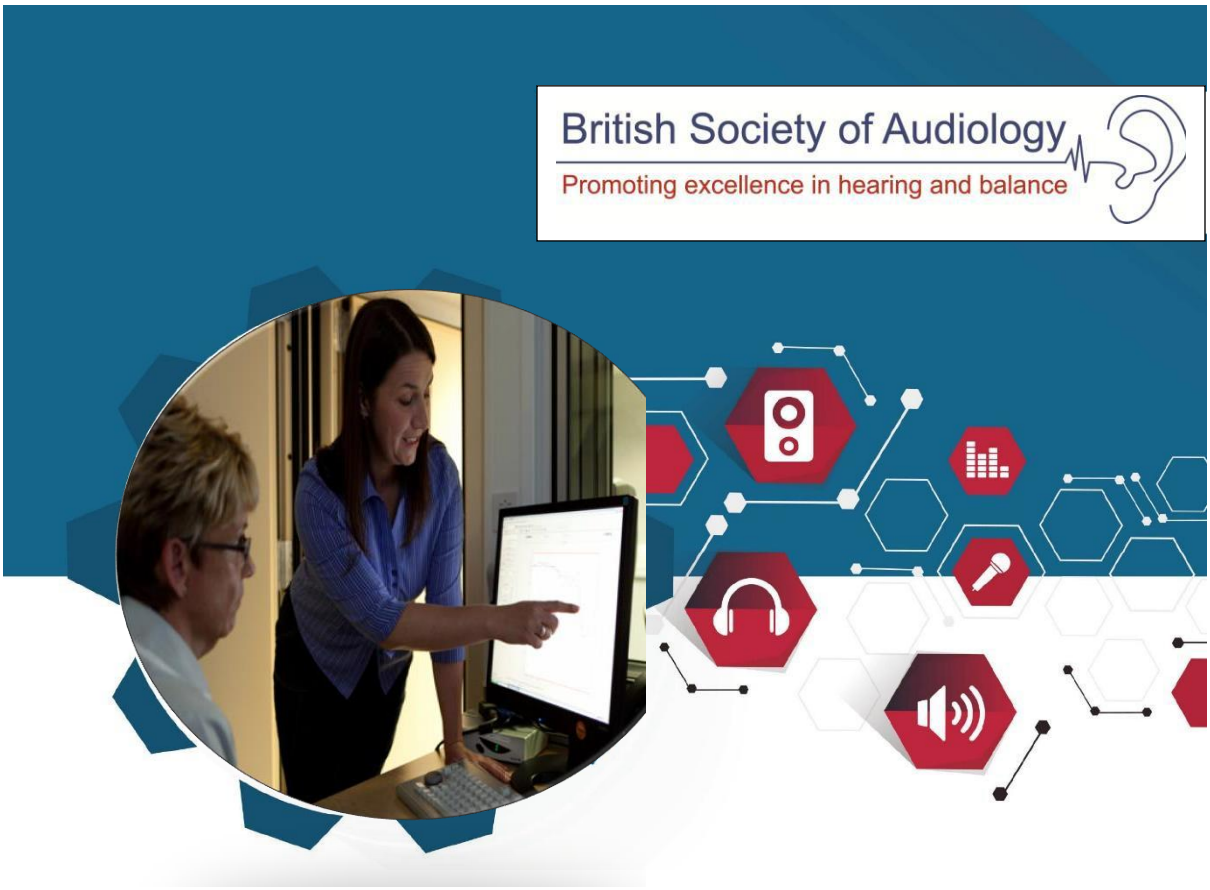

Practice Guidance

Tinnitus in adults

Date: October 2021

Due for review: October 2026

General foreword

This document presents Practice Guidance by the British Society of Audiology (BSA). This Practice Guidance represents, to the best knowledge of the BSA, the evidence-base and consensus on good practice, given the stated methodology and scope of the document and at the time of publication.

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1. Contents

2. Abbreviations

ALE = Activation Likelihood Estimation
ART = Acoustic Reflex Threshold
CBT = Cognitive Behaviour Therapy
CI = Cochlear Implant
CT = computed tomography
DBS = Deep Brain Stimulation
ENT = Ear Nose and Throat
GP = General Practitioner
HADS = Hospital Anxiety and Depression Scale
IAPT = Improving Access to Psychological Therapies
IQIPS = Improving Quality In Physiological Services
ISI = Insomnia Severity Index
kHz = kiloHertz
LDL = Loudness Discomfort Level
MTG = Middle Temporal Gyrus
MRI = Magnetic Resonance Imaging
PTM = Progressive Tinnitus Management
SF = Solution-Focused
rTMS = Repetitive Transcranial Magnetic Stimulation
tACS = Transcranial Alternating Current Stimulation
tDCS = Transcranial Direct Current Stimulation
TENS = Transcutaneous Electrical Stimulation
TFI = Tinnitus Functional Index
THI = Tinnitus Handicap Inventory
THQ = Tinnitus Handicap Questionnaire
TIMP = Tinnitus Individual Management Plan
TQ = Tinnitus Questionnaire
TRQ = Tinnitus Reaction Questionnaire
TRT = Tinnitus Retraining Therapy
TSI = Tinnitus Severity Index
VAS = Visual Analogue Scale
ULL = Uncomfortable Loudness Level
VNS = Vagus Nerve Stimulation

3. Introduction

Tinnitus is the perception of a sound or sounds in the ear or head without there being an external source (McFadden, 1982). Tinnitus affects between 12-30% of the adult population and for about 3% of the population tinnitus becomes bothersome and distressing (McCormack et al., 2014). Those people may experience symptoms that negatively affect their quality of life and might require clinical intervention. Symptoms can include sleep disturbances, hearing difficulties, difficulties with concentration, social isolation and emotional difficulties including anxiety, depression, irritation or stress (Davis & El Rafaie, 2000). Tinnitus can be described as either objective or subjective. Objective tinnitus can be heard by an examiner. Objective tinnitus has a physical source and is generated in or near the ear, sometimes it can have a neurological origin which might need immediate referral. Subjective tinnitus does not involve an identifiable sound source and cannot be heard by an examiner. Subjective tinnitus is caused by abnormal activity at some point or points of the auditory system. In many cases tinnitus is idiopathic and not traceable to medical causes. In most cases tinnitus is accompanied by some degree of hearing loss (Shargorodsky et al., 2010). It is estimated that 75% of people with hearing loss might have tinnitus and up to 80% of people with tinnitus have hearing loss (NHS England, 2019).

The aim of this guidance is to promote uniformity in the evidence-based assessment and management of adult patients with tinnitus. Use of the guidance will support shared decision-making with patients to facilitate individualised care. It was established for every health professional involved in tinnitus assessment and treatment, including but not limited to general practitioners (GPs), ear nose, and throat (ENT) doctors, audio-vestibular physicians, neurologists, audiologists, psychiatrists, psychologists, and therapists.

3.1 Shared Decision-making

It is implied throughout this document that the subject should be involved in shared decision-making when undertaking audiological intervention, receiving subsequent information and understanding how it will impact on the personalisation of care. Individual preferences should be taken into account and the role of the clinician is to enable a person to make a meaningful and informed choice. Audiological interventions bring a variety of information for both the clinician and the subject that can be used for counselling and decision-making regarding technology and anticipated outcomes.

4. Development of the guidance

The topics and structure of this guidance document were informed by a review of existing clinical practice guidelines for tinnitus, what is reported in service evaluation literature, and discussion and consensus among the members of the multidisciplinary BSA Tinnitus and Hyperacusis Special Interest Group members. Topics were considered suitable and useful for inclusion if there existed either (1) high-

level research evidence such as randomised controlled trials and systematic reviews, or (2) evidence that a need for guidance existed on a topic to inform current clinical practice such as practices identified from published service evaluations or expert knowledge that a procedure is currently used in clinical practice.
The methodological strategy for developing this guidance was informed by the AGREE II tool domains which measure guideline quality in terms of rigour and transparency (APPENDIX 1).

5. Assessment

Tinnitus is a symptom associated with multiple medical disorders (Table 1) therefore an assessment of all potential causes should be conducted. When referring patients for a specific diagnostic test, medical necessity as well as financial cost must be considered. It is recommended that the choice of a diagnostic pathway is based on the patient's history and initial basic diagnostic assessment.

5.1 Assessment of tinnitus in primary care settings

On average GPs see two patients per month presenting with tinnitus as their primary complaint, equating to approximately one million consultations for tinnitus in primary care in the UK annually (El-Shunnar et al., 2011). Many people complain that tinnitus services are difficult to access and express dissatisfaction with their experience of primary care (McFerran et al., 2018). Guidance for GPs on tinnitus is available from a number of sources (Table 2).

Table 1. Disorders associated with tinnitus

Anxiety	Phobias Anxiety Generalised anxiety disorder Mixed anxiety and depressive disorder Clinical depression
Hearing/ Vestibular	Hearing loss (e.g. presbyacusis, noise induced hearing loss, sudden hearing loss) Disturbance of auditory perception Hyperacusis Vestibular disorders Wax blockage of outer ear canal Otitis of outer ear canal Obliterative exostoses Otitis media with effusion Chronic suppurative otitis media Acute and chronic labyrinthitis Otosclerosis Ménière's disease Vestibular schwannoma (acoustic neuromas) Acoustic shock Cerebello-pontine angle tumours (other than schwannoma)
Mood	Adjustment disorder Dysthymia Depressive episode Recurrent depressive episodes
Reaction to severe stress and adjustment	Acute reaction to burdening Post-traumatic stress disorder Somatic symptoms disorder Illness anxiety disorder Psychological factors and behavioural factors in another classified disease

Table 2. Sources of information for primary care providers

British Academy of Audiology. *Guidance for Primary Care: Direct Referral of Adults with Hearing Difficulty to Audiology Services* [online]. 2016. Available from http://www.baaudiology.org/about/publications/
National Institute for Health and Care Excellence. Tinnitus [online]. 2010. Available from http://cks.nice.org.uk/tinnitus#!scenario
National Institute for Health and Care Excellence. Tinnitus: assessment and management NICE guideline [NG155] [online]. 2020. https://www.nice.org.uk/guidance/ng155
Dowrick C, Kay T and Osman E. *Eight Minute Primary Care Tinnitus Consultation* [online]. 2012. Available from www.tinnitus.org.uk/primary-care-tinnitus-consultation
British Tinnitus Association. *Tinnitus Guidance for GPs* [online]. 2017. Available from www.tinnitus.org.uk/guidance-for-gps
Department of Health. *Provision of Services for Adults with Tinnitus. A Good Practice Guide* [online]. 2009 Available at: http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093844
British Society of Hearing Aids Audiologists. *Referral Guidelines for HCPC registered Hearing Aid 1 Dispensers* [online]. 2017. Available from https://www.bshaa.com/write/MediaUploads/BSHAA%20Publications/BSHAA_Guidance_For_Further_Referral_In_Audiology_Clinic_-_Jan_2018.pdf
Seidman MD. *BMJ Best Practice: Tinnitus* [online]. 2018. Available from https://bestpractice.bmj.com/topics/en-gb/364

The general advice is summarised below:

5.1.1 History

Information gathered from the patient will indicate whether onward referral is necessary.

