Tinnitus: assessment and management

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Action on Hearing Loss	General	General	Action on Hearing Loss welcomes the opportunity to submit comments on the proposed updates to the NICE guideline scope for "Tinnitus." Action on Hearing Loss (formerly RNID) is the main charity for people with hearing loss and tinnitus across the UK. Our vision is of a world where deafness, hearing loss and tinnitus do not limit or label people and where people value and look after their hearing. We help people confronting deafness, tinnitus and hearing loss to live the life they choose. We enable them to take control of their lives and remove the barriers in their way. We give people support and care; develop technology and treatments and campaign for equality. Our response will focus on key issues that relate to people with tinnitus. We are happy for the details of this response to be made public. Please do contact us if you require further information or evidence.	Thank you for your comment.
Action on Hearing Loss	General	General	Action on Hearing Loss welcomes that the guidance will focus on varying groups of people affected by tinnitus.	Thank you for your comment.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			More than 11 million people in the UK have hearing loss, about 1 in 6 of the population. The prevalence of hearing loss increases with age. One in 10 adults across the UK suffers from tinnitus,[1] with recent data showing that this increases to nearly 17% of 40 to 69-year olds and 25-30% of over 70s.[2] An estimated 32,000 new cases of tinnitus were diagnosed in England in 2015. Deafness, tinnitus and hearing loss are serious health conditions that can have a significant impact on health and wellbeing. Tinnitus can have a negative impact on a person's mental health, relationships with family and friends and their ability to sleep, concentrate and work.	
Action on Hearing Loss	3	75	The draft scope currently describes tinnitus sound matching as objective. Current tinnitus sound and/ level matching tests measure the patient's subjective perception of tinnitus sound, pitch and volume[3]. Objective tests which can be part of the test battery	Thank you for your comment, we have deleted 'objective' from the scope.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			and inform us more about the current state of the hearing system, include Tympanogram, Otoacoustic emissions (OAEs) and Acoustic reflex thresholds (ARTs). There should be a clear distinction between subjective and objective tests in the guideline.	
Action on Hearing Loss	4	General	We feel earwax removal should be included under management, as it can cause tinnitus temporarily in some cases.[4] In England, the Department of Health has published a good practice guide for tinnitus care,[5] which describes a stepped-care approach, with the primary-care doctor offering initial reassurance and diagnosis of simple remediable causes, such as earwax or infection, and referral to secondary care when tinnitus is severe or associated with hearing loss. In some areas, direct access to audiology services and wax removal services is offered. However, anecdotally, we have heard reports of there being confusion about what wax removal services are	Thank you for your comment. We are unable to cover all areas of tinnitus diagnosis and management and so have prioritised the areas where we feel that a review of the clinical and cost effectiveness evidence is most valuable.The NICE pathway, developed after the guideline is published, will be able to link between this and the hearing loss guideline.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			available locally and what is most suitable for an individual needing to get their wax removed. We have received reports of limited or no access within primary care to wax removal services, but as the guidance states, this could well be caused by confusion about ear syringing that is no longer recommended as a procedure and individuals not receiving information about other wax removal services available. The draft NICE guidance for hearing loss states that wax removal services should be encouraged in primary and community care settings as long as there are health professionals trained to carry out the procedure and the right equipment available.[6] Additionally, the draft NICE guidance for hearing loss also states that if the tinnitus has 'significantly changed in nature' and 'significant change in tinnitus is defined as one which the patient reports as significant' then 'examination should exclude other causes for change such as wax or infection.'[7] Therefore we feel	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			wax removal plays an important part in the management of tinnitus.	
Action on Hearing Loss	4	General	The draft scope currently includes 'self-management' but we believe 'self-help' will be received better by the public. Other organisations such as the NHS[8] and the BTA[9] use the same terminology (self-help). We also feel information on support groups should be detailed in this section.	Thank you for your comment. Self-help is taken to mean measures that are initiated by patients themselves. As we have limited time to produce the guideline we have not prioritised this area for inclusion in the scope.
Action on Hearing Loss	4	General	Currently sleep hygiene is not mentioned in the draft. We feel this should be included as sleep difficulties are among the most frequent complaints associated with tinnitus, which leads to more distress.[10] This reduces quality of life for many individuals and can also cause other health conditions as a result.[11]	Thank you for your comment. Sleep hygiene may be included under self-management strategies, which has been moved to the 'providing information' area of the scope.'This will be explored with the guideline committee during the development stage of the guideline.. This will be explored with the guideline

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				committee at the protocol development stage of the guideline. Furthermore sleep hygiene is covered by the NICE Clinical Knowldege Summary on insomnia, available from: https://cks.nice.org.uk/insomnia#!topicsummary
Action on Hearing Loss	4	90	We welcome the inclusion of gingko biloba in this guideline but its non-use should be clearly outlined. A Cochrane review conducted in 2013 concludes that there is limited evidence that Ginkgo biloba is effective for tinnitus when this is the primary complaint.[12] The largest study by Drew et al reported no difference between control and experimental groups at the end of the trial.[13]	Thank you for your comment. We have removed ginkgo biloba from the scope. Stakeholder comments indicated that ginkgo biloba is not the only complimentary medicine used for tinnitus. As the guideline can only cover a limited number of topics for evidence reviews we considered that it would be inconsistent to include only ginkgo biloba and complementary therapies should not be prioritised over other topics in the scope.
Action on Hearing Loss	4	91, 92	When describing antidepressants and anxiolytics, the guideline should clearly state that they do not manage tinnitus but rather manage comorbid conditions such	Thank you for your comment. The guideline will cover identification of depression / anxiety as co-morbid conditions and signpost to existing NICE guidelines on

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			as depression and anxiety. However in 'line 100' it states that comorbid conditions such as depression and anxiety will not be covered, which contradicts this. Such medication will not treat the tinnitus but the associated anxiety and depression. Research shows that there is a strong link between tinnitus and stress but there is no conclusive evidence that stress causes tinnitus.[14]	management of depression and anxiety. Anxiolytics and antidepressants have been removed from the management section of the scope.
Audiology, Withington Community Hospital	3	61	Will any considerations be made for children under 5? We are aware of some children of communicative age (3+) that have commented or complained about "noises in the ears" or increased sound intolerance. We are unsure why the minimum age is 5.	Thank you for your comment. We have removed 'over 5' to ensure that those under 5 are also covered by the guideline.
Audiology, Withington Community Hospital	3	63	Will patients with misophonia or phonophobia be considered? Often cases of misophonia or phonophobia are referred to us from those who use "hyperacusis" as an umbrella term.	Thank you for your comment. Misophonia or phonophobia would be included under hyperacusis.We have mentioned hyperacusis as those patients may not be able to benefit from certain treatments. We have made this a little clearer by removing hyperacusis from the specific considerations to the equality considerations part of the scope and

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				have broadened this to include 'sound sensitivities, such as hyperacusis (intolerance to every day sounds that cause significant distress and affects day-to-day activities)'.
Audiology, Withington Community Hospital	4	88	We feel the following management options should be considered: mindfulness; meditation; relaxation, physiotherapy (for somatic tinnitus or associated muscular skeletal issues).	Thank you for your comment. Mindfulness, meditation and relaxation may be included under self-management, which has been moved to the 'providing information' area of the scope'. This will be explored with the guideline committee at the development stage of the guideline.
Audiology, Withington Community Hospital	4	104	We think that if hyperacusis is not considered in the scope of this document then it should be considered in a separate document.	Thank you for your comment. Management of hyperacusis may be considered for future NICE guideline topics. New topics are chosen by the Department of Health and Social Care or NHS England.
Audiology, Withington Community Hospital	7	168	Combination hearing aids and sound generators are two completely different things. We feel their clinical and cost effectiveness should be considered separately.	Thank you for your comment. We have rewritten the questions to make this clearer..

