National Institute for Health and Care Excellence

Draft for consultation

Tinnitus: assessment and management

Questionnaires to assess tinnitus

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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ISBN

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1.1 Review question: What is the most clinically and cost-effective questionnaire to assess tinnitus?

1.2 Introduction

The only ways to assess tinnitus severity and impact currently are via a subjective measure such as a questionnaire, clinical discussion or visual analogue scales. Many tinnitus questionnaires have been developed and in this chapter consideration has been given to the clinical efficacy for each measure and their abilities to demonstrate clinical change.

Questionnaires vary in terms of the areas and detail that they cover. In addition to a standard clinical history, examination and hearing assessment, many clinicians offer psychometric questionnaires. Tinnitus can affect people's quality of life, sleep, and mood. Questionnaires can be specifically related to tinnitus and hearing in order to evaluate tinnitus annoyance, distress and severity. Other questionnaires can be used to measure general depression, anxiety, quality of life and insomnia. No questionnaires have been developed for assessing tinnitus in children.

By assessing people's tinnitus with a good questionnaire, the health professional and person with tinnitus are better able to develop a management plan targeted to the individual's needs. This review has been carried out to inform recommendations about which questionnaires are most clinically and cost effective and valuable in contributing to the best possible management strategy for a person with tinnitus.

Separate reviews focus more specifically on assessment of psychological impact and quality of life (evidence reviews F and G).

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 and adults

Intervention(s)	Questionnaires:
	• Validated questionnaire for the assessment of tinnitus severity:
	  ○ Tinnitus questionnaire (TQ)
	  ○ Tinnitus handicap inventory (THI)
	  ○ Tinnitus handicap questionnaire (THQ)
	  ○ Tinnitus reaction questionnaire (TRQ)
	  ○ Tinnitus functional index (TFI)
	  ○ Mini TQ
	  ○ International tinnitus inventory

Comparison(s)	• Standard care (history and physical examination) • Compared to each other
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 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 which met the protocol were identified.

1.7.1.3 Benefits and harms

Our review found no evidence that has evaluated the clinical effectiveness of questionnaires to assess tinnitus. The committee noted that whilst no evidence was identified this is a crucial part of the management pathway and therefore consensus recommendations were made.

It was discussed that there are many questionnaires used to assess tinnitus in adults in the UK, the most commonly used questionnaires being the THI, TFI, TQ and Mini-TQ.

The committee noted that out of the most commonly used questionnaires; TFI provides the broadest assessment of the impact of tinnitus with domains covering a variety of components and it can be used to measure change. The THI, whilst covering a variety of domains, has more of a focus on psychological aspects. The committee felt that if more information is required about the psychological impact of tinnitus, the TQ or Mini-TQ would be appropriate and should inform decisions about referral for psychological treatments (see evidence review L).

These questionnaires have the benefit of taking a measure of the impact of a person's tinnitus and allowing a more informed discussion with the person of potential treatment

strategies. They sometimes can help to spot false positives. There are minimal harms associated with questionnaires. Whilst they take some time to complete, this is outweighed by the benefits to the future management strategy.

Current practice is that questionnaires to assess tinnitus are mainly completed within secondary or tertiary care (e.g. ENT and audiology) with people referred for tinnitus that bothers them. Assessment of tinnitus in primary care is currently patchy and may often only include looking in the ears and history-taking. The committee decided to make a research recommendation to examine the optimal method for assessing tinnitus in primary care settings (including consultation questions, physical examinations and questionnaires).

The use of questionnaires should be particularly considered in secondary care before-and-after interventions have been initiated, to assess the impact of tinnitus and the benefits of the interventions. The committee noted that questionnaires can be used as a decision-aid for healthcare professionals to assist in discussions around tailoring management strategies with the person.

The committee discussed that whilst there are no specific questionnaires to assess tinnitus in children and young people, it is important that age-appropriate measures are used. Measures can include goal-based measures such as a visual analogue scale, for example the ‘tinnitus thermometer’. A consensus recommendation was made for this population.

