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# A multidisciplinary European guideline for tinnitus: diagnostics, assessment, and treatment

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## Contents



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Appendix B Method for the development of an implementation plan
Appendix C Somatosensory tinnitus
Appendix D Characteristics and psychometrics of existing tinnitus health-related quality-of-life instruments
Appendix E Cognitive therapy and cognitive behavioural therapy

## Chapter 1: General introduction

### 1.1 Motivation for the guideline

Tinnitus involves the percept of a sound or sounds in the ear or head without an external source. Most individuals experiencing tinnitus have a neutral reaction to the percept. However, for some it becomes a problem. Bothersome (distressing) tinnitus might be better described as a negative emotional and auditory experience, associated with, or described in terms of, actual or potential physical or psychological harm [10]. Objective tinnitus is defined as the perception of a sound which has a physical source generated in or near the ear. An external observer can perceive objective tinnitus. Subjective tinnitus does not involve an identifiable sound source so cannot be heard by examination. It is caused by anomalous activity in the auditory system. Subjective tinnitus is a highly complex condition with a multifactorial origin and, therefore, heterogeneous patient profiles. In most people, tinnitus is not traceable to medical causes. In

**Table 1** Frequent tinnitus comorbidities

| | |
|---|---|
| Hearing and vestibular disorders | Hearing loss (H90.5)<br>Disturbance of auditory perception (H93.2)<br>Hyperacusis (H93.2)<br>Vestibular disorders (H81) |
| Mood disorders | Adjustment disorder (ICD-10: F43.2)<br>Dysthymia (ICD-10: F34.1)<br>Depressive episode (ICD-10: F32.0, F32.1, F32.2, F32.3):<br>Recurrent depressive episodes (ICD-10: F33.0, F33.1, F33.2, F33.3) |
| Anxiety disorders | Phobic disorders (ICD-10: F40.)<br>e. g., specific phobia (ICD-10: F40.2)<br>Anxiety disorder (ICD-10: 41.)<br>Generalised anxiety disorder (ICD-10: F41.1)<br>Anxiety and depressive disorder, mixed (ICD-10: F41.2) |
| Reaction to severe stress and adjustment disorders | Acute reaction to burdening (F43.0)<br>Posttraumatic stress disorder (ICD-10: F43.1)<br>Somatoform disorders<br>Somatisation disorder (ICD-10: F45.0)<br>Hypochondriasis (ICD-10: F45.2)<br>Psychological factors and behavioural factors in another classified disease (ICD 19: F54)<br>Insomnia (G47) |

most cases there is no available curative treatment [7, 45]. Standard treatment, assessment, and referral-trajectories are poorly defined, not well established, and often insufficient. The lack of standard guidelines likely leads to untreated, under-, as well as over-treated patients [15, 21, 26, 34, 56]. This leads to increasing complaints, prolonged suffering, and loss of societal participation, health-care overuse, and endless referral trajectories, resulting in an enormous psychological, societal, and economic burden in Europe. There is therefore a need for a European harmonised guideline for the assessment and treatment of tinnitus. Through development and implementation of this guideline, we anticipate that assessment and treatment of tinnitus will be significantly more effective, leading to reduced suffering and frustration for patients, their families, and clinicians alike.

## 1.2 Aim of the guideline

The main goal of this guideline is to establish uniformity in the assessment and treatment of adult patients with subjective tinnitus. In addition, this guideline aims to establish consistency in policy to optimise referral trajectories and reduce over- and under-assessment and treatment. Guidance for detailed clinical definition and characterisation of cases is also included. Experts from different disciplines from across Europe have joined forces to develop standardisation procedures for easy, practicable, and meaningful patient profiling. The guideline should be used as a tool to support shared decision-making with patients to facilitate individualised care.

## 1.3 Delineation of the guideline

Tinnitus is a common auditory symptom, which may result in serious burden particularly when there are comorbidities. Tinnitus can present in many forms. 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 individualised treatment.

## 1.4 Intended users of the guideline

This guideline was established for every health professional involved in tinnitus assessment and treatment, including but not limited to: general practitioners; ear, nose, and throat doctors (ENT); neurologists; audiologists; psychiatrists; psychologists; maxillofacial doctors; nurses; therapists; basic and clinical researchers. It was designed to be accessible to researchers, tinnitus patients and their significant others, patient organisations, policy-makers, and any other relevant stakeholders.

## 1.5 Main classifications for subjective tinnitus

### Acute, sub-acute, and chronic tinnitus

Tinnitus is acute if the patient has experienced it for less than 3 months and is considered sub-acute after 3 months. It is termed "chronic" when the patient has experienced it for 6 months or more. Assessing whether tinnitus is acute or chronic is relevant to the choice of certain treatments.

### Possible comorbidities

Comorbidities can be pre-existent or induced by tinnitus. Frequently psychological, psychosomatic, and/or psychiatric comorbidities are associated with tinnitus [42, 68, 77]. Anxiety, depression, and insomnia are commonly found in patients with tinnitus. The higher the level of distress, the more likely comorbid disorders are present [24, 44]. On suspicion of psychological comorbidity, further assessment and treatment should be undertaken by appropriate specialists (psychologist, psychosomatic specialist, psychiatrist, or neurologist). A list of comorbidities that may be observed in tinnitus patients is given in **Table 1**.

### Profile of severity

Tinnitus severity can be graded using multi-item tinnitus questionnaire scores where there is a valid grading system provided. It can also be (more subjectively) graded according to structured medical history. For example, the structured tinnitus interview by Biesinger et al. [8] allows tinnitus severity to be classified into one of four grades based on level and frequency of impairment (see **Table 2** for an adapted version of this grading system).

**Table 2** Tinnitus grading system

| Grade | Description |
|---|---|
| 1 | No distress, no impairment |
| 2 | Tinnitus impairs (e. g. emotion, cognition, attention, task performance) occasionally/ occurs under stressful situations and mainly in silence |
| 3 | Tinnitus regularly impairs (e. g. emotion, cognition, attention, task performance) occurs in several situations |
| 4 | Tinnitus constantly leads to impairment (e. g. in emotion, cognition, attention, task and daily life interference) occurs in all situations |

### Characteristics of tinnitus

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 might be pulsatile (either synchronous with the heartbeat or not) or non-pulsatile, and both may be objective or subjective (see Appendix A for further information on pulsatile tinnitus).

## 1.6 Epidemiology of tinnitus

Studies of tinnitus prevalence are not free of methodological problems; they use different definitions of tinnitus, or address selected age or professional groups. Most studies report conservative tinnitus prevalence rates to be between 10 and 19% of adults [6, 23]. The phantom auditory sensation of tinnitus is chronically perceived by roughly one in three of elderly adults [1, 59]. Tinnitus is commonly associated with hearing loss, noise exposure, ageing and stress [27, 31, 55, 58, 67] and less often with other otologic, neurologic, infectious, and drug-related effects and other comorbidities [76]. In the tinnitus population the prevalence of hyperacusis (reduced tolerance to everyday sounds) is 40–86% according to different studies [2, 35].

## 1.7 Pathophysiology of tinnitus

Most of our knowledge on tinnitus pathophysiology originates from animal research. Firstly, tinnitus is related to "aberrant" neural activity (that is not produced by physically measurable sounds from the environment) that is generated at some level of the auditory system. Secondly, the tinnitus-related signal is interpreted as an auditory percept and can be associated with distress. Tinnitus has been suggested to result from an increased firing rate, increased synchrony between neural discharges, or an aberrant pattern of oscillatory activity (possibly resulting in an increase of neural firing synchrony; [62]). In most cases, tinnitus is believed to be associated with some degree of cochlear damage. There can be cochlear damage not detected by a standard audiogram. Indeed, it has been shown that high-threshold cochlear fibres (that are activated well above absolute threshold) can be uncoupled from their corresponding inner hair cells and/or degenerated after moderate noise trauma [50, 51, 73].

One can distinguish between the peripheral and central mechanisms that can result in the generation of the tinnitus-related activity. Many mechanisms may account for cochlear tinnitus (related to cochlear aberrant spontaneous activity): activation of N-methyl-D-aspartate receptors [25, 66], shift in the operating point of outer hair cells [19, 48, 61], decoupling of outer hair cell stereocilia [49], and increase in the endo-cochlear potential [63]. Central forms of tinnitus are then thought to result from aberrant neural discharges produced by central changes which may be triggered by hearing loss. Many central mechanisms that can account for the generation of the tinnitus-related activity have been proposed [20]. The vast repertoire of mechanisms involved in homeostatic plasticity may account for central hyperactivity after hearing loss. The reorganisation of the cortical tonotopic map may also play a role in tinnitus generation, by increasing synchrony of discharges between cortical neurons. This mechanism is likely not involved in tinnitus in people without hearing loss [43] or those with a pantonal hearing loss.

Somatosensory inputs can modulate neural activity in the cochlear nucleus [69–71]. The excitatory modulation of these inputs on the auditory pathway is enhanced after hearing loss and can be responsible for the noise-induced central hyperactivity (potentially associated with tinnitus) after noise trauma [18, 75].

Finally, the thalamus may play a direct role in generating tinnitus-related activity. The reduction of sensory inputs is thought to hyperpolarise thalamic neurons, which leads to the generation of bursts of action potentials in the thalamus and cortex. This activity can be maintained by the cortico-thalamic pathway and the activation of the reticular nucleus sending inhibitory inputs back to specific nuclei of the thalamus [52, 53].

## 1.8 Mechanisms of tinnitus awareness and distress

Tinnitus is not necessarily associated with distress. Indeed, 6–20% of people with tinnitus consider it bothersome [59]. This indicates a partial dichotomy between mechanisms generating the tinnitus-related signal and those responsible for tinnitus distress. It has been proposed that non-auditory brain regions evaluate the tinnitus-related signal. If the tinnitus-related activity is not negatively reinforced, this neural activity is blocked from reaching conscious perception (i. e. habituation occurs). If, on the other hand, the tinnitus-related activity is negatively reinforced (e. g. because tinnitus is concomitant to a life event or associated with negative thoughts), the limbic and autonomic nervous systems are activated, attention is directed to tinnitus, and tinnitus-related distress develops. This model postulates that tinnitus awareness and tinnitus-related distress result from the mechanisms of conditioned reflex [37, 40]. Another model suggests that tinnitus-related activity (enhanced activity in the gamma frequency range) becomes a conscious percept only if it is associated with co-activation of self-awareness and salience brain networks, i. e. anterior cingulate

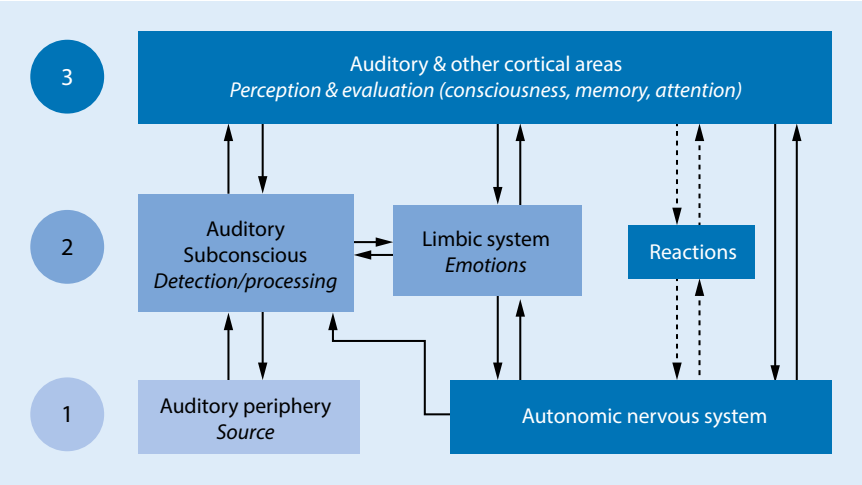


**Fig. 1** ▲ The neurophysiological model of tinnitus

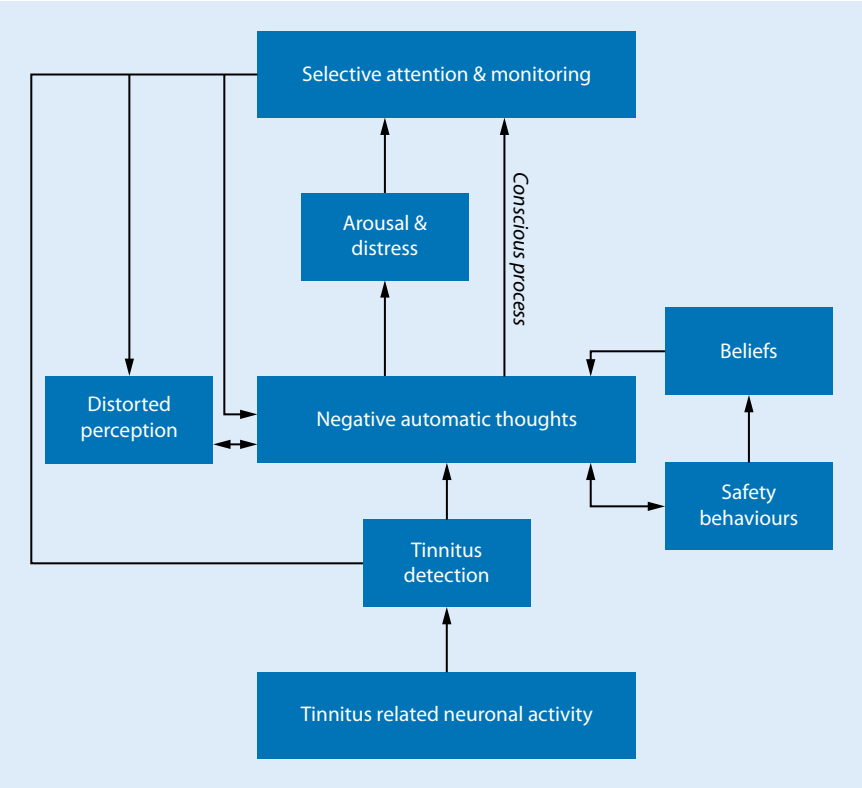


**Fig. 2** ▲ The cognitive model of tinnitus

cortex, ventromedial prefrontal cortex, insula, amygdala and parahippocampus [17]. A somewhat different model suggests that irrelevant information is tuned out by an inhibitory gating mechanism. Whereas the thalamic reticular nucleus, activated by subcallosal regions (nucleus accumbens and ventromedial prefrontal cortex), is supposed to block the activity of sensory thalamus through its inhibitory influence, in this model it is supposed that the inhibitory gating mechanism may not block irrelevant information properly (including the tinnitus-related activity) if part of the circuit such as the subcallosal regions is lesioned [46, 47, 64].