- Note characteristics of the tinnitus – is it pulsatile, asymmetric, constant or intermittent?
- Ask how bothersome and distressing it is and what is the impact on the patient's life,

- Take a history, including determining any triggers e.g. noise exposure, head injury, medication changes, stress,
- Check for associated symptoms including deafness, dizziness, earache, or ear discharge.

5.1.2 Examination

- Perform an otoscopic examination to exclude wax build up, ear infections etc.,
- Check blood pressure and perform routine blood tests if clinically indicated: test for hypo- and hyperthyroidism, hyperlipidaemia, anaemia, vitamin B12 deficiency, zinc deficiency,
- Full cranial nerve examination,
- In cases of pulsatile tinnitus, auscultation to ears, head and neck to exclude a bruit.

5.1.3 Tinnitus red flags

Firm indications that a patient with tinnitus should be referred to secondary care as an otological emergency include:

- Sudden onset pulsatile tinnitus,
- Tinnitus in association with neurological symptoms and/or signs,
- Tinnitus associated with vertigo,
- Tinnitus following head trauma,
- Tinnitus associated with unexplained sudden hearing loss (developed over a period of 3 days or less),
- Tinnitus associated with formed auditory hallucinations or imagery,
- Tinnitus with suspected stroke.

Patients should be referred to an ENT/audiology specialist if they have:

- Unilateral tinnitus,
- Objective tinnitus
- Pulsatile tinnitus (tinnitus that pulsates synchronously with the heartbeat),
- Tinnitus in association with asymmetric hearing loss,
- Tinnitus with vestibular symptoms,
- Tinnitus causing psychological distress,
- Tinnitus associated with rapidly worsening hearing loss (over a period of 4 to 90 days).

People with bothersome and distressing tinnitus should be referred for audiological assessment. Depending on local arrangements referral may be via ENT or directly to audiology.

5.1.4. Tinnitus management in primary care

Information and reassurance that tinnitus is common, usually improves with time, and is not a sinister symptom is all that is required for many patients, particularly if it is delivered in a positive way, whilst

validating their experiences. Negative phrases such as “There’s nothing that can be done” or “You will have to learn to live with it” should be avoided as they can focus the patient’s attention on their tinnitus and increase distress. It is important to be empathetic and encourage self-management.

Treatment of any potential underlying cause, e.g. excessive ear wax or ear infections, should be undertaken. Advice about using self-management techniques, including sound enrichment, relaxation techniques and tinnitus support groups should be offered. There is no indication for any drug in tinnitus management, although drugs may be considered for the management of associated symptoms such as vertigo, anxiety, depression, or insomnia.

5.1.5 Resources for primary care

Resources that those who work in primary care may find useful include the NICE guideline [NG155] Tinnitus: Assessment and Management (https://www.nice.org.uk/guidance/ng155), NICE guideline [NG98] Hearing loss in adults: assessment and management (https://www.nice.org.uk/guidance/ng98), ‘Eight Minute Primary Care Tinnitus Consultation’ (www.aintreehospitals.nhs.uk/.../8-minute-primary-care-tinnitus-consultation-final.pdf) and resources that patients can be referred to including the British Tinnitus Association website (tinnitus.org.uk), helpline 0800 018 0527, and ‘Take on Tinnitus’ resource (takeontinnitus.co.uk).

5.2 History taking

History taking should include tinnitus, hearing, medical, psychiatric/psychological, lifestyle, fears/anxieties, and patient expectations. A typical history should include:

5.2.1 Tinnitus history

Onset: when was tinnitus first noticed; what are the associated clinical factors/triggers (noise trauma, stress, recent events, acute illness, other); was it a sudden onset or did symptoms start gradually with a continuous increase?

Course and duration of tinnitus: Is the tinnitus progressive, regressive or stationary.

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?

Impact: Is tinnitus bothersome/interfering with daily life (sleep-difficulties, task-interruptions, fearful reactions, cognitive-attentional problems, negative affect, affecting sense of identity)? A standardised questionnaire should be used to establish the degree to which a patient experiences tinnitus as bothersome and distressing (See section: 5.3).

5.2.2 Audiological history and prioritisation

Assessment of hearing loss, perceived 'ear-fullness' (pressure), sensitivity to everyday sounds (or hyperacusis), problems in balance/ dizziness/ vertigo, associated otalgia (ear ache) or aural discharge.

5.2.3 Medical history

ENT, orthopaedics (cervical, dental, jaw), internal medicine (thyroid, hypertension, cardiovascular, anaemia), mental disorders (psychological, psychiatric). Presence of co-morbidities / drug history/ medications; ototoxic drugs (e.g., chemotherapy, antimalarial drugs, anti-depressants, anti-epileptics); long term pharmacological consumption (e.g. antidepressants, anxiolytics), smoking, and recreational drugs.

5.2.4 Other history

Occupational history, hobbies/leisure activities, noise exposure, head/neck trauma, social support status, education, recent life events.

Clinicians should introduce the rationale for conducting an assessment. Explain that it is necessary to take this general history to enable you to decide together on the best approach for treatment and encourage patients to ask any questions throughout. It should be explained that chronic tinnitus is determined by psychological, social, environmental and biological factors, so it is important to find out about all these aspects. Use of a standardised tinnitus questionnaire may support this discussion but should not prevent an attentive conversation that is focussed on the patient's experience and concerns, and what they believe about their tinnitus.

5.3 Questionnaires

Tinnitus severity can be defined as a function of the level of how bothersome and distressing it is to an individual. It can range from mildly problematic to completely debilitating with significant social and economic consequences (Andersson, 2002). Tinnitus severity is a general concept that encompasses a wide variety of complaints or negative consequences reported by patients, such as emotional distress, sleep and concentration problems. Questionnaires may help to provide the means to quantifying tinnitus severity by defining grades of tinnitus symptoms and to assess changes in tinnitus severity at follow up and after clinical intervention but should be viewed as part of the overall clinical picture. Open ended questions to assess the impact and effect on quality of life will also assist in deciding the overall severity, and risk of suicide. Questionnaire items grouped together, referred to as subscales, can

measure several different complaints, in varying degrees, which together are hypothesised to capture the overall concept of tinnitus severity. Consequently, the use of questionnaires (overall score and subscales) can play a vital role in diagnosing patients, supplementing the oral history and effectively triaging patients into the most appropriate interventions such as intensive management or education and advice. For example, high scores on items measuring complaints about sleep could be used as a starting point for discussions or guide the treatment pathway.

To be clinically useful, the questionnaire should provide (1) a thorough assessment of the relevant presenting symptoms of the construct (i.e. tinnitus severity) to support planning of treatments, (2) reliable quantification of individual differences in terms of the perceived severity and the meaning (interpretability) of the overall scores (i.e. its diagnostic capabilities), and (3) have the capacity to be sensitive to changes in health status over time, to permit the assessment of the efficacy of different treatments and interventions (i.e. its evaluative properties) (Kirshner & Guyatt, 1985; Frei et al., 2011).

Numerous questionnaire measures of tinnitus severity are available (see Table 3), although the validity and reliability of these questionnaires varies (Fackrell et al., 2014). It is recommended that tinnitus severity be evaluated for each patient with at least one multi-item questionnaire measure. The Tinnitus Functional Index (TFI) and the Tinnitus Handicap Inventory (THI) are the most commonly used questionnaires in tinnitus services in UK NHS Audiology departments (Hoare et al., 2015). The TFI (Meikle et al., 2012) has been evaluated in a UK patient population and has excellent diagnostic capabilities, especially in terms of the depth of information provided through the subscales and the proposed grading system to aid interpretability of the scores (Henry et al., 2016: Fackrell et al., 2016/2016a/2018). Whilst, the THI (Newman et al., 1996) has been shown to have excellent diagnostic capabilities and an established grading system to aid interpretation of the scores for treatment pathways, the THI does not provide the same depth of information on the negative consequences of tinnitus as the TFI (Baguley & Andersson, 2003, Fackrell et al., 2014). A brief description of these questionnaires is provided below (section 5.3.1 and 5.3.2).

Clinicians may also choose to use questionnaires to measure mood, mental health, general health and wellbeing, or insomnia. In a recent systematic review of existing guidelines for tinnitus assessment in clinical practice (Fuller et al., 2017), Visual Analog Scales and Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983) are referred by almost all existing tinnitus guidelines. Additionally, the NICE common mental health guidance recommends completing the brief measure for assessing Generalised Anxiety Disorder (GAD-2; Spitzer et al., 2006) to assess a person who you may suspect of having anxiety.

This guidance also recommends asking the following two questions: 'During the last month, have you often been bothered by feeling down, depressed or hopeless?' and 'During the last month, have you often been bothered by having little interest or pleasure in doing things? to assess suspected depression (Mann & Gilbody, 2011) (NICE Common mental health guidance, 2011). If the person answers 'yes' to either of these questions further assessment for depression should be considered. Beyond these, the Clinical Outcomes in Routine Evaluation (CORE-OM) provides a measure of distress (Evans et al., 2000). Table 3 provides a brief overview of these questionnaires. For more detailed descriptions see Appendix 2.

Table 3. Overview of the questionnaires for tinnitus assessment

Questionnaire	Assessment	Outcome measure	N° items	Subscales	Response options	Score calculations & range	Grading system	Useful references
Tinnitus Functional Index (TFI)[a] Measure of the impact of tinnitus, encompassing a range of problem domains and treatment-related changes	✓	✓	25	1. Intrusiveness 2. Sense of Control 3. Cognition 4. Sleep 5. Auditory 6. Relaxation 7. Quality of Life 8. Emotional	11-point scale (0 -10): Range of descriptors used	**Total:** Sum all scores for 22 items (exclude Auditory items) and divide by 2.2 **Subscale:** Sum all scores for items and divide by N° of items in subscale **Range:** 0 to 100 (high impact)	No problem 0 – 7 Small problem 7 – 26 Moderate problem 27 – 48 Big problem 49 – 70 Very big problem 71 – 100 [k]	Fackrell et al., (2016/ 2016a/ 2018)
Tinnitus Handicap Inventory (THI)[b] Measure of emotional and catastrophising effects of tinnitus	✓		25	1. Functional 2. Emotional 3. Catastrophic	3-point Likert scale: Yes(4) Sometimes(2) No(0)	**Total:** Sum all scores for the items **Range:** 0 to 100 (high severity)	Slight 0 – 16 Mild 18 – 36 Moderate 38 – 56 Severe 58 – 76 Catastrophic 78 – 100[l]	Newman et al. (1998) McCombe et al.(2001) Baguley & Andersson, (2003)