The committee wanted to encourage research into age-appropriate questionnaires (in particular the designing of questionnaires and subsequent evaluation) for children and young people and made a research recommendation. They hope that this will inform future updates of the guideline by allowing more specific recommendations to be made.

No evidence was identified that evaluated the use of questionnaires for the assessment of tinnitus with people with learning disability, cognitive impairment or visual impairment. Whilst the prevalence of tinnitus in these populations in the UK is unknown, the committee discussed the need for ensuring that these populations are appropriately assessed and made a consensus recommendation to use other measures such as visual analogue scales. The committee made a research recommendation to encourage research into ability-appropriate questionnaires.

Lay representatives on the committee noted that it is crucial that questionnaire results are discussed with people with tinnitus. Healthcare professionals should discuss the results and how the questionnaire findings inform possible management (as described in the recommendations for tinnitus support (see Evidence review A: tinnitus support). This will enable people with tinnitus to feel fully engaged with their care and make informed decisions about interventions that are most appropriate for them.

1.7.2 Cost effectiveness and resource use

There were no economic evaluations or clinical evidence available to support the use of one questionnaire over another. The committee therefore used their clinical experience to form a consensus recommendation that the TFI should be used as an initial assessment tool for adults due to its ability to provide a wide breadth of information about the impact of tinnitus. While other questionnaires are available, the committee explained the TFI is the only tinnitus questionnaire validated to measure change and therefore it was specifically named as the preferred questionnaire in the recommendation. There was also the view that recommending a single questionnaire would help standardise practice.

The committee have specified that the TFI be used in secondary care only. The rationale for this is that the committee were conscious of the potential resource impact of completing and discussing these questionnaires in primary care where general practitioners are limited on time. In the absence of clinical and economic evidence, the committee opted for a research recommendation to identify the most clinical and cost-effectiveness methods of assessing

tinnitus in primary care. The committee were of the view that using the TFI in secondary care would be cost-neutral because the TFI is freely available and mostly completed outside the consultation room with only the results discussed with the clinician. Therefore, extra staff time is not required to complete the TFI. In the absence of the questionnaire, the committee indicated that a clinician would still have to enquire about the impact of tinnitus on the lives of people with tinnitus. If this enquiry was sufficiently comprehensive, it would require the same amount of staff time as discussing the results of the TFI. Therefore, using the TFI would provide a clearer structure for the relevant questions that should be asked and would help to standardise practice. The committee highlighted it was important to measure the impact and benefit of interventions so that alternative strategies could be employed to help a person with bothersome tinnitus. As people with tinnitus will already be expected to attend a post-intervention appointment and this recommendation will not require an additional consultation, this component of the recommendation is not expected to result in an additional expenditure.

Finally, those instances where the use of a questionnaire is not feasible (due to age, lack of comprehension or other reasons) a recommendation was made to use the visual analogue scale (VAS) before and after intervention. VAS can be completed relatively quickly and would not result in significant staff costs. The committee have also made two research recommendations to identify the most clinical and cost-effective questionnaire, the first for children and young people and the second for those with learning disabilities.

1.7.3 Other factors the committee took into account

The committee noted that questionnaires may not be accessible for every person, for example, in the case of visual or cognitive impairment or learning disability, or where language is a barrier. In these cases clinicians may use alternative methods to establish the impact of tinnitus and the effectiveness of interventions, such as visual analogue scales. The committee made a research recommendation to establish the most clinically and cost effective questionnaire to assess tinnitus in people with learning disability or cognitive impairment.

The lay representatives on the committee noted that there is a perception that people are sometimes dismissed from primary care, being told there is nothing that can be done to help. The committee made a research recommendation that further work should be conducted on the optimal method for assessing tinnitus in primary care settings (including consultation questions, physical examinations and questionnaires).

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Appendices

Appendix A: Review protocols

Table 2: Review protocol: What is the most clinically and cost-effective questionnaire to assess tinnitus?

