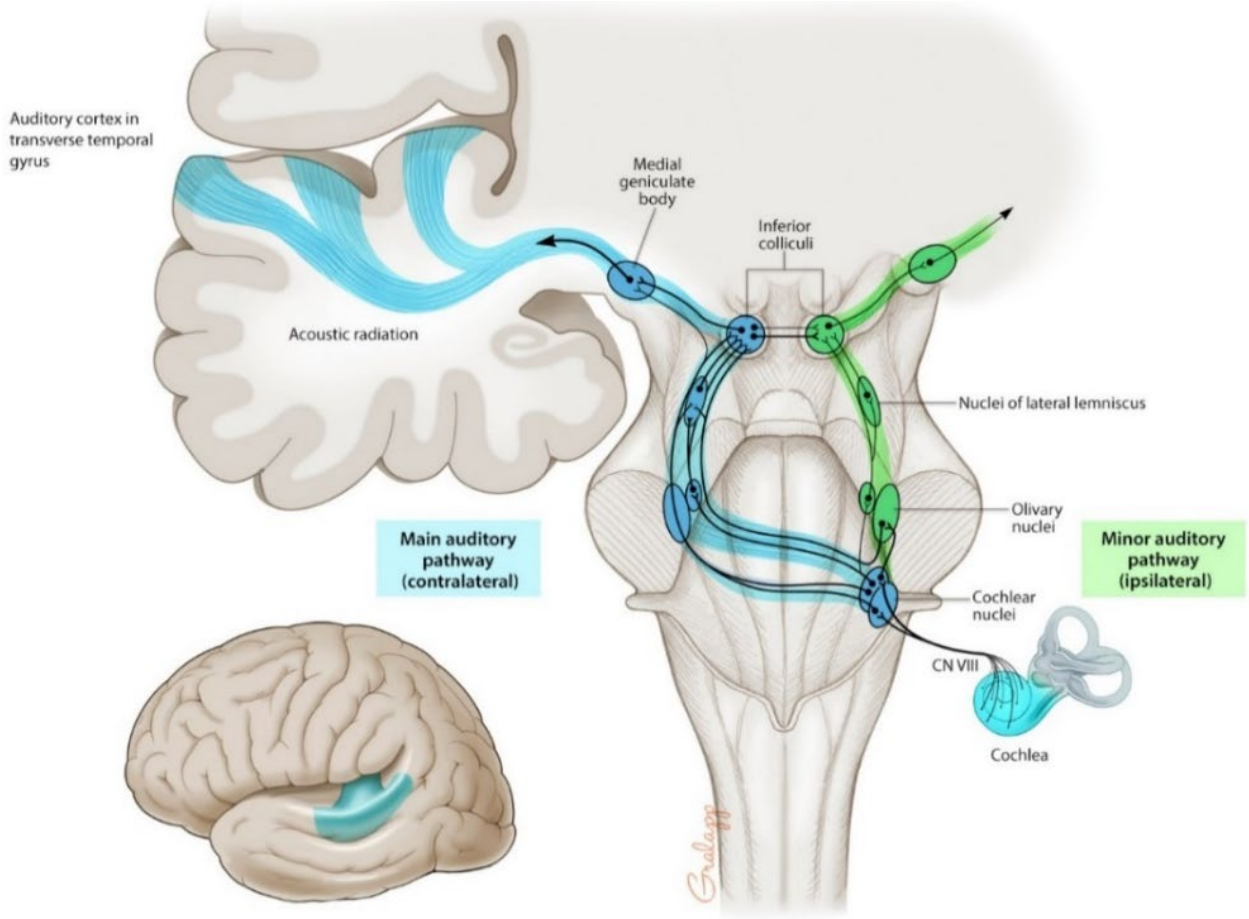


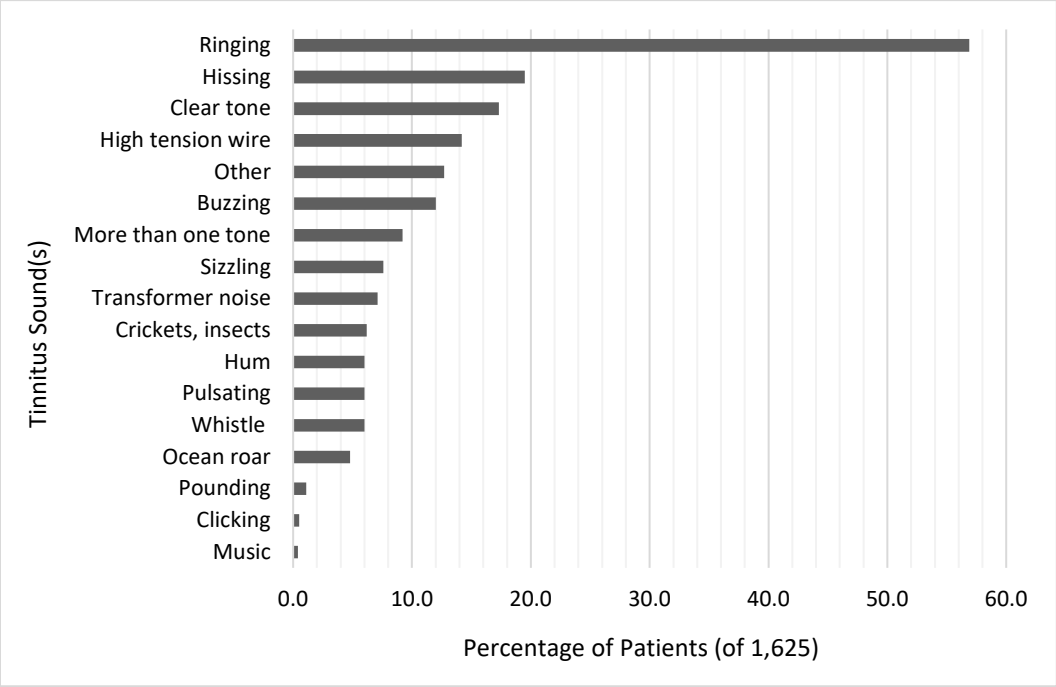
Illustration ©Chris Gralapp
Abbreviations: CN VIII: Cranial Nerve VIII

Functional imaging studies have also identified limbic regions of the brain activated in some people who experience bothersome tinnitus.(16–20) Limbic structures such as the amygdala have roles in decision making, memories processing, and generation of emotional responses, including fear and anxiety. The activation of limbic structures contributes to the negative reactions exhibited by some people in response to bothersome tinnitus. In addition, cortical structures mediating attention are also implicated in adults with chronic tinnitus.(16–20) Although attempts to suppress neural activity responsible for the perception of tinnitus are usually unsuccessful, effective coping strategies can help reduce patients' negative reactions (6, 21) and improve patients' QoL and functional status, even though the perception of tinnitus continues.

c. Type of Tinnitus Sounds

Figure 6 lists some of the most common tinnitus sounds patients perceive. These data are from patients who were seen in the Oregon Health and Science University Tinnitus Clinic.(22)

Figure 6. Predominant Tinnitus Sound(s) (23)



Data collected from patients at the Oregon Health and Science University Tinnitus Clinic indicate that tinnitus pitch-matched frequency tends to be lower as hearing loss worsens.(24) Stated another way, people with better hearing sensitivity (especially for higher frequency sounds) tend to perceive higher-pitched tinnitus.

Having thorough medical and audiological examinations is vital for patients with chronic tinnitus to identify underlying risk factors that might be contributing to the tinnitus. Successful diagnosis and treatment of some causes (especially hearing loss) might reduce the perception of tinnitus. However, if tinnitus continues to bother the patient after all identifiable risk factors have been treated, the clinical focus should be shifted from medical treatment to the provision of strategies to reduce the functional impact of tinnitus.(6, 25) This CPG contains strategies that can be implemented to help patients live more comfortably with tinnitus and improve their overall QoL.

B. Epidemiology and Impact on the General Population

a. Global Prevalence of Tinnitus

The subjective symptom of chronic tinnitus affects millions of people around the world.(5) Precise prevalence estimates for tinnitus are challenging to obtain because they vary according to the sources of data sampled and the specificity of questions asked of participants. In a systematic review (SR) and meta-analysis, Jarach et al. (2022) estimated that tinnitus is perceived by more than 749 million adults worldwide and is rated as a severe problem by more than 120 million people, mostly by those over age 65.(5) In other studies, participants with tinnitus were more often male than female and also usually exhibited hearing loss.(26) Kim et al. (2015) reported that risk factors

for tinnitus include a history of military service, unemployment, increased age, stress, history of hyperlipidemia, and unilateral or bilateral hearing loss.(27)

b. Prevalence of Tinnitus in the United States

Shargorodsky et al. (2010) analyzed National Health and Nutrition Examination Survey (NHANES) data from 1999–2004 and reported that approximately 50 million adults in the United States (U.S.) experienced tinnitus and that 16 million adults had frequent tinnitus in the past year.(28) The prevalence of frequent tinnitus increased with age, peaking at 14.3% in individuals between 60–69 years of age. Non-Hispanic White individuals had higher odds of frequent tinnitus compared with other racial and ethnic groups. Hypertension and a history of smoking were associated with an increased risk of frequent tinnitus, as were recreational noise exposure, firearm, and occupational noise exposure. Among study participants who had a hearing test, frequent tinnitus was associated with low-mid frequency (odds ratio [OR]: 2.37; 95% confidence interval [CI]: 1.76–3.21) and high frequency (OR: 3.00; 95% CI: 1.78–5.04) hearing impairment.

Bhatt et al. (2016) analyzed data from the 2007 National Health Interview Survey (2) the only year the survey asked respondents several questions about tinnitus. The data showed that 21.4 million adults (9.6±0.3%) had experienced tinnitus in the past 12 months. When asked about the duration of symptoms, 56.1% of respondents with tinnitus experienced the problem for longer than 5 years, and 27.0% for longer than 15 years.(2) Adults who had experienced tinnitus in the prior 12 months were significantly older than those who did not have tinnitus (mean age was 53.1 versus 45.0 years). In addition, those individuals with more severe symptoms tended to be older, with a direct correlation between increased tinnitus severity and increased age. Furthermore, tinnitus tended to be more prevalent in men (10.5%) than in women (8.8%), with no significant differences in severity between the two groups. Of those who reported experiencing tinnitus, 36.0% reported having nearly constant symptoms, 15.0% had noticeable symptoms at least once a day, 14.6% had noticeable symptoms at least once a week, and the remainder had symptoms less than weekly.(2) Regarding subjective severity, 7.2% of participants believed tinnitus to be a big or a very big problem, 20.2% a moderate problem, and 41.6% a small problem. The remaining 31.0% of participants were unbothered by their tinnitus. Asked when symptoms were most noticeable, 38.4% indicated bedtime.(2)

Hoffman and Reed (2004) reported that the prevalence of tinnitus in the United States increases with age and tends to be more prevalent among men than women for people aged 25–85 years.(29) Also, tinnitus prevalence increases with the severity of hearing loss in all age groups from 25–85+ years.(29)

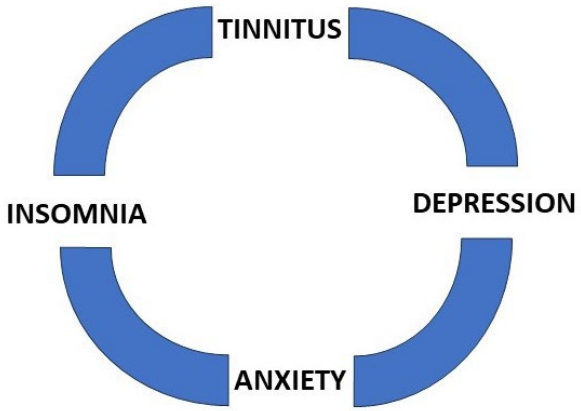
c. Impact of Tinnitus

In the general population, one in five individuals with chronic tinnitus describe it as “bothersome” enough to motivate them to seek clinical care.(30) Practice guidelines for

tinnitus management published in five different countries include recommendations for audiologic assessment and referral to behavioral health services, as needed.(31, 32)

The severity of tinnitus (i.e., the negative impact it can have on patients' lives) is positively correlated with insomnia, depression, anxiety, and other psychosocial factors, which can form a "vicious circle" of symptoms as shown in Figure 7.(33)

Figure 7. Vicious Circle of Symptoms



In this model, tinnitus that has been present for six months or more is likely to persist. Duckro et al. (1984) stated, "as with chronic pain, the treatment of chronic tinnitus is more accurately described in terms of management rather than cure."(25) As will be demonstrated in this guideline, this statement still holds true today, despite decades of focused research to find alternative treatments. For some patients, tinnitus can exacerbate co-occurring conditions, such as anxiety, depression, insomnia, or posttraumatic stress disorder (PTSD). Conversely, these co-occurring conditions can affect the severity of tinnitus.(34) Effective treatment of anxiety, depression, insomnia, or PTSD might decrease the severity of tinnitus and improve QoL.(35) Effective interventions should include management of tinnitus functional impact and associated co-occurring conditions. Daoud et al. (2022) concluded that when tinnitus negatively impacts patients' health-related QoL, multidisciplinary interventions are often required.(36)

C. Tinnitus in the Department of Defense Population

a. Screening for Tinnitus in United States Service Members

Active duty Service members are screened for tinnitus at multiple timepoints during their military career. All Service members are required to complete a DoD Periodic Health Assessment (PHA) every 12 months.(37, 38) Service members are queried about the presence and absence of tinnitus on the annual PHA (DD Form 3024) with the question, "Do you have persistent or recurring noises in your head or ears (for example: ringing, buzzing, humming)." If a Service member answers yes, the next question addresses medical care for tinnitus. The Pre-Deployment Health Assessment Form (DD Form 2795), the Post Deployment Health Assessment Form (DD 2796), and the Post Deployment Health Reassessment Form (DD Form 2900) might also be administered. The post deployment question about tinnitus asks the Service member, "During the past month, how much have you been bothered by noises in your head or ears (e.g., ringing, buzzing, crickets, humming, tone)" and the response options are "not at all," "a little," or "a lot."

All Army and Marine Corps Service members and noise-exposed Air Force and Navy Service members are required to undergo annual hearing tests. Audiometric thresholds

and responses to questions about hearing protection device use and tinnitus are recorded in the Defense Occupational and Environmental Health Readiness System - Hearing Conservation (DOEHRS-HC). Tinnitus is screened with the same question used for the deployment health assessment forms and the same response options. When a response of “bothered a lot” is entered into DOEHRS-HC, a referral for a diagnostic audiology exam with an audiologist is generated. Service members who report being bothered “a little” may request a referral for an audiology exam.

b. Tinnitus Prevalence and Incidence in the Department of Defense

Tinnitus prevalence estimates published are primarily derived from DOEHRS-HC and medical records. Worth noting is that estimating tinnitus prevalence based on DOEHRS-HC records is complicated by the fact that the DOEHRS-HC tinnitus screening question differentiates only between being bothered or not bothered by tinnitus and does not assess the presence versus absence of tinnitus. Most of the published data reports prevalence only for U.S. Army soldiers. A recent large-scale evaluation of tinnitus prevalence was conducted using DOEHRS-HC records collected between January 1, 2015, and September 30, 2019. Just under 1.5 million unique soldiers (active duty, Reserves, and National Guard) were tested during this timeframe, and 17.1% of the study population was recorded as being bothered a little or a lot by tinnitus.(39)

In a retrospective study of U.S. Army soldiers (active duty, Reserves, and National Guard) who were in Operation Iraqi Freedom (OIF) and were seen in an audiology clinic for post-deployment assessment, 30.8% of the Service members were diagnosed with tinnitus.(40) Other studies have found that for Service members with combat-related blast injuries, the prevalence of tinnitus is between 6.1% and 49.2%.(41–44)

Service members who have mild traumatic brain injury (mTBI) because of a combat injury are more likely to report tinnitus. For example, Service members who were deployed to OIF and were diagnosed with mTBI were more likely to report tinnitus (34.7%) compared with Service members not diagnosed with mTBI (17.9%).(45) A 2016 study by Karch et al. found that Service members with mTBI who were blast exposed reported tinnitus at a rate of 59%, whereas Service members with mTBI who were not blast exposed reported tinnitus at a rate of 40%.(46) Another study by Wilk et al. (2010) separated soldiers into two concussion groups, those with loss of consciousness (LOC) and those with a change in consciousness only (no LOC).(47) These two groups were further separated into those who were blast injured and those who were non-blast injured. Tinnitus prevalence for soldiers who experienced LOC was 34.4% for those blast injured and 15% for those non-blast injured. Tinnitus prevalence was 22.2% for blast-injured soldiers and 17% for non-blast–injured soldiers who reported a change in consciousness only.

The incidence rate of tinnitus has increased from 1.84 per 1,000 U.S. military Service members in 2001 to 6.33 per 1,000 Service members in 2015.(48) The prevalence of

tinnitus diagnosis varied across the services, with the Army at 37%, the Air Force at 32%, the Navy at 19%, and the Marine Corps at 12%.

D. Tinnitus in the Department of Veterans Affairs Population

a. Prevalence and Epidemiology of Tinnitus in United States Military Veterans

Among U.S. military Veterans, tinnitus is the most common service-connected disability, with 2,944,093 total recipients of compensation as of September 30, 2023, depicted in Table 2. Auditory injuries (such as hearing loss and tinnitus) in Veterans and Service members are sometimes associated with occupational exposures to loud noise or chemicals (such as solvents) or with otoacoustic trauma caused by bombs, blasts, traumatic brain injury (TBI), or any combination of the aforementioned trauma sustained during military service.(49, 50) Physical injuries such as head or neck trauma and structural damage to the auditory system (e.g., perforated eardrums) can also contribute to the development of tinnitus.

Table 2. Most Prevalent Service-Connected Disabilities in the Veterans Benefits Administration; Annual Benefits Report for Fiscal Year 2023 (51)

Disability	Number
Tinnitus	2,944,093
Limitation of flexion, knee	1,853,161
Paralysis of the sciatic nerve	1,502,563
Hearing loss	1,491,093
Lumbosacral or cervical strain	1,453,400
Posttraumatic stress disorder	1,451,153
Limitation of motion of the arm	1,034,311
Limitation of motion of the ankle	1,028,010
Migraine	954,038
Scars, general	937,680
Total number of most prevalent disabilities	14,649,502
Total number of disabilities	37,296,902

Folmer et al. (2011) used NHANES data to estimate the prevalence of hearing loss and tinnitus among male Veterans in the United States.(52) Between 1999 and 2006, pure tone audiometric data collected from male Veterans (n=845) were compared with pure tone thresholds collected from male non-Veterans (n=2,086). Questionnaire data collected between 1999 and 2004 was used to calculate and compare the prevalence of tinnitus for Veterans (n=2,174) and non-Veterans (n=4,995). In general, pure tone thresholds did not differ significantly between Veterans and non-Veterans for most frequencies tested (500–8000 hertz [Hz]). However, the overall prevalence of tinnitus was greater for Veterans (11.7%) than for non-Veterans (7.1%; $p<0.001$), with statistically significant differences in the 50–59 and 60–69 age groups.

Oleksiak et al. (2012) investigated auditory problems experienced by Veterans of Operation Enduring Freedom (OEF) and OIF diagnosed with mTBI and identified a subset of patients (n=75) who received a referral to audiology services following comprehensive evaluation for TBI.(53) Of the patients (n=37) who attended the audiology appointment, 60% reported hearing problems and 76% reported tinnitus. It is noteworthy that audiometric results were found to be within normal limits in 35% of the sample. Central auditory processing deficits were confirmed in 16% (n=6) of the 37 Veterans. In their review of studies involving Veterans of OEF, OIF, and Operation New Dawn, Theodoroff et al. (2015) reported that auditory complaints, such as hearing problems and tinnitus, have a high prevalence (often greater than 50%) among Veterans who experienced blast exposure, TBI, or PTSD.(50)

An ongoing longitudinal study by Henry et al. (2019) assessed lifetime noise, chemical and blast exposures, physical and psychiatric comorbidities, and other military and non-military exposures and outcomes that can affect auditory function in active duty Service members and recently separated Veterans.(54) Data from Veterans in the study (n=246) indicated the following prevalence rates of tinnitus: no tinnitus (28%), temporary/ occasional tinnitus (6%), intermittent tinnitus (22%), and constant tinnitus (44%).

b. Impact of Tinnitus on Service Members and Veterans

Tinnitus can be associated with anxiety, depression, sleep disorders, early-onset dementia, and other comorbidities contributing to decreased QoL among Service members and Veterans.(50, 55, 56) Henry et al. (2019) reported that 59% of Veterans and 44% of Service members with tinnitus rated the condition as a moderate, big, or very big problem.(54) The presence of tinnitus had negative effects on job performance, concentration, anxiety, depression, and sleep. In addition, evidence that bothersome tinnitus might affect short-term memory exists.(57, 58) Service members or Veterans suffering from PTSD are more likely to present with severe tinnitus symptoms and sound intolerance compared with Veterans without PTSD.(59)

Tinnitus and hearing loss acquired during military service might be exacerbated by subsequent exposure to non-military risk factors, including non-occupational noise exposure (e.g., recreational gunfire, power tools, machinery, music). Hearing loss and tinnitus are usually irreversible, meaning that affected Service members and Veterans might face a lifetime of clinical care to manage associated problems with sleep, concentration, mood, and communication difficulty. Additionally, tinnitus has been shown to be a greater burden for Veterans than chronic back pain in terms of health care costs and reduced productivity.(56) In a study of Veterans with tinnitus (n=891), Coco et al. (2023) reported that for every 1-point increase in the Tinnitus Functional Index (TFI) score, an 8% increase occurred in the odds of reporting a high level of negative impact on work functioning (OR: 1.08; 95% CI: 1.06–1.11).(60) Veterans with a comorbid TBI diagnosis, compared with those without, were more likely to have a high tinnitus-related impact on work functioning (OR: 2.69; 95% CI: 1.85–3.91).(60)

III. Scope of This Guideline

This CPG is based on published clinical evidence and related information available through April 7, 2023. It is intended to provide general guidance on best evidence-based practices (see Appendix A for additional information on the evidence review methodology). Although the CPG is intended to improve the quality of care and clinical outcomes (see Introduction), it is not intended to define a standard of care (i.e., mandated or strictly required care).

A. Guideline Audience

This CPG is intended for use by VA, DoD, and community-based providers involved in the care of Veterans and/or Service members and their adult beneficiaries with bothersome tinnitus.

B. Guideline Population

The patient population of interest for this CPG is adult patients (aged 18 years or older) with bothersome tinnitus who are eligible for care in the VA or DoD healthcare delivery systems, and those who receive care from community-based clinicians. It includes Veterans and Service members as well as their adult dependents.

IV. Highlighted Features of This Guideline

A. Highlights in This Guideline

This document is the first version of the VA/DoD Tinnitus CPG. This CPG provides recommendations for providers on the clinical assessment and care options for patients who report bothersome tinnitus.

This CPG is strengthened by the involvement of a broad spectrum of interested parties, including consumers and experts, in retrieving and summarizing clinical evidence, as well as VA and DoD providers across disciplines who are engaged in direct clinical care, research, and health care administration.

The recommendations in this CPG take the following factors into consideration: assessing confidence in the quality of the evidence; balancing desired outcomes with potential harms; supporting equity across subgroups; recognizing the potential for variation in patient values and preferences; and considering feasibility for implementation and acceptability for the full range of stakeholders. Due to rigorous adherence to GRADE methodology (e.g., lack of RCTs, study design limitations), the VA/DoD Tinnitus CPG Work Group did not have the evidence to make strong recommendations for this CPG.

Highlights in this CPG include the following.

- This CPG recognizes the complexities of tinnitus and common co-occurring conditions in military and Veteran populations. The recommendations are based on the most recent and practical scientific and clinical evidence.
- The recommendations and the algorithm are focused on reducing the impact of tinnitus and promoting wellness. They include patient education and counseling; use of various types of coping strategies (e.g., use of sound); and referrals to specialists as part of a multidisciplinary, patient-centered, holistic/whole health approach to providing care for tinnitus.
- Although most cases of chronic tinnitus cannot be "cured" or made quieter, several effective strategies to reduce the functional impact of tinnitus have been developed and are currently available. This CPG provides the most up-to-date information available so health care providers can counsel patients, assess their condition, and help them improve QoL and functional status with tinnitus. The goal of providing care for tinnitus is to facilitate improvement in the patient's QoL and functional status with tinnitus.

B. Components of This Guideline

This CPG provides clinical practice recommendations for the care of patients with bothersome tinnitus (see Recommendations). In addition, the Algorithm incorporates the recommendations in the context of the flow of patient care. This CPG also includes Research Priorities, which list areas the Work Group identified as needing additional research.

To accompany this CPG, the Work Group also developed toolkit materials for providers and patients, including a provider summary, a patient summary, and a pocket card, which can be found at https://www.healthquality.va.gov/index.asp.

C. Racial and Ethnic Demographic Terminology in This Guideline

Demographic terms referring to an individual's race or ethnicity (e.g., Hispanic, Latino or Latina, Asian, Native American, Black, African American, White) can be ambiguously defined and understood, reflecting diverse geographies, histories, cultures, and experiences. Aligned with the recent Executive Order on Further Advancing Racial Equity and Support for Underserved Communities through the Federal Government,[d] the Work Group used terms such as Black rather than African American and White rather than Caucasian to avoid presumptions about ancestry and to promote inclusivity, clarity, and consistency. However, to represent accurately the evidence on which this CPG is based, the Work Group generally deferred to racial and ethnic terminology as reported in the published SRs, clinical trials, and other studies comprising that evidence

[d] Executive Order on Further Advancing Racial Equity and Support for Underserved Communities Through The Federal Government | The White House

when summarizing or otherwise referring to those studies. Consequently, usage of demographic terms in this CPG might appear inconsistent.

V. Guideline Development Team

The VA Evidence Based Practice, Office of Quality and Patient Safety, in collaboration with the Clinical Quality Improvement Program, Defense Health Agency, identified the following four providers to serve as Champions (i.e., leaders) of this CPG's Work Group: Robert Folmer, PhD, and Tara Zaugg, AuD, from VA; and LaGuinn Sherlock, AuD, CCC-A, CH-TM, and Michele Spencer, AuD, CCC-A, CH-TM, from DoD.

The Work Group comprised individuals with the following areas of expertise: audiology, neurotology, nursing, pharmacy, psychology, sociology, and speech and hearing science. Table 3 lists the Work Group and Guideline Development Team members.

This CPG Work Group, led by the Champions, was tasked with

- Determining the scope of the CPG;
- Crafting clinically relevant key questions (KQ) to guide the systematic evidence review;
- Identifying discussion topics for the patient focus group and considering the patient perspective;
- Providing direction on inclusion and exclusion criteria for the systematic evidence review and the assessment of the level and quality of evidence; and
- Developing evidence-based clinical practice recommendations, including determining the strength and category of each recommendation.

The Lewin Team, including The Lewin Group, ECRI, Sigma Health Consulting, and Duty First Consulting, was contracted by VA to help develop this CPG.

Table 3. Guideline Work Group and Guideline Development Team

Organization	Names*
Department of Veterans Affairs	**Robert Folmer, PhD (Champion)**
	Tara Zaugg, AuD (Champion)
	Jenifer Beck, AuD
	Khaya Clark, PhD
	Maria Colandrea, DNP, NP-C, CORLN, FAANP
	Catherine Edmonds, AuD, CCC-A, CH-TM
	Catherine Kelley, PharmD
	Elizabeth Lima, PhD
	Sally Mahmood, AuD, CCC-A
	Idalisse Martinez, AuD, FAAA, CH-TM
	Paula Myers, PhD, CCC-A
	Sarah Theodoroff, PhD, CCC-A, FAAA

Organization	Names*
Department of Defense	**LaGuinn Sherlock, AuD, CCC-A, CH-TM (Champion)**
	Michele Spencer, AuD, CCC-A, CH-TM (Champion)
	Laurel Alstot, AuD
	Amy Boudin-George, AuD, CCC-A
	Carlos Esquivel, MD, FACS, FAAOA
	Suheily Lovelace, PhD
	David (Nick) Patterson, PharmD, BCPS
	CDR Sara Pulliam, PsyD, ABPP
	LTC Anthony Tolisano, MD
VA Evidence Based Practice, Office of Quality and Patient Safety Veterans Health Administration	James Sall, PhD, FNP-BC
	Jennifer Ballard-Hernandez, DNP, RN, FNP-BC
	René Sutton, BS, HCA, FAC-COR II
	Sarah Davis-Arnold, MSN, RN, NPD-BC, RCIS, EBP-C
	Lisa Wayman, PhD, RN
Clinical Quality Improvement Program Defense Health Agency	Isabella M. Alvarez, MA, BSN, RN
	Cynthia F. Villarreal, BSN, RN
	Lynn M. Young, BSN, RN, CIC
	Gwendolyn Holland, MSN, RN
The Lewin Group	Jennifer Weil, PhD
	Erika Beam, MS
	Kristen Godwin, MPH
	Inveer Nijjar, BS
	Charlie Zachariades, MSc
ECRI	Jim Reston, PhD, MPH
	Stacey Uhl, MS
	Dan Sztubinski, BS
	Michele Datko, MS
Sigma Health Consulting	James G. Smirniotopoulos, MD
	Frances M. Murphy, MD, MPH
Duty First Consulting	Kate Johnson, BS
	Anita Ramanathan, BA
	Jake Fausnacht, BS

*Additional contributor contact information is available in Appendix J.

VI. Summary of Guideline Development Methodology

The methodology used in developing this CPG follows the *Guideline for Guidelines*, an internal document of the VA/DoD EBPWG updated in January 2019 that outlines procedures for developing and submitting VA/DoD CPGs.(61) The *Guideline for Guidelines* is available at http://www.healthquality.va.gov/policy/index.asp. This CPG also aligns with the National Academy of Medicine's (NAM) principles of trustworthy CPGs (e.g., explanation of evidence quality and strength, management of potential

conflicts of interest [COI], interdisciplinary stakeholder involvement, use of SR and external review).(62) Appendix A provides a detailed description of the CPG development methodology.

A. Evidence Quality and Recommendation Strength

The Work Group used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach to craft each recommendation and determine its strength. Per the GRADE approach, recommendations must be evidence based and cannot be made based on expert opinion alone. The GRADE approach uses the following four domains to inform the strength of each recommendation (see Determining Recommendation Strength and Direction).(63)

1. Confidence in the quality of the evidence
2. Balance of desirable and undesirable outcomes
3. Patient values and preferences
4. Other considerations, as appropriate (e.g., resource use, equity, acceptability, feasibility, subgroup considerations)

Using these four domains, the Work Group determined the relative strength of each recommendation (*Strong* or *Weak*). The strength of a recommendation is defined as the extent to which one can be confident that the desirable effects of an intervention outweigh its undesirable effects and is based on the framework above, which incorporates the four domains.(64) A *Strong* recommendation generally indicates *High* or *Moderate* confidence in the quality of the available evidence, a clear difference in magnitude between the benefits and harms of an intervention, similar patient values and preferences, and understood influence of other implications (e.g., resource use, feasibility).

In some instances, insufficient evidence exists on which to base a recommendation for or against a particular therapy, preventive measure, or other intervention. For example, the systematic evidence review might have found little or no relevant evidence, inconclusive evidence, or conflicting evidence for the intervention. The manner in which this finding is expressed in the CPG might vary. In such instances, the Work Group might include among its set of recommendations a statement of insufficient evidence for an intervention that might be in common practice although it is unsupported by clinical evidence and particularly if other risks of continuing its use might exist (e.g., high opportunity cost, misallocation of resources). In other cases, the Work Group might decide to exclude this type of statement about an intervention. For example, the Work Group might remain silent where an absence of evidence occurs for a rarely used intervention. In other cases, an intervention might have a favorable balance of benefits and harms but might be a standard of care for which no recent evidence has been generated.

Using these elements, the Work Group determines the strength and direction of each recommendation and formulates the recommendation with the general corresponding text as shown in Table 4.

Table 4. Strength and Direction of Recommendations and General Corresponding Text

Recommendation Strength and Direction	General Corresponding Text
Strong for	We recommend . . .
Weak for	We suggest . . .
Neither for nor against	There is insufficient evidence to recommend for or against . . .
Weak against	We suggest against . . .
Strong against	We recommend against . . .

That a recommendation's strength (i.e., *Strong* versus *Weak*) is distinct from its clinical importance (e.g., a *Weak* recommendation is evidence based and still important to clinical care) is important to note. The strength of each recommendation is shown in Recommendations.

This CPG's use of GRADE reflects a more rigorous application of the methodology than previous iterations; the determination of the strength of the recommendation is more directly linked to the confidence in the quality of the evidence on outcomes that are critical to clinical decision making. The confidence in the quality of the evidence is assessed using an objective, systematic approach independent of the clinical topic of interest. Therefore, recommendations on topics for which designing and conducting rigorous studies might be inherently more difficult (e.g., randomized controlled trials [RCT]) are typically supported by lower quality evidence and, in turn, *Weak* recommendations). Recommendations on topics for which rigorous studies can be designed and conducted might more often be *Strong* recommendations. Per GRADE, if the quality of evidence differs across the relevant critical outcomes, the lowest quality of evidence for any of the critical outcomes determines the overall quality of the evidence for a recommendation.(65, 66) This stricter standard provides a consistent approach to determining recommendation strengths. Due to rigorous adherence to GRADE methodology (e.g., lack of RCTs, study design limitations), the VA/DoD Tinnitus CPG Work Group did not have the evidence to make strong recommendations for this CPG. For additional information on GRADE or CPG methodology, see Appendix A.

B. Categorization of Clinical Practice Guideline Recommendations

Evidence-based CPGs should be current. Except for an original version of a new CPG, staying current typically requires revision of a CPG's previous versions based on new evidence or as scheduled subject to time-based expirations.(67) For example, the U.S. Preventive Services Task Force (USPSTF) has a process for monitoring the emergence of new evidence that could prompt an update of its recommendations, and it aims to review each topic at least every five years for either an update or reaffirmation.(68)

Recommendation categories were used to track how the previous CPG's recommendations could be reconciled. These categories and their corresponding definitions are similar to those used by the National Institute for Health and Care

Excellence (NICE, England).(69, 70) Table 5 lists these categories, which are based on whether the evidence supporting a recommendation was systematically reviewed, the degree to which the previous CPG's recommendation was modified, and whether a previous CPG's recommendation is relevant in the updated CPG.

Additional information regarding these categories and their definitions can be found in Recommendation Categorization. The 2024 CPG recommendation categories can be found in Recommendations.

Table 5. Recommendation Categories and Definitions[a]

Evidence Reviewed	Recommendation Category	Definition
Reviewed[b]	New-added	New recommendation
	New-replaced	Recommendation from previous clinical practice guideline (CPG) was carried forward and revised
	Not changed	Recommendation from previous CPG was carried forward but unchanged
	Amended	Recommendation from previous CPG was carried forward with a nominal change
	Deleted	Recommendation from previous CPG was deleted
Not Reviewed[c]	Not changed	Recommendation from previous CPG was carried forward but unchanged
	Amended	Recommendation from previous CPG was carried forward with a nominal change
	Deleted	Recommendation from previous CPG was deleted

[a] Adapted from the NICE guideline manual (2012)(69) and Garcia et al. (2014)(70)

[b] The topic of this recommendation was covered in the evidence review carried out as part of the development of the current CPG.

[c] The topic of this recommendation was not covered in the evidence review carried out as part of the development of the current CPG.

C. Management of Potential or Actual Conflicts of Interest

Management of COIs for the CPGs is conducted as described in the *Guideline for Guidelines*.(61) Further, the *Guideline for Guidelines* refers to details in the VHA Handbook 1004.07 Financial Relationships between VHA Health Care Professionals and Industry (November 2014, issued by the VHA National Center for Ethics in Health Care)(71) as well as to disclosure statements (i.e., standard disclosure form completed at least twice by CPG Work Group members and the guideline development team).(61) The disclosure form inquires regarding relevant financial and intellectual interests or other relationships with, for example, manufacturers of commercial products, providers of commercial services, or other commercial interests. The disclosure form also inquires regarding any other relationships or activities that could be perceived to have influenced, or that give the appearance of potentially influencing, a respondent's contributions to the CPG. In addition, instances of potential or actual COIs among the CPG Work Group and the guideline development team were subject to random web-

based identification via standard electronic means (e.g., Centers for Medicare & Medicaid Services Open Payments, ProPublica).

Potential COIs were reported to VA and DoD program offices and reviewed with the Champions. VA and DoD program offices and the Champions determined further action as appropriate (e.g., clarifying role as Champion or Work Group member, recusing Work Group members from selected relevant deliberations). Disclosure forms are on file with the VA Office of Quality and Patient Safety and are available on request.

D. Patient Perspective

When developing a CPG, consideration should be given to patient perspectives and experiences, which often vary from those of providers.(65, 72) Focus groups can be used to help collect qualitative data on patient perspectives and experiences. VA and DoD Leadership arranged a virtual patient focus group on January 12, 2023. The focus group aimed to gain insight from patients with tinnitus of potential relevance and incorporate these insights into the CPG, as appropriate. Topics discussed included the patients' priorities, challenges they have experienced, information they have received regarding their care, and impacts of their care on their lives.

The patient focus group comprised a convenience sample of seven people. There were six men and one woman. Two participants were Veterans who received care from the VA health system, and four participants were Service members who received care from the DoD health system. One participant received care from both VA and DoD health systems. The Work Group acknowledges this convenience sample is not representative of all patients with tinnitus within the VA and DoD health care systems and, thus, findings are ungeneralizable and do not comprise evidence. For more information on the patient focus group methods and findings, see Appendix H. The patient focus group participants were provided the opportunity to review the final draft and provide additional feedback.

E. External Peer Review

The Work Group drafted, reviewed, and edited this CPG using an iterative process. For more information, see Drafting and Finalizing the Guideline. Once the Work Group members completed a near-final draft, they identified experts from VA and DoD health care systems and outside organizations generally viewed as experts in the respective field to review it. The draft was sent to those experts for a 14-business-day review and comment period. The Work Group considered all feedback from the peer reviewers and modified the CPG where justified, in accordance with the evidence. Detailed information on the external peer review can be provided by the VA Office of Quality and Patient Safety.

F. Implementation

This CPG and algorithm are designed for adaptation by individual health care providers with respect to unique patient considerations and preferences, local needs, and resources. The algorithm serves as a tool to prompt providers to consider key decision

points in the care for a patient with tinnitus. The Work Group submits suggested performance metrics for VA and DoD to use when assessing the implementation of this CPG. Robust implementation is identified in VA and DoD internal implementation plans and policies. Additionally, implementation entails wide dissemination through publication in the medical literature, online access, educational programs, and, ideally, electronic medical record programming in the form of clinical decision support tools at the point of care.

VII. Approach to Care in the Department of Veterans Affairs and the Department of Defense

A. Patient-Centered Care

Intended to consider patient needs and preferences, guideline recommendations represent a whole/holistic health approach to care that is patient-centered, culturally appropriate, and available to people with limited literacy skills and physical, sensory, or learning disabilities. VA/DoD CPGs encourage providers to use a patient-centered, whole/holistic health approach (i.e., individualized treatment based on patient needs, characteristics, and preferences). This approach aims to treat the particular condition while also optimizing the individual's overall health and wellbeing.

Regardless of the care setting, all patients should have access to individualized evidence-based care. Patient-centered care can decrease patient anxiety, increase trust in providers, and improve treatment adherence.(73, 74) A whole/holistic health approach (https://www.va.gov/wholehealth/) empowers and equips individuals to meet their personal health and wellbeing goals. Good communication is essential and should be supported by evidence-based information tailored to each patient's needs. An empathetic and non-judgmental approach facilitates discussions sensitive to sex, culture, ethnicity, and other differences.

B. Shared Decision Making

This CPG encourages providers to practice shared decision making, a process in which providers, patients, and patient care partners (e.g., family, friends, caregivers) consider clinical evidence of benefits and risks as well as patient values and preferences to make decisions regarding the patient's treatment.(75) Shared decision making is emphasized in *Crossing the Quality Chasm,* an Institute of Medicine, now NAM, report in 2001 (76) and is inherent within the whole/holistic health approach. Providers must be adept at presenting information to their patients regarding individual treatments, expected risks, expected outcomes, and levels or settings of care or both, especially where patient heterogeneity in weighing risks and benefits might exist. Veterans Health Administration and DHA have embraced shared decision making. Providers are encouraged to use shared decision making to individualize treatment goals and plans based on patient capabilities, needs, and preferences.

C. Patients with Co-occurring Conditions

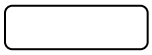
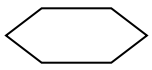
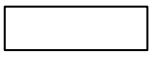
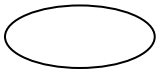
Co-occurring conditions can modify the degree of risk, impact diagnosis, influence patient and provider treatment priorities and clinical decisions, and affect the overall management approach to reduce tinnitus functional impact. Many Veterans, active duty Service members, and their families have one or more co-occurring conditions. Because tinnitus is sometimes accompanied by co-occurring conditions, managing tinnitus functional impact collaboratively with other care providers is often best. Some co-occurring conditions might require early specialist consultation to determine necessary changes in treatment or to establish a common understanding of how care will be coordinated. This approach might entail reference to other VA/DoD CPGs (e.g., for Suicide Risk, PTSD, Insomnia/Obstructive Sleep Apnea, Major Depressive Disorder, mTBI).[e]

VIII. Algorithm

This CPG's algorithm is designed to facilitate understanding of the clinical pathway and decision-making process used in managing patients with tinnitus. This algorithm format represents a simplified flow of the initial evaluation of tinnitus and management and improvement of QoL with tinnitus and helps foster efficient decision making by providers. It includes

- Steps of care in an ordered sequence,
- Decisions to be considered,
- Decision criteria recommended, and
- Actions to be taken.

