

Clinical Practice Guideline for the Diagnosis and Management of Tinnitus in Korea

Running Title: Clinical Practice Guideline for Tinnitus in Korea

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AUTHOR CONTRIBUTIONS

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ABSTRACT

Standardized, evidence-based guideline for tinnitus management is currently lacking in Korea. This guideline aims to provide evidence-based recommendations for the diagnosis and management of tinnitus in Korean adults, adapted to the Korean healthcare system. A multidisciplinary panel (eight otorhinolaryngologists, one neurologist, one psychiatrist, and one audiologist) conducted systematic literature searches up to 2025 using PubMed, Embase, Cochrane Library, KoreaMed, and KMBASE. Evidence quality was assessed using the GRADE methodology. Nine key clinical questions (KQs) were developed in PICO format, and recommendations were finalized through a modified Delphi process ($\geq 80\%$ agreement threshold).

Imaging is recommended for the evaluation of patients with pulsatile tinnitus or asymmetric hearing loss (Grade B). Tinnitus retraining therapy (TRT) and cognitive behavioral therapy (CBT) are conditionally recommended for patients with tinnitus (Grade B). Hearing aids are conditionally recommended for patients with tinnitus and coexisting hearing loss (Grade B). Sound therapy is conditionally recommended to reduce tinnitus-related distress (Grade B). Neuromodulation (transcranial direct current stimulation (tDCS) or repetitive transcranial magnetic stimulation (rTMS)) is conditionally recommended as an adjunctive treatment (Grade B). Routine zinc and vitamin supplementation are strongly recommended against for tinnitus symptom improvement (Grade D $\dagger$), whereas Ginkgo biloba may be considered for patients with subjective tinnitus (Grade B).

Most available evidence was predominantly of low or very low certainty. This guideline provides the first comprehensive evidence-based framework for tinnitus management in Korea. Behavioral and rehabilitative interventions provided the strongest evidence for reducing tinnitus-related distress. Considerations of Korean National Health Insurance coverage, regional accessibility, and patient preferences were integrated throughout the guideline development process. The primary therapeutic goal is to reduce tinnitus-related distress and improve functional outcomes, thereby enhancing overall quality of life.

KEYWORDS

Tinnitus; Practice Guideline; Republic of Korea; Evidence-Based Medicine; Cognitive Behavioral Therapy; Hearing Aids; Dietary Supplements

HIGHLIGHTS

- First evidence-based clinical practice guideline for tinnitus adapted to the Korean healthcare system, developed using GRADE methodology and modified Delphi consensus ($\geq 80\%$ agreement threshold).
- A multidisciplinary panel of 11 experts developed nine evidence-based recommendations covering imaging evaluation, behavioral therapies, rehabilitative interventions, neuromodulation, and dietary supplements.
- Behavioral and rehabilitative interventions, including cognitive-behavioral therapy, tinnitus retraining therapy, hearing aids, and sound therapy, are recommended for patients with tinnitus (Grade B).
- Neuromodulation (tDCS/rTMS) is conditionally recommended as adjunctive treatment (Grade B); routine zinc and vitamin supplementation are not recommended for tinnitus symptom improvement (Grade D $\dagger$); Ginkgo biloba may be considered for patients with subjective tinnitus (Grade B).
- Korean National Health Insurance coverage, regional accessibility, and patient preference data informed recommendation development and implementation strategies.

INTRODUCTION

Tinnitus, defined as the perception of sound in the absence of an external acoustic stimulus, is a common otologic symptom affecting 10% to 15% of adults worldwide [1-2]. In Korea, a nationwide survey reported a tinnitus prevalence of 19.7% among individuals aged 12 years and older [3]. The condition manifests as ringing, buzzing, hissing, or other phantom sounds, with severity ranging from minor annoyance to severe debilitation. Additionally, although many individuals with tinnitus adapt to their symptoms over time, a substantial proportion experience bothersome tinnitus that significantly impairs their quality of life [4], including sleep disturbances, difficulty concentrating, anxiety, depression, and impaired social functioning [5-6].

Despite the high prevalence and significant impact of tinnitus, management approaches have varied considerably across clinicians and institutions, largely owing to the absence of a standardized, locally tailored guideline specific to the Korean healthcare context. The American Academy of Otolaryngology-Head and Neck Surgery published a comprehensive clinical practice guideline in 2014, which has been a key reference for practitioners worldwide [7]. Additional guidelines have been developed in Germany [8], Europe [9], the United Kingdom [10], and Japan [11], providing frameworks for evidence-based practices adapted to their respective healthcare systems and patient populations.

However, these international guidelines do not adequately address the unique aspects of the Korean healthcare system, thereby necessitating local adaptation. Key considerations include national health insurance coverage policies that affect treatment accessibility, the limited availability of trained providers for specialized interventions, such as cognitive behavioral therapy (CBT) and tinnitus retraining therapy (TRT), along with cultural factors that influence patient preferences and treatment adherence. Therefore, direct application of these international guidelines without contextual adaptation may limit their clinical effectiveness and feasibility in Korea.

The heterogeneity in tinnitus management reflects the complex nature of this condition and the inherent challenges in tinnitus research. As a subjective symptom with variable presentation and substantial placebo effects, high-quality evidence for most tinnitus interventions remains limited [12-13]. Although recent research has contributed to an improved understanding of tinnitus pathophysiology and identified promising management strategies [14-15], the evidence base remains predominantly composed of low- to very-low-quality studies, as reflected in the GRADE assessments presented in this guideline.

This clinical practice guideline represents the first comprehensive, evidence-based framework for tinnitus management specifically developed for Korean adults. Developed through a systematic literature review, application of the GRADE methodology, and expert consensus via a modified Delphi process, this guideline provides nine evidence-based recommendations addressing imaging evaluation, behavioral therapies (TRT and CBT), hearing rehabilitation, sound therapy, neuromodulation, and dietary supplements. By adapting international evidence to the Korean healthcare context, this guideline aims to standardize clinical practice, improve patient outcomes, and support shared decision-making between clinicians and patients.

The primary target users of this guideline are otorhinolaryngologists, primary care physicians, neurologists, psychiatrists, audiologists, and other healthcare professionals involved in tinnitus management. The target population comprises adults (≥ 19 years) with primary tinnitus. Although the guideline predominantly focuses on primary tinnitus without an identifiable underlying pathology, it also incorporates essential diagnostic pathways to identify and evaluate potential secondary causes, including pulsatile tinnitus and asymmetric hearing loss. Pediatric patients were excluded from this guideline because of limited evidence regarding the efficacy of tinnitus interventions in this population and because of distinct clinical considerations in children and adolescents.

The primary therapeutic goal is to reduce tinnitus-related distress and improve functional outcomes, thereby enhancing overall quality of life.

MATERIALS AND METHODS

Target Population

This guideline was developed for application in the Korean healthcare system. The target population comprised adult patients aged ≥ 19 years with tinnitus. The guideline primarily focuses on primary tinnitus, defined as tinnitus for which no specific or treatable underlying cause is identified after standard clinical and audiological evaluation. Pediatric patients (< 19 years of age) and those with objective tinnitus were outside the primary scope of this guideline. Nevertheless, the evaluation of secondary causes, including pulsatile tinnitus and asymmetric hearing loss, is addressed as part of the recommended diagnostic assessment (KQ1).

Guideline Development Group

This clinical practice guideline was developed by a multidisciplinary Guideline Development

Group (GDG) appointed by the Korean Otological Society. GDG members were selected based on the following criteria: (1) board certification in their respective specialty with a minimum of 10 years of clinical experience in tinnitus management or related fields; and (2) active involvement in tinnitus-related clinical practice, research, or guideline development. The GDG comprised 11 experts: eight otorhinolaryngologists, one neurologist, one psychiatrist, and one audiologist. The panel was designed to represent all major clinical domains relevant to tinnitus, including auditory, neurological, and psychological aspects. All panel members disclosed potential conflicts of interest, which were managed in accordance with established guideline development procedures. The guideline development process adhered to the principles outlined in the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument [16]. The GDG operated with full editorial independence.

Literature Search and Selection

A comprehensive systematic literature search was conducted using major international databases (PubMed, Embase, and the Cochrane Library) and Korean (KoreaMed and KMBASE) databases to ensure the inclusion of international and locally relevant evidence. Search strategies incorporated combinations of Medical Subject Heading (MeSH) terms and keywords related to tinnitus, its assessment, and management. The overall methodology of the literature search and evidence appraisal is described in detail in a separate publication.

Studies that addressed the assessment or treatment of chronic tinnitus in adults were included, comprising randomized controlled trials, systematic reviews, meta-analyses, and relevant observational studies. Eligible publications were limited to those published in English or Korean that reported clinically meaningful outcomes, such as tinnitus severity, quality of life, or functional impairment. Studies focusing exclusively on animal models, pediatric populations, acute tinnitus, or objective or pulsatile tinnitus were excluded.

Two reviewers independently screened titles and abstracts, and disagreements were resolved through discussion or consultation with a third reviewer. Full-text articles were obtained and independently reviewed using standardized data extraction methods. The data extracted included study design, patient characteristics, interventions, comparators, outcomes, and results. Quality assessment of included studies was conducted concurrently with data extraction.

Evidence Evaluation

Evidence quality was assessed using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) methodology [17-18]. GRADE categorizes evidence quality as high, moderate, low, or very low based on the study design and factors that may increase or decrease confidence in the evidence. Randomized controlled trials were initially rated as high-quality evidence, whereas observational studies were initially rated as low-quality evidence. Evidence may be downgraded for risk of bias, inconsistency, indirectness, imprecision, or publication bias. Observational studies may be upgraded for large effect sizes, dose-response relationships, or when plausible confounders would reduce the observed effect.

Following the GRADE principles, recommendation strength was determined by considering not only evidence quality but also the balance of benefits and harms, patient values and preferences, and resource implications. Importantly, strong recommendations can be issued even when the certainty of evidence is low or very low, if the overall Evidence-to-Decision (EtD) framework supports a clear direction. The EtD framework encompasses benefits and harms, patient values, resource implications, and equity considerations. For each recommendation in this guideline, the direction and strength were therefore determined by the overall EtD judgment rather than evidence certainty alone; where a discrepancy exists between evidence certainty and recommendation strength, the rationale is explicitly documented within the respective key clinical question.

The recommendations were classified into five categories based on direction and strength, as summarized in Table 1. It is important to note that these recommendation categories are distinct from certainty of evidence, which was assessed separately using the GRADE methodology. A dagger (†) symbol indicates that a strong recommendation was adopted despite low certainty of evidence, based on the overall EtD judgment. For example, Recommendations 7-1 (zinc) and 7-2 (vitamins) received Grade D† (strong recommendation against routine use) despite low certainty of evidence, because the EtD assessment consistently favored placebo across all outcomes and no clinically meaningful benefit was identified.

Two GDG members independently assessed the quality of evidence for each outcome, and disagreements were resolved through discussion. Meta-analyses were conducted using random-effects models when appropriate. Statistical heterogeneity was assessed using the I^2 statistic. Publication bias was evaluated using funnel plots and Egger's tests when a sufficient number of studies were available. The minimum clinically important difference (MCID) for each outcome measure was

determined independently by each KQ working subgroup based on thresholds most widely cited in the tinnitus literature. As no universally agreed-upon MCID exists for tinnitus outcome instruments, values varied across KQs. For the THI, 7 points was applied in KQ6 (neuromodulation) based on Zeman et al. [19] and 10 points in KQ7-3 (Ginkgo biloba); the latter threshold falls within the range of 7.8–12 points reported in recent anchor-based MCID studies [20], reflecting variation inherent to the field and transparently documented within each KQ.