Tinnitus Handicap Questionnaire (THQ)[c] Measure of tinnitus handicap and to be sensitive to the changes in handicap over time	✓	✓	27	1. Physical, emotional & social effects 2. Hearing & communication ability 3. Individual perception of tinnitus	100-point scale: Strongly disagree (0) to strongly agree (100).	**Total:** Sum all scores for the items and divide by n° of items completed **Range:** 0 – 100 (high tinnitus handicap)	Bothersome tinnitus >22[m] Normative data is provided, but does not include grading system	Newman et al. (1995) Kennedy et al. (2004) Fackrell et al. (2014)
Tinnitus Reaction Questionnaire (TRQ)[d] Measure psychological distress related to tinnitus	✓		26	No clear subscales	5-point Likert scale: Not at all (0) to almost all the time (4)	**Total:** Sum all scores for the items **Range:** 0 to 104 (high psychological distress)	No grading system	Robinson et al. (2003) Fackrell et al. (2014)
Tinnitus Questionnaire (TQ)[e] Measure of tinnitus severity, in particular general and specific tinnitus complaints	✓		52	1. Emotional & cognitive distress 2. Intrusiveness 3. Auditory Perceptual difficulties 4. Sleep disturbance 5. Somatic complaints	3-point Likert scale: Not true (0) partly true (1) True (2)	**Total:** Sum 41 of the 52 items **Range:** 0 to 82 (increased tinnitus distress)	Mild 0 – 30 Moderate 31 – 46 Severe 47 – 59 Very severe 60 – 82[n]	Goebel & Hiller (1994) Hiller & Goebel (2004)
Tinnitus Severity Index (TSI)[f] Measure negative impact of tinnitus	✓		12	No subscales	5-point Likert scale: Never (0) Rarely (1) Sometimes (2) Usually (3) Always (4).	**Total:** Sum all scores for the items **Range:** 0 to 48 (high impact)	No grading system	Newman et al. (2014)
Hospital Anxiety and Depression Scale (HADs)[g] A brief measure of generalised symptoms of anxiety and depression	✓		14	1. Anxiety 2. Depression	3-point Likert scale: Range of descriptors used	**Total:** Sum all scores for the items **Range:** 0 to 42 (greater severity) **Subscale:** sum the 7 items **Range:** 0 to 21	Normal 0 – 7 Mild 8 – 10 Moderate 11 -15 Severe ≥16	Zöger et al. (2004)

Clinical Outcomes in Routine Evaluation (CORE-OM)[h] Measure of psychological distress	✓		34	No subscales	5-point Likert scale: not at all (0) to most of or all the time (4)	**Total:** Sum all scores for the items **Range:** 0 to 136 (high distress)	Mild psychological distress ≥34	Handscomb et al. (2016)
Generalised Anxiety Disorder brief measure (GAD-2)[i] Screening questions for anxiety	✓		2	No subscales	4-point Likert scale: Not at all (0) Several days (1) More than half the days (2) Nearly every day (3)	**Total:** Sum all the scores for the items **Range:** 0 to 6 (higher generalised anxiety)		Spitzer et al. (2006) Kroenke et al. (2007)
Insomnia Severity Index (ISI)[j] Measure of nature, severity and impact of insomnia	✓		7	No subscales	5-point Likert scale: no problem (0) to very severe problem (4)	**Total:** Sum all scores for the items **Range:** 0 to 28 (increased insomnia)	Absence 0 – 7 Sub-threshold 8 – 14 Moderate 15 – 21 Severe 22 – 28	Blais et al. (1997) Yang et al. (2009)

a: Meikle et al.,2012; b: Newman et al. 1996; Kuk et al., 1990; c: Wilson et al., 1991; d: e: Hallam et al., 1996; 2008; f: Meikle et al., 1995; g: Snaith & Zigmond, 1994; h: Evans et al., 2000; i: Spitzer et al. 2006; Kroenke et al., 2007; j: Bastien et al., 2001; k: Fackrell et al., 2018; l: McCombe et al., 2001; m: Sullivan et al., 1993; n: Goebel & Hiller, 1998

The use of self-devised questionnaires is not recommended, as is the use of visual analogue scales (VAS). Although VAS are often used to measure different complaints associated with tinnitus, such as loudness, annoyance or awareness of tinnitus, there is little evidence demonstrating the psychometric adequacy for differentiating levels of tinnitus severity between individuals and quantifying clinically significant change on the VAS following tinnitus intervention (Adamchic et al., 2012; Fackrell, 2016).

5.3.1 Tinnitus Functional Index (TFI)

The TFI was developed to be (1) discriminative to provide measures of tinnitus distress, (2) evaluative to provide a responsive measure of treatment-related changes, and (3) comprehensive to cover multiple domains of tinnitus severity. The 25-item questionnaire measures the functional impact of tinnitus,

encompassing eight different subscales measuring: Intrusiveness, Sense of control, Cognition, Sleep, Auditory, Relaxation, Quality of life, and Emotional distress. Patients rate the degree of tinnitus impact for each item on an 11-point Likert scale according to how they have felt over the past week (Meikle et al., 2012). The TFI has been specifically evaluated for use in clinical practice and research in the UK (Fackrell, 2016; 2016a; 2018). This national validation study showed the TFI and its subscales to have excellent reliability to differentiate between individuals perceived tinnitus impact, and valid constructs that were measuring different aspects of tinnitus impact. The Auditory subscale was found to be problematic for overall structure and total score. Therefore rather than summing all 25 items to calculate the total score as proposed by Meikle et al. (2012) for UK patients it is recommended to calculate the total score by summing the 22 items from the remaining seven subscales and dividing by 2.2 to give a total score out of 100. The higher scores still indicate the greater impact on everyday functioning. Each subscale can be scored separately, whereby the relevant three or four items are summed and weighted to give a score out of 100. The Auditory subscale should only be used to aid clinical interpretation. A grading system based on patient experience has been proposed for the UK, although detailed interpretation of what each grade means in terms of clinical implication has not yet been developed.

5.3.2 Tinnitus Handicap Inventory (THI)

The THI is the most commonly used questionnaire in clinical practice in the UK (Hoare et al., 2015). It was originally developed as a diagnostic tool to measure the emotional and catastrophising effects of tinnitus (Newman et al., 1996; Newman et al., 1998). Each of the 25 items is rated on a categorical 3-point scale (yes/no/sometimes). The total score reflects the sum of all responses with a maximum score of 100 indicating the greatest impact on everyday function. Although three subscales of the THI were proposed, the validity of these subscales have been questioned (Zachariae et al., 2000; Baguley & Andersson, 2003; Kennedy et al., 2004). Subsequent analyses indicated that the THI is a single factor structure with no viable subscales (Baguley & Andersson, 2003). The THI shows consistently high reliability to differentiate degrees of tinnitus severity, and the overall construct has been shown to measure aspects of everyday function, albeit more emotional components than originally proposed. A grading system based on expert opinion and the statistical properties of the scores has been developed and established in the UK to grade and diagnose tinnitus severity at intake assessment. It provides a detailed interpretation of the possible treatment pathways for each level of severity (Newman et al., 1998; McCombe et al., 2001). Again, these grades do not necessarily reflect the actual patient experience.

5.4 Diagnostic test battery

A primary otological/audiological diagnosis should be based on a thorough assessment to exclude possible causes of tinnitus. Assessment should include complete ear, nose, and throat examination including otoscopy to exclude the presence of wax, tympanic membrane abnormalities, otitis media with effusion, chronic otitis media, retro-tympanic mass or any other pathology. Palatal myoclonus and temporomandibular joint disorders should also be considered.

The minimum audiology test battery for adults with tinnitus should include:

- Otoscopy (examination of the ear with an otoscope) following BSA recommended procedures.
- Pure Tone Audiometry (PTA) including 3 kHz and 6 kHz following BSA recommended procedures. Where the patient has significant difficulty identifying tones due to the tinnitus, pulsed tones may be used and this should be noted on the audiogram – this should be the exception and not the rule.
- Tympanometry to identify or exclude possible middle ear pathology following BSA recommended procedures when indicated.

If used, Modified Tinnitus Masking Level (determining if sound input diminishes or removes the tinnitus perception) should be applied with caution. White noise is often used within sound generator and combination devices as a therapy for tinnitus and most audiometers are able to produce white noise. It is logical to expose the tinnitus patient to low level white noise to (1) assess whether white noise may have a beneficial effect, and (2) to assess whether the patient finds the sound soothing or alternatively has a dislike for it. This will support individualised use of sound in therapy. It is important to cautiously raise the level of the white noise in this procedure as if too loud it may exacerbate tinnitus and cause discomfort.

In addition to audiological evaluation, further ENT diagnostics should include whether tinnitus is objective (auscultation ideally in a sound proof room using an amplified stethoscope) or subjective, perceptional characteristics of the tinnitus sound (tonality, pitch, loudness), temporal properties (pulsatile or not, constant, intermittent, fluctuating), location (one or both ears, or in the head), and severity. It should also include assessment of hearing loss, perceived ‘ear-fullness’ (pressure), sensitivity to normal sound (or hyperacusis), problems in balance/ dizziness/ vertigo. Other medical history (thyroid, hypertension, cardiovascular, anaemia), mental disorders (psychological, psychiatric), presence of co-morbidities / drug history/ medications; ototoxic drugs (e.g. chemotherapy, antimalarial drugs); long term pharmacological consumption (e.g. antidepressants, anxiolytics), smoking, and recreational drugs, should be assessed.

Other history includes occupational history, hobbies/leisure activities, noise exposure, head/neck trauma, social support status, education, recent life events.

Further investigation or referral should be considered if clinically indicated:

- MRI (or contrast-enhanced CT if MRI is contraindicated) in cases of unilateral tinnitus and/or asymmetric hearing loss
- High frequency audiometry in cases of tinnitus with normal hearing at standard (conversational) frequencies
- Transient-evoked otoacoustic emissions and / or distortion product otoacoustic emissions
- Appropriate vestibular investigation (e.g. VNG evaluation, v-HIT, vestibular evoked myogenic potentials) in cases of dizziness, vertigo, or balance problems
- Functional cervical diagnostics for detecting tinnitus modulations in somatosensory tinnitus. Consider imaging of cervical spine in cervical pathology associated with somatosensory tinnitus.
- Dental examination (including temporomandibular joint) for detecting tinnitus modulations in temporomandibular joint dysfunction or bruxism
- MRI of the brain in abnormal auditory brainstem response or abnormal vestibular evoked myogenic potential

5.5 Assessments that should be avoided in a clinical setting

Measurement of the tinnitus percept itself is fraught with difficulty and is not recommended. Tests presenting high levels of sound that may exacerbate the tinnitus or cause discomfort to the patient should also be avoided, particularly when considering the known prevalence of concomitant hyperacusis. The clinician should also be aware of increased perception of loudness in autism (Khalfa et al., 2004).

1. Pitch-matching (determining the pitch of the perceived tinnitus) should be avoided where possible unless indicated, e.g. as part of a research protocol. Pitch-matching is notoriously difficult to achieve with any accuracy (Penner, 1983; Burns, 1984; Tyler & Conrad-Armes, 1983; Hoare et al., 2014). An attempt to create greater accuracy (Mcmillan et al., 2014) involved the use of 30 consecutive pitch match measurements which is inappropriate in a clinical setting due to the time involved and the likelihood of patient fatigue compared to the therapeutic or counselling benefit of such assessment. Researchers with specific equipment may be able to undertake these tests in 10 minutes but it is unlikely a standard tinnitus clinic will have similar specialist equipment.

2. Tinnitus Sensation Level (determining the perceived loudness of the tinnitus percept) should be avoided due to its inaccuracy and minimal therapeutic or counselling benefit. The sensation

level is based on the frequency of the pitch match which is unreliable. Accuracy may also be affected by the variability of tinnitus, recruitment, or hyperacusis.