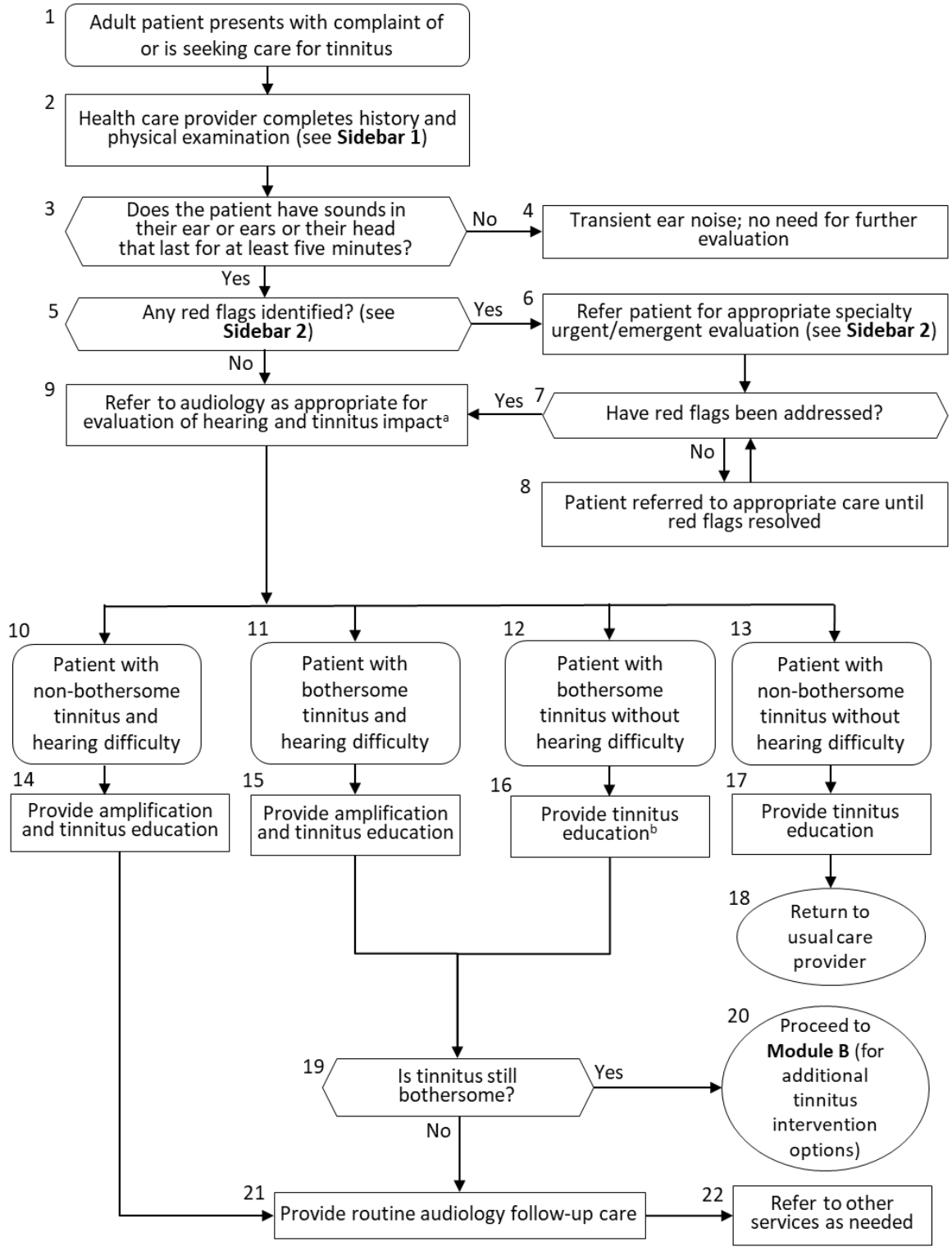
The algorithm is a step-by-step decision tree. Standardized symbols display each step, and arrows connect the numbered boxes indicating the order in which the steps should be followed.(77) Sidebars 1–5 provide more detailed information to assist in defining and interpreting elements in the boxes.

Shape	Description
	Rounded rectangles represent a clinical state or condition.
	Hexagons represent a decision point in the process of care, formulated as a question that can be answered "Yes" or "No."
	Rectangles represent an action in the process of care.
	Ovals represent a link to another section within the algorithm.

Appendix L contains alternative text descriptions of the algorithms.

[e] The VA/DoD Clinical Practice Guidelines are available at: https://www.healthquality.va.gov/

A. Module A: Initial Evaluation of Tinnitus



[a] If the patient has already been referred to audiology and does not indicate a need for care, then referral to audiology is unnecessary.

[b] Provide low gain hearing aids, sound generators, or both, as appropriate.

Sidebar 1: Relevant History and Symptoms

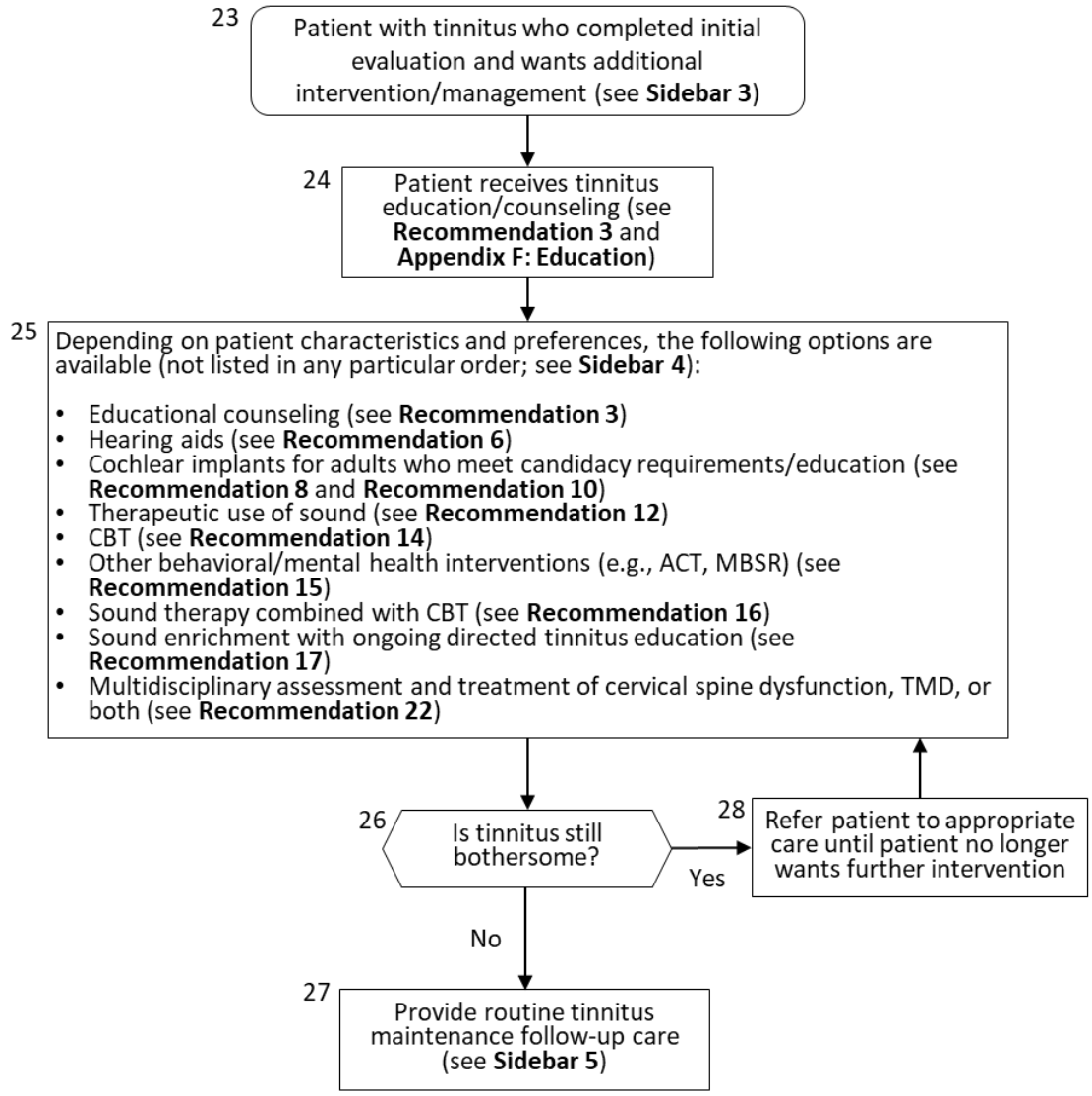
Provider should first rule out transient ear noise, defined as the perception of sound, usually occurring in one ear at a time and described as high-pitched ringing or tone, lasting fewer than five minutes, and sometimes accompanied by a sense of hearing loss and aural fullness. Transient ear noise is common and does not generally require clinical management. If transient ear noise is ruled out, the following pertinent information should be obtained (not in any particular order).

- Frequency, laterality, quality (e.g., pulsatile, non-pulsatile), and intensity of tinnitus
- Circumstance and date of onset of tinnitus
- Impact of tinnitus on sleep, daily activities, or quality of life (screen the patient with a validated instrument, when indicated)
- Hearing loss (e.g., asymmetric, bilateral, unilateral, sudden, recent)
- Ear pressure or fullness with normal ear exam
- Presence of co-occurring conditions, such as anxiety, stress, depression, insomnia, dental issues (e.g., temporomandibular disorder [TMD]), cervical issues
- History of head or neck injury; blast exposure; noise exposure; hearing difficulties; sound tolerance issues; ear pain, drainage, or both; dizziness or vertigo; or possible ototoxic medication (see Appendix C)

Sidebar 2: Suggested Referrals[a]			
Type	**If the patient**	**Refer to**	**Status/Considerations**
Urgent (Red Flag) Referrals	Has neurological deficits such as cranial nerve weakness/paralysis, severe vertigo, or stroke symptoms	Emergency department or otolaryngology	Emergency
	Expresses suicidal ideation	Behavioral/mental health or emergency department or 988 Suicide & Crisis Line	Assess for urgent conditions; report suicide ideation and provide escort, if necessary
	Has sudden or unexplained hearing loss or both and/or reports recent head, neck, or acoustic trauma or any combination of the aforementioned trauma	Audiology and otolaryngology	Emergency; must see audiologist before otolaryngologist as soon as possible, ideally on the same day or within 24 hours
	Has otalgia, otorrhea, vestibular symptoms, and/or sudden onset of pulsatile tinnitus.	Otolaryngology and audiology	Urgent; schedule otolaryngology exam as soon as possible
Non-urgent Referrals	Has depression, anxiety, or insomnia	Behavioral/mental health	Assess for urgent conditions; schedule behavioral/mental health assessment as appropriate
	Has hearing difficulties, sound tolerance issues	Audiology (and otolaryngology pro re nata [PRN])	Non-urgent; schedule audiology exam before patient sees otolaryngologist
	Has orofacial issues such as temporomandibular disorder (TMD)	Dental (and orofacial massage provider PRN)	Non-urgent; schedule dental exam before patient sees orofacial massage provider
	Has neck dysfunction or neck injury	Refer to physiotherapist or physical therapist	Non-urgent

[a] Adapted from Henry et al. (2010) Tinnitus Triage Guide (78)

B. Module B: Managing and Improving Quality of Life



Abbreviations: ACT: Acceptance and Commitment Therapy; CBT: cognitive behavioral therapy; MBSR: mindfulness-based stress reduction; TMD: temporomandibular disorder

Sidebar 3: Additional Support to Consider
Basic audiological services will adequately address tinnitus-related problems for many patients. For patients requiring further intervention, consider the following to improve quality of life. • Address the hearing problem regardless of the label the patient applies to it. Many people say they want help with tinnitus, but they really are seeking help with hearing difficulties. • Address sound tolerance problems. • Address behavioral/mental health comorbidities (e.g., mood disorders, insomnia). • Address specific problems associated with bothersome tinnitus (e.g., relationships with family members and others). • Address general health and wellness and engage with primary care. • Inform the patient of indications and timeframes when referrals for additional support are needed. • Describe stepped care approach or other patient-centered approaches based on services offered at local facility. • Monitor outcomes.

Sidebar 4: Evidence-Based Practices to Improve Quality of Life with Tinnitus		
Intervention	**Provided by**	**Description**
Educational counseling (see Recommendation 3)	• Audiologist • Otolaryngology • Behavioral/mental health	We suggest education and counseling to aid in decision making, with recommendations to provide patients with information about available management strategies, including counseling and sound therapy options; natural history and prognosis; the association between hearing loss and tinnitus; effects of lifestyle on tinnitus; importance of hearing protection and realistic expectations regarding improving quality of life (QoL) with tinnitus. We also suggest providing brochures, recommending available self-help books, and referring to health care professionals who offer evidence-based tinnitus care.
Hearing aids (activation of sound generator pro re nata [PRN]) (see Recommendations 6 and 7)	Audiologist	Refer to Module A of the Algorithm. We suggest hearing aid evaluation and fitting of hearing aids or combination instruments for patients, as appropriate, to maximize communication function; conduct follow-up assessment with validated hearing aid and tinnitus questionnaires at least one month following device fittings; and assess activation of the sound generator, as warranted.
Cochlear implant considerations when candidacy criteria are met (see Recommendations 8 and 10)	• Audiologist • Otolaryngology	We suggest cochlear implants for patients who derive no benefit from hearing aids and meet cochlear implantation candidacy criteria.

Sidebar 4: Evidence-Based Practices to Improve Quality of Life with Tinnitus		
Intervention	**Provided by**	**Description**
Sound enrichment with ongoing directed tinnitus education by an audiologist (see Recommendation 17)	Audiologist	We suggest sound-based enrichment with ongoing directed tinnitus education by an audiologist with repeated visits over time, such as the following. • **Tinnitus Activities Treatment (TAT)** involves a picture-based approach to counseling on thoughts and emotions, hearing and communication, sleep, and concentration in conjunction with partial masking sound therapy with noise or music set to the lowest level that provides relief. • **Tinnitus Retraining Therapy (TRT)** involves directed counseling aimed at reclassification of tinnitus to a category of neutral signals and sound therapy aimed at weakening tinnitus-related neuronal activity.
CBT (see Recommendation 14)	Behavioral/mental health	**Cognitive Behavioral Therapy (CBT)** is a time-limited structured therapy that aims to recognize and change unhelpful thoughts and behaviors with the goal of improving functioning and quality of life (QoL). See other uses of CBT below.
Sound therapy combined with CBT (see Recommendation 16)	• Audiologist • Behavioral/mental health	• Sound therapy combined with CBT can provide coping strategies to improve QoL with tinnitus even though tinnitus does not change. See above definition of CBT. • **Progressive Tinnitus Management (PTM):** The stepped-care program offers a standardized curriculum skills education intervention following basic audiologic care. The skills education is delivered collaboratively by an audiologist and a behavioral health care provider. The audiologist teaches patients about using sound to improve QoL with tinnitus and provides ongoing structure and support as the patients try out various sounds away from sessions to learn which sounds help them reach their goals for living better with tinnitus. The behavioral health care provider teaches coping strategies rooted in CBT, such as employing relaxation techniques, planning pleasant activities, and balancing thoughts and feelings. The behavioral health care provider also provides a structure for patients to try various CBT skills outside visits to learn which of those strategies help them reach their goals for living better with tinnitus. The combination of CBT and sound-based strategies allows patients access to a wide variety of strategies to try to discover which ones work best for them as an individual. Multiple visits as part of the PTM program provide structure and support as patients incorporate newly learned strategies into their daily lives.

Sidebar 4: Evidence-Based Practices to Improve Quality of Life with Tinnitus		
Intervention	**Provided by**	**Description**
Other behavioral/mental health interventions (e.g., ACT, cognitive therapy, MBSR, relaxation) (see Recommendation 15)	Behavioral/mental health	Behavioral/mental health interventions (such as the following below) for bothersome tinnitus. • **Acceptance and Commitment Therapy (ACT)** is an action-oriented approach to psychotherapy that aims to help patients stop avoiding, denying, and struggling with inner emotions and instead accept these feelings as appropriate responses to certain situations that should not prevent them from moving forward in their lives to accept their tinnitus and to commit to making necessary changes in their behavior, regardless of what is happening in their lives and how they feel about it. By taking steps to change behavior while at the same time learning to accept psychological experiences, individuals can eventually change their attitudes and emotional states. • **Mindfulness-Based Stress Reduction® (MBSR)** is a specific protocol involving secular intensive mindfulness training. • **Mindfulness** is moment-to-moment awareness of one's experience without clinging to judgements the mind naturally makes, which can reduce the negative impact of tinnitus.
Multidisciplinary approach for assessment and treatment of patients with bothersome tinnitus and temporomandibular disorder (TMD), cervical spine dysfunction, or both (see Recommendation 22)	• Audiologist • Dental provider • Physical therapist • Physiotherapist • Orofacial massage provider • Otolaryngology	We suggest multidisciplinary orofacial treatment, treatment of the cervical spine, or both for patients with somatosensory tinnitus influenced by TMD or cervical spine dysfunction.

Sidebar 5: Maintenance and Support

When individuals with bothersome tinnitus learn to cope better with the tinnitus functional impact, opportunities exist to plan for maintenance for the additional supports that might be needed to maintain or enhance quality of life with tinnitus. The collaborative planning process should incorporate the following.

- Education about tinnitus, including information about hearing conservation, personalized effectiveness of sound therapy and other strategies for clinical management, and opportunities for general wellness
- Shared decision making with the patient, patient care partners (where appropriate), and the multidisciplinary team
- Issues to think about
  - Defining the relationship with the provider, management team, or both; scheduling appointments, other contacts, and procedures for addressing urgent needs and referrals to other providers for management of co-occurring conditions
  - Planning monitoring of symptoms and adherence to an action plan
  - Discussing methods and availability of tools to support day-to-day self-monitoring
- Engaging caregivers, family members, and significant others in monitoring the need for additional support; when appropriate, identifying early warning signs of hearing loss or increased tinnitus with dangerously loud sounds and reporting sudden changes in hearing or tinnitus to the individual's provider

IX. Recommendations

The evidence-based clinical practice recommendations listed in Table 6 were made using a systematic approach considering four domains as per the GRADE approach (see Summary of Guideline Development Methodology). These domains include confidence in the quality of the evidence, balance of desirable and undesirable outcomes (i.e., benefits and harms), patient values and preferences, and other implications (e.g., resource use, equity, acceptability). Due to rigorous adherence to GRADE methodology (e.g., lack of RCTs, study design limitations), the VA/DoD Tinnitus CPG Work Group did not have the evidence to make strong recommendations for this CPG.

Some of the recommendations use the qualifier term "tinnitus management." The Work Group wants to emphasize that tinnitus management does not solely refer to the sound and perception of tinnitus. Evidence-based, patient-centered clinical care for tinnitus generally focuses on the impact of tinnitus on QoL, well-being, wellness, self-care, and management of co-occurring chronic conditions to improve clinical outcomes.

Table 6. Evidence-Based Clinical Practice Recommendations with Strength and Category

Topic	Sub-topic	#	Recommendation	Strength[a]	Category[b]
Monitoring		1.	We suggest using validated subjective outcome measures (e.g., Tinnitus Functional Index, Tinnitus Handicap Inventory) to monitor the effectiveness of tinnitus management.	Weak for	Reviewed, New-added
		2.	We suggest against psychoacoustic measures (e.g., minimum masking level, loudness matching) to monitor the effectiveness of tinnitus management.	Weak against	Reviewed, New-added
Education and Self-Management		3.	We suggest educational counseling to reduce the functional impact of tinnitus.	Weak for	Reviewed, New-added
		4.	There is insufficient evidence to recommend for or against the use of web-based or app-based self-management for tinnitus.	Neither for nor against	Reviewed, New-added
		5.	There is insufficient evidence to recommend for or against the use of computer-based games, training programs, or both for tinnitus self-care.	Neither for nor against	Reviewed, New-added
Amplification Devices	*Non-surgical*	6.	We suggest hearing aids for tinnitus management in adults with hearing loss (see narrative for discussion of patients without hearing loss).	Weak for	Reviewed, New-added
		7.	There is insufficient evidence to recommend for or against contralateral routing of signal/sound (CROS) hearing aids for tinnitus management in adults with single-sided deafness.	Neither for nor against	Reviewed, New-added
	Surgical	8.	We suggest cochlear implantation for tinnitus management in adults who meet candidacy requirements.	Weak for	Reviewed, New-added
		9.	There is insufficient evidence to recommend for or against implantable bone conduction devices (BCD) for tinnitus management in adults with single-sided deafness.	Neither for nor against	Reviewed, New-added
		10.	We suggest cochlear implants over implantable bone conduction devices (BCD) or contralateral routing of signal/sound (CROS) hearing aids for tinnitus management in adults with single-sided deafness who meet candidacy requirements.	Weak for	Reviewed, New-added
Sound-Based Intervention Alone		11.	There is insufficient evidence to recommend for or against auditory cognitive training (e.g., frequency discrimination training, auditory attention training) for the reduction of tinnitus distress and functional impact.	Neither for nor against	Reviewed, New-added
		12.	We suggest the therapeutic use of sound for tinnitus self-care.	Weak for	Reviewed, New-added
		13.	There is insufficient evidence to recommend for or against sound therapy with altered music (e.g., notched music therapy, spectrally altered music) to reduce the impact of tinnitus.	Neither for nor against	Reviewed, New-added

Topic	Sub-topic	#	Recommendation	Strength[a]	Category[b]
Behavioral Intervention Alone		14.	We suggest cognitive behavioral therapy (CBT) by a trained provider for adults with bothersome tinnitus.	Weak for	Reviewed, New-added
		15.	There is insufficient evidence to recommend for or against the following psychological interventions by a trained provider for adults with bothersome tinnitus (unranked). • Acceptance and Commitment Therapy (ACT) • Mindfulness-based therapies • Mindfulness-Based Stress Reduction (MBSR)	Neither for nor against	Reviewed, New-added
Combined Sound-Based and Behavioral Intervention		16.	We suggest sound therapy combined with cognitive behavioral therapy (CBT) for tinnitus management by a multidisciplinary team.	Weak for	Reviewed, New-added
		17.	We suggest sound enrichment with ongoing directed tinnitus education by an audiologist.	Weak for	Reviewed, New-added
Neuromodulation/ Neurostimulation		18.	There is insufficient evidence to recommend for or against repetitive transcranial magnetic stimulation (rTMS) for tinnitus management.	Neither for nor against	Reviewed, New-added
		19.	There is insufficient evidence to recommend for or against transcutaneous electric nerve stimulation (TENS) for tinnitus management.	Neither for nor against	Reviewed, New-added
		20.	There is insufficient evidence to recommend for or against transcranial direct current stimulation (tDCS) for tinnitus management.	Neither for nor against	Reviewed, New-added
		21.	We suggest against low-level laser therapy for tinnitus management.	Weak against	Reviewed, New-added
Manual Therapy		22.	We suggest a multidisciplinary approach for the assessment and treatment of patients with bothersome tinnitus and temporomandibular disorder (TMD), cervical spine dysfunction, or both to reduce the functional impact of tinnitus.	Weak for	Reviewed, New-added
Complementary and Integrative Health		23.	There is insufficient evidence to recommend for or against acupuncture for tinnitus management.	Neither for nor against	Reviewed, New-added

Topic	Sub-topic	#	Recommendation	Strength[a]	Category[b]
Herbals, Nutraceuticals, Supplements		24.	We suggest against the use of ginkgo biloba, dietary or herbal supplements, or nutraceuticals for tinnitus management.	Weak against	Reviewed, New-added
Pharmaco-therapy		25.	We suggest against the use of anticonvulsants, antidepressants, antiemetics, antithrombotics, betahistine, intratympanic corticosteroid injections, or n-methyl d-aspartic acid (NMDA) receptor antagonists for tinnitus management.	Weak against	Reviewed, New-added

[a] For additional information, see Determining Recommendation Strength and Direction.

[b] For additional information, see Recommendation Categorization.

A. Monitoring

Recommendation

1. We suggest using validated subjective outcome measures (e.g., Tinnitus Functional Index, Tinnitus Handicap Inventory) to monitor the effectiveness of tinnitus management.
   (Weak for | Reviewed, New-added)

2. We suggest against psychoacoustic measures (e.g., minimum masking level, loudness matching) to monitor the effectiveness of tinnitus management.
   (Weak against | Reviewed, New-added)

Discussion

Validated subjective outcome measures such as the TFI, Tinnitus Handicap Inventory (THI), Tinnitus Questionnaire (TQ), and Tinnitus Handicap Questionnaire (THQ) are valuable evaluation tools for monitoring the effectiveness of tinnitus interventions. Evidence suggests that these self-report measures are efficient in assessing tinnitus severity and responsiveness to treatment-related changes.(79–83)

Fernández et al. (2022) (n=22) and Henry et al. (2016) (n=167) compared pre- and post-treatment TFI and THI scores.(80, 81) Fernández et al. (2022) found that both the TFI and THI adequately assessed baseline tinnitus severity and responsiveness to treatment; however, the THI led to a slightly more pronounced decrease in scores post treatment compared with the TFI indicating a decrease in tinnitus severity. This study had a very small sample size, inadequate reporting of performance metrics, and a high loss to follow-up rate.(80) By contrast, Henry et al. (2016) compared the performance of the TFI with the THI and found that the TFI demonstrated a greater responsiveness to treatment-related change than the THI, but both instruments were responsive to change.(81) The

study used data from an ongoing RCT that evaluated the efficacy of “telephone tinnitus education” as an intervention for tinnitus to confirm the findings from an original TFI development study.(81) The results from Henry et al. (2016) confirmed sensitivity of the TFI along with its subscales, which enhanced credibility of the original findings.(81)

A 2019 RCT by Jacquemin et al. (n=100) conducted a comparison to determine the superiority between the Dutch TFI and the Dutch TQ.(82) The study demonstrated that the TFI and TQ work well in measuring treatment-related changes in self-perceived tinnitus burden. However, the TFI aligned more with self-reported perceived effect. This study featured a moderately sized sample, limited to individuals with chronic tinnitus. Only raw scores were provided in one analysis without accompanying standard deviations (SD).

A 2022 RCT by Connell et al. (n=117) assessed the validity of the FiveQ, a novel five-item questionnaire designed to measure tinnitus severity, by conducting a comparative analysis with the THI and the THQ in patients who received sound-based tinnitus intervention.(79) They found that the FiveQ had a high positive correlation with THI and THQ and showed greater responsiveness after six weeks of treatment. A high positive correlation was also noted between the THI and THQ, affirming their effectiveness as tinnitus assessment measures and providing support for their continued use in tinnitus management. The study had a moderately sized sample with a notably high rate of loss to follow-up.

Finally, a fifth RCT by Rabau et al. (2015) (n=34) assessed correlations between various tinnitus measurements, including psychoacoustic measures (e.g., minimal masking level (MML), loudness matching at 1 kilohertz [kHz]) and subjective outcome measurements (e.g., Tinnitus Impairment Questionnaire, TQ, numeric rating scale [NRS] for loudness and annoyance), and treatment-related changes over time.(83) The study showed that subjective measures were the most sensitive in detecting changes in tinnitus, as indicated by the effect size, and relying solely on psychoacoustic measurements is insufficient for substituting subjective outcome measures. This study had a small sample size, a restricted patient sample concerning sex distribution, and a lack of comprehensive methodological details. The evidence indicates that psychoacoustic measures fail to adequately capture changes in tinnitus over time.(83)

Some variation occurs in patient preferences regarding tinnitus evaluation and monitoring tools. The patient focus group participants expressed interest in assessing and tracking their progress over time. They emphasized that being able to measure their improvement allowed them to visualize their progress and remain engaged with their treatment plans. Participants also mentioned they found monitoring their progress without frequent questionnaires and measurement tools challenging. Further, considering that patients should be proficient in the administered questionnaires' language is important. Although questionnaires might pose a potential time burden, no documented evidence of associated harm exists.

Subjective outcome measures are typically more convenient and pose fewer burdens and implications than psychoacoustic measures. However, some patients might prefer psychoacoustic measures for a more hands-on approach and request audiometric testing. Psychoacoustic measures carry a higher potential for harms and burdens, including the possibility of introducing previously unnoticed symptoms, exacerbating symptoms, and, though exceedingly rare, causing acoustic trauma. Additionally, higher opportunity costs and equipment requirements are associated with psychoacoustic measures.

The Work Group systematically reviewed evidence related to these recommendations. (79–83) Therefore, they are categorized as *Reviewed, New-added* recommendations. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had some limitations, including small sample sizes, high loss to follow-up rates, and lack of important information about methodology and results.(79–83) For subjective outcome measures, the benefits of accurately monitoring the effectiveness of tinnitus management techniques and education outweighed the potential time burden, which was small. For psychoacoustic measures, the potential harm of introducing new symptoms, exacerbating symptoms, or causing acoustic trauma (very rare) slightly outweighed the benefits of supplementing assessment tools to evaluate tinnitus. Patient values and preferences were similar for subjective outcome measures but varied somewhat for psychoacoustic measures because some prefer questionnaires, although others might prefer a more hands-on clinical approach. Thus, the Work Group made the following recommendations: We suggest using validated subjective outcome measures (e.g., Tinnitus Functional Index, Tinnitus Handicap Inventory) to monitor the effectiveness of tinnitus management; and we suggest against psychoacoustic measures (e.g., minimum masking level, loudness matching) to monitor the effectiveness of tinnitus management.

B. Education and Self-Management

Recommendation

3. We suggest educational counseling to reduce the functional impact of tinnitus. **(Weak for | Reviewed, New-added)**

Discussion

Evidence suggests that educational counseling reduces the functional impact of tinnitus. A 2007 RCT by Henry et al. (n=269) randomized participants into three groups: (1) a group that received four sessions of group educational counseling based on Tinnitus Retraining Therapy (TRT) principles; (2) a group that attended four group discussion sessions without educational counseling ("traditional support"); and (3) a group that received no intervention.(84) Tinnitus Severity Index (TSI) scores showed a significant reduction for the educational counseling group from baseline to 6 months and from baseline to 12 months, but no significant changes were noted at these timepoints for the traditional support and no-treatment groups. Henry et al. (2007) (84) was included in an

SR by Xiang et al. (2020),(85) which was retrieved as part of the systematic evidence review for this CPG. However, all the studies in this SR, except for Henry et al. (2007), compared educational counseling with other interventions using educational counseling as a control condition. The SR by Xiang et al. (2020) did not address the question of the effectiveness of educational counseling and, therefore, was not considered as part of the evidence base for this recommendation.(85)

Little variation occurs in patient preferences regarding the value of educational counseling. The patient focus group participants noted the importance and positive impact of patient education and did not note a significant burden associated with patient education. Educational counseling requires resources such as time and trained personnel, and educational materials might have to be adjusted for patient populations with cognitive, literacy, or language differences or any combination of the aforementioned differences.

The Work Group systematically reviewed evidence related to this recommendation.(84) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The body of evidence was limited to one RCT, which had limitations including a high attrition rate (greater than 20%), absence of intention-to-treat analysis, unclear description of randomization/allocation concealment methods, and no possible blinding.(84) This single study with fewer than 400 participants examined only one type of educational counseling. These limitations resulted in the Work Group rating the confidence in the quality of the evidence as very low. However, the value of patient education in health care is well established, and education is a standard element of patient-centered care. As a result, the lack of well-designed, large-scale studies investigating the effectiveness of educational counseling specifically for tinnitus management is unsurprising, and this topic is likely to remain a low priority for future research in the field. The benefits of educational counseling for the reduction of functional impact of tinnitus outweighed the potential burden of time spent receiving education. Patient values and preferences for educational counseling were similar. Patient focus group participants emphasized the value and positive impact of patient education and expressed that their initial lack of understanding and knowledge about tinnitus might have delayed their care. Thus, the Work Group made the following recommendation: We suggest educational counseling to reduce the functional impact of tinnitus.

Recommendation

4. There is insufficient evidence to recommend for or against the use of web-based or app-based self-management for tinnitus.
   (Neither for nor against | Reviewed, New-added)

Discussion

In recent years, a substantial increase has occurred in the use of mobile technology, which provides an extra modality through which persons with tinnitus can access different

self-management tools. Products readily available include sound libraries, guided relaxation and wellness exercises, sleep hygiene guidance, and various combinations of sound and stress-reduction guidance. However, RCTs supporting the efficacy of web-based and app-based technology without direct provider involvement are lacking.

A randomized single-blind controlled trial by Searchfield et al. (2022) tested the hypothesis that a therapeutic application, UpSilent (USL), would provide superior tinnitus outcomes to a popular passive sound therapy application, White Noise Lite (WN), over a 12-week trial period.(86) UpSilent was developed to provide goal-based counseling using Wiki psychoeducation on sound strategies, goal setting, sleep hygiene, attention control techniques, communication strategies, abbreviated progressive relaxation, and deep breathing exercises along with personalized passive and active game-based sound therapy. At 12 weeks, mean changes in TFI scores for the USL group (n=31) (17.83 points; SD: 19.87) were clinically meaningful (greater than 13 points reduction). The mean change in TFI scores for the WN group (n=30) was not clinically meaningful (10.12 points; SD: 21.36) nor statistically different from the USL group. Usability measures were similar for both groups. No adverse events were reported from either group. Secondary outcome measures using the Client Oriented Scale of Improvement in Tinnitus (COSIT) showed groups did not differ significantly at 12 weeks (USL: 2.83, SD: 0.82; WN: 2.54, SD: 0.78).

Overall findings of the very limited evidence available (one RCT) assessing a prototype personalized therapeutic application for tinnitus self-management favored the intervention over the control passive sound therapy application after 12 weeks of use, but the differences were not statistically significant.(86) The USL intervention had significant effects on TFI change score and ratings of annoyance, ability to ignore, and unpleasantness between baseline and 12 weeks of use.

The Work Group also considered the resource requirements of wireless or mobile device access, accessibility needs for patient assistance with technology support, and the lack of applicability of findings to the Veteran and Service member populations. The patient focus group participants emphasized the importance of self-management strategies and indicated that they found ways to self-treat that worked best for them. Additionally, they acknowledged the importance of education from providers in addition to self-directed learning. The therapeutic application in the RCT used goal-based self-education in addition to passive and active sound therapy.(86)

Further, the patient focus group participants expressed having positive experiences with providers who were well educated on tinnitus. They also recognized the importance of an interdisciplinary care team to effectively address all aspects of their tinnitus, suggesting self-management without the direct involvement of a provider might not always be the preferred modality of tinnitus care. However, no other studies on app-based or web-based self-management of tinnitus met the criteria for inclusion in the systematic evidence review. Despite the limited evidence of benefit, the Work Group

determined that little to no harm occurs in making patients aware of the availability of web-based or app-based self-management tools.

The Work Group systematically reviewed evidence related to this recommendation.(86) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had several limitations, including lack of blinding, small sample size, attrition, research conducted at a single site by the USL developers, and differences in the delivery method of the intervention versus the control (bone conduction device [BCD] with additional neck pillow with Bluetooth speakers versus air conduction earphones only for the control group). The benefits of web-based or app-based self-management of tinnitus slightly outweighed the potential harms, and no harms were reported in the limited available evidence. Patient values and preferences varied somewhat as noted above. Overall, the evidence related to this recommendation is limited to one RCT. Thus, the Work Group made the following recommendation: There is insufficient evidence to recommend for or against the use of web-based or app-based self-management for tinnitus.

Recommendation

5. There is insufficient evidence to recommend for or against the use of computer-based games, training programs, or both for tinnitus self-care.
   (Neither for nor against | Reviewed, New-added)

Discussion

Prototype computer-based games are available for tinnitus self-care that focus on auditory training by using sound in a variety of active perceptual training paradigms (e.g., frequency discrimination training [FDT], auditory cognitive training, auditory attention training). However, a limited number of RCTs supporting the efficacy of auditory training for tinnitus self-management have been conducted. Three RCTs examined the outcomes of computer-based games or training programs as a tinnitus self-management strategy in participants with chronic tinnitus (≥6 months).(87–89) Study populations were mostly limited to White males.

A crossover RCT (n=60) conducted in the United Kingdom evaluated FDT by integrating training with computer gameplay to evaluate intrinsic motivation.(87) Participants were randomly assigned over a four-week trial to either conventional task-based training (Star2) or one of two interactive game-based trainings (Treasure Hunter, Submarine).(87) Results showed no significant effect of training regime or interaction between time and training regime on the THQ and Visual Analogue Scale (VAS) loudness score and found no evidence that the type of gameplay modulates change in tinnitus handicap ($p>0.05$).(87)

An RCT (n=60) conducted in the United States evaluated the effect of a proprietary, computer-based cognitive training program modified for tinnitus (POSIT Science Brain Fitness Program – Tinnitus [BFP-T]).(88) After eight weeks of training, results showed

no difference in THI and TFI scores between the intervention versus the control (non-BFP-T) group.

An RCT (n=31) conducted in New Zealand compared the effect of a customized selective auditory attention game (Terrain) with a non-auditory game (Tetris) on tinnitus intrusiveness.(89) Sustained attention during 30-minute training sessions for 20 consecutive days was required. There was no statistical difference in TFI scores between the groups at nine weeks follow-up. However, there was an improvement in THI and tinnitus numeric scale (ability to ignore tinnitus) for the Terrain group compared with the Tetris group at nine weeks follow-up. Clinically meaningful scores between intervention and control were not evident on the primary measure (TFI) using the authors' standard of a minimum decrease of 13 points. However, clinically meaningful scores between intervention and control on the secondary measure (THI) were evident for the Terrain group. Group effect data showed a statistically significant change that favored the Terrain outcomes over the Tetris control.(89)

The Work Group considered the resource requirements of access to computer hardware and software as well as the resource use of time for both provider training and patient training. Other concerns around equity and acceptability were based on some patients' potential lack of agility and information technology literacy to use computer games, the feasibility of implementing games unavailable outside the RCTs, and limitations of generalizability of the findings to the Veteran and Service member populations who were not sampled in the evidence. Findings of the limited available evidence assessing FDT, auditory cognitive training, and auditory attention training did not indicate benefit of computer-based gaming intervention over the control for self-management of tinnitus without direct provider intervention.

The Work Group systematically reviewed evidence related to this recommendation.(87–89) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had many limitations, including small sample size, attrition, blinding, bias related to authors investigating commercial potential, and proprietary modification of BFP to BFP-T.(87–89) The benefits of computer-based gaming for self-management of tinnitus were balanced with potential harms (no harms were reported in the evidence). Patient values and preferences varied somewhat. Some patients might or might not prefer computers, gaming, or both because acceptance of these interventions might vary with age and availability. Thus, the Work Group made the following recommendation: There is insufficient evidence to recommend for or against the use of computer-based games, training programs, or both for tinnitus self-care.

C. Amplification Devices

a. Non-surgical

Recommendation

6. We suggest hearing aids for tinnitus management in adults with hearing loss (see narrative for discussion of patients without hearing loss).
   (Weak for | Reviewed, New-added)

Discussion

A hearing aid is a medical device, worn in the ear canal or behind the ear, and is typically recommended for individuals with hearing loss to improve speech understanding, communication, and sound awareness. Evidence from one SR and one RCT suggest that hearing aids reduce the functional impact of tinnitus.(90, 91)

A 2022 SR by Waechter and Jönsson (n=1,400) compared tinnitus functional impact measured by the THI, THQ, and TSI in participants with hearing loss (degree of hearing loss unspecified) and tinnitus.(90) The studies were categorized into two subgroups: (1) those with objective hearing aid verification and (2) those with no objective hearing aid verification. The study compared two interventions: hearing aid versus no hearing aid and verified hearing aid versus unverified hearing aid. Most of the studies in the SR used objective verification of hearing aid amplification with real-ear measurements. Real-ear measurements are conducted by inserting a thin tube attached to a microphone into the ear canal and measuring the output of the hearing aid in response to an external sound input. Real-ear measurements are the standard of care for objectively verifying appropriate amplification. The results of the study indicated a significantly greater reduction in tinnitus functional impact at 12 months follow-up for the participants in the hearing aid group as well as the participants in the verified hearing aid group.(90) A significantly greater reduction in tinnitus perceived loudness (measured by the VAS, TSI using the embedded loudness subscale, Tinnitus Experience Questionnaire, and NRS) was also found for the participants in the hearing aid group and the verified hearing aid group at up to 48 months follow-up. No adverse events or worsening of tinnitus were reported in the SR.(90) This SR was limited because of heterogeneity of included studies in meta-analyses. The exclusion criteria, fitting strategies, hearing aid experience, type of hearing aids, outcome measures, and ancillary treatments varied among studies. In addition, there was a high risk of bias because of inherent bias from the non-randomized comparative study design.

A 2022 RCT by Haines et al. (n=61) compared tinnitus functional impact measured by the TFI in participants with mild to moderate hearing loss and tinnitus.(91) The study investigated hearing aids plus treatment as usual (TAU) versus TAU alone. The main components of TAU consisted of information and education about tinnitus, informal counseling, advice on mobile applications, stress, sleep management, and relaxation techniques. Participants were fitted with hearing aids across five different audiology

clinics in the United Kingdom. Results indicated a significantly greater reduction in tinnitus functional impact at 12 months follow-up for the participants who received hearing aids plus TAU.(91) Some level of harm was associated with both groups. A small number of participants in both groups reported worsening of tinnitus or hearing or development of anxiety or depression. The RCT had limited generalizability because of the small sample size and the specific subpopulation (focus on participants with mild to moderate hearing loss).(91) The RCT also was limited because of the variability in hearing aid types, usage of hearing aids, hearing aid fitting strategies, hearing aid eligibility, and referral pathways among the five different audiology clinics.