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Audiology, Withington Community Hospital	7	175	Does mindfulness encompass relaxation techniques?	Mindfulness and relaxation may be included under self-management, which has been moved to the 'providing information' area of the scope. This will be explored with the guideline committee at the development stage of the guideline.
Audiology, Withington Community Hospital	7	179	The use of betahistine for tinnitus is controversial. Some papers have already disproved its effectiveness	Thank you for your comment. We will ascertain the clinical and cost effectiveness of the interventions during development of the Guideline.
Audiology, Withington Community Hospital	7	181	The use of ginko biloba for tinnitus is controversial. Some papers have already disproved its effectiveness	Thank you for your comment. We will ascertain the clinical and cost effectiveness of the interventions during development of the Guideline.
Audiology, Withington Community Hospital	9	217	In the "other therapies" box, we think relaxation, physiotherapy and alternative therapies should be considered.	Thank you for your comment. Relaxation and physiotherapy may be included under self-management, which has been moved to the 'providing information' area of the scope'. This will be explored with the guideline committee at the development stage of the guideline. Self-help is taken to mean measures that are initiated by patients themselves. As we have limited time to produce the

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				guideline we have not prioritised this area for inclusion in the scope.
BAAP (British Association of Audiovestibular Physicians)	General	General	The groups to be covered include children over 5, young people and adults. Tinnitus is not uncommon in children and its effect on children can be different to that on adults. For instance, it could affect their concentration, social interaction and school performance. As such on the assessment section, impact on schooling/academic performance and social interactions in children could be included. This should also be reflected in the outcome section to see if there has been an improvement in these areas. Apart from this, the document looks quite comprehensive	Thank you for your comment. We have removed 'over 5' to ensure that those under 5 are also covered by the guideline. Specific outcomes will be discussed by the guideline committee when developing the protocols for the evidence review.
British Academy of Audiology	General	General	The draft scope suggests that the guidelines will be published in 2020. We have reservations about this long time scale, especially given the variation in service provision for tinnitus across the country. We would fully support a more accelerated timescale for publication/implementation if this could be achieved.	Thank you for your comment. This is the standard timescale for guideline development.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Academy of Audiology	3	61	The scope suggests that only children over the age of 5 will be covered in the guidelines. Is there a reasoning behind the exclusion of those under 5 years of age. What will the guidelines suggest happens with children referred into tinnitus services who are under the minimum age range?	Thank you for your comment. We have removed 'over 5' to ensure that those under 5 are also covered by the guideline.
British Academy of Audiology	4	103	The draft scope suggests that people with comorbid conditions such as depression and anxiety will not be covered by this guideline. We suggest that there is a close relationship between anxiety and tinnitus, including in children, and managing the anxiety may well often significantly alleviate the tinnitus severity. For this reason we feel this group should be included, if only to offer recommendations for identification of the presence of these comorbidities and possible routes for onward referral.	Thank you for your comment. We are not excluding people with anxiety and depression. We will be covering the assessment of the psychological impact of tinnitus. We are not covering the management of depression and anxiety as there are other NICE guidelines covering this area which we can cross-refer to.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	1	19	Research on current treatments is also ongoing	Thank you for your comment this has been amended in the scope.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	2	41	Should extend to tertiary centres too	Thank you for your comment. We have changed this to 'Healthcare professionals providing NHS-commissioned services' to cover all relevant settings.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	3	64	Most tinnitus patients have cognitive difficulties so this is not a special consideration. Perhaps what was meant here was people with learning disability?	Thank you for your comment. We have changed this to include learning disability and cognitive impairment". We have used the term 'cognitive impairment' to cover people with any medical issue which affects their cognitive ability.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	3	69	Need a diagnostics section first	Thank you for your comment. We are covering diagnosis under our sections on assessment and further investigations. Some of these will be in primary care.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	3	72	Add – using validated tinnitus questionnaires	Thank you for your comment. Validated questionnaires will be included where appropriate. These may not be the only forms of assessment and this will be discussed by the guideline committee during development.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	3	75	Tinnitus "sound matching" is not an objective measurement. Suggest changing to subjective tinnitus match tests (in reality hardly ever used in the clinic setting)	Thank you for your comment, we have deleted 'objective' from the scope.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	3	76	Add blood tests (in selected cases).	Thank you for your comment. Blood tests results would not affect management of the tinnitus. So we do not consider that this is needed. We are unable to cover all areas of tinnitus diagnosis and management and so have prioritised the areas where we feel that a

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				review of the clinical and cost effectiveness evidence is most valuable.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	4	80	Add CTA and MRA (in selected cases)	Thank you for your comment. These have not been excluded as they will be included in imaging. Please note that the terminology 'imaging' has replaced 'radiological investigations' in the scope.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	4	81	Sleep hygiene should be listed, particularly as sleep is listed as a main outcome.	Thank you for your comment. Sleep hygiene may be included under self-management strategies, which has been moved to the 'providing information' area of the scope.'This will be explored with the guideline committee during the development stage of the guideline.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	4	82	Add signpost to BTA (and other local and national charities/support) and local support groups	Thank you for your comment. We do not signpost other organisations within the scope document.
British Society of Audiology Tinnitus and	4	84	Hearing aids and assistive listening devices (when required)	Assistive listening devices other than hearing aids are not included in the scope because we are only considering devices which are being offered because

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Hyperacusis Special Interest Group				of a patient's tinnitus. Patients with severe or profound hearing loss will be offered these devices regardless of whether they have tinnitus or not. We have included hearing aids in the scope as there is the possibility of prescribing these for patients with tinnitus and hearing loss whose hearing loss alone didn't require a hearing aid.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	4	85	Sound therapy here should be more defined to include behind-the-ear devices, and non-wearable sound generators.	Thank you for your comment. We agree these all may be included under the umbrella of sound generators. The guideline committee will decide on which interventions will be included when developing the protocols for the evidence review.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	4	86	Tinnitus programming devices is not meaningful. Reprogramming implies a known mechanism of effect and that of 'reprogramming could be hypothesised for all devices. This needs to either de removed, or the proposed mechanism of other management approaches also need to be included. 'Reprogramming' speaks more of marketing than anything.	Thank you for your comment we have amended the terminology to 'tinnitus neuromodulation devices'

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	4	88	Consider Solution-Focused Approach (not just cognitive behavioural therapy)	Thank you for your comment. The proposed wording does not limit us to cognitive behavioural therapy and the guideline committee will discuss this at the development stage of the guideline.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	4	89	Clarify this as 'client-centred' counselling.	Thank you for your comment. We think that all counselling is 'client centred' therefore do not need to specify this.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	4	90	Already covered by a Cochrane review?	**Thank you for your comment.** Thank you for your comment. We have removed ginkgo biloba from the scope. Stakeholder comments indicated that ginkgo biloba is not the only complimentary medicine used for tinnitus. As the guideline can only cover a limited number of topics for evidence reviews we considered that it would be inconsistent to include only ginkgo biloba and complementary therapies should not be prioritised over other topics in the scope.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	4	91	Not clear why these drug specifically, rather than a broad 'drugs' category. As much not 100% clear where Z drugs, beta blockers, antipsychotics etc. would fit.	Thank you for your comment. Because of limited time available we have prioritised only those interventions most commonly used or where we feel that a review of the clinical and cost effectiveness evidence is most valuable.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	6	142	Guidance on referral from all stages of the pathway required.	Thank you for your comment. This question is not limited to any specific part of the patient pathway.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	6	146	Diagnostic and measurement assessments?	Thank you for your comment. The draft questions in the scope will be used to develop more detailed review questions which will be more specific.
British Society of Audiology Tinnitus and Hyperacusis	6	148	Clinical and cost effectiveness. Doe this include indicators and risks	Thank you for your comment. The indications are covered by question 1.1. The guideline committee will decide on the most important outcome measures,

