National Institute for Health and Care Excellence

Draft for consultation

Tinnitus: assessment and management

Assessing psychological impact

NICE guideline

Intervention evidence review

September 2019

Draft for Consultation

This evidence review was developed by the National Guideline Centre

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and, where appropriate, their carer or guardian.

Local commissioners and providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

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1.1 Review question: What is the most clinically and cost-effective method of assessing the psychological impact of tinnitus?

1.2 Introduction

Tinnitus may impact on a person in a number of ways. The psychological impact is commonly the most obvious and the most profound. Changes in emotional state, including deterioration in mood, catastrophic thinking and avoidance behaviour are common. Children and young people may also describe distress; however, observations by others of changes in their emotional wellbeing and/ or behaviour are also important. A high proportion of people attending tinnitus clinics experience a sufficient degree of distress to merit a formal psychiatric diagnosis and health care professionals should be aware of this possibility in their assessment. Formal diagnosis is, however, rarely made.

Sleeping disturbance in the form of insomnia is one of the most common complaints among people attending tinnitus clinics; the process is thought to be the same as in insomnia in other contexts with psychological factors being the dominant influences in bringing about and maintaining the problem. Many people with tinnitus also complain of difficulties in concentration and listening difficulties. There can therefore be an impact on daily activities, both in terms of achievement and enjoyment.

Assessment of psychological impact is often carried out by clinical interview, discussion and with questionnaire measures of emotional state. Some questionnaires focus on anxiety symptoms, others on depression symptoms and some have a pan-diagnostic perspective. The content of the assessment will vary between professionals, for example by a GP, audiologist or clinical psychologist as appropriate. However, currently there is unnecessary variation across the country in the assessment of the psychological impact of tinnitus.

The aim of the review question is to determine the most clinically and cost-effective method of assessing the psychological impact of tinnitus. These assessments would be followed up by appropriate interventions for tinnitus and the resulting patient outcomes assessed.

1.3 PICO table

For full details see the review protocol in appendix A.

Table 1: PICO characteristics of review question

Population	People presenting to a healthcare setting with tinnitus Strata: Children/young people (up to 18 years) and adults
Intervention(s)	Questionnaires/interviews, e.g.: Adults • GAD7 • PHQ9 • CORE-OM • Tinnitus questionnaire (TQ and mini TQ) • Insomnia Severity Index

	• Tinnitus Handicap Inventory • Tinnitus Functional Index (TFI) • Fear of Tinnitus Questionnaire • Psychological Impact of Tinnitus Interview • Chronic Tinnitus Acceptance Questionnaire • Pittsburgh sleep quality index • Beck • HADS • Visual Analogue Scale • Interview Children • Paediatric Index of Emotional Distress Questionnaire (PI-ED 2010) • Revised Children's Anxiety and Depression Scale (RCADS) • The Mood and Feelings Questionnaire (MFQ) • Young Person's CORE-OM • The Children's Global Assessment Scale (CGAS) • BECK Youth inventories for children and adolescents • SDQ (parents and children's versions) • Mini-TQ for adolescents (qualitatively) • Goal-based measures • Visual Analogue Scale • Likert scales • Interview
Comparison(s)	• Compared to each other • Compared to no psychological assessment • General tinnitus questionnaire compared to specific psychological questionnaire
Outcomes	• Tinnitus severity (critical) Impact of tinnitus (critical): • Tinnitus distress • Tinnitus annoyance Health related QoL(critical): • QoL (tinnitus) • QoL Tinnitus percept (important): • Tinnitus loudness Other co-occurring complaints (important): • Depression • Anxiety • Anxiety and depression • Sleep Adverse events (important): • Safety

	• Tolerability • Side effects
Study design	• Systematic review of RCTs • RCT • If there is an inadequate amount of RCT data, non-randomised comparative studies will be considered.

1.4 Clinical evidence

1.4.1 Included studies

No relevant randomised controlled trial evidence comparing tinnitus questionnaires with other tinnitus questionnaires or standard care (history and physical examination) were identified. Consequently, non-randomised comparative studies were also assessed. However, no relevant studies were identified for inclusion.

1.4.2 Excluded studies

See the excluded studies list in appendix I.

1.5 Economic evidence

1.5.1 Included studies

No relevant health economic studies were identified.

1.5.2 Excluded studies

No health economic studies that were relevant to this question were excluded due to assessment of limited applicability or methodological limitations.

See also the health economic study selection flow chart in appendix G.

1.6 Evidence statements

1.6.1 Clinical evidence statements

- No relevant published evidence was identified.

1.6.2 Health economic evidence statements

- No relevant economic evaluations were identified.

1.7 The committee's discussion of the evidence

1.7.1 Interpreting the evidence

1.7.1.1 The outcomes that matter most

Tinnitus distress, annoyance and tinnitus severity were critical outcomes as they were thought to be common complaints for those with tinnitus and impact their quality of life.

Quality of life (tinnitus-related) and general quality of life were also critical outcomes due to their impact on the person with tinnitus.

Tinnitus loudness, anxiety, depression, sleep, safety, tolerability and side effects were thought to be important outcomes.

There was no outcome data for any of the outcomes.

The committee did not prioritise diagnostic accuracy outcomes such as sensitivity and specificity because they felt it was more useful to know about the effect on tinnitus outcomes and cost effectiveness of using questionnaires/interviews to assess the psychological impact of tinnitus in the pathway.