Additional studies on the comparative effectiveness of other types of amplification devices were included in the systematic evidence review.(92–94) However, because these studies evaluated comparative effectiveness rather than effectiveness, they were not used to inform the development of this recommendation. For example, the Work Group acknowledged that a sound generator mode (e.g., broadband noise) can be activated in the hearing aid based on the patient's needs. Sound generator modes are routinely available in most hearing aids. An SR by Sereda et al. (2018) compared tinnitus functional impact measured by the TFI in participants with hearing loss and tinnitus.(92) The study compared combination hearing aid (sound generator activated) versus hearing aid alone (sound generator deactivated). Results indicated no significant difference in the TFI between the combination hearing aid and hearing aid alone.

Few studies have investigated the effects of hearing aid fitting/programming strategies on tinnitus functional impact. A 2022 RCT by Joergensen et al. compared tinnitus functional impact measured by the THI and TFI in participants with high-frequency hearing loss and tinnitus.(93) The study compared combination broadband amplification (125 Hz to 10 kHz) hearing aid (intervention treatment) versus band-limited amplification (125 Hz to 3–4 kHz) hearing aid (active placebo/control). Results indicated a significant reduction in the THI and TFI for the group of subjects fitted with broadband amplification. In addition, the group of subjects fitted with broadband amplification also showed a significant reduction in tinnitus loudness and annoyance as measured by the VAS. Another RCT by Yakunina et al. (2019) compared tinnitus functional impact measured by the THI in participants with hearing loss and tinnitus fitted with hearing aids programmed with different hearing aid strategies.(94) This study compared wide dynamic range compression hearing aids versus frequency translation hearing aids versus linear frequency transposition hearing aids. Results indicated no significant difference in THI scores for the group of subjects fitted with wide dynamic range compression hearing aids, frequency translation hearing aids, or linear frequency transposition hearing aids.

Patient values and preferences are similar regarding hearing aids for tinnitus management in adults with hearing loss. The patient focus group participants emphasized that hearing aids were one of the most effective devices and treatments for

tinnitus. Additionally, the patient focus group participants made it clear that they need to use a variety of interventions, including auditory devices and self-management strategies throughout the day, to keep their symptoms at tolerable levels. However, some patients are unwilling to be fitted with hearing aids and to commit the time to acclimatize to hearing aids. In addition, costs might be associated with purchasing these devices for military retirees and their beneficiaries without VA benefits if the devices are not covered by their insurance. There are also costs to the VA and DoD systems associated with hearing aids and real-ear measurement equipment. Further, audiologists must take the time to perform real-ear measurements to verify amplification. Finally, generalization was limited to other subpopulations because the systematic evidence review did not retrieve evidence from other subpopulations (e.g., normal hearing without subjective hearing difficulty, normal hearing with subjective hearing difficulty [hidden hearing loss]). The Waechter and Jönsson (2022) study included participants with a degree of hearing loss unspecified, and the Haines et al. (2022) study reported the mean degree of hearing loss for participants to be in the mild to moderate range.(90, 91) Future studies should evaluate the efficacy of amplification as a tinnitus intervention related to hearing status (e.g., normal hearing without subjective hearing difficulty, normal hearing with subjective hearing difficulty [hidden hearing loss], mild/moderate/severe hearing loss).

The Work Group systematically reviewed evidence related to this recommendation.(90, 91) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was low. The body of evidence had some limitations, including small sample size, heterogeneous subpopulation, high risk of bias because of inherent bias from the non-randomized comparative study design, and no statistical corrections for the inclusion of known confounders.(90, 91) The benefits of hearing aids and reduced functional impact of tinnitus outweighed the potential harms. One RCT included a small number of subjects who reported worsening of tinnitus or hearing or development of anxiety or depression with both interventions.(91) Patient values and preferences were similar because the patient focus group participants emphasized that hearing aids were one of the most effective devices and treatments for their tinnitus. In addition, the participants highlighted the importance of self-management strategies and tinnitus education. Thus, the Work Group made the following recommendation: We suggest hearing aids for tinnitus management in adults with hearing loss (see narrative for discussion of patients without hearing loss).

Recommendation

7. There is insufficient evidence to recommend for or against contralateral routing of signal/sound (CROS) hearing aids for tinnitus management in adults with single-sided deafness.
   (Neither for nor against | Reviewed, New-added)

Discussion

Contralateral routing of signal/sound hearing aids are prescribed for patients with single-sided deafness (SSD). A CROS hearing aid is a device that routes sound arriving at the ear with severe to profound hearing loss to the contralateral ear with normal or near-normal hearing via a wireless connection. A trial of CROS amplification is required before surgical procedures for SSD (e.g., cochlear implantation, implanted BCDs). Very limited evidence exists to recommend for or against CROS hearing aids as a management tool for tinnitus. The systematic evidence review retrieved one RCT by Peters et al. (2021)(95) that examined the three-month and six-month outcomes using two tinnitus questionnaires (TQ and THI) for patients fitted with CROS hearing aids compared with a group of patients not fitted with CROS hearing aids. No significant reduction in TQ and THI scores occurred in the CROS hearing aid group throughout the six-month study period, thus indicating no reduction in tinnitus functional impact over the study period. Additionally, no significant difference was found between the CROS hearing aid group and the no treatment group at both three-month and six-month follow-ups.

The sample size of Peters et al. (2021) was small, with 58 participants completing the entire six-month trial (n=31 for the CROS group; n=27 for the no treatment group). The burden of wearing a CROS device is small; however, some patients with SSD do not want to wear devices in both ears. The maintenance of the device (e.g., changing or charging the batteries, keeping the device clean) can be burdensome to some individuals. No related adverse events were reported for patients fitted with CROS hearing aids, including no reports of tinnitus worsening while enrolled in the trial. Similarly, patients with no report of tinnitus at baseline did not develop tinnitus after being fitted with CROS hearing aids. The Abbreviated Profile of Hearing Aid Benefit (APHAB) showed improvement in ease of communication, reverberant conditions, and background noise subscales for the CROS hearing aid group versus the no treatment group at six-month follow-up. Results of the Speech, Spatial, and Qualities of Hearing Scale (SSQ) found improvement in the hearing speech and the quality of speech subscales for the CROS group versus the no-treatment group over the six-month study period.

Some variation occurs in patient preferences regarding this treatment. The patient focus group participants noted the significant benefit of hearing aids for tinnitus management. However, CROS hearing aids are used only for patients with SSD; therefore, they cannot be generalized to the entire patient population with tinnitus. Patients can have difficulty acclimatizing to CROS devices. Some patients with SSD report little to no difficulty hearing in everyday listening situations and are uninterested in a CROS hearing aid trial. Military retirees without VA benefits, as well as their beneficiaries, might have to pay out-of-pocket for these devices because insurance might not cover them.

The Work Group systematically reviewed evidence related to this recommendation.(95) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence

had some limitations, including no blinding and a small sample size.(95) The benefits of CROS hearing aids to manage tinnitus were balanced with the potential harms or burdens associated with wearing the device. Patient values and preferences varied somewhat because some patients might have difficulty adjusting to the CROS hearing aid device. Thus, the Work Group made the following recommendation: There is insufficient evidence to recommend for or against contralateral routing of signal/sound (CROS) hearing aids for tinnitus management in adults with single-sided deafness.

b. Surgical

Recommendation

8. We suggest cochlear implantation for tinnitus management in adults who meet candidacy requirements.
   (Weak for | Reviewed, New-added)

Discussion

Cochlear implantation is a surgical procedure designed to improve hearing and speech understanding for patients with severe to profound sensorineural hearing loss. Surgical indications have evolved and expanded in recent years to include patients with less severe hearing loss, SSD, or both.

Evidence from recent SRs and RCTs suggests that cochlear implantation is effective for the management of tinnitus in adults who meet candidacy requirements, largely derived from studies evaluating patients with SSD.(95–101) The confidence in the quality of the evidence was low based on the lowest GRADE rating for the critical outcomes. Critical outcomes used to make this determination included those that assessed tinnitus functional impact (e.g., THI, TQ). Important outcomes also considered included those related to tinnitus perceived loudness, QoL, and the self-perceived hearing handicap as measured by the APHAB.

In a large SR, Daher et al. (2023) found durable improvement in tinnitus outcomes following cochlear implantation, including for the THI up to 13 months, tinnitus perceived loudness up to 24 months, and QoL up to 36 months for subjects (n=736) with SSD compared with those who did not undergo cochlear implantation.(96) Peters et al. (2021) found that treatment with cochlear implantation (n=28) for patients with SSD improved THI, TQ, QoL, and self-perceived hearing handicap across the communication, listening, and aversiveness to sound categories as compared with patients with SSD who received no treatment (n=26).(95) An SR by Oh et al. (2023) included seven studies reporting sufficient data for a meta-analysis in patients with SSD and noted improved tinnitus management in patients (n=369) for whom tinnitus outcomes were reported following cochlear implantation, identifying a statistically significant reduction in tinnitus (standardized mean difference: -1.32; 95% CI: -1.85–-0.80).(97) Marx et al. (2021) noted a significant reduction in the VAS for the tinnitus severity measure, identifying a mean reduction of 30.5 (±36.5) points for those who

underwent cochlear implantation (n=25) compared with unchanged scores in those who were observed (n=26).(98) The findings suggest a dose-response resulting in even larger effects for those subjects with SSD deemed to have incapacitating tinnitus (n=20). Villavisanis et al. (2021) reported a significant reduction in THI after cochlear implantation (n=27) for patients with Meniere's disease, noting a mean difference reduction of 48.1 (95% CI: -95.25– -1.04) on THI for a subset of subjects (n=22) meeting inclusion for meta-analysis.(99) Similarly, Levy et al. (2020) reported a mean difference reduction in THI after cochlear implantation (n=86) of 35.4 (95% CI: 15.0–55.8) for patients with SSD, an effect that became even more apparent beyond 6 months of follow-up when compared with fewer than 6 months follow-up.(100) Although not included in the systematic evidence review nor impacting the strength of the recommendation, an SR by Yuen et al. (2021) concluded that a large percentage of subjects with bilateral hearing loss who underwent cochlear implantation also demonstrated substantial reductions in tinnitus functional impact.(101)

Evidence indicates some risk of harm associated with cochlear implantation. Two cases of superficial postoperative infections were reported, including one patient who required explantation and reimplantation,(98) a low rate (3–5%) of worsening tinnitus symptoms,(100, 101) and one patient who exhibited persistent dizziness after surgery.(99) Other large studies not included in the systematic evidence review nor impacting the strength of this recommendation were also reviewed to assess the risks of cochlear implantation. These studies included a 0.07% overall rate of postoperative meningitis reported by Gowrishankar et al. (2023) (102) and a 0.10% rate of long-term facial nerve dysfunction reported by Thom et al. (2013).(103) Finally, a <5.0% risk of cochlear implant device failure (104) and a 6.7% risk of electrode migration exist,(105) each of which might necessitate explantation and reimplantation.

The benefits of cochlear implantation for tinnitus management in adults who meet candidacy requirements were considered to outweigh its harms and burdens. This determination was based on the available evidence, which indicated durable and clinically significant reductions in tinnitus functional impact and a very low rate of significant complications.

Some variation occurs in patient preferences regarding cochlear implantation for tinnitus management. The patient focus group participants noted the importance and usefulness of devices to improve their tinnitus and QoL, although cochlear implantation was not specifically referenced. Nevertheless, a proportion of patients who otherwise might be candidates for cochlear implantation would likely prefer to avoid surgical interventions when less invasive options exist. The U.S. Food and Drug Administration (FDA), in a letter exploring cochlear implantation for SSD, recommends that patients considering cochlear implantation have 2–4 weeks of experience wearing an appropriately fitted CROS hearing aid before surgery.(106, 107) As such, with rare exceptions, patients are

required to exhaust nonsurgical treatment options before cochlear implantation candidacy is confirmed.

Other implications, such as resource use, equity, acceptability, feasibility, and subgroup considerations also are important to evaluate for this analysis. Cochlear implantation is a relatively resource-heavy intervention, requiring specialized equipment for both the surgery itself and the programming of the device afterward. Cochlear implantation is generally available only at medical centers, rather than at small community hospitals; therefore, equity concerns for individuals living a substantial distance away from institutions capable of supporting cochlear implantation cannot be ignored. Furthermore, studies have identified disparities in access to care among underrepresented minorities.(108) Travel expenses and costs related to missed work can be impactful. Potential measures to mitigate some of these costs, however, were explored in a recently published study evaluating the feasibility of implementing a telemedicine platform for cochlear implant programming for a VA population.(109) Although not included in the systematic evidence review nor impacting the strength of the recommendation, this same study demonstrated that telehealth for cochlear implant programming yielded reliable results consistent with in-person evaluations. Ongoing studies within DoD are exploring similar themes.

Acceptability issues related to patients unwilling or unable to commit to the time required for successful cochlear implantation are noted, as well. Multiple visits are required for cochlear implantation assessment, surgery, and programming after surgery. As mentioned, feasibility, in the form of general accessibility, is limited by the unique and specialized training required of cochlear implant-trained surgeons and audiologists.

Finally, subgroup considerations for VA and DoD patients are highlighted because they pertain to proximity to cochlear implantation centers and the ability to remain on active duty. Although outside the scope of this systematic evidence review and not used to inform the development of this recommendation, it is important to note the only study assessing military readiness and satisfaction for the active duty military population reported that the vast majority of active duty cochlear implant recipients were able to remain on active duty after surgery and reported a high degree of satisfaction.(110) Furthermore, the largest study to report on a DoD population who underwent cochlear implantation,(111) consisting of 11 active duty, 7 retired, and 10 dependents, found substantial improvements in QoL, mirroring the referenced studies above meeting criteria to develop this recommendation.

The Work Group systematically reviewed evidence related to this recommendation.(95–101) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was low. The body of evidence demonstrated very serious but generally unavoidable limitations for study quality and risk of bias (e.g., inability to blind participants or providers to the presence or absence of a cochlear implant) but generally no serious inconsistency, indirectness, or

imprecision.(95–101) The benefits of cochlear implantation for improving functioning and QoL outweighed the potential adverse events related to surgery. Patient values and preferences varied somewhat because some patients prefer non-invasive treatment options. Thus, the Work Group made the following recommendation: We suggest cochlear implantation for tinnitus management in adults who meet candidacy requirements.

Recommendation

9. There is insufficient evidence to recommend for or against implantable bone conduction devices (BCD) for tinnitus management in adults with single-sided deafness.
   (Neither for nor against | Reviewed, New-added)

Discussion

Bone conduction devices include a variety of hearing amplification devices that transmit sound to the inner ear by vibrating the skull to bypass the normal sound conduction pathway of the ear canal, tympanic membrane, and ossicular chain. Surgically implantable BCDs, specifically, are the focus of this recommendation.

Insufficient evidence exists to recommend for or against the use of implantable BCDs for tinnitus management in adults with SSD. One RCT by Peters et al. (2021) met the inclusion criteria to support this recommendation.(95) This RCT identified improvements in QoL at three and six months postoperatively, as measured by the SSQ, for each subdomain, when compared with no treatment. This outcome was considered important. Additionally, a statistically and clinically significant reduction was found in the APHAB across several subdomains, including ease of communication, listening under reverberant conditions, listening in background noise, and aversiveness of sounds. These outcomes also were considered important. For the critical outcome of tinnitus functional impact, Peters et al. (2021) found that treatment with BCDs (n=22) improved TQ at three and six months when compared with no treatment (n=26).(95) Tinnitus Questionnaire improvement was maintained for the intra-group comparison of the BCD cohort in which subjects were compared against themselves at baseline. Nevertheless, THI improvements were not maintained for this same intra-group comparison.

The evidence also indicated two serious adverse events for the BCD group, including two implant extrusions. One patient elected to undergo reimplantation and the other did not. On the balance of benefits and harms, the harms of implantable BCDs for tinnitus management in adults with SSD were considered to slightly outweigh its benefits. This finding was based on the available evidence, which indicated equivocal improvement for tinnitus functional impact and a low but real risk of significant complications.

Some variation occurs in patient preferences regarding implantable BCDs for tinnitus management in adults with SSD. The patient focus group participants noted the importance and usefulness of devices to improve their tinnitus and QoL, although BCDs

were not specifically referenced. A subset of patients who decline surgical intervention is always likely. Additionally, some patients might be unable to dedicate the time necessary for surgery, recovery, and requisite follow-up care. Costs are associated with these devices as well as specialty training requirements for both surgeons and audiologists who use these devices, which limits their accessibility. Costs and provider training potentially place increased travel and time burdens on Veterans and active duty Service members located farther from major medical centers capable of supporting this treatment option.

It is important to note that implantable BCDs were developed for treating hearing loss rather than tinnitus. More specifically, they are ideally suited for patients with conductive, rather than sensorineural, hearing loss.

The Work Group systematically reviewed evidence related to this recommendation.(95) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had major limitations, including a small sample size, a narrow population consisting of only SSD patients, and an inability to blind patients or providers to the treatment arm.(95) The potential harms of implantable BCDs, including device extrusion and need for reimplantation, were small but slightly outweighed the equivocal benefits for tinnitus functional impact. Patient values and preferences varied somewhat because some patients prefer non-invasive treatments or live a great distance from centers capable of supporting this technology. Thus, the Work Group made the following recommendation: There is insufficient evidence to recommend for or against implantable bone conduction devices (BCD) for tinnitus management in adults with single-sided deafness.

Recommendation

10. We suggest cochlear implants over implantable bone conduction devices (BCD) or contralateral routing of signal/sound (CROS) hearing aids for tinnitus management in adults with single-sided deafness who meet candidacy requirements.
    (Weak for | Reviewed, New-added)

Discussion

Evidence suggests cochlear implantation reduces the impact and distress of tinnitus compared with implantable BCDs or CROS hearing aids in adults with SSD. In an RCT by Peters et al. (2021), the cochlear implantation group, when compared with the BCD and CROS groups, was the only intervention group to have a significant reduction in THI scores compared with baseline at the three- and six-month follow-up appointments.(95) Additionally, the cochlear implantation group had a significant reduction in TQ scores at the three- and six-month follow-up appointments when compared with participants randomized into the CROS intervention group. At the three- and six-month appointments, the cochlear implantation group was the only group to have

a significant improvement for both the THI and TQ when compared with the no treatment group. Tinnitus questionnaires were completed only by participants reporting tinnitus throughout the trial; thus, the sample size for each group varied slightly throughout the study period. At the three-month follow-up appointment, 90 participants reported tinnitus (n=20 from the cochlear implantation group; n=18 from the BCD group; n=31 from the CROS group; n=21 from the no treatment group). A total of 94 participants reported tinnitus at the six-month follow-up appointment (n=21 from the cochlear implantation group; n=21 from the BCD group; n=28 from the CROS group; n=24 from the no treatment group). It is important to note that tinnitus did not develop in any participant after receiving one of the three interventions. Likewise, an SR by Donato et al. (2021) found a significant reduction in THI scores from baseline to six months for cochlear implant users (n= 17; average 37.97 point decrease) when compared with BCD users (n=10; average 9.890 point decrease).(112)

Although rare, potential adverse events are related to cochlear implantation surgery. Neither study considered in developing this recommendation reported related adverse events for the cochlear implantation group.(95, 112) As a benefit, cochlear implantation users showed an improvement in the ease of communication and reverberant condition subscales on the APHAB compared with BCD or CROS users or both in both of the studies. An improvement also occurred in the APHAB aversiveness subscale for the cochlear implantation group compared with the CROS group.(95) However, inconsistent results were reported for the background noise subscale of the APHAB. Donato et al. (2021) showed that the BCD group had significantly more improvement in listening to background noise than the cochlear implantation group;(112) whereas Peters et al. (2021) reported significant improvement in the background noise subscale compared with the BCD and CROS intervention groups.(95) At both three and six months, participants randomized to the cochlear implantation treatment group showed significantly better speech-hearing subscale scores on the SSQ questionnaire compared with participants in the BCD and CROS intervention groups. Similarly, the scores on the spatial hearing subscale of the SSQ were significantly higher for the cochlear implantation group compared with the BCD and CROS groups at both time periods.

Some variation occurs in patient preferences regarding this treatment. Some patients might decline cochlear implantation surgery because it is an invasive procedure. These patients might decide to continue using their CROS hearing aids (CROS hearing aids are required to be fitted on trial before cochlear implantation surgery for SSD). Other patients might prefer cochlear implantation but fail to meet the criteria or be a good candidate for it. Also, some patients with SSD might not perceive difficulty hearing or be interested in pursuing treatment options. Those who decide to proceed with the surgery must commit to the time required to adjust to the device as well as commit to surgical and audiological follow-up appointments. Finding a cochlear implantation surgeon, audiologist, or both near the patient's home might be difficult, so patients might have to travel a significant distance from their home for appointments.

The Work Group systematically reviewed evidence related to this recommendation.(95, 112) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had some limitations, including a lack of randomization, an observational study, and blinding of participants (112) as well as a small sample size and no blinding of participants.(95) The benefits of cochlear implants for tinnitus management in patients with SSD slightly outweighed the potential harm of adverse events, which was small. Patient values and preferences varied somewhat because some patients prefer non-invasive treatments or no treatment for SSD. Thus, the Work Group made the following recommendation: We suggest cochlear implants over implantable bone conduction devices (BCD) or contralateral routing of signal/sound (CROS) hearing aids for tinnitus management in adults with single-sided deafness who meet candidacy requirements.

D. Sound-Based Intervention Alone

Recommendation

11. There is insufficient evidence to recommend for or against auditory cognitive training (e.g., frequency discrimination training, auditory attention training) for the reduction of tinnitus distress and functional impact.
    (Neither for nor against | Reviewed, New-added)

Discussion

Auditory cognitive training has been studied to reduce tinnitus perception and some of its functional impact (e.g., difficulties with attention and concentration). Thus far, this intervention has been based on the gaming modalities using exercises that attempt to target auditory attention, auditory memory, auditory processing speed, and frequency discrimination. The search for behavioral interventions in tinnitus management yielded evidence on auditory cognitive training; therefore, the Work Group decided to develop a recommendation on this intervention. The studies that met the inclusion criteria for this recommendation involved computer-based training. No studies on non-computer-based auditory cognitive training met the inclusion criteria of the systematic evidence review.

Some evidence suggests that auditory cognitive training might improve attention, memory, and concentration in patients with tinnitus. However, the body of evidence is limited, and confidence in the quality of evidence is very low.

Wise et al. (2016) (n=31) compared a proprietary game that focused on selective auditory attention (Terrain) with a non-auditory sustained visual attention game (Tetris).(89) Their results suggest that the treatment might have reduced the tinnitus impact and improved selective auditory attention. However, this study had poor overall quality and a very low grade of evidence because of a questionable statistical significance given the sample size was very small.

Kallogjeri et al. (2017) (n=40) evaluated proprietary computer-based auditory intensive exercises and found a reduction in the THI score.(88) However, the difference between the intervention and the control groups was not statistically significant. In addition, no difference was found in cognitive test scores and other behavioral measures. Of the 20 patients in the intervention group, 10 (50%) self-reported improvement related to the intervention, and 6 (30%) reported qualitative subjective improvement related to tinnitus, memory, attention, and concentration. However, these improvements were not statistically significant.

An RCT by Xing et al. (2021) (n=64) compared an intervention group engaged in proprietary computer-based auditory intensive exercises with a control group assigned non-auditory games (e.g., sudoku, solitaire, crossword puzzles).(113) Xing et al. (2021) did not find a clinically significant improvement in the TFI scores, a critical outcome, or in other secondary outcomes.

A study by Hoare et al. (2014) (n=60) on FDT revealed no significant reduction in self-perceived tinnitus handicap, or reduction in tinnitus severity for the treatment group compared with the control group.(87)

The Work Group rated as very low the quality of evidence from these studies because of a small number of participants, blinding bias, study design bias, high attrition rate, large variation in treatment compliance, and changes in outcome measures not being statistically significant, particularly between the treatment groups and the control groups.

Evidence also indicated some level of harm associated with the Xing et al. (2021) study because a small number of patients within this trial experienced adverse events.(113) Two participants withdrew from the study because the sound in the auditory training worsened their tinnitus.

The Work Group systematically reviewed evidence related to this recommendation.(87–89, 113) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had some limitations, including small sample sizes, large risks of bias, serious study limitations, and confounders in the analysis.(87–89, 113) The potential harms (e.g., of adverse events and no statistically significant improvements) slightly outweighed the benefits of recommending auditory cognitive training for improving tinnitus outcomes (e.g., no significant improvement in tinnitus impact or auditory attention). Patient values and preferences varied somewhat because of high attrition, variation in treatment compliance, lack of interest in the games or programs used, and time commitment needed from participants. Other implications of these studies included factors related to the use of resources, acceptability, feasibility, and equity. Level of education, socioeconomic status, and technology literacy as well as length of treatment are also important factors to consider in future studies. Thus, the Work Group made the following recommendation: There is insufficient evidence to recommend for or against

auditory cognitive training (e.g., FDT, auditory attention training) for the reduction of tinnitus distress and functional impact.

Recommendation

12. We suggest the therapeutic use of sound for tinnitus self-care.
    (Weak for | Reviewed, New-added)

Discussion

The term sound therapy is commonly associated with tinnitus care and generically describes the therapeutic use of sound to reduce self-perceived tinnitus handicap, promote relaxation, and facilitate habituation to tinnitus. The use of sound for tinnitus self-care has been referred to as sound therapy, sound treatment, sound stimulation, and sound enrichment. Sound can be delivered with ear-level devices (e.g., hearing aids, sound generators, wireless earphones) or through external sound-playing devices (e.g., mobile phones, music devices, tabletop sound spas). Sound therapy can be generic or proprietary. Recommended use time varies across protocols and devices and can be implemented with or without professional guidance but is typically most effective when combined with professional guidance (see Recommendation 17).

Evidence suggests that the therapeutic use of sound (e.g., broadband noise, mixed pure tones, tinnitus-matched sound) reduces self-perceived tinnitus handicap.(114–117) Jin et al. (2022) found that longer hours of sound therapy delivered via earphones resulted in greater reductions in self-perceived tinnitus handicap and perceived tinnitus loudness, with groups using sound therapy 3–4 hours per day, having significant improvement relative to the group using sound therapy 1 hour per day during waking hours.(114) Participants in this study did not receive counseling. Li et al. (2019a) found a significant reduction in tinnitus handicap for the group using mixed pure tones but not for the group using broadband noise,(115) whereas Li et al. (2019b) found a significant reduction for complex sound treatment that combined pure tones, noise, and music. (116) Theodoroff et al. (2017) evaluated overnight use of sound stimulation and found reductions in tinnitus handicap, as well.(117) Participants in the study received orientation to sound stimulation and a short session of general tinnitus education.

By contrast, Hall et al. (2022) found no reduction in tinnitus handicap when participants used a proprietary device that delivered pure tones, either above and below the tinnitus pitch match, or generically in the frequency region of 500–4000 Hz, 4–6 hours per day.(118)

Some variation occurs in patient preferences regarding the therapeutic use of sound. The patient focus group participants noted that sound therapy with white noise delivered via hearing aids was an important component of their tinnitus management. However, some patients might perceive sound therapy as burdensome because of the time commitment required to achieve a therapeutic outcome. Some sound types might be unpleasant for the patient, in which case the sound is unlikely to have therapesutic value.

The Work Group systematically reviewed evidence related to this recommendation.(114–118) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was low. The body of evidence had some limitations, including small sample sizes, modest attrition rates, and lack of blinding. The benefits of the therapeutic use of sound for reducing self-perceived tinnitus handicap were balanced with the potential harm (e.g., increased tinnitus loudness, time necessary to achieve therapeutic effect). Patient values and preferences varied somewhat because some patients might be unwilling to spend time using sound therapy and might dislike the sound used for sound therapy; however, the patient focus group participants reported on the benefits of therapeutic use of sound as part of their tinnitus plan of care. Thus, the Work Group made the following recommendation: We suggest the therapeutic use of sound for tinnitus self-care.

Recommendation

13. There is insufficient evidence to recommend for or against sound therapy with altered music (e.g., notched music therapy, spectrally altered music) to reduce the impact of tinnitus.
    (Neither for nor against | Reviewed, New-added)

Discussion

Altered music, such as notched music therapy, has been used to alleviate tinnitus symptoms. Different methods have been used to alter the music, but a similar thread runs through all the studies, where the researchers remove acoustic energy from the music in the area of the patient's specific tinnitus frequency.

Insufficient evidence exists to recommend for or against the use of sound therapy with altered music for patients with bothersome tinnitus. Results are mixed, where some studies show reductions in tinnitus functional impacts using altered music, although others do not. Li et al. (2016) had mixed results.(119) Only the experimental group realized a significant improvement on the THI, but both the experimental and control groups had improvements at an early follow-up appointment based on TFI scores. Using the THI, Yoo et al. (2022) showed tinnitus functional improvements in both their experimental and control groups.(120) Both the experimental and control groups had THI score improvements in the Piromchai et al. (2020) and Tong et al. (2022) studies, as well.(121, 122) By contrast, Atipas et al. (2021) and Stein et al. (2016) each found no significant tinnitus functional impact improvements in their experimental groups, nor their control groups.(123, 124)

In addition to the mixed results among these studies, the authors used varied techniques to alter the experimental music as well as different control stimuli. For instance, Piromchai et al. (2020) reported that they used 48 preselected popular songs filtered at low, medium, or high pitches but did not report the specific filtering mechanisms.(121) Yoo et al. (2022), who did show improvements in both groups, and

Atipas et al. (2021), who did not show significant improvements in either group, each reported that they used the participant's favorite music and stripped it of the one-octave band centered on the individual's tinnitus pitch.(120, 123) In these studies' control groups, Piromchai et al. (2020) used the same 48 songs without any notch adjustment, whereas Yoo et al. (2022) used the participant's favorite music stripped of a random frequency relative to the tinnitus pitch, and Atipas et al. (2021) used the participant's favorite music unaltered.(120, 121, 123) Other authors used the following as their experimental therapies: personalized spectrally altered classical music (notch width not described),(119) participant's favorite music spectrally equalized with removal of a half-octave width centered at participant's tinnitus frequency,(124) and music chosen by each participant from a built-in library spectrally flattened and filter was half-octave band centered on tinnitus frequency.(122)

All the studies in this evidence base were small, with several having a high dropout rate. Although these studies described no true adverse events, Stein et al. (2016) reported that 31% of the 17 participants who withdrew from the study stated it had an adverse effect on their tinnitus (the specific effect was not described).(124) This outcome might not have been directly associated with the sound therapy but should be noted.

Some variation occurs in patient preferences regarding the use of altered music therapy. Some patients might be unwilling to listen to music for 1–2 hours every day, as recommended by the researchers in these studies. Further, the altered music might be particularly undesirable to patients who are musicians or who already have a regular hobby of listening to music. Opportunity costs are also a concern where patients who try this treatment might lose time when they could have tried more evidence-based or promising treatments. Most of these studies required that patients have hearing thresholds below than 70 decibels hearing level (dB HL), so these treatments cannot be generalized to patients with severe hearing loss.

Further, notched music therapy tends to be created and delivered through proprietary programs unavailable to many patients or providers in the VA and DoD. Audiologists are not routinely trained on how to develop the would-be therapeutic sound nor how to implement the therapy into the patient's plan of care. This fact and the time it would take to develop the altered music and regularly update it based on changing tinnitus frequencies in each patient would decrease the feasibility of wide use of this approach. Equity might be another consideration where patients must have some means of listening to the music (e.g., smartphone). Lastly, because VA and DoD are currently unable to provide these services, any use of them would come at a cost to the patient. Given that these treatments are unproven, they are unadvised.

The Work Group systematically reviewed evidence related to this recommendation.(119–124) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had some limitations, including a small sample size and study limitations in determining the

benefits of tinnitus functional impact. The benefits of altered music therapy varied among the studies but were balanced with the potential harm (e.g., an increase in tinnitus loudness, which was limited to a small subset of patients in one study). Patient values and preferences varied somewhat because some patients might prefer more evidence-based treatments, some might not want to listen to altered music for 1–2 hours every day, and patients with severe hearing loss might be ineligible for this therapy. Thus, the Work Group made the following recommendation: There is insufficient evidence to recommend for or against sound therapy with altered music (e.g., notched music therapy, spectrally altered music) to reduce the impact of tinnitus.

E. Behavioral Intervention Alone

Recommendation

14. We suggest cognitive behavioral therapy (CBT) by a trained provider for adults with bothersome tinnitus.
    (Weak for | Reviewed, New-added)

Discussion

Cognitive behavioral therapy is a form of psychological treatment focusing on the relationships among thoughts, feelings, and behaviors that lead to, or maintain, difficulties in functioning. Cognitive behavioral therapy targets current problems and symptoms and improves functionality by emphasizing changes in unhelpful ways of thinking (e.g., cognitive restructuring) and unhelpful behavior (e.g., behavioral activation) as well as improving ways of coping with problems (e.g., problem solving).

Evidence exists that CBT improves clinical outcomes in adults with bothersome tinnitus. Evidence from three SRs (125–127) and 1 RCT (128) suggests that CBT reduces tinnitus distress in the presence of bothersome tinnitus when compared with passive controls (e.g., waitlist control, online discussion forums)(126) and one active control.(128) The effectiveness of CBT with provider involvement is robust across modalities (e.g., in-person, internet-based, telephone).(126–128) However, insufficient evidence exists to suggest standalone, self-administered CBT without therapist contact as part of the intervention.

Available evidence points to variability in follow-up data post intervention, length of CBT intervention, and operationalization of guided versus self-administered CBT interventions. One SR of 10 studies (n=1,188) explored the efficacy of self-administered CBT defined as an intervention in which participants primarily review and learn CBT skills using a standardized manual through independent review with minimal behavioral/mental health provider–led CBT instruction.(126) Compared with passive controls (e.g., waitlist control, online discussion forums, information booklets), self-administered CBT with minimal therapist involvement led to lower tinnitus distress.

One SR of 12 RCTs (n=1,144) explored differences in primary outcome measures, categorizing interventions into three groups: cognitive, behavioral, and "mixed CBT."(125) Cognitive-only interventions included attention control, imagery, cognitive restructuring, and attention control plus cognitive restructuring. Behavioral/mental health–only interventions included relaxation training and mixed CBT consisting of in-person CBT, internet-delivered CBT (iCBT), and Acceptance and Commitment Therapy (ACT). Acceptance and Commitment Therapy is a psychotherapy approach characterized by compassionate exploration of what can and cannot be controlled. The goal of ACT is to alter patients' relationship with their tinnitus rather than to change the experience of the tinnitus perception. Experiential exercises are used to limit avoidance and increase willingness to experience unpleasant emotions, all with a non-judgmental stance. Using the framework of mindfulness, acceptance, and commitment to action and behavior change, individuals learn strategies to improve function. Taken together, results favored CBT with reductions in tinnitus distress.(125)

One SR of 10 RCTs (n=1,194) focused on exploring the efficacy of CBT in modalities other than in-person.(127) Nine of the RCTs explored iCBT, 1 RCT explored CBT delivered by telephone, and 1 RCT had self-administered CBT (with minimal provider involvement) using books. Tests for overall effectiveness suggests that these modalities might reduce tinnitus distress compared with passive controls. Available evidence suggests telemedicine CBT, in-person CBT, and self-administered CBT with some provider involvement led to similar degrees of reduction in tinnitus distress because no differences have emerged in available head-to-head comparisons.

Regarding secondary outcomes of interest, consistent evidence exists that CBT reduces symptoms of anxiety and depression as measured in study participants.(125, 126, 128) That anxiety and depression, in most studies, were measured dimensionally rather than based on clinical evaluations of whether participants met criteria for mood or anxiety disorders is noteworthy. These studies relied on self-reported, Likert-type scales to measure anxiety and depression rather than provider-driven evaluations to determine whether participants met clinical threshold for formal diagnoses. To a lesser extent, evidence also suggests that CBT interventions help improve sleep (128, 129) and QoL (129) in participants with bothersome tinnitus. Overall, based on the RCTs available, the efficacy of CBT for reducing tinnitus distress has been researched more often than other psychological interventions. It has both the most studies as well as greater evidence of effectiveness based on consistent findings in the literature. Evidence exists that improvement remains following an intervention's end. Weise et al. (2016) conducted a one-year follow-up post intervention and found that patients reported reduction in tinnitus distress, anxiety, depression, and sleep were sustained.(128)

Multiple factors affect the feasibility of CBT implementation. One is the limited availability of behavioral/mental health providers in the United States. When available, behavioral/mental health providers might lack the confidence to deliver CBT targeting the

functional impact of bothersome tinnitus without greater understanding of the condition. Other factors that might limit the implementation and availability of CBT as an effective and widely used intervention for tinnitus include the treatment duration (with typical CBT lasting from 1–3 months), access to technology to participate in telemedicine forms of CBT, level of education, and time commitment needed for participation. Cognitive behavioral therapy does remain a viable option given that participants in the patient focus group emphasized that tinnitus interacts with other conditions (e.g., anxiety, depression, sleep) and noted the importance of treating co-occurring conditions. Anecdotally, during patient focus groups, patient values and preferences varied somewhat because access to behavioral health practitioners is inconsistent, and some patients prefer shorter treatments. Perceived stigma associated with treatment for a chronic medical condition by a behavioral/mental health provider might also have an impact.

Regarding patient preferences, 1 RCT (130) included in the SR by Landry et al. (2020) (125) explored patient preferences regarding iCBT as compared with group CBT for chronic tinnitus. Participants receiving iCBT had access to online CBT modules they reviewed independently. Study participants were asked to identify treatment condition preferences before randomization. They were also asked about satisfaction with the treatment received at the end. Participants randomized into group CBT had greater satisfaction than participants receiving iCBT and rated group CBT (in-person) as more helpful.(125, 130) However, both CBT interventions (group CBT and iCBT) resulted in similar levels of improvement on tinnitus functional impact compared with the control (discussion forum). Treatment gains were sustained at the six-month follow-up.

The Work Group identified a lack of audiologic data in most CBT-focused studies as a potential limitation. Identifying the degree and type of hearing loss might be relevant because hearing-related problems are often confused with tinnitus-related problems.(128) The Work Group agreed that the inclusion of audiologic data in future studies is important to determine whether hearing ability affects patient outcomes with behavioral/mental health–only interventions.

The Work Group systematically reviewed evidence related to this recommendation. (125–129) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had some limitations, including small sample sizes, broad confidence intervals and imprecision inherent in the effect sizes.(125–129). The benefits of CBT (e.g., reduction in tinnitus distress; improvements in QoL; reduction in commonly related conditions in participants with tinnitus, such as anxiety, depression, and insomnia) outweighed the potential harm (e.g., of adverse events, which was small). Patient values and preferences varied somewhat because access to behavioral/mental health practitioners is inconsistent, and some patients prefer shorter treatments. Thus, the Work Group made the following recommendation: We suggest cognitive behavioral therapy (CBT) by a trained provider for adults with bothersome tinnitus.

Recommendation

15. There is insufficient evidence to recommend for or against the following psychological interventions by a trained provider for adults with bothersome tinnitus (unranked).
    - Acceptance and Commitment Therapy (ACT)
    - Mindfulness-based therapies
    - Mindfulness-Based Stress Reduction (MBSR)

    (Neither for nor against | Reviewed, New-added)

Discussion

Less evidence supports other psychological interventions (e.g., ACT, mindfulness-based therapies, mindfulness-based stress reduction [MBSR], relaxation training) for improving functional status in adults with bothersome tinnitus when compared with CBT. A common definition of mindfulness is paying attention to the present moment, on purpose, without judgment. Mindfulness-based stress reduction is a specific protocol that involves offering secular, intensive mindfulness training to assist people with stress, anxiety, depression, and pain. Mindfulness-based stress reduction teaches people how to increase mindfulness through yoga and meditation. Of note, the CPG used keywords "mindful" and "mindfulness-based stress reduction," among others, in its search and evaluation of RCTs using GRADE methodology. Only one SR was included in the evidence reviewed for this recommendation based on GRADE methodology.

One SR (n=750) consisting of 15 studies (six RCTs and nine pre-post studies) examined the effects of ACT and mindfulness-based therapies on hearing-related distress, depression, anxiety, and QoL in individuals with audiological problems.(131) These interventions are considered "Third Wave Therapies," with ACT being the most frequently evaluated intervention, followed by mindfulness-based therapies (e.g., mindfulness-based cognitive therapy [MBCT], MBSR). Results suggested that participants receiving ACT and mindfulness-based interventions have better outcomes compared with participants in control groups. However, treatment gains were not maintained at 6- and 12-month follow-up for ACT. Similar follow-up for mindfulness-based interventions was not examined. Wang et al. (2022) reported that ACT and mindfulness-based interventions produced similar improvements in anxiety and depression but gains were not maintained or observed at follow-up.(131) The impact of other mindfulness-based interventions on anxiety and depression was not included. The overall findings of the limited evidence available assessing the efficacy of ACT and mindfulness-based interventions suggest that hearing-related distress was reduced, but gains were not maintained at follow-up. The Wang et al. (2022) SR did not report results directly related to tinnitus.(131)

The Work Group systematically reviewed evidence related to this recommendation.(131) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The limited body of

evidence had significant limitations, including a limited number of studies, small sample sizes, and predominantly poor-to-fair methodological quality. The benefits of psychological interventions slightly outweighed the potential harms. Patient values and preferences varied largely because some patients might perceive stigma associated with treatment for a chronic medical condition by a behavioral/mental health provider, but patient focus group participants emphasized the importance of addressing their co-occurring health conditions. Thus, the Work Group made the following recommendation: There is insufficient evidence to recommend for or against the following psychological interventions by a trained provider for adults with bothersome tinnitus (unranked).

