***Audio-Vestibular Medicine***

# *Tinnitus:*

***Adapted Egyptian Clinical Practice Guideline***

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## Acronyms and Abbreviations

| | |
|---|---|
| *ABR* | *Auditory brainstem responses* |
| *BIH* | *Benign intracranial hypertension* |
| *CBC* | *complete blood count* |
| *CBT* | *Cognitive Behavioral Therapy* |
| *CBT4T* | *Cognitive behavioral therapy for tinnitus* |
| *CPG* | *Clinical Practice Guideline* |
| *CR®* | *co- ordinated reset* |
| *CT* | *Computed tomography* |
| *GRADE* | *Grading of Recommendations Assessment, Development and Evaluation* |
| *HADS* | *Hospital Anxiety and Depression Scale* |
| *MEGT* | *Multidisciplinary European Guideline for Tinnitus: Diagnostics, Assessment, and Treatment* |
| *MRI* | *Magnetic Resonance Imaging* |
| *RCTs* | *randomized controlled trials.* |
| *rTMS* | *Repetitive transcranial magnetic stimulation* |
| *tACS* | *Transcranial alternating current stimulation* |
| *tDCS* | *Transcranial direct current stimulation* |
| *TFI* | *Tinnitus Functional Index* |
| *THI* | *Tinnitus Handicap Inventory* |
| *THQ* | *Tinnitus Handicap Questionnaire* |
| *TMJ* | *Temporomandibular joint* |
| *TQ* | *Tinnitus Questionnaire* |
| *TRQ* | *Tinnitus Reaction Questionnaire* |
| *TRT* | *Tinnitus Retraining Therapy* |
| *TSI* | *Tinnitus Severity Index* |
| *TSQ* | *Tinnitus Severity Questionnaire* |
| *VEMP* | *vestibular evoked myogenic potential* |
| *vHIT* | *Video Head Impulse Test* |
| *VNG* | *Videonystagmography* |

## Glossary

Definitions:

- **Tinnitus:** Tinnitus involves the percept of a sound or sounds in the ear or head without an external source.

- **Pulsatile tinnitus:** a sound in the ear or head without an external source, that is perceived as pulses. It is either vascular (synchronous with the heartbeat) and non-vascular. Vascular causes can be subcategorized into arterial or venous.

- **Subjective Tinnitus:** Tinnitus heard by the patient only.
- **Objective Tinnitus:** Tinnitus heard by the patient and the examiner.

- **Acute Tinnitus:** Tinnitus of < 3 months duration.
- **Sub-acute Tinnitus:** Tinnitus from 3-6 months duration.
- **Chronic Tinnitus:** Tinnitus of >6months duration.

- **Habituation:** a decreased response to a stimulus on repetitive stimulation**.**

- **Hyperacusis:** oversensitivity to sounds, moderate level sounds perceived as loud, sounds others perceive as normal seem uncomfortably — and often unbearably loud. It's also described as decreased sound tolerance or intolerance to loud sounds.

## Executive Summary

*Tinnitus: Adapted Egyptian Clinical Practice Guideline (CPG)*

*Scope: The main goal of this guideline is to establish uniformity in the assessment and treatment of older children and adults with subjective tinnitus, for proper diagnosis of the possible cause of tinnitus to direct for proper treatment, and urgent referral if needed, and screening for the effects of tinnitus for proper management to improve the quality of life of tinnitus patients. The statements and flowchart of this guideline were adapted from the "Multidisciplinary European Guideline for Tinnitus: Diagnostics, Assessment, and Treatment (MEGT), (Cima et al.,2019).*

*I. Diagnostics, assessments, and outcomes:*

- *Statement 1:*

  *Ia. Minimum patient assessment:*

  *1) A comprehensive targeted patient history (Strong recommendation for).*

  *2) A thorough physical assessment to exclude possible treatable (physical/medical) causes of tinnitus (Strong recommendation for).*

  *3) A comprehensive diagnostic investigation: (pure tone audiometry, speech audiometry, sound tolerance assessment, evaluation of the perceptional quality of tinnitus, tympanometry and acoustic reflex). (Strong recommendation for).*

- *Statement 2:*

  *Ib. Further assessment by investigations Further assessment by AV investigations (ABR, OAE, VNG etc..) if clinically indicated or referrals (radiological/laboratory etc..) in special cases (Strong Recommendation for).*

- *Statement 3:*

  *Ic. Consider Red Flags that need urgent referral for Assessment/Management [1] (Strong Recommendation for).*

- *Statement 4:*

  *Id. Recommendation for Assessment by questionnaires, to assess Tinnitus severity in terms of distress/impact (Strong Recommendation for).*

*II. Treatment options and referral pathways:*

- *Statement 5:*

  *IIa. Drug/pharmacological treatment for (acute tinnitus) (Strong Recommendation Against). But Drug/pharmacological treatment for acute sudden hearing loss (Strong Recommendation for). Drugs for the treatment of chronic tinnitus (Strong Recommendation Against). Drugs for the treatment of comorbidities associated with tinnitus (anxiety, depression) may need drug treatment. (Conditional Recommendation for).*

- *Statement 6:*

  *IIb. Hearing loss interventions: i) Cochlear implantation only for patients meeting the hearing loss criteria for candidacy (Strong Recommendation for). ii) Hearing aids for the management of tinnitus and hearing loss (Conditional Recommendation for) Combination hearing aids (including amplification and sound generator in the same device) (Conditional Recommendation for).*

- *Statement 7:*

  *IIc. Neurostimulation: Transcranial electrical (direct or alternating current). Transcranial Vagus or Invasive neurostimulation treatments (whether direct Vagus, cortical surface or deep brain neural stimulator) (Conditional Recommendation against), or Acoustic CR® Neuromodulation: (Conditional Recommendation for), or Repetitive transcranial magnetic stimulation (Conditional Recommendation for).*

- *Statement 8:*

  *IId. Cognitive Behavioural Therapy (CBT) (Strong recommendation for).*

- *Statement 9:*

  *IIe. Tinnitus Retraining Therapy (TRT) (Conditional Recommendation for).*

- *Statement 10:*

  *IIf. Sound therapy (including masking, music, environmental sound) for acute relief purposes (Conditional Recommendation for). Sound therapy for long-term use (Conditional recommendation against).*

- *Statement 11:*

  *IIg. Dietary and alternative therapies (Strong recommendation Against).*

- *Statement 12:*

  *IIh. Acupuncture (Conditional recommendation against).*

- *Statement 13:*

  *III. Patient information and support (Strong Recommendation for).*

- *Statement 14:*

  *IV. Measuring the Tinnitus Treatment Outcome: Measuring improvement: by the use of the same tinnitus questionnaire for assessment (Strong Recommendation for).*

# Introduction, scope and audience

## Introduction and background

Tinnitus involves the percept of a sound or sounds in the ear or head without an external source. Tinnitus is a common auditory symptom, which may result in serious burden particularly when there are comorbidities. Tinnitus is a complex condition with a multifactorial origin. Tinnitus can present in many forms. Tinnitus can be any sound, but it is typically ringing, buzzing, hissing, or tonal. Some patients experience multiple sounds. For some the sound is persistent in quality and for others it changes. It can be constant or intermittent, and heard in one or both ears or inside the head. The sound can be perceived as either pulsatile or non-pulsatile. Pulsatile tinnitus can be either vascular or non-vascular. Tinnitus may be objective or subjective. It is necessary that clinicians identify all relevant tinnitus-related factors during tinnitus assessment. Treatment should be proposed based on an assessment that accounts for tinnitus as part of a complex system with intricate interactions between its constituent factors. A classification protocol should identify tinnitus clinically relevant patient profiles and offer a rational path to individualized treatment. Consensus on clinically relevant patient profiles, standard treatment, assessment, and referral trajectories has not been reached thus far. Additionally, inconsistent results in tinnitus studies, in experimental research, clinical trials, observational and cross-sectional research, represent a barrier to efficient standards in health care for tinnitus.