Recommendation Development

Based on the synthesized evidence, the GDG formulated nine key clinical questions (KQs) using the PICO (Population, Intervention, Comparison, Outcome) framework to define the scope of evidence review and guide recommendation development, from which nine evidence-based recommendations were derived. The KQ7 (dietary supplements) was further subdivided into three subrecommendations, addressing zinc (Recommendation 7-1), vitamins (Recommendation 7-2), and Ginkgo biloba (Recommendation 7-3) based on differing evidence bases and clinical usage patterns.

For each question, the panel evaluated the balance between benefits and harm, evidence quality and certainty, and patient values and preferences, as well as resource considerations specific to the Korean healthcare context, including insurance coverage, accessibility, and cost-effectiveness.

Draft recommendations underwent a modified Delphi consensus process to ensure rigorous expert agreement. In the first round, all recommendations were distributed to GDG members who independently rated their agreement using a 5-point Likert scale through anonymized online voting to minimize potential hierarchical bias and promote independent expert judgment. Consensus was defined a priori as $\geq 80\%$ agreement, representing a high threshold that enhances the credibility and reliability of the guideline.

Recommendations that did not achieve this threshold in the first round underwent a second Delphi round with anonymized comments from the panel members explaining their ratings. This iterative process allowed the panelists to reconsider their positions based on peer feedback while maintaining anonymity. Any remaining recommendations without consensus after the two rounds were discussed in face-to-face meetings until an agreement was reached.

Interventions Not Covered in This Guideline

Recommendations concerning validated questionnaire assessments, audiometric evaluations, and pharmacological treatments (e.g., anxiolytics and antidepressants) were not included in the final guideline, following stakeholder consultations during the development process. Regarding pharmacological treatments, anxiolytics and antidepressants were not included as a separate KQ for the following reasons: (1) their primary indication in tinnitus patients is comorbid psychiatric symptoms rather than tinnitus itself; (2) available RCT evidence specifically addressing tinnitus outcomes is limited and heterogeneous; and (3) prescribing decisions are more appropriately guided by psychiatric comorbidity assessment, which falls outside the scope of this guideline.

Patient Preference Survey

Patient values and preferences for this guideline were derived from a cross-sectional survey conducted separately and published independently [21]. Briefly, 45 adults with chronic tinnitus (mean age 50.7 ± 14.8 years; 62.2% male; median tinnitus duration 12 months) attending a tertiary otorhinolaryngology clinic were surveyed between May and June 2025 using a structured 36-item questionnaire in accordance with STROBE guidelines. The questionnaire assessed treatment preferences across 16 key domains, perceived information needs, and their impact on daily functioning. Tinnitus severity was quantified using the Tinnitus Handicap Inventory (THI) and Visual Analog Scale (VAS). These preference data were incorporated into the Evidence-to-Decision (EtD) framework for each key clinical question, along with evidence quality, benefit-harm balance, and resource considerations.

External Review

The draft guideline then underwent extensive external peer review to ensure scientific rigor and clinical applicability. To ensure objectivity, external reviewers were nominated by relevant professional societies and selected based on their clinical expertise and lack of involvement in the guideline development.

The external review panel comprised ten independent experts: four otorhinolaryngologists nominated by the Korean Audiological Society, three neurologists nominated by the Korean Neurological Association, and three psychiatrists nominated by the Korean Neuropsychiatric Association. All external review comments were systematically compiled and reviewed by the GDG. Each comment was addressed through either a revision of the guideline text or a documented explana-

tion for non-incorporation. The final guideline, which incorporated external review feedback, was approved by the board of directors of the Korean Otological Society prior to publication.

RECOMMENDATIONS

To facilitate clinical application, a summary of the recommendations and their strengths is provided in Table 2.

To facilitate clinical application, a stepwise algorithm summarizing the initial evaluation pathway for patients with tinnitus is presented in Figure 1. This algorithm guides clinicians through the identification of emergency signs, warning signs requiring imaging evaluation (KQ1), and routine assessment of patients without red flags, thereby providing a practical framework for the following recommendations.

Although a validated questionnaire assessment (THI/TFI) was not adopted as a separate key clinical question following stakeholder consultation, it remains a recommended component of the standard initial clinical assessment, as reflected in the evaluation pathway.

1. Imaging Studies: Grade B (Conditional For)

Clinicians may consider imaging evaluation in patients with pulsatile tinnitus or asymmetric hearing loss.

(Aggregate evidence quality: Very low, based on observational studies and expert consensus regarding standard practice)

Although most tinnitus cases are primary, a small proportion present secondary manifestations that require targeted intervention. Distinguishing these cases through selective imaging is essential, although routine imaging is limited by its low diagnostic yield in unselected populations. According to the evidence synthesis of 18 studies underlying this guideline, the diagnostic yield varies significantly depending on the clinical presentation.

Pulsatile tinnitus is a high-risk presentation with a substantially higher diagnostic yield than non-pulsatile tinnitus. Multiple retrospective observational studies have consistently demonstrated that imaging can identify the underlying etiology in a substantial proportion of patients with pulsatile tinnitus. Among the 14 studies involving 2,363 patients, the diagnostic rate across individual studies ranged widely from 26.0% to 90.7%, reflecting heterogeneity in patient selection, imaging protocols, and case-mix [22-35]. Early series using conventional angiography and CT reported

diagnostic yields of 26–46% [23,31,34–35], whereas more recent cohorts employing multimodality imaging strategies combining MRI/MRA, CTA, and digital subtraction angiography (DSA) achieved higher rates of 60–90% [28,32–33]. Notably, a substantial proportion of the identified lesions represented potentially treatable vascular conditions such as dural arteriovenous fistula (dAVF), sigmoid sinus wall anomaly, dehiscent jugular bulb, and aberrant carotid artery, supporting a targeted imaging approach in this subgroup [22,24,27–30,32–33].

Regarding specific imaging modalities, MRI combined with MRA is recommended as the initial modality for most patients with pulsatile tinnitus because it identifies vascular and soft tissue lesions without ionizing radiation [22,29]. Carotid duplex ultrasonography may serve as a screening tool for suspected dural arteriovenous fistula (dAVF). Tsai et al. reported a sensitivity of 78% and specificity of 97% for dAVF detection using duplex ultrasonography among 155 patients with pulsatile tinnitus [27]. DSA remains the reference standard for vascular lesion characterization, particularly when noninvasive imaging is inconclusive. Deuschl et al. reported additional diagnostic information in 24% of patients who underwent DSA after initial MRI/MRA [30]. CT angiography (CTA) and CT venography (CTV) are particularly valuable for detecting bony anomalies of the temporal bone, sigmoid sinus wall irregularities, and arterial lesions of the skull base [32–33]. Among 157 patients undergoing combined CTA/CTV, Formeister et al. identified a causative lesion in 90.7% of the cases, demonstrating the high diagnostic yield of arteriovenous phase CT [32].

In patients with asymmetric sensorineural hearing loss, imaging is critical to exclude retrocochlear pathologies, primarily vestibular schwannomas. Although the prevalence of vestibular schwannoma in the general population is extremely low (0.003–0.0052%) [36], studies have found that 12.3% of patients with asymmetric hearing loss and tinnitus exhibit abnormal MRI findings [37–40]. Individuals in this high-risk group showed a 1.34-fold higher relative risk of tumor detection than those with symmetric hearing loss [39].

In contrast, the diagnostic yield in patients with non-pulsatile, symmetric tinnitus is very low and often falls below 1% [40]. Therefore, routine imaging is not cost-effective and should be reserved for patients with focal neurological signs, asymmetric audiometric thresholds, or pulsatile characteristics. When imaging is performed and the results are negative, clinicians should use this information to provide patient reassurance as serious structural pathologies have been excluded. Although imaging evaluation has clinical value in appropriate presentations, current evidence is in-

sufficient to support its routine use in all patients with tinnitus, and clinical judgment based on individual risk factors, diagnostic sensitivity, accessibility, and cost considerations remains essential.

2. Tinnitus Retraining Therapy (TRT): Grade B (Conditional For)

Clinicians may consider tinnitus retraining therapy (TRT) for patients with tinnitus.

(Aggregate evidence quality: Very low, based on small randomized controlled trials with significant methodological limitations)

Notably, TRT is a structured treatment approach combining directive counseling based on a neurophysiological model with sound therapy using sound generators or environmental sound enrichment. Based on the evidence synthesis underlying this guideline, four randomized controlled trials involving adult patients with tinnitus (duration >3 months) were analyzed to evaluate the efficacy of TRT compared with no treatment, standard care, or general counseling.

The clinical efficacy of TRT has been variable and inconsistent across studies. Henry et al. (2007) reported that after 12 months, the TRT group showed a reduction in Tinnitus Severity Index (TSI) scores by 3.0 ± 6.6 points, compared with a 0.5 ± 4.9 point reduction in the control group [41]. Bauer et al. (2011) observed a modest improvement in Tinnitus Handicap Inventory (THI) scores, with a reduction of 12.8 ± 14.5 points in the TRT group versus 8.7 ± 14.0 points in the control group [42]. Bauer et al. (2017) demonstrated that when TRT was combined with hearing aids in patients with sensorineural hearing loss, the THI score decreased by 35.8 ± 16.5 points, significantly outperforming the control group's reduction of 18.0 ± 19.3 points [43]. However, Scherer et al. (2019), in a larger multicenter trial (151 participants), found no statistically significant difference in Tinnitus Functional Index (TFI) scores between TRT and standard care groups at 6 months (mean difference -1.1 points, 95% CI -8.1 to 5.9), with no evidence of sustained or clinically meaningful benefit at longer follow-up periods, indicating that TRT did not provide clinically meaningful benefits over standard care in this population [44].

The overall quality of evidence was considered very low because of the small sample sizes in earlier studies (16–74 patients), substantial inconsistencies in effect sizes across trials, challenges in blinding behavioral interventions, and the inability to fully exclude placebo effects and the natural course of tinnitus. Furthermore, TRT requires a significant time commitment, typically in-

volving directive counseling sessions lasting 1 to 1.5-h counseling sessions and at least 8 h of daily sound therapy over a period of 12 to 24 months [43].

In the Korean clinical setting, the availability of trained TRT practitioners is limited and intensive counseling sessions are generally not covered by the National Health Insurance System. Therefore, TRT should be considered primarily for motivated patients with bothersome tinnitus who understand the prolonged nature of treatment and have realistic expectations regarding its outcomes. Nevertheless, current evidence does not establish the superiority of TRT over other sound-based or counseling approaches, and the choice between available interventions should be guided by individual patient circumstances, preferences, and treatment accessibility.

3. Cognitive-Behavioral Therapy (CBT): Grade B (Conditional For)

Clinicians may consider cognitive-behavioral therapy (CBT) for patients with tinnitus.

(Aggregate evidence quality: Low, based on systematic reviews and multiple randomized controlled trials demonstrating significant improvements, though with some methodological limitations and heterogeneity)

Cognitive-behavioral therapy (CBT) is an evidence-based psychological intervention designed to modify maladaptive cognitive and behavioral responses to tinnitus. In addition to face-to-face delivery, Internet-based CBT (ICBT) and smartphone app-based CBT have emerged as accessible alternatives. Based on the evidence synthesis underlying this guideline, five RCTs involving patients with chronic subjective tinnitus were analyzed.