## 1.9 Theoretical models of tinnitus in more detail

### Habituation theory

Habituation theory [29] proposes that the negative interpretation of the tinnitus signal, and related heightened autonomic arousal levels, leads to dysfunctional cognitive processing and thereby distress. Hallam et al. [29] proposed that for most people repeated perception of the tinnitus sound teaches them that it is not worthy of attentional resources. In other words, to function effectively, the brain selects which stimuli to pay attention to and which stimuli to ignore. Hallam purported that most people learn that the tinnitus sound is of low informational value and thus not requiring a reaction. Consequently, tinnitus does not pose a problem for most people living with it. However, tinnitus-related *distress* does occur when these attentional processes are malfunctioning, which is more likely at times of increased stress and arousal, which in turn strains cognitive resources.

Habituation theory has remained largely theoretical, although tinnitus treatment approaches such as relaxation therapy, attention diversion techniques (directing attention away from tinnitus), and stress reduction by means of cognitive restructuring methods (aimed at altering beliefs about the tinnitus) have been based on its main premises. To treat tinnitus distress (or facilitate habituation to tinnitus), it was recommended that stress and arousal levels be reduced and to try and change the meaning of the tinnitus signal for the patient [28]. Research to date has yielded mixed evidence for the validity of habituation theory [7].

### Neurophysiological model

The neurophysiological model of chronic tinnitus (**Fig. 1**) is based on the premise that conditioned fear responses elicited by the tinnitus sound are the cause of the tinnitus becoming bothersome [36, 37]. This reasoning stems from animal research in which conditioning paradigms were used to induce tinnitus-like fearful behaviour in rats [38, 39]. The neurophysiological model distinguishes be-

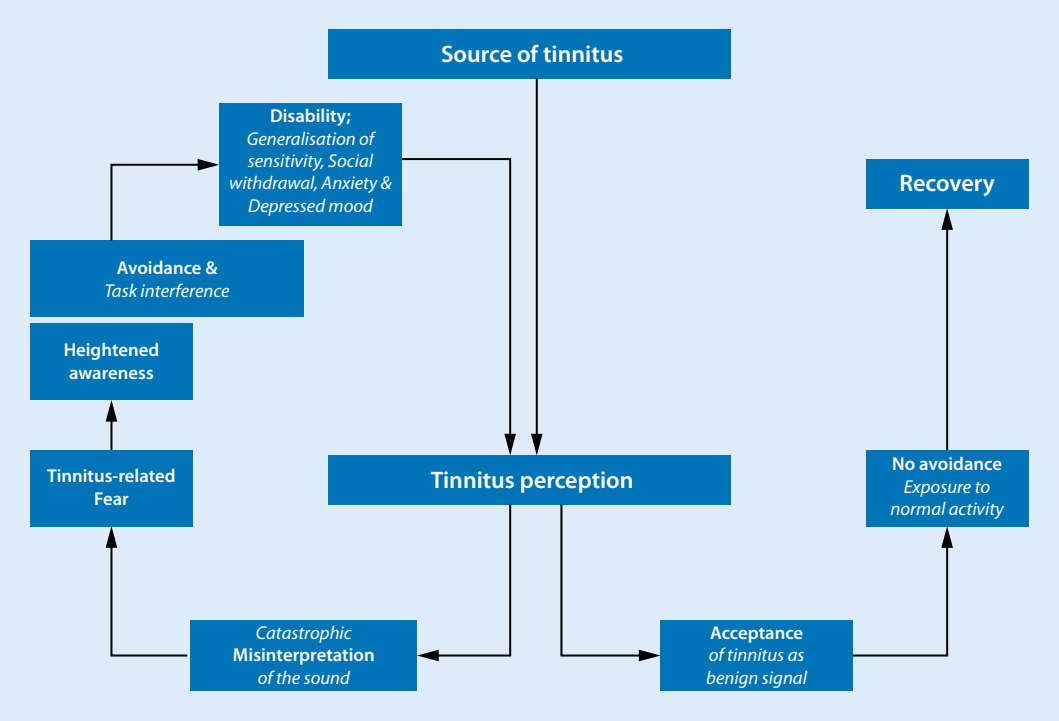


**Fig. 3** ◀ The fear-avoidance model of tinnitus (based on the fear-avoidance model of chronic pain [74])

tween three stages. Stage 1 involves generation of the auditory stimulus in the auditory periphery. Stage 2 involves detection of the tinnitus-related signal; and Stage 3 involves the perception evaluation of tinnitus. The neurophysiological model is mainly a model of tinnitus generation/detection, based on neurophysiological mechanisms.

## Cognitive model

McKenna et al. [57] propose a conceptual cognitive (behavioural) model of tinnitus distress whereby negative cognitive misinterpretations of the tinnitus signal, distress, and bodily arousal are provoked leading to inaccurate evaluations of sensory activity and distorted perceptions (**Fig. 2**). It is proposed that the resulting hypervigilance and distorted perception of the tinnitus sound contribute to a feedback cycle that exacerbates negative thinking and thus distress. The model attributes a fundamental role to the negative evaluation of tinnitus. The negative evaluation of the tinnitus can be viewed as comprising primary and secondary appraisals. For example, a person might initially appraise the tinnitus as being threatening to their health, and then make a secondary appraisal of their ability or inability to cope with it.

Evidence exists that cognitive processes, such as interpretation, attention, and memory, are indeed involved in chronic tinnitus suffering [5, 16, 60, 65, 72], and the validity of the cognitive model is currently being tested psychometrically [30].

## Fear-avoidance model

The fear-avoidance model of chronic tinnitus (**Fig. 3**) offers explanatory predictions about both the cognitive processes as well as the behavioural mechanisms of tinnitus [11, 12]. It predicts that individuals perceiving the tinnitus signal are subject to automatic emotional and sympathetic responses. These symptoms are misinterpreted as harmful or threatening. If the signal persists, the coinciding threatening (alarm) states, which indicate malignance of the signal, elicit conditioned (both classic and operant) fear responses, i. e. fear, increased attention, and safety-seeking (avoidance and escape behaviours). Safety behaviours become negatively reinforced through instant decreased fear, which is adaptive in the acute phase. In other words, by avoiding or not exposing themselves to tinnitus-related perceptions, patients learn that their fear instantly diminishes. However, through persistent avoidance of the tinnitus, tinnitus-eliciting, or tinnitus-increasing stimuli, fear and fear responses such as hypervigilance and safety-seeking are maintained. Avoidance behaviours subsequently lead to task interference and functional disability [9, 33, 41, 54]. The maintained high threat value of the tinnitus leads to increased tinnitus severity and distress, feeding into an endless cycle of increased disability [14].

A feature of the fear-avoidance model is that it predicts both a maladaptive pathway and an alternative more adaptive pathway. In the more adaptive pathway, a positive or neutral evaluation of the tinnitus (the system accepts it as being benign) results in no fear or low fear of tinnitus, distress, or avoidance behaviours.

These models differ in explaining how classic and operant learning principles contribute to tinnitus suffering. Nonetheless, there exists a large conceptual overlap between them. In both the neurophysiological model and McKenna's conceptual cognitive (behavioural) model it is hypothesised that effortful conscious alteration of negative interpretations will decrease arousal and distress because of tinnitus. Both models place less importance on the behavioural processes. The fear avoidance model, which is based on

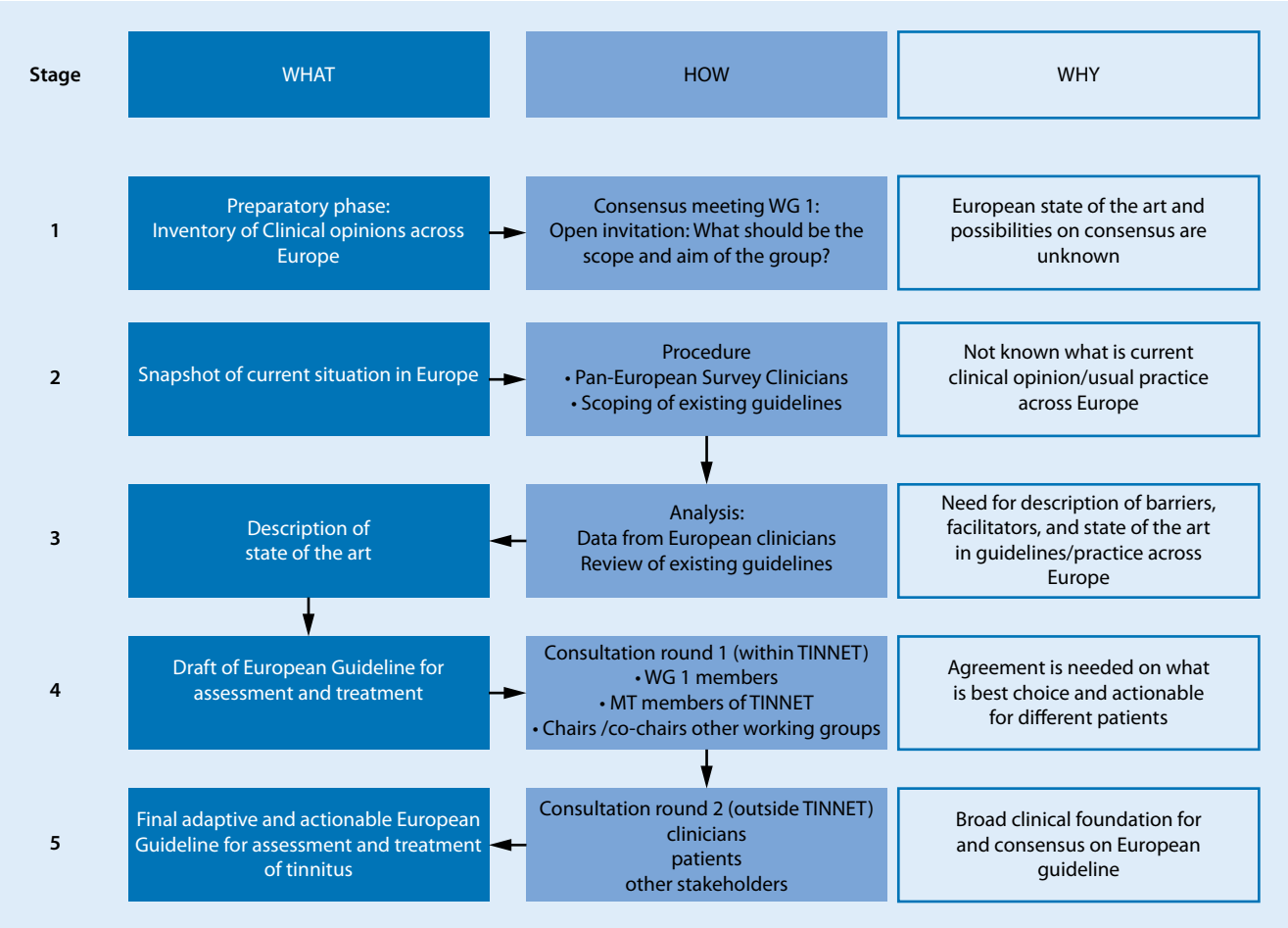


**Fig. 4** ▲ Individual stages in the development of current guideline: a roadmap. *WG* working group, *MT* management team

associative learning principles, offers both explanatory predictions about cognitive processes of change and predictions about behavioural mechanisms. This fear-avoidance approach integrates previous cognitive conjectures within a behavioural framework. This may prove helpful, both for discovering new venues for investigations and as a means of discovering why the cognitive as well as the behavioural treatment approaches are consistently found to be beneficial. It also offers a means of discerning which components work best and for whom.

Empirical data support the fear-avoidance model. Accumulating evidence indicates that a cognitive behavioural treatment, based on this fear-avoidance notion—which targets re-appraisal of, and exposure to, the tinnitus-sound—significantly reduces tinnitus distress, decreases tinnitus suffering, and improves quality and daily functioning of tinnitus patients [3, 4, 13, 120]. However, the cause–effect relationships of specific learning mechanisms are still unknown [11, 22, 32, 41].

# Chapter 2 Methods

## 2.1 Introduction

Tinnitus is a complex condition with a multifactorial origin. 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. Even though chronic tinnitus complaints represent enormous socioeconomic relevance [13, 80–82], research funding is still limited. Hence, there is increasing need for a European guideline for the assessment and treatment of tinnitus patients. The purpose of this chapter is to describe the methods used to develop this guideline.

### Duration and validity

This guideline consists of five chapters containing several modules. Some or all these modules may need revision or extension in the future. The current guideline steering group aims to pursue re-assessment and maintenance of the guideline within 5 years of the initial publication.

### Implementation

During the development of this guideline, the practicality and feasibility of the implementation of recommendations across Europe were considered at every stage (**Fig. 4**). Consensus was reached at the beginning of the project that a Eu-

**Table 3** Summary of barriers and facilitators identified from a pan-European survey

| | |
|---|---|
| *Barriers* | |
| 1 | Lack of knowledge about or non-existence of specialised tinnitus clinics or teams makes it difficult for tinnitus patients to find their way to the most appropriate professionals in a country |
| 2 | Lack of time or other resources for adequate counselling |
| 3 | Lack of time or other resources for professionals responsible for tinnitus patients to be able to adequately assess the distress level of tinnitus patients |
| 4 | Lack of multidisciplinary teams and/or availability of psychologists in southern and eastern European countries |
| 5 | High variation in available treatment options; more medical–pharmacological treatment in southern and eastern countries. Counselling–rehabilitative approaches more available in northern countries. When many treatment avenues are seen as viable, it may be difficult to reach consensus on what works for whom |
| 6 | The use of self-report instruments is much less common in southern and eastern countries |
| 7 | There are differences in how patients pay for treatment. If regulatory bodies in health care in a country are unwilling or unable to hold to the restrictions or recommendations stated in a guideline, the chances of implementation of this guideline drastically decrease |
| *Facilitators* | |
| 1 | Common ground in expert opinion that tinnitus is a central auditory symptom. This offers options for discussions on the definition of tinnitus in a European guideline |
| 2 | Consensus across regions on what conditions are relevant to or associated with tinnitus. Harmonisations such as these are to be highlighted where possible to facilitate implementation of a standard guideline |
| 3 | Although some minor differences in procedures were reported, most experts agree that otoscopy and pure tone audiometry are used. This finding facilitates discussions on diagnostics to include in the guidelines |
| 4 | The most commonly used questionnaire irrespective of region is the Tinnitus Handicap Inventory. This might facilitate discussions on assessment methods to recommend within a guideline |
| 5 | The percentage of respondents satisfied with current tinnitus health care in their country in southern and eastern Europe was low; less than half of respondents reported they were satisfied. Health-care professionals are likely to be positive towards progressive guidelines and towards changes in health care for tinnitus |

ropean guideline was to be as adaptive as possible, with the possibility that it can be tailored to resources and needs dictated by the participating countries[1]. The practicability of these recommendations and guidelines will need testing beyond the initial publication of the guideline; a method and criteria for the development of an implementation plan are provided in Appendix B.