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Special Interest Group				such as risks, when developing the protocols for the evidence review.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	6	159	..and in what formats	We are not sure what your comment means in relation to MRI and so are unable to provide a response.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	6	160	Add What is the clinical and cost effectiveness of CTA/MRA to investigate the cause of tinnitus? What is the clinical and cost effectiveness of blood tests to investigate the cause of tinnitus	Thank you for your comment. These have not been excluded as they will be included in imaging. Please note that the terminology 'imaging' has superseded 'radiological investigations'.Blood tests are not included as the results would not affect management of the tinnitus. We are unable to cover all areas of tinnitus diagnosis and management and so have prioritised the areas where we feel that a review of the clinical and cost effectiveness evidence is most valuable.
British Society of Audiology Tinnitus and Hyperacusis	7	3.6	Add change in validated tinnitus questionnaire scores	Thank you for your comment. We may be looking at questionnaires, the guideline committee will decide on this during the protocol development stage. However we would only include validated questionnaires.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Special Interest Group				
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	7	172	Add What is the clinical and cost effectiveness of sound therapy – wearable sound generators –v- desk top devices –v- free downloadable apps.	Thank you for your comment. The guideline committee will decide on the detail of the interventions to examine when developing the protocols for the evidence review.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	7	179	Instead of the current final 4 questions we would suggest there are two broad questions about 'drugs' (e.g. betahistine, antidepressants etc.) and supplement products (e.g. gingko, zinc..)	Thank you for your comment. Because of limited time available we have prioritised only those interventions most commonly used or where we feel that a review of the clinical and cost effectiveness evidence is most valuable**.** We have removed ginkgo biloba from the scope. As the guideline can only cover a limited number of topics for evidence reviews, based on stakeholder feedback we do not consider that complementary therapies should be prioritised over other topics in the scope.
British Society of Audiology Tinnitus and Hyperacusis	7	185	The list of main outcomes should include '**tinnitus intrusiveness'**.	Thank you for your comment. We have amended the list of outcomes to include the change in subjective perception of tinnitus and change in the impact of tinnitus. Please note that the list of outcomes is not

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Special Interest Group			The global tinnitus community has recently been involved in a project to identify how sound-, psychology- and drug-based tinnitus treatments should be commonly assessed before and after treatment. There now exist recommendations for a minimum standard of outcomes selected on the basis that they are: i) directly relevant to patients with tinnitus, to the healthcare professionals giving the treatment, and to the researchers designing the trial, ii) directly relevant to how the treatment is supposed to be working, and iii) are expected to be very sensitive to change during the treatment. See: http://tinnet.tinnitusresearch.net/index.php/recommendations See: Hall DA et al. Trends Hear. 2015 Jan-Dec; 19: 2331216515580272. The draft scope would therefore be well advised to consider these in their list of outcomes, especially '**tinnitus intrusiveness'** which was recommended	final and will be explored by the guideline committee at the protocol stage of the guideline development.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			irrespective of the type of tinnitus treatment in question.	
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	7	189	Tinnitus severity is not meaningful, it merely expresses the magnitude of complaining. It does not explain the dimension of complaint on which severity should be assessed. This means that there are limitations with this construct as a main outcome, in the way it is current phrased. In most instances, when researchers have used 'tinnitus severity' they are actually referring to 'the impact of tinnitus' as reported by the patient. It would be advisable to use this alternative wording: **Change in the impact of tinnitus**	Thank you for your comment. We have amended the list of outcomes to include the change in subjective perception of tinnitus and change in the impact of tinnitus. This list is not comprehensive; outcomes will be discussed by the guideline committee.
British Society of Audiology Tinnitus and Hyperacusis Special Interest Group	8	210	This reference is out of date as of 2017.	Thank you for your comment, we have updated this.
British Society of Audiology Tinnitus and Hyperacusis	9	217	In the final box, hearing aids+sound generators+counselling is another combined therapy.	Thank you for your comment,This is now covered by the box "combined therapies and devices"..