1.7.1.2 The quality of the evidence

Randomised controlled trials (RCTs) and systematic reviews of RCTs were searched for and assessed for eligibility but no relevant RCT evidence was identified which matched the review protocol. Consequently, non-randomised comparative studies were also searched for and assessed for eligibility. No relevant non-randomised comparative studies were identified.

1.7.1.3 Benefits and harms

The committee noted that whilst no evidence was identified, the assessment of the psychological impact of tinnitus is a crucial part of the management pathway and therefore consensus recommendations were made. The committee discussed the importance of assessing the psychological impact of tinnitus given that tinnitus can be associated with psychological disorders. All healthcare professionals should 'be alert' to symptoms of negative psychological symptoms at all stages of the clinical pathway. Assessment is usually carried out by discussion and with questionnaire measures of emotional state. The results can inform referrals and management strategies. Onward management may include interventions to help their psychological symptoms as well as how to manage their tinnitus and this can be tailored and informed by appropriate assessment.

The committee discussed that there is currently variation in how the psychological impact of tinnitus is assessed. In the absence of evidence, the committee agreed that the commonly used TQ and mini-TQ are appropriate questionnaires to use for a further assessment of the psychological impact of tinnitus. These questionnaires are primarily focused on assessing tinnitus-related psychological wellbeing.

The committee noted that if depression or anxiety is suspected in people with tinnitus attending healthcare settings, healthcare professionals should have a conversation with individuals about their mood. The NICE guideline on 'Common mental health problems: identification and pathways to care' (CG123) makes recommendations about assessment in adults including the types of questionnaires that can be used. The committee also agreed that the Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM) and other ability-appropriate measures could be used. CORE-OM is particularly useful for assessing the psychological impact of tinnitus where indications of depression and anxiety may be more subtle, but is also currently used in some mental health settings, CORE-OM does not attempt to differentiate anxiety from depression and assesses psychological state across four divisions (wellbeing, problems, functioning and risk).

The guideline committee decided that in the absence of any evidence specifically related to tinnitus that it was appropriate to cross-refer to CG123. The committee agreed that the recommendations in CG123 (with the inclusion of CORE-OM) currently present the best way to assess depression and anxiety in adults in both mental health settings and non-mental health settings. The application of the CG123 recommendations will contribute to the standardisation of clinical practice.

The committee discussed that insomnia is a common problem for people with tinnitus (including children and young people) and can have a significant impact on psychological well-being. 50% to 70% adults attending a hospital tinnitus clinic have insomnia.[5, 10] There is variation in how insomnia is assessed in current practice; the committee agreed that healthcare professionals should be alert to insomnia, asking questions to assess the impact. A questionnaire such as the Insomnia Severity Index (ISI) should be considered. The committee acknowledged that ISI is not commonly used in current practice but it is an appropriate measure that is freely available and easy to use. The ISI can also be used as a screening tool which can lead to a referral.

Additionally, no evidence was identified for questionnaires and interviews to assess psychological impact in children with tinnitus. The emotional, social, behavioural and psychological wellbeing of all children presenting with tinnitus at all stages of the pathway is important to consider. The committee noted that a psychological assessment of children and young people with tinnitus and their parents or carers using various measures (e.g. PIED, SDQ and RCADS) is encouraged in current practice. There is however variation in how this is applied.

All healthcare professionals working within the paediatric tinnitus pathway should be trained to identify symptoms of depression, and to assess children and young people who may be at risk of depression (in line with NG134 1.3.1 and 1.3.2), anxiety, other emotional distress and behavioural problems. As detailed in NG134 1.3.2 they should be trained in communication skills, screening of mood disorders, and have access to specialist supervision and consultation. Assessment discussions should be age appropriate and child-friendly, gathering information from both the young person and parents, and questionnaires specifically designed for use with children should be used as appropriate. They should discuss their assessment findings with the young person and their parents or carers and create a management plan. Professionals working within the paediatric tinnitus pathway should have knowledge of their local children and young people's mental health services and how to make referrals.

The guideline committee emphasised that it is crucial that the results of assessments should be discussed with people with tinnitus and how the findings might help them make informed decisions about their care (as described in the recommendations for tinnitus support (see Evidence review A: tinnitus support). This would enable people with tinnitus to feel fully engaged with their care.

1.7.2 Cost effectiveness and resource use

There were no economic evaluations available for this question. The committee explained that in practice, clinicians will often use the TQ or mini-TQ to assess the psychological impact of tinnitus – this is in addition to the TFI. Similar to the TFI, the TQ or mini-TQ questionnaire does not require additional staff time for questionnaire completion as they are frequently completed outside the consultation room.

Tinnitus can co-exist with anxiety and depression and therefore the committee have recommended that clinicians be alert to these symptoms at all stages of the pathway. Where the anxiety and depression exacerbates the psychological impacts of tinnitus, it is important that it is treated first using the guidelines in CG123, before the person can be provided relevant tinnitus specific interventions listed in this guideline. The committee recommended the use of the questionnaires in CG123 as well as the CORE or an ability appropriate measure to assess anxiety and depression. These questionnaires may be conducted during consultations, and could result in increased expenditure for the NHS, however the population is small and therefore the resource impact is not expected to be significant (less than £1m per annum). Furthermore, a failure to appropriately address anxiety and depression may result in the tinnitus specific interventions having reduced clinical effectiveness as the tinnitus is consistently exacerbated by the anxiety and depression. This could result in tinnitus

interventions to not be cost-effective for this population as the interventions would increase expenditure without sufficiently improving health outcomes.