3. Uncomfortable Loudness Levels (ULLs) also known as Loudness Discomfort Levels (LDLs) (determining the highest level of sound a patient can tolerate without discomfort) may exacerbate tinnitus and cause discomfort and should not be routinely performed in clinical situations, i.e. only when clinically indicated. In some situations (e.g. when fitting hearing aids to a patient's dynamic range) ULLs can be useful but then the test should be performed with particular care with tinnitus patients (see BSA recommended procedure for ULLs).

4. Similarly, Acoustic Reflex Threshold (measurement of the lowest level of sound which will trigger contraction of the stapedial muscle) presents high levels of sounds which could exacerbate tinnitus and cause discomfort (Hunter et al., 1999), and therefore should be administered with care.

5.6 Recognising severe distress/suicidal ideation/ensuring safeguarding

Clinicians should be alert to issues arising from and associated with severe distress such as safety, lifestyle (drugs or alcohol dependence), and assess the level of support the individual patient has (i.e. are they alone or have family/friends who are supportive). Assessment should include whether there are recent significant life events, or history of self-harm. These would indicate an urgent communication with the individual's GP or named Community Psychiatric Nurse and ensure responsive procedures is in place with appropriate signposting e.g. to The Samaritans, local IAPT service, or sleep clinic. Clinicians should also be familiar with signs of psychosis, including auditory hallucinations and hysterical symptoms, and the need for Psychiatric evaluation in these cases.

Questionnaires can aid in the assessment of risk or presence of severe distress and suicidal ideation. For example, CORE-OM asks subjects to rate the statement "I made plans to end my life". Use of the CORE-OM therefore can facilitate consistent clinical assessment of suicide risk. Asking about suicide is not harmful. For a guide to assessment of suicide risk in depression see: https://www.dpt.nhs.uk/download/2hn1ZTaUXY or for a mental health toolkit see: https://www.rcgp.org.uk/clinical-and-research/resources/toolkits/mental-health-toolkit.aspx

For patients in acute crisis follow organisational policies and local Standard Operating Procedures (if available). Alert the patients GP as a matter of urgency by telephone and follow this up with an urgently typed letter. In acute crisis the patient may need to be taken immediately to a secondary care emergency department for support from a Crisis Management Team. Consider escorting patient if suicidal ideations are present.

Clinicians should also be aware of their own needs and the needs of colleagues for clinical supervision and peer support because of working with anxious or depressed individuals with tinnitus.

5.7 Record keeping

By their nature, tinnitus appointments take more time and delve deeper into a patient's history than a standard hearing assessment; the likelihood for a practitioner to forget to record elements of the discussion is therefore greater if they are not noted during the session. It is suggested therefore that without bypassing the good communication strategy of facing the patient when conversing, notes are recorded contemporaneously. Most clinical systems record into databases and a clinician repeatedly turning to a screen might reduce trust and congruence. Making paper-based notes to be inputted/scanned in immediately after the appointment may be a way to avoid this. It is important to record positive and negative findings so that the clinical record accounts the questions that were asked and not just significant findings. For example, if a patient responds "no" to 'do you ever experience vertigo', then the clinician should record that *No vertigo is experienced.* Usually, physiological assessments are stored automatically and may only require referencing in the patients record. It is of particular importance to highlight in the patients records where there is severe distress/suicidal ideation and what safeguarding has been considered/put in place.

6. Management

The available management options for tinnitus aim to reduce the perception of the internal sound by introducing or amplifying external noise or interrupting tinnitus-generating activity. Treatments also aim to manage the emotional reaction caused by the sound through patient education, counselling, and relaxation (Hoare et al., 2015). There are also many acoustic, electrical, and pharmacological treatments to managing tinnitus which are considered emerging as they continue to be evaluated and refined through research. The use of shared decision-making tools is recommended (Pryce et al., 2017).

6.1 Explanation of the cause(s) of tinnitus

The possible cause(s) of the tinnitus should be discussed at a level sufficient to allay any anxieties/fears. The explanation may include details of pathophysiology, prognosis, and treatment options. Multiple factors are proposed to influence tinnitus including hearing loss, acoustic trauma, age, ototoxic drugs, head injury, diet, hypertension, heightened blood lipids, alcohol, and intrinsic factors such as genes (Pawelczyk et al., 2012). However, these factors do not influence individuals in the same way and not everyone will develop tinnitus as a result. Indeed evidence shows that up to 50% of tinnitus patients do not attribute their tinnitus to any particular cause (Stouffer & Tyler, 1990). In addition, the experience of tinnitus can vary widely from patient to patient with respect to the perceived characteristics of the experienced sound (e.g. tonal vs broadband), its localisation (in one or both ears or head): its time

course (continuous, fluctuating, intermittent), its modifying factors (e.g. reduction by masking) and its co morbidities (e.g. hearing loss, hyperacusis, insomnia) (Langguth, 2017).

6.1.1 Hearing loss

Hearing loss is common in tinnitus (Langguth et al., 2013). Shargorodsky et al. (2010) found that those with hearing impairment were more likely to report tinnitus, and epidemiology data shows that hearing loss is a risk factor for tinnitus development (Hoffman & Reed, 2004). Furthermore, evidence shows that tinnitus spectrum is often related to the pattern of hearing loss (Norena et al., 2002; Schecklmann et al., 2012).

6.1.2 Acoustic or chemical trauma

Evidence shows that acute acoustic trauma is often immediately followed by tinnitus (Mrena et al., 2002) including from firearm shooting (Mrena et al., 2002), car airbag release (Stankiewicz et al., 2000), minutes of exposure to music tones or noise (Chermak & Dengerink 1987), to hours of exposure to recreational music (Metternich & Brusis, 1999). Ototoxic drugs such as salicylates and aminoglycoside antibiotics are linked to tinnitus (Sand et al., 2007). Cancer treating drugs such as cisplatin are also ototoxic and cause hearing loss and tinnitus.

6.1.3 Genetics

Some studies suggest tinnitus may be hereditary (Hendrickx et al., 2007; Kvestad et al., 2010). A recent longitudinal twin study confirms a moderate genetic influence of tinnitus. Specifically, they found significantly higher coincidence in identical twins compared to non-identical twins. The authors also reported that the degree to which genetic influences are correlated between tinnitus and hearing thresholds ranged from 0.33 to 0.49 suggesting the presence of some common genes affecting tinnitus and hearing thresholds (Bogo et al., 2017). Sand et al. (2007) found an association whereby monogenetic disorders, which cause gene mutations, also include secondary chronic tinnitus. Sand (2006) found that the risk of developing tinnitus in conjunction with hearing impairment is significantly reduced in carriers of the Met in Val66Met variant of the gene encoding Brain Derived Neurotrophic Factor (BDNF) (Sand et al., 2006). Although the identification of genetic factors in tinnitus is promising, there are many challenges such as phenotypic heterogeneity, variable penetrance, contradicting data on heritability, and limited data on the early onset of tinnitus (Pawelczyk et al., 2012).

6.1.4 Brain associations

Various brain regions including the auditory network (Leaver et al., 2016), default mode network (Chen et al., 2014; Leaver et al., 2016), dorsal attention network (Burton et al., 2012; Schmidt et al., 2013), ventral attention network (Burton et al., 2012), and visual network (Chen et al., 2014) are suggested to be involved in tinnitus. The precise brain abnormalities and neuro-pathophysiological mechanisms, however, are still unclear (Chen et al., 2017). Chen et al. (2017) used the activation likelihood estimation (ALE) algorithm to identify the common core resting state brain regions in chronic tinnitus across nine

selected neuroimaging studies. The whole brain meta-analysis identified that the core areas of abnormal activity lie in the middle temporal gyrus (MTG), formal cortex, parahippocampus, insula, cerebellum, cuneus and thalamus. Notably none of these areas are part of the auditory cortex. It is unclear whether these findings are a cause or effect of tinnitus.

6.2 Sound therapy

Sound therapy is the preferred mode of audiological tinnitus management in many countries including in the UK (Hobson et al., 2012). Sound-based therapy usually involves electronic devices which are used to produce sounds for therapeutic use. Historically, sound was used to mask tinnitus, i.e. reduce tinnitus loudness or make tinnitus inaudible (Hoare et al., 2014a). However, current views on sound therapy acknowledge that masking is only one of the goals of sound therapy. Suggested benefits of sound-based interventions include making tinnitus less audible (masking, reducing contrast between external environment and tinnitus), providing distraction from tinnitus, promoting relaxation, providing 'sound enrichment', and triggering neuroplastic changes within the brain (Henry et al., 2008; Newman & Sandridge, 2012). The above can be achieved without achieving complete or even partial masking of tinnitus. Henry et al. (2004, 2008) applied the definition of tinnitus relief as a reduction in annoyance caused by tinnitus, regardless of the mechanism by which it was achieved (masking, partial masking or not masking the tinnitus). However, even sounds that do not mask tinnitus could provide relief by aiding relaxation (soothing sounds) or providing distraction from tinnitus (interesting sounds) (Henry et al., 2008).

The research evidence underpinning sound therapy is generally of low quality and so sound is recommended as an option for clinicians to consider (Hobson et al., 2012). The authors concluded sound therapy is safe but there is a lack of strong evidence for effectiveness. However, they cautioned that the lack of evidence for effectiveness is not equivalent to evidence of ineffectiveness. One of the reasons for the lack of evidence identified by authors was the application of combined approaches in many of the studies (e.g. Tinnitus Retraining Therapy). There is a rich literature describing the principles of various management programmes such as Tinnitus Retraining Therapy, Tinnitus Masking or Progressive Tinnitus Management and providing guidelines on different aspects of tinnitus management using sound therapy (Tutaj et al., 2018). Most programmes however, do not specifically recommend the use of a certain type of device but suggest that positive results could be achieved using sound therapy in general, regardless of the mode of delivery. All of the above programmes consist of various components from which each was postulated to play an important role in management of tinnitus. Practices are highly variable however with different management programmes followed by different clinics (Tutaj et al., 2018).

Tunkel et al. (2014) stated that clinicians might recommend sound therapy to patients with persistent, bothersome tinnitus. However, sound therapy was presented only as an option as the strength of evidence for its effectiveness was low. Examples of sound therapy options listed were: i) environmental

enrichment devices (table-top sound machines, CD recordings or personal audio players, table-top water fountains, fans, TV, radio, apps on smartphones or tablets); ii) sound generators including ear-level sound generators that produce broadband noise for patients with normal or near normal thresholds; hearing technology that incorporates wireless, portable, audio-streaming devices that can be connected, via a mini-jack plug or Bluetooth, to a variety of audio sources (e.g. - MP3 player, smartphone, tablet). Tunkel et al. (2014) stated that patients' preferences should play a significant role in deciding whether to pursue sound therapy, and in choosing the particular option.

6.2.1 Sound enrichment

People with tinnitus often describe it as more noticeable or bothersome in a quiet environment, for example at night. Listening to other sounds can make the tinnitus less intrusive (Hobson et al., 2012). Sound enrichment should be used at a level that is a little quieter than the tinnitus sound. Some people have used masking (loud noise which covers the tinnitus) but this does not encourage habituation and the tinnitus can appear loud when the masking is removed. The choice of sound is a personal one. Suitable sounds include natural environment sounds (for example through an open window), recorded natural sounds, noise from a fan, music, radio or white noise. Sound can be delivered through CDs, mp3s, radio, smartphone apps, table-top sound generators, wearable (in-ear) sound generators, or combination hearing aids/sound generators.