- Acceptance and Commitment Therapy (ACT)
- Mindfulness-based therapies
- Mindfulness-Based Stress Reduction (MBSR)

F. Combined Sound-Based and Behavioral Intervention

Recommendation

16. We suggest sound therapy combined with cognitive behavioral therapy (CBT) for tinnitus management by a multidisciplinary team.
    (Weak for | Reviewed, New-added)

Discussion

Evidence suggests that the combined use of sound therapy and CBT, under the direction of a multidisciplinary team, improves patient outcomes for bothersome tinnitus.(116, 132, 133) Li et al. (2019b) found that the combination treatment approach of CBT plus sound therapy for the treatment of patients with tinnitus was associated with reductions in patient-rated tinnitus handicap (as measured by the THI) and a wide range of psychological concerns as measured by Symptom Checklist-90 (e.g., anxiety, depression, psychotic somatization, interpersonal sensitivity, hostility, terror, phobic anxiety) when compared with sound therapy alone.(116) Studies from Henry et al. (2017, 2018) found that the combination of sound therapy with CBT (based on the Progressive Tinnitus Management [PTM] program) was more effective than non-treatment waitlist control groups for decreasing tinnitus impact and improving patients' degree of confidence in their ability to self-manage their tinnitus reactions.(132, 133)

None of the studies reported adverse effects. A moderate level of attrition was observed, consistent with the general attrition rate seen in behavioral or mental health therapy studies, likely because of the time-intensive nature of the treatment.

No studies directly compared the effectiveness of CBT as a standalone treatment with the combination of CBT and sound therapy. The body of evidence of CBT as a standalone intervention supports the use of CBT alone as an effective tool for the management of bothersome tinnitus (see Recommendation 14). However, standalone CBT requires a larger burden on the behavioral/mental health provider's time (typically

8–14 sessions), and the Work Group noted that the CBT portions of the combination treatments were generally less behavioral health provider time intensive (2–3 sessions). The Work Group also noted that some aspects (e.g., mindfulness, relaxation training) could be provided by different disciplines to further ease the behavioral health provider's time commitment. Nationwide behavioral/mental health provider shortages create barriers to forming multidisciplinary teams, so reducing the time commitment of CBT providers might improve access to care for combination therapies.

Some variation occurs in patient preferences regarding this treatment. Patient focus group participants noted that extensive treatment times can be burdensome because of the time required to attend the training classes and to complete daily homework for weeks to months depending on the treatment plan used. However, they also noted the importance of multidisciplinary teams, and they appreciated providers who implemented patient-centered action plans. Patients value having a person-centered action plan that allows them to take a more active role in managing their tinnitus, and the combination of CBT and sound therapy uses action plans in their treatment process. Societal stigma against seeking behavioral/mental health treatment might also be mitigated using multidisciplinary teams, which draw less attention to the behavioral/mental health aspect of the treatment plan.

The Work Group systematically reviewed evidence related to this recommendation.(116, 132, 133) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had some limitations, including lack of blinding and small study sizes (n<400),(116, 132, 133) no description of the randomization method or allocation concealment,(116) and high attrition (25–33%).(132) The benefits of combined sound therapy and CBT (i.e., improved outcomes of tinnitus impact as well as improved symptoms of anxiety and depression) outweighed the potential harm. No harms were reported in the reviewed studies. Patient values and preferences varied somewhat because although patients appreciate multidisciplinary team approaches, sometimes they are unable or unwilling to commit to the time required for more intensive longer treatment plans. Thus, the Work Group made the following recommendation: We suggest sound therapy combined with cognitive behavioral therapy (CBT) for tinnitus management by a multidisciplinary team.

Recommendation

17. We suggest sound enrichment with ongoing directed tinnitus education by an audiologist.
    (Weak for | Reviewed, New-added)

Discussion

Evidence supports the use of sound enrichment combined with ongoing directed tinnitus education provided by an audiologist to improve QoL and reduce the negative impact of

tinnitus as measured by statistically validated outcome instruments. Four studies were included in the body of evidence to support the recommendation.(134–138) Three of the four studies comprised multiple study groups, each of which included sound enrichment combined with multiple sessions of tinnitus-specific education provided by an audiologist.(135–137) The fourth study compared sound enrichment combined with multiple sessions of tinnitus-specific education delivered by an audiologist to a group provided with hearing aids for hearing loss, and multiple sessions of education focused only on improving communication with hearing loss.(134) All studies included in the body of evidence demonstrated clinically relevant changes in tinnitus functional impact measures for all study comparison groups. The only study that showed a significant difference in outcomes among groups was the study that included a control group that received an intervention only for hearing and not for tinnitus.(134)

A TRT trial included three study groups.(135, 137) Two of the three groups were provided with TRT-based counseling and education. To evaluate the contribution of sound therapy to reductions in self-perceived tinnitus handicap, one of the TRT groups received ear-level sound generators and the other TRT group received placebo sound generators. A third group received multiple sessions of standard-of-care counseling that included encouragement to enrich the sound environment but did not include provision of ear-level devices. All groups received multiple sessions of directed tinnitus education by an audiologist, and all participants were encouraged to enrich their sound environment. The results revealed reductions in self-perceived tinnitus handicap across all three groups, with no significant differences among the groups.(135, 137)

Henry et al. (2016) compared outcomes among three study groups.(136) Participants in all three groups received multiple sessions of educational counseling focused on tinnitus that included encouragement to enrich their sound environment. One group received TRT-based counseling, one received counseling based on the tinnitus masking method, and the third was a control group that received counseling that avoided concepts specific to TRT or tinnitus masking and emphasized the value of sound enrichment. All three groups were issued hearing aids for hearing loss when appropriate. Only the TRT and tinnitus masking groups were provided with ear-level sound generators, usually in combination with a hearing aid. All three groups showed reductions in distress from tinnitus, and no significant differences in outcomes among the groups were reported.(136)

Tyler et al. (2021) conducted a study with three groups of participants with bothersome tinnitus.(138) All three groups were provided with Tinnitus Activities Treatment (TAT) over multiple sessions, which included encouragement to enrich the sound environment. One group combined TAT with full masking from ear-level devices, another group combined TAT with partial masking from ear-level devices, and the third group was provided with only TAT (no ear-level devices were issued).(138) All three groups improved, and there were no significant differences in outcomes among the three groups.

Bauer et al. (2017) compared two groups of participants with bothersome tinnitus.(134) One group received ear-level sound generators and TRT-based counseling, which encourages enrichment of the sound environment. The second group was issued hearing aids appropriate for their hearing loss and multiple sessions of counseling focused only on improving communication with hearing loss. Bauer et al. (2017) was the only study included in the body of literature with a control group given no tinnitus-specific intervention and was also the only study that found a significant difference in outcomes between study groups.(134) Both groups showed reductions in tinnitus-related distress. The group provided with a tinnitus-specific intervention improved significantly more than the group provided with an intervention for hearing loss only.

The confidence in the quality of the overall evidence was very low; however, robust improvements in QoL were seen across multiple comparator groups from various research teams using different educational counseling methods. No clear connections were found between any of the interventions and adverse outcomes.

Each of the studies in the body of evidence was designed to compare various conditions (e.g., type of tinnitus counseling, method of sound enrichment), and all but one study failed to find a difference between comparator groups. Though the intention for each study was not to develop an evidence base supporting the overall premise that ongoing tinnitus-focused education and counseling by an audiologist combined with various methods of sound enrichment is effective, the collective body of evidence is encouraging in that it shows a robust reduction in tinnitus-related distress when those conditions are met.

Some variation occurs in patient preferences regarding tinnitus interventions that combine educational counseling with sound enrichment, sound therapy, or both. Most patient focus group participants expressed value in the use of hearing aids combined with counseling and reported a desire for tinnitus-focused care from competent providers. However, although the interventions included in the body of evidence are aligned with the patient focus group's expressed values and preferences, the members' willingness to attend multiple sessions and use certain devices as a source of sound enrichment likely varies. The burdens associated with the interventions include the cost of hearing aids, ear-level sound generators, or both, when indicated; the cost and time associated with providing training to providers on protocol-driven interventions; and the cost and time associated with an intervention that requires repeated visits.

The Work Group systematically reviewed evidence related to this recommendation.(134–138) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had some limitations, including relatively large degrees of attrition, impossibility of masking of the outcome assessor, and the fact that only one of the studies included a comparator group without a tinnitus-specific intervention.(134–138) The benefits of multiple sessions of tinnitus-focused educational counseling, provided

by an audiologist, combined with sound enrichment (e.g., reduced distress from tinnitus as measured by statistically validated tinnitus outcomes instruments) outweighed the small risk of adverse events. Patient values and preferences varied somewhat because of the participants' willingness to attend multiple sessions and willingness and ability to use certain devices as a source of sound enrichment. However, patient focus group participants noted preferences for using hearing aids combined with counseling and a desire for tinnitus-focused care from competent providers, which in many cases will be aligned with providing sound enrichment with ongoing directed tinnitus education. Thus, the Work Group made the following recommendation: We suggest sound enrichment with ongoing directed tinnitus education by an audiologist.

G. Neuromodulation/Neurostimulation

Recommendation

18. There is insufficient evidence to recommend for or against repetitive transcranial magnetic stimulation (rTMS) for tinnitus management.
    (Neither for nor against | Reviewed, New-added)

Discussion

Transcranial magnetic stimulation (TMS) has been investigated as a potential treatment for chronic tinnitus since 2003.(139, 140) This non-invasive intervention delivers electromagnetic pulses through a coil to the patient's scalp. Ultimately, some of this energy is transmitted through the skull and affects the activity of underlying neural tissue. When a succession of TMS pulses is delivered to a scalp target during a treatment session, the procedure is called rTMS. Repetitive transcranial magnetic stimulation is FDA-approved for the treatment of major depression. For this application, 10 or 20 pulses per second are delivered to the left prefrontal region of the patient's head, to stimulate that brain region and reduce the severity of depression. A series of daily rTMS sessions is usually conducted over the course of 4–6 weeks for the treatment of depression.(141) Initial studies of rTMS for tinnitus, not included in the systematic evidence review, delivered 1 pulse per second to the temporal region of the patient's head.(139, 140) The lower stimulation rate is theorized to suppress neural activity associated with tinnitus perception. Different research studies of rTMS for tinnitus have conducted a series of daily sessions over the course of 5–30 days or more.(142, 143) More recent studies of rTMS for tinnitus stimulated the prefrontal region of the patient's head with 10 or 20 pulses per second, sometimes followed by a course of lower frequency stimulation (1 pulse per second, or 1 Hz) to the temporal region.(144, 145)

An SR of 28 studies (n=947) by Lefebvre-Demers et al. (2021) included rTMS investigations for tinnitus that stimulated frontal regions, temporal regions, or both in succession.(143) Stimulation rates varied from 1–50 Hz, and the number of participants in each study ranged from 4–146. Lefebvre-Demers et al. (2021) concluded that active rTMS, as compared with sham (or placebo), was an effective treatment for tinnitus.(143) Also, stimulation of the temporal region was more effective than frontal lobe stimulation.

Liang et al. (2020) published an SR and meta-analysis of 29 studies (n=1,228) of rTMS for tinnitus.(146) A variety of scalp stimulation locations, stimulation rates, number of pulses per session, number of treatment sessions, and outcome measures were included in this SR. Liang et al. (2020) concluded that rTMS seems to be effective for tinnitus treatment, but larger-sample, multisite, randomized, double-blind clinical trials are necessary for further verification of its efficacy.(146)

In their meta-analysis of non-invasive brain stimulation interventions for tinnitus, Chen et al. (2020) concluded that rTMS with "priming" (i.e., higher frequency stimulation of the left frontal region, followed by low frequency stimulation of the temporal region) was associated with significantly greater reduction in tinnitus severity compared with sham (placebo) rTMS.(147) Findings from an RCT (n=48) by Noh et al. (2020) agreed that sequential dual-site rTMS (frontal, then temporal) was superior to single-site or sham stimulation for tinnitus treatment.(144)

Repetitive transcranial magnetic stimulation is not recommended for patients with a history of seizures or epilepsy because the procedure might lower their seizure threshold. Patients with electronic implants (e.g., heart pacemakers, deep brain stimulation devices) should also be excluded. Adverse events resulting from rTMS can include headaches, eye or facial muscle twitches, and localized discomfort at the stimulation site. In most cases, these side effects are temporary and resolve soon after rTMS stops. However, some patients choose to discontinue rTMS treatment because of these side effects.

Although rTMS is FDA approved for the treatment of depression, it is unapproved for the treatment of tinnitus. Therefore, rTMS treatment for tinnitus is less readily available. Also, though the evidence summarized above indicates that rTMS might be effective for chronic tinnitus, larger clinical trials are necessary to identify the most practical and efficacious treatment protocols. Most studies of rTMS for tinnitus involved relatively small sample populations and varied greatly in terms of stimulation parameters, number of sessions, outcome measures, and follow-up. Standardized protocols of rTMS for tinnitus must be developed and tested before the procedure can be clinically implemented on a large scale. Providers who administer rTMS to this patient population should also be knowledgeable about other effective tinnitus management strategies that could augment the procedure and benefit patients.

The Work Group systematically reviewed evidence related to this recommendation.(143, 144, 146, 147) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had some limitations, including relatively small sample sizes and variability in how studies of rTMS for the treatment of tinnitus were conducted. Larger, multisite clinical trials are needed to standardize treatment protocols and maximize the efficacy of this intervention. The benefits of rTMS for tinnitus slightly outweighed the potential harms, which can include side effects of headaches, eye or facial muscle twitches, and localized

discomfort at the stimulation site. Patient values and preferences varied somewhat because rTMS for tinnitus is currently less readily available. Although rTMS shows some promise for the treatment of chronic tinnitus, it will require significant equipment costs and provider training; it also necessitates a significant time commitment to complete a course of treatment sessions. Thus, the Work Group made the following recommendation: There is insufficient evidence to recommend for or against repetitive transcranial magnetic stimulation (rTMS) for tinnitus management.

Recommendation

19. There is insufficient evidence to recommend for or against transcutaneous electric nerve stimulation (TENS) for tinnitus management.
(Neither for nor against | Reviewed, New-added)

Discussion

Insufficient evidence exists that the use of TENS improves tinnitus outcomes. Transcutaneous electric nerve stimulation is the application of electric current produced by a device to stimulate nerves or other tissues for therapeutic purposes. The systematic evidence review identified one RCT and two SRs, all of which were of very low quality evidence.(148–150)

An RCT by Aydoğan et al. (2022) sought to examine the effectiveness of TENS on alleviating tinnitus in individuals with normal hearing (<20 dB HL at 0.5, 1.0, 2.0, and 4.0 kHz).(148) For a study on tinnitus, it is surprising that the main eligibility criterion was a pain score (≥ 45) on a section of the Short Form-36 survey. None of the eligibility criteria were related to tinnitus characteristics (e.g., constant versus intermittent), duration (e.g., acute versus chronic), or how bothersome it was (e.g., TFI or THI score).(148) These issues and concerns with the statistical analyses reduce confidence in the evidence reported.

Byun et al. (2020) included a total of 17 studies in their SR.(149) It is important to emphasize the heterogeneity of the studies included in Byun et al. (2020) in terms of the electrical stimulation devices, different protocols used, various stimulus frequencies, number of treatments, and location of electrical stimuli delivered (e.g., pinna, mastoid, temporomandibular joint, finger, neck).(149) An SR by Yang et al. (2021) reviewed various types of electrical stimulation, including TENS.(150) Four studies in the SR assessed the efficacy of TENS on tinnitus severity as measured by the THI, and 1 used the TQ as its primary outcome. Several of the studies reported that TENS reduced tinnitus severity, but the sample sizes were small and electrode placements and control conditions were variable. Because of the serious limitations and poor quality of results reported in the RCT and both SRs, the Work Group concluded that the evidence was insufficient to recommend for or against this treatment. Of note, no studies that specifically evaluated TENS for somatosensory tinnitus, in which the tinnitus perception

is associated with an underlying biomechanical condition, were included in the evidence base.

Some variation occurs in patient preferences regarding the use of any non-invasive device to alleviate tinnitus or reduce how bothersome it is. The Work Group also discussed the patient burden and out-of-pocket expense associated with purchasing a commercially available TENS device. Additionally, the TENS device has FDA clearance for only temporary relief of pain associated with sore muscles and is unapproved specifically for tinnitus. Therefore, using TENS for tinnitus management would be considered an off-label use of any commercially available TENS device.

The Work Group systematically reviewed evidence related to this recommendation.(148–150) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had some limitations, including poor methodological quality and various types of bias (e.g., selection, performance, reporting) in studies conducted in both of the SRs.(149, 150) The possible benefits of TENS for tinnitus management were balanced with the potential harms related to adverse events reported in studies, which ranged from occasional tingling, scalp pain, and skin irritation to dizziness, headache, and facial numbness, all of which were temporary. Patient values and preferences varied somewhat (i.e., some patients prefer to try non-invasive devices for tinnitus). Thus, the Work Group made the following recommendation: There is insufficient evidence to recommend for or against transcutaneous electric nerve stimulation (TENS) for tinnitus management.

Recommendation

20. There is insufficient evidence to recommend for or against transcranial direct current stimulation (tDCS) for tinnitus management.
    (Neither for nor against | Reviewed, New-added)

Discussion

Transcranial direct current stimulation has been investigated as a potential treatment for chronic tinnitus.(143, 151) This intervention involves attaching two electrodes to the patient's scalp or forehead, a cathode and an anode, which are connected to a power source, often a nine-volt battery. When the circuit is complete and activated, current flows from one electrode to the other, presumably having some effect on underlying neural tissue. The use of tDCS is not FDA cleared for any condition. Adverse events resulting from tDCS can include skin irritation at the electrode sites.(152)

Lefebvre-Demers et al. (2021) published an SR and meta-analysis of 9 studies (n=253) of tDCS for tinnitus.(143) Scalp stimulation locations included prefrontal regions, temporoparietal regions, or both. The number of neuromodulation sessions ranged from 1–10 and follow-up assessments ranged from 0–3 months after treatment. Tinnitus outcome measures included the TFI, THI, and TQ questionnaires. The meta-analysis by

Lefebvre-Demers et al. (2021) did not support the hypothesis that tDCS diminishes tinnitus symptoms.(143) Although active tDCS resulted in a clinically significant change in tinnitus severity scores compared with sham tDCS, the difference did not reach statistical significance.

An SR of 14 studies by Martins et al. (2022) (n=1,031) included tDCS investigations for tinnitus that stimulated prefrontal regions, the left temporoparietal area, or both.(151) Their meta-analysis showed that tDCS significantly decreased tinnitus loudness and severity, but a subgroup analysis showed a significant effect for only left temporoparietal area stimulation for loudness.(151)

In a meta-analysis of non-invasive brain stimulation interventions for tinnitus (n=149), Chen et al. (2020) concluded that cathodal tDCS over the left dorsolateral prefrontal cortex combined with transcranial random noise stimulation over the bilateral auditory cortex was associated with significant reduction in tinnitus severity.(147) An RCT by Mares et al. (2022) (n=39) indicated that bifrontal tDCS resulted in modest improvement in the auditory subdomain of the TFI.(153)

Because tDCS is not FDA cleared for any condition, the treatment is less readily available at VA, DoD, or most other medical facilities. Also, although some of the evidence summarized above indicates that tDCS might be effective for chronic tinnitus, the results of other studies indicate that the treatment is inefficacious. Most studies of tDCS for tinnitus have involved relatively small sample populations and have varied greatly in terms of stimulation parameters, number of sessions, outcome measures, and follow-up. Larger, placebo-controlled clinical trials are necessary to determine whether tDCS might be a viable treatment option for tinnitus.

The Work Group systematically reviewed evidence related to this recommendation. (143, 147, 151, 153) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had some limitations, including relatively small sample sizes and variability in how studies of tDCS for the treatment of tinnitus were conducted. The benefits of tDCS for tinnitus were balanced with the potential harms, which can include skin irritation at the electrode sites. Patient values and preferences varied somewhat because tDCS for tinnitus is less readily available at this time. Thus, the Work Group made the following recommendation: There is insufficient evidence to recommend for or against transcranial direct current stimulation (tDCS) for tinnitus management.

Recommendation

21. We suggest against low-level laser therapy for tinnitus management.
    (Weak against | Reviewed, New-added)

Discussion

We suggest against low-level laser therapy (LLLT) to improve outcomes in patients with tinnitus.(154–156) This intervention uses a laser that emits wavelengths in the infrared or near-infrared range (approximately 600–900 nm), usually with an output of 50–60 milliwatts, and directs the energy toward a particular location, such as the mastoid or tympanic membrane.(157) Evidence from a single RCT (155) and one SR (154) showed no difference in tinnitus outcomes for LLLT at post-treatment or six-week follow-up when compared with sham control. Evidence from another single RCT had different findings, but this study was of low quality with serious limitations and imprecision, resulting in low strength of evidence.(156)

Some patient burden and out-of-pocket expense associated with LLLT are indicated. In the absence of compelling evidence of improved outcomes, the Work Group determined that the time burden and cost of specialized treatment slightly outweighed any unlikely benefit. Additionally, although LLLT is FDA approved for the treatment of some musculoskeletal injuries, it is unapproved for tinnitus; therefore, using LLLT for tinnitus management would be considered off-label use.

Some variation occurs in patient preferences regarding this treatment, but emphasizing that most patients and providers are unfamiliar with this treatment is important. Further, access to this treatment is limited because it is not FDA approved for tinnitus, making it unlikely for a DoD or VA audiologist or otolaryngologist to have the necessary training or ability to refer patients to receive LLLT for tinnitus.

The Work Group systematically reviewed evidence related to this recommendation. (154–156) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was low. The body of evidence had some limitations, including small sample sizes in the two RCTs (155, 156) and confounders in the analysis.(154–156) The potential harms and burdens of LLLT slightly outweighed the potential benefits (e.g., possible improvement in visual NRS of tinnitus loudness from a single study with low strength of evidence). Patient values and preferences varied somewhat because some patients prefer specialized alternative treatments. Thus, the Work Group made the following recommendation: We suggest against low-level laser therapy for tinnitus management.

H. Manual Therapy

Recommendation

22. We suggest a multidisciplinary approach for the assessment and treatment of patients with bothersome tinnitus and temporomandibular disorder (TMD), cervical spine dysfunction, or both to reduce the functional impact of tinnitus. **(Weak for | Reviewed, New-added)**

Discussion

Evidence that met the criteria to be included in this CPG pertaining to somatosensory tinnitus is reviewed in this section. Somatosensory tinnitus, also known as somatic tinnitus, is a subtype of tinnitus where the tinnitus characteristics (e.g., loudness, pitch) can be modulated by voluntary movements of the eyes, head, neck, or jaw or any combination of such parts of the body.(7, 158, 159) That clinical consensus does not exist regarding the definition or diagnostic criteria for somatosensory tinnitus is noteworthy.(160) A hallmark of this type of tinnitus is that it is influenced by activation of auditory, somatosensory, and sensorimotor systems.(159) The evidence for this recommendation comes from two RCTs(161, 162) and one SR discussed below.(163)

Van der Wal et al. (2020) showed that orofacial physical therapy improved outcomes related to tinnitus impact for patients with bothersome tinnitus and TMD, which refers to dysfunction of the temporomandibular joint, masticatory muscles, or surrounding musculature or any combination of these.(161) In this RCT, physical therapists were trained to administer a specialized treatment consisting of orofacial physical therapy. When warranted, occlusal splints were fit by dentists to address grinding of teeth. The therapy was individualized for each patient, consistent with the best clinical practice in orofacial treatment. The intervention went beyond standard orofacial treatment and addressed sleep hygiene, lifestyle considerations, relaxation therapy, and other aspects of healthy living. For patients with co-occurring cervical spine problems, mobilizations and exercises were added to the treatment plan. Findings showed a statistically significant reduction in tinnitus severity in patients with somatosensory tinnitus associated with TMD and emphasized the importance of having a multidisciplinary team (e.g., otolaryngologists, audiologists, physical therapists, dentists) involved in the care of patients with somatosensory tinnitus.(161)

An RCT by Delgado de la Serna et al. (2020) investigated cervico-mandibular manual therapy combined with exercise and education administered by physical therapists to improve outcomes, specifically reduce TMD pain and tinnitus severity, in tinnitus patients with co-occurring TMD.(162) Their findings showed that compared with education and exercises alone, combining cervico-mandibular therapy with education and exercises resulted in statistically significant improved outcomes.

The effects of manual therapy on QoL in patients with somatosensory tinnitus was evaluated in an SR by Sharma et al., (2022). Three RCTs met their criteria to be included: Delgado de la Serna et al. (2020) mentioned above, Bonaconsa et al. (2010), and Michiels et al. (2016).(162, 164, 165) The evidence from these three RCTs suggests that manual therapy combined with home exercises to address co-occurring cervical spine dysfunction is helpful in reducing tinnitus functional impact. This evidence was determined to be weak because of methodological concerns in Bonaconsa et al. (2010), and although improvement was shown in the RCT by Michiels et al. (2016), the effects were small.(164, 165)

The studies summarized in Sharma et al. (2022) demonstrate that patients with somatosensory tinnitus might benefit from physical therapy services (e.g., manual therapy) to address the underlying cervical spine dysfunction or TMD that co-occurs with their tinnitus.(163) In these situations, some factors to consider are as follows.

1. Before administering this treatment, physical therapists would need specialized training, which would involve time and costs associated with it.
2. Providing combined care in this way would involve a multidisciplinary team (e.g., physical therapists, dentists, audiologists, otolaryngologists), which sometimes necessitates a referral to a specialist and might be infeasible for all patients to receive, even if warranted.
3. Access to this treatment would be limited as a result of few providers with adequate training and overall a lack of familiarity with assessment and treatment options for somatosensory tinnitus.

Findings from numerous case reports, non-randomized studies, and review articles failed to meet the criteria to be included in the systematic evidence review for this CPG and, as such, are outside the scope of the review and did not influence the development of this recommendation. They are worth mentioning here to increase awareness of the various therapeutic approaches that have been evaluated to reduce the functional impact of somatosensory tinnitus, such as acupuncture, dry needling with manual stimulation, and myofascial trigger point deactivation.(166–168) The common theme in the literature on this topic is that therapeutic approaches for somatosensory tinnitus target the co-occurring musculoskeletal condition.

The Work Group systematically reviewed evidence related to this recommendation. (161–163) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was low. The body of evidence had some limitations, including statistical analyses that adjusted for some but not all potential confounders, inability to determine the direction of association between co-occurring condition variables and tinnitus treatment outcomes, and lack of ability to include blinding as part of the study design in some of the work reviewed. Additional limitations include a lack of generalizability to all patients with bothersome tinnitus. For patients with somatosensory tinnitus and TMD or cervical spine dysfunction, the benefits of orofacial treatment or manual therapy outweighed the potential harms and burdens, which in this case refers to patient and provider time burden rather than adverse effects. Patient values and preferences varied somewhat. Thus, the Work Group made the following recommendation: We suggest a multidisciplinary approach for the assessment and treatment of patients with bothersome tinnitus and temporomandibular disorder (TMD), cervical spine dysfunction, or both to reduce the functional impact of tinnitus.

I. Complementary and Integrative Health

Recommendation

23. There is insufficient evidence to recommend for or against acupuncture for tinnitus management.
(Neither for nor against | Reviewed, New-added)

Discussion

As part of Traditional Chinese Medicine, acupuncture is used widely for tinnitus in many Asian countries.(169) The Work Group examined four SRs (169–172) and two RCTs (173, 174) on acupuncture. In one SR that evaluated the effectiveness of TENS, laser therapy, acupuncture, or placebo control, some evidence indicated that acupuncture might be effective in reducing self-perceived tinnitus handicap as measured by the THI, and tinnitus loudness and tinnitus annoyance outcomes as measured by the VAS.(170) In addition, three other SRs indicated that acupuncture might provide subjective benefit for tinnitus as indicated by the VAS, subjective feeling outcomes (i.e., feeling better, normal, or worse),(172) and the THI.(169, 171) The two RCTs reviewed showed that acupuncture led to greater improvements in tinnitus functional impact, as measured by the THI (i.e., tinnitus annoyance as measured by the Portuguese version of the THI, and improvement in tinnitus-related QoL, respectively),(173, 174) and in VAS outcomes in obese patients with chronic subjective idiopathic tinnitus.(174)

Although the quality of one SR was determined to be moderate,(170) the quality of the others was low.(169, 171, 172) The overall quality of the SRs was limited by methodological flaws, including variation in the number of acupuncture sessions reported, use of inconsistent outcome measures, and the characterization of the type of tinnitus (e.g., tinnitus as chief complaint, acute tinnitus fewer than three months). For example, Liu et al. (2016) stated that the duration of tinnitus symptoms in the samples varied from 3 days–30 years.(172) The Work Group defined “chronic” tinnitus as lasting six months or longer. In addition, one critical methodological flaw across the body of evidence was related to variation in the type of acupuncture used (e.g., manual, electro, warm needle). Furthermore, in some studies, there was limited information on the acupuncture points targeted in the interventions.

Some variation occurs in patient preferences and values regarding acupuncture. Some patients dislike needles, although others do not mind them. The patient focus group participants reported that they appreciated a variety of interventions to manage their tinnitus, so acupuncture might be acceptable to some patients. Concerns regarding resource use, equity, and subgroup considerations were also discussed when developing this recommendation. In terms of resource use, provider training and space are required for acupuncture treatments. Acupuncture is unavailable in some communities, so equity is another factor to consider. Finally, subgroup considerations might include patients who are ineligible for acupuncture based on contraindications (e.g., skin conditions, bleeding disorders).

The Work Group systematically reviewed evidence related to this recommendation. (169–174) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was low. The body of evidence had some limitations, including a lack of detail regarding whether patients had bothersome tinnitus,(169) a lack of detail on the regions of the body that were manipulated, and a lack of detail on which pressure points were manipulated.(170) Evidence was also retrieved comparing different types of acupuncture, but that evidence was mixed.(169, 175) The benefits of acupuncture for improvement in critical and important outcomes (e.g., tinnitus functional impact, VAS) slightly outweighed the potential harm (e.g., of adverse events, which was small). Patient values and preferences varied somewhat because some patients dislike needles. Thus, the Work Group made the following recommendation: There is insufficient evidence to recommend for or against acupuncture for tinnitus management.

J. Herbals, Nutraceuticals, Supplements

Recommendation

24. We suggest against the use of ginkgo biloba, dietary or herbal supplements, or nutraceuticals for tinnitus management.
(Weak against | Reviewed, New-added)

Discussion

Herbal supplements are dietary supplements containing one or more vitamins, herbs, minerals, botanicals, amino acids, enzymes, or animal tissues from organs or glands.(176) Nutraceuticals are defined as formulations aimed at improving specific dietary requirements while offering preventive care. The term nutraceuticals combines the words nutrition and pharmaceuticals.(177) The FDA does not regulate the herbal and nutraceutical industry as strictly as it does for prescription medications. Notably, the FDA does not review supplements for safety and effectiveness before they are marketed. As a result, scientific evidence is lacking to globally support the use of herbal supplementation. Additionally, without FDA regulation, formulations vary among products, and ingredients listed on the label might not accurately reflect those contained in dietary supplements.(176) Herbals and nutraceuticals have been studied in patients with tinnitus; however, the confidence in the quality of these studies has been reported to be low to very low because of small sample size and risk of bias.(178–186)

Ginkgo biloba (GB) is an herbal supplement derived from the Maidenhair or ginkgo tree that has been used for centuries in China for medicinal treatments.(187) Gingko biloba has metabolites such as flavonoids, terpenoids, and trilactones, which are reported to have benefits including anti-inflammatory, antioxidant, and cytotoxic properties.(187) Ginkgo biloba has been investigated to treat blood circulation disorders (e.g., cerebrovascular, peripheral vascular disorders), memory disorders (e.g., dementia, Alzheimer disease), and conditions such as tinnitus, but research is inconclusive on the clinical effectiveness and mechanism of action.(187, 188) The most common side effects

include mild gastrointestinal complaints; however, serious adverse reactions have been reported, including bleeding, interaction with anticoagulant medication, and seizures.(189)

Evidence suggests that the use of GB alone does not improve outcomes in tinnitus functional impact, tinnitus perceived loudness, or QoL in patients with bothersome tinnitus.(180, 182, 183) An SR by Sereda et al. (2022) included 12 RCTs (n=1,915), 11 of which compared GB with a placebo and found little to no effect on the THI scores, QoL, and tinnitus perceived loudness scores.(183) In four studies, adverse events were also analyzed, which showed zero adverse events with GB use.(183) That the studies did not look at concomitant use of medications is important to note. One of the studies compared GB plus hearing aids versus GB alone. No improvement in tinnitus functional impact and tinnitus perceived loudness with GB was found.(183)

Although some other studies had different findings, these studies were smaller and of lower quality. Spiegel et al. (2018) conducted a meta-analysis of five randomized placebo-controlled clinical trials using GB in patients with mild to moderate dementia with tinnitus and dizziness.(179) They used an 11-point scale assessing the presence and severity of tinnitus. Of the patients with tinnitus at baseline (n=773), there was a mean reduction in tinnitus severity with GB use (mean difference: -1.06; 95% CI: -1.77–-0.36; p=0.003). There were significant issues with the measurement of tinnitus in patients with dementia. First, a standardized tinnitus scale was not used. The five studies had small sample sizes ranging from 19 to 102 patients. Lastly, ratings that were done with dementia patients might be unreliable.(179) Conversely, Chauhan et al. (2022) (n=58) conducted a randomized double-blinded clinical trial of GB plus antioxidant use in patients with tinnitus.(182) The study randomized patients to GB plus antioxidants versus placebo for six months. No difference between the groups was found when measuring with the tinnitus functional impact questionnaire.

Regarding the treatment of tinnitus with herbal or dietary supplements and nutraceuticals, 13 studies looked at the management of tinnitus with zinc supplementation, cyanocobalamin (vitamin B12), Hanekobokuto, Nigella sativa, antioxidants, Cistanche Yishen granules (CYG), Neurotec (containing herbal extracts of Rosa Canina, Urtica Dioica, and Tanacetum Vulgare), and others.(178, 180, 181, 184–186, 190, 191) The studies that looked at zinc, vitamin B12, Hangekobokuto, and Nigella sativa showed no significant improvement.(185, 190, 191)

An SR by Person et al. (2016) reviewed 3 RCTs (n=209) comparing zinc to placebo. The SR found no statistical difference in tinnitus functional impact, overall severity of tinnitus, or tinnitus perceived loudness. The SR was limited by a lack of continuity between trials, a low number of enrollees, low quality evidence, and a high risk of bias.(190) Vitamin B12 was reviewed in an RCT by Singh et al. (2016).(185) This RCT (n=40) randomized participants with tinnitus to receive B12 injections in the intervention group and isotonic saline in the control group. At 10 weeks follow-up, there was no statistical difference in tinnitus functional impact or tinnitus perceived loudness

regardless of vitamin B12 deficiency. The results were limited by the low number of enrollees, short follow-up time, and a high risk of bias.(185) Another herbal medication studied in tinnitus management is Hangekobokuto, a Japanese herbal supplement used to treat anxiety. One RCT by Ino et al. (2013) reviewed this supplement (n=76) and found no difference in tinnitus functional impact (p=0.73) or tinnitus perceived loudness (p=0.96).(191) The study was limited by the low number of patients as well as the tablet burden (12 tablets per day).(191) Lastly, Nigella sativa was compared with a placebo in an RCT (n=40) for patients with Meniere's disease experiencing tinnitus and showed no clinical or statistical difference in tinnitus functional impact (p=0.28) or tinnitus perceived loudness (p=0.71) (measured in decibels).(184) This trial was small, had very low quality evidence, and the patients were followed for nine months.(184)

Although some studies showed improvements with antioxidants and CYG, these studies were smaller and of lower quality. An RCT by Petridou et al. (2019) compared antioxidants with placebo (n=70) in which the antioxidant group received one multivitamin-multimineral a day with their meal and an alpha-lipoic acid tablet twice a day versus the placebo group receiving three placebo tablets at the same timepoints.(181) The use of an antioxidant supplement showed no difference in tinnitus functional improvement (p=0.410) and tinnitus frequency (p=0.82). However, results from the THI (p=0.015), MML (p<.001), and tinnitus loudness (p<0.001) measures favored antioxidant use.(181) This trial had a small enrollment, study bias, and a short follow-up of three months. Another RCT examined CYG versus placebo in patients with glomerulonephritis and tinnitus.(178) This study (n=89) had a one-month follow-up measuring tinnitus perceived loudness, sleep, and tinnitus functional impact. Data from this study favored the use of CYG for all three outcomes: TFI (p<0.05), tinnitus perceived loudness (p<0.05), and sleep (p<0.05); however, the study was small, had a short follow-up, and low diversity patient population (patients with chronic nephritis), which does not reflect the general population.(178) Khosravi et al. (2023) compared Neurotec 100 mg twice a day with placebo in a double randomized clinical trial in patients (n=103) with tinnitus.(186) Data from this study favored the use of Neurotec at three months follow-up in all outcomes: THI (p=0.017), mood disturbance score (p=0.045), sleep disturbance score (p=0.010), and tinnitus perceived loudness score (p=0.043). However, the study was small, had a short follow-up, and the supplement (Neurotec) is less readily available within the United States.(186)

Some variation occurs in patient preference regarding the management of bothersome tinnitus. The patient focus group noted that self-management strategies to treat tinnitus varied in effectiveness. No consistent research outcomes exist to prove the efficacy of GB, herbal or dietary supplements, and nutraceuticals to manage tinnitus. Further, the cost of these supplements and the risk of drug interactions can be burdensome for patients.

The Work Group systematically reviewed evidence related to this recommendation. (178–186, 190, 191) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had limitations, including small sample size, heterogeneity in study interventions, and inability to generalize outcomes to the general population. The harms of using GB, nutraceuticals, and herbal supplements to treat bothersome tinnitus slightly outweighed the potential benefits. These harms include potential side effects, risk of drug interactions, and a lack of FDA regulation. Patient values and preferences varied somewhat because some patients might prefer non-invasive treatments, but the Work Group considered factors such as the high cost of supplements and lack of consistency with formulations of GB, nutraceuticals, and herbal supplements. With these considerations, the Work Group made the following recommendation: We suggest against the use of ginkgo biloba, dietary or herbal supplements, or nutraceuticals for tinnitus management.

K. Pharmacotherapy

Recommendation

25. We suggest against the use of anticonvulsants, antidepressants, antiemetics, antithrombotics, betahistine, intratympanic corticosteroid injections, or n-methyl d-aspartic acid (NMDA) receptor antagonists for tinnitus management. **(Weak against | Reviewed, New-added)**

Discussion

No medications have been approved by the FDA for tinnitus management. However, treatment of co-occurring conditions (e.g., depression, anxiety) might improve a patient's ability to tolerate the symptoms of bothersome tinnitus. The effect of treating co-occurring conditions on outcome measures of tinnitus symptoms is briefly discussed elsewhere in the guideline (see Patients with Co-occurring Conditions and Appendix C).

Anticonvulsants (gabapentin, carbamazepine, oxcarbazepine)

The systematic evidence review identified an RCT and a network meta-analysis (NMA) evaluating gabapentin, carbamazepine, and oxcarbazepine medications for tinnitus management.(192, 193) Anticonvulsants potentially suppress central auditory hyperactivity that might be related to tinnitus. Anticonvulsants are believed to reduce tinnitus by augmenting the action or levels of neurotransmitters (e.g., gamma-aminobutyric acid, glutamate) or by inhibiting cell depolarization by blocking voltage-gated sodium channels. Gabapentin is an inhibitory neurotransmitter acting on voltage-gated calcium channels. Three RCTs in the NMA evaluated the use of anticonvulsants and suggested that gabapentin showed no difference in tinnitus functional impact versus placebo at up to 8 weeks.(193) A small study in the NMA also reported that the combination of gabapentin and lidocaine was superior to placebo at 6 weeks.(193) When evaluating perceived loudness (VAS intensity or loudness), one RCT found that

daily administered gabapentin improved tinnitus severity (VAS) in patients with acoustic trauma after 6 weeks.(192) There was a reduction in VAS in both treatment and placebo groups of at least 30%. Although gabapentin might improve tinnitus caused by acoustic trauma or in combination with lidocaine, insufficient evidence exists supporting the effectiveness of gabapentin in the treatment of chronic tinnitus. A significant benefit from carbamazepine or oxcarbazepine has not been confirmed in placebo-controlled trials.(193)

The Work Group developed a *Weak against* recommendation for the use of anticonvulsants because of the lack of evidence to support the benefit of using these agents for tinnitus management, based on assessment of critical and important outcome measures of tinnitus identified by the Work Group. The studies evaluated were of small size and short duration with low confidence in the quality of evidence across critical outcomes. The study that favored gabapentin was in combination with intradermal lidocaine injection.(193) The one RCT evaluating gabapentin after acoustic trauma lacked details on the mechanism of injury and limited the audiometric threshold measurements to 500, 1000, and 2000 Hz.(192) Because of the lack of evidence for benefit, any risk for adverse events might lead to an unfavorable risk versus benefit profile.