Beukes et al. (2018) enrolled 146 patients (72 and 74 patients in the intervention and control groups, respectively) in an 8-week audiologist-guided ICBT program. The completion rates were 72% and 78% in the intervention and control groups, respectively. At 8 weeks, the TFI decreased by an average of 21 points in the intervention group versus 5 points in the control group; 51% of intervention participants achieved clinically significant improvement versus 5% of controls, and 41% of the intervention group reached a TFI score below 25, indicating minimal tinnitus impact. Treatment gains were fully maintained at the 2-month follow-up [45]. Walter et al. (2025) randomized 187 patients (94 in the intervention group and 93 controls) to immediate versus delayed (3-month waitlist) smartphone-based CBT (Kalmeda application) for 9 months. Pooled analysis showed TQ score reductions of 12.49 points at 3 months (Cohen's $d=1.15$) and 18.48 points at 9 months (Co-

hen's $d=1.38$), both $p<0.001$, indicating very large effect sizes [46]. Walter et al. (2023) reported that in the first 3-month controlled period (163 completers), the intervention group showed a TQ reduction of 13.36 ± 1.00 points ($p<0.0001$) versus 0.63 ± 0.98 points in the waitlist group ($p=0.517$), with a between-group difference of 12.73 ± 1.38 points (Cohen's $d=1.10$, 95% CI 0.85–1.41); clinically meaningful improvement (MCID ≥ 6.65 points) was achieved in 72.7% of the intervention group versus 22.0% of controls ($p=0.0001$) [47]. Weise et al. (2016) enrolled 124 patients in a 10-week ICBT trial (62 patients per group; completion rate $>83.7\%$). The ICBT group showed a large between-group effect on THI scores (from 53.39 to 32.56; Hedges $g=0.85$, 95% CI 0.47–1.20) and on the Mini-TQ (from 16.19 to 8.51; $g=1.08$, 95% CI 0.71–1.64). Clinically reliable change (RCI) was achieved in 72.6% on the THI and 76.6% on the Mini-TQ, with high-functioning status (RCI met and THI ≤ 36) in 56.5%; within-group effect sizes at follow-up were $1.38 \leq d \leq 1.77$ [48]. McKenna et al. (2017) randomized 85 patients to an 8-week group mindfulness-based cognitive therapy (MBCT; $n=39$) or relaxation training (RT; $n=36$). TQ scores decreased significantly in both groups; MBCT achieved a 6.3-point greater reduction than RT at post-treatment (95% CI 1.3–11.4, $p=0.016$) and a 7.2-point greater reduction at the 6-month follow-up (95% CI 2.1–12.3, $p=0.006$), with an effect size of 0.56 (95% CI 0.16–0.96). TFI also improved significantly in both groups (MBCT: 63.2 $\rightarrow$ 42.2; RT: 66.5 $\rightarrow$ 49.2), with MBCT showing significantly greater TFI reduction at the 6-month follow-up ($p=0.01$) [49].

A systematic review of the evidence further supports the efficacy of CBT. Martinez-Devesa et al. (2010) analyzed eight RCTs (468 participants) and identified CBT as effective in reducing tinnitus-related distress. No serious adverse events were reported across the included studies, supporting its favorable safety profile [50].

The overall quality of evidence was rated as low because of challenges in blinding, heterogeneity in CBT delivery formats and outcome measures, and attrition across trials. The overall benefit-harm balance favors CBT as an intervention.

In a Korean patient preference survey, 44.4% of respondents expressed active interest in CBT, and 51.1% required more information before deciding, with only 4.4% declining treatment. The preferred delivery formats were one-on-one face-to-face counseling (40.0%), structured institutional programs (22.2%), online/mobile self-directed learning (20.0%), and small-group therapy (6.7%) [21]. The high proportion of patients requiring additional information underscores the need for patient education and diverse delivery modalities to improve patient accessibility and acceptance.

In Korean clinical settings, face-to-face CBT requires trained specialists (psychiatrists and clinical psychologists) and is currently classified as a non-reimbursed service by the National Health Insurance System. In Korea, a domestic smartphone app-based CBT program has received approval as a digital therapeutic from the Ministry of Food and Drug Safety (MFDS); however, it remains outside national health insurance coverage. This program is distinct from the Kalmeda application referenced in the clinical evidence above, which was developed in Germany. Geographic and cost barriers may limit access in primary care settings and rural areas, and ICBT and app-based CBT represent important alternatives for improving equity. CBT is effective not only for tinnitus-related functional disability but also for comorbid emotional (e.g., depression and anxiety) and cognitive and behavioral problems, such as avoidance behaviors and sleep disturbance. Accordingly, CBT should be prioritized in patients with high tinnitus-related distress and comorbid emotional or psychiatric symptoms.

4. Hearing Aids: Grade B (Conditional For)

Clinicians may consider hearing aids for patients with tinnitus and co-existing hearing loss. (Aggregate evidence quality: Low, based on systematic reviews and multiple observational studies, with limited randomized controlled trials)

Hearing aids are an established intervention for patients with bothersome tinnitus and concomitant hearing loss. According to the evidence synthesis underlying this guideline, three studies involving 241 adults (intervention: 123, control: 118) with tinnitus lasting ≥ 12 months and co-existing hearing loss were analyzed [51-53]. The mean age was 55.7 years (range, 41–71 years), with a similar sex distribution between the groups.

Kam et al. (2024) conducted the sole RCT among the included studies, enrolling 38 participants in a 3-arm trial comparing informational counseling (IC) only (n=12), IC with hearing aid fitting (n=13), and IC with individualized music stimulation (n=13) over 12 months. A statistically significant treatment difference was observed among the three groups in the Chinese Tinnitus Functional Index (TFI-CH) at 12 months ($F=3.34$, $p=.04$, partial $\eta^2=.16$). Only the hearing aid group showed a significantly greater treatment effect than the IC-only group (TFI-CH MD -21.77), supporting combined hearing aid use and counseling for patients with mild hearing loss [51]. Lee et al. (2022) conducted a retrospective cohort study of 116 patients with tinnitus and hearing loss; 59

patients chose hearing aid fitting alongside counseling and 55 received counseling alone. At 6 months of follow-up, THI improvement was statistically significant only in the hearing aid group, and between-group VAS differences were also statistically significant (MD -0.85 for tinnitus loudness on VAS) [52]. Folmer and Carroll (2006) followed 150 patients for 6–48 months after the initial evaluation: 50 used hearing aids (alone, without counseling), 50 used sound generators, and 50 did not use ear-level devices. Hearing aid users showed a 23% reduction in Tinnitus Severity Index (TSI) scores (MD -4.20), with VAS tinnitus loudness decreasing from 7.5 to 6.3 [53].

In the meta-analysis of these three studies, VAS tinnitus intensity showed no statistically significant between-group difference for the RCT (MD -0.85 , 95% CI -2.26 to 0.60) or non-randomized studies (MD -0.17). However, THI in the non-randomized studies showed a significant reduction (MD -12.30 , 95% CI -19.59 to -5.01), and secondary outcomes TFI-CH (MD -21.77) and TSI (MD -4.20) also demonstrated significant effects. The overall pooled THI estimate showed an MD of -10.13 (95% CI -21.57 to 1.31), with the confidence interval crossing zero. More than 70% of participants experienced symptom relief, and effect sizes were larger in those with co-existing hearing loss (THI reduction -10 to -20 points).

The certainty of evidence was rated as low owing to three factors: high selection bias from retrospective designs in 66.7% of the studies, imprecision because the confidence interval of the pooled THI estimate crossed zero, and limited sample size (mean 76.3 participants per study). Notably, hearing aids may cause harm in specific populations. In patients with reactive tinnitus or hyperacusis, amplified sounds may exacerbate symptoms, and adverse effects have been reported in those with normal hearing.

In a Korean patient preference survey, only 26.7% of respondents expressed an active interest in hearing aids, the lowest among all treatment modalities, whereas 33.3% declined (the highest refusal rate) and 40.0% required more information [21]. Among the factors considered most important when selecting a hearing aid, tinnitus relief efficacy was rated the highest (57.8%), followed by hearing improvement (26.7%), comfort and convenience (17.8%), and cost and insurance coverage (13.3%). The relatively high refusal rate suggests that patients' concerns about appearance, cost, and comfort may significantly influence treatment decisions and that thorough pre-treatment counseling on benefits and limitations is essential.

In Korean clinical settings, high initial acquisition costs and limited insurance reimbursements create access disparities, particularly for low-income patients, older adults, and those living in rural

areas. This was rated as the most unfavorable equity impact among all KQs in this guideline. However, hearing aids serve the dual purpose of correcting hearing loss while providing additional tinnitus relief benefits, and are considered feasible for implementation in clinical practice. Expert evaluation before fitting is essential in patients with reactive tinnitus or hyperacusis. Although hearing aids are recommended for hearing loss interventions, evidence for tinnitus relief remains limited. Clinical judgments incorporating the degree of hearing loss and tinnitus, patient discomfort, and individual preferences should guide the decision to prescribe hearing aids.

5. Sound Therapy: Grade B (Conditional For)

Clinicians may consider sound therapy for patients with tinnitus to reduce tinnitus-related distress.

(Aggregate evidence quality: Low, based on observational studies and limited randomized trials with methodological limitations)

Sound therapy encompasses a range of interventions — including sound generators, notched music, music therapy, and white/pink noise embedded in hearing aids or extended-wear devices — that aim to reduce the perceived prominence of tinnitus through acoustic enrichment. Although TRT (KQ2) incorporates sound therapy as a structural component, TRT and sound therapy were evaluated as distinct key questions in this guideline; KQ2 addresses the full TRT protocol, including directive counseling, whereas KQ5 focuses specifically on the acoustic enrichment component of sound therapy, independent of structured counseling. Scherer et al. (2019), included in both KQs, is cited in KQ2 for its evaluation of the overall TRT protocol and in KQ5 specifically for its sound therapy outcomes. This distinction is clinically meaningful: TRT is a structured, therapist-delivered program requiring trained practitioners and a prolonged treatment commitment, whereas sound therapy as addressed in KQ5 encompasses a broader and more accessible category of acoustic interventions that can be delivered independently of formal TRT protocols. By separating these KQs, the guideline allows clinicians to consider the acoustic component of treatment based on individual patient circumstances and available resources. According to the evidence synthesis underlying this guideline, six RCTs involving adult patients with subjective tinnitus were analyzed. Comparators included placebo sound generators, hearing aid amplification alone, or counseling without sound therapy, with follow-up periods of 12–24 weeks. The primary outcomes included

VAS (loudness/annoyance), TFI, THI, and TQ.

Scherer et al. (2019) conducted a large multicenter RCT comparing TRT, which incorporates structured sound therapy alongside directive counseling, with standard care and found no statistically significant between-group differences in tinnitus-related quality of life outcomes [44]. Dos Santos et al. (2014) evaluated sound generators combined with conventional amplification versus amplification alone in a randomized blind clinical trial [54]. Henry et al. (2015) validated a combination hearing aid and tinnitus therapy device by comparing combination instruments with hearing aids alone and found no clear superiority of the combination devices in most tinnitus outcomes [55]. Henry et al. (2017) compared extended-wear hearing aids, conventional hearing aids, and combination instruments in a multicenter RCT trial with within-group improvements across all amplification strategies [56]. Tong et al. (2023) compared tailor-made notched music training (TMNMT) to TRT in a randomized trial, reporting improvements in both groups but no significant between-group difference [57]. Argstatter et al. (2015) evaluated neuro-music therapy according to the Heidelberg model versus a single educational counseling session and reported benefits in the music therapy group [58].

In the meta-analysis of these six RCTs, sound therapy demonstrated a statistically significant improvement only on VAS (MD -0.78). For the TFI, THI, and TQ, the confidence intervals crossed zero, indicating uncertain and limited benefits for these primary tinnitus distress outcomes. No serious adverse events were reported in the included RCTs, confirming that the harm was minimal. The overall net benefit is considered small or uncertain, and the available evidence is insufficient to support sound therapy as a routine first-line treatment. However, the favorable harm-benefit ratio supports its use as an adjunctive intervention.

The certainty of evidence was rated as low because of unclear randomization procedures, inadequate allocation concealment, limited blinding, small sample sizes, heterogeneity in treatment protocols, and variation in outcome measures across trials.

In a Korean patient preference survey, 72.3% of respondents expressed an active desire to receive sound therapy, which was the highest acceptance rate among all interventions evaluated [21]. However, more than half of the respondents expected complete resolution of tinnitus, underscoring the importance of realistic expectation-setting and thorough patient education regarding the expected effects and limitations of sound therapy before initiating treatment.