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Special Interest Group				
British Tinnitus Association	General	General	There is no discussion of subjective tinnitus measures, which are the most common measures used, there aren't any objective measures The document confuses the terms 'objective' and 'subjective' throughout for example; sound matching isn't objective (line 75), the document later describes under outcomes 'change in subjective tinnitus loudness' (line 188)	Thank you for your comment, we have deleted 'objective' from the scope.
British Tinnitus Association	General	General	There is no mention in assessment or management of sleep or any subjective testing (which is the most common), yet sleep is an outcome (line 193) how will this be 'covered'?	Thank you for your comment. Sleep may be included under self-management strategies, which has been moved to the 'providing information' area of the scope.'This will be explored with the guideline committee during the development stage of the guideline.
British Tinnitus Association	1	19	Should be amended to include research into existing treatments too, e.g. 'Research on existing and possible new treatments continues.'	Thank you for your comment this has been amended in the scope.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Tinnitus Association	3	64	The meaning of cognitive difficulties and relation to this point is unclear	Thank you for your comment. We have changed this to cognitive impairment. We have used the term 'cognitive impairment' to cover people with any medical issue which affects their cognitive ability.
British Tinnitus Association	3	69	Diagnosis of tinnitus is not here and should be included, also primary care interventions in assessment and diagnosis is not present	Thank you for your comment. We are covering diagnosis under our sections on assessment and further investigations. Some of these may be delivered in primary care.
British Tinnitus Association	4	82	Does self-management need to be more precisely defined as this means very different things to different people – should self-help also be included as a separate term?	Thank you for your comment. We have moved self-management to come under the providing information part of the guideline. In the scope self-management refers to strategies provided by healthcare professionals in collaboration with patients. The strategies to be included will be considered with the guideline committee when developing the protocols for the evidence review. Self-help is taken to mean measures that are initiated by patients themselves. As we have limited time to produce the guideline we have not prioritised this area for inclusion in the scope.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Tinnitus Association	4	85	Seems strange that 'tinnitus reprogramming devices' are included. This is not a term in widespread use. Also assuming that devices such as acoustic neuromodulation are included in this term, then these would not be viewed by the manufacturers as 'sound therapy.'	Thank you for your comment. We have amended the terminology to 'tinnitus neuromodulation devices'
British Tinnitus Association	4	91, 92, 94	Confusing as to why these drugs have been singled out. Would it be better to ask one question around drugs licensed for tinnitus?	Thank you for your comment. Because of limited time available we have picked prioritised only those interventions most commonly used or where we feel that a review of the clinical and cost effectiveness evidence is most valuable . We need to list the drugs that we are including in order to define and limit our databases searches.
British Tinnitus Association	4	102	This will not always be possible, e.g. if a hearing aid is prescribed to treat the hearing loss and thereby ameliorating the tinnitus	Thank you for your comment. Management of hearing loss is covered by the NICE Hearing Loss guideline currently in development, however we will look at how hearing aids can help to alleviate the symptoms of tinnitus.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Tinnitus Association	4	103	It is not always possible to untangle these from the tinnitus. There will always be some treatment of depression anxiety via treating the tinnitus	Thank you for your comment. We recognise that depression and anxiety may be related to tinnitus. We are not covering the management of depression and anxiety, however, as there are other NICE guidelines covering this area which we can cross-refer to.
British Tinnitus Association	4	88, 89	These terms seem to overlap. Would it be better to be more specific e.g. CBT, client centred counselling, etc.	Thank you for your comment. The draft questions in the scope will be used to develop more detailed review questions which will be more specific.
British Tinnitus Association	6	146	Not sure this question is answerable in the current format	Thank you for your comment. The draft questions in the scope will be used to develop more detailed review questions which will be more specific.
British Tinnitus Association	6	172	See comment 6	Thank you for your comment. We have amended the terminology to 'tinnitus neuromodulation devices'.
British Tinnitus Association	8	210	This has been updated and the 2017 review should be referenced	Thank you for your comment, we have updated this.
CSF Leak Association	General	General	The CSF Leak Association welcomes the opportunity to comment on this draft scope. We work to raise the profile and support understanding of cerebrospinal	Thank you for your comment.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			fluid (CSF) leaks. We also aim to provide support and advice for sufferers, their families and supporters, and a resource for the medical profession.	
CSF Leak Association	3	73	Tinnitus and hyperacusis and indeed hearing impairment may, in some cases, be due to a CSF leak. The nature of the tinnitus may be highly variable, e.g. constant 'buzzing', pulsatile 'whooshing'. The mechanism for this symptom in patients with intracranial hypotension due to a CSF leak is unknown but may be due to traction on the cranial nerves. It is important to distinguish these cases are they are potentially reversible by treatment of the underlying leak. We would prefer to see an emphasis on taking a complete and thorough history when undertaking an initial assessment of tinnitus and noting that tinnitus accompanied any of the following should raise the assessing clinician's suspicion of a CSF leak and prompt referral to a neurologist (bearing in mind that atypical presentations are possible): • headache with a postural component • nausea	Thank you for your comment. We will discuss this when developing recommendations. Identification of red flags will be covered by "Identifying symptoms and features that need further investigation and specialist treatment" which is in the scope.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			• vomiting • double vision • pain behind eyes • photophobia • interscapular pain • a recent or not so recent history of dural puncture or trauma e.g. fall or whiplash	
CSF Leak Association	4	80	The wording should be changed so that 'radiological' is replaced with the word 'imaging' as only CT is a radiological investigation. MR imaging of the head is useful in the diagnostic workup of patients suffering with tinnitus where there is a suspicion of a CSF leak. Signs of intracranial hypotension may be seen on brain MRIs in some, but not all, patients with a CSF leak. A brain MRI read as 'normal' does not rule out a CSF leak and a full spine MRI should also be considered in these patients.	Thank you for your comment. We have amended the scope document to state 'imaging' rather than 'radiological investigations'. The guideline committee will keep this information on MR imaging in mind when they are developing the guideline.
CSF Leak Association	4	88	We recognise the, at times, profound impact of tinnitus and hyperacusis on a patient's well-being and we welcome consideration of psychological therapies as	Thank you for your comment. We are including tinnitus whatever the cause.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			part of the scope. We would prefer if this were to be expanded to include the benefit and outcomes of therapy when the tinnitus and hyperacusis is secondary to another condition, e.g. CSF leak, due to the higher degree of complexity involved.	
CSF Leak Association	6	142	See comment 2	Thank you for your comment. We will discuss this when developing recommendations. Identification of red flags will be covered by "Identifying symptoms and features that need further investigation and specialist treatment" which is in the scope.
CSF Leak Association	6	159	See comment 3	Thank you for your comment. We have amended the scope document with 'imaging' rather than 'radiological investigations'. The guideline committee will keep this information on MR imaging of the head in mind when we they are developing the guideline.
CSF Leak Association	7	147	See comment 4	Thank you for your comment. We are including tinnitus whatever the cause.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
ENT UK	4	102	Does this exclude the role of surgery in managing conditions where tinnitus may be a major symptom such as otosclerosis, Meniere's disease	Thank you for your comment. Yes this does exclude surgery. We have to prioritise our work to the time available and are therefore unable to cover management of underlying health conditions, of which tinnitus may only be a part.
ENT UK	4	102	We feel these should be considered as they contribute to comorbidities and hence cost	Thank you for your comment. We have to prioritise our work to the time available and are therefore unable to cover management of underlying health conditions, of which tinnitus may only be a part.
ENT UK	4	103	Again these are relevant comorbities which should be considered in view of cost implications	Thank you for your comment. We are not excluding those with anxiety and depression. We will be covering the assessment of the psychological impact of tinnitus. We are not covering the management of depression and anxiety because there are other NICE guidelines covering this area which we can cross-refer to.
National Community Hearing Association	General	General	We welcome the proposal to develop a NICE guideline on tinnitus but have some serious concerns about this draft scope • the non-inclusive nature of the proposed guideline development committee which,	Thank you for your comment. We have given responses to your specific comments. We aim to recruit a guideline committee that reflects the professionals that assess and manage tinnitus in the NHS. They will sign up to following NICE