6.2.2 Auditory training

Auditory training is postulated to provide a frequency-specific method for inducing neuroplasticity by expanding the cortical representation of the trained frequency, which makes it a potential strategy for management of tinnitus (Hoare et al., 2010). Herraiz et al. (2009) suggested that auditory training with an active listening task might alter the cortical tonotopic map associated with the generation of tinnitus in a way that abnormal representation of particular frequencies will be normalised. A systematic review by Hoare et al. (2010) included ten studies but only one randomised trial. The review concluded low to moderate quality of studies and insufficient evidence to recommend this option for management of tinnitus. Two further randomised controlled trials (RCTs) investigated effects of frequency discrimination training (Hoare et al., 2012, 2014b). Overall reduction in self-reported tinnitus handicap was observed in all groups regardless of the training stimulus used (a pure-tone standard at a frequency within their region of normal hearing, a pure-tone standard within the region of hearing loss or a high-pass harmonic complex tone spanning a region of hearing loss) leading authors to the conclusion that, rather than introducing alterations to cortical tonotopic map, auditory training might impact on a contributory mechanism such as selective attention or emotional state.

6.2.3 Acoustic Coordinated Reset Neuromodulation

Acoustic CR neuromodulation is a patterned stimulation where sequences of tones are used to target pathological neural synchrony associated with tinnitus (Hauptmann & Tass, 2007). Sound stimuli used are individualised and adjusted to patient's tinnitus pitch in a way that they constitute different frequencies around the dominant tinnitus pitch. In their review Wegger et al. (2017) provided a systematic overview of studies of acoustic CR neuromodulation as a treatment method for subjective tinnitus. In total eight publications were eligible for the review including 329 patients. The review concluded there was a low level of evidence, and questioned the postulated mechanism of the intervention. It concludes that further studies are needed before this method can be recommended for treatment of tinnitus.

6.2.4 Sound generating devices

This category includes ear-level devices, bedside or tabletop devices or even mobile applications. Sereda et al. (2018) concluded little current evidence for effectiveness of sound generators. Recent tinnitus management guidelines did not make any recommendations regarding use of sound generating devices for tinnitus management (Cima et al., 2019; NICE 2020). Tunkel et al. (2014) stated that patients' preferences should play a significant role in deciding which option should be chosen. Recommendations regarding choice of sounds or level of sound that should be used vary across the literature and often strongly depend on the management programme followed. E.g., Tinnitus Masking (TM) permits the use of any sound that provides maximum masking benefit (Henry et al., 2002). Therefore, the choice of sound is based on combination of effectiveness and acceptability for the patient. On the other hand, Tinnitus Retraining Therapy (TRT) recommends the use of broadband noise to be adjusted to a 'mixing' or 'blending' point (Jastreboff, 2007; Korres et al., 2010), or below that level (Jastreboff & Jastreboff, 2006) to allow for habituation.

The use of sound in Progressive Tinnitus Management (PTM) is flexible to address individual preferences and needs. Management plans are individualised (Henry et al., 2008). The PTM proposes a different role for different types of sounds including (1) soothing sounds (to produce sense of relief from tinnitus-associated stress), (2) background sound (passively diverting attention from tinnitus by reducing contrast between environment and tinnitus), and (3) interesting sounds (actively diverting attention away from tinnitus).

6.2.5 Hearing aids for tinnitus and hearing loss

The primary purpose of fitting a hearing aid is to reduce hearing difficulties and improve communication and there is evidence that hearing aids are effective at improving hearing-specific health-related quality of life, general health-related quality of life and listening ability (Ferguson et al., 2017). Although hearing aids are prescribed primarily to overcome hearing loss, they may also be effective for tinnitus. Hearing aids can amplify environmental sounds and mask or provide distraction from tinnitus. They can reduce listening effort and improve communication which can reduce stress and anxiety, commonly associated

with tinnitus (Surr et al., 1985; Carmen & Uram, 2002; Dillon 2012). Other possible mechanisms include physiological effect on tinnitus-related brain activity, by 'recalibrating central gain' (Schaette & Kempter, 2006; Schaette et al., 2010) or preventing maladaptive plastic changes in the brain related to hearing loss (Willott, 1996; Noreña, 2011).

Tinnitus guidelines across Europe recommend the use of hearing aids for people who have tinnitus and hearing loss (Fuller et al., 2017; Cima et al. 2020). Recent NICE guidelines for tinnitus assessment and management (NICE, 2020) provide different recommendations depending whether patients have tinnitus as well as communication difficulties. For patients with tinnitus and hearing loss who have communication difficulties the NICE guideline recommends fitting of hearing aids, however for patients with tinnitus and hearing loss who do not have communication difficulties hearing aids are presented as an option and decision left to individual clinical judgement. However, there are no further details what circumstances should be taken into consideration when making that decision and for which patients in that group hearing aids might be considered an option. Fitting of hearing aids for patients with tinnitus but no hearing loss is not recommended (NICE, 2020).

There is no robust evidence that shows that hearing aids are effective for the management of tinnitus. The Cochrane systematic review of sound therapy for tinnitus (Sereda et al., 2018) did not identify any randomised trials comparing hearing aids to waiting list control group, placebo or education/information only. The review included one randomised trial with 91 participants comparing hearing aid use to sound generator use (Parazzini et al., 2011). Several randomised controlled trials compared different types of amplification devices. Henry et al. (2017) compared conventional hearing aids with extended wear hearing aids. Three studies compared hearing aids (amplification only) with combination aids (Dos Santos et al., 2014; Henry et al., 2015; Henry et al., 2017); both groups received amplification. All studies concluded some benefit for tinnitus regardless of the device used. The Cochrane review of sound therapy for tinnitus (Sereda et al., 2018) concluded a lack of evidence for superiority of hearing aids over sound generators alone or combination devices. Within the individual studies all groups tended to improve, but there was no difference between groups in terms of the size of the reduction in self-reported tinnitus handicap. Further trials of effectiveness of hearing aids compared to no intervention, placebo intervention or other intervention not involving amplification are needed. A review by Hesse (2016) included lower level evidence but reported inconclusive and often contradictory evidence.

Despite inconclusive research evidence clinicians generally support the use of hearing aids especially when the patient reports hearing difficulties and has realistic expectations of the technology and a bothersome tinnitus (Sereda et al., 2015), but also where there is bothersome tinnitus alone, without reported hearing difficulties. There is also consensus in the clinical community that unilateral fitting of a hearing aid in patients with a bothersome tinnitus is not appropriate even if the patient has a unilateral tinnitus or an asymmetric hearing loss. Some authors report a reduction in tinnitus distress with both

unilateral and bilateral hearing aids regardless of the laterality of tinnitus (Brooks & Bulmer, 1981; Trotter & Donaldson, 2008). Other authors postulated that in the case of a unilateral hearing loss and tinnitus fitting the impaired ear is sufficient, whereas individuals with bilateral complaints require bilateral fitting (Melin et al., 1987; Zagólski, 2006). However, the efficacy of hearing aid fitting for tinnitus rather than the laterality of the fitting was the primary question and none of the studies to date offers high quality evidence for or against (Hoare et al. 2014c). There is no agreement in the literature regarding bilateral fitting of hearing aids for tinnitus. For example, Del Bo & Ambrosetti (2007) suggest that the best clinical result for someone with tinnitus requires bilateral rather than unilateral amplification. Trotter & Donaldson (2008), however, in describing a 25-year experience of hearing aids in tinnitus therapy, found no difference in tinnitus improvement between unilaterally and bilaterally aided patients.

6.2.6 Combination devices (i.e. combined amplification and sound generators)

Combination hearing aids combine amplification with a sound generation option within one device, and new generations of such devices offer the same quality of amplification as 'standard' hearing aids (Henry et al., 2004). Recent developments in technology have given rise to manufacturers incorporating a wireless streaming option into their devices, which allows any sound that might be beneficial in managing patients' tinnitus to be streamed into their hearing aids. Current combination aids offer different noise options (Hoare et al., 2013; Hoare et al. 2014a). Broadband noise (such as white, pink, red or brown) seems to be a standard option on most of the available devices. In addition, options for modulating or filtering broadband noise are available. Additional options available include noise shaped according to patients' audiogram, noise centred either at or away from the tinnitus frequency, or nature sounds (e.g. ocean sound).

The Cochrane review of sound therapy for tinnitus (Sereda et al., 2018) included four trials of combination devices, and concluded there was no evidence of superiority of combination devices over hearing aids. Within the individual studies all groups tended to improve, but there was no difference between groups in terms of the size of the reduction in self-reported tinnitus handicap. Further trials of effectiveness of hearing aids compared to no intervention, placebo intervention or other intervention not involving amplification are needed. Current tinnitus management guidelines do not make any specific recommendations regarding the use of combination devices for management of tinnitus (Cima et al., 2019; NICE 2020).

It is worth noting that wireless streaming is available with many combination devices, mainly through purchasing an additional device streamer (Tutaj et al., 2018). Wireless streaming options include music, environmental sounds, or even individually modified sounds (Piskosz, 2012; Piskosz & Dyrlund 2015; Powers & dos Santos 2015). Despite this availability there is limited number of studies looking at effectiveness of different noise options in combination hearing aids. Barozzi et al. (2016) compared the efficacy of 'nature' and 'technical sounds' for tinnitus. Nature sounds were streamed wirelessly to

participants' hearing aids, while 'technical sound' was a conventional broadband noise available on commercially available combination aids. Authors concluded that both approaches were effective in improving patients' coping with tinnitus. Searchfield et al. (2016) compared customised spatial (3D) masking (novel approach) to conventional bilateral masking. Spatial masking allowed presentation of masking at the same location in a 3D auditory space as tinnitus.

6.2.7 Cochlear implants

Cochlear implants are offered to people with profound hearing loss to improve hearing, therefore controlled studies on CIs for tinnitus alone without hearing loss do not exist (Zenner et al., 2017). Zenner et al. (2017) reviewed all studies investigating effectiveness of CIs for tinnitus and concluded that as long as hearing loss warranting cochlear implantation is present, presence of tinnitus might reinforce the indication for a CI. However, authors stated that deafness or hearing loss bordering on deafness need to be present as the main indication. Whilst cochlear implantation would not be recommended for tinnitus suppression alone (Cima et al., 2019), studies have shown an improvement in tinnitus awareness in the implanted ear when the cochlear implant is worn and turned on (Kompis et al., 2012; Kim et al., 2013; Kloostra et al., 2015). One study cited a decrease in tinnitus levels even when the cochlear implant was not worn (Demajumdar et al., 1999). Tinnitus suppression with bimodal hearing i.e. cochlear implant in one ear and a hearing aid in the contralateral ear has also been shown (Servais et al., 2017).

6.3 Neuromodulation treatments

Neurostimulation therapies aim to interfere on some level with abnormal neural activity and drive neuroplastic changes (Arle, 2011). Those interventions use electromagnetic, electrical, or acoustic stimulation to reverse abnormal activity associated with tinnitus and restore typical levels of activity. Another approach is pairing electrical and acoustic stimuli. This in theory should lead to a permanent reduction in tinnitus percept. Neuromodulation therapies should therefore result in changes in oscillatory activity in the brain. However, exactly what neurophysiological change would lead to reduction of tinnitus percept is not clear (Hoare et al., 2016). NICE guidelines did not make any recommendations regarding neuromodulation for tinnitus and made research recommendations to investigate clinical, cost effectiveness and safety of neuromodulation interventions for treating tinnitus in adults (NICE 2020).