[1] Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Israel, Italy, Lithuania, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom.

### Responsibility

The responsibility to maintain the guideline, for reassessment purposes and possible future revisions or extensions, lies with Drs. Rilana Cima and Derek Hoare.

## 2.2 Preparatory work

Activities, meetings, and studies performed for the development of this European guideline were supported by the TINNET—COST Action BM1306 (2014–2018), which aimed to establish a pan-European tinnitus network (researchresearch.net). Consensus was reached in the preparatory phase that the main aim of the TINNET Working Group 1 (WG1) was to develop a consensus-based meaningful, adaptive, and actionable European guideline for the assessment and treatment of tinnitus patients.

### European guideline steering group formation

In 2015 a selection of WG1 members of TINNET were nominated to become members of a guideline steering group for the development of this guideline. The group consists of representatives of all specialties and fields thought to be stakeholders in the clinical practice of tinnitus health care across Europe. All steering group members are responsible for the integral text of this guideline.

### Clinical demands and bottleneck analysis (Stage 1)

During the first preparatory (consensus) meeting with the WG1 members of TINNET, the chair (R.C.) inventoried clinical demands and possible bottlenecks. After this first meeting a roadmap was created for the agreed different stages of development of this guideline (**Fig. 4**).

### Understanding the state of the art (Stages 2 & 3): a pan-European survey

Tinnitus remains a scientific and clinical problem. In spite of increasing knowledge about its management and treatment, little impact on clinical practice has been observed. There is evidence that prolonged, obscure and indirect referral trajectories persist in usual tinnitus care.

It is widely acknowledged that efforts to change professional practice are more successful if barriers are identified and implementation activities are systematically tailored to the specific determinants of practice. The first step towards the development of meaningful and actionable European guidelines for the assessment and treatment of tinnitus patients involved scoping the existence and current knowledge of standards in tinnitus care. Here, we addressed this by performing a pan-European survey of experts, clinicians, and policy-makers to gain insight into the status quo of expert views on treatment and assessment, standards, and guidelines in tinnitus health care throughout Europe.

**Table 4** Summary of recommendations from a systematic review of clinical practice guidelines for tinnitus

| |
|---|
| *Summary of recommendations regarding the assessment of subjective tinnitus* |
| – Conduct a physical examination to exclude possible (physical) causes of tinnitus |
| – Conduct an audiological assessment |
| – Establish the degree to which a patient experiences subjective tinnitus as bothersome or distressing using a validated and reliable questionnaire such as the Tinnitus Questionnaire, Tinnitus Handicap Inventory, or Tinnitus Functional Index |
| – In situations where patients appear to be experiencing a degree of distress or difficulties related to living with tinnitus, consider making a referral for an assessment by a psychologist or psychiatrist |
| – Variations exist in recommendations regarding the use of imaging studies (e. g. magnetic resonance imaging) |
| *Summary of therapeutic recommendations regarding the treatment of subjective tinnitus* |
| – Provide information about tinnitus and treatment options |
| – Use hearing aids only when patients have a diagnosed hearing loss |
| – Specialised cognitive behavioural therapy for tinnitus should be offered to patients |
| – There is a lack of consensus on the use (or otherwise) of sound therapy for tinnitus |
| – Prescribed and herbal medicines and dietary supplements should not be used for the sole treatment of tinnitus |
| – Transcranial magnetic stimulation is not recommended as a treatment for tinnitus |

**Table 5** Levels of evidence (Oxford)

| Level | Therapy/prevention, aetiology/harm |
|---|---|
| 1a | Systematic review (SR) of randomised controlled trials (RCTs) |
| 1b | Individual RCT (with narrow confidence intervals) |
| 1c | All or none effects |
| 2a | SR (with homogeneity) of cohort studies |
| 2b | Individual cohort study (including low-quality RCT; e. g. <80% follow-up) |
| 2c | "Outcomes" research; ecological studies |
| 3a | SR (with homogeneity) of case–control studies |
| 3b | Individual case–control study |
| 4 | Case series (and poor-quality cohort and case–control studies) |
| 5 | Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" |

Survey results showed that there are significant differences in reports on national health-care structure, tinnitus definitions, characteristics of the tinnitus patient, and management, treatment, and diagnostic options, particularly notable when comparing northern, southern, and eastern European countries. Results indicate seven important barriers to be taken into consideration if a European clinical guideline is to be implementable (**Table 3**). Additionally, five facilitators were defined. Overall, the findings of this study confirm the need for a European guideline to provide consistency and promote equity of access to services for all tinnitus patients.

## Systematic review of existing guidelines

A systematic review was performed to collect all available guidelines and identify fields of agreement and remaining open questions about tinnitus assessment and treatment. The tinnitus assessments (diagnostics and measures), processes and treatment options recommended by the respective guidelines were compared and summarised. Methods are described in brief here and are reported in full by Fuller et al. [79].

**Selecting guidelines for the review.** Guidelines were considered eligible for inclusion if they fit the definition, and no publication date or language restrictions were imposed. Guidelines on objective tinnitus, referral pathways, or a specific type of assessment or treatment procedure were excluded. Guidelines were identified through a systematic search for "tinnitus" and "guideline" using Medline, PubMed, and the Cumulative Index to Nursing and Allied Health Literature, as well as the EMBASE databases. In addition to these, the National Guideline Clearinghouse (www.guideline.gov), National Institute for Health and Clinical Excellence (NICE; https://www.nice.org.uk/), Guideline International Network (GIN; http://www.g-i-n.net/), and Google were searched, and a hand-search of reference lists of any included guidelines was undertaken. International experts were also contacted to ask if they were aware of any guidelines that had not already been identified from the search results. Final searches were conducted on 2 May 2016. Two reviewers independently screened each search result. Five documents fitting the definition of guidelines were included, from the USA, Germany, Sweden, The Netherlands, and Denmark. Data extraction was conducted in a structured way by two independent reviewers and the quality of each guideline was evaluated using the AGREE II tool [78].

**Findings.** The absence of guidelines for most countries contributes to the explanation for the variations that exist in assessment and treatment of tinnitus internationally. Across guidelines, differences in recommended assessment procedures tend to relate to specific techniques, questionnaires, diagnostic tests, or types of scanning techniques rather than to the assessment of tinnitus severity, hearing loss, psycho-social problem(s), and the presence of severe physical pathology causing the tinnitus. Consensus exists on the need to exclude a physical cause of tinnitus, conducting an audiometric assessment of the patient, using standardised questionnaires to measure degrees of tinnitus-related distress and, when relevant, making referrals for further psychological assessment. Summary recommendations emerging from the systematic review are provided in **Table 3**.

**Table 6** Levels of recommendation

| Strength of recommendation | Valence of recommendation | Description |
|---|---|---|
| **Strong recommendation** Most or all individuals will be best served by the recommended course of action | For | Level 1a, 1b, or 2a evidence that the desirable effects of an intervention outweigh its undesirable effects |
| | Against | Level 1a, 1b, or 2a evidence that the undesirable effects of an intervention outweigh its desirable effects |
| **Weak recommendation** Not all individuals will be best served by the recommended course of action | For | Level 2b, 2c, or 3a evidence that the desirable effects of an intervention probably outweigh its undesirable effects |
| | Against | Level 2b, 2c, or 3a evidence that the undesirable effects of an intervention probably outweigh its desirable effects |
| **No recommendation** | Not applicable | Only level 3b, 4, or 5 evidence available, or highest level of evidence shows no clear trade-off between desirable effects of an intervention and its undesirable effects, or individual patient's reactions to undesirable effects are likely to be so different that it makes little sense to think about typical values and preferences |

## 2.3 Development of the European clinical guideline

Results from the survey and the systematic review of guidelines were used to select and evaluate the modules included in Chap. 3, "Diagnostics, assessments, and outcomes", and Chap. 4, "Treatment options and referral pathways".

### Inclusion

We included assessment methods and diagnostic tools where there was evidence of their use and indication that they are clinically useful (see Chap. 3 for further details). Treatment methods (treatment elements or protocols, devices, or procedures) were included if high-level research evidence (randomised clinical trials, meta-analyses) was available and/or a need existed that the guideline informed clinical practice (i. e. practices identified in the survey results; see **Table 4**).

### Exclusion

Treatment methods (treatment elements or protocols, devices, or procedures) were not included when not supported by high-level research evidence and when only weak evidence was available (case reports, case control, and retrospective studies), and/or the need existed that the guideline informed clinical practice (i. e. practices identified in the survey results). Further assessment methods, diagnostic tools, treatment methods (treatment elements or protocols, devices, or procedures) may be included in future revisions or extensions of this guideline if new research evidence becomes available or a need to inform new practices is identified.

### Levels of evidence

Quality of evidence for the treatment methods (treatment elements or protocols, devices, or procedures) included in Chap. 4 was guided by the Oxford Centre of Evidence method[2] (see **Table 5**).

### Levels of recommendation

The recommendation level for each treatment method (treatment elements or protocols, devices, or procedures) included in Chap. 4 was guided by the GRADE system[3] (**Table 5**), whereby only high-level evidence (Levels 1a–2b; randomised controlled trials [RCTs] and systematic reviews) was considered in making a recommendation for or against treatment. Where only low-level evidence existed (2c-5), we automatically make a judgment of "no recommendation" (see **Table 6**).

[2] http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/.

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

## 2.4 Consultation rounds and consensus

### Consensus method on the drafts of the clinical European guideline

Initial drafts of this guideline were subjected to review in two consultation rounds. The comments from each round were aggregated and addressed across three consensus meetings of the steering group (held in July and November 2017, and in January 2018).

Consultation round 1 involved only members of TINNET, being:

- Members of WG1
- Members of the TINNET management committee
- Representatives of all other TINNET working groups

Consultation round 2 involved stakeholders outside TINNET, being:

- Patient representatives/associations
- Professional associations/national professional representatives
- Committee members of existing national guidelines
- Policy-makers
- EU commission members

Contributors in both consultation rounds were invited to comment on consecutive drafts of the guideline. For each comment submitted, contributors were asked to rate whether they felt their comment reflected what they considered to be an essential change to the guideline (rated as 1), or was a recommend change (rated as 2), or was simply a note for the author to consider (rated as 3).

### Consensus meetings

In the consensus meetings, steering members voted whether to implement a change to the guideline based on the comment. Contributors received feedback on all comments. The feedback included whether the change was made or not. Where changes were not made in response to a comment (i. e. there was author consensus not to imple-

**Table 7** Some known conditions associated with tinnitus

| Site of affection | Associated conditions |
|---|---|
| Outer ear | Wax blockage of outer ear channel<br>Otitis of outer ear channel<br>Obliterative exostoses |
| Middle ear | Otitis media with effusion<br>Otosclerosis |
| Inner ear | Presbyacusis<br>Noise-induced hearing loss<br>Ménière's disease<br>Sudden hearing loss<br>Acoustic neuromas |
| Muscular | Palatal myoclonus<br>Tensor tympani myoclonus<br>Patency of eustachian tube |
| Cardiovascular | Glomus jugular or glomus tympanicum<br>Mitral or aortic stenosis |
| Pharmacological | Benzodiazepines withdrawal<br>Induction from ototoxic drugs |
| Metabolic | Hyperthyroidism<br>Diabetes<br>Hypertension |
| Haematologic | Anaemia |
| Arthrogenous | Dysfunction of temporomandibular joint<br>Cervical dysfunction |
| Impairment of cognitive–emotional reaction system | Concentration disturbance<br>– Attentional problems<br>– Memory deficit<br>– Executive function deficit<br>Loss of control/helplessness/resignation<br>Dysfunctional thoughts: catastrophising<br>– Fear reactions<br>– Safety behaviours (avoidance) |
| Psychological/psychiatric | – Psychological trauma<br>– Distress<br>– Major affective event<br>– Depression<br>– Anxiety/panic disorder |
| Trauma | – Traumatic brain injury<br>– Neurosurgical |

ment a change based on the comment), a rationale for the decision was provided.

In total, 395 comments on the first draft were submitted in consultation round 1 by 33 within-TINNET contributors. In the second consultation round, an additional 25 outside-TINNET contributors submitted 265 comments on the second draft.

### Authorisation

All contributors were asked to indicate if they did not want their details to be included in the contributor list of the final version of the guideline.

## Chapter 3 Diagnostics, assessments, and outcomes

### 3.1 Introduction

Many factors can contribute to the onset of tinnitus. It is a symptom associated with multiple medical disorders (**Table 7**). In addition to hearing-related causes, other potential causes must be individually identified or excluded. In most cases, the aetiology of tinnitus is unknown, and many clinical approaches are dedicated to helping patients cope with their tinnitus rather than to treating the cause [37, 62, 84].

When referring patients for a specific diagnostic algorithm, for example in the case of acute tinnitus, the medical necessity as well as financial cost must be considered in each individual case. Instead of using rigid diagnostic steps, it is recommended to choose a diagnostic pathway based on the patient's history and on basic diagnostics (for an example of a diagnostic pathway, see the Tinnitus Research Initiative flowchart at www.tinnitusresearch.org).

The following sections outline recommended progressive levels of diagnostics and assessment of tinnitus. The content and structure of these sections were informed by multiple sources in two steps. First, the authors reviewed diagnostics and assessments that are currently used across Europe [15], and the recommended diagnostics and assessments included in existing national clinical practice guidelines (USA, Denmark, Sweden, Germany, and The Netherlands; Fuller et al. [79]). An initial proposal was thereafter agreed by consensus of the authors based on knowledge of current use in clinical practice specifically for tinnitus, and therefore of the need to provide endorsement of those procedures considered safe and clinically useful (and exclude those that were considered not). This section was heavily revised according to comments received in both rounds of expert consultation.

### 3.2 Minimum patient assessment

A comprehensive patient history is the foundation of diagnosis, accurately grading tinnitus severity and identifying relevant comorbidities. To exclude treatable medical conditions, e. g. otitis media, otosclerosis, wax blockage of outer ear channel, or acoustic neuroma among other putative causes, a detailed tinnitus characterisation should include whether tinnitus is objective (can be heard by an external observer) or subjective (can only be heard by the patient), perceptional characteristics of the tinnitus sound (tonality, pitch, loudness), temporal properties (pulsatile or not, constant, intermittent, or fluctuating), location (in one or both ears, or in the head), and severity (assessed by score on suggested

measures, see Sect. 3.4 "Assessment by questionnaires").