### Scope

The scope of this guideline is the establishment of uniformity in the assessment and treatment of older children and adults with subjective tinnitus, for proper diagnosis of the possible cause of tinnitus to direct for proper treatment, and urgent referral if needed, and screening for the effects of tinnitus for proper management to improve the quality of life of tinnitus patients.

### Target Audience

*ENT and Audio-Vestibular Medicine Physicians, to be used to make and inform clinical decisions regarding management of older children and adults with subjective tinnitus and/or appropriate referral.*

**Areas that are not covered**

1. Managing hearing loss without tinnitus.

2. Managing sound sensitivities (Such as hyperacusis)

   without tinnitus.

3. Managing underlying health conditions causing tinnitus.

4. Managing comorbid conditions such as depression and anxiety.

**Expected benefit(s) or outcome(s):** Diagnosis of the possible cause of tinnitus to direct for proper treatment, and urgent referral if needed, and screening for the effects of tinnitus for proper management to improve the quality of life of tinnitus patients.

## Methods

***Methods of development***

*Stakeholder Involvement: Individuals who were involved in the development process. included the above-mentioned Audiology Chief Manager, Audiology Executive Manager, Assembly Board, Grading Board and Reviewing Board.*

*Information about target population experiences, views and preferences were not applicable for this topic.*

***Search method***

*Electronic database searched:*

*Pubmed, Medline, Egyptian Knowledge Bank, Medscape, WebMD, Google Scholar*

***Keywords:***

*Adults; Guidelines; Tinnitus*

*The adaptation cycle passed over: set-up phase, adaptation phase (Search and screen, assessment: currency, content, quality & /decision/selection) and finalization phase that included revision and external reviewing. We used modified adapt process that consisted of three main phases, including planning and set-up, adaptation, and development of a final product.*

***Time periods searched:*** *from January 2010 to March 2020).*

***Results***

*Three audio-vestibular medicine experts assessed the six tinnitus guidelines, where the multidisciplinary European guideline for tinnitus: diagnostics, assessment, and treatment, 2019 [2], gained the highest scores as regards the currency, contents, and quality (Annex 2: tables 1-3 [3]).*

*It was graded by 20 expert audio-vestibular medicine consultants and reviewed by 3 expert audio-vestibular medicine physicians reviewers, and 1 neurologist reviewer and 1 psychiatrist reviewer and 2 radiologists physicians reviewers, to improve quality, gather feedback on draft recommendations. The external review was done through a rating scale as well as open-ended questions.*

***Intended Users of the guideline:*** *ENT and Audio-Vestibular Medicine Physicians, to be used to make and inform clinical decisions regarding management of older children and adults with subjective tinnitus and/or appropriate referral.*

*Setting: Primary, secondary and tertiary care centers & hospitals, and related specialties***.**

N.B. **Levels of evidence**: Quality of evidence for the treatment methods (treatment elements or protocols, devices, or procedures) was guided by the (GRADE Working Group, 2013**).** The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach to Decision frameworks **(Table 1)**

**N.B. Levels of recommendation:** The recommendation level for each treatment method (Treatment elements or protocols, devices, or procedures) was guided by the GRADE system [3], **Interpretation of strong and conditional recommendations for an intervention is shown in table (1).**

**Table (1): The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to Decision frameworks (GRADE Working Group 2013) [3]**

| Grade | Definition |
|---|---|
| High | We are very confident that the true effect lies close to that of the estimate of the effect. |
| Moderate | We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different |
| Low | Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect. |
| Very Low | We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect |

[4] http://www.gradeworkinggroup.org.

**Table (2): Interpretation of strong and conditional recommendations for an intervention [5]**

| **Audience** | **Strong recommendation** | **Conditional recommendation** |
|---|---|---|
| Patients | Most individuals in this situation would want the recommended course of action; only a small proportion would not.<br><br>Formal decision aides are not likely to be needed to help individuals make decisions consistent with their values and preferences. | Most individuals in this situation would want the suggested course of action, but many would not |
| Clinicians | Most individuals should receive the intervention.<br><br>Adherence to the recommendation could be used as a quality criterion or performance indicator. | Different choices will be appropriate for individual patients, who will require assistance in arriving at a management decision consistent with his or her values and preferences. Decision aides may be useful in helping individuals make decisions consistent with their values and preferences. |
| Policymakers | The recommendation can be adopted as policy in most situations. | Policymaking will require substantial debate and involvement of various stakeholders. |

**[5]** WHO handbook for guideline development – 2nd ed. Chapter 10, page 129

## Recommendations

*The following statements and flowchart were adapted from the "Multidisciplinary European Guideline for Tinnitus: Diagnostics, Assessment, and Treatment, 2019" (MEGT) [2] which has the highest scores as regards the currency, contents, and quality.*

**Recommendations statements**

| | |
|---|---|
| **Accepted statements** | |
| **Modified statements** | |
| **Added statements** | |

| Clinical questions | Action Recommendation | Level of Evidence (High, moderate, low, very low) | Strength of recommendation After Adaptation by Egyptian AVM: (Strong, conditional | Study Type | Reference |
|---|---|---|---|---|---|
| **1. Diagnostics, assessments, and outcomes:** | | | | | |
| **<u>1.a.</u> Minimum patient assessment (It is crucial to perform a detailed history/ clinical examination)** | **There are causal diagnostics and severity-oriented diagnostics:**<br>**I. <u>A comprehensive patient history:</u>**<br>**1) Tinnitus** history.<br>2) Thorough **audiological** history and complaint prioritization.<br>**3) Medical** history.<br>4) Presence of **comorbidities**/**drug** history/**medications**.<br>5) Relevant **personal** history, **occupational** history, hobbies/ leisure activities, **noise** exposure, head/ neck **trauma**, social support status, education, recent life events. | **Very Low** | **Strong Recommendation for** | **Expert's opinion** | **6** |
| **<u>1.a.</u> Minimum patient assessment (It is crucial to perform a detailed history/ clinical examination)** | **1) Tinnitus history**: Tinnitus involves the percept of a sound or sounds in the ear or head without an external source.<br>• **Onset, course, duration:**<br>Since when. sudden or gradually with a continuous increase? It can be acute < 3 months, sub-acute (3-6 months) or chronic (>6months) duration.<br>Important associated clinical factors (noise trauma, stress, recent events, acute illness, other).<br>• **Unilateral or bilateral?**<br>• **Character?**<br>• **<u>Modulation?</u>** (Helps to differentiate causes of objective tinnitus which can be pulsatile or non-pulsatile (<u>Somatosensory tinnitus</u> [respiratory, | **Very Low** | **Strong Recommendation for** | **Expert's opinion** | **6** |