The committee indicated that there was a subgroup of people who have tinnitus who also suffer from insomnia. When people do report symptoms of insomnia, the committee recommended using the Insomnia Severity Index (ISI). While the use of this questionnaire would be a change to practice, it would not be used in all people with tinnitus and only those who have problems sleeping. Similar to the rationale for treating anxiety and depression, it is important insomnia is treated first to ensure people with tinnitus derive the full benefits of the tinnitus specific interventions.

The recommendation advocating the consideration of the TQ would be cost-neutral and would not result in a change to practice. The use of questionnaires to assess anxiety and depression may result in increased expenditure in the tinnitus population, however it is a recommendation which is consistent with a previous guideline (CG123) and is not expected to exceed the limit for a significant resource impact (£1m per annum). Finally, use of the ISI could result in increased expenditure; however, the resource impact is expected to be a limited as the recommendation only applies to a subgroup of people with tinnitus.

Ensuring that symptoms such as insomnia, anxiety and depression are treated appropriately will ensure the tinnitus pathway is cost-effective because the existence of these symptoms could limit the heath gains (in terms of quality of life) that could be generated by the tinnitus specific interventions.

1.7.3 Other factors the committee took into account

Use of the ISI to assess insomnia will contribute to a change in current practice; this questionnaire is not widely used within the UK for people with tinnitus. The ISI has a cut off point for “clinical insomnia” so should not result in inappropriate referrals.

References

1. Andersson G, Kaldo-Sandstrom V, Strom L, Stromgren T. Internet administration of the Hospital Anxiety and Depression Scale in a sample of tinnitus patients. Journal of Psychosomatic Research. 2003; 55(3):259-262

2. Cho CG, Chi JH, Song JJ, Lee EK, Kim BH. Evaluation of anxiety and depressive levels in tinnitus patients. Korean Journal of Audiology. 2013; 17(2):83-9

3. Henry JL, Kangas M, Wilson PH. Development of the psychological impact of tinnitus interview: A clinician-administered measure of tinnitus-related distress. International Tinnitus Journal. 2001; 7(1):20-26

4. Hiller W, Goebel G. Rapid assessment of tinnitus-related psychological distress using the Mini-TQ. International Journal of Audiology. 2004; 43(10):600-604

5. Marks E, McKenna L, Vogt F. Cognitive behavioural therapy for tinnitus-related insomnia: evaluating a new treatment approach. International Journal of Audiology. 2019; 58(5):311-316

6. National Institute for Health and Care Excellence. Developing NICE guidelines: the manual [Updated October 2018] London. National Institute for Health and Care Excellence, 2014. Available from: https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview

7. Ozcankaya R, Dogru H. Depression and anxiety symptoms in tinnitus patients. Biomedical Research. 2001; 12(3):221-224

8. Rizzardo R, Savastano M, Maron MB, Mangialaio M, Salvadori L. Psychological distress in patients with tinnitus. Journal of Otolaryngology. 1998; 27(1):21-25

9. Robinson SK, McQuaid JR, Viirre ES, Betzig LL, Miller DL, Bailey KA et al. Relationship of tinnitus questionnaires to depressive symptoms, quality of well-being, and internal focus. International Tinnitus Journal. 2003; 9(2):97-103

10. Smith H, Fackrell K, Kennedy V, Barry J, Partridge L, Hoare DJ. A scoping review to catalogue tinnitus problems in children. International Journal of Pediatric Otorhinolaryngology. 2019; 122:141-151

11. Zoger S, Svedlund J, Holgers KM. The Hospital Anxiety and Depression Scale (HAD) as a screening instrument in tinnitus evaluation. International Journal of Audiology. 2004; 43(8):458-464

Appendices

Appendix A: Review protocols

Table 2: Review protocol: What is the most clinically and cost-effective method of assessing the psychological impact of tinnitus?

ID	Field	Content
0.	PROSPERO registration number	Not registered
1.	Review title	The clinical and cost-effective methods of assessing the psychological impact of tinnitus
2.	Review question	What is the most clinically and cost-effective method of assessing the psychological impact of tinnitus?
3.	Objective	The review aims to evaluate the clinical effectiveness and cost-effectiveness of different methods (questionnaires or interviews) that are utilised by different healthcare professionals for the assessment of the psychological impact of tinnitus. These questionnaires or interviews would be followed up by appropriate treatments for tinnitus and the resulting patient outcomes assessed. Psychological impact in this instance covers anxiety, depression, fatigue, insomnia, distress, suicidal ideation, stress (emotional exhaustion), mental health, wellbeing, relationships, communication, frustration, helplessness, hopelessness and lack of control in adults.
4.	Searches	The following databases will be searched: • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR)

		• Embase • MEDLINE • CINAHL, Current Nursing and Allied Health Literature • PsycINFO Searches will be restricted by: • English language • Human studies • Letters and comments are excluded. Other searches: • Inclusion lists of relevant systematic reviews will be checked by the reviewer. The searches may be re-run 6 weeks before final committee meeting and further studies retrieved for inclusion if relevant. The full search strategies will be published in the final review.
5.	Condition or domain being studied	Tinnitus
6.	Population	Inclusion: People presenting to a healthcare setting with tinnitus Strata: • Children/young people (up to 18 years) • Adults Exclusion: None
7.	Intervention/Exposure/Test	Questionnaires/interviews, e.g.: Adults: • GAD7