It is crucial to perform a detailed clinical examination/history of the tinnitus patient. There are causal diagnostics and severity-oriented diagnostics.

### Tinnitus history and clinical examination

1. Tinnitus history
   - Onset: Since when is tinnitus perceived; what are important associated clinical factors (noise trauma, stress, recent events, acute illness, other); was it a sudden onset or did symptoms start gradually with a continuous increase?
   - Modulation: Can the tinnitus percept be modulated by: orofacial, cervical or eye movements, head positions, movements of the jaw, tension of jaw muscles, physical exertions?
   - Severity/impact of the tinnitus: Is the tinnitus bothersome/interfering with daily life (sleep difficulties, task interruptions, fearful reactions, cognitive-attentional problems, negative affect). A questionnaire should be used to establish the degree to which a patient experiences subjective tinnitus as bothersome or distressing (see Sect. 3.4 for more details). Furthermore, the level of tinnitus awareness is of importance: Can tinnitus be perceived only in silence or also in noise; is the tinnitus easily masked or amplified by ordinary background noise; are there changes in tinnitus loudness?
2. Thorough audiological history and prioritisation: Assessment of hearing loss, perceived "ear fullness" (pressure), sensitivity to normal sound (or hyperacusis), problems in balance/dizziness/vertigo
3. Medical history: ear, nose and throat, orthopaedic, cervical, dental, jaw, internal medicine (thyroid, hypertension, anaemia), mental disorders (psychological, psychiatric)
4. Presence of comorbidities/drug history/medications; ototoxic drugs (e.g. chemotherapy, antimalarial drugs); long-term pharmacological consumption (e.g. antidepressants, anxiolytics)
5. Relevant personal history, occupational history, hobbies/leisure activities, noise exposure, head/neck trauma, social support status, education, recent life events

### Essential primary diagnostic steps

Conduct a thorough physical–medical assessment to exclude possible (physical) causes of tinnitus:

Complete ear, nose, and throat examination, especially otoscopy (preferably micro-otoscopy) to exclude presence of wax, tympanic membrane rupture, otitis media with effusion, chronic otitis media, retro-tympanic mass or any other pathology.

Special consideration should be given in rare tinnitus causes (e.g. palatal myoclonus, temporomandibular joint [TMJ] disorders).

A comprehensive diagnostic investigation should include pure tone audiometry, speech audiometry, and evaluation of the perceptional quality of tinnitus (e.g. loudness, pitch, and minimum masking estimations), sound tolerance, tympanometry, and acoustic reflex including auscultation of the ear and carotid artery in pulsatile tinnitus, as clinically indicated. Care must be taken in performing loudness-based tests, particularly where there is evidence of recent fluctuations in loudness or intensity of the patient's tinnitus.

## 3.3 Further assessment

### Further investigations or referrals in special cases

Only to be considered if clinically indicated:

- Auditory brainstem responses and/or magnetic resonance imaging (MRI) in cases of unilateral tinnitus and/or asymmetric hearing loss consider
- High-frequency audiometry in cases of tinnitus with normal hearing at standard (conversational) frequencies
- Further sound tolerance assessment (e.g. loudness discomfort level) for sound sensitivity grading or hearing aid settings
- Residual inhibition to evaluate short-term effects of sound on the tinnitus
- Transient-evoked otoacoustic emissions and/or distortion product otoacoustic emissions in cases of normal standard audiogram and suspicion of cochlear dysfunction
- Caloric testing, and vestibular evoked myogenic potential, as indicated in cases of dizziness, vertigo, or balance problems
- 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 (see Appendix C for further information on somatosensory tinnitus)
- Dental examination (including TMJ) in a quiet environment for detecting tinnitus modulations in TMJ dysfunction or bruxism
- MRI of the brain in abnormal auditory brainstem response or abnormal vestibular evoked myogenic potential

## 3.4 Assessment by questionnaires

### Tinnitus severity in terms of distress/impact

Tinnitus severity can be defined as a function of the level of distress or impact that tinnitus has on the individual. For a small proportion of patients (5–8%) tinnitus is severely distressing and therefore disabling [83]. Since distress refers to the general aversive state, instruments to measure this construct usually include sub-domains which are hypothesised to contribute to tinnitus severity. These instruments are therefore hybrid in that they measure several concepts as a means of capturing tinnitus distress.

There are several instruments in use for assessing level of severity of tinnitus complaints. In a review on disease-specific health-related quality-of-life (HR-QoL) instruments used to measure outcomes in tinnitus trials, six commonly used HR-QoL tinnitus instruments were identified [89].

The Tinnitus Handicap Inventory (THI; [94]) was developed to measure the impact of tinnitus on daily life. It has three subscales; functional, emotional,

and catastrophic responses to the tinnitus. Both the overall questionnaire and the functional and emotional subscales show good internal consistency. However, a unifactorial structure was found in subsequent validation studies [90].

The Tinnitus Questionnaire (TQ; [88]) has six domains; emotional distress, cognitive distress, intrusiveness, auditory and perceptual difficulties, sleep disturbances, and somatic complaints because of the tinnitus. The TQ items are internally consistent; the subscales lack internal consistency, however.

The Tinnitus Reaction Questionnaire (TRQ; [95]) was developed to measure distress related to tinnitus. It has four sub-scales: general distress, interference, severity, and avoidance of the tinnitus.

The Tinnitus Severity Index (TSI; [92]) was introduced as a measure of how much tinnitus negatively impacts a patient's life and how bothersome patients perceive their tinnitus to be. Two items specifically measure how much tinnitus interferes with daily life activities.

The Tinnitus Handicap Questionnaire (THQ; [91]) was intended to measure patients' perceived degree of handicap due to tinnitus. The THQ has three domains: physical health/emotional status/social consequences, hearing and communication, and personal viewpoint on tinnitus. Seven items specifically address the interference of the tinnitus on daily activities; four of which address hearing difficulties, two items address social interactions and one item addresses sleep difficulties because of the tinnitus. The THQ subscales fail on internal consistency however.

The Tinnitus Severity Questionnaire (TSQ; [85]) is a short, unified measure, with two items specifically addressing interference of the tinnitus, one item on sleeping habits and one on impairment of concentration.

More recently, the Tinnitus Functional Index (TFI) was developed as a new measure of the severity and negative impact of tinnitus, both for use as a diagnostic tool and for measuring treatment-related changes in tinnitus [93]. The TFI is a multi-domain questionnaire, measuring tinnitus-related distress/severity as a function of predominantly psychological constructs, such as attention, worry, anxiety, depression as well as the more functional constructs such as hearing, social life, and activity level [86].

The TQ and the THI are widely used in clinical practice and clinical trials [87]. Additionally, almost all existing clinical practice guidelines [79] recommend using the Hospital Anxiety and Depression Scale [96] to assess negative affect coinciding with or reactionary to tinnitus.

Appendix D summarises the characteristics and psychometric properties of the seven tinnitus-specific instruments described here.

### Recommendation

**Tinnitus patients who report complaints/show decompensation (grade 2 and higher; see ◘ Table 2) should be evaluated with at least one measure of tinnitus-related disability, such as the TQ or THI.**

## Chapter 4 Treatment options and referral pathways

### 4.1 Available treatments and evidence

#### Informed knowledge

Clinicians should educate patients with tinnitus about treatment strategies. For an extended presentation of the information that should be conveyed, see Chap. 5.

#### Drug/pharmacological

### Weak recommendation against

**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 randomised trials.**

It is common that treatment of acute tinnitus is given according to treatment of acute sudden hearing loss. However, in both cases the evidence base for treatment is scarce [99]. Therefore, if tinnitus occurs acutely without hearing loss, the standard cortisone therapy is not recommended. Present psychosomatic factors can play a decisive role [118]. Therapeutic approaches such as intratympanic steroid treatment have no effect on tinnitus [168]. Any increase in tinnitus severity or distress in chronic tinnitus should not be treated as new-onset tinnitus. This should be regarded and treated as a fluctuation of chronic tinnitus [119].

For chronic tinnitus, many classes of drugs have been used or trialled, including various anti-arrhythmics, anticonvulsants, anxiolytics, glutamate receptor antagonists, antidepressants, muscle relaxants, and others [45], with little evidence of benefit over harm [169]. The Cochrane review of antidepressants for tinnitus [100] identified six RCTs (610 patients) on the topic. Only one study was judged to be of high quality. This study compared the effect of Paroxetine (a serotonin re-uptake inhibitor) with placebo, finding no significant difference in effect between groups. No effect was seen for trazadone (serotonin antagonist and reuptake inhibitor) and a small effect was seen for tricyclic antidepressants, but the reviewers concluded this could have been due to methodological issues in the studies. Side effects were commonly reported including sedation, sexual dysfunction, and dry mouth. Nonetheless, antidepressants are often successfully applied in the treatment accompanying depression and anxiety, not for improvement of the tinnitus.

Jufas and Wood [131] provided a systematic review of benzodiazepines for tinnitus also finding six clinical trials which examined the use of diazepam, oxazepam, and clonazepam. There were mixed results across studies and methodological issues which reduced confidence in the estimate of effect they reported. Thus, they concluded that benzodiazepine use for subjective tinnitus does not have a robust evidence base and that these drugs must be used with caution because of serious side effects.

**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.**

### Hearing loss interventions

**Cochlear implants.** Despite the relatively limited number of cochlear implant users, there are many studies of their effects on tinnitus. In a systematic review of the effects of cochlear implantation on tinnitus in patients with bilateral hearing loss, five studies were found which reported on changes in tinnitus after implantation [157]. Based on tinnitus questionnaire scores, the review found total suppression of tinnitus in 30–37% of patients, a decrease in 29–72% of patients, no change in 0–30% of patients, and a worsening in 0–25% of patients across studies. Of course, RCTs are not applicable in this context. Small case–control studies (3b) have shown the efficacy of cochlear implantation in patients with unilateral deafness and persistent, bothersome tinnitus. Hence, larger studies are necessary to confirm these findings.

**No recommendation for (tinnitus); recommendation for (deafness)**

**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**

**Hearing aids.** Hearing loss is one of the most prevalent chronic diseases and causes of disability [176]. The consequences of hearing loss in the overall health condition of the people suffering from it are significant. It has been suggested that the reduced physical and mental activity and secondary social isolation caused by hearing loss [98] increase the risk of cognitive decline/dementia [138], mental illness [140] and depression [105, 140]. Although tinnitus has been strongly associated with hearing loss, the degree of hearing loss cannot linearly predict tinnitus severity. Only 50% of patients with hearing loss experience tinnitus including many patients who are profoundly deaf [133, 156]. In addition, 10% of tinnitus sufferers have normal pure tone audiometry [161, 162]. Furthermore, tinnitus occurs in different percentages in groups of patients with various causes of hearing loss ranging from 30% (in ototoxicity) to 90% (in acoustic trauma). The significant benefit of hearing aids for hearing difficulties have been demonstrated in RCTs [111, 128, 144].

It has also been suggested that hearing aids reduce tinnitus awareness, and thereby stress [109], and reduce central auditory gain [152] and homeostatic hyperactivity [177], implicating them in tinnitus. It has been hypothesised [109] that increasing bandwidth (the frequency range of sounds amplified) may improve effectiveness. 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. Yet there is minimal high-level evidence for the efficacy of hearing aids for tinnitus in systematic reviews; Hoare et al. [124] included just one RCT [151] which found hearing aids to be beneficial but equally effective to sound generators for tinnitus. Two subsequent RCTs compared hearing aids with combination hearing aids [116] and conventional hearing aids with combination hearing aids or deep-fit hearing aids [117] in patients with hearing loss and tinnitus. Both trials concluded that all devices offered some equivalent benefit for tinnitus. Hesse [119] included lower-level evidence studies in their systematic review but found study results to be contradictory and concluded that convincing prospective studies are required.

**Weak recommendation for**

**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.**

**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.**

### Neurostimulation

Neurostimulation treatments are hypothesised to alter tinnitus-generating neural firing. They can be invasive or non-invasive, and use electromagnetic, electrical, or sound stimuli. However, the precise neural mechanism by which changes occur at both local and network levels is not fully understood [123, 158]. Moreover, with non-invasive treatments, the precise area of the brain to be stimulated is unknown. Non-invasive treatments include transcranial electrical stimulation, vagus nerve stimulation (transcutaneous), repetitive transcranial magnetic stimulation (rTMS), and acoustic coordinated reset (CR) neuromodulation. Invasive treatments include vagus nerve stimulation (implantable device), cortical surface stimulation, and deep brain stimulation.

**Transcranial electrical stimulation.** Transcranial direct current stimulation (tDCS) delivers low-level direct current (about 0.5–2 mA) via scalp electrodes to the cortex. Thereby, some current is conducted through the scalp and some flows into the cerebral cortex where it is hypothesised to increase or decrease cortical excitability (depending on the polarity) in the brain regions where it is applied. It was first proposed as a treatment for tinnitus by Fregni et al. [112]. The most recent systematic review of tDCS included 17 studies but only two RCTs [166]. It concluded that there was insufficient evidence to determine whether tDCS was effective for tinnitus. The review called for further RCTs of tDCS and studies involving variations to the stimulation protocol. Many RCTs of tDCS have subsequently been conducted [101, 102, 149, 163, 172], which report it to be safe but with little or no effect on tinnitus.

Transcranial alternating current stimulation (tACS) involves the delivery of alternating current (constant polarity changes) between electrodes placed on

the skin over cortical regions of interest. It is hypothesised to affect up- and down-regulation of synapses, possibly affecting change in oscillatory cortical activity. There are few studies investigating tACS. One randomised study concluded there are no effects on tinnitus [172].

### No recommendation

**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.**

**Vagus nerve stimulation.** Stimulation of the vagus nerve is a means of stimulating the cholinergic nucleus basalis, which in turn has been shown to induce sustained changes in cortical organisation. By this mechanism, vagus nerve stimulation, paired with sound stimuli (to promote reorganisation in the auditory cortex), is a hypothesised treatment for tinnitus. Experimental studies have examined the safety and efficacy of vagus nerve stimulation, both direct (i. e. implanted electrode) and transcutaneous, paired with acoustic stimulation for tinnitus [108, 129, 134, 136, 178]. Tyler et al. [171] conducted a prospective randomised double-blind controlled pilot study of the effects of direct vagus nerve stimulation paired with tones on tinnitus. They reported high compliance, mild, well-tolerated adverse effects, but no significant between-group difference in tinnitus at the end of their 6-week randomisation period.