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|---|---|---|---|---|---|
| | articular]).<br><br>**N.B.** Pulsatile tinnitus follows a person's heartbeat and can be either subjective or objective. It is commonly associated with venous and arterial abnormalities. Pulsatile tinnitus can be discriminated as venous or arterial, based on whether it disappears with pressure in the jugular vein or not). The overall approach and assessment of patients with pulsatile tinnitus differs from that for patients with subjective tinnitus, and special clinical investigations should be implemented because serious and potentially reversible causes might be found.<br><br>**N.B.** Somatosensory tinnitus is considered when it can be modulated by somatic stimulation or movement.<br><br>Modulation by:<br>Orofacial, cervical or eye movements?<br>Head positions?<br>Movements of the jaw, tension of jaw muscles?<br>Physical exertions? breathing?<br><br>In some cases, pulsatile tinnitus can be modulated by movement of the head or upper lateral neck.<br><br>• **Severity/impact of the tinnitus**: the degree established by a questionnaire<br><br>• **Is the tinnitus bothersome/ interfering with daily life** (sleep difficulties, task interruptions, fearful reactions, cognitive-attentional problems, negative affect)?<br><br>A **questionnaire** should be used to establish the degree to which a patient experiences subjective tinnitus as bothersome or distressing (see Sect. **1.d.** for more details).<br><br>• The level of tinnitus **awareness**:<br><br>- perceived only in silence or also in noise?<br><br>- easily masked or amplified by ordinary background noise?<br><br>- changes in tinnitus loudness? | | | | |
| **1.a. Minimum patient assessment (It is crucial to perform a detailed history/ clinical** | **2) Thorough audiological history and analysis of the complaint and complaint prioritization:**<br><br>o "Ear fullness", or<br><br>o Hyperacusis. | **Very Low** | **Strong Recommendation for** | **Expert's opinion** | **6** |

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|---|---|---|---|---|---|
| **examination)** | o problems in balance/ dizziness/**vertigo** | | | | |
| **1.a. Minimum patient assessment (It is crucial to perform a detailed history/ clinical examination)** | **3) Medical history:**<br>• ear, nose and throat,<br>• orthopaedic,<br>• cervical,<br>• dental, jaw,<br>• internal medicine,<br>• mental disorders (psychological, psychiatric). | **Very Low** | **Strong Recommendation for** | **Expert's opinion** | **6** |
| **1.a. Minimum patient assessment (It is crucial to perform a detailed history/ clinical examination)** | **4) Presence of comorbidities/drug history/ medications; ototoxic drugs; long-term pharmacological consumption (e. g. antidepressants, anxiolytics)** | **Very Low** | **Strong Recommendation for** | **Expert's opinion** | **6** |
| **1.a. Minimum patient assessment (It is crucial to perform a detailed history/ clinical examination)** | **5) Relevant personal history, occupational history, hobbies/leisure activities, noise exposure, head/ neck trauma, social support status, education, recent life events** | **Very Low** | **Strong Recommendation for** | **Expert's opinion** | **6** |
| **1.a. Minimum patient as- sessment (It is crucial to per- form a detailed history/ clinical examination)** | **II- Conduct a thorough physical–medical assessment to exclude possible treatable (physical/medical) causes of tinnitus:**<br>➢ **Complete ear, nose, and throat examination,**<br>• **especially Otoscopy (preferably micro-otoscopy)** to exclude presence of wax, tympanic membrane rupture, otitis media with effusion, chronic otitis media, or any other pathology. In Otoscopy: Special attention to retro-tympanic mass, Schwartz sign, in addition to other clinical examination for pulsatile tinnitus:<br>• Ask the patient to tick his/her finger in each pulse, while taking radial pulse<br>• Press jugular vein and ask patient whether tinnitus is alternated | **Very Low** | **Strong Recommendation for** | **Expert's opinion** | **6** |

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| | • Use a stethoscope for auscultation of the ear (mastoid, external auditory meatus) and carotid artery (neck), and chest in pulsatile tinnitus, as clinically indicated.<br><br>Special consideration should be given in rare tinnitus causes (e. g. palatal myoclonus, temporomandibular joint [TMJ] disorders).<br><br>• **<u>A comprehensive diagnostic investigation</u>:**<br>• **Pure tone audiometry,**<br>• **Speech audiometry,**<br>• **Evaluation of the perceptional quality of tinnitus** (e.g., Loudness, pitch, and minimum masking estimations),<br>• **Sound tolerance assessment by Loudness Discomfort Level for tones,** to be used for sound sensitivity grading or hearing aid settings.<br>• **Tympanometry and acoustic reflex**<br>N.B. <u>Care must be taken in performing any of the previous loud- ness-based diagnostic investigations, particularly where there is evidence of recent fluctuations in loudness or intensity of the patient's</u> tinnitus or reduced sound tolerance. | | | | |
| **<u>1.b.</u> Further assessment** | **III- Further investigations or referrals in special cases. <u>Only to be considered if clinically indicated:</u>**<br>➢ **Auditory brainstem responses (ABR) and/or magnetic res- onance imaging (MRI).**<br>➢ **High-frequency audiometry** in cases of tinnitus with normal hearing at standard (conversational) frequencies.<br>➢ **Further Radiological evaluation for pulsatile tinnitus [7, 8, 9]:**<br>✓ **Arterial pulsatile tinnitus:**<br>• Carotid triplex (stenosis)<br>• Computed tomography angiography (glomus, aneurysms, atherosclerosis, arteriovenous malformations) | **Very Low** | **Strong Recommendation for** | **Expert's opinion** | **6, 7, 8, 9** |

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| | ✓ **Venous pulsatile tinnitus:**<br>• Magnetic resonance angiography (arteriovenous malformations, empty sella syndrome, Arnold–Chiari malformation, Sylvius aqueduct stenosis, sigmoid sinus diverticulosis, etc.).<br>• N.B. high-resolution, temporal bone CT in case of retrotympanic mass (glomus tympanicum, aberrant internal carotid artery, or jugular bulb abnormalities) if diagnosed, no other imaging stud- ies are needed [9].<br>• When imaging is normal, consider benign intracranial hypertension (BIH), especially in patients with a high body mass index.<br>**Further investigations or referrals in special cases. Only to be considered if clinically indicated:**<br>• **Residual inhibition** to evaluate short-term effects of sound on the tinnitus<br>• **Transient-evoked otoacoustic emissions and/or distortion product otoacoustic emissions** in cases of normal standard audiogram and suspicion of cochlear dysfunction<br>• **Vestibular investigations: e.g., videonystagmography (VNG), video head impulse test (vHIT), and vestibular evoked myogenic potential (VEMP)**, as indicated in cases of dizziness, vertigo, or balance problems<br>• **Functional cervical diagnostics in a quiet environment** for detecting tinnitus modulations in somatosensory tinnitus. Consider imaging of cervical spine in cervical pathology associated with somatosensory tinnitus.<br>• **Dental examination (including temporomandibular joint (TMJ))** in a quiet environment for detecting tinnitus modulations in TMJ dysfunction or bruxism<br>• **Laboratory investigations, [e.g., complete blood count (CBC)**: for hyperdynamic circulation (anemia, etc..) …etc..]<br>• **Fundus examination:** for Benign intracranial hypertension (BIH)<br>**MRI of the bra**in in abnormal auditory brainstem response or abnormal vestibular evoked myogenic potential**.** | | | | |

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|---|---|---|---|---|---|
| **<u>1.c.</u> Red Flags that need urgent referral for Assessment/ Management** | 1. Unilateral tinnitus<br>2. Tinnitus in association with asymmetric or unilateral sensorineural hearing loss<br>3. Pulsatile tinnitus<br>4. Tinnitus in association with significant acute vertigo<br>5. Tinnitus secondary to head trauma<br>6. Tinnitus in association with significant neurological symptoms and/or signs<br>7. Tinnitus causing psychological distress. | **Very Low** | **Strong Recommendation for** | **Expert's opinion** | **1** |
| **<u>1.d.</u> Assessment by questionnaires** | **Tinnitus severity in terms of distress/impact:**<br>Tinnitus patients who report complaints/ show decompensation (grade 2 and higher: (**refer to the flowchart**) should be evaluated with a measure of tinnitus-related disability, such as:<br>➢ The Tinnitus Handicap Inventory (**THI**) questionnaire) (Newman et al., 1996) [10]<br>➢ The Tinnitus Questionnaire (**TQ**) (Hallam, 1996) [11]<br>➢ The Tinnitus Reaction Questionnaire (**TRQ**) (Wilson et al., 1991) [12]<br>➢ The Tinnitus Severity Index (**TSI**) (Meikle et al, 1995) [13].<br>➢ The Tinnitus Handicap Questionnaire (**THQ**) (Kuk et al.,1990) [14]<br>➢ The Tinnitus Severity Questionnaire (**TSQ**) (Coles et al., 1991) [15<br>➢ The Tinnitus Functional Index (**TFI**) questionnaire (Meikle et al, 2012) [16]<br>The **TQ** and the **THI** are widely used in clinical practice and clinical trials. Additionally, almost all existing clinical practice guidelines recommend using the **Hospital Anxiety and Depression Scale** (HADS) [17] to assess negative affect coinciding with or reactionary to tinnitus. | **Very Low** | **Strong Recommendation for** | **Expert's opinion** | **6** |