		• PHQ9 • CORE-OM • Tinnitus questionnaire (TQ and mini TQ) • Insomnia Severity test • Tinnitus Handicap Inventory • Tinnitus Functional Index (TFI) • Fear of Tinnitus Questionnaire • Psychological Impact of Tinnitus Interview • Chronic Tinnitus Acceptance Questionnaire • Pittsburgh sleep quality index • Beck • HADS • Visual Analogue Scale • Interview Children/young people (up to 18 years): • Paediatric Index of Emotional Distress Questionnaire (PI-ED 2010) • Revised Children's Anxiety and Depression Scale (RCADS) • The Mood and Feelings Questionnaire (MFQ) • Young Person's CORE-OM • The Children's Global Assessment Scale (CGAS) • BECK Youth inventories for children and adolescents • SDQ (parents and children's versions) • Mini-TQ for adolescents (qualitatively) • Goal-based measures • Visual Analogue Scale • Likert scales • Interview
8.	Comparator/Reference standard/Confounding factors	• Compared to each other • Compared to no psychological assessment • General tinnitus questionnaire compared to specific psychological questionnaire
9.	Types of study to be included	• Systematic reviews • RCTs • If there is an inadequate amount of RCT data, non-randomised comparative studies will be considered

10.	Other exclusion criteria	• Non-English language studies • Studies will only be included if they report one or more of the outcomes listed above • Descriptive (non-comparative) studies will be excluded • Non-English version of questionnaires
11.	Context	N/A
12.	Primary outcomes (critical outcomes)	• Tinnitus severity Impact of tinnitus: • Tinnitus distress • Tinnitus annoyance Health related QoL: • QoL (tinnitus) • QoL
13.	Secondary outcomes (important outcomes)	Tinnitus percept: • Tinnitus loudness Other co-occurring complaints: • Depression • Anxiety • Anxiety and depression • Sleep Adverse events: • Safety • Tolerability • Side effects
14.	Data extraction (selection and coding)	EndNote will be used for reference management, sifting, citations and bibliographies. Titles and/or abstracts of studies retrieved using the search strategy and those from additional sources will be screened for inclusion. The full text of potentially eligible studies will be retrieved and will be assessed for eligibility in line with the criteria outlined above. 10% of the abstracts will be reviewed by two

		reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. An in-house developed database; EviBase, will be used for data extraction. A standardised form is followed to extract data from studies (see Developing NICE guidelines: the manual section 6.4) and for undertaking assessment of study quality. Summary evidence tables will be produced including information on: study setting; study population and participant demographics and baseline characteristics; details of the intervention and control interventions; study methodology' recruitment and missing data rates; outcomes and times of measurement; critical appraisal ratings. A second reviewer will quality-assure the extracted data. Discrepancies will be identified and resolved through discussion (with a third reviewer where necessary).
15.	Risk of bias (quality) assessment	Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual. For Intervention reviews the following checklist will be used according to study design being assessed: • Systematic reviews: Risk of Bias in Systematic Reviews (ROBIS) • Randomised Controlled Trial: Cochrane RoB (2.0) Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.
16.	Strategy for data synthesis	Where possible, data will be meta-analysed. Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5) to combine the data given in all studies for each of the outcomes stated above. A fixed effect meta-analysis, with weighted mean differences for continuous outcomes and risk ratios for binary outcomes will be used, and 95% confidence intervals will be calculated for each outcome.

		Heterogeneity between the studies in effect measures will be assessed using the I^2 statistic and visually inspected. We will consider an I^2 value greater than 50% indicative of substantial heterogeneity. Sensitivity analyses will be conducted based on pre-specified subgroups using stratified meta-analysis to explore the heterogeneity in effect estimates. If this does not explain the heterogeneity, the results will be presented using random-effects. GRADE pro will be used to assess the quality of each outcome, taking into account individual study quality and the meta-analysis results. The 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) will be appraised for each outcome. Publication bias is tested for when there are more than 5 studies for an outcome. Other bias will only be taken into consideration in the quality assessment if it is apparent. Where meta-analysis is not possible, data will be presented and quality assessed individually per outcome. If sufficient data is available to make a network of treatments, WinBUGS will be used for network meta-analysis.
17.	Analysis of sub-groups	• People with learning disability or cognitive impairment • Visual impairment • Literacy level • Non English language speakers • Hearing loss • Mode of delivery
18.	Type and method of review	☐ Intervention ☐ Diagnostic ☐ Prognostic ☐ Qualitative ☐ Epidemiologic ☐ Service Delivery ☒ Other – diagnostic test and treat

19.	Language	English		
20.	Country	England		
21.	Anticipated or actual start date	27/06/18		
22.	Anticipated completion date	11/03/20		
23.	Stage of review at time of this submission	Review stage	Started	Completed
		Preliminary searches	☐	☑
		Piloting of the study selection process	☐	☑
		Formal screening of search results against eligibility criteria	☐	☑
		Data extraction	☐	☑
		Risk of bias (quality) assessment	☐	☑
		Data analysis	☐	☑
24.	Named contact	5a. Named contact National Guideline Centre 5b Named contact e-mail Tinnitus@nice.org.uk 5e Organisational affiliation of the review National Institute for Health and Care Excellence (NICE) and the National		