### No recommendation

**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.**

**Repetitive transcranial magnetic stimulation.** Repetitive transcranial magnetic stimulation (rTMS) uses strong electric current generated within a coil to create fast-oscillating magnetic fields. When used in treatment, the coil is placed next to the head over the target brain area. It is hypothesised that the energy from the magnetic fields penetrates the skull to cause depolarisation of the superficial cortical neurons; rTMS for tinnitus has been studied extensively. The most recent systematic review [165] included 15 studies and concluded on a significant effect of treatment. However, high variability in study design and reported outcomes was noted and thus the review concluded the need for large-scale trials and replication studies. Safety was not reported in this review. A Cochrane review [143] included five RCTs and concluded that (1) there was limited support across studies that rTMS was beneficial, and (2) there was insufficient information to conclude it was safe in the long term.

### Recommendation against

**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.**

**Acoustic coordinated reset (CR®) neuromodulation.** Acoustic CR® neuromodulation is a sound therapy involving a randomised sequence of four "phase resetting" tones adjusted to the patient's dominant tinnitus pitch that are hypothesised to generate a lasting desynchronisation of the pathological brain rhythms causing tinnitus. A systematic review of acoustic CR® neuromodulation included eight studies [175]. It concluded that the available evidence indicates the treatment to be safe but that there is insufficient evidence of its effectiveness for clinical implementation of this treatment. The review also concluded that the hypothesised mechanism of effect is unproven.

### No recommendation

**Acoustic CR® neuromodulation is safe but there is no high-level evidence of effectiveness. Recommendation is based on systematic review.**

**Invasive neurostimulation treatments.** Invasive forms of tinnitus treatment are highly experimental and span vagus nerve stimulation with an implanted device, chronic electrical vestibulocochlear nerve stimulation, brain surface (extradural) implanted electrodes, and deep brain neural stimulator implantation. That they are invasive means they are not a viable option for widespread use. Research to date is limited to a small number of cases and in each the precise neural mechanism by which changes occur at both local and network levels is not fully understood (for a comprehensive review, see Hoare et al., [123]). There are no RCTs or systematic reviews to date.

### No recommendation

**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.**

## Cognitive behavioural therapy

### Strong recommendation for

**There is high-level evidence for the effectiveness and safety of CBT for tinnitus. Recommendation is based on systematic review and one further RCT.**

Cognitive behavioural therapy approaches share the premise that human suffering (psychological distress) and resulting problems are based in malfunctioning information processing, emotional reactivity, and behavioural mechanisms (see Appendix E for further general information on CBT). The CBT approaches have led to a plethora of evidence-based cognitive behavioural treatments for mental and somatic health disorders [127]. Cognitive behavioural therapy is an integrative and pragmatic therapy where the aim is to modify dysfunctional behaviours and beliefs to reduce symptoms, increase daily life functioning, and ultimately promote recovery from the disorder [110]. Confusion often exists about the differences between cognitive therapy and CBT. Since CBT stems from the convergence of two distinct theoretical schools, the radical behavioural school (first wave)

and the cognitive school (second wave), CBT entails a diversity of both cognitive and behavioural principles and methods, and usually a combination of these are used in therapeutic sessions. Therefore, both cognitive and behavioural treatment elements can be found when reviewing CBT procedures in general and thus in tinnitus intervention/treatment research as well.

Cognitive behavioural theory and treatment have been applied in tinnitus research for decades and the results of the effectiveness of CBT approaches for tinnitus have been shown to vary in decreasing tinnitus severity/distress, tinnitus-related fear, tinnitus disability, and tinnitus-related cognitive problems and in improving daily life functioning [13, 120, 126, 139, 141]. Establishing the effectiveness of CBT in tinnitus health care and research is difficult because patients report to suffer in various life domains. In addition to general problems with daily functioning because of concentration difficulties and sleep deprivation, despair, depression, fear, and worry are amongst the most incapacitating. Disagreement still exists on what tinnitus-related domains and outcomes to measure, why, and how [122], and in the research literature there is as of yet no standardisation of outcome selection. Additionally, often the investigated tinnitus CBT approaches vary in number of treatment sessions, hours spent in therapy, group versus individual formats, face-to-face versus Internet- or book-based self-help therapies, combinations of different treatment elements, and tinnitus diagnostics and outcome assessments.

Since the most recent Cochrane review of CBT for tinnitus was published [139], a new Cochrane CBT review protocol has been published [22]. This review will include more recent RCTs and comply with the latest Cochrane standards.

The most recently published review of CBT interventions for tinnitus was a historical and narrative overview in which a range of study designs in addition to RCTs were included, but one in which neither a risk of bias assessment was undertaken, nor a meta-analysis conducted [84]. These methodological issues make it harder to draw conclusions about the strength of any treatment effects and risks of bias in the evidence included in the narrative synthesis. Cognitive behavioural therapy for tinnitus (CBT4T) often includes a combination of several elements (such as education, counselling, exposure, mindfulness, relaxation, hearing rehabilitation). In a large RCT it was found that specialised CBT for tinnitus showed significant better group differences in improvement in quality of life ($d = 0.24$), decreasing severity of tinnitus ($d = 0.43$) and tinnitus disability ($d = 0.45$), as well as decreasing depressive and anxious symptoms, when compared with general audiological counselling and diagnostics only [13].

Despite the afore-mentioned limitations and the need to be cautious about the exact effectiveness of CBT for tinnitus in general, at present, a specialised stepped-care CBT4T [13] is the only available therapeutic health-care intervention for tinnitus supported by a high-quality clinical trial. Stepped-care CBT4T has been implemented across several Dutch clinical centres as the cost-effective treatment option. Additionally, stepped-care CBT4T is generally well received by patients and is potentially a cost-effective means for reducing the reactivity [80]. The treatment can be defined as a stepped-care [4]multimodal CBT4T approach in which audiological diagnostics, treatment and consultation as well as CBT-treatment elements are combined.

Self-help CBT interventions (Internet-based or otherwise) appear efficacious in decreasing tinnitus distress when compared with passive control conditions, and less so when compared with active face-to-face CBT treatment [147]. Additionally, treatment attrition in trials of self-help (Internet-based or otherwise) CBT interventions is high. Nonetheless, CBT in a self-help format might be a useful alternative to support tinnitus patients who are unable or unwilling to take part in a face-to-face CBT treatment.

[4] A stepped-care approach is a framework for organising health services based on individual patients' needs, with a gradual increase in the intensity of the care at each level [174].

**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.**

## Tinnitus retraining therapy

### No recommendation

**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.**

One widely used treatment is tinnitus retraining therapy (TRT), which is based on the neurophysiological model of tinnitus [37]. Tinnitus retraining therapy is a specific implementation of general tinnitus habituation therapy, which utilises directive counselling to decrease the negative tinnitus-evoked reactions and sound to decrease the strength of tinnitus signal [130]. The principal goal of TRT is to achieve habituation of tinnitus through the retraining of the brain [130, 164]. It means that owing to the high level of plasticity of the central nervous system, it is possible to reduce the responsiveness to repeated stimulation with neutral sound stimuli and trough the counselling [164]. In this process, the limbic system and autonomic nervous system are the main systems responsible for negative tinnitus-evoked reactions, because those areas are activated when one stimulus is associated in the category of unpleasant or dangerous stimuli, which results in reactions of stress, anxiety, panic attack, or loss of well-being (*fight, flight, or freeze*). But, tinnitus without negative association leads to the extinction of a response to tinnitus. Thus, the goal of TRT is to prevent tinnitus from activating the limbic system and automatic nervous system—habituation of reaction—and when the habituation of reaction is fully achieved, the patient does not experience negative tinnitus-evoked reaction. After this, the cerebral cortex—habituation of perception—is automatically activated, because the brain habituates to all unim-

**Table 8** Categories of tinnitus retraining therapy for patients with tinnitus and hyperacusis

| Category | Impact on life | Tinnitus | Subjective hearing loss | Hyperacusis | Prolonged sound induced exacerbation | Treatment |
|---|---|---|---|---|---|---|
| 0 | Low | Present | Not present | Not present | Not present | Abbreviated version of counselling |
| 1 | High | Present | Not relevant | Not present | Not present | Full counselling and sound therapy with sound generators |
| 2 | High | Present | Significant presence | Not present | Not present | Full counselling and sound therapy with combination instruments |
| 3 | High | Not relevant | Not relevant | Present | Not present | Full counselling with stress issues related to hyperacusis and sound therapy using sounds generators and hearing aids |
| 4 | High | Not relevant | Not relevant | Present | Present | Full counselling, sound therapy with sound generators set at the threshold |

portant stimuli. If the patient achieves this habituation of perception, tinnitus is blocked before it reaches the consciousness level and the patient does not hear tinnitus [164].

Based on a medical evaluation of tinnitus, patients are placed into one of five general categories that guide the treatment recommended (**Table 8**). Each one of five categories is associated with a specific variant of TRT treatment, and all patients receive counselling and sound therapy, with substantial differences. Sound therapy has an important role in TRT. Specifically, sound therapy acts by providing the auditory systems with constant neutral signs with sound generators, hearing aids, or background noise. This decreases the contrast between tinnitus-related neural activity and background activity. Furthermore, the sound therapy interferes with the detection of tinnitus signal and decreases the gain within the auditory pathways [119, 135, 164].

The Cochrane review of TRT [153] found only one trial that met their inclusion criteria, concluding that the trial was of low quality and no final conclusions concerning the efficacy of TRT can be drawn. The same single study was also included in a more recent systematic review of CBT and TRT, although in this review the study was rated as high quality [113].

## Sound therapy

### No recommendation

**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.**

Acoustic stimulation may be the oldest approach aimed at improving tinnitus. It is at least the most "natural" one, as tinnitus patients can experience every day that an external acoustic source can mask their tinnitus. This simple and intuitive approach has been (and is still) widely used. Importantly, this approach is not aimed at treating the causes of tinnitus but simply at helping to manage the consequences of tinnitus. It is used in different ways. Other acoustic approaches have been developed to interfere with the tinnitus causes. For these methods, the assumptions relative to the tinnitus mechanisms are critical. All these methods assume that tinnitus results from central changes after hearing loss that can be reversed by appropriate acoustic stimulation.

In general, acoustic stimulation has been shown to modestly improve tinnitus condition in several independent low-quality studies. It is unclear whether 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.). Tinnitus is a highly heterogeneous entity and acoustic stimulation may be very beneficial for some patients while completely ineffective for others. The "central" model of tinnitus assumes that the central changes due to sensory deprivation involved in tinnitus generation are reversible. However, some changes resulting from sensory deprivation might be difficult to reverse, especially when sensory deprivation has been present for many years. It may not be possible to compensate fully for deprived inputs by means of acoustic stimulation. Indeed, the cochlea (and/or cochlear nerve) can have nonfunctional areas, which are called "dead regions". The presence of "dead regions" prevents any acoustic stimulation from activating the auditory centres within the corresponding projecting areas.

**Tinnitus masking therapy.** Many studies have shown that tinnitus masking therapy (TMT) can provide some relief for certain tinnitus subjects. However, only a few of the studies included placebo controls [126] and the different studies are not always comparable, as they used different questionnaires and protocols, with some studies even using their own custom questionnaires. Henry et al. [115] compared the efficacy of TMT and TRT, finding that both methods led to self-reported improvements in tinnitus, but that TRT was superior to TMT in reducing tinnitus-related distress, especially in the group of patients for whom "tinnitus is a very big problem." Most of the improvement induced by TMT was achieved during the first 3–6 months of treatment, while TRT induced a steady

improvement over the course of the treatment (18 months). A more recent study, however, showed that TMT and TRT had similar effects on tinnitus when both were associated with counselling [170]. Finally, a randomised controlled study showed that TRT (masker + counselling) significantly improved tinnitus handicap [151].

**Neuromonics approach.** Neuromonics treatment consists of an acoustic stimulation combining music and broadband noise [106, 107, 114]. The spectrum of this combination is customised to provide an equalised stimulation over the audible frequency range. In addition to providing stimulation within the deprived sensory region, the acoustic stimulation is also designed to promote relaxation and relief. These effects are reinforced and complemented by counselling. Patients undergoing Neuromonics treatment are permitted to completely mask their tinnitus in the early stages of the treatment to maximise relief and relaxation (2 months). This initial stage is also intended to maximise the amount of stimulation of the deprived sensory region. In a second stage (4 months), the patients are discouraged from masking their tinnitus to facilitate desensitisation [107]. In an RCT by the manufacturers, this method was reported to significantly improve tinnitus. The study design included two groups with different modules of Neuromonics intervention, but participants self-adjusted the prescribed treatment for what they felt worked best, such that the intervention was no longer different between groups and their data were pooled. Overall, however, they reported clinically significant changes in tinnitus severity at 6 months for 86% of Neuromonics patients. Few independent studies of Neuromonics have been conducted. Of note, Newman and Sandridge [145] compared the cost-effectiveness and cost utility of Neuromonics versus ear-level sound generators at about one third of the cost. Both interventions resulted in reduced tinnitus handicap score with no difference in improvement between groups.

**Notched music stimulation.** A recent approach investigated the effects of notched music on tinnitus, the notch (1 octave width) being chosen to correspond to the tinnitus pitch [148, 167]. The notched music was intended to reduce tinnitus-related cortical activity within the notch, possibly through increasing lateral inhibition [150]. After 12 months of regular listening, this approach was reported to reduce self-reported tinnitus loudness, by around two points on a ten-point scale (eight subjects were treated with the notched music). The authors interpreted this approach as reversing the "maladaptive cortical reorganisation by the notched music training".

**Customised music stimulation.** It has been suggested that tinnitus may result from the central changes accompanying hearing loss [146]. An implication of this model is that an appropriate acoustic stimulation may reverse the central changes due to hearing loss, including those involved in tinnitus generation. In this context, hearing aids may improve the tinnitus condition by restoring sensory inputs thereby reversing the tinnitus-related central changes due to hearing deprivation. Recently, an RCT investigated the effects of their own product aimed at reversing the tinnitus-related central changes using a customised music stimulation [137]. Tinnitus severity was significantly reduced according to the THQ questionnaire (by 34%). Tinnitus severity estimated from the TFI, however, was not changed by the method.

**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.**

## Dietary and alternative therapies

### Recommendation against

**There is evidence that dietary and alternative therapies (e. g. Ginkgo biloba, melatonin, zinc, or other dietary supplements) have no proven efficacy and pose potential harm in the management of tinnitus. Recommendation is based on RCTs and systematic reviews with methodological concerns.**

***Ginkgo biloba.*** *Ginkgo biloba* is the most commonly used herbal supplement for tinnitus. The two latest systematic reviews included three RCTs on *Ginkgo biloba* for tinnitus as a primary complaint [121, 173]. A Cochrane review, first published in 2004 and most recently updated in 2013, concluded that *Ginkgo biloba* was not effective [121]. A second systematic review included five RCTs, with most trials having low methodological rigour [173]. The results were favourable toward Ginkgo, but the authors stated that a firm conclusion about efficacy was not possible. A meta-analysis pooled data from six RCTs and concluded that there was no benefit of Ginkgo over placebo [159]. *Ginkgo biloba* can interact with other blood thinners to cause serious bleeding and can worsen bleeding risk in patients with underlying clotting disorders [155].