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|---|---|---|---|---|---|
| | N.B. There are available tinnitus questionnaires in **Arabic language** to be used by Egyptians: Arabic translation of the already present Tinnitus questionnaires and newly developed and validated Arabic Tinnitus questionnaires:<br>Arabic translation of the THI [18, 19], TRQ [20], TFI [21] Arabic translation of HADS [22], Tinnitus Primary Function Questionnaire (TPFQ) (Tyler et al., 2014) [23] Arabic translation [24]. Available Newly Developed Arabic Tinnitus questionnaires, Arabic Tinnitus Reaction Questionnaire [25], Arabic Tinnitus Cognition Questionnaire [26], Arabic self-assessment Tinnitus distress scale [27] | | | | |

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| Clinical questions | Action Recommendation | Level of Evidence (High, moderate, low, very low) | Strength of recommendation After Adaptation by Egyptian AVM: (Strong, conditional | Study Type | Reference |
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| **Treatment options and referral pathways. Available treatments and evidence:** | | | | | |
| **2. a. Drug/ pharmacological** | Treatment of **acute** tinnitus is given according to treatment of acute sudden hearing loss. But, if tinnitus occurs acutely without hearing loss, the standard cortisone therapy is not recommended. Therapeutic approaches such as intratympanic steroid treatment have no effect on tinnitus.<br><br>Any increase in tinnitus severity or distress in chronic tinnitus should not be treated as new onset tinnitus but should be regarded and treated as a fluctuation of chronic tinnitus. | **Very Low** | **Strong Recommendation Against (acute tinnitus), but Strong Recommendation for (acute sudden hearing loss)** | **Expert's opinion** | **28** |
| | For **chronic** tinnitus, many classes of drugs have been used or trialed, including various antiarrhythmics, anticonvulsants, anxiolytics, glutamate receptor antagonists, antidepressants, muscle relaxants, and others, with little evidence of benefit over harm.<br><br>There is no evidence for the effectiveness of drug treatments specifically for tinnitus but evidence for potentially significant side effects. Recommendation is based on systematic reviews and randomized trials. No drug can generally be recommended for the treatment of chronic tinnitus. However, psychiatric comorbidities associated with tinnitus (anxiety, depression) may need drug treatment. Antidepressants should not be prescribed to tinnitus patients without the diagnosis of depression. | **High** | **Strong Recommendation Against (chronic tinnitus), but Conditional Recommendation for (associated comorbidities)** | **Systematic Reviews** | **6, 29, 30** |
| **2. b. Hearing loss interventions**<br><br>**2. b.i. Cochlear implants.** | Cochlear implantation is recommended only for patients meeting the hearing loss criteria for candidacy. Recommendation for tinnitus based on evidence for safety but low-level evidence of effectiveness.<br><br>Also, a recent systematic review (Assouly et al., 2021) [32], where patients in the included studies had tinnitus as a primary complaint, i.e., all had asymmetrical hearing loss or single-sided deafness, revealed that electrical stimulation by cochlear implants in patients with a primary complaint of tinnitus has a | **High** | **Strong Recommendation Against (tinnitus), but Strong Recommendation** | **Systematic Reviews** | **6, 31, 32** |

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| | positive impact on tinnitus distress. Nevertheless, only small sample sizes were found, and studies showed considerable risks of bias. | | **for (deafness)** | | |
| **2. b. Hearing loss interventions**<br><br>**2. b. ii. Hearing aids.** | • Hearing aids are recommended for the management of hearing loss and should be considered as an option for patients with tinnitus and hearing loss. Recommendation is based on evidence of effectiveness and safety in RCTs of hearing aids for hearing loss and tinnitus, and systematic reviews considering hearing aids for tinnitus.<br><br>• Hearing aids should not be offered to tinnitus patients without hearing loss. Tinnitus might be a parameter to be considered in hearing aid fitting and consequent relevant decision-making. | **High** | **Conditional Recommendation for** | **Systematic Reviews, RCTs** | **33-38** |
| | • **Combination hearing aids (including amplification and sound generator in the same device) are another option for patients who may benefit from both amplification and passive sound stimulation.**<br><br>**Hearing aids are found to be equally beneficial to combination hearing aids for tinnitus with hearing loss.** | **High** | **Conditional Recommendation for** | **RCT** | **39** |
| **2.c. Neurostimulation:**<br><br>**2.c. i. Transcranial electrical stimulation.**<br><br>• **2.c. ia. Transcranial direct current stimulation (tDCS)**<br><br>**2.c. ib. Transcranial alternating current stimulation (tACS)** | **There is evidence for safety but no evidence for the effectiveness of transcranial electrical stimulation for tinnitus. Recommendation is based on systematic review and RCTs.** | **High** | **Strong Recommendation Against** | **Systematic Review, RCTs** | **40-45** |
| **2.c. ii. Transcranial Vagus nerve stimulation.** | Paired with sound stimuli (to promote reorganization in the auditory Cortex: **There is evidence for safety but insufficient evidence that vagus nerve stimulation treatments have effects on tinnitus. Recommendation is based on the lack of RCTs or systematic review.** | **moderate** | **Conditional Recommendation Against** | **RC pilot study** | **46** |
| **2.c. iii. Repetitive transcranial magnetic stimulation (rTMS)** | A recent study (Galal et al., 2020) [47] included five randomized controlled double-blind trials in this systematic review investigating the efficacy of rTMS for at least six months post treatment, one followed up monthly for 10 months. TMS reduced the THI score and decreased the severity of tinnitus in 45% of patients and lead to a complete recovery in 32% of cases in one study. However, the meta-analysis demonstrated lack of significant effect of TMS on tinnitus management. An updated meta-analysis (Yin et al, 2021) [48] demonstrated that rTMS improved tinnitus-related symptoms, in terms of the short-term and long-term effects (6 months) on the THI scores, but the TQ and BDI scores demonstrated little immediate benefit. Future research on large samples in multi-centre settings with longer follow-up durations was recommended. | **High** | **Conditional Recommendation for** | **Systematic Reviews, meta-analysis** | **47, 48** |