Antidepressants (paroxetine, sertraline, fluoxetine, trazodone, nortriptyline)

Antidepressants have been investigated as a treatment for tinnitus because the auditory cortex is rich in serotonin receptors. Evidence from four RCTs included in the NMA evaluated antidepressants (e.g., paroxetine, sertraline) and failed to show a significant benefit in reducing tinnitus functional impact (e.g., THI, TSI, THQ).(193) The use of fluoxetine alone or in combination with alprazolam improved the tinnitus functional impact (THI) and VAS scores compared with placebo in patients with chronic subjective tinnitus at 4 weeks.(194) The TSI scores decreased in both treatment groups after treatment; however, the difference between the single therapy and the combination revealed no significant difference.(194) The use of trazodone in a small study (n=43) showed no difference in QoL compared with placebo in individuals at up to 8 weeks of follow-up.(193) There was also no difference in QoL after administration of nortriptyline versus placebo.(193)

The Work Group developed a *Weak against* recommendation for the use of antidepressants because of the lack of evidence to support the benefit of using these agents for tinnitus management based on assessment of critical and important outcome measures of tinnitus identified by the Work Group. The NMA and RCT were of low quality evidence.(193, 194) The RCT evaluated fluoxetine alone and in combination with alprazolam and showed a reduction in the Beck Depression Inventory in the treatment groups.(194) The severity of anxiety in the fluoxetine and control group increased significantly (p=0.003). Seven individuals left the combination group as a result of side effects. Commonly reported side effects of antidepressants include sexual dysfunction, drowsiness, and dry mouth. That tinnitus is listed as a rare side effect of all available

antidepressants is also concerning.(194) Although the evidence base indicates that antidepressants might affect patients with tinnitus, the benefits of these agents remain unclear. The action statement does not apply to patients with anxiety, seizure disorder, or depression, where treatment with these agents could be indicated and useful. Because of the lack of evidence for benefit, any risk for adverse events might lead to an unfavorable risk versus benefit profile.

Antiemetics (vestipitant, ondansetron)

One small type II clinical pharmacological study (n=60) by Taslimi et al. (2013) favored ondansetron over placebo with a significant change in the TSI.(195) The study included dose increases every 3 days up to a final dose of 16 mg/day for 4 weeks. However, the study failed to show a difference in the THI scores.(195) A short 2-week study evaluating vestipitant (neurokinin-1-substance p antagonist) did not show a significant change in the tinnitus functional impact.(193) Vestipitant is unavailable in the United States and is under development by GlaxoSmithKline as an antiemetic, anxiolytic, for tinnitus and insomnia.

The Work Group developed a *Weak against* recommendation for the use of antiemetics because of the lack of evidence to support the benefit of using these agents for tinnitus management based on assessment of critical and important outcome measures of tinnitus identified by the Work Group. Additionally, vestipitant is unavailable for use in the United States. Because of a lack of evidence for benefit, any risk for adverse events might lead to an unfavorable risk versus benefit profile.

Antithrombotics (sulodexide, pentoxifylline, cilostazol)

Antithrombotic agents consist of two classes of medications, including antiplatelets (e.g., aspirin, cilostazol, pentoxifylline) and anticoagulants (e.g., heparin, warfarin). The potential mechanism for using antithrombotic agents for subjective tinnitus is unknown. In one RCT by El Beaino et al. (2018), twice-daily oral sulodexide use was compared with placebo in patients (n=124) with chronic subjective tinnitus and followed for 40 days.(196) The primary endpoint included the THI and Mini-Tinnitus Questionnaire (Mini-TQ). Sulodexide improved THI ($p<0.03$) and Mini-TQ ($p<0.01$) results statistically more than placebo. Although no patients withdrew from treatment with sulodexide, a numerically higher number of patients reported epigastric pain and constipation compared with none in the placebo group.(196)

Sulodexide is a combination of low molecular weight heparin and dermatan sulfate possessing antithrombotic, profibrinolytic, and anti-inflammatory effects. It is not approved for use in the United States and, therefore, is unavailable. No ongoing studies were identified on ClinicalTrials.gov (https://www.clinicaltrials.gov/) for the management of tinnitus using sulodexide.

An RCT by Prochazkova et al. (2018) (197) comparing pentoxifylline to ginkgo biloba extract in patients (n=197) with chronic tinnitus was included in an NMA of pharmacologic treatments for tinnitus by Chen et al. (2021).(193) In the RCT by Prochazkova et al. (2018), medications were taken twice daily for 12 weeks.(197) Tinnitus outcome measures included the Mini-TQ, tinnitus loudness and annoyance, the Hospital Anxiety and Depression Scale (HADS), and the Sheehan Disability Scale. No differences between pentoxifylline and ginkgo biloba were found in the tinnitus outcomes studied. No studies were identified comparing pentoxifylline to placebo, so the benefit of pentoxifylline in tinnitus management is unclear. Adverse events were reported in both the pentoxifylline group (n=36) and the ginkgo biloba extract group (n=20). No serious adverse events were reported.(197)

In one RCT (phase 2a pilot study) by Lim et al. (2016), cilostazol was compared with placebo in patients (n=50) followed for 4 weeks; both medications were taken twice daily.(198) Outcome measures included THI, VAS for tinnitus severity, and short-form health survey (SF-36) assessed at baseline, 2 weeks, and 4 weeks. No differences were noted in total THI scores between groups. Statistical differences were observed at 4 weeks in favor of cilostazol for the THI subscale (catastrophic), VAS for tinnitus severity, and physical function subscale (SF-36). Limitations of the study include higher THI severity scores and functional subscales in the placebo group at baseline. One patient in the placebo group and 11 patients in the cilostazol group withdrew as a result of persistent headaches.(198)

The Work Group developed a *Weak against* recommendation for the use of antithrombotics because of the lack of evidence for benefits and risk of adverse events from pentoxifylline or cilostazol. The harms and other factors (i.e., sulodexide is not FDA approved for use in the United States) were determined to slightly outweigh the benefits.

Betahistine (antihistamine)

An RCT (n=62) by Castilho et al. (2023) included adult patients with primary tinnitus who were randomized to betahistine or placebo for 90 days.(199) The primary outcome measure was a change in the THI from baseline to after treatment. The median difference in THI between betahistine and placebo was -2 points (95% CI: -8–6; p=0.75), indicating no difference.(199) No differences were reported in secondary measures.

One SR of five RCTs by Wegner et al. (2018) compared betahistine to placebo in adults with subjective idiopathic tinnitus.(200) The authors noted that although the ability to pool data was limited, no differences were identified between the TSI and perceived loudness (VAS) between betahistine and placebo.

No other RCTs of antihistamines for the management of tinnitus were identified as part of the systematic evidence review.

In addition to the lack of evidence supporting the benefit of betahistine in the management of tinnitus, other reasons for developing a *Weak against* recommendation include not being approved for use in the United States. Although the Work Group acknowledges access to betahistine is possible for managing Meniere's disease, accessibility is expected to vary, and compounding might be required. This creates differences in equity, resource use, and feasibility considerations.

Intratympanic corticosteroid injections (dexamethasone and methylprednisolone)

Evidence from three RCTs included in an NMA by Chen et al. (2021) evaluated intratympanic dexamethasone injections in patients with tinnitus.(193) All three of the RCTs compared intratympanic dexamethasone injections with placebo in patients with idiopathic tinnitus unresponsive to medical treatment (n=107),(201) in patients with acute unilateral tinnitus of presumed cochlear origin (n=54),(202) and in patients with "refractory" tinnitus (n=30).(203). In the RCT by Yener et al. (2020), patients were randomized to receive six intratympanic injections of dexamethasone or placebo (isotonic solution) as two injections per week for 3 weeks.(201) The primary outcome was THI measured at baseline, 1 week, one month, and six months after protocol completion. No differences were reported between dexamethasone and control at 1 week, but statistically lower THI scores were reported at one (p=0.05) and six months (p=0.037) after treatment with dexamethasone when compared with placebo.(201) In the RCT by Lee et al. (2018), intratympanic dexamethasone versus placebo (normal saline) was administered four times over 2 weeks.(202) The THI and VAS scores significantly improved in both groups with no statistical differences between groups after 4 weeks.(202) In the third RCT by Choi et al. (2013), patients with refractory tinnitus were randomized to receive intratympanic dexamethasone injection or placebo (saline) four times over 2 weeks.(203) No difference was found in THI scores between groups at 4 weeks.(203) Adverse events were not reported in any of the three RCTs.

One RCT by Topak et al. (2009) (204) was included in an NMA by Chen et al. (2021) (193) and compared intratympanic methylprednisolone injections with placebo (saline solution) in patients with subjective tinnitus of cochlear origin and refractory to medical treatment (n=70). The treatment was administered as three injections once weekly for 3 weeks. No differences in THI or other outcome measures were observed at 5 weeks. Adverse events were mild and included pain on injection, vertigo, burning around the ear and throat, and bitter taste.

The Work Group developed a *Weak against* recommendation for the use of intratympanic corticosteroids because of the lack of evidence to support the benefit of using these agents for tinnitus management. Other factors the Work Group identified that impacted the recommendation strength and might cause variation in patient acceptance include accessibility to treatment (i.e., specialists might be necessary to administer injections), resource use, patient acceptability, risk for adverse events (e.g., non-healing tympanic

membrane), and time for travel and appointments. Additionally, the dose and frequency of injections are inconsistent across trials; thus, an effective regimen is unknown.

n-methyl d-aspartic acid receptor antagonists (acamprosate, gacyclidine, esketamine gel, neramexane)

Two RCTs included in the NMA by Chen et al. (2021) compared acamprosate with placebo for tinnitus management.(193) In the RCT by Farhadi et al. (2020), patients (n=20) with chronic tinnitus were randomized to receive acamprosate (n=9) or placebo (n=11) three times daily for 30 days.(205) Although authors reported a significant improvement in THI and VAS scores from baseline in the acamprosate group but not in the placebo group, between-group analyses showed no differences in outcomes between acamprosate and placebo. Four patients discontinued treatment as a result of gastrointestinal adverse events or loss of interest.(205) The RCT by Sharma et al. (2012) used a crossover design in patients (n=40) with tinnitus and varying degrees of sensorineural hearing loss to compare the effect of acamprosate with placebo on tinnitus severity, QoL, and VAS to assess loudness with each treatment.(206) Acamprosate or placebo was taken three times daily for 40 days followed by a 7-day washout period, and then patients were crossed over to the alternate treatment. Improvement in tinnitus scores was reported in 92.5% of patients receiving acamprosate versus 12.5% of patients receiving placebo. Although the authors reported using objective and subjective measures for assessing response, the objective measure was noted as a reduction in tinnitus loudness. Whether tinnitus outcome measures identified by the Work Group were used to assess tinnitus is unclear.(206)

One combination phase 1/2 RCT of gacyclidine by Maxwell et al. (2021) explored the efficacy and safety of a single intratympanic injection of OTO-313 (gacyclidine) versus placebo in patients with tinnitus.(207) Outcomes explored included safety, TFI, ratings of tinnitus loudness and annoyance, and patient global impression of change. Gacyclidine was well tolerated and demonstrated improvements in TFI and other outcome measures versus placebo, although statistical comparisons were done ad hoc.(207) One phase 2 RCT (not included in the system evidence review) examined the safety and efficacy of a single intratympanic injection of gacyclidine or placebo (solution of medium chain triglycerides) in patients with moderate to severe unilateral tinnitus.(208) Tinnitus Functional Index scores were reduced in both the gacyclidine and placebo groups; improvements in a daily rating of loudness and annoyance and patient global impression of change scores were similar between groups. The authors concluded that gacyclidine did not significantly benefit patients with tinnitus and attributed the null finding to a “high placebo” response.(208)

Reports indicate that Otonomy, the company developing gacyclidine as a treatment for tinnitus, has discontinued the development of OTO-313, gacyclidine. Gacyclidine is not approved for use in the United States for any indication.

Two RCTs examined the efficacy and safety of intratympanic injections of AM-101 (esketamine gel for injection) in patients with acute inner ear tinnitus (eligible patients included those with acute acoustic trauma, idiopathic sudden sensorineural hearing loss, or acute otitis media).(209, 210) In a phase 2 RCT (n=2,480) by van de Heyning et al. (2014), the efficacy and safety of intratympanic esketamine injection, in two different doses (0.27 or 0.81 mg/mL), were compared with placebo in patients with acute inner ear tinnitus.(209) The treatment was given as three injections over 3 consecutive days and follow-up was through 90 days. The primary endpoint was improvement in MML from baseline to 90 days and improvement in the Tinnitus Loudness Questionnaire and Tinnitus Acceptance Questionnaire (annoyance) as coprimary endpoints. Other critical and important endpoints included the THI-12 questionnaire and sleep difficulties. No change in MML was observed with either the low or high dose versus placebo, but the higher dose of esketamine gel showed improvement in sleep, tinnitus loudness, and THI-12 score.(209) In the RCT by Staecker et al. (2017) (n=343), the safety of repeated intratympanic injections with AM-101 (esketamine gel for injection) was assessed in patients with persistent acute tinnitus after traumatic cochlear injury or acute otitis media.(210) Patients received either esketamine gel 0.87 mg/mL or placebo given as three injections over 3–5 consecutive days and followed for 84 days. The primary endpoint was the incidence of clinically important deterioration in hearing from baseline to 35 days. No serious adverse events were reported and the incidence of meaningful deterioration in hearing was low and did not differ from placebo. No other differences in adverse events were reported, and 92% of tympanic membranes were reported to be closed in 1 week and in all patients at 84 days.(210)

One RCT by Suckfull et al. (2011) included in the NMA by Chen et al. (2021) evaluated the efficacy and safety of neramexane in patients with moderate to severe subjective tinnitus (n=431).(193, 211) In the RCT, patients were randomized to receive 25, 50, or 75 mg neramexane daily or a placebo. The primary outcome was the change from baseline to 16 weeks in the THI-12 questionnaire. No statistical difference was found between neramexane and placebo in THI-12 score at 16 weeks. The most common adverse event reported with neramexane was dizziness, which appeared to be dose dependent.(211)

Gacyclidine, esketamine gel, and neramexane are unapproved for use in the United States for any indication. Companies involved in developing gacyclidine (Otonomy) and esketamine gel (Altamira/Auris Medical) as possible treatments for tinnitus have either halted future development or are regrouping because of null findings in several studies. Esketamine gel failed phase 3 studies include TACTT2 (NCT01803646) and TACTT3 (NCT02040194) 2018, which failed in August 2016 and March 2018, respectively. Although not included in the systematic evidence review for this guideline, one phase 2 RCT by Searchfield et al. (2023) did not show a benefit of intratympanic gacyclidine injection versus placebo.(208)

The Work Group developed a *Weak against* recommendation for the use of NMDA receptor antagonists because of the lack of evidence to support the benefit of using these agents for tinnitus management, based on assessment of critical and important outcome measures of tinnitus identified by the Work Group. Other factors include a lack of availability of gacyclidine, esketamine gel, and nermexane for use in the United States. Because of a lack of evidence for benefit, any risk for adverse events might lead to an unfavorable risk versus benefit profile.

Some variation occurs in patient preferences regarding the use of anticonvulsants, antidepressants, antiemetics, antithrombotics, betahistine, intratympanic corticosteroid injections, and NMDA receptor antagonists for tinnitus management. Most patients would likely prefer a medication with evidence of benefit and there might be concerns with known side effects or potential for adverse events. Some patients also might dislike receiving injections and might prefer non-invasive treatment options.

The Work Group systematically reviewed evidence related to this recommendation. (192–196, 198–200, 207, 209, 210) Therefore, it is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was very low. The body of evidence had multiple limitations, including small sample size in the majority of trials, many single-site studies, unequal groups at baseline, availability of drug of interest in the United States, early phase studies (e.g., phase 1 or 2, pilot studies), many studies conducted outside the United States, and confounders in the analysis.(192–196, 198–200, 207, 209, 210) The harms and burdens of using anticonvulsants, antidepressants, antiemetics, antithrombotics, betahistine, intratympanic corticosteroid injections, and NMDA receptor antagonists for tinnitus management (e.g., adverse events, accessibility, unequal access, resource use, availability of specialists for intratympanic injections) slightly outweighed the potential benefits, which were mostly lacking in the evidence reviewed. Patient values and preferences varied somewhat because of some patients' preference for non-invasive treatments, potential for adverse events, concerns with using medications that lack evidence of benefit, and time to travel for appointments for intratympanic injections. Thus, the Work Group made the following recommendation: We suggest against the use of anticonvulsants, antidepressants, antiemetics, antithrombotics, betahistine, intratympanic corticosteroid injections, or n-methyl d-aspartic acid (NMDA) receptor antagonists for tinnitus management.

X. Research Priorities

During the development of the 2024 VA/DoD Tinnitus CPG, the Work Group identified areas in which high-quality, well-designed studies in the targeted population (active duty Service member, Veteran, or both) are needed. These areas include ones that require stronger evidence to support current recommendations and those that require evidence to inform new recommendations in future CPGs. After assessing the currently available

evidence, the Work Group identified the following topics and corresponding recommended actions for future research.

A. Monitoring

- Conduct a review of published literature/research to report on harms associated with tinnitus interventions.
- Use validated tinnitus outcome measures in all future studies of tinnitus interventions.
- Evaluate pre- and post-treatment effects of tinnitus interventions using validated outcome measures.

B. Education and Self-Management

- Compare the efficacy of web-based or app-based training as standalone tinnitus care with provider-guided tinnitus care combined with self-management.
- Evaluate the efficacy of combining web-based or app-based training with guided tinnitus care.
- Conduct independent trials of the therapeutic application of UpSilent at multiple sites and compare it with other applications.
- Evaluate different parameters and hardware, and greater personalization and interaction involving artificial intelligence on individualized goals for tinnitus self-care.

C. Amplification Devices

- Evaluate the efficacy of amplification as a tinnitus intervention and function of hearing status (e.g., normal hearing, hidden hearing loss, mild/moderate/severe hearing loss).
- Investigate the effects of hearing aid programming strategies on reducing the functional impact of tinnitus.

D. Auditory Treatment

- Determine whether auditory training protocols are effective for reducing tinnitus functional impact and improving QoL and secondary outcomes (e.g., sleep, depression, anxiety).
- Evaluate the therapeutic benefits of auditory cognitive training on functional status.
- Compare active versus passive sound therapy and the effects on tinnitus outcome measures, tinnitus functional impact/QoL, and secondary outcomes (e.g., sleep, depression, anxiety).

E. Behavioral Treatment

- Evaluate the therapeutic and long-term effects of different forms of CBT interventions and the benefits of cognitive training on tinnitus functional impact/QoL and secondary outcomes (e.g., sleep, depression, anxiety).
- Determine which specific elements of CBT are most effective for managing the functional impact of tinnitus.
- Conduct studies with larger sample sizes to evaluate the therapeutic and long-term effects of psychotherapies other than CBT on tinnitus functional impact/QoL and secondary outcomes (e.g., sleep, depression, anxiety).
- Compare the effectiveness of a variety of psychological interventions on tinnitus functional impact/QoL.
- Conduct studies focused on internet-based therapies other than CBT and evaluate the effects on tinnitus functional impact/QoL.
- Conduct studies that compare a full treatment program of CBT with other subsets of treatment programs (e.g., without CBT) on tinnitus functional impact/QoL.
- Evaluate the efficacy of CBT interventions delivered via mobile apps for tinnitus.
- Evaluate the influence of co-occurring conditions (e.g., behavioral/mental health conditions, insomnia) on tinnitus outcomes.
- Conduct studies that include audiologic data to determine whether hearing ability affects patient outcomes with psychotherapy-only interventions.

F. Combined Auditory and Behavioral Treatment

- Examine group versus individual modalities for combined auditory therapy and CBT for tinnitus management.
- Conduct studies that specifically examine the effectiveness of CBT alone and CBT combined with sound therapy.

G. Neuromodulation/Neurostimulation

- Conduct large multisite, randomized, placebo-controlled clinical trials of rTMS to identify the most effective protocols for reducing the perception of tinnitus, severity of tinnitus, or both.
- Conduct large RCTs of TENS and tDCS to determine whether these interventions are effective for reducing the perception of tinnitus, severity of tinnitus, or both.

H. Manual Therapy

- Conduct large clinical trials of physical therapy, chiropractic, and other forms of spinal manipulation to determine whether these interventions are effective for reducing the perception of tinnitus, severity of tinnitus, or both, especially for

individuals who have somatic components associated with their auditory symptoms.

I. Complementary and Integrative Health

- Evaluate the comparative effectiveness of different types of acupuncture as a tinnitus intervention.
- Evaluate the comparative effectiveness of different types of complementary and integrative whole health approaches to improve QoL with tinnitus.
- Evaluate the effectiveness of biofeedback to reduce tinnitus functional impact.

J. Pharmacotherapy

- Use tinnitus assessments (perception and functional impact) as outcome measures in clinical trials of medications designed to regenerate or reactivate hair cells and restore cochlear functions.
- Conduct large clinical trials to determine whether effective pharmacological treatment of behavioral/mental health disorders (e.g., major depressive disorder, generalized anxiety disorder) is associated with reductions in tinnitus severity for patients who experience these co-occurring conditions.

Appendix A: Guideline Development Methodology

A. Developing Key Questions to Guide the Systematic Evidence Review

To guide this CPG's systematic evidence review, the Work Group drafted 20 KQs on clinical topics of the highest priority for the VA and DoD populations. The KQs followed the population, intervention, comparison, outcome, timing, and setting (PICOTS) framework, as established by the Agency for Healthcare Research and Quality (AHRQ). Table A-1 lists and describes the PICOTS elements.

Table A-1. PICOTS (212)

PICOTS Element	Description
Population or Patients	Patients of interest. It includes the condition or conditions, populations or sub-populations, disease severity or stage, co-occurring conditions and other patient characteristics or demographics.
Intervention or Exposure	Treatment (e.g., drug, surgery, lifestyle changes), approach (e.g., doses, frequency, methods of administering treatments), or diagnostic or screening test or both used with the patient or population.
Comparator	Treatment or treatments (e.g., placebo, different drugs) or approach or approaches (e.g., different dose, different frequency, standard of care) being compared with the intervention or exposure of interest described above.
Outcomes	Results of interest (e.g., mortality, morbidity, quality of life, complications). Outcomes can include short, intermediate, and long-term outcomes.
Timing, if Applicable	Duration or follow-up of interest for the particular patient intervention and outcome to occur (or not occur).
Setting, if Applicable	Setting or context of interest. Setting can be a location (e.g., primary, specialty, inpatient care) or a type of practice.

Because of resource constraints, all KQs of interest to the Work Group could not be included in the systematic evidence review. Thus, the Work Group selected the 20 highest priority KQs for inclusion (see Table A-3).

Using the GRADE approach, the Work Group rated each outcome on a 1–9 scale (7–9, critical for decision making; 4–6, important, but not critical, for decision making; and 1–3, of limited importance for decision making). Critical and important outcomes were included in the evidence review (see Outcomes); however, only critical outcomes were used to determine the overall quality of evidence (see Determining Recommendation Strength and Direction).

a. Populations

Key Question	Population
1–11, 13, 14, 17–20	Adults with bothersome tinnitus
12	Adults with bothersome tinnitus with co-occurring conditions
15-16	Adults with bothersome tinnitus and either normal hearing, normal hearing (with hidden hearing loss), mild to moderate hearing loss, or severe to profound hearing loss

b. Interventions and Comparators

KQs	Interventions	Comparators
1	Tinnitus Questionnaires/Surveys/Interviews such as: • Tinnitus Functional Index (TFI) • Tinnitus Handicap Inventory (THI) • Tinnitus Reaction Questionnaire (TRQ) • Visual Analogue Scale (VAS) for Loudness • Tinnitus Questionnaire (TQ)	• Other evaluation tools
2	• Audiological counseling • Tinnitus reassurance • Tinnitus education	• No tinnitus reassurance • No tinnitus education • No audiological counseling • People on wait lists • Usual care
3	• Mindfulness (e.g., Mindfulness Based Stress Reduction for Tinnitus) • Mobile apps • Websites (e.g., podcasts, online courses, sound files, or other websites)	• Guided Care • Usual care
4	• Clinical video telehealth • Email/secure messages • Home telehealth • Store and forward telehealth/asynchronous • Telephone • Video	• In-person intervention
5	• Auditory cortical stimulation • Electromagnetic stimulation • Implanted vagus nerve stimulation • Invasive brain stimulation (such as deep brain stimulation) • Bimodal (auditory and trigeminal nerve) stimulation device for tinnitus • Low level laser therapy	• Sham intervention • Usual care

KQs	Interventions	Comparators
5 (cont.)	• Low energy ultrasound • Repetitive transcranial magnetic stimulation (rTMS) • Transcranial direct current stimulation (tDCS) • Transcutaneous nerve stimulation • Vagus nerve stimulation	
6	• Pharmacotherapy class • Anesthetics • Antiarrhythmics • Anticonvulsants • Antidepressants • Antihistamines • Anxiolytics • Calcium channel blockers • Corticosteroids • Diuretics • Glutamate receptor antagonists • Intratympanic medications • Muscle relaxants • Other See Table A-2 for list of specific medications in each of the drug classes listed above.	• Placebo • Usual care
7	• Acupressure • Acupuncture • Biofeedback • Dance • Healing touch • Hypnotherapy • Manual Therapy • Massage • Meditation • Music or art therapies • Physical Therapy • Spinal manipulation (e.g., chiropractic, osteopathic manipulation) • Other complementary and integrative health interventions in the literature	• Placebo/sham • Usual care
8	• Acupressure • Acupuncture • Biofeedback • Dance	• Other complementary and integrative health intervention

KQs	Interventions	Comparators
8 (cont.)	• Healing touch • Hypnotherapy • Manual Therapy • Massage • Meditation • Music or art therapies • Physical Therapy • Spinal manipulation (e.g., chiropractic, osteopathic manipulation) • Other complementary and integrative health interventions in the literature	
9	• Aerobic exercise • Nutritional counseling (e.g., sodium or caffeine, restriction) • Qigong • Restrict alcohol consumption • Smoking cessation • Supported employment • Tai Chi • Wellness techniques such as ♦ Deep breathing ♦ Focused Breathing ♦ Guided Imagery ♦ Mindful eating ♦ Progressive Relaxation ♦ Relaxation ♦ Sleep modifications ♦ Stress management techniques • Yoga	• Usual care
10	• Botanicals • Cannabis/cannabinoids • Chinese herbs • Dietary supplements • Ginkgo biloba • Lipoflavonoid • Magnesium • Melatonin • Minerals • Ozone • Phytochemicals • Prebiotics	• Placebo • Usual care

KQs	Interventions	Comparators
10 (cont.)	• Probiotics • Psilocybin • Vitamins • Zinc	
11	• Alcohol or substance use disorder • Anxiety • Blast exposure • Chronic pain • Dementia/cognitive deficits • Depression • Gambling addiction • Gaming addiction/disorder • Head injury/traumatic brain injury (TBI) • Hearing loss • Homelessness • Inadequate sleep (i.e., insomnia, sleep disorders) • Psychiatric disorders (e.g., psychosis/schizophrenia) • Trauma (i.e., posttraumatic stress disorder [PTSD]) • Sound tolerance conditions (e.g., hyperacusis) • Social isolation • Suicidality • TBI / Blast exposure • Temporomandibular joint disorder (TMJ) • Unemployment	• Absence of co-occurring conditions
12	• Any treatment for tinnitus	• No treatment for tinnitus
13	• Customized sound-based therapies (such as notched noise, music, amplitude modulated tones, auditory discrimination training) • Other sound/acoustic enrichment (such as bedside/table top sound generators, environmental sounds, radio, CD/mp3 download, smartphone app) • Other proprietary sound devices (e.g., neuromonics) • Wearable sound generator/ masking device	• Usual care/control group (no amplification device)

KQs	Interventions	Comparators
14	• Customized sound-based therapies (such as notched noise, music, amplitude modulated tones, auditory discrimination training) • Other sound enrichment (such as bedside/table top sound generators, environmental sounds, radio, CD/mp3 download, smartphone App) • Other proprietary sound devices (e.g., neuromonics) • Wearable sound generator/ masking device	• Other auditory intervention (sound therapy and sound enrichment)
15	• Bone conduction (any method) • Combination devices (hearing aid and sound generator) • Hearing aid • Implantable devices (including cochlear implants for adults with severe to profound hearing loss, bone-anchored hearing aids, bone-conduction hearing implants, bone-bridge/middle-ear devices)	• Usual care/control group (no amplification device)
16	• Bone conduction (any method) • Combination devices (hearing aid and sound generator) • Hearing aid • Implantable devices (including cochlear implants for adults with severe to profound hearing loss, bone-anchored hearing aids, bone-conduction hearing implants, bone-bridge/middle-ear devices)	• Other amplification device
17	• Acceptance and commitment therapy (ACT) • Behavioral activation (modern forms) • Behavioral health interventions to address co-occurring conditions • Cognitive behavioral therapy (CBT) • Coping effectiveness training (CET) • Counseling on lifestyle and coping approaches (including talk therapy) • Dialectical behavioral therapy (DBT) • Eye Movement Desensitization and Reprocessing (EMDR) • Functional analytic psychotherapy (FAP) • Metacognitive therapy (MCT) • Mindfulness-based cognitive therapy (MBCT) • Mindfulness-based interventions • Mindfulness-based stress reduction (MBSR) • Support groups • Team-based care	• Usual care

KQs	Interventions	Comparators
18	• ACT • Behavioral activation (modern forms) • Behavioral health interventions to address co-occurring conditions • CBT • CET • Counseling on lifestyle and coping approaches • DBT • EMDR • FAP • MCT • MBCT • Mindfulness-based interventions • MBSR • Support groups • Team-based care	• Other behavioral intervention
19	• Progressive tinnitus management (PTM) • Tinnitus retraining therapy (TRT) • Tinnitus Activities Treatment (TAT) • Mindfulness Based Stress Reduction for Tinnitus • Neuromonics Tinnitus Therapy	• Usual care
20	• ACT • Behavioral activation (modern forms) • Behavioral health interventions to address co-occurring conditions • CBT • CET • Counseling on lifestyle and coping approaches • DBT • EFT • EMDR • FAP • MCT • MBCT • Mindfulness-based interventions • MBSR • Problem-solving therapy • Solution-focused therapy • Support groups • Team-based care	• Bone conduction (any method) • Combination devices (hearing aid and sound generator) • Customized sound-based therapies (such as notched noise, music, amplitude modulated tones, auditory discrimination training) • Hearing aid • Implantable devices (including cochlear implants for adults with severe to profound hearing loss, bone-anchored hearing aids, bone-conduction hearing implants, bone-bridge/middle-ear devices) • Other sound/acoustic enrichment (such as bedside/tabletop sound generators, environmental sounds, radio, CD/mp3 download, smartphone app) • Other proprietary sound devices (e.g., neuromonics) • Wearable sound generator/ masking device

Table A-2. List of Medications for KQ 6

Class	Agent	
Anesthetics	• Lidocaine • Procaine	
Antiarrhythmics	• Flecainide • Lidocaine	• Mexiletine • Tocainide
Anticonvulsants	• Carbamazepine • Gabapentin • Lamotrigine • Phenytoin	• Pregabalin • Primidone • Valproic Acid
Antidepressants	• Amitriptyline • Bupropion • Fluoxetine • Nortriptyline • Paroxetine	• Protriptyline • Sertraline • Trazodone • Trimipramine
Antihistamines	• Cetirizine • Chlorpheniramine • Dexchlorpheniramine	• Fexofenadine • Loratadine • Meclizine
Anxiolytics	• Benzodiazepines (alprazolam, clonazepam, diazepam, flurazepam, oxazepam, lorazepam, triazolam)	
Calcium channel blockers	• Amlodipine • Nifedipine • Nimodipine	
Corticosteroids	• Dexamethasone • Glucocorticoid (prednisone) • Methylprednisolone	
Diuretics	• Bumetanide • Chlorothiazide • Furosemide	• Hydrochlorothiazide • Torsemide
Glutamate receptor antagonists	• Acamprosate • Memantine	
Muscle relaxants	• Baclofen • Cyclobenzaprine	

Class	Agent	
Other	• Atorvastatin • Clonidine • Doxepin • Eszopiclone • Flindokalner (BMS-204352) • Gacyclidine (OTO-313) intratympanic injection (Phase 2 study enrolled [Feb 2022]) • Intratympanic steroid injection (or tympanic injections) • Lemborexant • Naltrexone	• Nicotinic acid • Nitrous oxide • Opioid analgesics • Pentoxifylline • Ramelteon • Scopolamine • Suvorexant • Vardenafil • Tympanic injections • Zaleplon • Zolpidem
The following drugs were listed as having a potential to exacerbate tinnitus: (*listed as both possible treatment and may worsen tinnitus)	• Acetazolamide • Acetylsalicylic acid (aspirin) • Alcohol • Alprazolam* • Aminoglycosides (gentamicin, tobramycin) • Amitriptyline* • Amphotericin • Aztreonam • Barbiturates • Benzodiazepines* • Carbamazepine* • Diclofenac • Diltiazem • Erythromycin • Etodolac • Fluoxetine* • Ibuprofen • Itraconazole	• Ketorolac • Loratadine* • Lidocaine* • Lisinopril • Loop diuretics (furosemide, torsemide, bumetanide)* • Methotrexate • Misoprostol • Naproxen • Nifedipine* • Oral contraceptives • Prazosin • Piroxicam • Propofol • Quinine and chloroquinine • Salicylates • Triazolam* • Vancomycin

c. Outcomes

KQ	Critical Outcome(s)	Important Outcome(s)
1	• Tinnitus Functional Impact (e.g., Tinnitus Functional Index [TFI]; Tinnitus Handicap Inventory [THI]; Tinnitus Questionnaire [TQ]) • Tinnitus perceived loudness (e.g., Visual Numeric Scale [VNS], Visual Analogue Scale [VAS])	• Anxiety (e.g., State Anxiety Index, Hospital Anxiety and Depression Scale [HADS], posttraumatic stress disorder [PTSD] assessments, Generalized Anxiety Disorder-7 [GAD-7]) • Depression (e.g., Beck Depression Inventory [BDI], Hamilton Depression Scale, HADS) • Perceived stress (e.g., Perceived Stress Scale 4 [PSS-4], 10, 13, 14) • Quality of life (e.g., Whole Health Organization Quality of Life [WHOQOL], 12-Item Short Form Health Survey [SF-12], 36-Item Short Form Health Survey [SF-36], Global Quality of Life Scale) • Sleep (e.g., Pittsburgh Sleep Quality Index)
2, 3, 4, 11	Tinnitus Functional Impact (e.g., TFI; THI; TQ)	• Anxiety (e.g., State Anxiety Index, HADS, PTSD assessments, GAD-7) • Depression (e.g., BDI, Hamilton Depression Scale, HADS) • Perceived stress (e.g., PSS-4, 10, 13, 14) • Quality of life (e.g., WHOQOL, SF-12, SF-36, Global Quality of Life Scale) • Sleep (e.g., Pittsburgh Sleep Quality Index) • Tinnitus perceived loudness (e.g., VNS, VAS)
5, 6	• Adverse events (e.g., safety, tolerability, side effects such as hyperacusis or skin irritation, perceived worsening of tinnitus) • Tinnitus Functional Impact (e.g., Tinnitus Functional Index (TFI); THI; TQ)	• Anxiety (e.g., State Anxiety Index, HADS, PTSD assessments, GAD-7) • Depression (e.g., BDI, Hamilton Depression Scale, HADS) • Quality of life (e.g., WHOQOL, SF-12, SF-36, Global Quality of Life Scale) • Sleep (e.g., Pittsburgh Sleep Quality Index) • Tinnitus perceived loudness (e.g., VNS, VAS)
7, 8, 10, 13, 14	Tinnitus Functional Impact (e.g., TFI; THI; TQ)	• Adverse events (e.g., safety, tolerability, side effects such as hyperacusis or skin irritation, perceived worsening of tinnitus) • Anxiety (e.g., State Anxiety Index, HADS, PTSD assessments, GAD-7) • Depression (e.g., BDI, Hamilton Depression Scale, HADS) • Quality of life (e.g., WHOQOL, SF-12, SF-36, Global Quality of Life Scale) • Sleep (e.g., Pittsburgh Sleep Quality Index) • Tinnitus perceived loudness (e.g., VNS, VAS)

KQ	Critical Outcome(s)	Important Outcome(s)
9	• Quality of life (e.g., WHOQOL, SF-12, SF-36, Global Quality of Life Scale) • Tinnitus Functional Impact (e.g., TFI; THI; TQ)	• Anxiety (e.g., State Anxiety Index, HADS, PTSD assessments, GAD-7) • Depression (e.g., BDI, Hamilton Depression Scale, HADS) • Perceived stress (e.g., PSS-4, 10, 13, 14) • Sleep (e.g., Pittsburgh Sleep Quality Index) • Tinnitus perceived loudness (e.g., VNS, VAS)
12	• Anxiety (e.g., State Anxiety Index, HADS, PTSD assessments, GAD-7) • Depression (e.g., BDI, Hamilton Depression Scale, HADS) • Insomnia • PTSD	• Mental health care utilization • Suicidal behavior
15, 16	Tinnitus Functional Impact (e.g., TFI; THI; TQ)	• Adverse events (e.g., safety, tolerability, side effects such as hyperacusis or skin irritation, perceived worsening of tinnitus) • Anxiety (e.g., State Anxiety Index, HADS, PTSD assessments, GAD-7) • Depression (e.g., BDI, Hamilton Depression Scale, HADS) • Quality of life (e.g., WHOQOL, SF-12, SF-36, Global Quality of Life Scale) • Reduction in self-perceived hearing handicap as measured by hearing questionnaires (HHIA/E, APHAB) • Tinnitus perceived loudness (e.g., VNS, VAS)
17, 18	Tinnitus Functional Impact (e.g., TFI; THI; TQ)	• Anxiety (e.g., State Anxiety Index, HADS, PTSD assessments, GAD-7) • Depression (e.g., BDI, Hamilton Depression Scale, HADS) • Perceived stress (e.g., PSS-4, 10, 13, 14) • Quality of life (e.g., WHOQOL, SF-12, SF-36, Global Quality of Life Scale) • Reduction in activity avoidance (activities important to the patient) • Sleep (e.g., Pittsburgh Sleep Quality Index)

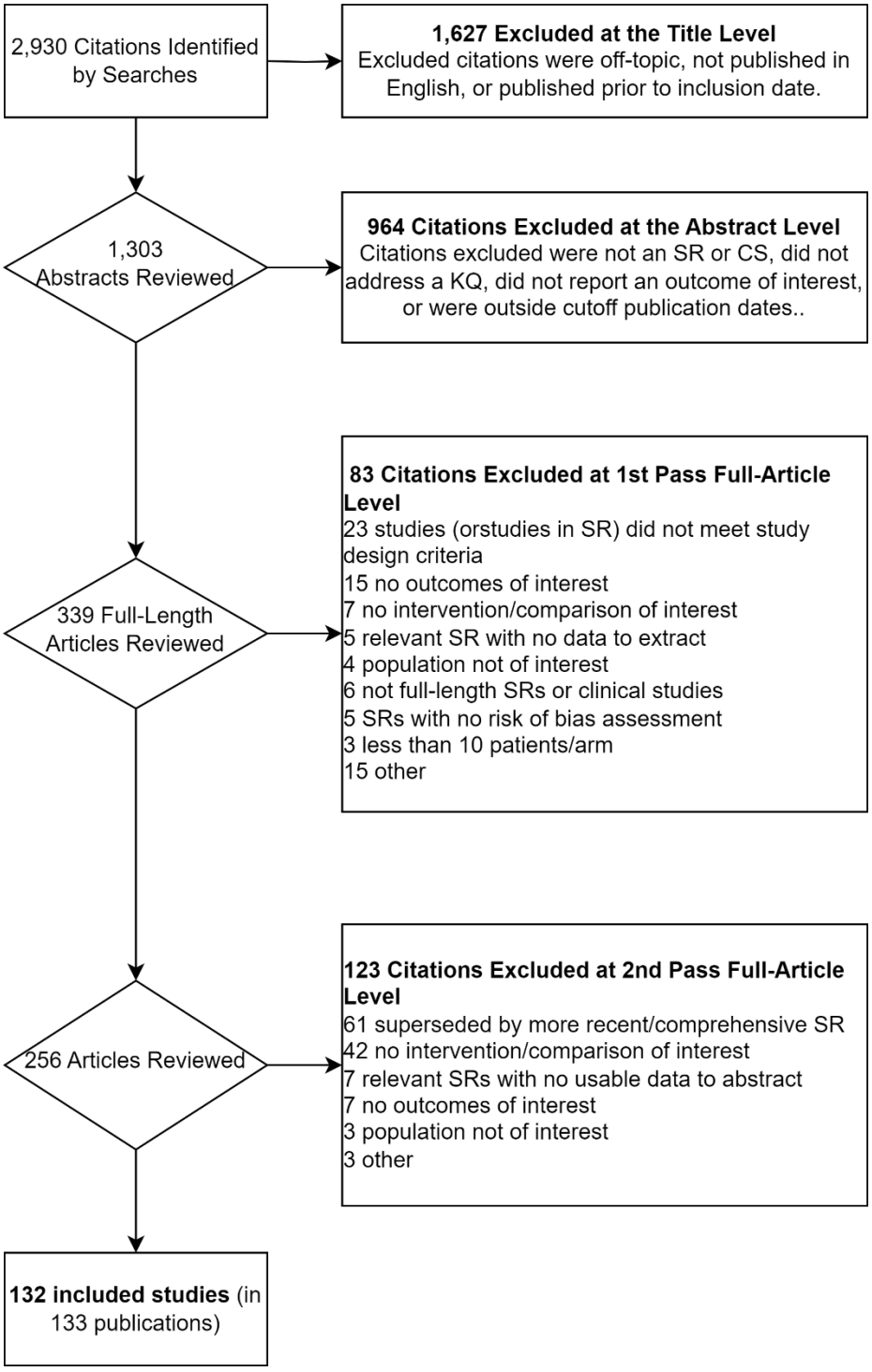
KQ	Critical Outcome(s)	Important Outcome(s)
19	Tinnitus Functional Impact (e.g., TFI; THI; TQ)	• Anxiety (e.g., State Anxiety Index, HADS, PTSD assessments, GAD-7) • Depression (e.g., BDI, Hamilton Depression Scale, HADS) • Quality of life (e.g., WHOQOL, SF-12, SF-36, Global Quality of Life Scale) • Reduction in activity avoidance (activities important to the patient) • Reduction in self-perceived hearing handicap as measured by hearing questionnaires (HHIA/E, APHAB) • Sleep (e.g., Pittsburgh Sleep Quality Index)
20	Tinnitus Functional Impact (e.g., TFI; THI; TQ)	• Adverse events (e.g., safety, tolerability, side effects such as hyperacusis or skin irritation, perceived worsening of tinnitus) • Anxiety (e.g., State Anxiety Index, HADS, PTSD assessments, GAD-7) • Depression (e.g., BDI, Hamilton Depression Scale, HADS) • Quality of life (e.g., WHOQOL, SF-12, SF-36, Global Quality of Life Scale) • Sleep (e.g., Pittsburgh Sleep Quality Index) • Tinnitus perceived loudness (e.g., VNS, VAS)

B. Conducting the Systematic Review

Based on the Work Group's decisions regarding the CPG's scope, KQs, and PICOTS statements, the Lewin Team produced a systematic evidence review protocol before conducting the review. The protocol detailed the KQs, PICOTS criteria, methodology to be used during the systematic evidence review, and the inclusion and exclusion criteria to be applied to each potential study, including study type and sample size. The Work Group reviewed and approved the protocol.