**Melatonin.** Melatonin is a hormone secreted by the pineal gland that is involved with regulation of the sleep–wake cycle. Three RCTs, with a total of 193 participants, studied melatonin to treat tinnitus, and each demonstrated benefit with the greatest improvement in those patients with severe tinnitus and insomnia [154]. However, given the small number of overall patients studied and the methodological limitations, including lack of a placebo group in the largest trial, these results should be interpreted with caution. Although another study demonstrated potential benefit for patients with concomitant sleep disturbance due to tinnitus, this study lacked randomisation, blinding, or placebo control [142]. Only one study reported possible adverse effects of melatonin, which included bad dreams and fatigue [160].

**Dietary supplements.** Three RCTs of zinc as a treatment for tinnitus, with a total of 205 participants, showed inconsistent results [97, 103, 104]. It was suggested that benefit could be associated with underlying zinc deficiency.

Several other dietary supplements have been used for tinnitus, including lipoflavonoids, garlic, homeopathy, traditional Chinese/Korean herbal medicine, honeybee larvae, and other various vitamins and minerals. Evidence for the efficacy of these therapies for tinnitus does not exist [155].

**No recommendation**

**There is evidence for safety but little high-level evidence for the effectiveness of acupuncture. Recommendation is based on systematic review.**

**Acupuncture.** No recommendation can be made regarding the effect of acupuncture in patients with persistent bothersome tinnitus, based on poor-quality trials, no benefit, and minimal harm. A systematic review in 2012 on acupuncture for the treatment of tinnitus included nine RCTs, with a total of 431 participants [132]. However, this systematic review highlighted the heterogeneity among study designs as well as their methodological limitations using the Cochrane tool for assessing risk of bias. Variations in study design included types of acupuncture intervention, frequency, intensity and duration of treatment sessions, selection of other control groups, variability with blinding, and selection of outcome measures, many of which were not validated [132]. The authors concluded that the small number of RCTs of acupuncture for the treatment of tinnitus, with small sample size and methodological issues, were insufficient to make conclusions about effectiveness.

### 4.2 Referral options and criteria, triage, and a stepwise proposal

A stepped-care approach that provides a standard pathway based on patient need, including the disciplines involved, assessments, and treatments at each stage, is presented in **Fig. 5**. The steps proposed in the flowchart are based on the studies executed within the framework of the current guideline and the consensus meetings held within the steering committee. The barriers and facilitators of each member-country of the TINNET project have been taken into consideration, with a gradual increase in the intensity of the care at each level to be implemented according to health-care policy, available resources and health-care coordination within the specific country, region, or state. Suggested cut-off scores on the THI and TQ have been included as an example. For other instruments on tinnitus severity, we refer the reader to Chap. 3.

#### A stepwise multi-disciplinary approach

On the basis of the evidence described at present, we suggest that a CBT-based approach, whether in groups or individually, is the most evidence-based choice for effectively relieving tinnitus complaints. Tinnitus treatment aimed at the sound-perception level, such as sound therapy, including the use of hearing aids prescribed for tinnitus relief only, masking devices, ear-level sound generators, sound perceptual training, or other sound generating technology, however, has not been proven to have an additional effect on counselling or CBT, or as a standalone treatment. Nevertheless, evidence indicates the merits of audiological diagnostics, counselling, and education to decrease tinnitus suffering as well. On the basis of the current evidence, we suggest that the best tinnitus treatment strategy might be CBT based. Research suggests that next to otolaryngological/medical diagnostics, an overall CBT-based framework in tinnitus management is advisable, from audiological diagnostics (assessment of hearing and prescription of hearing aids if indicated to increase hearing function) and tinnitus counselling to psychological diagnostics and tinnitus treatment, since all studies showed benefits from some form of education, information, and/or counselling initially for all patients, and for the more severely impaired a more intensive CBT treatment. Moreover, tinnitus standard care might be best organised in a multi-disciplinary manner, using a stepped-care approach [13, 174], gradually increasing intensity of treatment in steps, so that most patients can be treated effectively with a fairly short process (diagnostics and information/education), and additional treatment steps can be indicated for those suffering on a more severe level.

## Chapter 5 Patient information and support

### 5.1 Confirming knowledge and dispelling myths. Key messages to prepare the patient for treatment and beyond

It is essential to successful tinnitus treatment that patients are empowered to self-care, that they are provided with reliable information and learning resources, and that they are signposted to appropriate sources of support [34]. Patients need to understand tinnitus, how distressing tinnitus is managed, and what sources of information and support are available to them beyond their treatment sessions.

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. Information should never be negative, e. g. "there is nothing that can be done" or "you will just have to learn to live with tinnitus".

Having information about tinnitus can be very powerful. Many patients start their tinnitus journey by looking for information on the Internet and while there is some accurate and useful information available on the Internet, there is also a lot of very unhelpful information [202]. Patients may read "nightmare" stories on the Internet, or hear inaccurate "facts" from friends, family, or even a clinician. Dispelling such myths is crucial.

In the assessment described in Chap. 3, 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.

There is no cure for subjective tinnitus, but patients can be treated to help them

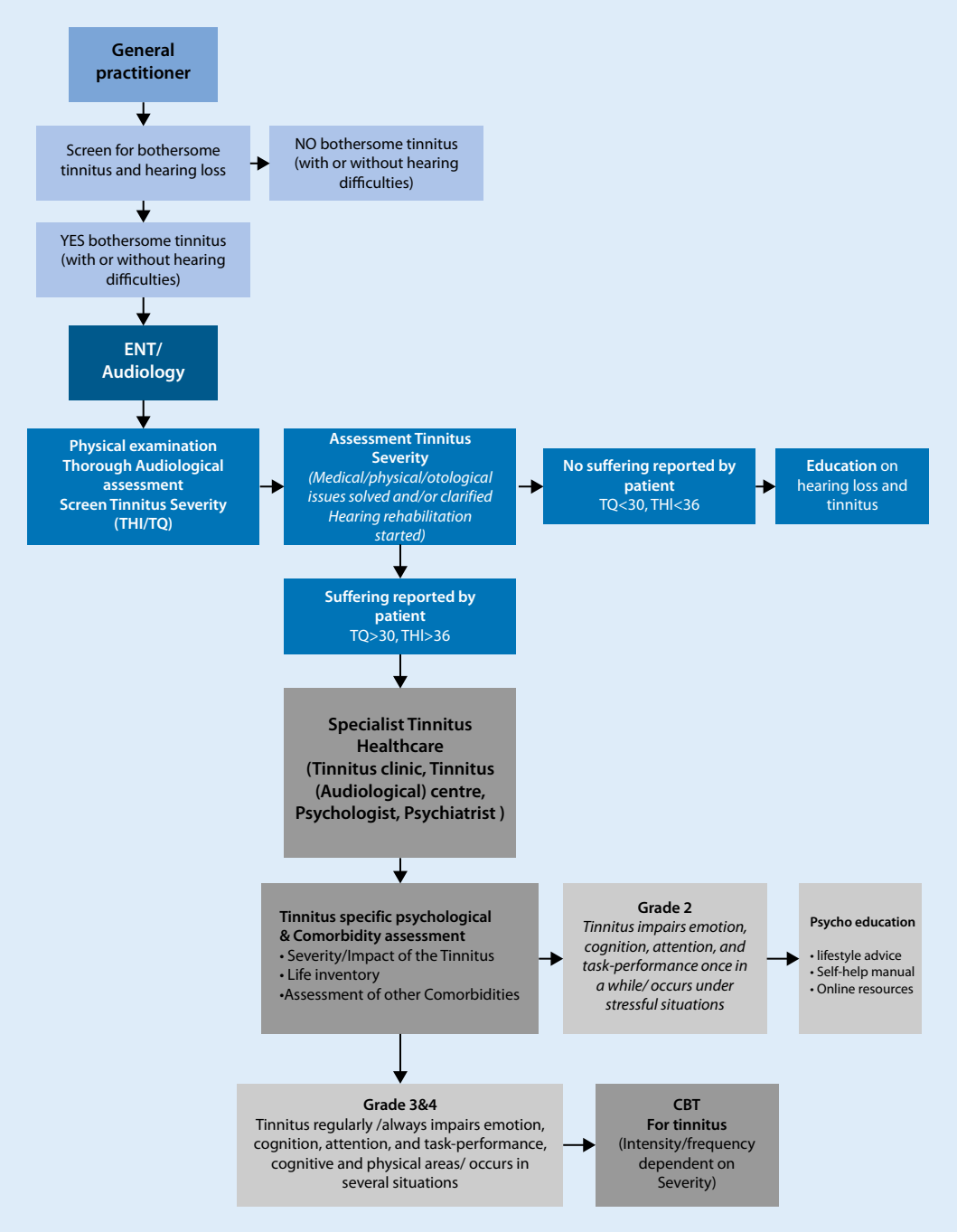


**Fig. 5** ◄ Criteria for assessment and treatment of tinnitus. *CBT* cognitive behavioural therapy, *THI* Tinnitus Handicap Inventory, *TQ* Tinnitus Questionnaire

habituate and to reduce the functional impact of their tinnitus. The functional impact might include sleep disturbance, difficulty concentrating, problems with hearing, and difficulty relaxing. Patients can learn to manage their reactions to tinnitus, thereby improving their quality of life.

## 5.2 Information that should be given to patients

Patient information and resources (e. g. decision aids) need to be sufficient to allow them to reach a shared decision with the clinician about their treatment and to fully engage themselves in the process of care [182, 208, 212]. Initial information and advice need to be given that will enable patients to have immediate strategies to alleviate tinnitus. Treatments may include hearing aids, sound-generating devices, medicines, and ways to learn how to cope with tinnitus. Depending on what is available locally, tinnitus care might involve the family doctor, an ear, nose and throat (ENT) specialist or an audiovestibular physician, hearing therapists or specially trained audiologists, clinical psychologists, nurses, or other clinical professionals [15, 21, 34, 187].

**Table 9** Common myths/misconceptions and information for patients

| Example myth/ misconception | Example information |
|---|---|
| Having tinnitus means you will go deaf | It should be explained to the patient that this is not the case. Everyone's hearing deteriorates as they get older, but tinnitus does not *cause* hearing loss. In many cases, tinnitus is caused by pre-existing hearing loss, but not the other way around [204] |
| Tinnitus is temporary and will go away | It should be explained that tinnitus can be temporary, but often it is not. The attitude of "hoping" or "wishing" it will go away when it does not go away causes additional distress and monitoring, thus driving tinnitus distress [57] |
| Tinnitus will get worse over time | It should be explained that tinnitus can be affected by life situations that make it more bothersome in time. In general, the severity of tinnitus decreases over time [207] |
| Hearing aids will make the tinnitus louder | Where there is a hearing loss as well as tinnitus, and the hearing loss can be compensated by hearing aids, the hearing aids may also help to address tinnitus. Hearing aids amplify external sounds, i. e. those in our environment; hearing aids cannot and do not amplify an internal noise, which is what the tinnitus noise is [211] |
| Caffeine makes tinnitus worse | This may be the case for a small number of individuals; however, a clinical trial found that caffeine had no effect on tinnitus severity [213]. In fact, the same study reported a significant negative effect of caffeine withdrawal, concluding there is no evidence to justify caffeine abstinence as a therapy to alleviate tinnitus. However, the consumption of coffee does influence sleeping patterns. If there are sleeping problems associated with tinnitus, then coffee consumption should be limited |
| Tinnitus means there is a very serious underlying illness | Although there are many conditions that may cause or exacerbate tinnitus, it is extremely rare that it is a symptom of a serious illness [179] |

Patient information and support topics should be tailored to the patient's need and what is available to them. Topics include:

- What is tinnitus? What causes and maintains it?
- Pulsatile tinnitus (follows heartbeat)
- Common misunderstandings and myths
- Hearing loss and hearing aids
- Ear wax removal
- Hyperacusis and tinnitus
- Protecting your hearing
- Habituating to tinnitus
- Relaxation
- Monitoring tinnitus
- Use of sound
- Dealing with sleep problems
- Dealing with emotional consequences of tinnitus
- Self-help and support groups

## What is tinnitus? What causes and maintains it?

Even though tinnitus is a symptom and not a disease, it can lead to illness in some people. Tinnitus should be explained to the patient as a sensation of hearing a sound in the absence of any external sound and their reaction to it. It can be reassuring for patients to describe the various ways in which people experience tinnitus. Different patients will hear different types of sound, for example ringing, buzzing, whooshing, or humming, and occasionally tinnitus has a musical quality. Tinnitus might be continuous or intermittent. It might seem like it is heard in one or both ears, inside the head, or it might be difficult for the patient to describe where it is coming from. Tinnitus is very common (about 10–19% of the population) and is reported in all age groups including children. It is more common in people who have hearing loss or other ear problems, but it can also be found in people with normal hearing. Most people find that it does not affect them in any way. Some people find it moderately annoying, while others finding it very troublesome [172, 189].

It is important to explain that for subjective tinnitus, exactly how and why it occurs is not yet fully understood but that research is ongoing. It is thought that tinnitus is the sound of activity within the auditory system, which can generally be heard in a silent environment, but in the presence of normal environmental sounds it is "filtered" out by the brain because it does not have meaning.

Although an underlying cause of tinnitus is rarely known, it is commonly linked to *hearing loss*. Age-related "wear and tear" in the inner ear is a common cause of sensorineural hearing loss [204]. It can also be linked to exposure to loud sounds such as occupational or leisure noise [180]. If relevant, it should be explained to the patient that tinnitus is also associated with disorders causing *conductive hearing loss* such as ear wax blockage and otosclerosis [204]. With any ear condition, the amount of information being sent to the brain can change. Research suggests that tinnitus results from the compensatory adaptation of the central auditory system to hearing loss.

Note that tinnitus is sometimes associated with emotional stress, use of certain medications, ear infections, ear, head or neck injuries, neurological disorders including acoustic neuroma, metabolic disorders including hypothyroidism, hyperthyroidism, and diabetes. Patients should be reassured that tinnitus is rarely an indication of a serious disorder.

Some clinicians invite patients to a *group tinnitus information session*, following which they can request individual therapy if they wish [203]. Some patients find the group session alone adequate to reassure them and no further treatment is needed. Group sessions have the advantage of considerably reducing patient waiting times until their first appointment.