Regarding equity and resources, the cost of sound generators and requirements for digital literacy

may create access barriers for economically vulnerable populations, older adults, and those in rural areas. Conversely, high smartphone penetration rates and availability of otorhinolaryngology services in Korea are facilitating factors for app-based sound therapy implementation. Improvements in reimbursement policies, digital accessibility, and availability of low-cost devices are required to ensure equitable access.

Sound therapy is generally recommended as part of a multimodal management strategy rather than as a standalone treatment. Clinicians should provide pre-treatment education on realistic expectations, costs, and safe volume management, and should implement regular monitoring during treatment. Because sound therapy may help divert attention from tinnitus and reduce the associated emotional distress, it is most appropriately used in combination with tinnitus counseling, TRT, or cognitive behavioral therapy.

6. Neuromodulation: Grade B (Conditional For)

Clinicians may consider neuromodulation techniques (tDCS or rTMS) as adjunctive treatment for patients with tinnitus.

(Aggregate evidence quality: Low for tDCS, based on randomized controlled trials with small sample sizes and heterogeneous stimulation protocols; Low–Moderate for rTMS, based on randomized controlled trials showing modest and inconsistent effects)

Neuromodulation techniques, including transcranial direct current stimulation (tDCS) and repetitive transcranial magnetic stimulation (rTMS), aim to modify the aberrant neural activity and maladaptive plasticity underlying tinnitus through external electrical or magnetic stimulation. This guideline evaluated six tDCS RCTs and eight rTMS RCTs in adults with subjective tinnitus. Although both modalities share the same conditional recommendation, their evidence profiles differ. tDCS demonstrated a clinically meaningful reduction in tinnitus handicap, exceeding the minimum clinically important difference in a meta-analysis, whereas rTMS showed only modest, inconsistent effects that did not meet this threshold in most large controlled trials. Clinicians should consider this difference when discussing treatment options.

tDCS

Abtahi et al. (2018) enrolled 51 patients (35 completers) in a double-blind, randomized, sham-

controlled trial comparing left temporal area (LTA) and right DLPFC cathodal tDCS versus bifrontal tDCS (2 mA, 20 min/session, 5 sessions/week, 10 sessions over 2 weeks). In the anodal group, THI decreased from 72.93 ± 10.11 to 46.40 ± 15.36 immediately after treatment (reduction: 26.53 points, 36.4%) and was maintained at the 1-month follow-up (49.68 ± 14.49 ; 23.25-point improvement, 31.9%). Clinically meaningful response (THI reduction ≥ 20 points) was observed in 72% (18/25) of participants [59]. Han et al. (2024) enrolled 30 patients with normal hearing and severe subjective tinnitus in a prospective, randomized, single-blind, sham-controlled trial that compared single- and dual-session bilateral prefrontal tDCS (left F3 anode/right F4 cathode: 2 mA, 20 min, twice weekly for 4 weeks). The dual-session group ($n=11$, baseline THI 76.36 ± 11.41) showed significant THI improvement at 4 ($p=0.007$) and 8 weeks ($p=0.008$); the single-session group ($n=10$, baseline THI 76.00 ± 14.58) also improved similarly (4 weeks $p=0.012$, 8 weeks $p=0.011$); whereas the sham group ($n=9$, baseline THI 73.67 ± 9.70) showed no significant change. VAS loudness improved significantly from week 2 in both active groups (single-session baseline 7.10 ± 1.66 ; dual-session baseline 6.90 ± 1.76 ; $p<0.01$), whereas the sham group (baseline 7.22 ± 1.20) showed improvement only at week 8 ($p=0.024$). Beck Depression Inventory (BDI) improved significantly in the dual-session group (baseline 18.45 ± 9.13) at 4 ($p=0.005$) and 8 weeks ($p=0.003$), but not in the single-session (baseline, 22.7 ± 7.48) or sham groups (baseline 19.77 ± 8.73). THI ≥ 20 -point improvement rates were 50.0% (single-session) and 45.5% (dual-session) versus 22.2% (sham; $p=0.008$ and $p=0.011$, respectively) [60]. Hyvärinen et al. (2016) randomized 43 patients (35 analyzable) to self-administered home tDCS in a double-blind, sham-controlled trial (LTA anodal or bifrontal: 2 mA, 20 min, 10 consecutive days). The overall THI decreased by a mean of 5.0 points ($p<0.05$); however, there was no significant between-group difference. Group-level changes were as follows: LTA anodal ($n=10$): $37.2 \pm 17.8 \rightarrow 32.8 \pm 17.5$ (-4.4 ± 11.2); bifrontal ($n=9$): $40.2 \pm 15.0 \rightarrow 34.2 \pm 23.4$ (-6.0 ± 13.1); sham ($n=11$): $54.4 \pm 21.5 \rightarrow 49.6 \pm 22.6$ (-4.7 ± 11.1); $F(2,27)=0.05$, $p=0.95$ [61]. Yadollahpour et al. (2024) randomized 48 patients with tinnitus refractory to bilateral auditory cortex tDCS (left AC anode/right AC cathode; $n=26$) or sham ($n=22$; 2 mA, 20 min, 5 sessions/week for 2 weeks) using a double-blind RCT. The tDCS group showed highly significant improvements in THI and VAS scores (loudness and distress) compared with the sham group ($p<0.001$). Age, sex, tinnitus duration, laterality, and baseline THI were not significantly associated with treatment response [62]. Souza et al. (2020) randomized 24 patients to receive LTA anodal/right DLPFC cathodal tDCS ($n=12$) or sham tDCS ($n=12$; 2 mA,

20 min, 5 consecutive days) in a double-blind sham-controlled trial. THI in the active group decreased from 53.00 ± 22.94 to 40.6 ± 18.1 post-treatment and was maintained at 42.1 ± 20.3 at 1 month; the sham group showed virtually no change (baseline 44.17 ± 18.76 ; post: 43.7 ± 16.3 ; 1 month: 45.8 ± 18.7). The group $\times$ time interaction was significant ($F(1,22)=13.53$, $p<0.0001$; $\eta^2=0.381$). VAS annoyance decreased significantly in the active group (baseline 7.50 ± 1.51) versus no change in the sham group (baseline, 7.50 ± 2.02 ; $t(22)=-5.322$, $p<0.001$). VAS loudness decreased from 7.36 ± 0.77 to 5.60 ± 1.78 (active) versus 7.47 ± 0.91 to 6.76 ± 1.52 (sham; $p=0.036$). EEG analysis revealed significant decreases in theta band power across 804 voxels (limbic, frontal, and parietal regions) and beta-1 band power across two voxels (temporal region) [63]. Pal et al. (2015) randomized 42 patients to receive auditory cortex cathodal/prefrontal anodal tDCS ($n=21$) or sham tDCS ($n=21$; 2 mA, 20 min, 5 consecutive days) in a double-blind, parallel RCT. THI showed a gradual but nonsignificant decline: active group $46.7 \pm 20.0 \rightarrow 42.1 \pm 20.3$ (1 month) $\rightarrow 39.6 \pm 21.8$ (3 months); sham group $46.4 \pm 18.2 \rightarrow 45.8 \pm 18.7$ (1 month) $\rightarrow 45.0 \pm 20.0$ (3 months); $F(1,22)=1.02$, $p=0.32$. Cohen's d was 0.08 (95% CI -0.52 to 0.69) at 1 month and 0.18 (95% CI -0.43 to 0.78) at 3 months. Secondary outcomes including the Subjective Tinnitus Severity Scale (STSS), Hospital Anxiety and Depression Scale (HAD), and VAS tinnitus intensity also showed no significant treatment effect [64].

rTMS

Rossi et al. (2007) applied 1 Hz rTMS to the left temporoparietal area (120% MT, 1200 pulses/day, 5 days) in a randomized, double-blind, crossover, sham-controlled trial (active $n=14$, analyzed). Active rTMS produced a 35% improvement in perceived tinnitus loudness from baseline, whereas the sham treatment showed no significant change. However, the therapeutic effect was transient, with a tendency to return to baseline levels by 2 weeks post-treatment [65]. Hoekstra et al. (2013) applied bilateral auditory cortex 1 Hz rTMS (110% MT, 2000 pulses/hemisphere, 5 consecutive days) to 50 patients (active, $n=26$; sham, $n=24$) in a prospective, randomized, sham-controlled trial with a 6-month follow-up. Both groups improved over time, but neither TQ (primary outcome) nor THI showed a significant between-group difference (THI: $45.0 \pm 21.0 \rightarrow 41.0 \pm 19.0$ in the active group vs $44.0 \pm 22.0 \rightarrow 43.0 \pm 24.0$ in the sham group). In the severe tinnitus subgroup (baseline TQ >35), the active group showed a greater improvement trend (TQ reduction of 5 points vs. 1 point) [66]. Piccirillo et al. (2013) applied left temporoparietal 1 Hz rTMS (110% MT, 5

sessions/week for 4 weeks, 20 sessions in total) to 14 patients in a crossover, double-blind RCT. Active rTMS produced a median THI reduction from 52 (range, 34–92) to 47 (range, 18–78; reduction, 10 points), and sham rTMS from 52 to 44 (range, 16–79; reduction, 6 points). The median between-group difference was 4 points (95% CI –9 to 10; $p=0.36$). Notably, THI $\geq 25\%$ improvement was achieved by three patients in the active group versus four in the sham group [67]. Bilici et al. (2015) randomized 74 patients to receive 1 Hz rTMS ($n=15$), 10 Hz rTMS ($n=15$), 1 Hz rTMS + paroxetine ($n=15$), paroxetine alone ($n=15$), or sham ($n=15$) for 2 weeks (110% MT, 5 sessions/week, 10 sessions). 1 Hz and 10 Hz rTMS groups showed significant THI reductions (1 Hz: $58.7 \pm 24.7 \rightarrow 40.7 \pm 24.3$, $p=0.005$; 10 Hz: $42.7 \pm 18.9 \rightarrow 33.6 \pm 17.7$, $p=0.001$), whereas sham showed no change ($42.4 \pm 21.4 \rightarrow 43.1 \pm 20.4$). The 1 Hz rTMS + paroxetine group showed a non-significant reduction ($44.5 \pm 26.8 \rightarrow 38.3 \pm 26.5$, $p=0.126$) with no additional benefit over rTMS alone [68]. Landgrebe et al. (2017), in the largest multicenter RCT ($n=163$), applied 1 Hz rTMS to the left primary auditory cortex (110% MT, 2000 pulses/session, 10 sessions over 2 weeks). TQ change was 0.5 points in active ($n=71$; baseline $43.1 \pm 14.7 \rightarrow 42.7 \pm 15.8$) and sham groups ($n=74$; baseline $42.1 \pm 13.8 \rightarrow 42.6 \pm 16.5$); the adjusted mean difference was 1.0 point (95.19% CI –3.2 to 1.2, $p=0.36$). No secondary outcomes, including the THI, depression, or quality of life, showed significant between-group differences [69]. Sahlsten et al. (2017) applied electric field-navigated 1 Hz rTMS to the left auditory cortex (10 sessions over 2 weeks) in 39 patients (active, $n=19$; sham, $n=20$) with a 6-month follow-up. VAS loudness decreased in both groups (active: $56.3 \pm 14.5 \rightarrow 36.0 \pm 14.0$; sham: $61.9 \pm 14.1 \rightarrow 42.0 \pm 19.0$) without significant between-group difference. Clinically meaningful responder rates (VAS + THI improvement) were numerically higher in the active group at 1 month (42% vs. 15%, $p=0.082$) and 3 months (37% vs. 10%, $p=0.065$); however, the difference was not statistically significant [70]. Li et al. (2022) randomized 104 patients with unilateral tinnitus to ipsilateral ($n=29$), contralateral ($n=23$), bilateral ($n=30$), or sham ($n=22$) 1 Hz rTMS (110% MT, 10 sessions over 2 weeks). Ipsilateral stimulation significantly reduced VAS scores ($5.8 \pm 1.8 \rightarrow 4.5 \pm 1.9$, $p<0.05$), with the greatest reduction in patients with left-sided tinnitus ($5.8 \pm 2.0 \rightarrow 4.3 \pm 1.9$). Bilateral stimulation also reduced VAS ($4.5 \pm 2.1 \rightarrow 3.9 \pm 2.2$, $p<0.05$), but only in left-sided tinnitus patients ($4.6 \pm 2.2 \rightarrow 3.7 \pm 2.1$). Overall responder rates ($\geq 10\%$ VAS reduction) were 56.1% (ipsilateral), 46.7% (bilateral), 8.3% (contralateral), and 8.3% (sham) [71]. Folmer et al. (2015) randomized 64 patients to temporal cortex 1 Hz rTMS ($n=32$; baseline TFI 44.8 ± 19.4) or sham ($n=32$; baseline TFI 40.6 ± 22.2 ; $\leq 110\%$ MT,

2000 pulses/session, 10 sessions over 2 weeks) with 26-week follow-up. Active rTMS produced a mean TFI reduction of 13.8 points (30.8%) versus 2.9 points (7.1%) in the sham group at 26 weeks. Responder rates (TFI improvement ≥ 7 points) were 56% (18/32) in the active group versus 22% (7/32) in the sham group ($p < 0.005$). All 11 patients with baseline TFI ≥ 50 in the active group responded, compared with 4/11 in sham. These effects were maintained for 26 weeks with no serious adverse events [72].