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| **2.c.iv. Acoustic co-ordinated reset (CR®) neuromodulation.** | **Acoustic CR® neuromodulation is** a sound therapy involving a randomized sequence of four "phase resetting" tones adjusted to the patient's dominant tinnitus pitch that are hypothesized to generate a lasting desynchronization of the pathological brain | **High** | **Conditional Recommendation for** | **Systematic review** | **49** |
| **2. c.v. Invasive neurostimulation treatments:**<br><br>**2. c.v.i. Direct (i. e. implanted electrode) Vagus nerve stimulation, paired with acoustic stimulation for tinnitus**<br><br>**chronic electrical vestibulocochlear nerve stimulation**<br><br>**2. c.v.ii. Cortical surface stimulation brain surface (extradural) implanted electrodes,**<br><br>**2.c.v.iii. Deep brain neural stimulator implantation.** | **There is no high-level evidence for the effectiveness or safety of invasive treatments for tinnitus. Recommendation is based on lack of RCTs or systematic review.** | **very low** | **Conditional Recommendation against** | **a scoping review** | **50** |
| **2.d. Cognitive Behavioural Therapy (CBT)** | **Cognitive behavioural therapy for tinnitus (CBT4T)** to modify dysfunctional behaviours and beliefs. It often includes a combination of several elements (such as **education**, **counselling**, **exposure**, **mindfulness**, **relaxation**, **hearing rehabilitation**).<br><br>**Stepped-care multimodal CBT4T approach** in which: **audiological diagnostics, treatment** and **consultation** as well as **CBT-treatment elements** are combined.<br>➢ Face-to-face CBT treatment<br>➢ CBT in a self-help format (internet-based or otherwise).<br><br>**CBT should be guided and monitored by specialized doctors i.e., psychiatrists.**<br><br>**There is high-level evidence for the effectiveness and safety of CBT for tinnitus. Recommendation is based on systematic review and one further RCT.** | **High** | **Strong Recommendation for** | **Systematic Review, RCT** | **51, 52** |

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| **2.e. Tinnitus Retraining Therapy (TRT)** | Based on the neurophysiological model of tinnitus. It utilizes **directive counselling** to decrease the negative tinnitus-evoked reactions and **sound** to decrease the strength of tinnitus signal. The principal goal of TRT is to achieve **habituation of tinnitus** through the re- training of the brain.<br><br>Based on a medical evaluation of tinnitus, patients are placed into one of **five general categories,** each with a specific variant of TRT treatment, and all patients receive counselling and sound therapy, with substantial differences. Sound therapy acts by providing the auditory systems with constant neutral signs with sound generators, hearing aids, or background noise.<br><br>**There is evidence for safety but little high-level evidence for the effectiveness of TRT.**<br><br>**Based on availability of a recent meta-analyses and systematic review (Han et al., 2021) [53],** analysis of limited studies low-quality evidence with a high risk of bias showed that the TRT was an **effective** treatment for tinnitus, which could improve the response rate of tinnitus and reduce the THI scale. | **High** | **Conditional Recommendation for** | **meta-analyses and systematic review** | **38, 53** |
| **2.f. Sound therapy** | **There is evidence for safety but little high-level evidence for the effectiveness of sound therapy. Recommendation is based on RCTs and a systematic review**.<br><br>**Sound therapy (including masking, music, environmental sound) may be useful for acute relief purposes but is not considered an effective intervention with long-term results.**<br><br>• **Acoustic stimulation might improve tinnitus through some interaction with tinnitus mechanisms, through the partial or complete masking of tinnitus, and/or through certain cognitive influences (diversion, stress management etc.).**<br><br>• **Sound therapy is used in different ways, and includes:**<br><br>➢ **Tinnitus masking therapy.**<br><br>➢ **Neuromonics approach.** consists of an acoustic stimulation combining music and broadband noise and counselling. The spectrum of this combination is customized to provide an equalized stimulation over the audible frequency range and provide stimulation within the deprived sensory region, and to promote relaxation and relief.<br><br>➢ **Notched music stimulation.** the notch (1 octave width) being chosen to correspond to the tinnitus pitch. This approach is thought to reverse the "maladaptive cortical reorganization".<br><br>**Customized music stimulation.** aimed at reversing the tinnitus-related central changes due to hearing deprivation | **High** | **Conditional Recommendation for** | **RCTs Systematic Review** | **54-60** |

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| **2.g. Dietary and alternative therapies** | There is evidence that dietary and alternative therapies have no proven efficacy and pose potential harm in the management of tinnitus. Recommendation is based on RCTs and systematic reviews with methodological concerns.<br><br>**Dietary and alternative therapies (e.g.**<br><br>➢ Ginkgo biloba**.** herbal supplement<br><br>➢ **Melatonin:** a hormone secreted by the pineal gland that is involved with regulation of the sleep– wake cycle.<br><br>➢ **Dietary supplements.**<br>• Zinc,<br>• lipoflavonoids,<br>• garlic,<br>• homeopathy,<br>• traditional Chinese/Korean herbal medicine,<br>• honeybee larvae, and<br><br>Other various vitamins and minerals. | **High** | **Strong Recommendation Against** | **Systematic Review,** | **61-66** |
| **2.h. Acupuncture.** | There is evidence for safety but little high-level evidence for the effectiveness of acupuncture. Recommendation is based on systematic review | **High** | **Conditional Recommendation Against** | **Systematic Review, RCTs** | **67** |
| **3. Patient information and support.** | • It is essential to successful tinnitus treatment that patients are provided with reliable information and learning resources.<br><br>• The provision of information should be timely and fill gaps in knowledge, dispel myths, offer hope, and provide key messages that are a framework for treatment.<br><br>• Information should never be negative.<br><br>In the assessment, information is gathered about how tinnitus is affecting the patient in their daily life, about their understanding of tinnitus, and their concerns or fears surrounding it. This can be used to explore with them how their beliefs about tinnitus and the meaning they attach to it influences how they think, feel, and react to it. Health-care professionals should be compassionate to the concerns and fears expressed by patients. | **High** | **Strong Recommendation for** | **Cochrane Review** | **68** |

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| | → **Patient information and support topics should be tailored to the patient's need and what is available to them. Topics include:**<br>➢ What is tinnitus?<br>➢ What causes and maintains it?<br>➢ Pulsatile tinnitus (follows heartbeat)<br>➢ Common misunderstandings and Myths<br>➢ Hearing loss and hearing aids<br>➢ Ear wax removal<br>➢ Hyperacusis and tinnitus<br>➢ Protecting your hearing<br>➢ Habituating to tinnitus<br>➢ Relaxation<br>➢ Monitoring tinnitus<br>➢ Use of sound<br>➢ Dealing with sleep problems<br>➢ Dealing with emotional consequences of tinnitus<br>➢ Self-help and support groups | | | | |
| **4- Measuring The Tinnitus Treatment Outcome** | **Measuring improvement:**<br>**by finding a change from a degree of severity to less degree of severity after an intervention, using the same questionnaire before and after the intervention, or**<br>**by finding a minimum clinically significant change in a before- after treatment score (a meaningful response criterion) by using the THI or TFI Questionnaires:**<br>➢ **7-point reduction in THI** (Newman et al., 1996) [10]**, even if no change in tinnitus degree of severity**.<br>➢ **13-point reduction in TFI** (Meikle et al., 2012) [16], **even if no change in tinnitus degree of severity**.<br>**N.B. Arabic language tinnitus questionnaires are available for use by the Egyptians** [18-27]. | **High** | **Strong Recommendation for** | **Systematic Review** | **6, 69, 70** |

## Research needs.

*Research questions.*

*There is a need to conduct randomized controlled trials (RCTs) to determine the efficacy of Sound therapy.*

*There is a need to conduct RCTs to determine the efficacy of Neuromodulation.*

*There is a need to conduct RCTs to determine the efficacy of Combining therapies.*

*There is a need to determine the efficacy and safety of different management strategies for tinnitus and hyperacusis in children.*

## Monitoring and evaluating the impact of the guideline.

***Monitoring/ Auditing Criteria:*** to assess guideline implementation or adherence to recommendations.

- *Performing a targeted history and thorough Basic Audiological Evaluation as a minimum patient assessment, with further audio-vestibular investigations only if indicated, and urgent referral of any tinnitus Red Flags.*
- *Providing information about tinnitus and treatment options.*
- *Prescribing hearing aids only when patients have a diagnosed hearing loss.*
- *Specialized cognitive behavioral therapy for tinnitus should be offered when needed.*

## Updating of the guideline

***Updating Procedure:***

*Any recommendation of this guideline will be updated when new evidence that could potentially impact the current evidence base for this recommendation is identified. If no new reports or information are identified for a particular recommendation, the recommendation will be revalidated. The focus will be on recommendations supported by very-low- or low certainty evidence and where new recommendations or a change in the published recommendations may be needed.*