## Common myths and misconceptions about tinnitus

Where myths or misconceptions about tinnitus are identified during assessment, it is important to provide information to dispel those myths and misconceptions. Some of these are commonly observed in clinical practice (**Table 9**).

## Hearing loss and hearing aids

Patients with tinnitus often attribute hearing problems to tinnitus and thus part of assessment is to determine how much of a patient's complaint is due to a hearing problem and how much is due specifically to the tinnitus [192]. Hearing loss is often an unnoticeable and gradual process, and many people are surprised when they are told that they have a hearing loss. For patients who have even a mild hearing loss and tinnitus, there is consensus that using hearing aids may be helpful because they amplify normal environmental sounds which otherwise may not be heard and may thus reduce the perception of tinnitus [124, 209]. Where they are available, clinicians should discuss hearing aids or combination hearing aid options.

## Hyperacusis and tinnitus

Many people who experience tinnitus also report hyperacusis, an increased sensitivity to everyday sounds that makes them uncomfortable to hear [186]. A natural response can be to block out as much sound as possible, for example using ear protection, but avoiding sound can make hyperacusis, and tinnitus, worse. Often using sound in a very controlled way can improve hyperacusis [198].

## Looking after your hearing

Exposure to loud noise can cause a temporary shift in hearing thresholds as well temporary tinnitus or make existing tinnitus worse. Patients should be informed that these temporary changes will likely resolve within a few days following the noise insult but that repeated episodes of noise exposure increase the likelihood that the tinnitus will become worse in the longer term [195].

The clinician should teach the patient what is "too loud". Examples of what is too loud are:

- If you have to shout to be heard by somebody around a meter away
- If you find your hearing is dulled after exposing yourself to noise
- If you find a ringing or buzzing in your ears (tinnitus) after exposing yourself to noise
- If a sound is painfully or uncomfortably loud, stop exposure immediately

People should take care of their hearing by wearing proper ear protectors for activities that are "too loud", e. g. using power tools or being near noisy motors for any amount of time. Ear protection is also important if the patient attends live music events or plays in a band or orchestra. Ear protection should not be used if ordinary, everyday sounds are uncomfortable [198].

Patients should also be educated to limit the amount of time and the volume when they are listening to music through earbuds or headphones. A simple 60/60 rule can be useful; never turn the volume above 60% and restrict listening time with earbud headphones to 60 min per day. At higher volumes, the amount of listening time needs to be reduced significantly. Earmuff-style or noise-cancelling headphones are preferable. For leaflets on safe listening volumes available in many languages, visit www.who.int/pbd/deafness/activities/MLS/en/.

## Adaptation

A thorough clinical assessment will determine where and when tinnitus is more and less intrusive, and a follow-on discussion should include what can be done to make the patient's environment more "tinnitus friendly", e. g. introducing some low-level sound. It is important to explain that, whilst many people have tinnitus, only some are aware of it all the time or bothered by it. This is because people often get used to the noises just as we get used to other noises around us (e. g. air conditioning, a clock ticking) in the short term, i. e. they adapt to the presence of those unimportant sounds. If our attention is focused on something else, it may be possible to "forget" the tinnitus at times and thus reduce its impact. It is a new sensation and patients need to give themselves time to adapt to it. Most people find that their tinnitus seems to settle down over time as they notice it less. There is good evidence from clinical trials that in general tinnitus becomes less bothersome over time, even without doing anything [193, 207].

Patients should be encouraged to keep doing the things they enjoy. If they start living life differently to accommodate the tinnitus, it is going to seem more of a problem. They may need to do some things differently, however. For example, if they enjoy reading but it becomes a quiet activity where tinnitus is more noticeable they may need to start using some background music or environmental noise. The important thing is that they find ways to keep doing what they enjoy.

## Relaxation

Patients should be reassured that it is perfectly normal to feel anxious or afraid because of tinnitus, especially when they first experience it [57, 214]. Tinnitus works a bit like an "emotional barometer"—it is often more intrusive when there is anxiety or fear around. Tinnitus might become more bothersome when under duress.

If patients can learn to relax more, they will be less anxious and afraid and so notice their tinnitus less. There are many forms of relaxation such as progressive muscle relaxation or deep-breathing exercises, and these can be guided by a person, audio, or written instructions (e. g. www.tinnitus.org.uk/relaxation). A relatively easy way your patient might relax is to find somewhere peaceful and just slow their breathing down (they may have some sound on in the background). A simple relaxation exercise is to take a few slow deep breaths and pay full attention to the feeling of the breath entering the body, filling the lungs, and leaving the body.

Both adaptation and relaxation *take time*. It may be useful for patients to create some catchphrases to use when tinnitus is being more bothersome, such as "Calming tinnitus takes time".

## Monitoring tinnitus

If life is planned around tinnitus it is given much importance, and this prevents the patient adapting to it. Simply put, patients should not avoid activities they think may make their tinnitus worse. Patients should not be putting their life on hold. Tinnitus does not have to control their life. Each time the patient tries to "monitor" their tinnitus they are guiding their attention to it; there is, however, no evidence that this would make tinnitus worse. They should be advised to engage in normal activities when they no-

tice themselves trying to monitor their tinnitus.

## Use of sound

Patients should be advised on the use of sound to reduce the intrusiveness of tinnitus in quiet situations such as when trying to sleep, work, or to read in a quiet environment. Patients should be advised to experiment with the type and volume of different sounds to find what suits them best in different situations. Examples of what can be useful include opening a window to let in sounds, leaving a television on in the background, static noise from a radio, noise from a fan, or recorded environmental sounds produced by a bedside generator [199].

Some research suggests that sound volumes that allow for constant exposure to a very low level of tinnitus help the patient adapt to their tinnitus [126, 153]. Higher sound volumes may make tinnitus inaudible. but for some patients this may make the tinnitus more noticeable when the sounds are turned off. A wide variety of non-wearable and wearable sound therapy devices are available that can be helpful for some patients.

## Addressing sleep problems

Many patients report difficulty in getting to sleep or staying asleep because of tinnitus. It can be a vicious cycle where worrying about tinnitus and/or worrying about the sleep difficulty makes it even more difficult to sleep. Whilst in a patient population most will complain of sleep problems, in the general population most people with tinnitus sleep well and their tinnitus is no different in quality from those who do not sleep well. If sleep is a problem then it may be helpful for the patient to learn about the biology of sleep, the internal biological clock, and sleeping patterns.

People who have tinnitus and sleep poorly tend to worry more at night than people with tinnitus who sleep well [183]. Patients should be advised that working through problems during waking hours is better than doing so in the middle of the night when they have nothing else to occupy them. One strategy patients might try is to insert a "worry moment" of 10–15 min into their daily schedule, ideally in the early evening. At that time, they can write down (or think about) all the worries, plans, comments, questions that come to their mind. The good thing about our brain is that "a thought once thought, can be filed away". In other words, the patient should know they can control their worry. Another strategy to counter worry involves "thought stopping"; patients may use methods such as simple breathing exercises (e. g. exhale three times consciously, or simply verbalising the word "STOP" out loud). The practice of relaxation and breathing exercises puts the body in a state that allows for rest, reduces worry, and increases the effectiveness of your biological clock. General advice:

- Plan participation in any sports or other high-energy activities for the afternoon or early evening (rather than later). Ritually "powering-off" in the last 2 h before bed, e. g. dimming the lights, only engaging in low-intensity energy activities, avoiding aggravating television shows or late-night discussions.
- Be aware that caffeinated drinks and alcohol can negatively affect sleep, as does smoking, and the consumption of meals within 2 h of going to bed. Warm milk has a sedating effect.
- Ensure an ambient temperature in the bedroom. Reserve the bedroom for sleeping (and intimacies). Try and limit any other activities (even reading and watching television) to as little as possible in the bedroom. Try to get into a routine of going to bed at a fixed time each night, but, at the same time, go to bed only when tired.
- When the preferred sleep pattern is disturbed (e. g. when travelling or working in shifts), take as little sleep (naps) as possible outside your normal routine.

## Addressing psychological problems

The clinician should emphasise to patients that although there is no cure there are many things that they can do to make tinnitus less of a problem. There are a wide variety of psychological treatment options available, from providing the basic information described earlier, to treatment elements that focus on certain problems with thoughts, emotions, and behaviours leading to functional difficulties (concentration, sleep, daily activities). The patient should be provided with information about the treatment options available locally.

One structured approach to tinnitus treatment is *tinnitus retraining therapy (TRT;* [130]). The basis of TRT is that tinnitus is prioritised by the brain as an important signal. This treatment uses bilateral sound generators or hearing aids at a certain sound level to try to reduce the percept of tinnitus so ad to allow patients to adapt to the tinnitus sound. Sound is used in combination with directive (educational) counselling. Most clinicians who treat tinnitus use some elements of TRT (e.g. Cima et al. [13], who used the neurophysiological model to explain tinnitus) but the strict method is not frequently used because it is resource intensive and there is limited evidence for its effectiveness [153].

*Cognitive behavioural therapy (CBT)* is a psychological approach to treating tinnitus that has substantial high-level evidence for its effectiveness [84, 120, 125, 139]. The basic premise should be explained to the patient. It works on the principle that when the patient becomes aware of tinnitus, they respond negatively to it. For example, the patient develops a belief that something is seriously wrong with them (belief) and this leads to anxiety and fear (emotion), and unhelpful behaviours such as avoiding silence (behaviour). Cognitive behavioural therapy helps patients to recognise which beliefs or behaviours are unhelpful. They then work with their clinician (usually a psychologist, specialist audiologist, or hearing therapist) to develop different ways of responding to the tinnitus that ultimately make it less bothersome (see Appendix E).

A clinician-guided Internet-delivered version of CBT is available in some countries and there is good evidence for its effectiveness when delivered by this medium [215].

*Mindfulness-based interventions,* or simply *mindfulness,* have been classified as a psychological treatment aimed at

psychological distress associated with a range of complaints [196] and typically consists of up to ten group sessions. Mindfulness trains the skill of being mindful, fostering moment-to-moment awareness, and observing emotions, sensations, and cognitions non-judgmentally. The rationale for using mindfulness is that if the patient stops trying to avoid unpleasant sensations (such as tinnitus) they will be able to perceive the tinnitus without the struggle. The approach offers individuals a new way to relate to thoughts that allow them to reduce their tendency to engage in negative and catastrophic thoughts. Mindfulness for tinnitus has been tested in clinical trials with evidence that it is feasible as a treatment for tinnitus [141, 197] and may be beneficial in reducing negative emotions, rumination, and psychological difficulties [206].

*Acceptance and commitment therapy (ACT)* has its roots in the behavioural tradition (see Appendix E). The focus in ACT is on functional utility of thoughts and actions, and not on their "right- or wrongfulness" [190]. One of the key elements of ACT is to help experience psychological events (thoughts, perceptions, and emotions) in a non-judgmental way, not trying to change or modify those events. This leads to a more functional awareness of how thoughts, emotions, and behaviours create and maintain distress. Since *mindfulness* promotes present-moment awareness and observation in a non-judgmental way, it has become an integrated part of the ACT protocol.

### Self-help

Self-help resources are shown to be useful in reducing tinnitus-related distress with mixed evidence for effects on comorbid symptoms such as depression [188]. Self-help books are widely available, and some provide complete programmes of self-help for tinnitus. For example, the book *Tinnitus: A Self-Management Guide for the Ringing in Your Ears* by Henry & Wilson [191] provides a series of exercises focused on a cognitive behaviour modification approach, and there is some from a controlled study [200] that it is beneficial. *Living with Tinnitus and Hyperacusis* [201] looks at strategies for living with tinnitus and hyperacusis. It includes a complete programme of self-help covering causes and mechanisms of tinnitus and hyperacusis; their impact; effective treatments; relaxation and sound therapy; relieving stress; and avoiding relapse.

Hundreds of mobile applications have been developed specifically for use in hearing health care, including for tinnitus [205]. For tinnitus, most were developed to assess the characteristics of a person's tinnitus over time, or to provide sound-enrichment options [210]. Unfortunately, we are at present unable to validate these apps or identify which might be useful.

It should be acknowledged that the patient's family and others may not understand what tinnitus is and how it might affect the patient. If that is the case, it can be helpful for them to talk to someone who has experience of tinnitus. One option would be for them to attend a tinnitus self-help group or support group. These groups facilitate an exchange of information between its members; patients can keep informed on the latest information and share treatment experiences by talking to others with similar problems [181, 184]. Groups may be lay- or clinician-led. Where possible these groups should be facilitated or attended by a clinician to prevent misinformation from being conveyed. Group activities may include lectures from different related disciplines. Clinicians should be aware of local groups or consider forming one if there is no support group locally.

Some patients may be unwilling or unable to attend a face-to-face self-help or support group. An alternative for these patients may be to take part in an online support group (OSG; [194]). These groups share many of the supposed benefits of face-to-face groups such as being a means to share experiences and seek or provide emotional support. Equally, they risk patients being exposed to inaccurate or misleading information [185]. As such, OSGs need to be appropriately moderated, ideally by a clinician.

## 5.3 Further information and support

National registered charities for tinnitus are a reliable source of information and support for people with tinnitus. Clinical professional organisations also provide patient information and leaflets.

- The *British Tinnitus Association* (www.tinnitus.org.uk/) provides a helpline and information leaflets (in English) that are free to all, and a quarterly magazine for its members.
- The *Ida Institute* (http://idainstitute.com/) has worked in collaboration with the *British Tinnitus Association* to produce a web resource (www.tinnituskit.com) providing basic information about tinnitus and how to deal with it.
- The *Charité German Tinnitus Foundation* (www.deutsche-tinnitus-stiftung-charite.de/die_stiftung/) provides online information in German and English (www.deutsche-tinnitus-stiftung-charite.de/en/tinnitus/).
- The *German Tinnitus League* (www.tinnitus-liga.de) provides information only in German.
- The *American Tinnitus Association* (www.ata.org/) provides online information and podcasts in English on tinnitus causes, treatment, and the research they support.
- The *Dutch Tinnitus Association* (www.stichtinghoormij.nl/) provides online newsletters, information and publishes about patient meetings and recent results from the research they support.
- The *Dutch ENT-Guideline* can be found here: https://richtlijnendatabase.nl/richtlijn/tinnitus/behandeling_van_patienten_met_tinnitus.html (only available in Dutch).
- The *National Institute on Deafness and other Communication Disorders* provides information and PDF leaflets on hearing health and research, available in English and Spanish: www.nidcd.nih.gov/health/tinnitus
- The *French Patients' Tinnitus Association* (www.france-acouphenes.org/).