Meta-analysis and Summary

In the meta-analysis, tDCS reduced THI by a mean of 10.47 points (95% CI -15.13 to -5.77) compared with sham, exceeding the MCID of 7 points; effects were larger and more sustained with multi-session, higher-dose protocols. By contrast, rTMS showed THI reductions of -1.68 points within 6 months and -2.94 points beyond 6 months, neither meeting the MCID; the VAS standardized mean difference was -0.31 . The overall net benefit was estimated to be small to moderate for tDCS and small for rTMS. The adverse events for both modalities were mild and transient, including skin irritation, headache, and transient tinnitus exacerbation, with no serious adverse events reported. The certainty of evidence was rated as low for tDCS, moderate for rTMS within 6 months, and low for rTMS beyond 6 months (based on THI outcomes). The clinical applicability of both modalities remains limited by substantial protocol heterogeneity across trials, uncertain durability of treatment effects beyond short-term follow-up, and the potential contribution of sham-response to observed improvements, particularly in studies with small sample sizes. In a Korean patient preference survey, 51.1% ($n=23$) of patients required additional information before deciding on neuromodulation, 31.1% ($n=14$) expressed active interest, and 17.8% ($n=8$) declined. Efficacy and success rates were rated as the most important factors in treatment decisions (57.8%), followed by safety and adverse effects (22.2%) [21]. The most common concern was worsening tinnitus (60.0%), underscoring the need for shared decision-making supported by standardized decision aids, with realistic goal setting framed as improvements in loudness, distress, and quality of life.

Regarding resources and equity, tDCS equipment costs approximately 20–30 million KRW and rTMS costs 40–100 million KRW; neither modality is currently covered by the national health insurance for tinnitus. rTMS has out-of-pocket costs of 50,000–200,000 KRW per session and is available only at academic hospitals and specialized centers, creating significant regional and eco-

nomic access disparities. Quality gaps may also arise between institutions depending on the availability of neuronavigation. Neuromodulation is positioned as an adjunctive rather than a first-line treatment, reserved for patients with severe refractory tinnitus who have not responded adequately to standard treatments (TRT, CBT, and sound therapy) and should be performed only at experienced institutions. In patients with an inadequate response to standard treatments, neuromodulation may be selectively considered as an adjunctive option, depending on patient preference, cost, and accessibility.

7-1. Zinc: Grade D[†] (Strong Against Routine Use)

Clinicians should not recommend zinc supplementation as routine treatment for tinnitus symptom improvement.[†]

(Aggregate evidence quality: Low, based on randomized controlled trials showing lack of efficacy)

Three RCTs involving adult patients with tinnitus were analyzed according to the evidence synthesis underlying this guideline. Similarly, a Cochrane systematic review found insufficient evidence supporting zinc supplementation for tinnitus relief in the general population [73].

Paaske et al. (1991) conducted a double-blind, placebo-controlled trial in Denmark, enrolling 48 patients (zinc group, n=23; placebo group, n=25; age, 29–77 years; mean, 60 vs. 48 years; 31 male and 17 female). Zinc sulfate (ZnSO₄) 100 mg (equivalent to 22 mg elemental Zn²⁺) was administered orally three times daily for 8 weeks. The primary outcome was a Tinnitus Score (0–10). Clinically meaningful improvement was not observed in either group; 2 patients in the zinc group versus 2 in the placebo group showed improvement (p=1.0). The dropout rate was approximately 4% and no serious adverse events were reported [74]. Arda et al. (2003) conducted a randomized, prospective, placebo-controlled trial in Turkey that enrolled 41 patients (zinc, n=28; placebo, n=13). The Zn group received 50 mg Zn daily for 8 weeks. Although a trend toward improvement was observed — tinnitus loudness decreased from 59.6 to 49.9 dB (reduction, 9.7 dB) and subjective tinnitus score decreased by a mean of 1.41 points — neither change was statistically significant (tinnitus loudness: p=0.23; tinnitus score: p=0.08). The dropout rate was 6.7% in the zinc group and 35% in the placebo group [75]. Coelho et al. (2013) conducted a randomized, placebo-controlled, crossover trial in Brazil enrolling 116 elderly patients aged ≥60 years (mean age approxi-

mately 67.5 years; 66% male, 34% female). Zinc sulfate (ZnSO_4) 220 mg was administered daily for 16 weeks. Of the 89 patients included in the analysis, the proportion achieving ≥ 20 -point improvement in Tinnitus Handicap Questionnaire (THQ) was 5% (5/93) in the zinc group versus 2% (2/94) in the placebo group; tinnitus loudness change was also not statistically significant. Dropouts occurred in 13 (zinc) and 15 (placebo) patients, primarily because of gastrointestinal discomfort, metallic taste, and constipation [76].

In the meta-analysis, zinc supplementation showed no clinically meaningful benefit compared with placebo across tinnitus-related outcomes: tinnitus loudness (SMD, -0.05), VAS (SMD, -0.01), and THI (SMD, -0.08). The confidence intervals were wide, indicating high uncertainty in the effect estimates. No serious adverse events were reported in the included RCTs. However, inconsistent adverse event collection and limited confidence in the safety profile were reported. The overall net benefit was small or absent, and the harm-benefit balance was insufficient to support zinc use as a routine tinnitus intervention.

In a Korean patient preference survey, 40.0% of patients expressed an active desire for nutritional supplement therapy, whereas 51.1% required additional information; 52.9% of those with prior pharmacologic treatment experience reported no benefit [21]. Therefore, unrealistic expectations regarding zinc supplementation must be addressed proactively with clear information on the limited evidence and potential harm before initiating treatment.

Regarding equity and resources, zinc supplements are relatively inexpensive (approximately 10,000–30,000 KRW per month) and available without prescriptions, presenting low access barriers. However, they are not covered by the national health insurance, and their cost-effectiveness has not yet been established. The culturally favorable perception of health supplements in Korea may lead patients to self-administer without medical consultation, potentially increasing health risks, particularly in vulnerable populations with limited access to information on the adverse effects of excess intake.

Based on these considerations — (1) small and uncertain benefit, (2) no outcome meeting the MCID, (3) an EtD assessment favoring placebo over zinc, and (4) unclear patient preferences — zinc supplementation is graded D $\dagger$. Evidence supporting the use of zinc for the improvement of tinnitus symptoms is insufficient, and its routine use is not recommended. However, zinc supplementation may be considered as an adjunct to correct this deficiency in patients with confirmed zinc deficiency.

7-2. Vitamins: Grade D† (Strong Against Routine Use)

Clinicians should not recommend vitamin supplementation as routine treatment for tinnitus symptom improvement.†

(Aggregate evidence quality: Low, based on limited trials with inconsistent results)

Based on the evidence synthesis underlying this guideline, three RCTs involving adult patients with subjective tinnitus were analyzed to evaluate nicotinamide (vitamin B3) and vitamin B12. Hulshof et al. (1986) conducted a double-blind, placebo-controlled RCT administering 70 mg of nicotinamide three times daily (total 210 mg/day) for 30 days. The primary outcome was tinnitus symptom improvement, assessed using a questionnaire and recorded as a binary (improved/not improved) measure. In the treatment group, 44% of the patients reported symptomatic improvement compared with only 8% in the placebo group, indicating a statistically significant between-group difference. However, no dropout rate was reported, and no validated tinnitus severity scale (THI, TFI, or VAS) was used. The binary outcome without continuous measurement, absence of long-term follow-up, and lack of independent replication substantially reduced confidence in these findings [77]. Singh et al. (2016) enrolled 40 patients with chronic tinnitus (mean age 38.4 years; 16 male, 24 female; mean tinnitus duration 1.36 years) in a double-blind, placebo-controlled RCT in India (August 2012 – August 2013). Of the enrolled patients, 42.5% had a vitamin B12 deficiency. Patients were randomized to methylcobalamin 1500 µg intramuscular injection once weekly for 6 weeks (n=20) or normal saline 0.1 mL by the same method (n=20). The primary outcome was the Tinnitus Severity Index (TSI, 0–100). In the B12-deficient subgroup, TSI improved significantly ($36.5 \pm 7.6 \rightarrow 28.3 \pm 6.2$, $p < 0.016$), whereas no significant improvement was observed in non-deficient patients. No subgroups in the placebo arm showed significant changes. No dropouts were reported (0%) [78]. Dadgarnia et al. (2024) conducted the largest vitamin B12 RCT to date, enrolling 140 patients with idiopathic tinnitus (mean age approximately 59 years) in Iran and randomizing them to oral vitamin B12 500 µg once daily for 1 month (n=70) or placebo (n=70), followed by 3 months of follow-up. The primary outcomes were THI and VAS tinnitus loudness scores. THI showed no significant change in either group (B12 group: $71.24 \rightarrow 71.89$, $p = 0.259$; placebo: $73.56 \rightarrow 72.46$, $p = 0.521$), and VAS was similarly unchanged (B12 group: $7.67 \rightarrow 7.66$, $p = 0.851$; placebo: $7.71 \rightarrow 7.56$, $p = 0.386$). No dropouts were reported (0%) [79].

In the meta-analysis, vitamin supplementation showed no clinically meaningful difference from placebo: THI (MD, -0.60; MCID, ≥ 7 not met), VAS (MD, +0.10), and tinnitus relief rate (RR 1.44; 95% CI 0.26–7.96). Wide confidence intervals indicated high uncertainty and precluded reliable conclusions regarding efficacy. No serious adverse events were reported; however, all the included trials were small and short-term, leaving insufficient long-term safety evidence. The overall net benefit was small or uncertain, and the harm-benefit balance did not support routine supplementation.

In a Korean patient preference survey, 40.0% of patients expressed an active desire for nutritional supplement therapy, whereas 51.1% required additional information; 52.9% of those with prior pharmacologic treatment reported no benefit [21]. Considering that Singh et al. (2016) demonstrated significant improvement only in B12-deficient patients, indiscriminate prescriptions in non-deficient patients should be avoided.

Regarding equity and resources, vitamin supplements are inexpensive and do not require specialized equipment or personnel, making them highly feasible in practice. However, its cost-effectiveness has not been established and is not covered by national health insurance, which may impose a cumulative financial burden with prolonged use. The culturally favorable perception of health supplements in Korea may lead patients to continue self-administration without medical guidance, despite insufficient scientific evidence.