ID	Field	Content
0.	PROSPERO registration number	Not registered
1.	Review title	The clinical and cost-effective methods to assess tinnitus
2.	Review question	What is the most clinically and cost-effective questionnaire to assess tinnitus?
3.	Objective	The review aims to evaluate the clinical effectiveness and cost-effectiveness of different questionnaires that are utilised by different healthcare professionals for the assessment of tinnitus. These questionnaires would be followed up by appropriate treatments for tinnitus and the resulting patient outcomes assessed. History and physical examination (checking blood pressure, otoscopy, auscultation of pulsatile tinnitus) are methods for assessing tinnitus which are always carried out therefore this review is looking at the addition of a validated questionnaire to these methods.
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 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: Validated questionnaire for the assessment of tinnitus severity: • Tinnitus questionnaire (TQ) • Tinnitus handicap inventory (THI) • Tinnitus handicap questionnaire (THQ) • Tinnitus reaction questionnaire (TRQ)

		• Tinnitus functional index (TFI) • Mini TQ • International tinnitus inventory
8.	Comparator/Reference standard/Confounding factors	• Compared to each other • Standard care (history and physical examination)
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

<table>
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Hearing loss
Mode of delivery</td></tr>
<tr><td>18.</td><td>Type and method of review</td><td colspan="3">☐ Intervention
☐ Diagnostic
☐ Prognostic
☐ Qualitative
☐ Epidemiologic
☐ Service Delivery
☒ Other – diagnostic test and treat</td></tr>
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<tr><td>20.</td><td>Country</td><td colspan="3">England</td></tr>
<tr><td>21.</td><td>Anticipated or actual start date</td><td colspan="3">27/06/18</td></tr>
<tr><td>22.</td><td>Anticipated completion date</td><td colspan="3">11/03/20</td></tr>
<tr><td rowspan="6">23.</td><td rowspan="6">Stage of review at time of this submission</td><td>Review stage</td><td>Started</td><td>Completed</td></tr>
<tr><td>Preliminary searches</td><td>☐</td><td>☑</td></tr>
<tr><td>Piloting of the study selection process</td><td>☐</td><td>☑</td></tr>
<tr><td>Formal screening of search results against eligibility criteria</td><td>☐</td><td>☑</td></tr>
<tr><td>Data extraction</td><td>☐</td><td>☑</td></tr>
<tr><td>Risk of bias (quality)</td><td>☐</td><td>☑</td></tr>
</table>

		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, assessment, questionnaires
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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1 **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