6.3.1 Transcranial Magnetic Stimulation (TMS)

TMS is a non-invasive method of inducing electrical currents in the brain but the precise mechanism as a treatment for tinnitus is still poorly understood (Meng et al., 2011). The Cochrane review of repetitive TMS included five trials with 233 participants describing different devices delivering different waveforms at different frequencies (Meng et al., 2011). Authors concluded very limited support for the use of low-frequency rTMS for the treatment of patients with tinnitus. Short term safety was demonstrated in the

studies, however no data were available on the long term safety of rTMS. It is worth noting that based on the above evidence the European tinnitus guideline recommends against use of TMS for treatment of tinnitus (Cima et al., 2019).

6.3.2 Transcranial Alternating Current Stimulation (tACS)

tACS involves the delivery of alternating current (constant polarity changes) between electrodes placed on the skin over the cortex. It is hypothesised to affect upregulation and downregulation of synapses and may have an effect on oscillatory cortical activity, indicating it for tinnitus (Ironside & Walsh, 2013). Studies to date have failed to show positive effects of tACS for tinnitus (Vanneste et al., 2013, 2013a).

6.3.3. Transcranial direct current stimulation (tDCS)

tDCS delivers low direct currents (0.5–2mA) via scalp electrodes to the cerebral cortex that result in the modulation of cortical excitability for variable periods of time (Shekhawat et al., 2015). A systematic review by Song et al. (2012) identified only two randomised trials investigating effectiveness of tDCS and concluded that efficacy of tDCS in tinnitus could not be fully confirmed. Authors stated however, that both studies seemed to lead to improvement in tinnitus intensity. tDCS therefore holds promise and should be trialled further.

6.3.4 Transcutaneous electrical stimulation (TENS)

Lee et al. (2014) investigated effectiveness of transcutaneous electrical nerve stimulation (TENS) applied to the external pinna in 65 participants with moderate severity tinnitus and comparing it to the sham stimulation. Only two participants had a long-term improvement after treatment with TENS.

6.3.5 Vagus nerve stimulation (VNS)

This method pairs the electrical stimulation of the vagus nerve either through implanted electrode (VNS) or transcutaneous (tVNS) with acoustic stimulation (Hoare et al., 2016). Efficacy of VNS and tVNS have been assessed in individual pilot studies which do not allow for definitive conclusions to be made (Hoare et al., 2016; Zenner et al., 2017). Those methods are therefore considered experimental (Zenner et al., 2017).

6.3.6 Deep Brain Stimulation (DBS)

DBS involves the implantation of a neurostimulator within the brain to deliver electrical pulses (Hoare et al., 2016). Human studies of DBS are principally aimed at alleviating other coexisting conditions such as Parkinson's disease, tremor. Therefore, the interacting effects of these comorbidities with tinnitus are not known. As there is limited evidence of efficacy of that treatment method for tinnitus, this method is considered experimental (Hoare et al., 2016).

6.4 Drugs

There is currently no Food & Drug Administration or otherwise approved drug for the treatment of tinnitus. Furthermore, the American Academy of Otolaryngology and European guidelines explicitly recommends against the routine prescription of antidepressants, anticonvulsants, anxiolytics, or intratympanic medications where the primary indication is persistent bothersome tinnitus (Tunkel et al., 2014; Cima et al., 2019). The search for an effective drug specifically for tinnitus has to date been unsuccessful. Part of the problem is our limited understanding of the fundamental neurophysiology of tinnitus.

For chronic tinnitus many classes of drugs have been used or trialled, including various antiarrhythmics, anticonvulsants, anxiolytics, glutamate receptor antagonists, antidepressants, muscle relaxants, and others (Langguth & Elgoyhen, 2012) with little evidence of benefit over harm (Tunkel et al., 2014). The Cochrane review of antidepressants for tinnitus (Baldo et al., 2012) identified six randomised controlled trials (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) to 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 those studies. Side effects were commonly reported including sedation, sexual dysfunction, and dry mouth. Nonetheless, antidepressants are often successfully applied in the treatment of accompanying depression and anxiety, not for improvement of the tinnitus.

Cochrane review by Wegner and colleagues (2018) concluded absence of evidence to suggest that betahistine had an effect on subjective idiopathic tinnitus when compared to placebo. The evidence also suggested that betahistine was generally well tolerated with a similar risk of adverse effects to placebo treatments. The NICE guideline recommended against the use of betahistine for the treatment of tinnitus (NICE, 2020).

Jufas & Wood (2015) provided a systematic review of benzodiazepines for tinnitus 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 need to be used with caution because of serious side effects. Gabapentin and other GABAergic drugs have also been suggested as a possible drug management for tinnitus. However, a systematic review of the literature found no evidence of effectiveness (Aazh et al, 2011).

Therapeutic approaches such as the intratympanic steroid treatment (such as might be used in acute hearing loss) have no specific effect on tinnitus (Topak et al., 2009). Any increase in tinnitus severity or

distress in chronic tinnitus should be regarded and treated as a fluctuation of chronic tinnitus reaction (Hesse, 2016).

6.5 Cognitive Behavioural Therapy

Cognitive Behavioural Therapy (CBT) approaches share the premise that psychological distress and resulting problems emerge from problems and biases in information processing, emotional reactivity, and behavioural mechanisms people find themselves in. CBT approaches have led to a plethora of evidence-based cognitive behavioural treatments for mental and physical health disorders (Hofmann et al., 2012). CBT 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 better quality of life (Dobson & Dozois, 2010). CBT entails a diversity of both cognitive and behavioural principles and methods, and usually a combination of these are used in therapeutic sessions.

Cognitive behavioural theory and treatment has been applied in tinnitus research for decades and the results on the effectiveness of CBT approaches for tinnitus has been shown to vary in decreasing tinnitus severity/distress, tinnitus related fear, tinnitus-disability, tinnitus related cognitive problems, and improving daily life functioning (Martinez-Devesa et al., 2010; Hesser et al., 2011; Hoare et al., 2011; Cima et al., 2012; McKenna et al., 2017). Two prominent models in the field are the Cognitive Model (McKenna et al., 2014) and the Fear and Avoidance Model (Cima et al., 2018). Both provide a description of the maintenance of tinnitus as a bothersome and distressing problem, and are used to underpin therapeutic approaches.

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 (such as education, counselling, exposure, mindfulness, relaxation, hearing rehabilitation), and tinnitus diagnostics and outcome assessments.

Despite above mentioned limitations and the need to be cautious about the exact effectiveness of CBT for tinnitus in general, at present**,** CBT is the only management approach supported by a high quality clinical trial (Cima et al., 2012). In this large RCT it was found that specialised CBT for tinnitus showed significantly better effects in improving quality of life, decreasing severity of tinnitus and tinnitus-disability, as well as decreasing depressive and anxious symptoms, when compared to general audiological counselling and diagnostics only.

A recent Cochrane review assessed the effects and safety of CBT for tinnitus (including all forms, combinations, and modes of application) (Fuller et al., 2020). Twenty-eight RCTs (2733 participants) were included. The authors concluded that CBT is likely to be effective in improving tinnitus symptom severity. Synthesis of 10 studies comparing no intervention or a waiting list control condition to CBT showed that CBT significantly reduced tinnitus symptom severity. The review also found CBT to be

superior to standard audiological care, tinnitus retraining therapy, and other types of treatment, in reducing tinnitus symptom severity. The evidence regarding improvements in anxiety, depression, and general quality of life was however uncertain or limited. There was also a lack of studies demonstrating long term benefit (6-12 months).

Both European and NICE tinnitus guidelines recommend CBT as a management option for people with tinnitus-related distress (Cima et al., 2019; NICE 2020). NICE guideline recommended a stepped approach with three steps in the following order: 1) digital tinnitus-related cognitive behavioural therapy; 2) group-based tinnitus-related psychological interventions; 3) individual tinnitus-related CBT. Person would move to the next step of the therapy if they did not benefit or declined a previous step.

6.6 Client-centred counselling

Client centred counselling or the 'person centred approach' was developed by Carl Rogers (Rogers, 1951). This unique approach encompasses six core conditions (Rogers, 1957, 1959) the practitioner shows acceptance of the patient/client, valuing their worth as a human via congruence, unconditional positive regard and empathy. The importance of empathy and listening skills should not be underestimated and can be the key to building good patient-clinician relationships by way of offering emotional support. Client centred counselling should involve open ended questions, paraphrasing, reflection on meanings, reflection on feelings, structuring and summarising (Jenkins, 2000). In terms of tinnitus management, client centred counselling can offer a way of promoting patient self-growth and acceptance of tinnitus.

Whilst some authors have recommended the use of client centred counselling in tinnitus management (Tyler et al., 2001), there has been limited research into the effectiveness of this intervention. The limited research which has been conducted reported patients found client centred counselling more effective than CBT, education, sound generators, or hearing aids in helping them manage their tinnitus (Aazh et al., 2016).

6.6.1 Solution-Focused Therapy

The Solution-Focused (SF) approach concentrates on the patient's 'preferred future'. That is, it invites the participants to develop a picture of what life would look like without the problem, i.e., tinnitus or what life would look like *without the tinnitus mattering so much*. Indeed, in some cases patients' spontaneous solutions involve befriending the tinnitus, e.g. as an ever-present companion. It therefore makes various assumptions including that educating the patient in what exacerbates tinnitus (psycho-education) is not always necessary; the patient needs to know more about the solution rather than the problem. Where the subject uses technology, e.g. noise generators, they are tailored to the patient's 'preferred future', to work alongside the patient's expertise.

The focus of SF is on what matters to the patient, appreciation of and working with the patient's strengths, resourcefulness and relevant knowledge (including a knowledge of what help works best for them). Suggestions made to patients are minimal, with the exceptions of an invitation, should the patients find it useful, for them actually to notice what's working well, and do more of it towards the patient's own preferred future. The SF approach shares many qualities with client-centred counselling, CBT, ACT, including an emphasis on building a strong working alliance with the patient, although not necessarily aimed at an acceptance of tinnitus, given that the patient may not want to do that.

SF approaches have been published for many years and there is an emerging evidence base for the use of SF principles in healthcare settings (Zhang et al., 2018). In terms of SF for tinnitus, few studies have yet been published (Bold., 2011; Bray et al., 2014) .

6.7 Self-management

Self-help is a useful strategy for reducing tinnitus related distress in some people (Greenwell et al., 2016). A number of approaches can be used, and an individual with tinnitus may benefit from a tailored and personalised approach.

Information and education: Understanding tinnitus and what influences it can help a person better manage the condition. There is a plethora of information about tinnitus available online, but it can be of variable quality (Greenwell et al., 2016). The British Tinnitus Association, who follow the information standard principles, produces a wide range of accurate and up-to-date information leaflets on tinnitus related topics, which are written by clinicians. They can be obtained from http://www.tinnitus.org.uk or 0800 018 0527.