		Guideline Centre
25.	Review team members	From the National Guideline Centre: • Dr Jennifer Hill [Guideline lead] • Ms Sedina Lewis/Ms Julie Neilson [Senior systematic reviewers] • Dr Richard Clubbe [Systematic reviewer] • Mr David Wonderling [Health economist lead] • Mr Emtiyaz Chowdhury [Health economist] • Ms Jill Cobb [Information specialist] • Dr Giulia Zuodar [Project manager]
26.	Funding sources/sponsor	This systematic review is being completed by the National Guideline Centre which receives funding from NICE.
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: [NICE guideline webpage].
29.	Other registration details	N/A
30.	Reference/URL for published protocol	N/A
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of

		publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
32.	Keywords	Tinnitus, psychological impact, questionnaires, interview
33.	Details of existing review of same topic by same authors	N/A
34.	Current review status	☐ Ongoing ☒ Completed but not published ☐ Completed and published ☐ Completed, published and being updated ☐ Discontinued
35..	Additional information	N/A
36.	Details of final publication	www.nice.org.uk

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2 **Table 3: Health economic review protocol**

Review question	All questions – health economic evidence
Objectives	To identify health economic studies relevant to any of the review questions.
Search criteria	• Populations, interventions and comparators must be as specified in the clinical review protocol above. • Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis). • Studies must not be a letter, editorial or commentary, or a review of health economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English.
Search strategy	A health economic study search will be undertaken using population-specific terms and a health economic study filter – see appendix B below.

Review strategy

Studies not meeting any of the search criteria above will be excluded. Studies published before 2003, abstract-only studies and studies from non-OECD countries or the USA will also be excluded.

Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014).[6]

Inclusion and exclusion criteria

- If a study is rated as both 'Directly applicable' and with 'Minor limitations' then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile.
- If a study is rated as either 'Not applicable' or with 'Very serious limitations' then it will usually be excluded from the guideline. If it is excluded then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile.
- If a study is rated as 'Partially applicable', with 'Potentially serious limitations' or both then there is discretion over whether it should be included.

Where there is discretion

The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below.

The health economist will be guided by the following hierarchies.

Setting:

- UK NHS (most applicable).
- OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden).
- OECD countries with predominantly private health insurance systems (for example, Switzerland).
- Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations.

Health economic study type:

- Cost–utility analysis (most applicable).
- Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis).
- Comparative cost analysis.
- Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations.

Year of analysis:

- The more recent the study, the more applicable it will be.
- Studies published in 2003 or later but that depend on unit costs and resource data entirely or predominantly from before 2003 will be rated as 'Not applicable'.
- Studies published before 2003 will be excluded before being assessed for applicability and methodological limitations.

Quality and relevance of effectiveness data used in the health economic analysis:

- The more closely the clinical effectiveness data used in the health economic

	analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

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Appendix B: Literature search strategies

The literature searches for this review are detailed below and complied with the methodology outlined in Developing NICE guidelines: the manual.[6]

For more detailed information, please see the Methodology Review.

B.1 Clinical search literature search strategy

Searches were constructed using a PICO framework where population (P) terms were combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are rarely used in search strategies for interventions as these concepts may not be well described in title, abstract or indexes and therefore difficult to retrieve. Search filters were applied to the search where appropriate.

Table 4: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline (OVID)	1946 – 02 April 2019	Exclusions
Embase (OVID)	1974 – 02 April 2019	Exclusions
The Cochrane Library (Wiley)	Cochrane Reviews to 2019 Issue 4 of 12 CENTRAL to 2019 Issue 4 of 12 DARE, and NHSEED to 2015 Issue 2 of 4 HTA to 2016 Issue 4 of 4	None
CINAHL, Current Nursing and Allied Health Literature (EBSCO)	Inception – 02 April 2019	Exclusions
PsycINFO (ProQuest)	Inception – 02 April 2019	Exclusions

Medline (Ovid) search terms

1.	Tinnitus/
2.	tinnit*.ti,ab.
3.	1 or 2
4.	letter/
5.	editorial/
6.	news/
7.	exp historical article/
8.	Anecdotes as Topic/
9.	comment/
10.	case report/
11.	(letter or comment*).ti.
12.	or/4-11
13.	randomized controlled trial/ or random*.ti,ab.
14.	12 not 13
15.	animals/ not humans/
16.	exp Animals, Laboratory/
17.	exp Animal Experimentation/

18.	exp Models, Animal/
19.	exp Rodentia/
20.	(rat or rats or mouse or mice).ti.
21.	or/14-20
22.	3 not 21
23.	limit 22 to English language

1 **Embase (Ovid) search terms**

1.	tinnitus/
2.	tinnit*.ti,ab.
3.	1 or 2
4.	letter.pt. or letter/
5.	note.pt.
6.	editorial.pt.
7.	Case report/ or Case study/
8.	(letter or comment*).ti.
9.	or/4-8
10.	randomized controlled trial/ or random*.ti,ab.
11.	9 not 10
12.	animal/ not human/
13.	Nonhuman/
14.	exp Animal Experiment/
15.	exp Experimental animal/
16.	Animal model/
17.	exp Rodent/
18.	(rat or rats or mouse or mice).ti.
19.	or/11-18
20.	3 not 19
21.	limit 20 to English language