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

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

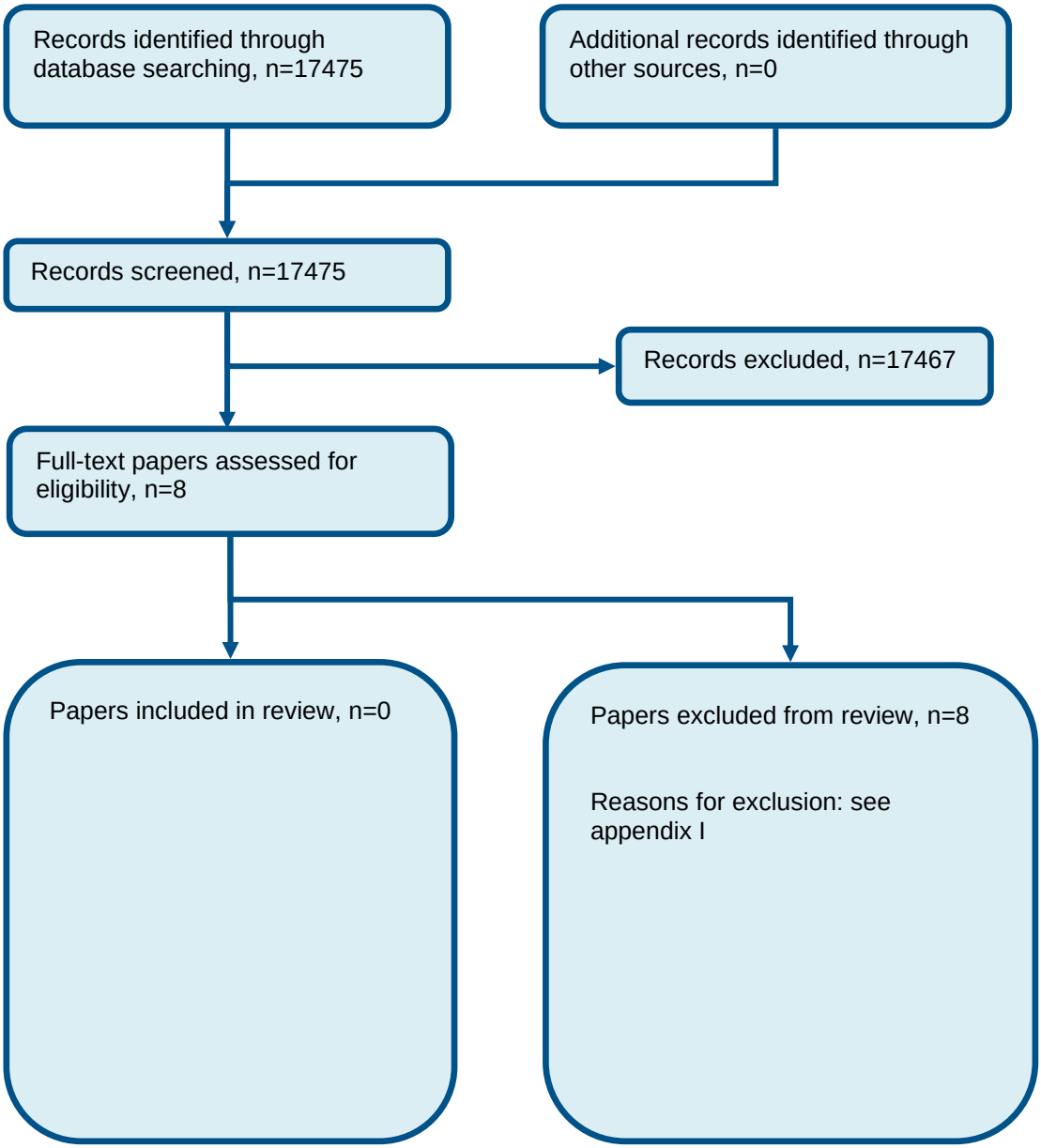
1 **NHS EED and HTA (CRD) search terms**

#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 what is the most clinically and cost-effective questionnaire to assess tinnitus



Appendix D: Clinical evidence tables

No evidence identified.