Online support: E-health projects have been found to be effective in helping to manage other medical conditions. The British Tinnitus Association developed an on-line resource www.takeontinnitus.co.uk which comprises of seven learning modules covering aspects of living well with tinnitus.

Complementary or alternative therapies: A number of complementary therapies have been suggested for treating tinnitus, including acupuncture, osteopathy, reflexology, and Hopi candles. Studies into these treatments tend to be of poor quality, or study designs are so varied as to make definitive conclusions impossible. It is therefore not possible to recommend any complementary therapy as a treatment for tinnitus. Some are associated with risk of harm however, e.g. there is no evidence of effectiveness of Hopi ear candles and good evidence that their use can damage the ears. The American FDA have grave reservations about ear candles and have produced related guidance: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm200277.htm. Interestingly, the Hopi people have distanced themselves from the use of ear candles and have claimed that such devices have never been used by the Hopi tribe. They have requested that such candles should not be attributed to the Hopi people.

Diet: A number of people with tinnitus associate fluctuations in their tinnitus with certain foods or drinks. However, there is no robust evidence to link foods to tinnitus (Nondahl et al., 2010, 2011).

Dietary supplements including ginkgo biloba, melatonin, zinc, and magnesium are not recommended for treating tinnitus. There has been no randomised control trial or systematic review published to date which proves efficacy for any supplement, and some supplements have the potential to cause harm (Coelho et al., 2016, Hilton et al., 2013, Posadzki et al., 2013).

Exercise: Regular exercise helps the body achieve a higher level of well-being (Penedo & Dahn, 2005). Higher levels of physical activity have been associated with lower levels of tinnitus distress (Carpenter-Thompson et al., 2015). Gentle exercise, such as walking or swimming, is recommended.

Relaxation: Tinnitus can seem to be more intrusive when people are stressed and anxious. Reducing these feelings by use of relaxation techniques can also reduce tinnitus distress (McKenna et al., 2010). Relaxation techniques that can be used include progressive muscle relaxation, visualisation, meditation, yoga, tai chi and qigong. Some Audiology departments run relaxation sessions and the British Tinnitus Association produces two information sheets discussing relaxation techniques (available from their website).
Meditation: Mindfulness is a form of meditation that is about learning to pay attention to the present moment, on purpose and non-judgementally. There is a growing body of evidence that mindfulness can lead to improvements in tinnitus severity, psychological distress and disability (McKenna et al., 2017). Mindfulness was also recently incorporated into CBT (McKenna et al., 2017; Fuller et al., 2020). Mindfulness is taught by learning formal meditation practices. The British Tinnitus Association produced an information sheet discussing mindfulness and signposting to additional resources available from their website.

Sleep: Many patients report difficulty in getting to sleep or staying asleep because of tinnitus. People who have tinnitus and who sleep poorly tend to worry more at night than people with tinnitus who sleep well (Crönlein et al., 2016). Sleep is very much a matter of habit and routine, and poor sleep results often results from poor routines. Advice on sleep is readily available – the British Tinnitus Association has a factsheet on tinnitus and sleep disturbance (available from their website). Where available, patients who have pre-existing sleep disorders, or who require formal input for insomnia, can be referred to their local IAPT service for CBT.

Tinnitus support groups: The benefits of peer support for people with tinnitus include development of new coping skills, learning practical problem solving, learning to relax and manage stress, increased feelings of control and confidence, and gaining inspiration and support from others. The British Tinnitus

Association facilitates a network of independent tinnitus support groups around the UK. Information on local groups can be found at https://www.tinnitus.org.uk/find-a-support-group.
For those unable or unwilling to attend groups in person, online forums can provide an alternative. These share many of the benefits, such as sharing experiences and providing emotional support. However, there is a risk of misleading information being provided, and forums should be appropriately moderated (Ainscough et al., 2018).

6.8 Management in populations with additional needs

Populations with additional needs which may be encountered include those with poor literacy, people who cannot understand English, poor understanding or memory retention, adults with learning disabilities, people with post-traumatic stress, veterans, and prison populations. When working with special populations the clinicians should ascertain at a minimum

- Presence of tinnitus (accepting that some patients may have difficulty expressing distress/ annoyance)
- Other signs of tinnitus distress
- Modified diagnostic tests in accordance with BSA recommended procedures
- Proficient interpreters
- Modifying explanations, advice and information giving

Where the patient is considered ready then clinicians should recommend or advocate self-help materials and at the same time make them easy to use and convenient to the patient. Clinicians need to be aware of and explore what is available e.g. BTA information leaflets are available in easy read, large print and audio format. Action on Hearing Loss also offer factsheets in large print, Braille, and audio format. The 'Steps for Stress' booklet and some online resources are also available in popular languages e.g. Cantonese, Polish, and Urdu. (http://www.stepsforstress.org/templates/Inner/order-booklet.php).

Veterans are 3.5 times more likely than the general population to suffer from hearing loss (The Royal British Legion, 2014), and likely tinnitus also. Veterans are more likely to experience related social and psychological conditions, for example anxiety and depression, prior to experiencing tinnitus. They may therefore require specialised support in learning how to manage their tinnitus (Burns-O'Connel et al., 2019). For example, specific support groups aimed at ex-Service personnel may be more accommodating for veterans so their shared understanding of past occupational experiences may be appreciated and help to achieve effective support group outcomes. Like other people who experience mental health issues, veterans may find group support intimidating and may prefer to be offered online or one-to-one support.

The evidence for hearing loss prevalence in prisons is scant and for tinnitus even less. What little research there is indicates a higher prevalence of hearing loss in the prison population than in the

general population. This would suggest that tinnitus might also have a greater prevalence in the prison population than the general population. The plight of the inmate may well contribute to the tinnitus distress, in particular the long hours in a cell with little else to focus on and increased levels of anxiety from having to cope within a prison system. Cognitive behavioural therapy, mindfulness and relaxation exercises may be additionally beneficial for this group. This is an area which requires further research.

7. Individual management plan and follow-up

A tinnitus individual management plan (TIMP) is the jointly agreed strategy between the clinician and the patient at the end of the initial assessment which the patient can follow with the aim of reducing the impact of their tinnitus. It will be formed by prioritising those activities which, jointly agreed, will have the best impact on the tinnitus for the patient. The strategy should be documented, taken away (with complementary information) by the patient and brought back to the review appointment. Often a standardised template may be used to easily create a TIMP with pertinent areas to each particular patient highlighted.

It is recommended that complementary information supplied is of a standardised nature and assessed for ease of understanding. The British Tinnitus Association has a wide variety of these information documents available on their website (https://www.tinnitus.org.uk/) which are of high quality and freely available to download. Links to other web based information are also valuable (http://www.tinnituskit.com/ and https://www.actiononhearingloss.org.uk/).

Information and contact details of any local self-help or support groups should be included in the TIMP.

The TIMP should contain the clinic's contact information for the patient to arrange or rearrange appointments and seek advice when required. It should also show the time and date of the review or follow up appointment. Advice may also be sought from other tinnitus support Freephone telephone lines e.g. The British Tinnitus Associations Helpline 0800 0180527 or Action on Hearing Loss's Tinnitus Helpline 0808 8086666.

If a patient has been referred to an ENT consultant the TIMP should also explain why this is and contain information to reduce any anxiety regarding the referral. At the review or follow-up appointment the TIMP should be discussed with regards to how the patient has been able to implement the strategy outlined in the document, any benefits of doing so, and to update with further suggestions if required.

8. Measuring outcome

Given the move towards evidence-based commissioning, and to demonstrate the effectiveness of tinnitus management within clinical practice, it is essential to use a tinnitus-specific questionnaire that has been developed and validated to measure changes in tinnitus severity over time. The changes in tinnitus severity pre- and post-treatment should be evaluated for each patient using at least one tinnitus-specific questionnaire as a primary outcome. Tinnitus questionnaires are often used as outcome measures for detecting change in tinnitus severity after an intervention (Kamalskiet al., 2010; Newman et al., 2014). Questionnaires need the ability to detect small changes that truly reflect changes in tinnitus severity, not measurement error. Additionally, clinically meaningful interpretations of those changes in scores should be used in order to confidently show that the observed change corresponds to changes in patient experience of their tinnitus (Jaeschke et al., 1989; Terluin et al., 2009; De Vet et al., 2011). For example, a detectable change in TFI score is possible without any corresponding change in the patient experience of their tinnitus; the patient may not feel better.

Only the THQ and TFI were specifically designed to measure outcomes using fine-grained interval measurement units. Although the TRQ was proposed as an outcome measure, there is a lack of evidence demonstrating the psychometric adequacy for quantifying clinically significant change following tinnitus intervention. Hence, the Tinnitus Functional Index is recommended for measuring outcome.

8.1 Tinnitus Functional Index

The TFI uses a fine-grained 0 to 10 response scale for each item, therefore designed to capture small changes in tinnitus impact over time (Meikle et al., 2012). The UK evaluation of the TFI in clinical practice and research has shown that the TFI and subscales has excellent ability to reliably measure changes in tinnitus impact over short (1-2 weeks) and long (3, 6, 9 months) time periods (Fackrell et al., 2016; 2016a). The TFI is responsive to changes in tinnitus impact above measurement error. Meikle et al. (2012) proposed that a 13-point difference between pre- and post-intervention TFI scores would reflect true change in tinnitus impact. For the UK, based on patient experience of perceived change in their tinnitus and statistical properties of the scores, a minimal important change of ≥18 points in the total TFI scores between pre- and post-intervention is recommended for use (Fackrell et al., 2016).

Secondary outcomes may include questionnaire measures of generalised depression and anxiety. The most common general questionnaire used in tinnitus services in the UK as an outcome measure was the HADS (Hoare et al., 2015). Additionally, in their review of questionnaires for assessing outcomes,

Newman et al (2014) highlighted a number of secondary measures including HADS. Although HADS uses a course-grained response scale, it has been shown to be reliable at measuring changes in cognitive and emotional symptoms associated with depression and anxiety (Andersson et al., 2003; Snaith & Zigmond, 1994; Zöger et al., 2004).

9. Feedback to referrer

Effective and timely communication is crucial in healthcare and clinical letters are the mainstay for communication between referrers (usually from primary care) and hospital colleagues. NHS England Commissioning for Quality and Innovation national goals include targets for the completion of out-patient clinical letters sent to GPs (usually 95% within 14 days). This communication is a vital source of information to both referrers and patients, and it can also be used to promote the services available and to evidence the individual outcomes of patients. There is evidence that patients' memory for medical information following consultations is poor and this may lead to poor adherence to management plans (Kessels, 2003). The NHS Plan (2000) set out a vision of reform which included "letters about an individual patient's care will be copied to the patient". In reality an opt-in process of obtaining copies of clinical letters is typical in many National Health Service trusts.

Guidance for the implementation of the clinical record headings in electronic out-patient letters is available from the Professional Record Standards Body (https://theprsb.org/wp-content/uploads/2018/02/Outpatient-Letter-Standards-Final-Report-Draft-2.1-FINAL.pdf)
. A number of fields are identified:

- Mandatory e.g. demographics, attendance details, adverse reactions, clinical summary, name and title of person completing the record, etc.
- Required e.g. history, procedures, diagnosis, plan and actions, information and advice given, medications and medical devices, etc.