Figure A-1 below outlines the systematic evidence review's screening process (see also the General Criteria for Inclusion in Systematic Review. In addition, Table A-3 indicates the number of studies that addressed each of the questions.

Figure A-1. Study Flow Diagram



Abbreviations: CS: clinical study; KQ: key question; SR: systematic review

Alternative Text Description of Study Flow Diagram

Figure A-1. Study Flow Diagram is a flow chart with nine labeled boxes linked by arrows that describe the literature review inclusion-exclusion process. Arrows point down to boxes that describe the next literature review step and arrows point right to boxes that describe the excluded citations at each step (including the reasons for exclusion and the numbers of excluded citations).

1. Box 1: 2,930 Citations Identified by Searches
    a. Right to Box 2: 1,627 Citations Excluded at the Title Level
        i. Citations excluded at this level were off-topic, not published in English, or published prior to inclusion date.
    b. Down to Box 3
2. Box 3: 1,303 Abstracts Reviewed
    a. Right to Box 4: 964 Citations Excluded at the Abstract Level
        i. Citations excluded at this level were not an SR or CS, did not address a KQ, did not report an outcome of interest, or were outside cutoff publication dates.
    b. Down to Box 5
3. Box 5: 339 Full-Length Articles Reviewed
    a. Right to Box 6: 83 Citations Excluded at 1st Pass Full-Article Level
        i. 23 studies (or studies in SR) did not meet study design criteria, 15 no outcomes of interest, 7 no intervention/comparison of interest, 5 relevant SR with no data to extract, 4 population not of interest, 6 not full-length SRs or clinical studies, 5 SRs with no risk of bias assessment, 3 less than 10 patients/arm, 15 other.
    b. Down to Box 7
4. Box 7: 256 Articles Reviewed
    a. Right to Box 8: 123 Citations Excluded at 2nd Pass Full-Article Level
        i. 61 superseded by more recent/comprehensive SR, 42 no intervention/comparison of interest, 7 relevant SRs with no usable data to abstract, 7 no outcomes of interest, 3 population not of interest, 3 other.
    b. Down to Box 9
5. Box 9: 132 included studies (in 133 publications)

Table A-3. Evidence Base for Key Questions (KQ)

KQ Number	KQ	Number and Study Type
1	What is the comparative utility of evaluation tools for monitoring effectiveness of care for adults with bothersome tinnitus?	3 randomized controlled trials (RCT), 1 cohort study, and 3 single-arm studies
2	What is the effectiveness of tinnitus education for improving clinical outcomes in adults with bothersome tinnitus?	1 systematic review (SR) and 1 RCT
3	What is the effectiveness of web-based or app-based self-management without direct involvement of a provider for improving clinical outcomes in adults with bothersome tinnitus?	1 SR and 4 RCTs
4	What is the comparative effectiveness of telehealth/telemedicine intervention vs. in-person intervention for improving clinical outcomes in adults with bothersome tinnitus?	1 SR
5	What is the effectiveness of neurostimulation/neuromodulation for improving clinical outcomes in adults with bothersome tinnitus?	6 SRs and 11 RCTs
6	What is the effectiveness of pharmacotherapy for improving clinical outcomes in adults with bothersome tinnitus?	2 SRs and 9 RCTs
7	What is the effectiveness of complementary/ integrative health interventions for improving clinical outcomes in adults with bothersome tinnitus?	5 SRs and 5 RCTs
8	What is the comparative effectiveness of complementary/ integrative health interventions for improving clinical outcomes in adults with bothersome tinnitus?	1 SR and 4 RCTs
9	What is the effectiveness of lifestyle interventions for improving clinical outcomes in adults with bothersome tinnitus?	4 RCTs
10	What is the effectiveness of herbals, nutraceuticals, and supplements for improving clinical outcomes in adults with bothersome tinnitus?	3 SRs and 8 RCTs
11	What is the effect of co-occurring conditions – and changes in these conditions – on intervention outcomes in adults with bothersome tinnitus?	6 prognostic observational studies
12	What is the effect of interventions for bothersome tinnitus on outcomes for co-occurring psychiatric conditions in adults with bothersome tinnitus?	2 SRs
13	What is the effectiveness of sound therapy for improving clinical outcomes in adults with bothersome tinnitus?	1 SR and 7 RCTs
14	What is the comparative effectiveness of sound therapy for improving clinical outcomes in adults with bothersome tinnitus?	8 RCTs
15	What is the effectiveness of amplification devices for improving clinical outcomes in adults with bothersome tinnitus with a) Normal hearing without subjective hearing difficulty; b) Normal hearing with subjective hearing difficulty (hidden hearing loss); c) Mild/moderate hearing loss; d) Severe/profound hearing loss?	7 SRs and 4 RCTs

KQ Number	KQ	Number and Study Type
16	What is the comparative effectiveness of amplification devices for improving clinical outcomes in adults with bothersome tinnitus with a) Normal hearing without subjective hearing difficulty; b) Normal hearing with subjective hearing difficulty (hidden hearing loss); c) Mild/moderate hearing loss; d) Severe/profound hearing loss?	2 SRs and 6 RCTs
17	What is the effectiveness of behavioral interventions for improving clinical outcomes in adults with bothersome tinnitus?	2 SRs and 3 RCTs
18	What is the comparative effectiveness of behavioral interventions for improving clinical outcomes in adults with bothersome tinnitus?	1 SR and 1 RCT
19	What is the effectiveness of combined auditory plus behavioral interventions for improving clinical outcomes in adults with bothersome tinnitus?	6 RCTs (in 7 publications)
20	What is the comparative effectiveness of behavioral interventions to audiology interventions for improving bothersome tinnitus in adults?	3 RCTs
	Total Evidence Base	**132 studies (in 133 publications)**

a. General Criteria for Inclusion in Systematic Evidence Review

- RCTs or SRs published on or after January 1, 2013, to April 7, 2023.
- If multiple SRs addressed a key question, we selected the most recent and/or comprehensive review. Systematic reviews were supplemented with RCTs published subsequent to the systematic review.
- Studies had to be published in English.
- Publication must have been a full clinical study or systematic review; abstracts alone were not included. Similarly, letters, editorials, and other publications that were not full-length clinical studies were not accepted as evidence.
- Systematic reviews must have searched MEDLINE or EMBASE for eligible publications, performed a risk of bias assessment of included studies, and assessed the quality of evidence using a recognizable rating system, such as GRADE or something compatible (e.g., the Strength of Evidence grading used by the Evidence-based Practice Centers of the AHRQ). If an existing review did not assess the overall quality of the evidence, evidence from the review must have been reported in a manner that allowed us to judge the overall risk of bias, consistency, directness, and precision of evidence. We did not use an existing review as evidence if we were unable to assess the overall quality of the evidence in the review.
- Study must have enrolled at least 20 patients (10 per study group). Small sample size is associated with increased risk of bias and we downgraded small studies in

the GRADE domain of precision: one downgrade for imprecision of a single study with <200 patients per study arm.

- Newer Cochrane reviews already take into account small sample-size in their estimation of risk of bias. In these cases, where sample size already contributed to the assessment of the evidence, we did not downgrade those data a second time.

- Study must have enrolled at least 80% of patients who meet the study population criteria: adults with bothersome tinnitus. If a study enrolled fewer than 80% of patients meeting this criterion, it must have presented separate results for this patient subgroup.
- Study must have reported on at least one critical or important outcome of interest.

b. Key Question Specific Criteria for Inclusion in Systematic Evidence Review

- For all KQs except KQ 1 and 11, studies must have been SRs or prospective RCTs with an independent control group. Crossover trials were not included unless they reported data for the first phase of the study separately.
- In addition to RCTs and SRs, KQ 1 and 11 included observational comparative study designs that addressed the specific comparisons outlined for each of these KQs.

c. Literature Search Strategy

Information regarding the bibliographic databases, date limits, and platform, provider, or both can be found in Table A-4. See Appendix K for additional information on the search strategies, including topic-specific search terms and search strategies.

Table A-4. Bibliographic Database Information

Name		Date Limits	Platform or Provider
Bibliographic Databases	Embase (Excerpta Medica) and MEDLINE	January 1, 2013 through April 7, 2023	Elsevier
	PsycInfo	January 1, 2013 through April 7, 2023	OVID
	PubMed (In-process, Publisher, and PubMedNotMedline records)	January 1, 2021 through April 7, 2023	National Library of Medicine (NLM)
Grey Literature	Agency for Healthcare Research and Quality (AHRQ)	January 1, 2013 through April 7, 2023	AHRQ
	U.S. Department of Veterans Affairs (VA) Evidence Synthesis Program	January 1, 2013 through April 7, 2023	VA

d. Rating the Quality of Individual Studies and the Body of Evidence

The Lewin Team assessed the methodological risk of bias of individual diagnostic, observational, and interventional studies using the U.S. Preventive Services Task Force

(USPSTF) method. Each study is assigned a rating of *Good*, *Fair*, or *Poor* based on a set of criteria that vary depending on study design. Detailed lists of criteria and definitions appear in Appendix VI of the USPSTF procedure manual.(213)

Next, the Lewin Team assessed the overall quality of the body of evidence for each critical and important outcome using the GRADE approach. This approach considers the following factors: overall study quality (or overall risk of bias or study limitations), consistency of evidence, directness of evidence, and precision of evidence. The overall quality of the body of evidence is rated as *High*, *Moderate*, *Low*, and *Very Low*.

C. Developing Evidence-Based Recommendations

In consultation with the VA Office of Quality and Patient Safety and the Clinical Quality Improvement Program, Defense Health Agency, the Lewin Team convened *a* 3.5 day in-person recommendation development meeting from October 24–27, 2023, to develop this CPG's evidence-based recommendations. Two weeks before the meeting, the Lewin Team finalized the systematic evidence review and distributed the report to the Work Group; findings were also presented during the recommendation development meeting.

Led by the Champions, the Work Group interpreted the systematic evidence review's findings and developed this CPG's recommendations. The strength and direction of each recommendation were determined by assessing the quality of the overall evidence base, the associated benefits and harms, patient values and preferences, and other implications (see Determining Recommendation Strength and Direction).

a. Determining Recommendation Strength and Direction

Per GRADE, each recommendation's strength and direction is determined by the following four domains.(63) Information on each domain, questions to consider, and the resulting judgment can be found in Table A-5.

1. Confidence in the Quality of the Evidence

Confidence in the quality of the evidence reflects the quality of the body of evidence supporting a recommendation (see Rating the Quality of Individual Studies and the Body of Evidence). The options for this domain include *High*, *Moderate*, *Low*, or *Very Low*. These four ratings are a direct reflection of the GRADE ratings for each relevant critical outcome in the evidence review (see Outcomes). Per GRADE, if the quality of evidence differs across the relevant critical outcomes, the lowest quality of evidence for any of the critical outcomes determines the overall quality of the evidence for a recommendation.(65, 66)

The recommendation strength generally aligns with the confidence in the quality of evidence. For example, *Strong* recommendations are typically supported by *High* or *Moderate* quality evidence. However, GRADE permits *Low* or *Very Low* quality evidence to support a *Strong* recommendation in certain instances (e.g., life-threatening situation).(63)

2. Balance of Desirable and Undesirable Outcomes

The balance of desirable and undesirable outcomes (i.e., benefits and harms) refers to the relative magnitudes or tradeoffs of anticipated benefits (e.g., increased longevity, reduced morbidity, improved QoL, decreased resource use) and harms (e.g., decreased longevity, increased complications, impaired QoL). The options for this domain include *benefits outweigh harms/burdens*, *benefits slightly outweigh harms/burdens*, *benefits and harms/burdens are balanced*, *harms/burdens slightly outweigh benefits*, and *harms/burdens outweigh benefits*. This domain assumes most providers will offer patients an intervention if its advantages exceed the harms. The Work Group's understanding of the benefits and harms associated with the recommendation influenced the recommendation's strength and direction.

3. Patient Values and Preferences

Patient values and preferences is an overarching term that includes patients' perspectives, beliefs, expectations, and goals for health and life as they might apply to the intervention's potential benefits, harms, costs, limitations, and inconvenience. The options for this domain include *similar values*, *some variation*, and *large variation*. For instance, there might be *some variation* in patient values and preferences for a recommendation on the use of acupuncture because some patients might dislike needles. When patient values seem homogeneous, this domain might increase the recommendation's strength. Alternatively, when patient values seem heterogeneous, this domain might decrease a recommendation's strength. As part of this domain, the Work Group considered the findings from the patient focus group carried out as part of this CPG update (see Appendix H).

4. Other Implications

Other implications encompass the potential consequences or other impacts that might affect the strength or direction of the recommendation. The options for this domain, for example, include resource use, equity, acceptability, feasibility, and subgroup considerations. The following are example implications related to equity and subgroup considerations, respectively: some of the indicated population might be geographically remote from an intervention (e.g., complex radiological equipment); a drug might be contraindicated in a subgroup of patients.

Table A-5. GRADE Evidence to Recommendation Framework

Decision Domain	Questions to Consider	Judgment
Confidence in the quality of the evidence	• Among the designated critical outcomes, what is the lowest quality of relevant evidence? • How likely is further research to change the confidence in the estimate of effect?	• High • Moderate • Low • Very Low
Balance of desirable and undesirable outcomes	• What is the magnitude of the anticipated desirable outcomes? • What is the magnitude of the anticipated undesirable outcomes? • Given the best estimate of typical values and preferences, are you confident that benefits outweigh harms/burdens or vice versa?	• Benefits outweigh harms/ burdens • Benefits slightly outweigh harms/burdens • Benefits and harms/burdens are balanced • Harms/burdens slightly outweigh benefits • Harms/burdens outweigh benefits
Patient values and preferences	• What are the patients' values and preferences? • Are values and preferences similar across the target population? • Are you confident about typical values and preferences?	• Similar values • Some variation • Large variation
Other implications (e.g., resource use, equity, acceptability, feasibility, subgroup considerations)	• What are the costs per resource unit? • Is this intervention generally available? • What is the variability in resource requirements across the target population and settings? • Are the resources worth the expected net benefit from the recommendation? • Is this intervention and its effects worth withdrawing or not allocating resources from other interventions?	Various considerations

b. Recommendation Categorization

A summary of the recommendation categories and definitions is available in Table 5. For this new CPG, all recommendations were categorized as *Reviewed, New-added* (see Recommendations). *Reviewed*, *New-added* recommendations are original, new recommendations based entirely on evidence included in the systematic evidence review.

D. Drafting and Finalizing the Guideline

The Work Group wrote, reviewed, and edited three drafts of the CPG using an iterative review process to solicit feedback on and make revisions to the CPG. The first and second drafts were posted online for 20 and 14 business days, respectively, for the Work Group to provide feedback. Draft 3 was made available for a 14-day peer review and comment (see External Peer Review). The Work Group reviewed all feedback

submitted during each review period and made appropriate revisions to the CPG. Following the Draft 3 review and comment period, the Work Group reviewed external feedback and created a final draft of the CPG. The Champions then presented the CPG to the VA/DoD EBPWG for approval. The Work Group considered the VA/DoD EBPWG's feedback and revised the CPG, as appropriate, to create the final version. To accompany the CPG, the Work Group produced toolkit products, including a provider summary, quick reference guide, and patient summary. The VA/DoD EBPWG approved the final CPG and toolkit products in June 2024.

Appendix B: Routine Care

Patients who report tinnitus during a clinical evaluation should be asked additional questions regarding initial onset, frequency of occurrence, duration, and laterality. In some cases (e.g., unilateral tinnitus, pulsatile tinnitus), the patient should be referred for a medical workup (see Algorithm). The provider must also determine whether the patient is bothered by their tinnitus and the extent to which it interferes with daily activities or QoL. When such problems are reported, the patient is characterized as having bothersome tinnitus and might need additional evaluation to facilitate appropriate recommendations and referrals, as described below.

A. Referral

Patients with tinnitus might enter the health care system from diverse points of service. Some patients initially seek services from primary care providers, although others might seek care at an emergency department, walk-in/urgent care clinic, or specialty care provider (e.g., audiology, otolaryngology, neurology, behavioral/mental health). Patients reporting bothersome tinnitus should be triaged for appropriate referral.

Triage, the referral plan of tinnitus care, or both should be a collaboration between the health care provider and the patient. The National Center for Rehabilitative Auditory Research (NCRAR) created referral recommendations for any health care provider to use when evaluating patients with tinnitus. The NCRAR referral recommendations are part of the PTM protocol referred to as Level 1 Referral and are applicable regardless of the health care system point of entry.(78) Refer to the Algorithm for more information on referral and triage.

B. Clinical Care

a. Audiological Evaluation

The purpose of the audiological evaluation is to determine whether hearing loss is present and to rule out medical risk factors contributing to tinnitus. At a minimum, the audiological evaluation for a patient presenting with a complaint of tinnitus should include a thorough case history, otoscopy, measurement of pure tone air and bone conduction thresholds, word recognition ability, and acoustic immittance testing.(214) Although not recommended in this CPG as useful for diagnosis, intervention, or treatment, psychoacoustic measures (e.g., pitch matching, loudness matching, residual inhibition, and MML) may be completed at the discretion and clinical judgment of the audiologist.

A thorough case history is essential to document symptoms and co-occurring conditions as well as to determine whether referral to other medical providers, services, or both is indicated. See the Algorithm for case history questions for patients presenting with a primary complaint of bothersome tinnitus.

The external auditory canals and tympanic membranes should be examined via otoscopy. Ear canal obstructions such as cerumen impaction should be identified as a potential contributor to tinnitus. Cerumen management should be completed before audiological testing.

Acoustic immittance measurements should include ear-specific tympanometry. Acoustic reflex threshold testing to help exclude certain middle ear, or retrocochlear pathologies, or both can be completed but should be approached with caution and with the clinical judgment of the audiologist. Some patients with bothersome tinnitus have reduced sound tolerance, and acoustic reflex threshold testing might exacerbate tinnitus.(7)

b. Tinnitus Impact Assessment

Tinnitus can have a significant impact on various aspects of an individual's life, including sleep, emotional well-being, concentration, subjective hearing ability, socialization, and overall QoL. Tinnitus impact assessments should involve evaluating the multifaceted effects of tinnitus on different areas of an individual's life to help the health care professional gain insight into the effects of tinnitus and tailor treatment plans accordingly. Several standardized and validated questionnaires are available to evaluate tinnitus impact (e.g., TFI, THI). In addition, the Tinnitus and Hearing Survey may be administered to facilitate prioritization of the patient’s needs or desires for an intervention for tinnitus, hearing, sound tolerance, or a combination of these potential problems.(214)

Sound tolerance conditions (e.g., hyperacusis, misophonia, phonophobia) often co-occur with tinnitus.(215, 216) Although clinical consensus does not exist on best practices for assessing sound tolerance conditions, several tools have been found to be useful. Screening for sound tolerance conditions is important because when they co-occur with tinnitus some patients might avoid using a sound-based approach for tinnitus care as a consequence of difficulty tolerating sound. In those cases, addressing the sound tolerance problem first might improve acceptance to using sound to improve QoL with tinnitus. Recommendations regarding evaluation and management of sound intolerance disorders are outside the scope of this CPG, but health care providers should be aware that these co-occurring conditions can affect outcomes. For more information, see Aazh et al. (2018), Fagelson & Baguley (2018), Henry et al. (2022), and Pienkowski et al. (2014).(217–220)

Validated questionnaires screen for other specific areas that can impact or might be impacted by tinnitus distress, such as comorbid behavioral/mental health conditions (e.g., Patient Health Questionnaire-9 [PHQ-9], GAD-7, HADS). Questionnaires about sleep hygiene might be indicated when a patient reports sleep disturbance. See Appendix E for more specific information regarding the intended use and interpretation of these questionnaires.

c. Hearing Aid Assessment, as Warranted

Hearing aids are recommended for patients who have hearing loss and bothersome tinnitus.(7, 221) Subjective hearing difficulty, when feasible, should be addressed as a first step in tinnitus care.(214) Some patients with normal or borderline hearing and subjective hearing complaints might benefit from low-gain hearing aids to help with tinnitus and hearing problems.(214)

d. Referrals, as Warranted

Based on the case history, audiological evaluation, and patient needs, the audiologist should develop a follow-up action plan to include specialized audiological testing (e.g., electrophysiological tests). Patients may be referred to other appropriate health care providers or services as needed but should be evaluated urgently by an otolaryngology provider or referred to the emergency department if they report sudden onset hearing loss with or without accompanying sudden onset tinnitus.(7) For more information on referrals, see the Algorithm.

If a medical risk factor for tinnitus is identified (e.g., middle ear effusion, otosclerosis) or if the patient reports tinnitus that is unilateral or pulsatile, the patient should be referred to an otolaryngology provider. The purpose of an otolaryngology evaluation is to rule out associated medical conditions that might be contributing to tinnitus. It is important to note that not all patients with tinnitus require an evaluation by an otolaryngology provider (see the Algorithm). The otolaryngology provider will obtain a thorough case history, examine the ear (using an otoscope or microscope), and might perform auxiliary examinations to screen hearing status, such as tuning fork tests.

Patients who report risk factors for a behavioral/mental health disorder (e.g., PTSD, depression, anxiety) should be referred to a behavioral/mental health provider.(7) Patients who report suicidal ideation should be referred immediately to a behavioral/mental health provider or an emergency department in the absence of available behavioral/mental health support.(7) A non-urgent referral to a dental provider, an orofacial provider, or both is suggested for patients with TMD (see Sidebar 2). A non-urgent referral to a physical therapist or physiotherapist is suggested for patients with neck complaints or a whiplash-like trauma preceding the onset of tinnitus.

e. Hearing Conservation

Patients should be counseled regarding hearing conservation to include education, training on hearing health hazards, and proper insertion and use of hearing protection devices when exposed to hazardous noise. Hazardous noise is one of the main risk factors for tinnitus. Research has shown that the more temporary threshold shifts an individual experiences after noise exposure, the higher the probability they will have tinnitus.(222)

f. Lifestyle Considerations

Health care providers commonly recommend modifications in diet, lifestyle, or both, such as reducing consumption of salt, caffeine, or both, for tinnitus or other medical conditions (e.g., Meniere's disease, hypertension, diabetes). However, inconclusive scientific literature exists regarding whether caffeine intake, dietary factors, or both impact tinnitus.(223–227) A healthy diet and lifestyle might improve overall health, which might reduce problems associated with tinnitus and improve QoL. To ensure safety, patients should be advised to consult with their health care provider regarding dietary concerns or when making changes to their diet, exercise routine, or both.

g. Medications

Specific medications might contribute to the onset of tinnitus or might aggravate tinnitus in some cases. Patients should not change or discontinue their medication before consulting with their health care provider, prescribing provider, or both. See Appendix C for more information regarding medication and tinnitus.

C. Collaborative Guided Plan of Care

A collaborative guided plan of care should be established after the audiological assessment. Tinnitus care should be patient centered and personalized to the tinnitus-specific functional impacts via discussion of shared goals and tinnitus care options.

a. Tinnitus Intervention

Interventions for tinnitus are delivered by health care providers in many disciplines, including alternative and complementary medicine. Most often, audiologists, otolaryngology providers, and behavioral/mental health providers are directly involved in a variety of tinnitus interventions individualized to the patient with tinnitus-specific needs. Patients referred for secondary tinnitus might have rare conditions that have surgical and medication treatment options. Teaching strategies to reduce the impact of tinnitus are most often provided by audiologists, with or without collaboration with behavioral/mental health providers (e.g., TRT, PTM).(132, 228) Psychologists or other trained behavioral/mental health providers might use additional CBT sessions or other coping skill techniques in addition to TRT or PTM. Regardless of the patient-selected intervention, a personalized action plan should be collaboratively created with realistic goals centered on living better with tinnitus versus unrealistic goals of making the tinnitus quieter or being cured (see Appendix F).

b. Using Sound to Improve QoL with Tinnitus

Sound can be used therapeutically to help mitigate the negative effects of tinnitus and improve QoL. See Appendix D for sound devices and sound delivery options. Using sound is an important component of improving QoL for most people with bothersome tinnitus. Providers and patients must work together to determine the most suitable use of sound and intervention to meet patient needs.(7, 229, 230)

c. Tinnitus Education

A review of tinnitus education concluded that educating patients about tinnitus is essential in the plan of care to reduce the functional impact of tinnitus and improve QoL.(72) Tinnitus education can be provided in person, virtually, individually, and in group sessions. Identifying patients' expectations about outcomes and shared goals is important. More detailed information can be found in Appendix F.

d. Motivational Interviewing

Motivational interviewing (MI) is a patient-centered, goal-oriented, evidence-based counseling approach widely used in health care settings. It can help engage and motivate individuals with tinnitus to make positive changes to improve QoL. Motivational interviewing promotes collaboration and intrinsic motivation and supports positive behavioral changes toward better health and well-being. Motivational interviewing provides a paradigm shift for providers from a "find a problem and fix it" approach to establishing a partnership with the patient through collaborative conversations to motivate the patient to commit to change. Additionally, MI involves collaborative goal setting to ensure that goals are aligned with the patient's values and priorities. This approach allows patients to lead the way to explore options that could work for them with carefully managed guidance and support from the provider.(231–233)

e. Evaluating Outcomes, Further Stepped Care, and Referrals

Patients requiring clinical intervention for tinnitus differ widely with respect to the impact of tinnitus on their daily lives. The spectrum of clinical needs across patients is broad, ranging from basic education about tinnitus to long-term individualized support. Tinnitus care should be provided in a stepwise hierarchical approach to provide clinical services only to the degree needed by the patient. A collaborative guided plan of care should include ongoing assessment of tinnitus impact using tinnitus questionnaires (see Appendix E) to identify which situations impact QoL. Depending on the severity of the impact, the guided plan of care might include referrals to other services (see Referral), provision of continued supportive services, or both, if QoL outcomes fail to improve (see the Algorithm). Personalized interventions should be adjusted to the tinnitus-specific impacts via shared decision making after educating the patient on further tinnitus management options. This approach will allow for collaborative modification of individualized action plans, maximized health and coping function to live better with tinnitus, and improved functional status.

Appendix C: Medication-Related Considerations in Managing Patients with Bothersome Tinnitus

No medications have been approved by the FDA to treat tinnitus and no cure exists. Providing care focuses on improving QoL with tinnitus. Therefore, encouraging patients to address with their health care provider any co-occurring conditions that also reduce QoL (e.g., anxiety, depression, PTSD, chronic pain, sleep disorders) is useful. Many of these co-occurring conditions can be successfully treated with medication (or other methods), which might contribute to overall improved QoL.

Some medications are known to be ototoxic and might lead to or contribute to bothersome tinnitus (see Table C-1). However, the risks of these medications must be balanced with the benefits of treatment when considering whether to continue treatment, reduce the dose, or discontinue the medication. In general, if the decision is made to continue a medication believed to contribute to or worsen tinnitus, the lowest effective dose should be used for the shortest possible duration.

Table C-1. Drugs That Might Cause or Worsen Tinnitus (list is not all-inclusive)

Type	Drug[a]	Comments
Alpha 1-adrenergic receptor blockers	• Doxazosin • Prazosin	Rare reports, <1%
Angiotensin converting enzyme inhibitors (ACE-I)	• Benazepril • Captopril • Enalapril • Lisinopril • Others	
Anti-neoplastic drugs used for chemotherapy (hearing should be monitored before and during therapy)	Cisplatin	Ototoxic
	Carboplatin	Ototoxic
	Oxaliplatin	Ototoxic
Anti-inflammatory agents	Salicylates	Ototoxic in high doses (generally reversible), over-the-counter doses of aspirin are not ototoxic
	Nonsteroidal anti-inflammatory drug (NSAID)/cyclooxygenase 2 (COX-2) inhibitors • Celecoxib • Diclofenac • Ibuprofen • Indomethacin • Naproxen • Others	Dose-related, reversible on discontinuation, over-the-counter doses of ibuprofen and naproxen are not ototoxic

Type	Drug[a]	Comments
Antibiotics	Aminoglycosides • Gentamicin* • Amikacin* • Neomycin* • Tobramycin*	Ototoxic
	Fluoroquinolones • Ciprofloxacin	Ototoxic in up to 1% of patients in clinical trials and post-marketing surveillance; tinnitus reported in <1% of patients
	Macrolides • Erythromycin • Azithromycin • Clarithromycin	Ototoxic (high dose erythromycin might cause temporary or reversible hearing loss); risk increases with intravenous administration, hepatic or renal impairment, and advanced age
	Tetracyclines • Doxycycline • Minocycline • Tetracycline	Reversible, occurs with higher doses, and is more common in women
	Vancomycin	Ototoxic in high doses
Antidepressants	Tricyclic antidepressants (TCA) • Amitriptyline • Desipramine • Doxepin Selective serotonin reuptake inhibitors (SSRI) • Fluoxetine • Sertraline	
Anticonvulsants	Carbamazepine	
	Valproic acid	Ototoxic
Antimalarials	Chloroquine	Ototoxic in high doses
	Hydroxychloroquine	Ototoxic in high doses
	Quinine	
Calcium channel blockers	Diltiazem	Tinnitus with concomitant use of ototoxic drugs
	Nicardipine	Tinnitus reported with monotherapy (i.e., one drug)
	Verapamil	Tinnitus reported with monotherapy (i.e., one drug) and when used with ototoxic drugs

Type	Drug[a]	Comments
Loop diuretics	• Bumetanide • Ethacrynic acid • Furosemide	• Ototoxic in high doses and when used for prolonged periods • Primarily affects patients with renal impairment; generally reversible • Ethacrynic acid has the greatest potential for ototoxicity; cases of irreversible hearing loss have been reported in patients with renal failure.
Miscellaneous	Benzodiazepines (e.g., diazepam)	Discontinuation of long-term use associated with tinnitus
	Isotretinoin	Reported in clinical trials and post-marketing surveillance
	Lidocaine and other local anesthetics	
	Opioids and illicit drugs	Retrospective studies, case reports suggest ototoxicity might occur with use and misuse of opioids, illicit drugs, or both.
	Proton pump inhibitors (e.g., omeprazole, lansoprazole)	Rare reports, <1%

[a] Tinnitus might be reported as an adverse event from a class of medications (e.g., class-effect of ACE-I). Therefore, agents from a specific class, but not listed in the table, might also cause, or worsen tinnitus.

Ototoxic medications directly result in damage to cochlear (cochleotoxic) and vestibular (vestibulotoxic) structures in the inner ear, which can lead to acquired hearing loss and tinnitus. An article by Steyger (2021) provides a review of the mechanisms leading to damage to the auditory system after exposure to these medications.(234) A study by Rizk et al. (2020) provides a more complete summary of ototoxic medications including grading and reversibility indexes.(235) When taking ototoxic medications, noise exposure can result in more severe damage than would occur with either source alone. The synergistic interaction of noise and ototoxic medications, such as aminoglycosides and antineoplastic agents, directly results in hearing loss and tinnitus at high rates. Health care providers are encouraged to explain to patients that because of the combined effects of ototoxic medication and noise exposure, they are more vulnerable to experiencing auditory damage, which is the reason for strongly encouraging them to use hearing protection when exposed to moderate and high levels of noise. Both national organizations for audiology, the American Speech-Language-Hearing Association and the American Academy of Audiology, have published audiological management guidelines for ototoxicity monitoring.(236, 237)

When patients question whether their medication is possibly contributing to their tinnitus, consider asking these following questions.

- Did the tinnitus worsen when the medication was started or when the dose was increased?
- Did the tinnitus improve when the dose was decreased, or when the medication was withheld?
- Did the tinnitus return when the medication was restarted?

If no connection exists between the timing of changes in tinnitus and changes in medication, stopping any medication or medications prescribed for other conditions is unlikely to change the tinnitus perception. In these instances, discussing the importance of addressing ways to improve overall health and well-being and how that approach relates to improving QoL with tinnitus is recommended.

Appendix D: Devices

Patients with bothersome tinnitus are routinely advised by audiologists to avoid silence and enrich their sound environment. Sound enrichment generally refers to adding sounds to the acoustic environment (external sound) to reduce the perceptual contrast between tinnitus (internal sound) and the external acoustic environment. Sound enrichment might also induce relaxation or distract attention from the tinnitus and thus reduce the stress response that is activated by bothersome tinnitus.

Sound enrichment can be implemented with non-medical or medical devices. Sound can be delivered with ear-level devices (e.g., hearing aids, sound generators, wireless earphones) or through external sound-playing devices (e.g., phones, music devices, tabletop sound machines). Sound therapy can be generic or proprietary.

Sources of sound from non-medical devices include natural and recorded environmental sounds, music, and speech. Examples of environmental sounds include sounds made by fans, water fountains, and nature. Music can include any genre and be instrumental only or can include lyrics. Music and non-music sound applications are widely available for streaming through smartphones and external speakers to provide soothing and background sound enrichment. Music can also be used as an interesting sound when the patient is actively listening. Other interesting sounds might involve speech as a sound source, such as a television show, a movie, an audiobook, or a podcast. Patients might benefit from sound enrichment more readily if they understand the purpose of sound enrichment (see Appendix F).

Several medical devices are currently available for reducing tinnitus functional impact with sound; however, no evidence supports the superiority of one device over another in terms of benefit to the patient. The primary indication for device use is bothersome tinnitus that negatively impacts daily function, QoL, or both. Table D-1 lists FDA cleared medical devices with the mode of stimulation, type of sound, and recommended use time; inclusion in this table does not imply endorsement of any of these devices by the VA/DoD Tinnitus CPG Work Group. Recommended use time varies across devices, which has implications for patient preferences. Medical devices include but are not limited to ear-level sound generators (e.g., tinnitus maskers), hearing aids, combination devices (e.g., hearing aid plus sound generator), and tinnitus treatment devices. Combination devices are available from all the major hearing aid manufacturers. The devices can be programmed to provide amplification only, amplification plus sound therapy, and sound therapy alone. Sound therapy options include customizable noise that can be varied in frequency response and modulation or fractal tones. Another type of sound therapy is notch therapy, based on the premise that decreasing external stimulation in the frequency region of the tinnitus might decrease hyperactivity in the corresponding regions of the central auditory system, thereby diminishing the perception of tinnitus. Notch therapy can be applied to amplification, noise, or music. Notch therapy is typically limited to patients with tonal tinnitus. Medical devices

marketed for tinnitus that became commercially available as of May 2023 include Lenire®, Levo®, and Neuromonics®.

Table D-1. Medical Devices[a] for Tinnitus, available as of May 2023

Medical Device	Mode of Stimulation	Type of Sound	Recommended Use Time
Hearing aids (amplification only)	Auditory	Sounds in the listener's acoustic environment	Daily during waking hours
Sound generators (ear-level)	Auditory	• Broadband noise (e.g., white, pink, brown) • Simulated water sounds • Fractal tones	Recommended use time varies as a function of tinnitus management protocol, ranging from pro re nata (PRN) to a minimum of eight hours/day.
Levo	Auditory	Tinnitus-matched pure tone plus broadband noise	During sleep
Neuromonics Oasis Pro	Auditory	Music plus broadband noise	Minimum two hours/day for 6–8 months; daily usage can be reduced to fewer hours per day if tinnitus disturbance lessens after 2 months.
Neuromod Lenire	Bimodal (auditory and electrical)	Tones plus broadband noise	One hour/day

[a] Inclusion of medical devices in this table does not imply endorsement.

Patient preferences based on lifestyle, acceptability, and sound preference are important considerations for individual tinnitus care. The commercially available medical devices for tinnitus described above differ in type and implementation of stimulation and cost. Patient preference, hearing status, psychosocial factors, tinnitus self-efficacy, and provider expertise play a significant role in reducing the functional impact of tinnitus.(238) As such, a patient-centered approach that considers all the factors has the greatest likelihood of resulting in a favorable outcome.

Realistic expectations regarding the management of tinnitus functional impact using sound enrichment and medical devices are essential because medically cleared tinnitus-specific devices have not been proven to be superior to non-tinnitus–specific sound generating devices. Most patients with bothersome tinnitus are seeking a solution that eliminates tinnitus perception, but such a solution does not exist for the majority of those with chronic tinnitus. In addition to realistic expectations, another important consideration is the patient's tinnitus self-efficacy, which refers to the patient's confidence in their ability to perform specific skills such as using hearing aids or sound generators to improve QoL with tinnitus.(239)

In summary, sound enrichment can be accomplished with non-medical and medical devices. The Work Group made a recommendation on the use of therapeutic sound (see Recommendation 12) despite the presence of weak evidence because the benefits outweighed the harms, sound enrichment is accessible, and the patient focus group participants reported it as a beneficial part of a tinnitus plan of care.

Appendix E: Quick Guide to Questionnaires and Assessment Instruments in Clinical Practice

Given the highly subjective nature of tinnitus, the assessment of problems associated with tinnitus and self-perception of the functional impact of tinnitus is critical to the appropriate and successful management of patients with tinnitus. Questionnaires are designed to measure universal aspects of tinnitus, enhance understanding of patient-specific concerns, and facilitate assessment of intervention efficacy. However, the clinical provider should not rely on questionnaire scores in isolation to determine whether a given intervention has been helpful. Asking patients whether improvement has occurred in the aspects of their lives affected by tinnitus is important.

Table E-1 briefly describes a sample of validated questionnaires appropriate for administration to patients reporting bothersome tinnitus.

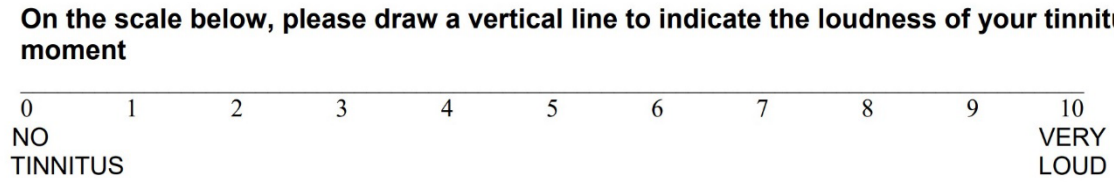
Table E-1. Sample of Validated Questionnaires

Questionnaire	Intended Use	Interpretation	Comments
Tinnitus and Hearing Survey (THS) (240)	Facilitation of communication between patient and provider about hearing loss, tinnitus, and sound tolerance	Most effective use is as tool to quickly and efficiently separate hearing problems from tinnitus problems and to screen for sound tolerance problems.	• Questionnaire results allow providers to describe available, relevant interventions; patients can then decide which intervention or interventions are a good match for the problem or problems they wish to address and for compatibility with their lifestyle. • Cutoff scores are available for triaging patients in certain settings.
Tinnitus Functional Index (TFI)(241)	Assessment of baseline functional impact of tinnitus and treatment-related changes	0–17 Not a problem 18–31 Small problem 32–53 Moderate problem 54–72 Big problem 73–100 Very big problem	• Copyrighted questionnaire[a] • Score is influenced by subjective hearing problems, hearing loss, or both. • Key advantages of TFI compared with THI are its extensive emphasis on content validity in item selection, its 0–10 response scale (versus THI's three-level scale), greater responsiveness, and eight subscales (versus three for THI). If TFI's greater responsiveness is upheld in clinical trials, it could result in future trials requiring fewer patients to achieve statistical significance.

Questionnaire	Intended Use	Interpretation	Comments
Tinnitus Handicap Inventory (THI) (242)	Assessment of impact of tinnitus on everyday function	0–16 No or slight handicap 18–36 Mild handicap 38–56 Moderate handicap 58–100 Severe handicap	THI is less sensitive to post-treatment changes than TFI.
Tinnitus Reaction Questionnaire (TRQ) (243)	Measurement of psychological distress related to tinnitus	>17 Significant tinnitus-related psychological distress	TRQ can be used to compare tinnitus-related psychological distress pre- or post-treatment or both.
Visual Analog Scale (VAS)/ Visual Numeric Scale (VNS) for Tinnitus Loudness (244)	Assessment of baseline self-perceived loudness and treatment-related changes in loudness	Higher numbers indicate higher subjective loudness (see Figure E-1 for an example).	VAS and VNS scores for tinnitus loudness should not be used in isolation, but rather as part of tinnitus evaluation and management protocol.