Appendix E: Forest plots

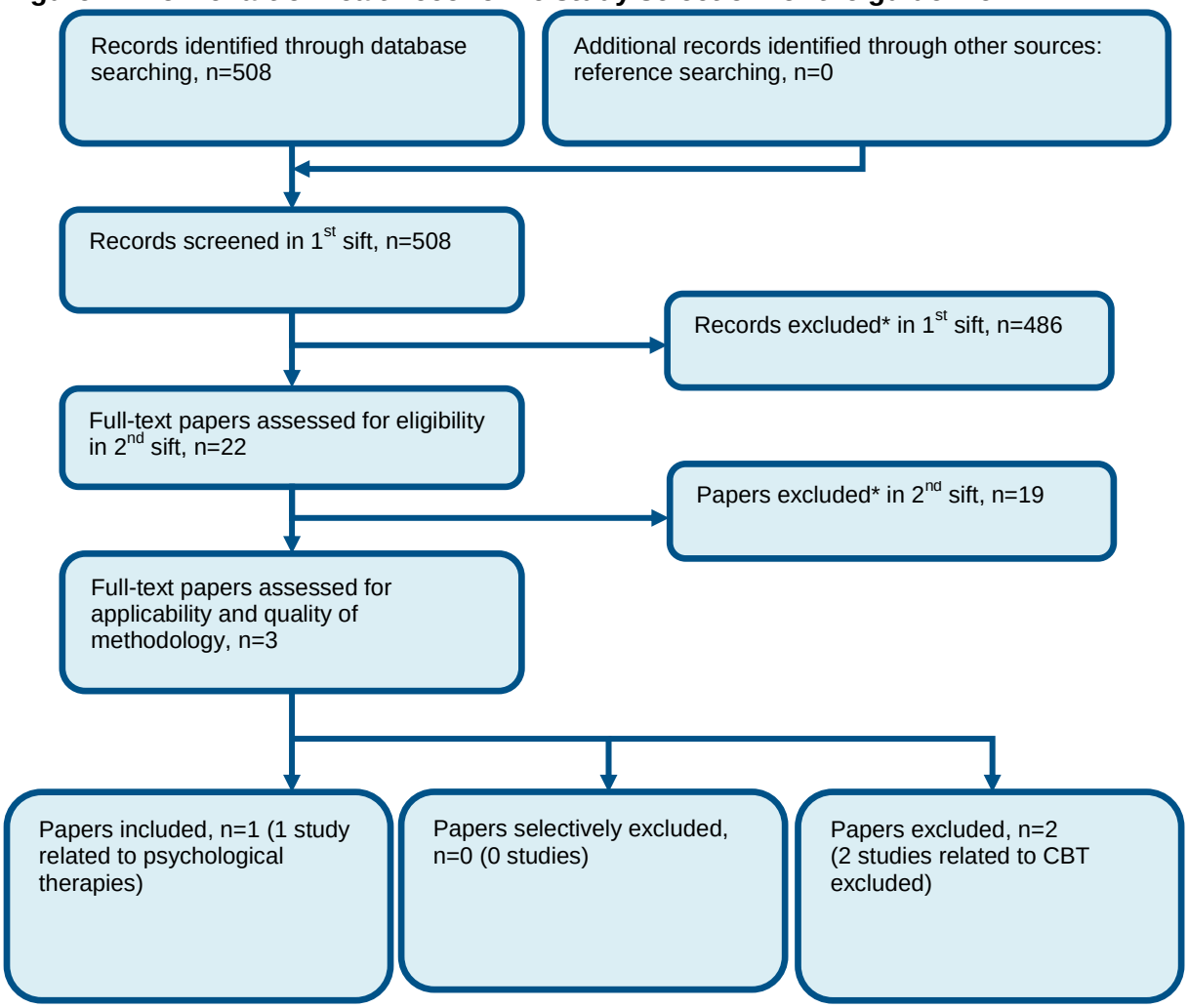
No evidence identified.

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
Aazh 2017[1]	No relevant outcome data; incorrect study design (survey)
Baguley 2000[2]	No relevant outcome data
Ciocon 1995[3]	Incorrect study design (narrative)
Fackrell 2018[4]	No relevant outcome data
Jüris 2013[5]	No relevant outcome data; incorrect study design (cross-sectional study)
Newman 1996[7]	No relevant outcome data; incorrect study design (standardization study)
Schlee 2016[8]	No relevant outcome data; incorrect study design (observational)
Searchfield 2007[9]	No relevant outcome data; incorrect study design (prospective cohort study)

H.2 Excluded health economic studies

None.

Appendix I: Research recommendations

I.1 Method for assessing tinnitus in primary care settings

Research question: What is the optimal method for assessing tinnitus in primary care settings (including consultation questions, physical examinations and questionnaires)?

Why this is important:

There is currently uncertainty about the approach that should be taken when assessing people with tinnitus in primary care in the UK. There is an urgent need for standardisation of assessment in primary care. Once a method for assessing tinnitus has been identified, training on how to use the optimal method can be integrated within GP training so that GPs are well-equipped to deal with the high volume of people presenting with tinnitus. Consequently, people with tinnitus will have a more positive experience in primary care and will be referred appropriately in line with the recommendations.