Optional e.g. social context, assessment scales, family history, patient and carer wishes, etc.

10. Developing the service

10.1 Tinnitus workforce development

Formal training in the UK for the management of tinnitus has reduced since the reduction of the hearing therapy training courses and implementation of the BSc in Audiology. Appropriate training is therefore often sought once the individual is employed in a healthcare setting. It is recommended that appropriate training be undertaken in line with the services available at the point of care. For instance, if a service delivers Mindfulness Based Cognitive Therapy (MBCT), the professional delivering the course

should complete the recognised training for that modality. Where no formal training exists, the BSA encourages professionals to use alternative resources such as the British Tinnitus Association, which provide a range of training opportunities, or to contact colleagues who are experienced in managing tinnitus to seek advice pertaining to relevant training within their service. Attendance at a recognised tinnitus course is recommended. The use of ongoing peer review, clinical supervision and regional tinnitus networks is also recommended. Healthcare professionals should work within their scope of practice and also continue to develop their scope of practice via accredited routes as appropriate.

10.2 Continuing Professional Development (CPD)

In line with the recommendations of the HCPC and RCCP, CPD is recommended to ensure professional skills and knowledge are up to date. CPD for audiologists may include a range of activities that should be relevant to the job role.

10.3 Quality Standards

Services should ensure that they continue to provide high quality patient care through a system of ongoing quality management and service improvement. This may be achieved via internal and external peer review and audit processes, e.g. via the Improving Quality in Physiological Services (IQIPS) assessment and accreditation scheme. Adherence to national and country-specific audiology quality standards and commissioning frameworks should further ensure high quality patient care.

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12. APPENDIX 1. AGREE II tool domains

1. Scope and Purpose

A clear description of the population (i.e., patients, public, etc.) covered by a guideline should be provided. The age range, sex, clinical description, and comorbidity may be provided

To adhere to the highest standard in methodological rigour and transparency we looked to the

2. Stakeholder involvement

The guideline development group includes individuals from relevant professional groups. The views and preferences of the target population (clinicians, patients, etc.) have been sought. The target users of the guideline are clearly defined.

3. Rigour of development

Systematic methods were used to search for evidence.
The criteria for selecting the evidence are clearly described.
The strengths and limitations of the body of evidence are clearly described.
The methods for formulating the recommendations are clearly described.
The health benefits, side effects, and risks have been considered in formulating the recommendations.
There is an explicit link between the recommendations and the supporting evidence.
The guideline has been externally reviewed by experts prior to its publication.
A procedure for updating the guideline is provided.

4. Clarity of presentation

The recommendations are specific and unambiguous.
The different options for management of the condition or health issue are clearly presented.
Key recommendations are easily identifiable.

5. Applicability

The guideline describes facilitators and barriers to its application.
The guideline provides advice and/or tools on how the recommendations can be put into practice.
The potential resource implications of applying the recommendations have been considered.
The guideline presents monitoring and/or auditing criteria.

6. Editorial independence

The views of the funding body have not influenced the content of the guideline.
Competing interests of guideline development group members have been recorded and addressed.

13. APPENDIX 2. Detailed description of questionnaires used for tinnitus assessment

13.1 Tinnitus Handicap Questionnaire (THQ)

The THQ was developed to comprehensively measure a patient's tinnitus handicap in particular the effects of tinnitus on hearing and communication, physical health, social and emotional status and to be sensitive to the changes in handicap over time (Kuk et al., 1990). For each of the 27 items, patients indicate their agreement by assigning a number between 0 (strongly disagree) to 100 (strongly agree). The overall score reflects the sum of all responses, averaged to give a score out of 100. Higher scores again indicate higher levels of tinnitus handicap. Kuk et al. (1990) originally proposed a three-factor structure but the 4-items measuring "individual perception of tinnitus" (factor 3) were found to be unreliable. As a consequence, two subscales ("physical, emotional and social effects" and "hearing and communication ability") were considered reliable enough to calculate individually, although this structure has been questioned and has not been confirmed (Kennedy et al., 2004; Fackrell et al., 2014). The THQ does show high reliability to distinguish individual differences in tinnitus handicap (Newman et al., 1995). Although the THQ has provided normative data, which is helpful in determining individual severity relative to others, it does not provide clinical interpretations of the scores. There is no grading system to provide clinical meaning to the scores.

13.2 Tinnitus Reaction Questionnaire (TRQ)

The 26-item TRQ uniquely is the only questionnaire listed here that was specifically designed to measure an individual component of tinnitus severity; psychological distress related to tinnitus (Wilson et al., 1991). Primarily developed to be an assessment of the effects of psychological interventions on tinnitus (treatment-related change), but is also used to distinguish between the levels of tinnitus-related distress. For each item, ratings are made on a categorical 5-point scale with the anchors from: not at all (0) to almost all of the time (4). The total score ranges from 0 to 104, with a higher score denoting higher levels of distress. It is unclear whether there are any valid subscales. Both a four factor and two factor structure have been proposed, but neither have been fully confirmed and as such only overall score is recommended for use. The TRQ has been shown to have high reliability to distinguish individual levels of tinnitus-related distress from psychological distress (Wilson et al., 1991; Robinson et al., 2003), although it has been suggested that it is measuring generalised distress above tinnitus-related distress (Fackrell et al., 2014). Again, there is no evidence of a grading system for categorising tinnitus severity being developed.

13.3 Tinnitus Questionnaire (TQ)

The longest questionnaire identified, the TQ is a 52-item questionnaire that was designed to be a diagnostic measure of tinnitus severity, in particular general and specific tinnitus complaints (Hallam, 1996; 2008). Patients rate each item using a categorical three-point response scale; not true (0), partly true (1) and true (2). To calculate the total score, only 41 of the items are summed so that the total score ranges from 0 –82, with higher scores indicating increased tinnitus distress. The TQ has five subscales reflecting emotional distress, intrusiveness, sleep disturbance, auditory difficulties and somatic complaints. The TQ has been adopted by Germany, and as such the majority of the reliability and validity assessments, including the development of the mini-TQ (12-item), have been conducted in German clinical populations (GHTQ; Hiller & Goebel, 2004; Goebel & Hiller, 1994). That said, the 52-item TQ and its subscales were shown to reliably measure tinnitus severity and individual differences in the degree of tinnitus severity in a UK population. The grading system was developed in Germany based on the statistical properties of the scores. Patient experience was potentially overlooked during the development of the grading system.

13.4 Tinnitus Severity Index (TSI)

The TSI was specifically designed to measure the negative impact of tinnitus on a patient's life, in particular the effects on work, social activities and overall quality of life (Meikle et al., 1995). For each of the 12 items, patients indicate the level of agreement using one of five response options; Never (0), Rarely (1), Sometimes (2), Usually (3), and Always (4). The total score ranges from 0 to 48, with a higher score indicating higher impact. Although there is some evidence to suggest that the TSI has high reliability (Kamalski et al., 2010; Newman et al., 2014), the evidence for diagnostic ability is limited, in particular the reliability of the construct has not been fully assessed and no interpretability of the scores have been provided.

13.5 Hospital Anxiety and Depression Scale (HADS)

The 14-item HADS provides a brief measure of generalized symptoms of anxiety (7 items) and depression (7 items), such as cognitive and emotional aspects. Each item is scored using a 0–3 Likert scale with descriptors. The total score is calculated by summing all 14 items with scores ranging from 0 to 42. Each subscale can be scored by summing the 7 items, with scores ranging from 0 to 21. Higher scores indicate greater severity, with recommended interpretations of the scores as follows: 0 –7 normal, 8 –10 mild, 11–15 moderate, and ≥16 severe (Snaith & Zigmond, 1994). If more than one item is missing a score then it is recommended to not calculate the total subscale score (Smarr & Keefer, 2011). For tinnitus, HADs has been shown to reliably detect individual differences in depression and anxiety in a

clinical tinnitus population (Zöger et al., 2004), and via internet-administration (Andersson et al., 2003). For screening for anxiety and depression symptoms in a tinnitus population, Zöger et al. (2004) recommended the optimal cut-off score for each subscale was ≥5.

13.6 Clinical Outcomes in Routine Evaluation (CORE-OM)

The CORE-OM is a 34-item self-report measure of psychological distress (Evans et al., 2000). Patients are asked to respond to questions about their emotions and actions during the previous week on a 5-point Likert scale (from 'not at all' to 'most of or all the time.') There are a mix of positive and negative items (positive items are reverse-scored) and the total score ranges from 0-136. A cut-off score of 34 has been suggested as the minimum indicator of mild psychological distress within the clinical range. Handscomb et al (2016) validated the CORE-Om with a tinnitus population and recommend its use in tinnitus clinics.

13.7 Generalised Anxiety Disorder brief measure

The Generalised Anxiety Disorder brief measure-7 (GAD-2) consists of two items that represemt core anxiety symptoms and as such can be can be used as a screen for anxiety (Kroenke et al., 2007). Patients are asked to state how much in last two weeks they have been bothered by feeling nervous, anxious or on edge and not being able to stop or control worrying on a four-point likert scale f(rom 'not at all' to 'nearly everyday'). Scores on the GAD-2 scale range from 0 to 6, with higher scores indicating more anxiety. According to the NICE common mental health guidance, if a person scores 3 or more then consider further assessment and referal to an appropriate healthcare professional (NICE Common mental health guidance, 2011).

13.8 Two identification questions on depression

The NICE common mental health guidance recommends asking the following two questions if you suspect a person is feeling depressed (NICE Common mental health guidance, 2011; Mann & Gilbody, 2011):

- 'During the last month, have you often been bothered by feeling down, depressed or hopeless?'
- 'During the last month, have you often been bothered by having little interest or pleasure in doing things?

Each question simply elicits a yes or no answer and if a person answers 'yes' to either of these questions further assessment for depression should be considered. This includes refer the person to an appropriate healthcare professional. These questions should not be confused with the Patient Health Questionnaire depression scale (PHQ-2; Kroenke et al., 2003). Although the PHQ-2 consists of the same two questions, the PHQ-2 responses are scored according to a 4 point Likert scale not yes/no and the recall of symptoms is framed over the previous two weeks not a month (Kroenke et al., 2003; Mann & Gilbody, 2011). Clinicians should be aware that the NICE guidance recommends the above two questions with yes/no responses (NICE Common mental health guidance, 2011).

13.9 Insomnia Severity Index

The Insomnia Severity Index (ISI) is a seven-item questionnaire assessing the nature, severity, and impact of insomnia over the previous month (Bastien et al., 2001) including severity of problems with sleep onset, sleep maintenance, early morning awakening, sleep dissatisfaction, interference of sleep difficulties with daytime functioning, noticeability of sleep problems by others, and distress caused by the sleep difficulties. Each item is scored on a five-point Likert scale where 0 = no problem; 4 = very severe problem. The total score ranges from 0 to 28 and is interpreted as absence of insomnia (score 0–7); sub-threshold insomnia (score 8–14); moderate insomnia (score 15–21); or severe insomnia (score 22–28). A 6-point reduction is recommended to represent a clinically meaningful improvement (Yang et al., 2009). Three versions of the ISI are available to be completed by patient, clinician, and significant others. The ISI has demonstrated adequate psychometric properties (Blais et al., 1997)