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			combined with paucity of evidence, risks skewing the recommendations and wasting NHS resources • use of inaccurate framing data • over-estimation of need • over-looking the primary presentation and intervention • over-looking the community service • not recognising that first presentation is usually in primary care or community audiology and may not require onward referral • a lack of clarity about the interconnectedness of the draft guideline on *hearing loss in adults: assessment and management* and this draft scope. We are very happy to expand further on our comments if this would be helpful. **Guideline Development Committee**	processes and methods as outlined in the NICE guidelines manual, including the conflicts of interest policy. We have robust methods for guideline production and this includes the stakeholder consultation on the draft guideline. This stage acts as an additional extra check that the recommendations are sensible and it is usual for amendments to recommendations to be made where stakeholders present good reasoning for changes.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Getting Committee membership right is always an important part of the NICE guideline development process. With tinnitus, this is more important than ever as we anticipate that NICE will find limited evidence for this topic and/or is likely to grade evidence as low to very low quality. This means the role of Committee members will be critical in identifying best practice and making recommendations. It is vital therefore that the Committee submits itself to the highest standards in these regards, so that process weaknesses do not undermine the validity of its recommendations when it publishes its draft guideline in 2019. This means ensuring that the Committee is not compromised at any stage through robust identifications of conflicts of interest, and each member rigorously and constructively challenges gaps in evidence and what might be presented by particular professional perspectives as best/routine practice.	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			As currently constituted the Committee members might not be a representative sample of the workforce nor see a representative sample of the tinnitus population in their own practice. If that is not rectified the inherent bias should be corrected for. To demonstrate this we would ask NICE to ensure that all Committee members: ▪ declare all conflicts of interest, including whether they are members of specific sector membership organisations (including any recently expired memberships) – this is important to ensure the confidence of external and non-represented stakeholders ▪ are reminded of the importance of not introducing any sector or organisation specific content into the guideline development process ▪ acknowledge and take account of the changing landscape of service delivery in the NHS. For example that they do not disregard the increasing role of Hearing Aid Dispensers (HADs) and	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			community hearing care providers (including independent sector providers) in the delivery of NHS hearing services in 50% of CCGs, and do not make assumptions about the scope of practice of HADs or unregulated audiology staff in hospital settings ▪ are aware that any claims that are made will be documented and published so that stakeholders can assess and challenge their validity Such discipline will build trust amongst stakeholders that NICE recommendations have been robustly tested and are valid. We appreciate that NICE has a conflicts of interest policy and other processes in place to mitigate against the risks highlighted above and apologise for labouring the point. However this is because, following a recent guideline, we are not as confident as we once were in the NICE processes for ensuring that final guidelines serve the best interests of patients, the NHS and taxpayers. We have experience of a draft NICE guideline inadvertently facilitating 'upcoding[i] or	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			embracing skewed guidance which campaign groups might support but no NHS commissioner could, or should, as they would waste NHS resources. This undermines the validity of NICE guidelines, which we are very keen to support and publicise as the evidence-based 'gold standard'.	
National Community Hearing Association	General	165 - 166	"What is the clinical and cost effectiveness of hearing aids for people with hearing loss and tinnitus?" We do not think this is a suitable question for this guideline and suggest it is removed or restricted to a literature search question. People are not fitted with hearing aids for tinnitus, they are fitted with hearing aids for hearing loss. The NICE guideline on *hearing loss in adults: assessment and management* already addresses the cost-effectiveness of hearing aids in a NHS setting and the population it covers, adults with hearing loss, already includes those with hearing loss and tinnitus because of how this cohort is likely to present.	Thank you for your comment. People may opt for hearing aids where they have both hearing loss and tinnitus but may not where they had hearing loss alone, Many patients who present with tinnitus are unaware that they have a hearing loss and may be resistant to the idea of trying a hearing aid. Looking at the clinical and cost effectiveness of hearing in those with hearing loss and tinnitus can help us guide patients in the decision making process. We are not restricting the pathway to hospital led services and will be considering primary care.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			The marginal utility weights for people with and without tinnitus therefore might be something the Committee wants to include out of interest but it is not clear that this would be the best use of NICE resources as it is unclear what value this would add to the existing body of knowledge. We feel that if NICE were to decide to use its resources to undertake a new cost effectiveness analysis this should be focussed on pathways mapped out in a real world setting across the range of NHS provision, not only hospital led services (see Comment 1).	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
National Community Hearing Association	1	20-25	**Using Accurate Framing Data in Scope** Our understanding, from experience, is that NICE does not always check or change data between the guideline scope and final draft guideline so the protocol is crucial in framing the final guideline. In the past NICE has claimed there is no reason to amend data in the guideline scope because any issues will be picked up during guideline development and that the final guideline will provide a summary of the evidence and present a more comprehensive picture. Our experience show that this is not invariably the case and that statistics tend not to be updated at a later date but are instead 'lifted and dropped' untested into the final guideline. This is compounded by the fact that stakeholders generally view the final guideline scope as an evidence-based document and, understandably, frame and interpret subsequent review questions in that context (e.g. if NICE states that 6 million people have	Thank you for your comment. We have changed the figure to that reported by NHS England in its Commissioning Services for People with Hearing Loss: A Framework for Clinical Commissioning Groups document, available at:https://www.england.nhs.uk/wp-content/uploads/2016/07/HLCF.pdf. In response to point 3; the research that the scope is referring to is the following study: https://bmchealthservres.biomedcentral.com/track/pdf/10.1186/s12913-017-2527-2?site=bmchealthservres.biomedcentral.com,