Criteria for selecting high-priority research recommendations

PICO question	**Population:** People (children, young people and/or adults) presenting to primary care with tinnitus
	
	Interventions:
	• Validated questionnaires or measure for the assessment of tinnitus severity, e.g.
	  ○ Tinnitus questionnaire (TQ)
	  ○ Tinnitus handicap inventory (THI)
	  ○ Tinnitus handicap questionnaire (THQ)
	  ○ Tinnitus reaction questionnaire (TRQ)
	  ○ Tinnitus functional index (TFI)
	  ○ Mini TQ
	  ○ International tinnitus inventory
	• Published consultation tools
	
	Comparison:
	• Standard consultation (e.g. history taking, consultation questions and physical examination)
	• Interventions compared to each other
	
	Outcomes:
	• Tinnitus severity (critical)- measured using validated questionnaires
	
	Impact of tinnitus, measured using validated questionnaires: -(critical)
	• Tinnitus Distress
	• Tinnitus Annoyance
	
	Health related QoL, measured using validated questionnaires: (critical)
	• QoL (EQ-5D)

	Tinnitus percept, measured using validated questionnaires: • Tinnitus Loudness (important) Other co-occurring complaints measured using validated questionnaires (important) • Depression • Anxiety • Anxiety and depression • Sleep •
Importance to patients or the population	Tinnitus is a highly prevalent and heterogeneous condition with no established primary care management strategies. There are estimated to be over 1 million primary healthcare appointments for tinnitus per annum (Stockdale, 2017) and a general consensus amongst patients that current tinnitus provision is unsatisfactory (McFerran, 2018). Therefore, better ways to assess and manage tinnitus in primary care are urgently needed. Improved primary care assessment and management of tinnitus would likely increase patient satisfaction and optimise management pathways. This should mean that more patients receive the right support and interventions in a timely fashion and therefore patient outcomes should improve.
Relevance to NICE guidance	New evidence in this area may mean that future updates of the NICE Tinnitus guideline are able to make practice recommendations on how people reporting tinnitus are assessed by primary care.
Relevance to the NHS	McFerran et al (2018) identified a revolving door healthcare problem with current management, with many tinnitus patients reporting multiple primary care appointments. Improved primary care management and onward referral should reduce the number of appointments per patient. May also lead to improved training for primary care doctors around tinnitus or identify a training need. New evidence may identify an increased need for training healthcare professionals in primary care in how to assess people with tinnitus. For example, training may need to be conducted in how to deliver questionnaires.
National priorities	• Department of Health's Provision of Services for Adults with Tinnitus: A Good Practice Guide (2009)
Current evidence base	No evidence was identified within this guideline that investigated the use of different methods (consultation questions, examinations and questionnaires) in primary care.
Equality	No equality issues are addressed.
Study design	Primary research in the form of randomised controlled trials, within primary healthcare settings.
Feasibility	The committee acknowledged that use of tinnitus questionnaires such as THI, TFI and TQ may not be feasible within a primary care appointment as completion can be time-consuming. The types of questionnaires that can be evaluated are not restricted to those listed in the 'PICO question' section above.
Other comments	The committee noted that primary care consultation tools have been developed for the assessment of tinnitus by NHS trusts. Assessing the

	effectiveness of these tools can be informative in improving the assessment of tinnitus in primary care.
Importance	• High: the research is essential to inform future updates of key recommendations in the guideline.

I.2 Tinnitus questionnaires for children and young people

Research question: What is the most clinically and cost-effective tinnitus questionnaire to assess tinnitus in children and young people?

Why this is important:

Children and young people commonly experience tinnitus, but this symptom is often unreported and the evidence base to support the assessment and treatment of tinnitus in children is lacking. The evaluation of a paediatric tinnitus assessment instrument is of vital importance to allow an appropriate appraisal of tinnitus burden, to allow triage, and to monitor change (i.e. outcomes of management strategies). The committee were unaware of existing questionnaires and so new research should develop and test questionnaires for children and young people with tinnitus.