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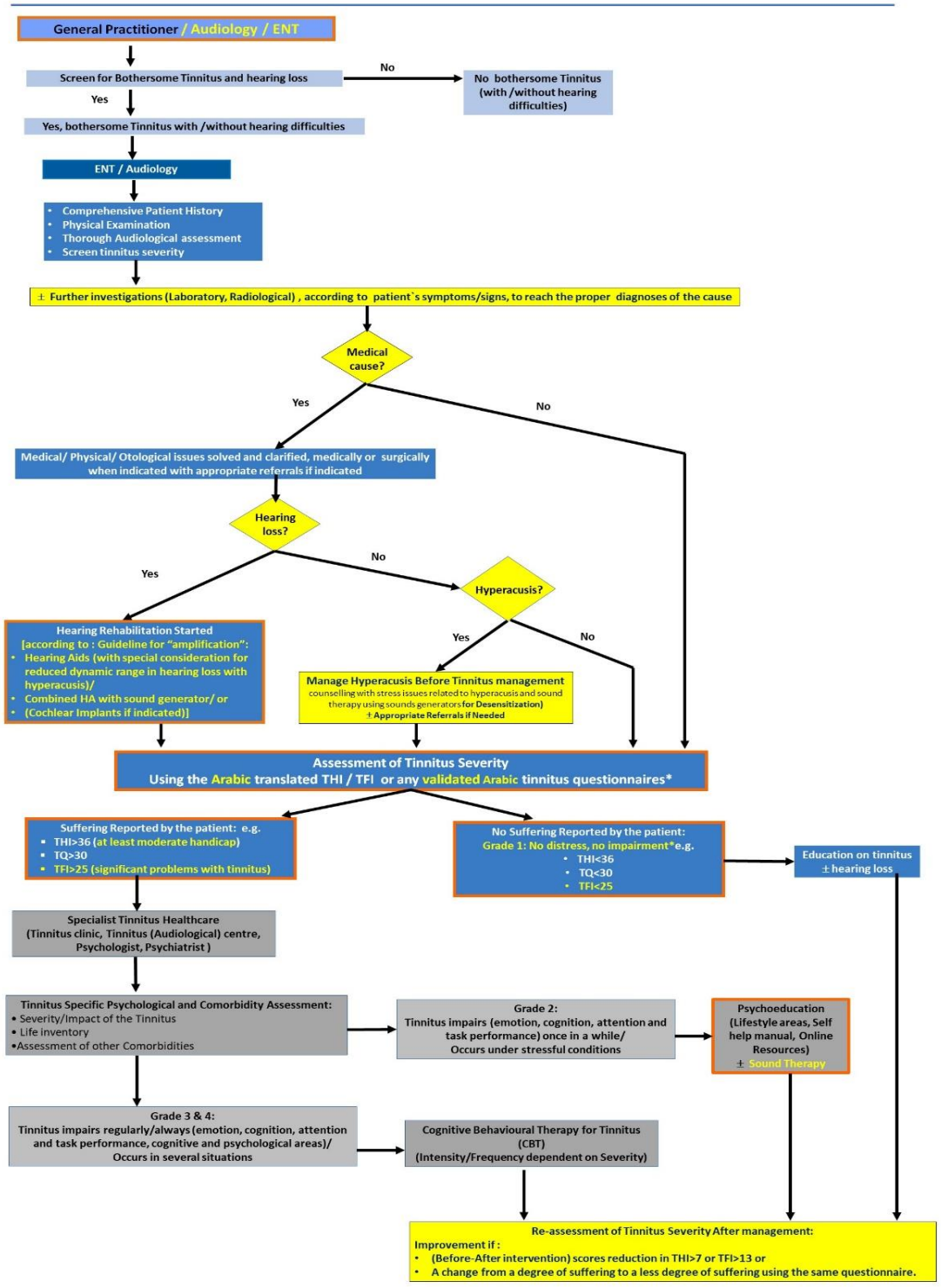
## *Annexes*

***Editorial Independence:***

- *This guideline was developed without any external funding.*
- *All the guideline development group members have declared that they do not have any competing interests.*

## Annex 1: Guideline Flowchart

Criteria for Assessment and Treatment of Tinnitus After Adaptation from The chosen Guideline (Cima et al., 2019).




*N.B.*

- *Tinnitus grades from (Cima et al., 2019)*
- *Added items in the flowchart in yellow highlights*
- *Modified items in the flowchart in orange borders , with the added text in yellow colour.*

** Refer to the references for the Arabic Language Tinnitus questionnaires.*

**Annex 2: <u>Tables of appraisal of selected guidelines:</u> currency (table 1), content (table 2), and quality (table 3), of the selected guidelines {2, 71, 72, 73, 74, 75], according to the Practice guidelines evaluation and adaptation cycle [3].**

**Table 1. Guidelines Currency**

| | Guideline Name | Responsible organization | Date of publication | Expected review date | Date of original details in the reference |
|---|---|---|---|---|---|
| 1 | Multidisciplinary European guideline for tinnitus: diagnostics, assessment, and treatment, | Multidisciplinary | 2019 | February 2023 | 2018 |
| 2 | AAO-HNS | American Academy of Otolaryngology—Head and Neck Surgery Foundation | 2014 | Not Reported | 2013 |
| 3 | BSA - Practice Guidance Tinnitus in adults, for consultation | British Society of Audiology | 2019 | August 2023 | 2019 |
| 4 | German S3 guideline O17/064: Chronic tinnitus, | German Society of Otorhinolaryngology and Head and Neck Surgery | 2015 | Feb 2020 | 2014 |
| 5 | Clinical practice guidelines for diagnosis and treatment of chronic tinnitus in Japan, | Oto-Rhino-Laryngological Society of Japan | 2019 | Not Reported | 2016 |
| 6 | Tinnitus NICE guideline [NG155] | National Institute for Health and Care Excellence, UK | 11 March 2020 | Not Reported | 2019 |

**Table 2. Assessment of Content.**

| Criteria | Guideline A | Guideline B | Guideline C | Guideline D | Guideline E | Guideline F |
|---|---|---|---|---|---|---|
| | European | AAO-HNS | British | German | Japanese | NICE |
| Credibility | 9 | 9 | 9 | 9 | 9 | 9 |
| Observability | 8 | 8 | 8 | 8 | 7 | 8 |
| Relevance | 9 | 8 | 8 | 8 | 8 | 8 |
| Relative advantage | 8 | 7 | 8 | 7 | 6 | 9 |
| Easy to install and understand | 8 | 8 | 7 | 8 | 6 | 8 |
| Compatibility | 8 | 8 | 7 | 6 | 8 | 8 |
| Testability | 8 | 8 | 8 | 7 | 8 | 8 |
| Total score | 58 | 56 | 55 | 53 | 52 | 58 |

**Table 3. Assessment of Quality (CPG Appraisal tool):**

| Domain | Guideline A | Guideline B | Guideline C | Guideline D | Guideline E | Guideline F |
|---|---|---|---|---|---|---|
| | European | AAO-HNS | British | German | Japanese | NICE |
| 1.Transparency | A | A | A | A | A | A |
| 2. Conflict of interest | A | A | A | A | B | A |
| 3. Development group | A | B | B | B | B | B |
| 4. Systematic review | A | A | A | A | A | A |
| 5. Grading of evidence | A | A | A | A | A | A |
| 6. Recommendations | A | A | A | A | A | A |
| 7. External review | A | A | A | A | B | A |
| 8. Updating | A | C | A | B | C | A |