Based on these considerations — (1) all outcomes below MCID, (2) an EtD assessment favoring placebo or equivalent, and (3) uncertain patient preferences — vitamin supplementation is graded D $\dagger$. Evidence supporting the use of vitamins for tinnitus symptom improvement is insufficient, and routine use is not recommended. However, supplementation may be considered as an adjunct in patients with confirmed vitamin deficiency for the purpose of correcting that deficiency.

7-3. Ginkgo Biloba: Grade B (Conditional For)

Clinicians may consider Ginkgo biloba for patients with subjective tinnitus to improve tinnitus symptoms.

(Aggregate evidence quality: Low, based on randomized controlled trials with inconsistent results)

Ginkgo biloba is among the most commonly used herbal supplements for tinnitus, with proposed

mechanisms including improved cerebral blood flow, antioxidant effects, and neuroprotective properties. According to the evidence synthesis underlying this guideline, six randomized controlled trials (RCTs) in adult patients with subjective tinnitus were analyzed.

Cekkayan et al. (1996) conducted a randomized placebo-controlled trial in Turkey that enrolled 67 patients aged 14–70 years with subjective tinnitus, allocated to betahistine (n=28), Ginkgo biloba extract (n=26; standardized tablets 9.6 mg ginkgo glycosides per tablet, three times daily), or placebo (n=13) for 3 months. The primary outcome was patient-rated tinnitus intensity (0–4 scale), assessed at baseline and 3 months. Tinnitus intensity decreased by 1.50 points (37.5%) in the Ginkgo group, 1.39 points (35%) in the betahistine group, and 0.53 points (13%) in the placebo group, suggesting greater reduction in both active arms versus placebo. No dropouts were reported (0%). However, statistical test values were not provided, which limited the interpretation of significance [80]. Drew et al. (2001) conducted a large double-blind, randomized, placebo-controlled trial in the UK, enrolling patients aged 18–70 years with tinnitus lasting >1 year. Ginkgo biloba extract 50 mg three times daily (n=559) or a matching placebo (n=562) was administered for 12 weeks (mean age, approximately 53 years; 60% male). Of the enrolled patients, 956 were included in the primary analysis (overall dropout rate, 14.7%, or 165/1121). All outcomes — tinnitus loudness (change difference 0.01, 95% CI –0.16 to 0.19) and troublesome nature (difference 0.03, 95% CI –0.17 to 0.17) — showed no significant difference between groups [81]. Polanski et al. (2016) conducted a prospective, double-blind, randomized, placebo-controlled trial in elderly patients aged ≥60 years with tinnitus (mean age, 72.6 years; comorbidities: hypertension, 65.5%; dyslipidemia, 15.5%; hypothyroidism, 15.5%). The participants were randomized into four groups for 6 months: Ginkgo biloba extract 120 mg/day (n=12), alpha-lipoic acid 60 mg + vitamin C 600 mg/day (n=13), papaverine 100 mg + vitamin E 400 mg/day (n=15), or placebo (n=13). The primary outcome was the THI score. Changes in THI score (p=0.848) and THI grade (p=0.441) were not significantly different across groups (Ginkgo: 32.8 → 29.0; placebo: 28.2 → 24.2). No dropouts were reported [82]. Rejali et al. (2004) conducted a double-blind, randomized, placebo-controlled trial comparing Ginkgo biloba extract 120 mg once daily (n=31) with a placebo (n=29) for 12 weeks. The primary outcomes were THI, Glasgow Health Status Inventory (GHSI), and audiometric thresholds. No significant between-group differences were found for any outcome: THI (–4.7 vs –2.2, p=0.51), GHSI (1.94 vs 2.52, p=0.78), hearing threshold (0.32 vs 1.00 dB, p=0.69), OR for THI improvement (OR 1.24, 95% CI 0.89–1.71). Dropouts included one death and one lost

to follow-up in the Ginkgo group, and two lost to follow-up and two with worsening comorbidities in the placebo group [83]. Chauhan et al. (2023) used an open-label, randomized, placebo-controlled design to compare Ginkgo biloba 60 mg twice daily (T1, n=24), Ginkgo biloba 60 mg twice daily plus antioxidants (T2: β -carotene 20 mg, vitamin C 200 mg, vitamin E 200 mg, selenium 50 μ g; n=23), or placebo (T0, n=22) over 12 weeks. THI reduction rates were as follows: T2 (combination), 36%; T1 (Ginkgo alone) -17.9%; and T0 (placebo), 1.2%. The VAS score decreased by 22.6% at T2. The dropout rates were T0 12%, T1 11%, T2 8%. Despite these findings, the open-label design, single study design, limited sample size, and insufficient information on correction for multiple comparisons represent a substantial risk of bias [84]. Morgenstern et al. (1997) conducted a prospective, double-blind, randomized, placebo-controlled trial in adults with subjective tinnitus and normal hearing. Ginkgo biloba extract EGb 761 (40 mg per tablet; 9.6 mg flavone glycosides, 2.4 mg terpene lactones), three tablets daily (total 120 mg), was administered for 12 weeks. Of 99 randomized patients, 73 were included in the analysis (active, n=35; placebo, n=38; dropout rate, 26%). Tinnitus loudness: placebo 44.3 $\rightarrow$ 45.1 dB (unchanged); Ginkgo 42.2 $\rightarrow$ 39.0 dB (decrease). Tinnitus intensity: placebo -14%, Ginkgo -30.6%. Although the Ginkgo group showed greater reductions in both outcomes, the high dropout rate, short-term single-country design, and selection of hearing-normal patients limit its generalizability [85].

A systematic review by von Boetticher (2011) concluded that although Ginkgo biloba appears safe and well-tolerated, evidence for its efficacy in tinnitus remains inconclusive, noting that most positive studies were small and methodologically limited [86]. The 2022 Cochrane systematic review found insufficient evidence to support Ginkgo biloba in tinnitus, citing substantial heterogeneity in the study design, preparation, dosing, and outcome measures [87]. Ginkgo biloba EGb 761 has also been evaluated for sudden hearing loss, and Reisser et al. (2001) found it comparable to pentoxifylline in a randomized double-blind trial, providing a broader context for its use in audiovestibular conditions [88].

In the meta-analysis, Ginkgo biloba extract reduced THI by a mean of 7.09 points (95% CI, -11.21 to -2.97), which was statistically significant but did not reach the MCID of 10 points; between-study heterogeneity was high ($I^2=67.7\%$). VAS (MD, -0.07) and tinnitus loudness (MD, -4.10 dB) also showed reduction trends without statistical significance. No serious adverse events were reported; mild gastrointestinal symptoms and headaches were the most common. Notably, patients taking anticoagulants or those with a bleeding tendency were excluded from most trials, leaving

the safety data for these high-risk groups unconfirmed. The overall net benefit is small, but the harm is minimal, and some improvement trends are consistent.

In a Korean patient preference survey, 40.0% of patients expressed an active desire for supplement therapy, and 51.1% required additional information [21]. Cultural familiarity with naturally derived substances supports psychological acceptability; however, patient education is required to align expectations with realistic treatment goals.

Regarding equity and resources, Ginkgo biloba is not covered by the national health insurance and requires full out-of-pocket payments, which may impose a financial barrier for economically vulnerable patients. Oral administration does not require specialized equipment or personnel, making it highly feasible in practice; however, its use is restricted in patients on anticoagulants owing to the risk of bleeding.

Based on these considerations, Ginkgo biloba was graded as B (Conditional For). The GDG acknowledges that the current evidence, including the 2022 Cochrane systematic review and multiple international guidelines, does not support the routine use of Ginkgo biloba to treat tinnitus. The meta-analytic findings in the guideline similarly demonstrated only a modest THI reduction that did not reach the established MCID of 10 points, with high between-study heterogeneity ($I^2=67.7\%$).

Nevertheless, after two rounds of open public consultations involving clinicians and patient representatives, the GDG reached a consensus on issuing a conditional recommendation permitting selective use. This decision was primarily informed by three contextual factors: (1) Ginkgo biloba is currently one of the most widely prescribed pharmacological agents for tinnitus in Korean clinical practice, reflecting established prescribing patterns that cannot be dismissed without adequate alternatives; (2) the overall harm profile is minimal, with no serious adverse events reported across the included trials, such that harm does not outweigh the modest and uncertain benefits; and (3) for patients with limited access to behavioral or rehabilitative interventions, Ginkgo biloba may represent a pragmatic option when prescribed with appropriate expectations. The GDG emphasizes that this recommendation does not imply an efficacy equivalent to that of behavioral interventions and should not substitute evidence-based treatments where available. Caution is required in patients taking anticoagulants or those with a bleeding tendency.

DISCUSSION

This guideline synthesizes the best available evidence to provide the first comprehensive evidence-based framework for tinnitus management adapted to the Korean healthcare context. Several key findings and their clinical implications warrant further discussion.

First, tinnitus is a heterogeneous condition that requires individualized, patient-centered approaches. Selective imaging in high-risk presentations is essential. Patients with pulsatile tinnitus or asymmetric hearing loss have substantially higher rates of identifiable pathology, including vascular anomalies and retrocochlear lesions, than those with non-pulsatile, symmetric tinnitus, in whom routine imaging is not cost-effective.

Second, the primary goal of tinnitus treatment is to reduce tinnitus-related distress and improve quality of life. Establishing appropriate clinical expectations and achieving meaningful patient outcomes are fundamental to effective tinnitus management. Treatments with the strongest evidence target distress reduction and functional improvement using psychological and rehabilitative approaches.

Third, behavioral and rehabilitative interventions represent the cornerstone of evidence-based tinnitus management. CBT effectively reduces tinnitus-related distress with durable effects. Internet-based CBT (iCBT) and smartphone-based applications have demonstrated clinically meaningful improvements and offer scalable alternatives given the limited availability of trained CBT providers and the lack of insurance reimbursement in Korea. Hearing aids benefit patients with comorbid hearing loss through the dual mechanisms of communication improvement and acoustic enrichment, with significant tinnitus handicap reductions observed, particularly when combined with structured counseling. Sound therapy and TRT provide additional adjunctive options, although the evidence quality remains limited, with high heterogeneity across trials.

Fourth, the use of dietary supplements requires careful clinical consideration. Zinc and vitamin supplementation consistently failed to demonstrate clinically meaningful benefits in patients with tinnitus and are strongly recommended against routine use, except in patients with documented deficiencies for whom corrective supplementation is appropriate. Ginkgo biloba showed a statistically significant but subthreshold THI improvement, with inconsistent individual trial results. It may be selectively considered with appropriate caution in patients without anticoagulant contraindications. The divergence in grading between Ginkgo biloba (Grade B) and zinc/vitamins (Grade D⁺) warrants explanation, as all three interventions failed to meet their respective MCIDs. The critical distinction lies in the direction and consistency of evidence within the EtD framework. For

zinc and vitamins, the EtD assessment consistently favored placebo across all outcomes, with no clinically meaningful trend toward benefit. In contrast, Ginkgo biloba demonstrated a statistically significant THI reduction that, while subthreshold, trended consistently in a favorable direction across multiple trials, with a minimal harm profile. Furthermore, Ginkgo biloba is one of the most commonly used pharmacological agents for tinnitus in Korean clinical practice, and the GDG determined that a conditional rather than prohibitive recommendation was appropriate given this pragmatic context and the absence of adequate alternatives for patients with limited access to behavioral interventions. Fifth, emerging neuromodulation techniques such as tDCS and rTMS show differential evidence profiles. tDCS demonstrated clinically meaningful THI reductions exceeding the MCID in a meta-analysis, with more consistent effects in multi-session, higher-dose protocols. In contrast, most large, well-controlled rTMS trials have failed to demonstrate significant benefits over the sham group, although short-term outcomes showed moderate-quality evidence of modest improvement. However, the overall certainty of evidence remains limited owing to small sample sizes, short follow-up periods, and heterogeneity in stimulation protocols. Both modalities are currently not covered by the Korean National Health Insurance and are available only at academic centers, limiting their applicability to carefully selected refractory cases.