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			tinnitus, then the proposed questions and priorities will be read in that context). For these reasons it is important that NICE reviews the data in this tinnitus scope. The fact NICE currently appears to be relying on campaign organisation statistics rather than hard data is concerning when NICE is looking to develop a cost-effective guideline for the NHS. As a minimum we would suggest reviewing the statistics and statements between lines 20 and 25 as below : **1. Current text, lines 20-21*, "Tinnitus occurs in approximately 6 million people in the UK (10% of the population)"*** **Recommended alternative: *"It is estimated that between 10 percent and 15 percent of adults will have tinnitus, with 3 percent of adults likely to require a clinical intervention for their tinnitus"*** (Reference, page 12, NHS England, 2016, Commissioning Services for People with Hearing	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Loss: A Framework for Clinical Commissioning Groups, https://www.england.nhs.uk/wp-content/uploads/2016/07/HLCF.pdf) It may well be appropriate for campaigning organisations to present the prevalence of tinnitus as 10% but this, in our view, is unhelpful in a NICE scoping document because it misframes the case and is unlikely to lead to a robust and credible final NICE guideline which will support effective NHS service planning. Although we do not expect the Committee to do a literature review at this stage, we can provide the following detail. The likely overall prevalence of tinnitus is between 10.1% and 14.5%[ii], but only 20% of people with tinnitus are likely to find their tinnitus bothersome enough to seek help[iii] – i.e. between 2% and 3% of the, typically adult, population might seek/require help for tinnitus. This provides an estimate of about 1.5 million people rather than 6 million.	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			This is why we feel the NHS England text recommended above will better reflect population need than the text in the existing NICE guideline scope. We hope using this alternative will also help minimise the risk of any economic analysis or research questions missing significant heterogeneity in "the tinnitus population" - e.g. a 2014 Cochrane review notes that tinnitus can resolve spontaneously within minutes to weeks, but is to be considered chronic – therefore less likely to resolve spontaneously – when experienced for three months or more[iv]. 2. **Current text, lines 22-23, "Around 1% of the population has tinnitus that severely affects quality of life"** ▪ **Recommended alternative: "Around 0.5% of the population has tinnitus that severely affects quality of life"** For the reasons given above we think it is important that the NICE Committee develops this guideline	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			(including framing questions and search strategies) based on realistic estimates of population need (not campaign literature!) Coles (1984) is often cited to claim that the robust National Study of Hearing found 0.5% of the population suffered from tinnitus that severely affected their life[v]. Coles (1984) however reported 0.5% as part of a pilot study[vi], not the main arm of the National Study of Hearing as is often claimed[vii]. Therefore it is possible that even 0.5% is an overestimate. This NICE guideline is the first time we have seen that estimate doubled and do not understand where this estimate has come from. If the Committee does not want to use the suggestion above, or would like to include a more comprehensive breakdown of the tinnitus population to inform their work, they could use: ▪ *Of the 10% of people that might report tinnitus, 2.8% will describe it as moderately annoying, 1.6%*	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			as severely annoying and 0.5% will report it severely affects their ability to lead a normal life [viii]. This would also be our preference as we believe it will help develop a more practical and evidence-based NICE guideline. 3. **Current text, lines 24-25 "Recent study data show the cost of tinnitus treatment to the NHS to be £750 million per year"** **It is not clear where this figure has come from and whether that is a reliable source (e.g. NHS Digital). We would suggest omitting this, if it cannot be substantiated.** **Overestimating Population Need** Normally we would not comment on statements like this in a draft scope but, after studying the NICE *hearing loss in adults: assessment and management* draft guideline, we now realise how important it is to make certain the Committee ensures the data it uses is reviewed by an independent economist at NICE to	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			ensure the final guideline is not left open to challenge. This will be more important than ever in the tinnitus guideline as the underlying evidence-base is unlikely to be robust.	
National Community Hearing Association	2	34 - 35	Whist we fully support the guideline aim of reducing unwarranted variation in assessment and management of tinnitus, it is important to note that one of the major barriers to addressing tinnitus in the past has been how it has been defined and who has defined it.	Thank you for your comment. After reviewing the clinical and cost effectiveness evidence the guideline committee will discuss possible recommendations taking into account current systems and implementation considerations. We will take into account the NICE hearing loss guideline and ensure that the Tinnitus guideline complements rather than duplicates this work.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Too often definitions have been defined by lobbying and campaign groups rather than public health or epidemiological experts and this has overestimated the scale of tinnitus. Such overestimation can, of itself, act as a barrier to NHS commissioners taking effective action to commission appropriate services for fear of being overwhelmed by demand This is why, as noted in Comment 2 above, it is important for NICE to carefully define and describe need throughout its guideline, and not to be caught out by misinterpretation or overegging of statistics in this particular area. **First-Line Presentation/Intervention** Realism is very important to ensure that providers in straightened circumstance are *not* able to use this tinnitus guideline to generate unnecessary demand or create new pathways simply to generate additional revenue as this will lead to future distortions in NHS resource allocation.	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			As noted above many people with tinnitus will not come forward for support, however it cannot be assumed that this is always an indication of unmet need. Moreover, importantly the vast majority of people with tinnitus are likely to be seen in routine adult hearing care; for example 75% of people with hearing loss might experience tinnitus and addressing the hearing loss might help resolve their tinnitus[ix]. A significant proportion will be reassured and not require further support. This will compare with 20% to 30% of people who will report tinnitus with normal hearing[x]. In a real world setting this will mean the majority of the population with tinnitus will actually be served using the NICE guideline on *hearing loss in adults: assessment and management* (which includes tinnitus with hearing loss). As the tinnitus guideline will cover people both with and without hearing loss, there is likely to be significant overlap with the NICE guideline on *hearing*	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			loss in adults: assessment and management and it is important not to double-count. It is not clear from the draft scope whether NICE has fully addressed how best to focus its work to minimise duplication. We hope the final guideline scope will address the above concerns. Most of these were raised at the 'guideline scope workshop' stage, so NICE will have the feedback on record and will hopefully choose to revisit and act on them.	
National Community Hearing Association	2	41	**Community Hearing Services** As noted above, it is very important for the credibility of the guideline for it to be as thorough and evidence-based as possible. This is why we were surprised to see the scope apparently over-looking the community workforce of HADs/audiologists and a key delivery arm of NHS hearing services.	Thank you for your comment. We recognise the importance of community providers. We have amended the scope to say 'Healthcare professionals providing NHS-commissioned services' so that all relevant settings are covered.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			To correct this, we urge NICE to **correct line 41 to read** ▪ "Healthcare professionals in primary, **community** or secondary care, commissioners and providers (of relevant services)" Without referencing the community here, (compounded by not having community provider input to the guideline development Committee), the sector is likely to be misinterpreted as consisting only of the traditional NHS model of primary care/GPs and hospitals and, in our experience, such a misinterpretation is then likely to be read-across into the final guideline.	
National Community Hearing Association	4	101	We agree that "managing hearing loss without tinnitus" should not be covered. This is covered by the NICE guideline on *hearing loss in adults: assessment and management.* That guideline also covers people with hearing loss and tinnitus. Given that the eligible population does not divide easily between these two NICE guidelines, we believe that the interrelationship	Thank you for your comment. We will ensure that we do not duplicate the work on the hearing loss guideline. After the guideline is published, a pathway of the patient's care will be created on the NICE website, which will show the interrelationship between the two guidelines.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			between the two guidelines needs to be made clearer. See also comment 3 above.	
National Community Hearing Association	6	142 - 145	We are concerned about similarities between the development of this guideline and the early development stages of the partner NICE guideline on *hearing loss in adults: assessment and management.* In the latter case NICE chose to ignore early feedback which in turn led to gaps in the final draft guideline as a result In this case this risk is particularly high in points 1.1 and 1.2 on page 6 lines 142-145. The guideline development Committee needs to - recognise and be clear that the vast majority of tinnitus patients will visit a GP or report tinnitus during an audiology visit for hearing difficulties e.g. during history and symptom taking at an appointment for age-related hearing loss - take care that it avoids the risk of falling into the 'trap' of the "medical model of care".	Thank you for your comment. These questions are not limited to any specific part of the patient pathway. We recognise the importance of G.P. input and plan to recruit two G.P.s to the guideline committee as well as two Audiologists/Audiological Scientists. Recommendations will be made following a thorough search of the evidence in line with the protocol and the guideline committee will decide on the relevant settings for each review.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			This latter weakness in the guideline development process for *hearing loss in adults: assessment and management* led to key literature on referral routes being excluded because literature search questions were framed around "medical led questions". As a result review questions did not always reflect a real world setting which has left the guideline open to challenge and in consequence means the evidence will need to be reviewed. For this guideline therefore we would ask • for it to be made explicit that the vast majority of people with tinnitus are likely to access care from a GP or audiology in the first instance, not all of whom will require onward referral • that the Committee shapes its guideline questions to capture research that might have taken place across the range of clinical settings to avoid missing relevant literature to inform its work and recommendations.	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Neuromod Devices Limited	1	17	The draft scope describes the fact that the type and severity of tinnitus varies from person to person, but there is no later reference to subtypes of tinnitus. We believe that further attention should be given to the different known subtypes of tinnitus, as the diagnostic and treatment options should be designed to take subtypes into account: For example, pulsatile and non-pulsatile tinnitus have different underlying causes and can be treated differently. Somatic and non-somatic tinnitus can be assessed via physical therapy and manipulation. Tonal and atonal tinnitus may be differentiated from one another. You refer to, and we welcome your inclusion of tinnitus with hyperacusis in the scope. You refer to managing hearing loss without tinnitus as being out of scope, however the scope document does not cover reviewing the subtypes of tinnitus associated with noise induced hearing loss, with hearing loss or with hyperacusis. We believe that each of these subtypes are important and should be addressed comprehensively.	Thank you for your comment. We are planning to include pulsatile tinnitus. Depending on the individual question the guideline committee will decide which types of tinnitus need to be stratified in the review.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Neuromod Devices Limited	1	24	Tinnitus may also be associated with loss of productivity as the distressing symptoms of tinnitus may cause loss of employment or income, particularly if the working environment is a noisy environment that may have caused or continue to exacerbate the tinnitus experience. We believe it is important to incorporate consideration of the impact of tinnitus on the ability to work and carry on activities of daily living.	Thank you for your comment. For each review question covered by the guideline, the guideline committee will consider whether ability to work and ability to carry out activities of daily living are critical or important outcomes to include in the review protocol for the question. Consideration of the impact of tinnitus on ability to work and carry on with daily activities might also be picked up through health related quality of life outcomes (for example the EQ-5D health related quality of life questionnaire includes ability to carry out daily activities as one of its five dimensions). For original health economic analyses conducted for clinical guidelines, NICE uses a National Health System and Personal Social Services perspective and does not include the costs of loss of productivity. This is to ensure that recommendations do not discriminate against people who are not of working age (e.g. elderly or young people).
Neuromod Devices Limited	3	72	The section should include the identification of the particular subtypes of tinnitus, e.g., , pulsatile versus non-pulsatile, somatic versus non-somatic, with or	Thank you for your comment. Depending on the individual question the guideline committee will decide

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			without hyperacusis or reduced sound tolerance, with or without hearing loss, with or without noise-induced hearing loss.	which types of tinnitus need to be stratified in the review.
Neuromod Devices Limited	3	75	We believe the use of the word "objective" in this line may be misleading. All tests of tinnitus rely on the patient to communicate with the clinician, and so cannot be truly referred to as fully objective as there will be a subjective component influenced by the patient's ability to understand clinical instructions and to relay their experience to the evaluating clinician. Indeed later in Section 3.6 on page 7 lines 188 and 189 these assessments are referred to as subjective.	Thank you for your comment, we have deleted 'objective' from the scope.
Neuromod Devices Limited	3	75	Should this section include assessing Hyperacusis? e.g., by measuring the Uncomfortable Loudness Level or using validated assessments such as the Khalfa Questionnaire.	Thank you for your comment. The focus of this guideline is on tinnitus and therefore we won't be looking at assessment of hyperacusis. However, the guideline committee will consider how suitable different treatments are for patients with hyperacusis. We recognise that the inclusion of hyperacusis as a group to be given specific consideration may cause confusion so have moved it to 'equality considerations' and have broadened this to include 'sound sensitivities, such as hyperacusis (intolerance to every