[a] Request permission to use from Oregon Health and Science University, available at https://apps.ohsu.edu/research/tech-portal/technology/view/1004796.

Figure E-1: Sample Tinnitus Visual Numeric Scale



When behavioral/mental health concerns are suspected, the Work Group recommends that providers discuss the biopsychosocial factors that can contribute to tinnitus and related functioning. Providers should also assess the patient's interest in pursuing behavioral health treatment to address tinnitus-related distress or mental health symptoms that might contribute to or exacerbate their tinnitus. This assessment can be done in a variety of ways based on standards of care and available resources in each clinic (e.g., primary care behavioral health, specialty mental health, clinical health psychology). Validated behavioral health screening questionnaires, as outlined in Table E-2 below, have also been used to screen for specific concerns. As with any questionnaire, results do not necessarily indicate a need for further services but should be combined with overall patient concerns and desire for further services, unless specifically outlined in policy (e.g., for concerns related to suicide). One way to assess a patient's interest in pursuing a referral to such services is to include language, such as the following, on intake packets or within the clinical assessment: "For many people, stress and mood concerns can contribute to their tinnitus symptoms, and treatment for those concerns can help to optimize health and reduce symptoms. Are you interested in hearing more about a potential referral for behavioral health?"

Table E-2. Behavioral Health Screening Questionnaires

Questionnaire	Intended Use	Interpretation	Comments
Patient Health Questionnaire 9-item (PHQ-9) (245)	Assessment of self-reported depression, focusing on symptoms' duration	0–4 Minimal depression 5–9 Mild depression 10–14 Moderate depression 15–19 Moderate-severe depression 20–27 Severe depression	5–9 Patient might need referral to behavioral health. >9 Refer patient to behavioral health.
Generalized Anxiety Disorder 7-item (GAD-7) (246)	Screening tool and indicator of severity of GAD	0–4 Minimal anxiety 5–9 Mild anxiety 10–14 Moderate anxiety >14 Severe anxiety	• Score >9 is indication for referral to behavioral health. • Tool might be insensitive to posttraumatic stress disorder (PTSD).
Hospital Anxiety and Depression Scale (HADS) (247)	Assessment of psychological distress in non-psychiatric patients with subscale for anxiety and subscale for depression	Per subscale 0–7 Normal 8–10 Mild 11–15 Moderate 16–21 Severe	If either subscale score is >8, refer patient to behavioral health.

Table E-3, below, briefly describes an example of a whole health/personal health assessment tool appropriate for administration to patients reporting bothersome tinnitus.

Table E-3. Whole Health/Personal Health Inventory

Questionnaire	Intended Use	Interpretation	Comments
Personal Health Inventory (PHI) - Short (248)	• Assessment of overall physical/mental/emotional wellbeing and quality of life • Identification of what matters most and determination of self-care goals	• Interpretation is unique to individual. • Personal health planning is customized with shared decision making between patient and provider. • Focus is on individual needs, values, priorities, and circumstances to empower patient to learn necessary skills for self-care.	There is a long version of the PHI, as well.

Appendix F: Education

Tinnitus education should be patient centered to address the patient's concerns regarding tinnitus. The patient-centered approach has been shown to greatly enhance individual motivation to make adaptive changes to improve health.(74) Patients should participate in the process of defining the tinnitus impact and identifying specific behavior changes for coping with tinnitus to improve their QoL. Tinnitus education should provide the tools to facilitate self-management of tinnitus functional impact. The essential elements of effective self-management programs described by Wagner et al. (1996) are still applicable today and described in Table F-1 (with application to tinnitus care).(249, 250)

Table F-1. Effective Self-Management Program Essential Elements Applied to Tinnitus Care Education (250)

Effective Self-Management Program Essential Elements	Explanation	Application to Tinnitus Care
Collaborative problem definition	Providers and patients define the problem together. Identifying patients' expectations about outcomes and shared goals is important.	Many tinnitus assessment tools (see Appendix E) exist for patients to define their tinnitus-related problems (or impact) with their providers.
Targeting, goal setting, and planning	Programs should target issues of greatest priority to patient and health care provider; set realistic goals, expectations, or both; and develop an individualized management plan. Process should be guided by consideration of patients' readiness to change and self-efficacy.	Intervention should focus on teaching patients how to develop individualized action plans to help them live better with tinnitus and manage situations where their tinnitus impacts them most. Shared goals should focus on improving quality of life (QoL) with tinnitus.
Self-management training and support services	Education on disease management, behavioral support programs, physical activity, wellness, maintenance of health, and interventions that address emotional demands of having a chronic condition is relevant.	Services provide general information on how the auditory system functions and what happens following noise exposure, injury, and so forth that can result in hearing loss, risk factors associated with tinnitus, or both. Patient satisfaction is often associated with goal-oriented action plans that focus on improving QoL with tinnitus.
Active and sustained follow-up	Evidence shows that reliable follow-up at regular intervals, initiated by providers, leads to better outcomes.	Tinnitus intervention includes active and sustained follow-up agreed between patient and provider.

A. Purpose of Patient Education

Effective patient education is a process whereby the health care provider continually identifies, assesses, and addresses the patient's current needs and works with the patient to facilitate development of the knowledge, skills, attitudes, and self-awareness necessary to improve functional status with tinnitus. Patient education is designed to

support the understanding and use of strategies and behaviors to improve QoL with tinnitus.

Some patient education theories related to facilitating changes in health behavior are particularly relevant to tinnitus care as they apply to the PTM educational curriculum adopted for use in VHA and DoD.(251) These theories provide support for the educational tools and activities used with PTM. Educational theories relevant to the PTM described in Henry et al. (2009) include adult learning (andragogy), the health belief model, self-efficacy, and locus of control.(251)

Patients with tinnitus should be discouraged from monitoring their tinnitus because continually focusing on the tinnitus perception increases awareness of it. Rather, patients should be encouraged to monitor improvements in comfort, QoL, and function in response to using health coping strategies. With support from providers, patients should identify when their tinnitus is problematic and develop action plans to cope with those situations.

Follow these steps to guide patients to learn and use effective coping strategies.

1. Make sure the education is understandable and well-matched with individual patient abilities and expectations.
2. Use interactive teaching strategies (e.g., patient and provider, patient and significant other, peer group; encourage patients to ask questions).
3. Make sure patients understand the various coping strategies they have been taught. Use teach-back to confirm the patient's understanding.
4. Demonstrate empathy and interest in how patients integrate use of coping strategies into their daily lives.

For a patient not using coping strategies to improve QoL with tinnitus given the guidance above, proceed as below.

- Ask the patient to explain barriers to learning, practicing, or using coping strategies.
- Avoid offering advice. Do not propose an immediate solution; rather, guide the patient in problem-solving skills, and ask permission before sharing information.
- Determine whether the patient believes that coping strategies will improve QoL with tinnitus. If not, assess the patient's beliefs about the problem.
- Use motivational interviewing counseling skills to help the patient find the motivation to make positive behavior changes and consistently use coping strategies.
- Work with the patient to identify and set SMART (specific, measurable, action-oriented, realistic, timed) goals that align with their goals and preferences to move toward the desired behavior change.

The interested reader should also see Henry et al. (2009) for in-depth guidance.(251)

B. Tinnitus Patient Education Content

A scoping review of tinnitus education concluded that educating patients about tinnitus is important to changing their perception of the symptom and improving their coping behaviors.(249) A critical component of patient education is identifying patients' goals, preferences, and outcome expectations. The educational content might include basic anatomy and physiology of the auditory system; hearing conservation; general coping strategies, such as attention diversion and sound enrichment options; a description of the clinical features of tinnitus; the purpose of tinnitus intervention; acknowledgment of the social and psychological challenges of living with tinnitus; the day-to-day impact of tinnitus; realistic expectations; and the negative beliefs typically associated with tinnitus.(132, 252, 253)

a. Outcome Expectations

The purpose of tinnitus care is to learn to live better with tinnitus by using effective and sustainable self-management strategies to reduce tinnitus-related distress instead of unhelpful attempts at eliminating the tinnitus itself (i.e., a cure). That patients might misattribute hearing difficulty to their tinnitus is important to note; therefore, any report of subjective hearing difficulty should be assessed by an audiologist and be managed appropriately.

b. Patient-Centered SMART Goals

Health care providers should work with their patients to identify their self-care goals to improve QoL with tinnitus (see Table F-1). One of the many tools available to identify goals and monitor outcomes of intervention for tinnitus is a modified version of the Client Oriented Scale of Improvement (COSI) used in aural rehabilitation, called the COSI in Tinnitus (COSIT).(254) SMART goals help providers support patients and empower them to take action. SMART goal setting is one of the best ways to guide behavior change based on what is important to the patient (the COSIT goal), the desired clinical outcome, and the specific action that the patient wants to take to improve living with tinnitus. SMART goals help break down the overall goal (COSIT goal) into smaller goals that are easier to reach. Setting achievable goals increases success and helps turn healthy behavior changes into long-term habits.

C. Tinnitus Patient Education Format

Adults differ in their preferred learning style.(255) A variety of patient education formats are available to address preferred learning styles, including visual, aural, haptic, and interactive modalities. Teaching coping strategies for tinnitus can employ a variety of patient education methods in various modalities, including one-on-one, groups, print materials, videos, mobile apps, and online modalities.

a. Books and Videos

Many books and videos are available describing tinnitus from the perspectives of people with tinnitus and providers who offer tinnitus care. Patients can choose the perspective most meaningful to them.

b. Applications

Mobile technology, including smartphones, provides a medium through which patients can access health-related information such as tinnitus intervention options (e.g., apps for relaxation, elements of CBT education, sounds, sleep hygiene). The CPG Work Group does not endorse specific products or services. An important component of successful digital health is talking with health care providers before using a self-directed app. Before subscribing, patients are advised to check the app's cancellation and data privacy policies.

c. Posters

Posters are a novel way to disseminate tinnitus education in the clinic waiting room. Aazh et al. (2009) described the adoption of an educational poster for patients to learn about tinnitus and choose whether to receive supplemental materials (print materials; sound generator; join waitlist to be scheduled for additional counseling, a hearing aid, or both) based on the treatment options presented in the poster.(256)

D. Health Literacy

Personal health literacy refers to how well a patient finds, understands, and uses information and services to inform health-related decisions and actions for themselves and others. Low health literacy is associated with poorer health outcomes such as lower levels of self-efficacy, increased mortality, poor health status, reduced QoL, and high health care use and cost. Zheng et al. (2018) quantitatively evaluated the relationship between health literacy and QoL based on a systematic review and meta-analysis.(257) The authors concluded that health literacy was moderately correlated with QoL. Haun et al. (2015) showed the average per-patient cost for those with inadequate and marginal health literacy was significantly higher than for those with adequate health literacy.(258) Of interest, Morrison et al. (2023) recently demonstrated that both active duty Service members and Veterans treated at military otolaryngology clinics demonstrated higher health literacy rates than patients without a history of military service.(259) Recognizing which patients might have low health literacy is difficult, so organizations and health care providers have a responsibility to address health literacy. Therefore, health care providers should use health literacy universal precautions and assume all patients and caregivers might have difficulty comprehending health information. The AHRQ Health Literacy Universal Precautions Tool Kit includes practical ideas for primary care practices and can be found at https://www.ahrq.gov/health-literacy/quality-resources/tools/literacy-toolkit/index.html.

Appendix G: Additional Resources for Providers and Patients

Inclusion of the following organizations and resources does not imply endorsement by the VA/DoD Tinnitus CPG Work Group.

- American Academy of Audiology Certificate Holder—Tinnitus Management (CH-TM)
- American Academy of Audiology—Tinnitus
- American Speech-Language-Hearing Association
    - View the evidence maps/tinnitus
- American Tinnitus Association
- DoD Hearing Center of Excellence
- Ida Institute
- National Institute on Deafness and Other Communication Disorders
- PTM—NCRAR Provider Resources
- Tinnitus Patient Resources—NCRAR
- VHA Behavioral Health Apps
- VHA Behavioral Health Web-Based Courses
- VHA Whole Health
- Veteran Health Library

Appendix H: Patient Focus Group Methods and Findings

A. Methods

VA and DoD Leadership recruited seven participants for the focus group, with support from the Champions and other Work Group members, as needed. Although participant recruitment focused on eliciting a range of perspectives likely relevant and informative in the CPG development process, the patient focus group participants were not intended to be a representative sample of VA and DoD patients. The participants were not incentivized for participation or reimbursed for travel expenses. The Work Group, with support from the Lewin Team, identified topics on which patient input was important to consider in developing the CPG. The Lewin Team developed, and the Work Group approved a patient focus group guide covering these topics. The focus group facilitator led the discussion using the guide to elicit patient perspectives about patient treatment and overall care. Given the limited time and the range of interests of the focus group participants, not all questions were addressed.

B. Patient Focus Group Findings

a. Participants reported that tinnitus has an impact on multiple aspects of their lives (e.g., activities of daily functioning, QoL, interpersonal relationships, mental and physical health).

- Participants noted that they must remain preoccupied throughout the day to decrease the severity of their tinnitus symptoms.
- Tinnitus symptoms render many daily tasks (e.g., washing the dishes) nearly unbearable.
- Participants emphasized that their tinnitus symptoms have negatively impacted their personal and professional relationships.

b. Participants emphasized that tinnitus is a neurological condition that can be complicated by or otherwise interact with other conditions (e.g., anxiety, sleep disorders, PTSD, suicidal ideation), and they emphasized the importance of access to an interdisciplinary care team.

- Participants acknowledged the importance of early detection and highlighted the need for treating tinnitus as a neurological condition.
- Participants reported having comorbid mental health disorders, such as PTSD and anxiety. One participant shared having survived two suicide attempts.
- Participants recognized the importance of an interdisciplinary care team in effectively addressing all aspects of their tinnitus.

c. Participants valued a person-centered treatment action plan. Participants reported a desire to assess and follow their progress over time.

- Participants appreciated providers who implemented person-centered treatment action plans and noted that action plans allowed them to take a more active role in their treatment.
- Participants stated that the treatment of tinnitus should focus mainly on improving QoL and helping individuals do what they love.
- Participants struggled to track progress in their treatment without frequent questionnaires and measurement tools.

d. Participants described experiences with treatments that they have found to be successful, including devices (e.g., hearing aids, Alpha-Stim, white noise generators), non-pharmacological interventions (e.g., online or in-person counseling or both, mindfulness), and self-management strategies (e.g., distractions, exercise, background noise, music).

- Participants emphasized that hearing aids were one of the most effective devices and treatments for their tinnitus.
- Participants discussed the effectiveness of non-pharmacological approaches, such as counseling and mindfulness, and expressed a desire to explore them further.
- Participants underscored the importance of distractions and staying occupied for relieving tinnitus. They discussed their personal self-management strategies and how they incorporate them in their daily life.
- Participants noted sleep was important for the management of their tinnitus.

e. Participants expressed that their lack of knowledge about tinnitus, as well as some providers' lack of knowledge about the condition, led to delayed care, inadequate care, inappropriate care (e.g., arising from biases based on age and other patient factors), and worsening tinnitus over time.

- Participants shared their positive experiences with providers who are well-educated on tinnitus versus negative experiences with providers who might not be well versed on tinnitus care.
- Participants expressed perceived provider stigma regarding aging and hearing.
- Participants emphasized the importance of education and noted that a lack of knowledge of tinnitus might have delayed care before a formal diagnosis.

Appendix I: Evidence Table

Table I-1. Evidence Table[a,b,c]

#	Recommendation	Evidence	2024 Strength of Recommendation	Recommendation Category
1.	We suggest using validated subjective outcome measures (e.g., Tinnitus Functional Index, Tinnitus Handicap Inventory) to monitor the effectiveness of tinnitus management.	(79–83)	Weak for	Reviewed, New-added
2.	We suggest against psychoacoustic measures (e.g., minimum masking level, loudness matching) to monitor the effectiveness of tinnitus management.	(79–83)	Weak against	Reviewed, New-added
3.	We suggest educational counseling to reduce the functional impact of tinnitus.	(84) **Additional reference** (85)	Weak for	Reviewed, New-added
4.	There is insufficient evidence to recommend for or against the use of web-based or app-based self-management for tinnitus.	(86)	Neither for nor against	Reviewed, New-added
5.	There is insufficient evidence to recommend for or against the use of computer-based games, training programs, or both for tinnitus self-care.	(87–89)	Neither for nor against	Reviewed, New-added
6.	We suggest hearing aids for tinnitus management in adults with hearing loss (see narrative for discussion of patients without hearing loss).	(90, 91) **Additional references** (92–94)	Weak for	Reviewed, New-added

[a] Evidence column: The first set of references listed in each row in the evidence column constitutes the evidence base for the recommendation. To be included in the evidence base for a recommendation, a reference had to be identified through a systematic evidence review carried out as part of the development of this CPG. The second set of references in the evidence column (called "Additional References") includes references that provide additional information related to the recommendation but that were not identified through the systematic evidence review. These references were, therefore, not included in the evidence base for the recommendation and did not influence the strength and direction of the recommendation.

[b] Strength of Recommendation column: The VA/DoD Tinnitus CPG was developed using the GRADE approach to determine the strength of each recommendation. Refer to the Determining Recommendation Strength and Direction section for more information.

[c] Recommendation Category column: Refer to the Recommendation Categorization section for more information on the description of the categorization process, the categories, and their definitions.

#	Recommendation	Evidence	2024 Strength of Recommendation	Recommendation Category
7.	There is insufficient evidence to recommend for or against contralateral routing of signal/sound (CROS) hearing aids for tinnitus management in adults with single-sided deafness.	(95)	Neither for nor against	Reviewed, New-added
8.	We suggest cochlear implantation for tinnitus management in adults who meet candidacy requirements.	(95–101) **Additional references** (102–111)	Weak for	Reviewed, New-added
9.	There is insufficient evidence to recommend for or against implantable bone conduction devices (BCD) for tinnitus management in adults with single-sided deafness.	(95)	Neither for nor against	Reviewed, New-added
10.	We suggest cochlear implants over implantable bone conduction devices (BCD) or contralateral routing of signal/sound (CROS) hearing aids for tinnitus management in adults with single-sided deafness who meet candidacy requirements.	(95, 112)	Weak for	Reviewed, New-added
11.	There is insufficient evidence to recommend for or against auditory cognitive training (e.g., frequency discrimination training, auditory attention training) for the reduction of tinnitus distress and functional impact.	(87–89, 113)	Neither for nor against	Reviewed, New-added
12.	We suggest the therapeutic use of sound for tinnitus self-care.	(114–118)	Weak for	Reviewed, New-added
13.	There is insufficient evidence to recommend for or against sound therapy with altered music (e.g., notched music therapy, spectrally altered music) to reduce the impact of tinnitus.	(119–124)	Neither for nor against	Reviewed, New-added
14.	We suggest cognitive behavioral therapy (CBT) by a trained provider for adults with bothersome tinnitus.	(125–129) **Additional references** (130)	Weak for	Reviewed, New-added
15.	There is insufficient evidence to recommend for or against the following psychological interventions by a trained provider for adults with bothersome tinnitus (unranked). • Acceptance and Commitment Therapy (ACT) • Mindfulness-based therapies • Mindfulness-Based Stress Reduction (MBSR)	(131)	Neither for nor against	Reviewed, New-added

#	Recommendation	Evidence	2024 Strength of Recommendation	Recommendation Category
16.	We suggest sound therapy combined with cognitive behavioral therapy (CBT) for tinnitus management by a multidisciplinary team.	(116, 132, 133)	Weak for	Reviewed, New-added
17.	We suggest sound enrichment with ongoing directed tinnitus education by an audiologist.	(134–138)	Weak for	Reviewed, New-added
18.	There is insufficient evidence to recommend for or against repetitive transcranial magnetic stimulation (rTMS) for tinnitus management.	(143, 144, 146, 147) **Additional references** (139–142, 145)	Neither for nor against	Reviewed, New-added
19.	There is insufficient evidence to recommend for or against transcutaneous electric nerve stimulation (TENS) for tinnitus management.	(148–150)	Neither for nor against	Reviewed, New-added
20.	There is insufficient evidence to recommend for or against transcranial direct current stimulation (tDCS) for tinnitus management.	(143, 147, 151, 153) **Additional reference** (152)	Neither for nor against	Reviewed, New-added
21.	We suggest against low-level laser therapy for tinnitus management.	(154–156) **Additional reference** (157)	Weak against	Reviewed, New-added
22.	We suggest a multidisciplinary approach for the assessment and treatment of patients with bothersome tinnitus and temporomandibular disorder (TMD), cervical spine dysfunction, or both to reduce the functional impact of tinnitus.	(161–163) **Additional references** (7, 158–160, 164–168)	Weak for	Reviewed, New-added
23.	There is insufficient evidence to recommend for or against acupuncture for tinnitus management.	(169–174) **Additional reference** (175)	Neither for nor against	Reviewed, New-added
24.	We suggest against the use of ginkgo biloba, dietary or herbal supplements, or nutraceuticals for tinnitus management.	(178–186, 190, 191) **Additional references** (176, 177, 187–189)	Weak against	Reviewed, New-added
25.	We suggest against the use of anticonvulsants, antidepressants, antiemetics, antithrombotics, betahistine, intratympanic corticosteroid injections, or n-methyl d-aspartic acid (NMDA) receptor antagonists for tinnitus management.	(192–196, 198–200, 207, 209, 210) **Additional references** (197, 201–206, 208, 211)	Weak against	Reviewed, New-added

Appendix J: Participant List

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Appendix K: Literature Review Search Terms and Strategy

Table K-1. EMBASE and MEDLINE in EMBASE.com Syntax

KQ #	Set #	Description	EMBASE Search String
KQ 1	#1	Tinnitus	'tinnitus'/de OR tinnitus:ti,ab,kw
	#2	Evaluation tools for monitoring - Controlled terms	'assessment of humans'/exp/mj OR 'disease assessment'/exp/mj OR 'questionnaire'/exp/mj OR 'tinnitus functional index'/mj OR 'tinnitus handicap inventory'/mj OR 'tinnitus handicap inventory score'/mj OR 'tinnitus handicap inventory questionnaire'/mj OR 'tinnitus reaction questionnaire'/mj OR 'tinnitus questionnaire'/mj
	#3	Evaluation tools for monitoring - Text words	'tinnitus functional index':ti OR 'tinnitus handicap':ti OR ((tinnitus NEXT/2 questionnaire):ti) OR vas:ti OR 'visual analog scale*':ti OR assess*:ti OR evaluat*:ti OR handicap:ti OR index*:ti OR indices:ti OR interview*:ti OR instrument*:ti OR inventor*:ti OR measur*:ti OR monitor*:ti OR prognos*:ti OR questionnaire*:ti OR scale*:ti OR screen*:ti OR score*:ti OR survey*:ti OR test:ti OR testing:ti OR tests:ti OR tool*:ti
	#4	Combine interventions	#1 AND (#2 OR #3)
	#5	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR veterinar*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))
	#6	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))
	#7	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#8	Combine exclusions (OR)	#5 OR #6 OR #7
	#9	English language	[english]/lim
	#10	Publication year	[2013-2023]/py
	#11	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)

KQ #	Set #	Description	EMBASE Search String
KQ 1 (cont.)	#12	Combine inclusions (AND)	#9 AND #10 AND #11
	#13	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#14	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab
	#15	Observational comparative studies	"case control study"/exp OR "cohort analysis"/de OR "comparative study"/exp OR "control group"/de OR "controlled clinical trial"/de OR "controlled study"/de OR "crossover procedure"/de OR "double blind procedure"/de OR "major clinical study"/de OR "observational study"/de OR "prospective 'case control study'/exp OR 'cohort analysis'/de OR 'comparative study'/exp OR 'control group'/de OR 'controlled clinical trial'/de OR 'controlled study'/de OR 'crossover procedure'/de OR 'double blind procedure'/de OR 'major clinical study'/de OR 'observational study'/de OR 'prospective study'/de OR 'single blind procedure'/de OR 'triple blind procedure'/de OR '2 arm*':ti,ab OR '3 arm*':ti,ab OR 'case control':ti,ab OR cohort*:ti,ab OR compar*:ti,ab OR (((controlled OR experimental OR 'non random*' OR nonrandom* OR observational OR prospective) NEXT/3 (design OR study OR trial)):ti,ab) OR 'cross over':ti,ab OR crossover:ti,ab OR 'double arm*':ti,ab OR 'double blind*':ti,ab OR 'matched controls':ti,ab OR group:ti,ab OR groups:ti,ab OR 'multiple arm*':ti,ab OR 'non inferiority':ti,ab OR noninferiority:ti,ab OR placebo*:ti,ab OR 'quasi experiment*':ti,ab OR quasiexperiment*:ti,ab OR registries:ti,ab OR registry:ti,ab OR sham:ti,ab OR 'three arm*':ti,ab OR 'triple arm*':ti,ab OR 'triple blind*':ti,ab OR 'two arm*':ti,ab OR versus:ti OR vs:ti
	#16	Combine study types (OR)	#13 OR #14 OR #15
	#17	Apply all filters	(#4 NOT #8) AND #12 AND #16
KQ 2	#1	Tinnitus	"tinnitus"/de OR tinnitus:ti,ab,kw
	#2	Reassurance / education	'coaching'/de OR 'consumer health information'/de OR 'counseling'/exp OR 'education'/exp OR 'reassurance'/de OR coach*:ti,ab,kw OR (('consumer health information':ti,ab,kw OR coping:ti,ab,kw) AND near:ti,ab,kw AND (mechanism*:ti,ab,kw OR skill*:ti,ab,kw OR strateg*:ti,ab,kw)) OR counsel*:ti,ab,kw OR educat*:ti,ab,kw OR 'patient information':ti,ab,kw OR psychoeducat*:ti,ab,kw OR reassur*:ti,ab,kw OR teach*:ti,ab,kw OR guidance:ti
	#3	Combine sets	#1 AND #2

KQ #	Set #	Description	EMBASE Search String
KQ 2 (cont.)	#4	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR veterinar*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))
	#5	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))
	#6	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#7	Combine exclusions (OR)	#4 OR #5 OR #6
	#8	English language	[english]/lim
	#9	Publication year	[2013-2023]/py
	#10	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)
	#11	Combine inclusions (AND)	#8 AND #9 AND #10
	#12	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#13	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab
	#14	Combine study types (OR)	#12 OR #13
	#15	Apply all filters	(#3 NOT #7) AND #11 AND #14

KQ #	Set #	Description	EMBASE Search String
KQ 3, KQ 4	#1	Tinnitus	"tinnitus"/de OR tinnitus:ti,ab,kw
	#2	Self-Management Apps and telehealth / telemedicine – controlled terms	'e-mail'/de OR 'e therapy'/de OR 'internet'/de OR 'mindfulness based stress reduction'/de OR 'mobile application'/exp OR 'mobile phone'/exp OR 'podcast'/de OR 'self care'/exp OR 'self-care software'/exp OR 'short message service'/de OR 'social media'/de OR 'tablet computer'/de OR 'teleconsultation'/exp OR 'telehealth'/de OR 'telemedicine'/de OR 'telemonitoring'/de OR 'telephone'/de OR 'telepsychiatry'/de OR 'telepsychology'/de OR 'telepsychotherapy'/de OR 'teletherapy'/de OR 'text messaging'/de OR 'video consultation'/de OR 'videoconferencing'/de OR 'web-based intervention'/de OR 'wireless communication'/de
	#3	Self-Management Apps and telehealth / telemedicine – text words *Note: terms for mindfulness and mindfulness-based stress reduction are searched with other key questions*	(((distance OR mobile OR remote OR tele OR virtual) NEAR/3 (care OR counseling OR counselor* OR consult* OR health OR medical OR medicine OR monitor* OR 141eterinary* OR 141eterinary* OR 141eterinary141py* OR therapy OR visit*)):ti) OR android*:ti OR app:ti OR apps:ti OR apple OR asynchronous*:ti OR automat*:ti OR chat*:ti OR cellphone*:ti OR 'computer based':ti OR 'connected care':ti OR cyber*:ti OR digital:ti OR 'e health*':ti OR ehealth*:ti OR 'e mail*':ti OR email*:ti OR 'e therapy':ti OR etherapy:ti OR facebook:ti OR 'face tim*':ti OR facetim*:ti OR 141eterinar*:ti OR internet:ti OR 'i-pad':ti OR ipad:ti OR 'i phone':ti OR iphone:ti OR 'lap top*':ti OR laptop*:ti OR 'm health*':ti OR mhealth*:ti OR 'mindfulness based stress reduction':ti,ab,kw OR (((mobil* OR portab*) NEXT/1 (computer* OR device* OR health OR tablet*)):ti) OR 'on line':ti OR online:ti OR phone:ti OR phones:ti OR podcast*:ti OR 141eterin:ti OR (self NEXT/1 (care OR help OR manag*)) OR 'short messag* service*':ti OR smart:ti OR smartphone*:ti OR (((sms OR text) NEXT/2 messag*):ti) OR ((social NEXT/1 (media OR network* OR platform*)):ti) OR software:ti OR 'store and forward':ti OR synchronous*:ti OR teams:ti OR technolog*:ti OR tele:ti OR teleconsult*:ti OR telecounsel*:ti OR telehealth*:ti OR telemed*:ti OR telemonitor*:ti OR telephone*:ti OR telepsych*:ti OR telerehab*:ti OR teletherapy:ti OR televisit*:ti OR texting*:ti OR video*:ti OR virtual*:ti OR web:ti OR website*:ti OR zoom:ti OR 'tele audiolog*':ti,ab,kw OR teleaudiolog*:ti,ab,kw
	#4	Combine sets	#1 AND (#2 OR #3)
	#5	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR 141eterinary*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))

KQ #	Set #	Description	EMBASE Search String
KQ 3, KQ 4 (cont.)	#6	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))
	#7	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#8	Combine exclusions (OR)	#5 OR #6 OR #7
	#9	English language	[english]/lim
	#10	Publication year	[2013-2023]/py
	#11	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)
	#12	Combine inclusions (AND)	#9 AND #10 AND #11
	#13	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#14	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab
	#15	Combine study types (OR)	#13 OR #14
	#16	Apply all filters	(#4 NOT #8) AND #12 AND #15
KQ 5	#1	Tinnitus	"tinnitus"/de OR tinnitus:ti,ab,kw
	#2	Neurostimulation / Neuromodulation: Broad, descriptive terms (invasive and noninvasive)	'electrostimulation'/de OR 'electrotherapy'/de OR 'nerve stimulation'/de OR 'nerve stimulator'/de OR 'neuromodulation'/de OR 'neuromodulator'/de OR electrostimulat*:ti,ab,kw OR electrotherap*:ti,ab,kw OR 'neuro modulat*':ti,ab,kw OR neuromodulat*:ti,ab,kw OR neurostimulat*:ti,ab,kw OR stimulat*:ti,ab,kw
	#3	Auditory cortical stimulation	'auditory stimulation'/de OR 'cortical stimulation'/de OR (('auditory cortex':ti,ab,kw OR 'auditory cortical':ti,ab,kw) AND stimulat*:ti,ab,kw) OR 'auditory stimulation':ti,ab,kw

KQ #	Set #	Description	EMBASE Search String
KQ 5 (cont.)	#4	Biomodal stimulation	'biomodal stimulation' OR ((('bi modal' OR bimodal) NEXT/2 (neuromodulat* OR neurostimulat* OR stimulat*)):ti,ab,kw) OR 'wrist band*':ti,ab,kw OR wristband*:ti,ab,kw OR lenire*:ti,ab,kw,dn,df OR neosensory:ti,ab,kw,dn,df
	#5	Electromagnetic stimulation	(('electro magnetic' OR electromagnetic) NEAR/3 (pulsed OR neurostimulat* OR stimulat*)):ti,ab,kw
	#6	Implanted stimulators	'auditory implant'/de OR 'implantable neurostimulator'/exp OR ((implant* NEAR/3 (auditory OR brainstem OR 'neuro modulat*' OR neuromodulat* OR 'neuro stimulat*' OR neurostimulat* OR stimulat*)):ti,ab,kw) OR ((peripheral NEXT/2 nerve NEXT/4 stimulat*):ti,ab,kw) OR implant*:ti
	#7	Invasive brain stimulation (e.g., deep brain stimulation)	'brain depth stimulation'/de OR 'deep brain stimulat*':ti,ab,kw OR ((invasive* NEAR/3 ('neuro modulat*' OR neuromodulat* OR 'neuro stimulat*' OR neurostimulat* OR stimulat*)):ti,ab,kw)
	#8	Low energy ultrasound	('echography'/exp OR 'physiotherapy ultrasound system'/exp OR 'physiotherapy ultrasound system/ neuromuscular stimulation system'/exp OR 'ultrasound scanner'/exp) AND 'ultrasound therapy'/exp OR 'low energy':ti,ab,kw OR 'low intensity':ti,ab,kw OR sonogra*:ti,ab,kw OR ultrasonic*:ti,ab,kw OR ultrasonogra*:ti,ab,kw OR ultrasound*:ti,ab,kw
	#9	Low-level laser (invasive)	'low level laser therapy'/de OR 'low level laser*':ti,ab,kw OR photobiomodulation:ti,ab,kw
	#10	Repetitive transcranial magnetic stimulation (rTMS)	'magnetic stimulation'/de OR 'magnetic stimulator'/exp OR 'transcranial magnetic stimulation'/exp OR 'repetitive peripheral magnetic stimulation'/de OR 'magnetic stimulat*':ti,ab,kw OR 'theta burst':ti,ab,kw OR tms:ti OR rpms:ti OR rtms:ti OR stms:ti
	#11	Transcranial direct current stimulation (tDCS)	'transcranial direct current stimulation'/de OR 'transcranial direct current stimulator'/de OR 'transcranial electrical stimulation'/de OR 'transcranial electrical stimulator'/exp OR 'direct current stimulat*':ti,ab,kw OR dcs:ti OR tdcs:ti
	#12	Transcutaneous nerve stimulation	'transcutaneous electrical nerve stimulation'/de OR 'transcutaneous electrical nerve stimulator'/de OR ((transcutaneous NEXT/3 stimulat*):ti,ab,kw) OR tens:ti
	#13	Vagus nerve stimulation (invasive and noninvasive)	'transcutaneous vagus nerve stimulator'/de OR 'vagus nerve stimulation'/de OR 'vagus nerve stimulator'/de OR (((vagal OR vagus) NEAR/3 stimulat*):ti,ab,kw) OR nvns:ti OR vns:ti
	#14	Combine sets	#1 AND (#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13)

KQ #	Set #	Description	EMBASE Search String
KQ 5 (cont.)	#15	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR veterinar*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))
	#16	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))
	#17	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#18	Combine exclusions (OR)	#15 OR #16 OR #17
	#19	English language	[english]/lim
	#20	Publication year	[2013-2023]/py
	#21	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)
	#22	Combine inclusions (AND)	#19 AND #20 AND #21
	#23	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#24	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab
	#25	Combine study types (OR)	#23 OR #24
	#26	Apply all filters	(#14 NOT #18) AND #22 AND #25
KQ 6	#1	Tinnitus	"tinnitus"/de OR tinnitus:ti,ab,kw
	#2	Pharmacotherapy - broad, general terms	'drug therapy'/exp/mj OR 'drug therapy'/lnk OR ((drug NEXT/1 (therap* OR treatment*)):ti) OR medication*:ti OR pharmacologic*:ti OR pharmacotherap*:ti

KQ #	Set #	Description	EMBASE Search String
KQ 6 (cont.)	#3	Anesthetics	'local anesthetic agent'/exp OR anaesthetic*:ti,ab,kw OR anesthetic*:ti,ab,kw OR lidocaine:ti,ab,kw OR procaine:ti,ab,kw
	#4	Antiarrhythmics	'antiarrhythmic agent'/exp OR 'anti arrhythmi*':ti,ab,kw OR antiarrhythmi*:ti,ab,kw OR flecainide:ti,ab,kw OR lidocaine:ti,ab,kw OR mexiletine:ti,ab,kw OR tocainide:ti,ab,kw
	#5	Anticonvulsants	'anticonvulsive agent'/exp AND 'mood stabilizer'/exp OR anticonvuls*:ti,ab,kw OR 'anti convuls*':ti,ab,kw OR 'anti epileptic*':ti,ab,kw OR antiepileptic*:ti,ab,kw OR 'anti seizure':ti,ab,kw OR antiseizure:ti,ab,kw OR carbamazepine:ti,ab,kw OR gabapentin:ti,ab,kw OR lamotrigine:ti,ab,kw OR phenytoin:ti,ab,kw OR pregabalin:ti,ab,kw OR primidone:ti,ab,kw OR valproate:ti,ab,kw OR 'valproic acid':ti,ab,kw
	#6	Antidepressants	'antidepressant agent'/exp OR amitriptyline:ti,ab,kw OR 'anti-depressant*':ti,ab,kw OR 'anti depressive*':ti,ab,kw OR antidepressant*:ti,ab,kw OR antidepressive*:ti,ab,kw OR bupropion:ti,ab,kw OR fluoxetine:ti,ab,kw OR nortriptyline:ti,ab,kw OR paroxetine:ti,ab,kw OR protriptyline:ti,ab,kw OR ((serotonin NEXT/3 (antagonist* OR inhibitor*)):ti,ab,kw) OR sertraline:ti,ab,kw OR snri*:ti,ab,kw OR ssri*:ti,ab,kw OR tricyclic*:ti,ab,kw OR trazadone:ti,ab,kw OR trimipramine:ti,ab,kw
	#7	Antihistamines	'antihistaminic agent'/exp OR 'anti histamin*':ti,ab,kw OR antihistamin*:ti,ab,kw OR cetirizine:ti,ab,kw OR chlorpheniramine:ti,ab,kw OR dexchlorpheniramine:ti,ab,kw OR fexofenadine:ti,ab,kw OR histamine*:ti,ab,kw OR loratadine:ti,ab,kw OR meclizine:ti,ab,kw OR meclozine:ti,ab,kw
	#8	Anxiolytics	'anxiolytic agent'/exp OR 'benzodiazepine derivative'/exp OR 'psychotropic agent'/exp OR alprazolam:ti,ab,kw OR 'anti anxiety':ti,ab,kw OR antianxiety:ti,ab,kw OR anxiolytic*:ti,ab,kw OR benzodiazepine*:ti,ab,kw OR clonazepam:ti,ab,kw OR diazepam:ti,ab,kw OR flurazepam:ti,ab,kw OR hypnosedative*:ti,ab,kw OR hypnotic*:ti,ab,kw OR lorazepam:ti,ab,kw OR oxazepam:ti,ab,kw OR psychotropic*:ti,ab,kw OR sedative*:ti,ab,kw OR tranquiliser*:ti,ab,kw OR tranquilizer*:ti,ab,kw OR triazolam:ti,ab,kw
	#9	Calcium channel blockers	'calcium channel blocking agent'/exp OR (calcium:ti,ab,kw AND next:ti,ab,kw AND (antagonist*:ti,ab,kw OR block*:ti,ab,kw OR inhibit*:ti,ab,kw)) OR amlodipine:ti,ab,kw OR nifedipine:ti,ab,kw OR nimodipine:ti,ab,kw
	#10	Corticosteroids	'corticosteroid'/exp OR 'dexamethasone derivative'/exp OR 'glucocorticoid'/exp OR corticosteroid*:ti,ab,kw OR dexamethasone:ti,ab,kw OR glucocorticoid*:ti,ab,kw OR methylprednisolone:ti,ab,kw OR prednisolone:ti,ab,kw OR prednisone:ti,ab,kw

KQ #	Set #	Description	EMBASE Search String
KQ 6 (cont.)	#11	Diuretics	'antihypertensive agent'/exp OR 'diuretic agent'/exp OR 'loop diurectic agent' OR 'thiazide diuretic agent'/exp OR bumetanide:ti,ab,kw OR chlorothiazide:ti,ab,kw OR diuretic*:ti,ab,kw OR furosemide:ti,ab,kw OR hydrochlorothiazide:ti,ab,kw OR torsemide:ti,ab,kw
	#12	Glutamate receptor antagonists	'glutamate receptor antagonist'/exp OR 'n methyl dextro aspartic acid receptor blocking agent'/exp OR acamprosate:ti,ab,kw OR ((glutamate NEXT/2 antagonist*):ti,ab,kw) OR memantine:ti,ab,kw
	#13	Intratympanic medications	'intratympanic drug administration'/de OR (((intratympanic OR tympanic OR transtympanic) NEAR/3 (infusion* OR injection* OR treatment* OR therap*)):ti,ab,kw)
	#14	Muscle relaxants	'muscle relaxant agent'/exp OR baclofen:ti,ab,kw OR cyclobenzaprine:ti,ab,kw OR 'muscle relaxant*':ti,ab,kw
	#15	Other pharmacotherapy agents	'antilipemic agent'/exp OR 'drugs used in the treatment of addiction'/exp OR 'hypnotic sedative agent'/exp OR 'narcotic analgesic agent'/exp OR 'nitrous oxide'/de OR 'opiate antagonist'/exp OR 'pyridine derivative'/exp OR atorvastatin:ti,ab,kw OR clonidine:ti,ab,kw OR doxepin:ti,ab,kw OR eszopiclone:ti,ab,kw OR flindokalner:ti,ab,kw OR gacyclidine:ti,ab,kw OR lemborexant:ti,ab,kw OR naltrexone:ti,ab,kw OR narcotic*:ti,ab,kw OR 'nitrous oxide':ti,ab,kw OR opiate*:ti,ab,kw OR opioid*:ti,ab,kw OR pentoxifylline:ti,ab,kw OR ramelteon:ti,ab,kw OR scopolamine:ti,ab,kw OR suvorexant:ti,ab,kw OR vardenafil:ti,ab,kw OR zaleplon:ti,ab,kw OR zolpidem:ti,ab,kw
	#16	Combine sets	#1 AND (#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15)
	#17	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR veterinar*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))
	#18	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))