This guideline has some limitations. Most recommendations are supported by evidence of low or very low certainty, reflecting the inherent challenges in tinnitus research, including the subjective nature of tinnitus, heterogeneous patient populations, diverse outcome measures, and substantial placebo effects. Most of the included studies were conducted in Western populations, and direct extrapolation to Korean patients requires caution, given the potential differences in healthcare access, cultural attitudes, and comorbidity profiles. Korea-specific data informing recommendations were largely limited to patient preference surveys and national insurance considerations, rather than randomized trial evidence. Additionally, the patient preference survey conducted to inform the EtD framework has inherent limitations in representativeness. The survey enrolled 45 patients from a single tertiary otorhinolaryngology clinic, which may not fully reflect the broader tinnitus population in Korea, including patients managed in primary care settings, those with varying socioeconomic backgrounds, or those with different tinnitus severity profiles. Accordingly, the preference data should be interpreted as indicative rather than definitive, and caution should be exercised in generalizing these findings to all Korean patients with tinnitus. Future guideline updates should incorporate larger, multicenter patient preference data to enhance generalizability. Alt-

though the modified Delphi process was employed to ensure rigorous expert agreement, several recommendations were ultimately informed by expert consensus in the context of limited or heterogeneous evidence, which may introduce subjectivity into the final recommendation statements. The GDG composition represents a further limitation. Although the panel was multidisciplinary, dedicated representation from clinical psychology, rehabilitation medicine, sleep medicine, and patient advocates was not included. Future guideline updates should consider broader multidisciplinary participation and formal patient representation within the GDG.

Comparison with International Guidelines

The present guideline was developed with explicit adaptation to the Korean healthcare context, integrating Korea-specific considerations into the EtD framework for every key clinical question. Patient values and preferences were informed by a prospectively conducted quantitative survey (n=45) [21], providing empirical acceptance and refusal rates that complement evidence quality assessments in a manner not previously reported in international tinnitus guidelines. The present guideline shares several fundamental positions with the existing international tinnitus guidelines [7-11]. Consistent with the AAO-HNS (2014), German S3 (2021), European TINNET (2019), and NICE (2020) guidelines, CBT is the intervention with the most robust evidence for reducing tinnitus-related distress, and hearing aids are recommended for patients with comorbid hearing loss. All guidelines concur that routine imaging is not indicated in patients with non-pulsatile, symmetric tinnitus given diagnostic yields below 1% and that the primary therapeutic goal is distress reduction and functional improvement rather than elimination of the tinnitus percept.

Several features distinguish the current guideline from their international counterparts. Most notably, Ginkgo biloba received a conditional recommendation (Grade B), a position that diverges from the AAO-HNS, German S3, and European guidelines, all of which recommend against its use, consistent with the 2022 Cochrane review [7-9]. This decision reflects pragmatic considerations specific to the Korean healthcare context. Ginkgo biloba is currently the most widely prescribed pharmacological agent for tinnitus in Korea, its harm profile is minimal, and it may serve as a practical alternative for patients with limited access to behavioral interventions. The GDG acknowledges that this recommendation is not supported by high-certainty evidence and should not be substituted for evidence-based behavioral therapies where available. Nonetheless, the overall EtD assessment justified a conditional recommendation rather than a recommendation against

its use, taking into account patient preferences, treatment acceptability, and contextual factors within the Korean healthcare setting, despite the low certainty of evidence. Regarding neuromodulation, most international guidelines either recommend against or do not address tDCS and rTMS. The present guideline evaluated both modalities through separate meta-analyses and found that tDCS, but not rTMS, produced clinically meaningful THI reductions that exceeded the established MCID. Nonetheless, both modalities are positioned as adjunctive options reserved for refractory cases at experienced centers, given the absence of national health insurance coverage and limited institutional availability. The overall EtD assessment justified a conditional recommendation based on the clinically meaningful MCID-exceeding THI reduction observed for tDCS and the minimal adverse event profile of both modalities, despite the low certainty of evidence. Finally, the present guideline is distinguished by the systematic integration of a prospectively conducted quantitative patient preference survey (n=45) [21] into the EtD framework for each recommendation, providing empirical acceptance and refusal rates that complement evidence quality assessments in a manner not reported by any prior international tinnitus guidelines. Korea-specific contextual factors, including NHI coverage status, out-of-pocket costs, regional accessibility, and equity implications, were also formally incorporated for every KQ, reflecting the European guidelines' call for country-specific adaptation while operationalizing it within a structured EtD framework (Supplementary Tables S1–S4).

Research Needs

However, there are substantial gaps in the literature. High-priority research needs include large, adequately powered, randomized controlled trials with validated outcome measures and long-term follow-up; Korea-specific epidemiological studies characterizing tinnitus prevalence and healthcare utilization; development and validation of culturally adapted CBT protocols deliverable through digital platforms; comparative effectiveness trials for optimal treatment sequencing within the National Health Insurance framework; identification of treatment response predictors to enable personalized management; and cost-effectiveness analyses to support insurance coverage decisions for evidence-based interventions. Research on the pathophysiology of tinnitus, particularly neuroimaging and electrophysiological biomarkers, is important for identifying novel therapeutic targets.

Implementation and Future Updates

Successful implementation requires clinician education regarding evidence-based principles, patient education to establish realistic expectations, healthcare system adaptations to improve access to CBT and hearing rehabilitation, and policy considerations regarding insurance coverage for effective interventions. The Korean Otological Society plans to review and update these recommendations every 3–5 years, or sooner, if significant new evidence emerges.

Disclaimer

This guideline is intended to support clinical decision-making, but does not replace clinical judgment. Individual patient circumstances, preferences, and values must be considered when applying the recommendations. The absence of a specific treatment in this guideline does not necessarily indicate a lack of clinical value; rather, it may reflect insufficient evidence at the time of development. These recommendations apply to adults with primary tinnitus and may not be appropriate for other tinnitus populations or clinical situations that have not been specifically addressed.

CONCLUSION

This clinical practice guideline provides the first comprehensive evidence-based framework for the diagnosis and management of tinnitus, specifically developed for the Korean healthcare context. A multidisciplinary panel of 11 experts derived nine evidence-based recommendations through a systematic literature review, GRADE methodology, and modified Delphi consensus. Behavioral and rehabilitative interventions, particularly CBT and hearing aids, provided the most consistent evidence for reducing tinnitus-related distress. Routine use of dietary supplements was not supported. Neuromodulation may be considered as an adjunctive therapy in refractory cases at experienced centers. The primary therapeutic strategy focuses on improving tinnitus-related quality of life through patient-centered, evidence-based management strategies adapted to the Korean healthcare system. This guideline will be periodically updated as new evidence emerges.

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CONFLICT OF INTEREST

No potential conflicts of interest relevant to this article were reported.

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Table 1. Recommendation Grade Classification

Grade	Direction & Strength	Clinical Implication
A	Strong For	Strong recommendation to perform; should be followed in most circumstances
B	Conditional For	Conditional recommendation to consider; individual patient circumstances guide the final decision
C	Conditional Against	Conditional recommendation against routine use
D	Strong Against	Strong recommendation against; should not be performed
I	Insufficient	Insufficient evidence to make a recommendation

†: Strong recommendation adopted despite low certainty of evidence, based on overall EtD framework assessment.

Table 2. Summary of Recommendations

No.	Key Question	Recommendation Statement	Grade	Certainty of Evidence
KQ1	Imaging Evaluation	Clinicians may consider imaging evaluation in patients with pulsatile tinnitus or asymmetric hearing loss.	B (Conditional For)	Very Low
KQ2	Tinnitus Retraining Therapy (TRT)	Clinicians may consider tinnitus retraining therapy (TRT) for patients with tinnitus.	B (Conditional For)	Very Low
KQ3	Cognitive-Behavioral Therapy (CBT)	Clinicians may consider cognitive-behavioral therapy (CBT) for patients with tinnitus.	B (Conditional For)	Low
KQ4	Hearing Aids	Clinicians may consider hearing aids for patients with tinnitus and co-existing hearing loss.	B (Conditional For)	Low
KQ5	Sound Therapy	Clinicians may consider sound therapy for patients with tinnitus to reduce tinnitus-related distress.	B (Conditional For)	Low
KQ6	Neuromodulation (tDCS/rTMS)	Clinicians may consider neuromodulation techniques (tDCS or rTMS) as adjunctive treatment	B (Conditional For)	Low (tDCS) / Low-Moderate (rTMS)

		for patients with tinnitus.		
KQ7-1	Zinc Supplementation	Clinicians should not recommend zinc supplementation as routine treatment for tinnitus symptom improvement.†	D† (Strong Against Routine Use)	Low
KQ7-2	Vitamin Supplementation	Clinicians should not recommend vitamin supplementation as routine treatment for tinnitus symptom improvement.†	D† (Strong Against Routine Use)	Low
KQ7-3	Ginkgo Biloba	Clinicians may consider Ginkgo biloba for patients with subjective tinnitus to improve tinnitus symptoms.	B (Conditional For)	Low

Grade A: Strong recommendation to perform an action. Grade B: Conditional recommendation: individual patient circumstances should guide the final decision. Grade D: Strong recommendation against an action. Grade I: Insufficient evidence to make recommendations.

In this guideline, no recommendations are classified as Grade A or Grade I.

†: Strong recommendation adopted despite low certainty of evidence, based on overall Evidence-to-Decision (EtD) framework assessment.

Certainty of evidence was assessed using the GRADE methodology: High, Moderate, Low, or Very Low.