2 **Cochrane Library (Wiley) search terms**

#1.	MeSH descriptor: [Tinnitus] explode all trees
#2.	tinnit*:ti,ab
#3.	#1 or #2

3 **CINAHL (EBSCO) search terms**

S1.	(MH "Tinnitus")
S2.	(MH "Tinnitus Retraining Therapy")
S3.	tinnit*
S4.	S1 OR S2 OR S3
S5.	PT anecdote or PT audiovisual or PT bibliography or PT biography or PT book or PT book review or PT brief item or PT cartoon or PT commentary or PT computer program or PT editorial or PT games or PT glossary or PT historical material or PT interview or PT letter or PT listservs or PT masters thesis or PT obituary or PT pamphlet or PT pamphlet chapter or PT pictorial or PT poetry or PT proceedings or PT “questions and answers” or PT response or PT software or PT teaching materials or PT website
S6.	S4 NOT S5

4 **PsycINFO (ProQuest) search terms**

1.	((MAINSUBJECT.EXACT.EXPLODE("Tinnitus") OR tinnit*) NOT (su.exact.explode("rodents") OR su.exact.explode("mice") OR (su.exact("animals") NOT (su.exact("human males") OR su.exact("human females"))) OR ti(rat OR rats OR mouse OR mice))) AND la.exact("ENG")Limits applied

B.2 Health Economics literature search strategy

Health economic evidence was identified by conducting a broad search relating to the tinnitus population in NHS Economic Evaluation Database (NHS EED – this ceased to be updated after March 2015) and the Health Technology Assessment database (HTA) with no date restrictions. NHS EED and HTA databases are hosted by the Centre for Research and Dissemination (CRD). Additional searches were run on Medline and Embase for health economics and quality of life studies.

Table 5: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline	2002 – 02 March 2019	Exclusions Health economics studies Quality of life studies
Embase	2002 – 02 March 2019	Exclusions Health economics studies Quality of life studies
Centre for Research and Dissemination (CRD)	HTA - Inception – 31 Mar 2018 NHSEED - Inception to March 2015	None

Medline (Ovid) search terms

1.	Tinnitus/
2.	tinnit*.ti,ab.
3.	1 or 2
4.	letter/
5.	editorial/
6.	news/
7.	exp historical article/
8.	Anecdotes as Topic/
9.	comment/
10.	case report/
11.	(letter or comment*).ti.
12.	or/4-11
13.	randomized controlled trial/ or random*.ti,ab.
14.	12 not 13
15.	animals/ not humans/
16.	exp Animals, Laboratory/
17.	exp Animal Experimentation/
18.	exp Models, Animal/
19.	exp Rodentia/
20.	(rat or rats or mouse or mice).ti.
21.	or/14-20

22.	3 not 21
23.	limit 22 to English language
24.	Economics/
25.	Value of life/
26.	exp "Costs and Cost Analysis"/
27.	exp Economics, Hospital/
28.	exp Economics, Medical/
29.	Economics, Nursing/
30.	Economics, Pharmaceutical/
31.	exp "Fees and Charges"/
32.	exp Budgets/
33.	budget*.ti,ab.
34.	cost*.ti.
35.	(economic* or pharmaco?economic*).ti.
36.	(price* or pricing*).ti,ab.
37.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
38.	(financ* or fee or fees).ti,ab.
39.	(value adj2 (money or monetary)).ti,ab.
40.	or/24-39
41.	quality-adjusted life years/
42.	sickness impact profile/
43.	(quality adj2 (wellbeing or well being)).ti,ab.
44.	sickness impact profile.ti,ab.
45.	disability adjusted life.ti,ab.
46.	(qal* or qtime* or qwb* or daly*).ti,ab.
47.	(euroqol* or eq5d* or eq 5*).ti,ab.
48.	(qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
49.	(health utility* or utility score* or disutilit* or utility value*).ti,ab.
50.	(hui or hui1 or hui2 or hui3).ti,ab.
51.	(health* year* equivalent* or hye or hyes).ti,ab.
52.	discrete choice*.ti,ab.
53.	rosser.ti,ab.
54.	(willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab.
55.	(sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab.
56.	(sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab.
57.	(sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab.
58.	(sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab.
59.	(sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab.
60.	or/41-59
61.	23 and (40 or 60)

1 **Embase (Ovid) search terms**

1.	tinnitus/
2.	tinnit*.ti,ab.

3.	1 or 2
4.	letter.pt. or letter/
5.	note.pt.
6.	editorial.pt.
7.	Case report/ or Case study/
8.	(letter or comment*).ti.
9.	or/4-8
10.	randomized controlled trial/ or random*.ti,ab.
11.	9 not 10
12.	animal/ not human/
13.	Nonhuman/
14.	exp Animal Experiment/
15.	exp Experimental animal/
16.	Animal model/
17.	exp Rodent/
18.	(rat or rats or mouse or mice).ti.
19.	or/11-18
20.	3 not 19
21.	health economics/
22.	exp economic evaluation/
23.	exp health care cost/
24.	exp fee/
25.	budget/
26.	funding/
27.	budget*.ti,ab.
28.	cost*.ti.
29.	(economic* or pharmaco?economic*).ti.
30.	(price* or pricing*).ti,ab.
31.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
32.	(financ* or fee or fees).ti,ab.
33.	(value adj2 (money or monetary)).ti,ab.
34.	or/21-33
35.	quality adjusted life year/
36.	"quality of life index"/
37.	short form 12/ or short form 20/ or short form 36/ or short form 8/
38.	sickness impact profile/
39.	(quality adj2 (wellbeing or well being)).ti,ab.
40.	sickness impact profile.ti,ab.
41.	disability adjusted life.ti,ab.
42.	(qal* or qtime* or qwb* or daly*).ti,ab.