- The *Belgian Patients' Tinnitus Association* (www.belgiqueacouphenes.be/).
- The *Danish Association of the Hard of Hearing* (https://hoereforeningen.dk) provides a helpline (open 8:00–21:00) run by volunteers with tinnitus, who have been trained at The Danish Association of the Hard of Hearing on guidance, support, and the structure of the Danish Health-Care System.
- The *Italian Au-Tu (Acufene Uniti–Tinnitus United;* www.au-tu.org) provides information in Italian both online and through meetings reporting the state of basic and clinical research on tinnitus and offers a moderated forum (for subscribers only) for tinnitus patients.
- The *Foundation for the Research of Tinnitus and Hyperacusis* (FINVAC): No online information found.


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## Compliance with ethical guidelines

**Conflict of interest.** R.F.F. Cima, B. Mazurek, H. Haider, D. Kikidis, A. Lapira, A. Noreña, and D.J. Hoare declare that they have no competing interests.

This article does not contain any studies with human participants or animals performed by any of the authors.

**Table A.1** Clinical examination in patients with pulsatile tinnitus

| Examination | Rationale |
|---|---|
| Ask the patient to tick his/her finger in each pulse, while taking radial pulse | Confirm that tinnitus is pulsatile and follows heartbeat |
| Otoscopy: Special attention to retrotympanic mass | Possibility of glomus jugulare or tympanicum, high jugular bulb, ectopic carotid artery |
| Press jugular vein and ask patient whether tinnitus is alternated | Discriminate between arterial and venous pulsatile tinnitus |
| Use a stethoscope to listen to mastoid, external auditory meatus, neck, and chest | Look for murmur, indicative of an arteriovenous abnormality |

# Appendix A

## Pulsatile tinnitus management

Pulsatile tinnitus follows a person's heartbeat and can be either subjective or objective [218]. It occurs in less than 5% of tinnitus patients [216]. It is commonly associated with venous and arterial abnormalities, either because of increased blood flow or stenosis. Pulsatile tinnitus can also 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. In this brief section, special examination aspects which should be implemented in addition to a typical and radiological evaluation algorithm are presented.

### Clinical examination

A summary of the clinical examination of patients with pulsatile tinnitus is presented in Table A.1 [217, 218].

### Radiological evaluation

The radiological evaluation of pulsatile tinnitus [216, 218–220] comprises:

### Arterial pulsatile tinnitus

- Carotid triplex (stenosis)
- Computed tomography angiography (glomus, aneurysms, atherosclerosis, arteriovenous malformations)

### Venous pulsatile tinnitus

- Magnetic resonance angiography (arteriovenous malformations, empty sella syndrome, Arnold–Chiari malformation, Sylvius aqueduct stenosis, sigmoid sinus diverticulosis, etc.).
- When imaging is normal, consider benign intracranial hypertension, especially in patients with a high body mass index.

# Appendix B

## Method for the development of an implementation plan

Per recommendation, and possibly per country/region, the following points need to be considered:

- In which time frame is it expected/recommended that the recommendation is implemented across Europe?
- What are the conditions that need to be met for the recommendation to be successfully implemented?
- What are the possible barriers per country/region for the recommendation to be successfully implemented?
- What are the possible facilitators per country/region for the recommendation to be successfully implemented?
- What is the impact on health-care costs for the implementation of the recommendation?
- Who is the responsible party to undertake the actions needed for successful implementation of the recommendation?

In considering the aforementioned points, we propose the following:

- Recommendations might be categorised according to level of recommendation (strong—weak—against). All recommendations in the European guideline should be weighed, according to the "strength" of the recommendation.
- For the strong recommendations, each point will need extensive investigation and reporting.
- For the weak recommendations, alternatives might be mentioned or considered.
- The recommendations against will be absolutely discouraged in favour of treatment/procedures with strong recommendations.

# Appendix C

## Somatosensory tinnitus

Tinnitus is considered somatosensory when it can be modulated by somatic stimulation or movement. It might also be considered a subtype of tinnitus that is associated with activation of the somatosensory, somato-motor, and visual-motor systems. Somatic modulation of tinnitus has been reported to be observable, when actively looked for, in up to 83% of tinnitus patients [229, 236, 239, 241]. Somatosensory tinnitus can be modulated by jaw clench [239] or eye movements [232, 235]. Temporomandibular joint dysfunction may cause somatosensory tinnitus [240]. In some cases, pulsatile tinnitus can be modulated by movement of the head or upper lateral neck [231].

## Pathophysiology

Somatosensory tinnitus is hypothesised to be related to abnormal cross-modal plasticity of somatic-auditory interactions [222, 226, 227, 230, 234]. Somatic modulation of tinnitus is assumed to result from abnormal auditory neural interactions within the central nervous system [237]. Cross-modal interaction is further supported by the observation of auditory cortical area activation in deafness as a result of somatosensory stimulation [222–224].

## Diagnosis

Somatosensory tinnitus should be considered when the patient can modulate the loudness or intensity of their tinnitus

by movement or tactile stimulation [221, 228, 233], and when they report [238]:

- Head or neck trauma.
- That they can modulate tinnitus quality by manipulation of teeth, jaw, or cervical spine.
- Frequent pain in head, neck, or shoulder girdle.
- Simultaneous onset of pain and tinnitus.
- Tinnitus is aggravated by incorrect body postures.
- Severe bruxism.

### Treatment

Treatment for somatosensory tinnitus tends to include: oro-myofacial therapy, splinting, physical therapy, relaxation therapy, somatic modulation therapy, electrical stimulation, and local cortisone injection [225].

## Appendix D

**Table D.1** Characteristics and psychometrics of existing tinnitus health-related quality-of-life instruments

| Instrument[a] | Developed to | Items | Scoring | Construct validity | Reliability (test re-test) | Subscales |
|---|---|---|---|---|---|---|
| Tinnitus Handicap Inventory (THI) | Measure level of perceived tinnitus severity | 25 | (0) never<br>(2) sometimes<br>(4) yes | + | + | Functional, emotional, catastrophic responses |
| Tinnitus Questionnaire (TQ) | Measure psychological aspects of tinnitus complaint and distress | 52 | True<br>Partly true<br>Not true | + | + | Emotional distress, cognitive distress, intrusiveness, auditory perceptual difficulties, sleep disturbance, somatic complaints |
| Tinnitus Reaction Questionnaire (TRQ) | Measure psychological distress due to tinnitus | 26 | (0) not at all<br>(4) almost all the time | + | + | General distress, interference, severity, avoidance |
| Tinnitus Severity Index (TSI) | Measure how much tinnitus negatively impacts a patient's life and how bothersome patients perceive their tinnitus to be | 12 | (0) never<br>(4) always | – | + | None |
| Tinnitus Handicap Questionnaire (THQ) | Measure patients' perceived degree of handicap due to tinnitus | 27 | (0) strongly disagree<br>(100) strongly agree | + | + | Physical health/emotional status/social consequences, hearing and communication, personal viewpoint |
| Tinnitus Severity Questionnaire (TSQ) | Measure tinnitus severity | 10 | 0 (not affected)<br>4 (always affected) | – | – | None |
| Tinnitus Functional Index (TFI) | Measure tinnitus severity and treatment-related change | 25 | 0 (not affected)<br>10 (always affected) | + | + | Intrusiveness, sense of control, concentration, sleep, hearing, relaxation, quality of life, emotion |

[a]Some of these questionnaires are already available in multiple languages. Hall et al. [258] provide a guide to translation and adaptation of hearing-related questionnaires

**Table E.1** The "third-wave" CBT treatments

| |
|---|
| *MBSR* |
| Mindfulness is a type of psychological treatment aimed at psychological distress, depressive symptoms, and anxiety, initially devised for individuals suffering from chronic disease. Mindfulness-based stress reduction (MBSR) was developed by Kabat-Zinn [196, 251]. MBSR protocols typically consist of up to ten group sessions. The focus lies on training of the skill of being mindful, which is a moment-to-moment awareness, and observing emotions, sensations, and cognitions non-judgmentally. Sessions are built around meditational skills, bodily exercises, and psycho-education. MBSR was developed for chronic pain sufferers and was later adapted for chronic diseases, such as heart disease, and recently adapted for tinnitus [206, 243, 250]. As a stand-alone treatment approach, mindfulness has been applied to many psychological disorders [245, 253]. Mindfulness is also an important component of other psychological treatments such as acceptance and commitment therapy (ACT), some forms of behavioural treatment, and cognitive therapy [190, 247, 255] |
| *ACT* |
| According to its founder [190], ACT has its roots in the behavioural tradition. ACT does not emphasise the accuracy or the content validity of cognitions and behaviours, as is the case in more cognitive approaches. ACT focuses on functional usefulness of thoughts and actions, and not on the "right- or wrong-fullness" [190, 249]. A key element of ACT is to decrease "experiential avoidance" [248]. ACT advocates experiencing psychological events (thoughts, perceptions, emotions) in a non-judgmental way, rather than trying to change or modify those events, leading to a more functional awareness of how thoughts, emotions, and behaviours create and maintain distress. Since MBSR approaches advocate present moment awareness and observation in a non-judgmental way, which results in decreased rumination and worry, it has been integrated within ACT protocols |

# Appendix E

## Cognitive therapy and cognitive behavioural therapy

Confusion often exists about the differences between cognitive therapy and cognitive behavioural therapy (CBT), as both terms are used interchangeably. Since CBT stems from the convergence of two distinct theoretical schools, the radical behavioural school (first wave) and the cognitive school (second wave), CBT entails both cognitive and behavioural principles and methods, and usually a combination of these are used in therapeutic sessions. Cognitive behavioural theory and treatment have been applied in tinnitus research for decades [246, 252, 254] and CBT approaches for tinnitus have been repeatedly shown to be effective in decreasing tinnitus distress, anxiety, and tinnitus annoyance, and improving daily life functioning. Although there are common elements across CBT-based treatments for tinnitus, the CBT approaches investigated vary in number of treatment sessions, hours spent in therapy, group versus individual formats, face-to-face versus Internet-based self-help therapies, combinations of different treatment elements, and tinnitus diagnostics and outcome assessments.

### The cognitive approach

The main premise of the cognitive approach is that cognitive factors maintain psychological distress. Typical cognitive therapeutic interventions (or so-called talking therapy) are aimed at: (1) correcting/changing "erroneous" beliefs or thought processes (cognitions), (2) current problems and thought processes, and not so much the past, and (3) advising patients to perform behavioural experiments in order to test the validity of maladaptive thoughts and beliefs [242, 244]. The cognitive model [57], in line with the cognitive tradition, posits that therapeutic strategies to change these maladaptive cognitions automatically lead to changes in emotional distress and problematic behaviours. These cognitive techniques seem to be helpful in the short term. In addition to educational counselling, techniques include but are not limited to "Socratic dialog", thought control, rational thought formulation, exploring automatic thoughts, and testing of thoughts and beliefs through behavioural experiments.

### A fear-avoidance approach

Recently, *exposure* therapy, a cognitive-behavioural treatment strategy, entered CBT treatment protocols for tinnitus [13]. Exposure therapy, also applied in CBT treatments for chronic pain [256], is a clinical application of what is called "extinction" of the association between two stimuli in classic learning theory terms. In the case of tinnitus patients, it is assumed they learn to be fearful of the tinnitus signal. That is, in the distressed tinnitus patient the initially neutral tinnitus signal became associated with sympathetic arousal (alarm detection; [37, 257]). According to fear-avoidance reasoning, the neutral tinnitus signal became a predictor of unwanted aversive states, hereby receiving a very negative value (danger). Patients interpret the signal as a sign of harm or injury, which is why they are so fearful, and selectively single out the tinnitus signal. They are eventually constantly interrupted and engaging in safety-seeking behaviour, because of these threat expectancies. These mechanisms are likewise at work in arachnophobes, for example. The spider, which is harmless, has become a sign of great danger, leading to extreme fear.

For arachnophobia, exposure procedures consist of repeated confrontations with spider-related images, objects, and eventually real-life spiders, which evoke the greatest fear of the patient. As a result of repeated exposure to the most feared stimuli, the patient learns that confrontation with spiders is not life-threatening, and therefore they are not in danger, and the fear of spiders dissipates (extinction). By analogy, the tinnitus patient is extremely fearful of perceiving the tinnitus. Even though the tinnitus is continuously present, the involuntary response is trying not to hear it, and trying to be minimally confronted with the tinnitus sound (avoidance). Patients do this by trying to control their sound environment, not thinking about it, directing their attention elsewhere, and consequently increasing their monitoring and awareness of their tinnitus. Consequently, cognitive resources are depleted, leading to task interruptions, more avoidance (safety-seeking), and eventually disruptions in

functional activities. In the long term, severe disability ensues, disrupting all life domains and leading to severe dysphoria.

This "new" forms of CBT for tinnitus typically includes the third-wave forms of therapy (see Table E.1) to enhance internal observations, increase moment-to-moment consciousness of the tinnitus, and to provide the ability of observing tinnitus-related emotions, sensations and cognitions non-judgmentally. Exposure therapy for tinnitus patients entails exposing them to their tinnitus sound, the interceptive sensations associated with the tinnitus, as well as their moment-to-moment narrative. To provide an appropriate context, exposure is performed in quiet circumstances. This way the patient experiences that the tinnitus sound is harmless, not dangerous, and listening to it in silent environments will not lead to catastrophe. They also learn that the aversive consequences are not always triggered. These experiences lead to a "neutralisation" of tinnitus by adaptation of fear expectancies; consequently, the tinnitus becomes less intrusive and bothersome, the more they engage in exposure.

## Comparing the treatments

The theoretical frameworks have strong conceptual overlap, and are based on the premise that the initially neutral tinnitus signal receives an "alarm" value, through classic conditioning. In turn, this negative tinnitus valence exacerbates negative responses in cognitions, emotions and behaviours, hindering the "normal" process of habituation. Tinnitus distress ensues; which is the very negative and aversive state when processes of adaptation and the efforts thereto have failed to return the organism to equilibrium or homeostasis.

Treatment avenues sometimes seem to be contradictory. The neurophysiological model-based tinnitus retraining therapy includes extensive education and (partial) masking of the signal (avoidance of the signal, by avoiding silence at all costs), hypothesising that both are required for habituation. The habituation theory and cognitive approaches purport that thought control and attention-diversion techniques (alter thoughts/beliefs about the tinnitus and actively directing attention away from the tinnitus) will be beneficial for habituation. For short-term habituation, these strategies may work. On the other hand, the fear-avoidance approach leads to an opposite treatment strategy, promoting exposure to tinnitus and eliminating avoidance tendencies (such as avoiding silence or directing attention away from tinnitus), to adjust threat expectancies and decrease fear.

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