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				day sounds that cause significant distress and affects day-to-day activities)'.
Neuromod Devices Limited	6	148	It is stated on page 3 line 63 that "Specific consideration will be given to people with tinnitus and hyperacusis", however, in this section there is nothing in scope to assess what is the most clinically and cost-effective method of assessing hyperacusis in patients with tinnitus. We believe that the scope should be expanded to incorporate assessments of hyperacusis and reduced sound tolerance.	Thank you for your comment. This guideline is focusing on tinnitus and therefore we will not be looking at diagnosis and management of hyperacusis. However, when reviewing the data on tinnitus, particularly the management of tinnitus, we will consider what management options are available for those with tinnitus and hyperacusis. We recognise that the inclusion of hyperacusis as a group to be given specific consideration may cause confusion so have moved it to 'equality considerations' and have broadened this to include 'sound sensitivities, such as hyperacusis (intolerance to every day sounds that cause significant distress and affects day-to-day activities)'.
Neuromod Devices Limited	6	142 and 143	This question implies that there are symptoms and features of tinnitus that do not merit further referral. Will the guideline scope provide guidance on how these patients will be managed without referral? What information should be provided by general	Thank you for your comment. We have purposefully not specified the setting in these questions. We will be making recommendations on how these patients will be managed effectively with or without referral for further investigations.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			practitioners and other primary care clinicians to patients who are deemed not to require further referral – we are aware that a large majority of patients who visit their general practitioner seeking a referral are advised to go home and learn to live with the tinnitus. We do not believe this is a cost-effective use of GP time nor that it delivers satisfactory outcomes. If the guideline determines that numerous patients do not merit referral, then the guideline scope should include recommendations on how these patients should be managed effectively in the primary care setting.	
Neuromod Devices Limited	7	172 173	Please provide more detail or explain more clearly in the scoping document what type of intervention is regarded as "tinnitus reprogramming devices" – we are not familiar with this terminology.	Thank you for your comment. we have changed this to 'tinnitus neuromodulation devices' which is a better understood term.
Neuromod Devices Limited	7	184	Please add a question to include in the scope - how will new therapeutic interventions that are introduced to the market while the guideline is being developed or after the guideline has been published be assessed? - What is the proposed process for determining whether new interventions offer cost effective improvements to the guidelines and how will the guidelines be updated	Thank you for your comment. We do a final search of the literature 6-8 weeks before we submit our first draft for consultation, to include any papers published during the guideline development phase. After publication, NICE have a process for checking new published evidence at regular intervals.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			if new interventions are determined to be more clinically and cost effective than existing approaches?	
Neuromod Devices Limited	7	185	Please include additional outcome measures in this section to reflect the overall experience of tinnitus and the impact on patients, such as Tinnitus Handicap Inventory (THI), Tinnitus Functional Index (TFI) and outcome measures related to hyperacusis such as Khalfa Hyperacusis Questionnaire. These may be best referred to collectively as Change in psychometric outcomes or may fall under change in health-related quality of life. Please ensure that it is clear that these psychometric measurement tools will be assessed, along with others that have been scientifically validated and published.	Thank you for your comment. We may be looking at questionnaires, the guideline committee will decide on this during the protocol development stage. However we would only include validated questionnaires.
Neuromod Devices Limited	7	189	We do not believe that tinnitus severity can be assessed reliably, nor that it is a meaningful assessment of the impact of tinnitus on patients. Tinnitus intrusiveness has been reliably and consistently referenced as an appropriate outcome measurement, and indeed has been confirmed as an important measure by the participants in the COMIT'ID study. Over 85% of participants said that tinnitus intrusiveness was important.	Thank you for your comment. We have amended the list of outcomes to include the change in subjective perception of tinnitus and change in the impact of tinnitus. This list is not comprehensive; outcomes will be discussed by the guideline committee.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	General	General	Comments from the Equality Impact assessment Very few children are ever referred to me – occasional older teenagers (6th form etc) children rarely present (a little like dizziness), (this is backed up with general clinical understanding I think) that this is because their 'settings' for what is unacceptable are more tolerant/still learning with regard to balance and the huge sound range of the world. Also their responsibilities for their own health is lower, less neurotic than adults, less awareness of worries that might agitate the adult population, and in having this starting point, vestibular compensation and tinnitus both settle more naturally. – however, the group that are referred to me are often children with PTSD, emotional needs, Attention deficit disorder or behavioural problems generally – again hyperacusis, misophonia and tinnitus are often tangled in children – when they do emerge they (and their parents) often need special input to turn things around. Child specialist psychology often called in……often a bigger mixed bag, much more complex than the adults, but rare referrals to me anyway…..	Thank you for your comments. The guideline committee will keep this information in mind when we they are developing the guideline. We recognise the importance of this and are in the process of recruiting a Child Psychologist onto the guideline committee.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	**3**	56	This is a very appropriate concern – the groups with profound hearing loss have reduced options for using sound therapy and learning difficulties may have reduced option for engaging with some aspects of counselling or discussion etc – in practice these groups are then encouraged to focus on what they *can* apply and this is supported (ie for learning difficulties this would be meticulous sound enrichment, for someone with a profound loss this would be more intense counselling to empower – so obviously those with *both* these presenting issues represent a significant challenge to work with)	Thank you for your comment. We have noted both of these groups in our equalities impact assessment and the needs of these groups will be considered during guideline development.
NHS England	**3**	75	Objective tests of tinnitus – (pitch match etc) as far as I understand, and in all my experience these were long ago identified as a waste of time. Apparently if you do objective tests one day, then redo them the next, the results will vary. Tinnitus perception may well alter with mood, stress, wellness levels etc – pitch match tests etc therefore currently serves no purpose for using white noise therapy (ie this is a wide band noise, not set around their reports of the tinnitus sound itself),	Thank you for your comment, we have deleted 'objective' from the scope.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			and the tests can be an unhelpful focus. It is more meaningful for patients to say 'it sounds like a bee' or 'it sounds like the ITU warning sound just before my father died' etc - as conversational assessment allows a deeper reflection on how the sound is being classified – a pitch match test does not contain any opening up for understanding the how the tinnitus is being heard emotionally, memory-wise and associations, fears for the future or offering insight into responses….however, this is debated of course by those who are interested in research….. is that for clinical time and value of clinician's input (and patient's time) pitch matching serves little use at the moment…	
NHS England	**3**	76	onwards covers these things appropriately!	Thank you for your comment.
NHS England	**4**	85	provision of sound therapy without counselling offers reduced outcomes.	Thank you for your comment. We have included sound therapy with and without counselling as management interventions. We will examine the outcomes when we conduct a thorough review of the evidence.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	**4**	90	**combined sound therapy and counselling therapy** empowers the individual to put into place a combination of three things – 1) stress management/self care, 2) sound therapy for tinnitus and 3) becoming more authoritative themselves on how they perceive the tinnitus, how they react to it and the process of bringing about a calmer response with less alarm. This helps to break the cycle at all points, helps to bring about change in a conditioned response, and is the desired approach for all tinnitus cases.	Thank you for your comment. The guideline committee will take this into account when they are developing the guideline.