Criteria for selecting high-priority research recommendations:

PICO question	**Population:** Children and young people presenting to a healthcare setting with tinnitus **Intervention(s):** Development and evaluation of • Validated questionnaires for the assessment of tinnitus severity tailored to children and young people **Comparison:** • Standard care (history and physical examination) • Interventions compared to each other **Outcome(s):** • Tinnitus severity (critical) Impact of tinnitus: -(critical) • Tinnitus Distress • Tinnitus Annoyance Health related QoL: (critical) • QoL (EQ-5D) Tinnitus percept: • Tinnitus Loudness (important) Other co-occurring complaints (important) • Depression • Anxiety • Anxiety and depression • Sleep
Importance to	Evidence based recommendations for questionnaires should improve

patients or the population	decision-making for children and young people with tinnitus whereby they can potentially be offered more appropriate and timely management strategies.
Relevance to NICE guidance	New research of clinical and cost effectiveness would enable children and young people to receive relevant assessment of their tinnitus and allow consideration to be given to how to optimally manage their tinnitus.
Relevance to the NHS	New evidence may identify an increased need for training healthcare professionals in primary care in how to assess people with tinnitus. For example, training may need to be conducted in how to deliver questionnaires.
National priorities	None.
Current evidence base	No evidence was identified within this guideline that investigated the use of tinnitus questionnaires for assessing tinnitus in children and young people.
Equality	Children and young people currently do not have the same level of assessment for their tinnitus as adults.
Study design	Randomised controlled trial or well-designed prospective or retrospective cohort study
Feasibility	This research should be feasible.
Other comments	The committee were not aware of any questionnaires for children and young people and these would need development, validation and testing.
Importance	Medium: the research is relevant to the recommendations in the guideline, but the research recommendations are not key to future updates.

I.3 Tinnitus questionnaires in people with learning disability or cognitive impairment

Research question: What is the most clinically and cost-effective tinnitus questionnaire to assess tinnitus in people with learning disability or cognitive impairment?

Why this is important:

There is currently variation in how tinnitus is assessed in people with learning disability or cognitive impairment. It is important that effective tinnitus questionnaires for this population are identified to ensure that healthcare professionals are well-equipped and that care is standardised across the UK. Use of an effective questionnaire can consequently inform the development of a management plan, allow an appropriate appraisal of tinnitus burden, to allow triage, and to monitor change (i.e. outcomes of management strategies). The committee were unaware of existing questionnaires and so new research should develop and test questionnaires for people with learning disability or cognitive impairment with tinnitus.

Criteria for selecting high-priority research recommendations:

PICO question	**Population:** Children, young people and adults who have a learning disability or cognitive impairment, presenting with tinnitus

	Intervention(s): Development and evaluation of • Validated questionnaires for the assessment of tinnitus severity tailored for people with a learning disability or cognitive impairment and tinnitus. **Comparison:** • Standard care (history and physical examination) • Interventions compared to each other **Outcomes:** • Tinnitus severity (critical) Impact of tinnitus: -(critical) • Tinnitus Distress • Tinnitus Annoyance Health related QoL: (critical) • QoL (EQ-5D) Tinnitus percept: • Tinnitus Loudness (important) Other co-occurring complaints (important) • Depression • Anxiety • Anxiety and depression • Sleep
Importance to patients or the population	There is currently no validated way to assess or measure tinnitus in people with a learning disability or cognitive impairment. Whilst the prevalence of tinnitus in this population is unknown, there is no reason to assume that tinnitus is less prevalent in this population. In fact, it may well be more prevalent. Therefore, there may be an unmet need that needs to be met.
Relevance to NICE guidance	This would enable a population to receive relevant assessment of their tinnitus and allow consideration to be given to how to optimally manage tinnitus in people with a learning disability or cognitive impairment.
Relevance to the NHS	A validated outcome measure of tinnitus in people with a learning disability or cognitive impairment will allow NHS staff the opportunity to assess tinnitus in a population where that is currently not feasible.
National priorities	N/A
Current evidence base	No evidence was identified that evaluated the use of tinnitus questionnaires for assessing tinnitus in children, young people or adults with learning disability or cognitive impairment exclusively.
Equality	This research recommendation addresses people with a learning disability or cognitive impairment, a group that needs special consideration.

Study design	Randomised controlled trial or well-designed prospective or retrospective cohort study
Feasibility	There should be no feasibility issues for the research
Other comments	The committee were not aware of any questionnaires for people with learning disabilities and cognitive impairment and these would need development, validation and testing.
Importance	Medium: the research is relevant to the recommendations in the guideline, but the research recommendations are not key to future updates.

1