KQ #	Set #	Description	EMBASE Search String
KQ 6 (cont.)	#19	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#20	Combine exclusions (OR)	#17 OR #18 OR #19
	#21	English language	[english]/lim
	#22	Publication year	[2013-2023]/py
	#23	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)
	#24	Combine inclusions (AND)	#21 AND #22 AND #23
	#25	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#26	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab
	#27	Combine study types (OR)	#25 OR #26
	#28	Apply all filters	(#16 NOT #20) AND #24 AND #27
KQ 7, KQ 8	#1	Tinnitus	"tinnitus"/de OR tinnitus:ti,ab,kw
	#2	Complimentary and integrative health - controlled terms	'acupressure device'/de OR 'acupuncture'/de OR 'acupuncture point'/exp OR 'alternative medicine'/exp OR 'art therapy'/de OR 'biofeedback'/de OR 'dance therapy'/de OR 'dancing'/de OR 'music therapy'/exp OR 'hypnotherapy'/de OR 'integrative medicine'/de OR 'manipulative medicine'/exp OR 'massage'/exp OR 'meditation'/exp OR 'osteopathic medicine'/exp OR 'phototherapy'/de OR 'physiotherapist'/de OR 'physiotherapy'/exp OR 'spine manipulation'/de

KQ #	Set #	Description	EMBASE Search String
KQ 7, KQ 8 (cont.)	#3	Complimentary and integrative health - text words	'acu point*':ab,ti,kw OR acupoint*:ab,ti,kw OR acupressure:ab,ti,kw OR acupuncture:ab,ti,kw OR 'art therapy':ab,ti,kw OR biofeedback:ab,ti,kw OR chiropract*:ab,ti,kw OR dance:ab,ti,kw OR dancing:ab,ti,kw OR electroacupuncture:ab,ti,kw OR homeopath*:ab,ti,kw OR hypnotherapy:ab,ti,kw OR 'light therapy':ab,ti,kw OR manipulat*:ab,ti,kw OR 'manual therapy':ab,ti,kw OR massag*:ab,ti,kw OR meditat*:ab,ti,kw OR 'mind-body':ab,ti,kw OR mindful*:ab,ti,kw OR 'music therapy':ab,ti,kw OR 'myofascial release':ab,ti,kw OR neurofeedback:ab,ti,kw OR 'non pharmacologic*':ab,ti,kw OR 'nonpharmacologic*':ab,ti,kw OR osteopath*:ab,ti,kw OR phototherapy:ab,ti,kw OR 'physical intervention*':ab,ti,kw OR 'physical therap*':ab,ti,kw OR physiotherap*:ab,ti,kw OR (((alternative OR complementary OR integrative) NEXT/3 (approach* OR intervention* OR manag* OR medical OR medicine* OR modalit* OR technique* OR therap* OR treat*)):ti)
	#4	Combine sets	#1 AND (#2 OR #3)
	#5	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR veterinar*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))
	#6	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))
	#7	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#8	Combine exclusions (OR)	#5 OR #6 OR #7
	#9	English language	[english]/lim
	#10	Publication year	[2013-2023]/py
	#11	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)

KQ #	Set #	Description	EMBASE Search String
KQ 7, KQ 8 (cont.)	#12	Combine inclusions (AND)	#9 AND #10 AND #11
	#13	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#14	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab
	#15	Combine study types (OR)	#13 OR #14
	#16	Apply all filters	(#4 NOT #8) AND #12 AND #15
KQ 9	#1	Tinnitus	"tinnitus"/de OR tinnitus:ti,ab,kw
	#2	Lifestyle interventions - controlled terms	'aerobic exercise'/de OR 'alcohol abstinence'/de OR 'breathing exercise'/exp OR 'diaphragmatic breathing'/de OR 'diet therapy'/exp OR 'guided imagery'/de OR 'healthy lifestyle'/de OR 'leisure'/exp OR 'lifestyle modification'/de OR 'mindful eating'/de OR 'mindfulness'/exp OR 'muscle relaxation'/de OR 'nutritional counseling'/de OR 'qigong'/de OR 'relaxation training'/de OR 'sleep hygiene'/de OR 'sleep quality'/de OR 'smoking cessation'/de OR 'smoking reduction'/de OR 'stress management'/de OR 'supported employment'/de OR 'tai chi'/de OR 'yoga'/exp
	#3	Lifestyle interventions - text words	aerobic*:ab,ti,kw OR ((alcohol NEAR/2 (abstinence OR abstain* OR avoid* OR lower* OR reduc*)):ab,ti,kw) OR ((breathing NEXT/1 (exercise* OR technique*)):ab,ti,kw) OR (((deep OR diaphragmatic OR focused) NEXT/1 breathing):ab,ti,kw) OR diet*:ab,ti,kw OR 'guided imagery':ab,ti,kw OR holistic*:ab,ti,kw OR ((lifestyle NEAR/4 (chang* OR intervention* OR modif*)):ab,ti,kw) OR meditat*:ab,ti,kw OR 'mind-body':ab,ti,kw OR mindful*:ab,ti,kw OR 'muscle relaxation':ab,ti,kw OR nutrition*:ab,ti,kw OR 'progressive relaxation':ab,ti,kw OR 'qi gong':ab,ti,kw OR qigong:ab,ti,kw OR 'relaxation therap*':ab,ti,kw OR 'relaxation training':ab,ti,kw OR ((sleep NEAR/2 (habit* OR hygiene)):ab,ti,kw) OR 'smoking cessation':ab,ti,kw OR ((stress NEAR/2 manag*):ab,ti,kw) OR 'tai chi':ab,ti,kw OR taichi:ab,ti,kw OR 'tai ji':ab,ti,kw OR taiji*:ab,ti,kw OR wellness:ab,ti,kw OR ((whole NEXT/1 (health OR person)):ab,ti,kw) OR yoga:ab,ti,kw OR yogic:ab,ti,kw
	#4	Combine sets	#1 AND (#2 OR #3)

KQ #	Set #	Description	EMBASE Search String
KQ 9 (cont.)	#5	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR veterinar*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))
	#6	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))
	#7	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#8	Combine exclusions (OR)	#5 OR #6 OR #7
	#9	English language	[english]/lim
	#10	Publication year	[2013-2023]/py
	#11	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)
	#12	Combine inclusions (AND)	#9 AND #10 AND #11
	#13	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#14	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab
	#15	Combine study types (OR)	#13 OR #14
	#16	Apply all filters	(#4 NOT #8) AND #12 AND #15

KQ #	Set #	Description	EMBASE Search String
KQ 10	#1	Tinnitus	"tinnitus"/de OR tinnitus:ti,ab,kw
	#2	Herbals, nutraceuticals, and supplements - controlled terms	'antioxidant'/exp OR 'cannabinoid'/exp OR 'chinese medicine'/de OR 'dietary supplement'/exp OR 'flavonoid'/exp OR 'ginko biloba' OR 'herbal medicine'/de OR 'iron'/de OR 'magnesium'/de OR 'medicinal plant'/exp OR 'mineral'/de OR 'ozone'/de OR 'ozone therapy'/de OR 'plant medicinal product'/exp OR 'prebiotic agent'/de OR 'probiotic agent'/exp OR 'psilocybine'/de OR 'supplementation'/exp OR 'vitamin'/exp
	#3	Herbals, nutraceuticals, and supplements - text words	antioxidant*:ti,ab,kw OR bioflavonoid*:ti,ab,kw OR botanical*:ti,ab,kw OR flavonoid*:ti,ab,kw OR lipoflavonoid*:ti,ab,kw OR cannab*:ti,ab,kw OR cbd:ti,ab,kw OR chinese:ti,ab,kw OR dietary:ti,ab,kw OR 'ginkgo biloba':ti,ab,kw OR herb:ti,ab,kw OR herbal:ti,ab,kw OR herbs:ti,ab,kw OR lipoflavonoid:ti,ab,kw OR magnesium:ti,ab,kw OR marijuana:ti,ab,kw OR melatonin:ti,ab,kw OR micronutrient*:ti,ab,kw OR mineral:ti,ab,kw OR minerals:ti,ab,kw OR nicotinamide:ti,ab,kw OR nutraceutical*:ti,ab,kw OR nutrient*:ti,ab,kw OR ozone:ti,ab,kw OR phytochemical*:ti,ab,kw OR phytomedic*:ti,ab,kw OR phytonutrient*:ti,ab,kw OR plant:ti,ab,kw OR plants:ti,ab,kw OR 'pre biotic*':ti,ab,kw OR prebiotic*:ti,ab,kw OR 'pro biotic*':ti,ab,kw OR probiotic*:ti,ab,kw OR psilocybin*:ti,ab,kw OR supplement:ti,ab,kw OR supplementation:ti,ab,kw OR supplements:ti,ab,kw OR vitamin*:ti,ab,kw OR zinc:ti,ab,kw
	#4	Combine sets	#1 AND (#2 OR #3)
	#5	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR veterinar*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))
	#6	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))

KQ #	Set #	Description	EMBASE Search String
KQ 10 (cont.)	#7	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#8	Combine exclusions (OR)	#5 OR #6 OR #7
	#9	English language	[english]/lim
	#10	Publication year	[2013-2023]/py
	#11	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)
	#12	Combine inclusions (AND)	#9 AND #10 AND #11
	#13	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#14	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab
	#15	Combine study types (OR)	#13 OR #14
	#16	Apply all filters	(#4 NOT #8) AND #12 AND #15
KQ 11, KQ 12	#1	Tinnitus	"tinnitus"/mj OR tinnitus:ti
	#2	Co-occurring conditions - broad terms	'comorbidity'/mj OR 'dual diagnosis'/mj OR 'co exist*':ti OR coexist*:ti OR 'co morbid*':ti OR comorbid*:ti OR 'co-occur*':ti OR dual*:ti OR secondary:ti
	#3	Addictive and substance use disorders	'addiction'/exp/mj OR 'alcohol abuse'/exp/mj OR 'behavioral addiction'/exp/mj OR 'drug abuse'/exp/mj OR 'drug dependence'/exp/mj OR 'pathological gambling'/exp/mj OR 'substance abuse'/mj OR (((alcohol* OR cannabis OR drug* OR heroin OR marijuana OR meth OR methamphetamine* OR narcotic* OR opiate* OR opioid* OR substance*) NEAR/3 (abus* OR addict* OR depend* OR disorder* OR habit* OR illegal* OR illicit* OR intoxica* OR misus* OR use OR uses OR user* OR using)):ti) OR gambling:ti OR addiction:ti OR substance*:ti

KQ #	Set #	Description	EMBASE Search String
KQ 11, KQ 12 (cont.)	#4	Behavioral and mental health conditions, including psychiatric conditions	'anxiety disorder'/exp/mj OR 'dissociative disorder'/exp/mj OR 'emotional disorder'/exp/mj OR 'mental disease'/mj OR 'mood disorder'/exp/mj OR 'neurosis'/exp/mj OR 'personality disorder'/exp/mj OR 'psychosis'/exp/mj OR 'posttraumatic stress disorder'/exp/mj OR 'schizophrenia'/exp/mj OR anxiety:ti OR bipolar:ti OR depressive:ti OR depression:ti OR dysthym*:ti OR mental*:ti OR 'mood disorder*':ti OR ((('post traumatic' OR posttraumatic) NEXT/1 stress):ti) OR psychiatr*:ti OR psycholog*:ti OR psychosis:ti OR psychotic:ti OR ptsd:ti OR schizophren*:ti OR 'stress-related disorder*':ti
	#5	Blast exposure / head injury	'battle injury'/mj OR 'blast injury'/mj OR 'head and neck injury'/exp/mj OR 'posttraumatic headache'/exp/mj OR (((blast OR brain OR facial OR head OR 'maxillo facial' OR maxillofacial OR 'oro facial' OR orofacial OR neck) NEAR/3 (injur* OR trauma)):ti) OR combat:ti OR concuss*:ti OR craniotom*:ti OR military:ti OR postconcuss*:ti OR 'post trauma*':ti OR posttrauma*:ti OR ((sexual NEXT/1 (abuse OR assault* OR trauma*)):ti) OR veteran*:ti OR whiplash:ti
	#6	Chronic pain	'chronic pain'/exp/mj OR arthrit*:ti OR fibromyalg*:ti OR osteoarthrit*:ti OR ((pain NEAR/2 (back OR cervical OR chronic OR joint* OR lumbar OR neck)):ti) OR temporomandibular:ti OR tmd:ti OR tmj:ti
	#7	Dementia / cognitive deficits	'dementia'/exp/mj OR 'mild cognitive impairment'/mj OR 'cognitive impairment*':ti OR dementia*:ti
	#8	Hearing loss or sound tolerance conditions (e.g., hyperacusis)	'auditory processing disorder'/exp OR 'hearing disorder'/de OR 'hearing impairment'/exp OR 'loudness recruitment'/de OR 'noise sensitivity'/de OR 'misophonia'/de OR 'phonophobia'/de OR (((auditory OR hearing) NEAR/2 (defect* OR difficult* OR disorder* OR impair* OR loss)):ti) OR deaf*:ti OR hyperacusis:ti OR (((hypersensitiv* OR sensitiv* OR tolerance) NEAR/2 (noise* OR sound*)):ti) OR misophonia:ti OR phonophobia*:ti
	#9	Sleep disorders	'sleep disorder'/exp/mj OR apnea*:ti OR apnoea*:ti OR dyssomnia*:ti OR hypersomnia*:ti OR hyposomnia*:ti OR insomnia*:ti OR narcoleps*:ti OR night*:ti OR parasomnia*:ti OR 'restless legs':ti OR sleep*:ti
	#10	Social problems	'homelessness'/mj OR 'social isolation'/exp/mj OR 'unemployment'/mj OR homeless*:ti OR isolation:ti OR underemploy*:ti OR unemploy*:ti
	#11	Suicidality	'suicidal behavior'/exp/mj OR suicid*:ti
	#12	Temporomandibular joint disorder	'temporomandibular joint disorder'/mj OR 'temporomandibular joint':ti OR tmd:ti OR tmj:ti
	#13	Combine sets	#1 AND (#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12)

KQ #	Set #	Description	EMBASE Search String
KQ 11, KQ 12 (cont.)	#14	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR veterinar*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))
	#15	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))
	#16	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#17	Combine exclusions (OR)	#14 OR #15 OR #16
	#18	English language	[english]/lim
	#19	Publication year	[2013-2023]/py
	#20	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)
	#21	Combine inclusions (AND)	#18 AND #19 AND #20
	#22	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#23	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab

KQ #	Set #	Description	EMBASE Search String
KQ 11, KQ 12 (cont.)	#24	Observational comparative studies	'case control study'/exp OR 'cohort analysis'/de OR 'comparative study'/exp OR 'control group'/de OR 'controlled clinical trial'/de OR 'controlled study'/de OR 'crossover procedure'/de OR 'double blind procedure'/de OR 'major clinical study'/de OR 'observational study'/de OR 'prospective study'/de OR 'single blind procedure'/de OR 'triple blind procedure'/de OR '2 arm*':ti,ab OR '3 arm*':ti,ab OR 'case control':ti,ab OR cohort*:ti,ab OR compar*:ti,ab OR (((controlled OR experimental OR 'non random*' OR nonrandom* OR observational OR prospective) NEXT/3 (design OR study OR trial)):ti,ab) OR 'cross over':ti,ab OR crossover:ti,ab OR 'double arm*':ti,ab OR 'double blind*':ti,ab OR 'matched controls':ti,ab OR group:ti,ab OR groups:ti,ab OR 'multiple arm*':ti,ab OR 'non inferiority':ti,ab OR noninferiority:ti,ab OR placebo*:ti,ab OR 'quasi experiment*':ti,ab OR quasiexperiment*:ti,ab OR registries:ti,ab OR registry:ti,ab OR sham:ti,ab OR 'three arm*':ti,ab OR 'triple arm*':ti,ab OR 'triple blind*':ti,ab OR 'two arm*':ti,ab OR versus:ti OR vs:ti
	#25	Combine study types (OR)	#22 OR #23 OR #24
	#26	Apply all filters	(#13 NOT #17) AND #21 AND #25
KQ 13, KQ 14	#1	Tinnitus	"tinnitus"/de OR tinnitus:ti,ab,kw
	#2	Sound therapy - controlled terms	'auditory masking'/exp OR 'auditory stimulation'/de OR 'mp3 player'/de OR 'sound generator'/de OR 'tinnitus masker'/exp OR 'tinnitus masking software'/de
	#3	Sound therapy - text words	((acoustic NEXT/1 (enrichment OR stimulation OR therapy)):ti,ab,kw) OR 'amplitude modulat*':ti,ab,kw OR ((auditory NEXT/1 (discrimination OR stimulation)):ti,ab,kw) OR cd:ti,ab,kw OR cds:ti,ab,kw OR download*:ti,ab,kw OR 'environmental sound*':ti,ab,kw OR masker*:ti,ab,kw OR masking:ti,ab,kw OR music:ti,ab,kw OR mp3:ti,ab,kw OR notched:ti,ab,kw OR radio:ti,ab,kw OR radios:ti,ab,kw OR ((sound NEXT/4 (device* OR enrichment OR generat* OR stimulat* OR therap* OR treatment*)):ti,ab,kw) OR neuromonics*:ti,ab,kw,dn,df
	#4	Combine sets	#1 AND (#2 OR #3)
	#5	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR veterinar*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))

KQ #	Set #	Description	EMBASE Search String
KQ 13, KQ 14 (cont.)	#6	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))
	#7	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#8	Combine exclusions (OR)	#5 OR #6 OR #7
	#9	English language	[english]/lim
	#10	Publication year	[2013-2023]/py
	#11	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)
	#12	Combine inclusions (AND)	#9 AND #10 AND #11
	#13	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#14	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab
	#15	Combine study types (OR)	#13 OR #14
	#16	Apply all filters	(#4 NOT #8) AND #12 AND #15

KQ #	Set #	Description	EMBASE Search String
KQ 15, KQ 16	#1	Tinnitus	"tinnitus"/de OR tinnitus:ti,ab,kw
	#2	Amplification devices	'amplification'/de OR 'amplifier'/de OR 'audiological software'/exp OR 'auditory implant'/exp OR 'cochlea prosthesis'/exp OR 'hearing aid'/exp OR 'middle ear implant'/exp OR 'middle ear prosthesis'/exp OR amplification:ti,ab,kw OR amplifier*:ti,ab,kw OR ((auditory NEXT/1 ('brain stem' OR brainstem) NEXT/1 implant*):ti,ab,kw) OR 'bone conduct*':ti,ab,kw OR (((cochlea* OR hearing OR 'middle ear') NEAR/2 (device* OR prosthe* OR implant*)):ti,ab,kw) OR 'hearing aid*':ti,ab,kw OR 'bone bridge*':ti,ab,kw,dn OR bonebridge*:ti,ab,kw,dn OR 'sound bridge*':ti,ab,kw,dn OR soundbridge*:ti,ab,kw,dn OR combin*:ti
	#3	Combine sets	#1 AND #2
	#4	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR veterinar*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))
	#5	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))
	#6	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#7	Combine exclusions (OR)	#4 OR #5 OR #6
	#8	English language	[english]/lim
	#9	Publication year	[2013-2023]/py
	#10	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)
	#11	Combine inclusions (AND)	#8 AND #9 AND #10

KQ #	Set #	Description	EMBASE Search String
KQ 15, KQ 16 (cont.)	#12	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#13	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab
	#14	Combine study types (OR)	#12 OR #13
	#15	Apply all filters	(#3 NOT #7) AND #11 AND #14
KQ 17, KQ 18, KQ 20	#1	Tinnitus	"tinnitus"/de OR tinnitus:ti,ab,kw
	#2	Behavioral interventions (controlled terms):	'acceptance and commitment therapy'/de OR 'behavioral activation'/de OR 'behavior therapy'/de OR 'cognitive behavioral therapy'/exp OR 'collaborative care team'/de OR 'coping effectiveness training' OR 'counseling'/exp OR 'dialectical behavioral therapy'/de OR 'emotion-focused therapy'/de OR 'eye movement desensitization and reprocessing'/de OR 'functional analytic psychotherapy'/de OR 'metacognitive therapy'/de OR 'mindfulness based cognitive therapy'/de OR 'mindfulness-based stress reduction'/de OR 'psychotherapy'/exp OR 'support group'/exp
	#3	Behavioral interventions - text words	'acceptance and commitment':ti,ab,kw OR ((behav* NEXT/2 (activat* OR approach* OR health OR intervention* OR manag* OR technique* OR therap* OR treat*)):ti,ab,kw) OR 'cognitive behav*':ti,ab,kw OR (((cognitive OR coping) NEXT/1 effectiveness NEXT/1 training):ti,ab,kw) OR counsel*:ti,ab,kw OR dialectic*:ti,ab,kw OR 'emotion* focused therapy':ti,ab,kw OR (('eye movement desensiti*' NEXT/2 reprocessing):ti,ab,kw) OR 'functional analytic':ti,ab,kw OR metacognitive:ti,ab,kw OR ((mindful* NEXT/2 (based OR 'cognitive therapy' OR 'stress reduction')):ti,ab,kw) OR psychotherap*:ti,ab,kw OR 'solution focused therapy':ti,ab,kw OR 'support group*':ti,ab,kw OR team:ti,ab,kw OR teams:ti,ab,kw
	#4	Combine sets	#1 AND (#2 OR #3)
	#5	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR veterinar*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))

KQ #	Set #	Description	EMBASE Search String
KQ 17, KQ 18, KQ 20 (cont.)	#6	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))
	#7	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#8	Combine exclusions (OR)	#5 OR #6 OR #7
	#9	English language	[english]/lim
	#10	Publication year	[2013-2023]/py
	#11	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)
	#12	Combine inclusions (AND)	#9 AND #10 AND #11
	#13	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#14	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab
	#15	Combine study types (OR)	#13 OR #14
	#16	Apply all filters	(#4 NOT #8) AND #12 AND #15
KQ 19	#1	Tinnitus	"tinnitus"/de OR tinnitus:ti,ab,kw
	#2	Auditory plus behavioral interventions	'mindfulness-based stress reduction'/de OR 'tinnitus retraining therapy'/de OR 'mindfulness based stress reduction':ti,ab,kw OR 'progressive tinnitus management':ti,ab,kw OR 'retraining therapy':ti,ab,kw OR 'tinnitus activities treatment':ti,ab,kw OR 'tinnitus retraining':ti,ab,kw OR neuromonics*:ti,ab,kw,df,dn
	#3	Combine sets	#1 AND #2

KQ #	Set #	Description	EMBASE Search String
KQ 19 (cont.)	#4	Animals	[animals]/lim NOT [humans]/lim OR ((animal:ti OR animals:ti OR canine*:ti OR dog:ti OR dogs:ti OR feline:ti OR hamster*:ti OR lamb:ti OR lambs:ti OR mice:ti OR monkey:ti OR monkeys:ti OR mouse:ti OR murine:ti OR pig:ti OR piglet*:ti OR pigs:ti OR porcine:ti OR primate*:ti OR rabbit*:ti OR rat:ti OR rats:ti OR rodent*:ti OR sheep*:ti OR swine:ti OR veterinar*:ti OR (vitro:ti NOT vivo:ti)) NOT (human*:ti OR patient*:ti))
	#5	Undesired publications	'book'/de OR 'case report'/de OR 'conference paper'/exp OR 'editorial'/de OR 'letter'/de OR book:it OR chapter:it OR conference:it OR editorial:it OR letter:it OR [conference abstract]/lim OR [conference paper]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR abstract:nc OR annual:nc OR conference:nc OR congress:nc OR meeting:nc OR proceedings:nc OR sessions:nc OR symposium:nc OR (book:pt NOT series:pt) OR 'conference proceeding':pt OR 'case report':ti OR comment*:ti OR editorial:ti OR letter:ti OR news:ti OR (protocol:ti AND (study:ti OR trial:ti) NOT ('therapy protocol*':ti OR 'treatment protocol*':ti))
	#6	Children and adolescents	(adolescen*:ti OR babies:ti OR baby:ti OR boys:ti OR child*:ti OR girls:ti OR infancy:ti OR infant*:ti OR juvenile*:ti OR neonat*:ti OR newborn*:ti OR nurser*:ti OR paediatric*:ti OR pediatric*:ti OR preschool*:ti OR 'school age*':ti OR schoolchildren*:ti OR teen*:ti OR toddler*:ti OR youth*:ti) NOT (adult*:ti OR men:ti OR women:ti)
	#7	Combine exclusions (OR)	#4 OR #5 OR #6
	#8	English language	[english]/lim
	#9	Publication year	[2013-2023]/py
	#10	Entry date	([01-01-1900]/sd NOT [07-04-2023]/sd)
	#11	Combine inclusions (AND)	#8 AND #9 AND #10
	#12	Systematic reviews and meta-analyses	('meta analysis'/exp OR 'systematic review'/de OR cochrane:jt OR [cochrane review]/lim OR systematic*:ti OR cochrane*:ti,ab OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR (search*:ti,ab AND (cinahl*:ti,ab OR databases:ti,ab OR ebsco*:ti,ab OR embase*:ti,ab*" OR sciencedirect* OR scopus* OR systematic* OR "web of knowledge*" OR "web of science")) OR (systematic* NEAR/3 review*)):ti,ab) NOT ((protocol NEXT/3 review) OR "review protocol" OR "scoping review"):ti)
	#13	Randomized controlled trials	'random sample'/de OR 'randomization'/de OR 'randomized controlled trial'/exp OR 'phase 3':ti,ab OR 'phase iii':ti,ab OR random*:ti,ab OR rct:ti,ab
	#14	Combine study types (OR)	#12 OR #13
	#15	Apply all filters	(#3 NOT #7) AND #11 AND #14

Appendix L: Alternative Text Descriptions of Algorithm

The following outline narratively describes the VA/DoD Tinnitus CPG Algorithm. An explanation of the purpose of the algorithm and description of the various shapes used within the algorithm can be found in the Algorithm section. The sidebars referenced within this outline can also be found in the Algorithm section.

Module A: Initial Evaluation of Tinnitus

1. Algorithm A begins with Box 1, in the shape of a rounded rectangle: "Adult patient presents with complaint of or is seeking care for tinnitus"
2. Box 1 connects to Box 2, in the shape of a rectangle: "Health care provider completes history and physical examination (see **Sidebar 1**)"
3. Box 2 connects to Box 3, in the shape of a hexagon, which asks the question, "Does the patient have sounds in their ear or ears or their head that last for at least five minutes?"
    a. If the answer is "Yes" to Box 3, then Box 5, in the shape of a hexagon, asks the question, "Any red flags identified? (see **Sidebar 2**)"
    b. If the answer is "No" to Box 3, then Box 4, in the shape of a rectangle: "Transient ear noise; no need for further evaluation"
4. Box 3 connects to Box 5, in the shape of a hexagon, which asks the question, "Any red flags identified? (see **Sidebar 2**)"
    a. If the answer is "Yes" to Box 5, then Box 6, in the shape of a rectangle: "Refer patient for appropriate specialty urgent/emergent evaluation (see **Sidebar 2**)"
        i. Box 6 connects to Box 7, in the shape of a hexagon, which asks the question, "Have red flags been addressed?"
            1. If the answer is "Yes" to Box 7, then Box 9, in the shape of a rectangle: "Refer to audiology as appropriate for evaluation of hearing and tinnitus impact"
            2. If the answer is "No" to Box 7, then Box 8, in the shape of a rectangle: "Patient referred to appropriate care until red flags resolved"
    b. If the answer is "No" to Box 5, then Box 9, in the shape of a rectangle: "Refer to audiology as appropriate for evaluation of hearing and tinnitus impact"
        i. Box 9 refers to footnote, "If the patient has already been referred to audiology and does not indicate a need for care, then referral to audiology is unnecessary."

5. Box 9 connects to Box 10, in the shape of a rounded rectangle: “Patient with non-bothersome tinnitus and hearing difficulty”; Box 11, in the shape of a rounded rectangle: “Patient with bothersome tinnitus and hearing difficulty”; Box 12, in the shape of a rounded rectangle: “Patient with bothersome tinnitus without hearing difficulty”; Box 13, in the shape of a rounded rectangle: “Patient with non-bothersome tinnitus without hearing difficulty”
6. Box 10 connects to Box 14, in the shape of rectangle: “Provide amplification and tinnitus education”
    a. Box 14 connects to Box 21, in the shape of a rectangle: “Provide routine audiology follow-up care”
    b. Box 21 connects to Box 22, in the shape of a rectangle: “Refer to other services as needed”
7. Box 11 connects to Box 15, in the shape of a rectangle: “Provide amplification and tinnitus education”
8. Box 12 connects to Box 16, in the shape of a rectangle: “Provide tinnitus education”
    a. Box 16 refers to footnote, “Provide low gain hearing aids, sound generators, or both, as appropriate.”
9. Box 13 connects to Box 17, in the shape of a rectangle: “Provide tinnitus education”
10. Box 17 connects to Box 18, in the shape of an oval: “Return to usual care provider”
11. Box 15 and Box 16 connect to Box 19, in the shape of a hexagon, which asks the question, “Is tinnitus still bothersome?”
    a. If the answer is “Yes” to Box 19, then Box 20, in the shape of an oval: “Proceed to **Module B** (for additional tinnitus intervention options)”
    b. If the answer is “No” to Box 19, then Box 21, in the shape of a rectangle: “Provide routine audiology follow-up care”
12. Box 21 connects to Box 22, in the shape of a rectangle: “Refer to other services as needed”

Module B: Managing and Improving Quality of Life

1. Algorithm B begins with Box 23, in the shape of a rounded rectangle: “Patient with tinnitus who completed initial evaluation and wants additional intervention/management (see **Sidebar 3**)”
2. Box 23 connects to Box 24, in the shape of a rectangle: “Patient receives tinnitus education/counseling (see **Recommendation 3** and **Appendix F: Education**)”
3. Box 24 connects to Box 25, in the shape of a rectangle: “Depending on patient characteristics and preferences, the following options are available (not listed in any particular order; see **Sidebar 4**):
    - Educational counseling (see **Recommendation 3**)
    - Hearing aids (see **Recommendation 6**)
    - Cochlear implants for adults who meet candidacy requirements/education (see **Recommendation 8** and **Recommendation 10**)
    - Therapeutic use of sound (see **Recommendation 12**)
    - CBT (see **Recommendation 14**)
    - Other behavioral/mental health interventions (e.g., ACT, MBSR) (see **Recommendation 15**)
    - Sound therapy combined with CBT (see **Recommendation 16**)
    - Sound enrichment with ongoing directed tinnitus education (see **Recommendation 17**)
    - Multidisciplinary assessment and treatment of cervical spine dysfunction, TMD, or both (see **Recommendation 22**)”
4. Box 25 connects to Box 26, in the shape of a hexagon, which asks the question, “Is tinnitus still bothersome?”
    a. If the answer is “Yes” to Box 26, then Box 28, in the shape of a rectangle: “Refer patient to appropriate care until patient no longer wants further intervention”
        i. Box 28 connects to Box 25
    b. If the answer is “No” to Box 26, then Box 27, in the shape of a rectangle: “Provide routine tinnitus maintenance follow-up care (see **Sidebar 5**)”

Appendix M: Glossary

Category	Term	Definition
General	Acute tinnitus	Acute tinnitus refers to recent onset (fewer than six months) and can last for a few minutes, hours, days, or weeks. Its onset might be associated with ear infection, medication, head or neck injury, recent hazardous noise exposure, occluding cerumen, and changes in blood pressure or metabolism.
	Bothersome tinnitus	Tinnitus that affects sleep, concentration, or mood
	Chronic (persistent) tinnitus	Chronic tinnitus (persistence for six months or more) can also result from the conditions listed under *acute tinnitus*.
	Constant tinnitus	Tinnitus that is always present
	Intermittent tinnitus	Tinnitus lasting five or more minutes and occurring at least once per week
	Multidisciplinary	Several different health care specialties working in parallel toward a shared goal for patient care
	Objective tinnitus	Tinnitus audible to another person and associated with vascular abnormalities or mechanical disorders
	Occasional tinnitus	Tinnitus lasting five or more minutes and occurring less than once per week
	Primary tinnitus	Tinnitus that is idiopathic and might or might not be associated with sensorineural hearing loss (7)
	Secondary tinnitus	Tinnitus associated with a specific underlying cause (other than sensorineural hearing loss) or an identifiable organic condition (7)
	Sensorineural hearing loss	Hearing loss caused by damage to the inner ear or the auditory nerve
	Single-sided deafness (SSD)	Unilateral profound sensorineural hearing loss
	Somatosensory tinnitus	Subtype of tinnitus associated with activation of the somatosensory, somatomotor, and visual-motor system A key characteristic of somatosensory tinnitus is that it is modulated by physical contact or movement.
	Subjective tinnitus	Tinnitus heard only by the patient
	Transient ear noise	Perception of sound, usually occurring in one ear at a time and described as high-pitched ringing, lasting fewer than five minutes Transient ear noise does not generally require clinical management.
Assessments	Beck Depression Inventory (BDI)	Questionnaire that assesses self-reported depression with a focus on severity of symptoms
	Generalized Anxiety Disorder 7-item (GAD-7)	Screening tool and indicator of severity of generalized anxiety disorder
	Hospital Anxiety and Depression Scale (HADS)	Questionnaire that assesses psychological distress in non-psychiatric patients with subscales for anxiety and depression

Category	Term	Definition
Assessments (cont.)	Insomnia Severity Index	Seven-item self-report questionnaire that assesses the severity of sleep problems
	Minimum masking level (MML)	Minimum intensity of an acoustic stimulus required to totally mask the tinnitus
	Numeric rating scale (NRS)	Numbered scale (e.g., 0–10 or 0–100) used to quantify the patient's tinnitus characteristics, such as subjective loudness and annoyance
	Patient Health Questionnaire-9 (PHQ-9)	Nine-item questionnaire to assess self-reported depression with a focus on duration of symptoms
	Pure tone average	Average of audiometric thresholds at a set of specific frequencies (e.g., 500, 1000, 2000 Hz)
	Tinnitus Functional Index (TFI)	Twenty-five item questionnaire to assess baseline functional impact of tinnitus and treatment-related changes
	Tinnitus Handicap Inventory (THI)	Twenty-five item questionnaire to assess self-perceived tinnitus handicap
	(Iowa) Tinnitus Handicap Questionnaire (THQ)	Twenty-seven item questionnaire to assess self-perceived tinnitus handicap
	Tinnitus and Hearing Survey (THS)	Nine-item survey to facilitate communication between patient and provider about hearing loss, tinnitus, and sound tolerance
	Tinnitus Primary Function Questionnaire (TPFQ)	Twenty-item questionnaire focusing on the primary activities affected by tinnitus
Interventions	Acceptance and Commitment Therapy (ACT)	Intervention that involves acceptance and mindfulness strategies combined with commitment and behavior-change strategies to increase psychological flexibility
	Acupuncture	Intervention consisting of the insertion of needles at strategic points on a body
	Bone conduction device (BCD)	Hearing device that transmits sound vibrations through the bones of the skull directly to the inner ear, bypassing the outer ear and middle ear The device can either be placed on the skull or be surgically implanted.
	Cochlear implant	Electronic device that stimulates the auditory nerve through electrodes placed in the cochlea, allowing perception of sound
	Cognitive behavioral therapy (CBT)	Form of psychological treatment that targets current problems and symptoms and improves functionality by emphasizing changes in unhelpful ways of thinking and unhelpful behavior and improving ways of coping with problems
	Contralateral routing of signal/ sound (CROS)	Type of hearing aid where a microphone is placed on the ear with little or no hearing and the receiver is placed on the ear with good or better hearing, and signals arriving at the poorer ear are routed to the opposite, better-hearing ear

Category	Term	Definition
Interventions (cont.)	Internet-delivered Cognitive Behavioral Therapy (iCBT)	Type of therapy provided through a computer or mobile device without the direct intervention of a practitioner
	Mindfulness-based stress reduction (MBSR)	Structured intervention based on mindfulness (i.e., attending to the present moment, without judgment) with components of relaxation and meditation
	Motivational interviewing (MI)	Client-centered directive counseling style to enhance the patient's motivation to change their behavior
	Progressive Tinnitus Management (PTM)	Stepped-care program that involves coordinated care between audiology and behavioral health and that includes education on the use of therapeutic sound and CBT coping skill techniques for tinnitus
	Repetitive transcranial magnetic stimulation (rTMS)	Non-invasive form of brain stimulation in which a changing magnetic field is used to induce an electric current at a specific area of the brain through electromagnetic induction An electric pulse generator, or stimulator, is connected to a magnetic coil connected to the scalp.
	Sound therapy	Therapeutic use of sound to reduce self-perceived tinnitus handicap, provide relief or distraction, promote relaxation, and facilitate habituation to tinnitus
	Tinnitus Activities Treatment (TAT)	Audiological tinnitus intervention that includes counseling of the whole person and considers individual differences and needs Four areas are addressed: thoughts and emotions, hearing and communication, sleep, and concentration.
	Tinnitus management	Evidence-based, patient-centered clinical care for tinnitus that focuses on the impact of tinnitus on quality of life, wellbeing, wellness, self-care, improvement of functional status, and management of co-occurring conditions to improve clinical outcomes
	Tinnitus Retraining Therapy (TRT)	Tinnitus intervention comprising educational counseling and sound therapy given according to a specific protocol
	Transcranial direct current stimulation (tDCS)	Neuromodulation approach where constant, low-level direct current is delivered via electrodes placed on the scalp or forehead
	Transcutaneous electrical nerve stimulation (TENS)	Use of a small, battery-operated device to provide continuous electrical impulses via surface electrodes to provide symptomatic relief by modifying tinnitus perception

Appendix N: Abbreviations

Abbreviation	Definition
ACT	Acceptance and Commitment Therapy
APHAB	Abbreviated Profile of Hearing Aid Benefit
BCD	bone conduction device
BFP-T	Brain Fitness Program - Tinnitus
CBT	cognitive behavioral therapy
CI	confidence interval
COI	conflict of interest
COSIT	Client Oriented Scale of Improvement in Tinnitus
CPG	clinical practice guideline
CROS	contralateral routing of signal/sound
CYG	Cistanche Yishen granules
dB HL	decibels hearing level
DBT	dialectical behavioral therapy
DoD	Department of Defense
DOEHRS-HC	Defense Occupational and Environmental Health Readiness System - Hearing Conservation
DHA	Defense Health Agency
EBPWG	Evidence-Based Practice Work Group
FAP	functional analytic psychotherapy
FDA	U.S. Food and Drug Administration
FDT	frequency discrimination training
fMRI	functional magnetic resonance imaging
GAD-7	Generalized Anxiety Disorder 7-item
GB	ginkgo biloba
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
HADS	Hospital Anxiety and Depression Scale
Hz	hertz
iCBT	internet-delivered cognitive behavioral therapy
kHz	kilohertz
KQ	key question
LOC	loss of consciousness
LLLT	low-level laser therapy
MBCT	mindfulness-based cognitive therapy
MBSR	mindfulness-based stress reduction®
MCT	metacognitive therapy
MI	motivational interviewing
MML	minimum masking level

Abbreviation	Definition
MRI	magnetic resonance imaging
mTBI	mild traumatic brain injury
NAM	National Academy of Medicine
NCRAR	National Center for Rehabilitative Auditory Research
NHANES	National Health and Nutrition Examination Survey
NMA	network meta-analysis
NMDA	n-methyl d-aspartic acid
NRS	numeric rating scale of loudness and annoyance
OEF	Operation Enduring Freedom
OIF	Operation Iraqi Freedom
OR	odds ratio
PHA	Periodic Health Assessment
PHQ-9	Patient Health Questionnaire 9-item
PICOTS	population, intervention, comparison, outcome, timing, and setting
PRN	pro re nata
PTM	Progressive Tinnitus Management
PTSD	posttraumatic stress disorder
QoL	quality of life
RCT	randomized controlled trial
rTMS	repetitive transcranial magnetic stimulation
SD	standard deviation
SF-12	12-Item Short Form Health Survey
SF-36	36-Item Short Form Health Survey
SMART	specific, measurable, action-oriented, realistic, timed
SR	systematic review
SSD	single-sided deafness
SSQ	Speech, Spatial, and Qualities of Hearing Scale
TAT	Tinnitus Activities Treatment
TAU	treatment as usual
TBI	traumatic brain injury
tDCS	transcranial direct current stimulation
TENS	transcutaneous electrical nerve stimulation
TFI	Tinnitus Functional Index
THI	Tinnitus Handicap Inventory
THQ	Tinnitus Handicap Questionnaire
~~**THS**~~	~~Tinnitus and Hearing Survey~~
TMD	temporomandibular disorder
TMS	transcranial magnetic stimulation
TQ	Tinnitus Questionnaire

Abbreviation	Definition
TRT	Tinnitus Retraining Therapy
TSI	Tinnitus Severity Index
USL	UpSilent
U.S.	United States
USPSTF	U.S. Preventive Services Task Force
VA	Department of Veterans Affairs
VAHCS	Department of Veterans Affairs Health Care Systems
VAS	Visual Analogue Scale
VHA	Veterans Health Administration
VNS	Visual Numeric Scale
WHOQOL	World Health Organization Quality of Life
WN	White Noise Lite

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