## Annex 3: The benefits and harms of all added, modified statements, N.B. No omitted statements

**Consideration Of Benefits and Harms that were considered when formulating the recommendations are shown in the following tables (4 & 5):**

### Table 4: Original and adapted Summary of CPG recommendations of the selected guideline:

| Statement Topic | Original statement | The statement to be adapted: Action | Benefits | Risk/Harm |
|---|---|---|---|---|
| **1.a. Minimum patient assessment (It is crucial to perform a detailed history/ clinical examination)** | **I) A comprehensive patient history:**<br>**1-Tinnitus history:** | **1- Tinnitus history:** ***Add a definition:*** *Tinnitus involves the percept of a sound or sounds in the ear or head without an external source.*<br>***Ask:***<br>○ **Unilateral or bilateral?**<br>***Ask:***<br>○ Character? ……, and is it **pulsatile**? | - The clinician and the patient should assure proper understanding of the **definition** of the complaint, for proper management or referral.<br>- **Unilateral** tinnitus is considered a ***red flag*** that prompts further site of lesion testing that may necessitate investigations and referrals for management of the cause.<br>- **Pulsatile** tinnitus is considered a ***red flag*** that prompts further investigations that may necessitates referrals for management of the cause. | - Misunderstanding of the complaint **can delay** proper management or referral e.g. d.d. auditory hallucination, environmental sounds…..<br>- **Unilateral** tinnitus and **pulsatile** tinnitus may underlie serious medical conditions. |

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| **1.a. Minimum patient assessment (It is crucial to perform a detailed history/ clinical examination)** | **I) A comprehensive patient history:**<br><br>**2-Thorough audiological history and complaint prioritisation:**<br><br>○ "ear fullness", or<br>○ hyperacusis,<br>○ problems in balance/ dizziness/**vertigo** | **Replace:**<br><br>**"**Thorough audiological history and complaint **prioritisation**"<br><br>By: "Thorough audiological history **and analyses of the** complaint": | The clinician should be aware to fully analyze the patient's complaint by asking leading questions as the patient may not pay attention to other symptoms that may guide in the diagnoses | complaint prioritisation may miss other important symptoms given less weight by the patient that may delay in the diagnosis |
| **1.a. Minimum patient assessment (It is crucial to perform a detailed history/ clinical examination)** | **Conduct a thorough physical–medical assessment to exclude possible treatable (physical/medical) causes of tinnitus:**<br><br>➢ **Complete ear, nose, and throat examination,**<br>**especially Otoscopy ……**<br><br>…….<br><br>*in* Otoscopy: Special attention to retrotympanic mass, | **Conduct a thorough physical–medical assessment to exclude possible treatable (physical/medical) causes of tinnitus:**<br><br>➢ **Complete ear, nose, and throat examination,**<br>**especially Otoscopy ……**<br><br>…….<br><br>*in* Otoscopy: Special attention to retrotympanic mass,<br><br>**Add:**<br><br>Schwartz sign | Schwartz sign is an important otoscopic finding suggestive of otosclerosis, a common cause for pulsatile tinnitus. | If the clinician is not aware of clinical findings to suspect the cause, he/she may waste time in unnecessary investigations instead of referral for needed investigations. |

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| **1.a. Minimum patient assessment (It is crucial to perform a detailed history/ clinical examination)** | **II. Conduct a thorough physical–medical assessment**<br><br>**sound tolerance**, | **II. Conduct a thorough physical–medical assessment**<br><br>**sound tolerance assessment by loudness discomfort level, for tones, to be used for sound sensitivity grading or hearing aid settings.** | Hyperacusis, is an important complain that must be considered in the tinnitus patient, and recruitment must be considered in case of associated sensorineural hearing loss (SNHL) | If not considered there would be difficulty in management of tinnitus and / or hearing aid fitting in case of associated SNHL. |
| **1.b. Further assessment** | **Further investigations or referrals in special cases. Only to be considered if clinically indicated:**<br><br>• **Auditory brainstem responses (ABR) and/or magnetic resonance imaging (MRI) in cases of unilateral tinnitus and/or asymmetric hearing loss** | **Further investigations or referrals in special cases. Only to be considered if clinically indicated:**<br><br>• **Auditory brainstem responses (ABR) and/or magnetic resonance imaging (MRI) if clinically indicated** | **Auditory brainstem responses (ABR) and/or magnetic resonance imaging (MRI) can be clinically indicated not only in cases of unilateral tinnitus and/or**<br><br>**asymmetric hearing loss, but there are other red flags for tinnitus, e.g. pulsatile tinnitus, tinnitus in association with significant acute vertigo, or with significant neurological symptoms and/or signs, or with word discrimination score inconsistent with PTA, etc…** | Limiting the indications may miss the diagnosis of dangerous underlying causes of tinnitus. |
| **1.b. Further assessment** | **Further sound tolerance assessment (loudness discomfort level) for sound sensitivity grading and** | Deleted here and added to: **1.a. Minimum patient assessment** | Hyperacusis, is an important complain that must be considered in the tinnitus patient, and recruitment must | If not considered there would be difficulty in management of tinnitus and / or hearing aid fitting in case |

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| | **hearing aid fitting).** | | be considered in case of associated sensorineural hearing loss (SNHL) | of associated SNHL. |
| **1.b. Further assessment** | **Further Radiological evaluation for pulsatile tinnitus:** ……<br><br>…… | **Further Radiological evaluation for pulsatile tinnitus: ……**<br><br>**……..**<br><br>**Add:**<br><br>N.B. high-resolution, temporal bone CT in case of retrotympanic mass (glomus tympanicum, aberrant internal carotid artery, or jugular bulb abnormalities) if diagnosed, no other imaging studies are needed (Sismanis, 2003).. | high-resolution, temporal bone CT is essential to diagnose possible causes of pulsatile tinnitus without the need for further costly imaging if a retrotympanic mass is detected on otoscopy. | If not suspected, unnecessary costly imaging would be done, and still diagnosis unreached |
| **1.b. Further assessment** | **Further investigations or referrals in special cases. Only to be considered if clinically indicated: ……..**<br><br>…… | **Further investigations or referrals in special cases. Only to be considered if** clinically indicated**:**<br>**……**<br><br>**……**<br><br>**Add:** | • Some important causes of pulsatile tinnitus can be suspected based on history and clinical examination. So, further investigations or referrals should be directed to the suspected cause which saves time, cost and effort and guides to early and proper management. | • If needed investigations are not done, this wastes time, money and effort and leads to delays in diagnoses and improper management. |

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| | | • **Laboratory investigations, [e.g., CBC:** *for hyperdynamic circulation (anemia, etc..)…***etc..]**<br><br>• **Fundus examination:** *for Benign intracranial hypertension (BIH).* | | |
| **1.d. Assessment by questionnaires** | **Tinnitus severity in terms of distress/impact:**<br>Tinnitus patients who report complaints/ show decompensation (grade 2 and higher: (**refer to the flowchart**) should be evaluated with a measure of tinnitus-related disability, such as:<br>➢ The Tinnitus Handicap Inventory (**THI**) questionnaire) *(Newman et al., 1996).*<br>➢ The Tinnitus Questionnaire (**TQ**) *(Hallam, 1996).*<br>➢ The Tinnitus Reaction Questionnaire (**TRQ**) *(Wilson et al., 1991.)*<br>➢ The Tinnitus Severity Index (**TSI**) *(Meikle et al, 1995).*<br>➢ The Tinnitus Handicap Questionnaire (**THQ**) *(Kuk et al.,1990).*<br>➢ The Tinnitus Severity Questionnaire (**TSQ**) *(Coles et al., 1991).*<br>➢ The Tinnitus Functional Index (**TFI**) questionnaire *(Meikle et al, 2012).* | **Tinnitus severity in terms of distress/impact:**<br>Tinnitus patients who report complaints/ show decompensation (grade 2 and higher: (**refer to the flowchart**) should be evaluated with a measure of tinnitus-related disability, such as: ……etc<br>**<u>In addition to that:</u>**<br>*N.B.* ***There are available tinnitus questionnaires in Arabic language to be used by Egyptians: Arabic translation of the already present Tinnitus questionnaires and newly developed and validated Arabic Tinnitus questionnaires [17-26].*** | • Arabic translation is easier for Egyptian patients to answer and get reproducible results, and an Arabic language tinnitus questionnaires are available for use by the Egyptians.<br><br>• Both the **TQ** and the **THI** have a scoring system of 3 choices only, making administration easy for the patients.<br>• Both the TQ and the THI have suitable subscales for patients' assessment.<br>• Both the THI and the TFI proved to be appropriate for measuring tinnitus severity as well as intervention-related change (**treatment outcome**). But the TFI is lengthy and has a bigger scale of answers.<br><br>• | • **Apart from the TQ** and the **THI,** other available tinnitus questionnaires have more than 3 choices which the **Egyptian patients would be reluctant and find it confusing to answer accurately.**<br>• |