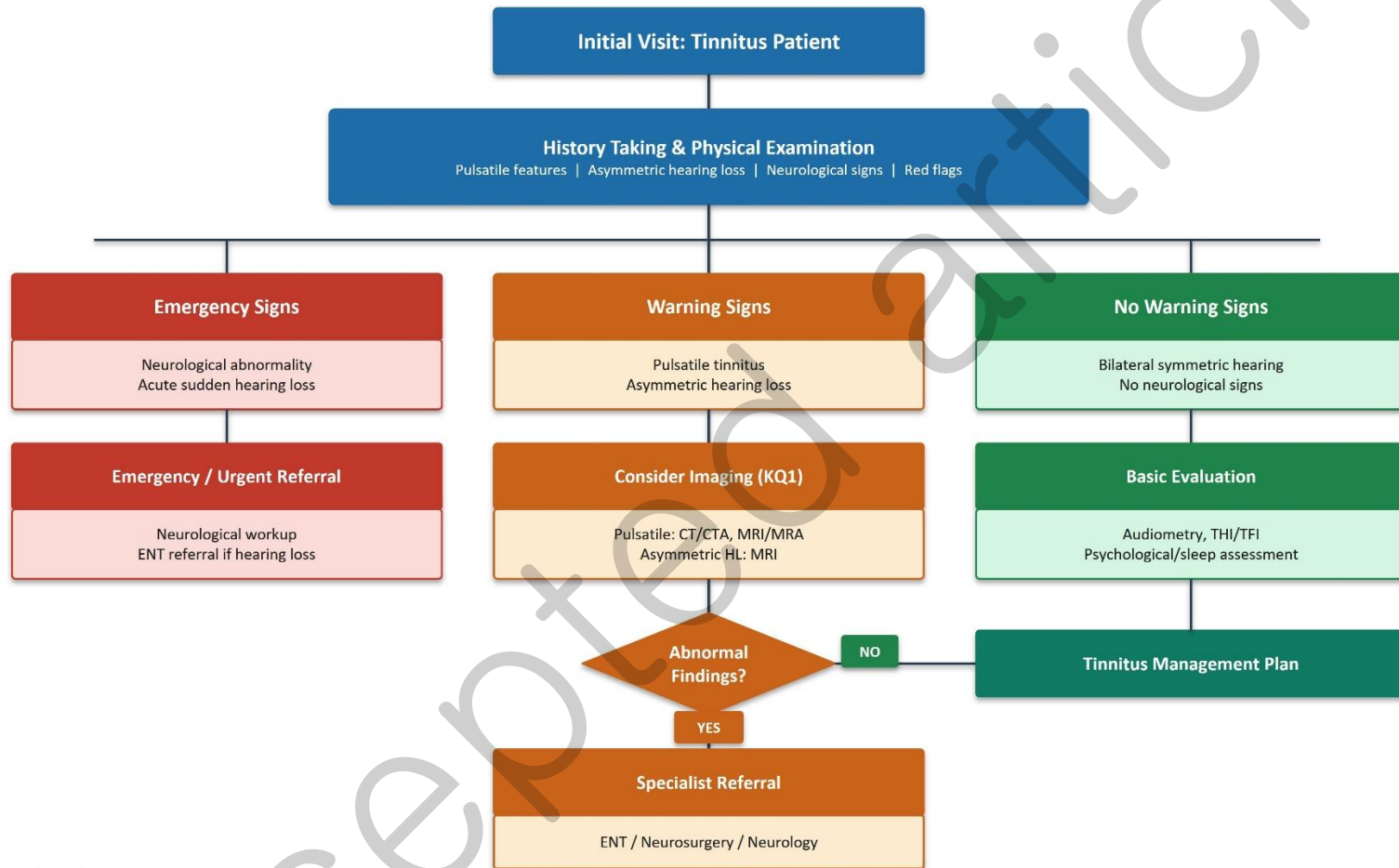
tDCS, transcranial direct current stimulation; rTMS, repetitive transcranial magnetic stimulation; TRT, tinnitus retraining therapy; CBT, cognitive-behavioral therapy.

FIGURE LEGENDS

Figure 1. Clinical algorithm for the initial assessment and evaluation of patients with tinnitus. ENT, otorhinolaryngology; HL, hearing loss; KQ, key question; MRA, magnetic resonance angiography; MRI, magnetic resonance imaging; THI, Tinnitus Handicap Inventory; TFI, Tinnitus Functional Index.

Accepted article

Figure 1.



KQ1 = Key Question 1 (Imaging); HL = Hearing Loss; THI = Tinnitus Handicap Inventory; TFI = Tinnitus Functional Index; ENT = Otorhinolaryngology; CT/CTA/MRI/MRA = imaging modalities.

Supplementary Material

Clinical Practice Guideline for Tinnitus in Korea

Supplementary Table S1. Overview of International Tinnitus Clinical Practice Guidelines

Feature	AAO-HNSF (USA, 2014)	German S3 (2021)	Japan (2020)	European TINNET (2019)	NICE (UK, 2020)	Korean (Current)
Year	2014	2021	2020	2019	2020	2025–2026
Organization	AAO-HNSF	DGHNO-KHC (20+ societies)	Japan Audiological Society	TINNET COST Action (24 countries)	NICE / Royal College of Physicians	Korean Otological Society
Methodology	AAO-HNSF CPG development manual	AWMF S3 (highest level)	COGS + AGREE	Oxford Levels of Evidence + GRADE	GRADE + economic analysis	GRADE + modified Delphi (≥80%)
Target population	Adults ≥18 yr, primary persistent (≥6 mo) bothersome	Chronic tinnitus (≥3 mo)	Non-pulsatile chronic tinnitus (≥3 mo)	Adult subjective tinnitus (acute + chronic)	Children, young people, and adults	Adults ≥19 yr, primary tinnitus
Pulsatile tinnitus	Excluded	Addressed separately	Excluded	Appendix	Included	Imaging only (KQ1)
Panel composition	Multidisciplinary (12 specialties + consumers)	20+ societies (ENT, psychiatry, psychology, dentistry, patient orgs)	Otolaryngologists (9 members)	Pan-European multidisciplinary	Multidisciplinary + lay members	11 experts (ENT, neurology, psychiatry, audiology)
No. of recommendations	13 KAS	25	10 CQs	~13 treatment categories	~15 recommendation areas	9 KQs
Patient preference integration	Consumer advocates on panel	Patient orgs on panel	External patient review	Patient orgs involved	Lay member (British Tinnitus Association)	Dedicated patient preference survey (n=45, published separately) [85]

KAS = Key Action Statement; KQ = Key Question; NHI = National Health Insurance; GRADE = Grading of Recommendations Assessment, Development and Evaluation; EtD = Evidence-to-Decision.

Supplementary Table S2. Comparison of Treatment Recommendations Across International Tinnitus Guidelines

Intervention	AAO-HNSF (USA, 2014)	German S3 (2021)	Japan (2020)	European TINNET (2019)	NICE (UK, 2020)	Korean (Current)
Educational counseling	Recommend	Strong recommend (shall)	Recommend (1B)	Part of CBT framework	Recommend (GC consensus)	— (not a separate KQ)
CBT	Recommend (Grade A)	Strong recommend (shall, 1a)	Recommend (1B)	Strong recommend	Recommend (stepped care)	Conditional For (Grade B)
Hearing aids (with HL)	Recommend	Recommend (should)	—	Weak recommend	Recommend (offer/consider)	Conditional For (Grade B)
TRT	— (under sound therapy)	Open recommend (can, without noisers)	Recommend (1B)	No recommendation	—	Conditional For (Grade B)
Sound therapy	Option	Recommend Against	Part of TRT (1B)	No recommendation	— (not addressed separately)	Conditional For (Grade B)
Noise generators / noisers	Part of sound therapy (Option)	Recommend Against	—	—	—	—
Pharmacotherapy (general)	Recommend Against	Strong Against (shall not)	Not recommended	Weak Against	—	Deliberately excluded
Betahistine	—	Against	—	—	Do not offer	—
Antidepressants / Anxiolytics	Against (for tinnitus)	Strong Against (for tinnitus)	Not recommended	Against (without depression dx)	—	Deliberately excluded
Ginkgo biloba	Against	Strong Against	Low evidence, no side effects noted	Against	—	Conditional For (Grade B)
Zinc	Against	Strong Against	—	Against	—	Strong Against (Grade D†)
Vitamins	—	Strong Against	—	—	—	Strong Against (Grade D†)
Melatonin	Against	Against	—	Against	—	—
rTMS	Against	Against	Not recommended (2C)	Against	—	Conditional For (Grade B, adjunctive)
tDCS	—	Against	—	No recommendation	—	Conditional For (Grade B, adjunctive)
Cochlear implant	—	Strong recommend (profound HL)	Consider (2C, profound HL)	No recommendation (for tinnitus)	—	—
Acupuncture	No recommendation	Against	Not recommended (2D)	No recommendation	—	—
Digital / Internet CBT	Discussed (promising)	Discussed (limited effectiveness)	—	Discussed (less than face-to-face)	Recommend (Step 1)	Discussed (Kalmeda app, MFDS approved)

† = Strong against despite low certainty of evidence (D-dagger), based on overall EtD framework assessment. HL = Hearing Loss; CBT = Cognitive Behavioral Therapy; TRT = Tinnitus Retraining Therapy; rTMS = repetitive Transcranial Magnetic Stimulation; tDCS = transcranial Direct Current Stimulation; MFDS = Ministry of Food and Drug Safety; GC = Guideline Committee; KQ = Key Question.

Supplementary Table S3. Comparison of Diagnostic and Assessment Approaches Across International Tinnitus Guidelines

Diagnostic Domain	AAO-HNSF (USA, 2014)	German S3 (2021)	Japan (2020)	European TINNET (2019)	NICE (UK, 2020)	Korean (Current)
Pure tone audiometry	Recommended	Required (basic)	Recommended (1B)	Required	Offered	— (not a separate KQ)
Tympanometry	Part of audiologic exam	Required (basic)	—	Required	Consider if indicated	—
OAE	—	Required (basic)	—	—	—	—
BERA / ABR	—	Required (basic)	—	—	—	—
Tinnitus matching	—	Required (basic)	Recommended (1B)	Recommended	—	—
Imaging — routine	Strong Against	Individualized	—	Not routine	Not routine	Not routine (yield <1%)
Imaging — pulsatile tinnitus	Indicated	Indicated	— (excluded)	Indicated (appendix)	Offer (MRA/MRI/CT)	Conditional For (Grade B, KQ1)
Imaging — asymmetric HL	Indicated	Indicated (MRI)	Indicated (2C)	Indicated (MRI)	Consider MRI	Conditional For (Grade B, KQ1)
Preferred questionnaire	THI, TRQ, THQ, TFI	TQ, Mini-TQ, THI, TFI	THI	THI, TQ, TFI	TFI	— (not addressed)
Severity grading	Bothersome vs. non-bothersome	4-grade system (1–4)	THI-based	4-grade system (1–4)	Tiered referral urgency	—
Psychiatric screening	Mood/suicidality screening	HADS recommended	Depression assessed	HADS recommended	Suicide risk → immediate referral	—
Somatosensory assessment	—	CMD screening (basic)	—	Appendix	—	—

OAE = Otoacoustic Emissions; BERA/ABR = Brainstem Evoked Response Audiometry; THI = Tinnitus Handicap Inventory; TFI = Tinnitus Functional Index; TQ = Tinnitus Questionnaire; TRQ = Tinnitus Reaction Questionnaire; HADS = Hospital Anxiety and Depression Scale; CMD = Craniomandibular Dysfunction; HL = Hearing Loss; KQ = Key Question.

Supplementary Table S4. Unique Features of Each International Tinnitus Clinical Practice Guideline

Guideline	Key Distinguishing Features
AAO-HNSF (USA, 2014)	• First evidence-based multidisciplinary tinnitus CPG • Bothersome vs. non-bothersome distinction as core framework • Cognitive screening (clock drawing test) for elderly (≥70 yr) • Clinical algorithm flowchart mapping all 13 KAS
German S3 (2021)	• Most comprehensive negative recommendations (17 "against") • Anti-noiser stance (recommend against noise generators) • Somatosensory tinnitus recognition with specific treatment • Conflict of interest-based evidence downgrading • Minority opinions (DGPPN) formally documented
Japan (2020)	• Habituation-focused treatment philosophy • Acknowledged CBT access limitations in Japanese clinical setting • Japan-specific NHI reimbursement constraints • 26-year update to Japanese tinnitus practice standards
European TINNET (2019)	• Pan-European scope (24 countries) • Adaptive design for country-specific implementation • Fear-avoidance model emphasis as basis for CBT • Stepped-care pathway with THI/TQ cut-offs (THI >36, TQ >30) • Comprehensive patient myth-correction table
NICE (UK, 2020)	• Stepped care CBT model (digital → group → individual) • Cost-effectiveness analysis-driven recommendations • Explicit betahistine prohibition ("Do not offer") • 5-tier referral urgency system • Expanded hearing aid indication (HL without communication difficulty)
Korean (Current)	• First Korean-specific tinnitus guideline • Dedicated patient preference survey integrated into EtD framework [85] • Korean NHI coverage and cost context for every recommendation • Ginkgo biloba conditional recommendation (diverging from international consensus) • Neuromodulation differentiated (tDCS vs. rTMS with separate meta-analyses) • Digital therapeutics (MFDS-approved Kalmeda app) recognized • Equity analysis for every KQ • D-dagger (†) notation for strong-against-despite-low-evidence

EtD = Evidence-to-Decision; NHI = National Health Insurance; MFDS = Ministry of Food and Drug Safety (Republic of Korea); KQ = Key Question. [85] Lee JM et al. *Am J Otolaryngol.* 2026;47:104790.