43.	(euroqol* or eq5d* or eq 5*).ti,ab.
44.	(qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
45.	(health utility* or utility score* or disutilit* or utility value*).ti,ab.
46.	(hui or hui1 or hui2 or hui3).ti,ab.
47.	(health* year* equivalent* or hye or hyes).ti,ab.
48.	discrete choice*.ti,ab.
49.	rosser.ti,ab.
50.	(willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab.
51.	(sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab.
52.	(sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab.
53.	(sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab.
54.	(sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab.
55.	(sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab.
56.	or/35-55
57.	20 and (34 or 56)
58.	limit 57 to English language

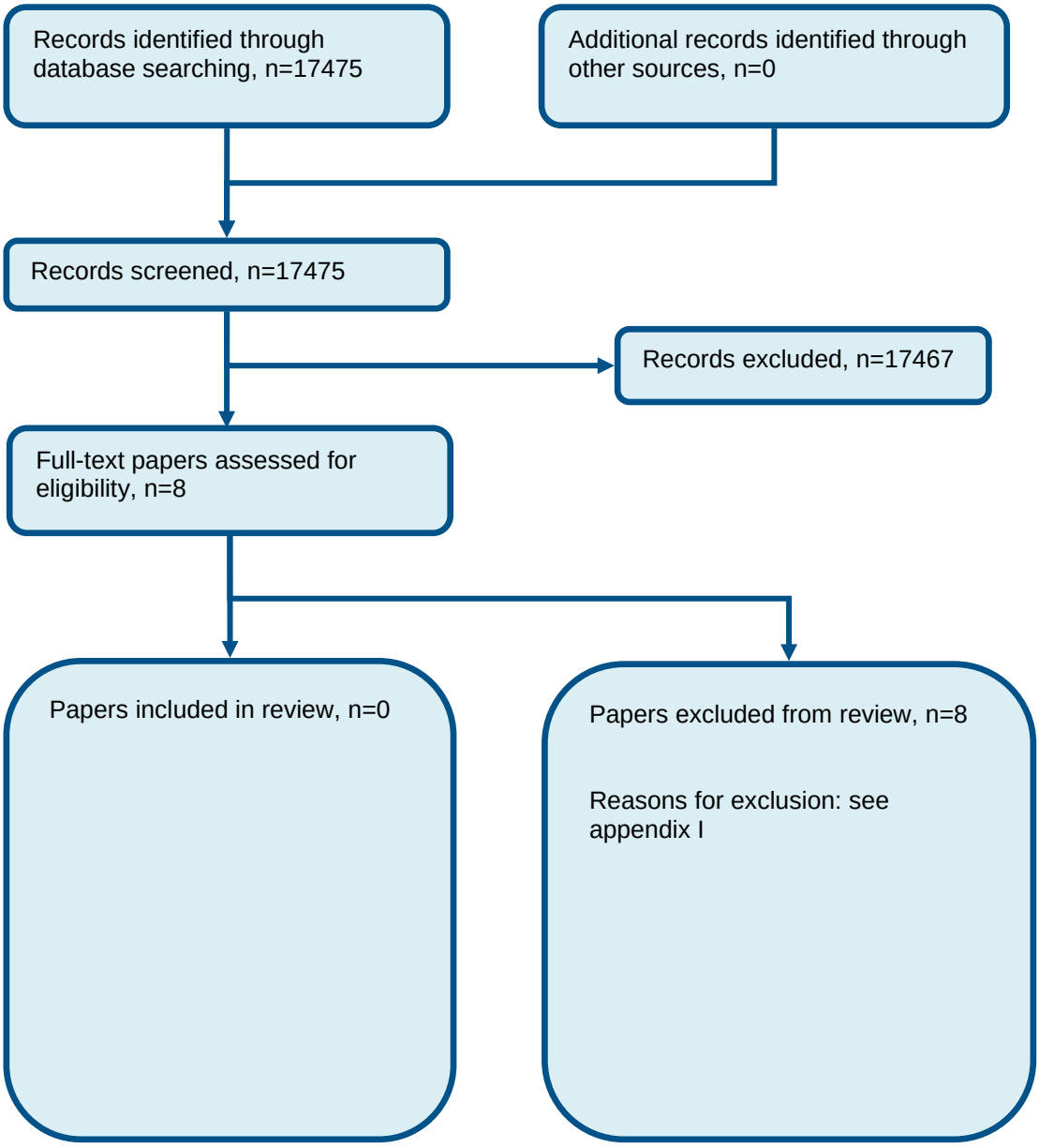
1 **NHS EED and HTA (CRD) search terms**

#1.	MeSH DESCRIPTOR Tinnitus EXPLODE ALL TREES
#2.	(tinnit*)
#3.	#1 OR #2

2

Appendix C: Clinical evidence selection

Figure 1: Flow chart of clinical study selection for the review of the most clinically and cost-effective method of assessing the psychological impact of tinnitus



Appendix D: Clinical evidence tables

No evidence identified.