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| | The **TQ** and the **THI** are widely used in clinical practice and clinical trials. Additionally, almost all existing clinical practice guidelines recommend using the **Hospital Anxiety and Depression Scale** *(Zigmond and Snaith, 1983)* to assess negative affect coinciding with or reactionary to tinnitus. | | | |
| **2.c. iii. Repetitive transcranial magnetic stimulation (rTMS).** | **No consistent evidence that repetitive transcranial magnetic stimulation is effective for tinnitus and no evidence that it is safe in the long term. Recommendation is based on systematic reviews.**<br>**(Level of Evidence 1a,**<br>**No Recommendation)** | **No consistent evidence that repetitive transcranial magnetic stimulation is effective for tinnitus and no evidence that it is safe in the long term. Recommendation is based on systematic reviews.**<br>In a recent study, TMS reduced the THI score and decreased the severity of tinnitus in 45% of patients and lead to a complete recovery in 32% of cases in one study. However, the meta-analysis demonstrated lack of significant effect of TMS on tinnitus management ***(Galal et al., 2020)*** | • Recent research shows some improvement with rTMS, so it is worthy to give the patients a chance for a possible improvement. | • patients may miss a chance for a possible improvement, that could be their best way of management. |

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| | | [47]**.**<br><br>An updated meta-analysis demonstrated that rTMS improved tinnitus-related symptoms, in terms of the short-term and long-term effects (6 months) on the tinnitus handicap inventory scores, but the TQ and BDI scores demonstrated little immediate benefit. Future research on large samples in multi-centre settings with longer follow-up durations was recommended (***Yin et al., 2021)*** [48]**.**<br><br>**(Level of Evidence 1a**<br><br>**Conditional Recommendation for)** | | |
| **2.d. Cognitive Behavioural Therapy (CBT)** | **Cognitive behavioural therapy for tinnitus (CBT4T**) to modify dysfunctional behaviours and beliefs. It often includes a combination of several elements (such as **education**, **counselling**, **exposure**, **mindfulness**, **relaxation**, **hearing rehabilitation**).<br><br>**Stepped-care multimodal CBT4T approach** in which: | **Cognitive behavioural therapy for tinnitus (CBT4T**) to modify dysfunctional behaviours and beliefs. It often includes a combination of several elements (such as **education**, **counselling**, **exposure**, **mindfulness**, **relaxation**, **hearing rehabilitation**).<br><br>**Stepped-care multimodal CBT4T approach** in which: **audiological diagnostics, treatment** and | In Egypt, CBT should be only performed by and/or<br><br>guided and monitored by specialized doctors i.e. psychiatrists, who can professionally deal with patients.<br><br>• | • non- psychiatrists performing CBT, may result adversely in noneffective management, or adverse effects on the patient. |

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| | **audiological diagnostics, treatment** and **consultation** as well as **CBT-treatment elements** are combined.<br>➢ Face-to-face CBT treatment<br>➢ CBT in a self-help format (internet-based or otherwise)<br>**Where there are pragmatic barriers and/or lack of resources, an initial step of CBT treatment might be performed by a competent non-psychological professional provided there is appropriate support.**<br>**There is high-level evidence for the effectiveness and safety of CBT for tinnitus. Recommendation is based on systematic review and one further RCT.** | **consultation** as well as **CBT-treatment elements** are combined.<br>➢ Face-to-face CBT treatment<br>➢ CBT in a self-help format (internet-based or otherwise)<br>**<u>CBT should be guided and monitored by specialized doctors i.e., psychiatrists.</u>**<br>**There is high-level evidence for the effectiveness and safety of CBT for tinnitus. Recommendation is based on systematic review and one further RCT.** | | |
| **<u>2.e. Tinnitus Retraining Therapy (TRT)</u>** | **There is evidence for safety but little high-level evidence for the effectiveness of TRT. Recommendation is based on availability of one RCT and two systematic reviews.** | **Based on availability of a recent meta-analyses and systematic review (Han et al., 2021) [53],** analysis of limited studies low-quality evidence with a high risk of bias showed that the TRT was | Recent research show improvement with TRT, so it is worthy to give the patients a chance for a possible improvement. | • patients may miss a chance for a possible improvement, that could be their best way of management. |

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| | **(Level of Evidence 1a, 1b,**<br><br>**No Recommendation)** | an **effective** treatment for tinnitus, which could improve the response rate of tinnitus and reduce the THI scale.<br><br>**(Level of Evidence 1a**<br><br>**Recommendation for)** | | |

## Table 5: Summary of Added CPG recommendations for the selected guideline:

| Statement Topic | --------- | The statement to be adapted: Action | Benefits | Risk/Harm |
|---|---|---|---|---|
| **<u>1.c.</u> Red Flags that need urgent referral for Assessment** | --- | **1) Unilateral tinnitus**<br>**2) Tinnitus in association with asymmetric or unilateral sensorineural hearing loss**<br>**3) Pulsatile tinnitus**<br>**4) Tinnitus in association with significant acute vertigo**<br>**5) Tinnitus in association with significant neurological symptoms and/or signs**<br>**6) Tinnitus causing psychological distress** | The clinician should be aware of red flags that need urgent referral for assessment and proper management of a potentially curable cause | A delay inappropriate referral hinders proper management and may be life threatening. |
| **4- Measuring the**<br>**Tinnitus Treatment Outcome** | -------- | **Measuring improvement:**<br>**by finding a change from a degree of severity to less degree of severity after an intervention, using the same questionnaire before and after the intervention, or**<br>**by finding a minimum clinically significant change in a before- after treatment score (a meaningful response criterion) by using the THI** | • Questionnaires are not only useful to assess tinnitus severity/impact but can also be used as **base line for follow-up** to determine prognosis and treatment effect on tinnitus severity.<br>• Most tinnitus questionnaires are optimized for measuring severity but do not show a **cut-off point for** significant change even | • **Tinnitus is a subjective complaint, so treatment outcome effect can only be assessed on follow-up using self-report questionnaires that assess tinnitus severity/impact.**<br>• In order to follow-up the prognoses after treatment, the **same self-report measure** should be used. |

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| | | **or TFI Questionnaires:**<br><br>➢ **7-point reduction in THI (*Newman et al., 1996) [10]*, even if no change in tinnitus degree of severity.**<br>➢ **13-point reduction in TFI *(Meikle et al., 2012) [16],* even if no change in tinnitus degree of severity.**<br>***N.B. An Arabic translation for the tinnitus questionnaires is available for use by the Egyptians.*** | with the same severity. Both the THI and the TFI proved to be appropriate for measuring tinnitus severity as well as intervention-related change (treatment outcome). | |