Appendix E: Forest plots

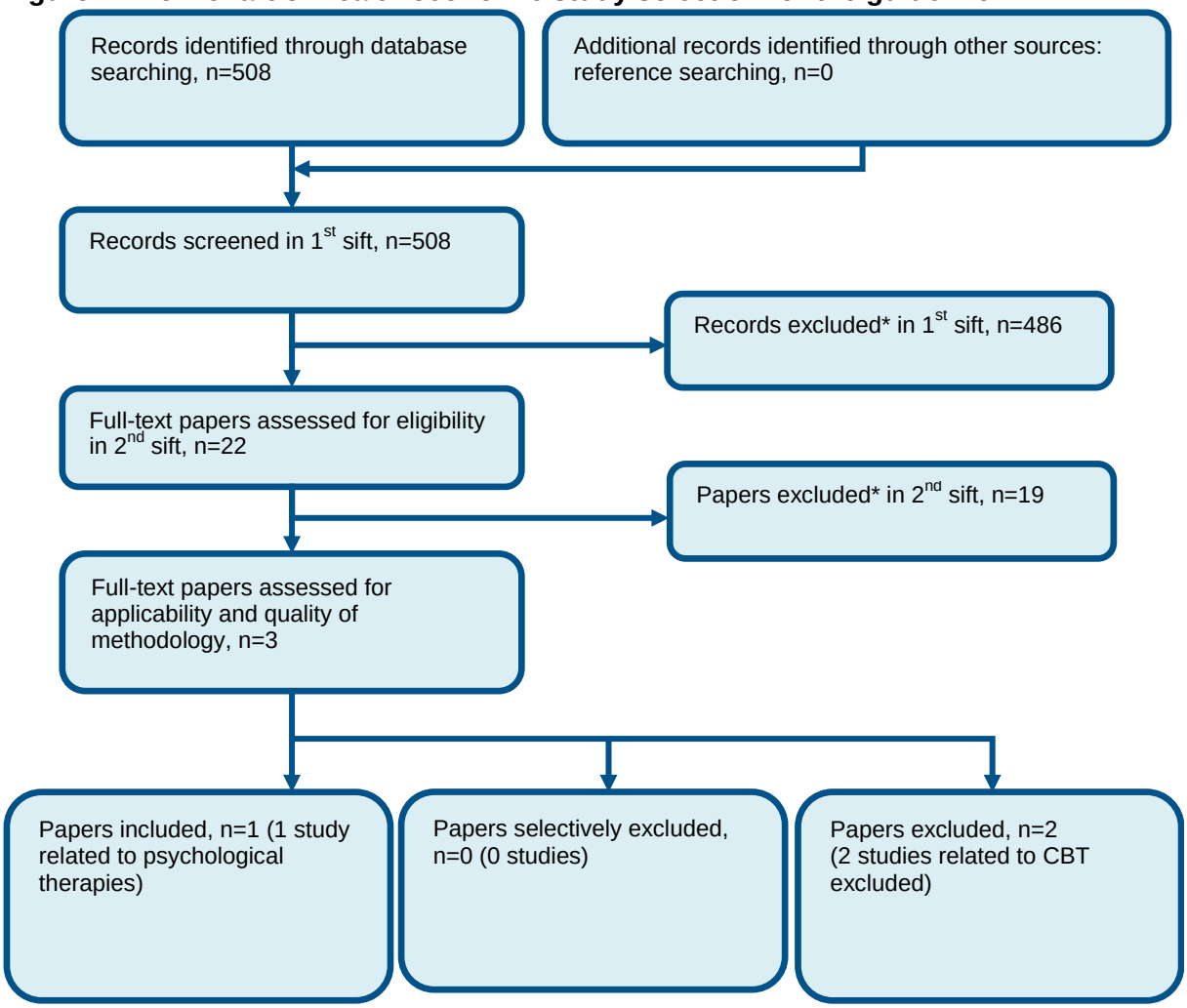
No evidence identified.

Appendix F: GRADE tables

No evidence identified.

Appendix G: Health economic evidence selection

Figure 2: Flow chart of health economic study selection for the guideline



* Non-relevant population, intervention, comparison, design or setting; non-English language

Appendix H: Excluded studies

H.1 Excluded clinical studies

Table 6: Studies excluded from the clinical review

Reference	Reason for exclusion
Andersson 2003[1]	Assessing mode of delivery (internet vs pencil and pen with clinician)
Cho 2013[2]	Incorrect comparison (all participants received one type of questionnaire)
Henry 2001[3]	Incorrect comparison (all participants received one type of questionnaire)
Hiller 2004[4]	Incorrect comparison (all participants received one type of questionnaire)
Ozcankaya 2001[7]	Incorrect comparison (Not assessing the effectiveness of questionnaires: cohort study assessing presence of tinnitus in hospital population)
Rizzardo 1998[8]	Incorrect comparison (all participants received one type of questionnaire)
Robinson 2003[9]	No relevant outcome data
Zoger 2004[11]	No relevant outcome data

H.2 Excluded health economic studies

None.