NHS England	**4**	91	not aware this helps	Thank you for your comment. We will examine the clinical and cost-effectiveness of all the interventions listed in the scope.
NHS England	**4**	92	I understand a study has shown this was inconclusive	Thank you for your comment. We hope to ascertain the clinical and cost-effectiveness of the interventions included in the scope.
NHS England	**4**	93	if needed, it usually does help	Thank you for your comment.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	**4**	104	tinnitus and hyperacusis do pretty often occur side by side. (a major reason hyperacusis has set in is the monitoring of tiny internal sounds, which then leads on to the heightened perception of everything, external sounds too) Hyperacusis referrals will often reveal that they have tinnitus on questionning, and often tinnitus referrals turn out to be quite heavy duty hyperacusis cases. – this is therefore an area that ought to be vaguely mentioned, in that hyperacusis referrals may well revert to being tinnitus cases after all and vice versa.	Thank you for your comment. This guideline is focusing on tinnitus and therefore we will not be looking at diagnosis and management of hyperacusis. However, when reviewing the data on tinnitus, particularly the management of tinnitus, we will consider what management options are available for those with tinnitus and hyperacusis. We recognise that the inclusion of hyperacusis as a group to be given specific consideration may cause confusion so have moved it to 'equality considerations' and have broadened this to include 'sound sensitivities, such as hyperacusis (intolerance to every day sounds that cause significant distress and affects day-to-day activities)'.
NHS England	**6**	146	this needs to be talking therapy – only through gaining insight into the disruption it causes can an assessment be made – eg disruption to sleep, concentration, processing information, anxiety/fear in relation to the tinnitus – it is also only possible to identify the people who really do not have much of a problem by talking therapy assessment – how often, when, where etc is conversational rather than mechanical testing	Thank you for your comment. The guideline committee will keep this information in mind when they are developing the guideline.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	**6**	149	essential for all cases!	Thank you for your comment.
NHS England	**6**	165	Hearing aids if needed can offer immediate relief from tinnitus in some cases	Thank you for your comment. We will look at the clinical and cost-effectiveness of hearing aids for those with hearing loss and tinnitus.
NHS England	**6**	151 – 153	there are questionnaires, but these are not reliable. People do not understand how to answer about tinnitus without more support to detangle how/where it fits in amongst other challenges (eg sleep disruption can be caused by many factors). Also cultural differences throw up very varied styles of answering questionnaires with scoring tendancies appearing to have some cultural influence (nb Matthew tried this, and the results were hopelessly unreliable to measure distress of tinnitus) and language barriers/increasing levels of English as a second language especially in inner cities,- means increasingly, paper questionnaires do not allow equality or reliability. I think an insightful counselling session rapidly gains insight into multi-factors.	Thank you for your comment. We will look at the most clinical and cost-effective way of assessing tinnitus, and this may include a counselling session. The guideline committee will discuss this when developing the protocols for the evidence review.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	**7**	167	combination aids (ie if a programme has BOTH white noise and amplification together on same programme) don't address the hearing loss needs for good clean amplification and will result in the individual straining to hear again – best avoided. However, ALL white noise generators are now programmed in a hearing aid model that has software for amplification too, so there may be some cases where both programmes (v low white noise) and very mild indeed amplification (for mild loss) could be set on different programmes, to use in different environments/doing different tasks.	Thank you for your The guideline committee will keep this information in mind when they are developing the guideline.
NHS England	**7**	170	for near normal hearing sound therapy works well (low volume white noise) as normal hearing is preserved (very open fit) and very low levels needed that calm central gain, but do not impact on hearing everyday speech etc.	Thank you for your comment. The guideline committee will keep this information in mind when they are developing the guideline.
NHS England	**7**	181	I understand Gingo Biloba was found to be of little help….(don't know where this study is though!)	Thank you for your comment. We will ascertain the clinical and cost effectiveness of the interventions during development of the Guideline.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	**7**	182	In my experience significant help from anti-depressnats if they are needed.	Thank you for your comment. We recognise that depression and anxiety may be related to tinnitus, however, we have removed the management of depression and anxiety from this scope, as there are other NICE guidelines covering this area which we can cross-refer to.
NIHR Nottingham Biomedical Research Centre	General	185	The list of main outcomes should include '**tinnitus intrusiveness'**. The global tinnitus community has recently been involved in a project to identify how sound-, psychology- and drug-based tinnitus treatments should be commonly assessed before and after treatment. There now exist recommendations for a minimum standard of outcomes selected on the basis that they are: i) directly relevant to patients with tinnitus, to the healthcare professionals giving the treatment, and to the researchers designing the trial, ii) directly relevant to how the treatment is supposed to be working, and iii) are expected to be very sensitive to change during the treatment.	Thank you for your comment. We have amended the list of outcomes to include the change in subjective perception of tinnitus and change in the impact of tinnitus. This list is not comprehensive; outcomes will be discussed by the guideline committee.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			<table><tr><th>Sound-based treatments</th><th>Psychology-based Treatments</th><th>t</th></tr><tr><td>tinnitus intrusiveness</td><td>tinnitus intrusiveness</td><td>t</td></tr><tr><td>ability to ignore</td><td>tinnitus acceptance</td><td>t</td></tr><tr><td>concentration</td><td>mood (including feelings of anxiety and depression)</td><td></td></tr><tr><td>quality of sleep</td><td>negative thoughts and beliefs</td><td></td></tr><tr><td>sense of control</td><td>sense of control</td><td></td></tr></table> See: http://tinnet.tinnitusresearch.net/index.php/recommendations See: Hall DA, Haider H, Kikidis D, Mielczarek M, Mazurek B, Szczepek AJ, Cederroth CR. Toward a Global Consensus on Outcome Measures for Clinical Trials in Tinnitus: Report From the First International Meeting of the COMiT Initiative, November 14, 2014, Amsterdam, The Netherlands Trends Hear. 2015 Jan-Dec; 19: 2331216515580272.	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			The draft scope would therefore be well advised to consider these in their list of outcomes, especially '**tinnitus intrusiveness'** which was recommended irrespective of the type of tinnitus treatment in question.	
NIHR Nottingham Biomedical Research Centre	1	20 - 21	"Tinnitus occurs in approximately 6 million people in the UK." This claim needs clarification about whether it is referring to **any current** tinnitus (usually defined as a tinnitus lasting for more than 5 min at a time), or **any current clinically relevant** tinnitus. The distinction is very important from a patient perspective. Moreover, I know the literature well, and I'm not familiar with the source of the 6 million figure. For example, the landmark National Study of Hearing conducted in the 1980's reported an overall prevalence of 15.2% in the general UK population. This is the most robust data that is currently available. See: McCormack A, Edmondson-Jones M, Somerset S, Hall D. A systematic review of the reporting of tinnitus prevalence and severity. Hear Res. 2016 Jul;337:70-9.	Thank you for your comment. We have changed the figure to that reported by NHS England in its Commissioning Services for People with Hearing Loss: A Framework for Clinical Commissioning Groups document, available at:https://www.england.nhs.uk/wp-content/uploads/2016/07/HLCF.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NIHR Nottingham Biomedical Research Centre	1	19	"Research on possible new treatments…" should be "Research on existing and possible new treatments…"	Thank you for your comment this has been amended in the scope.
NIHR Nottingham Biomedical Research Centre	2	41	It is important to acknowledge tertiary care because there are some specialist centres with considerable tinnitus expertise in the UK.	Thank you for your comment. We have changed the text so that all relevant settings are covered. The text now reads: 'Healthcare professionals providing NHS-commissioned services'.
NIHR Nottingham Biomedical Research Centre	3	General	Throughout, the draft scope section 3.3 there is an implicit bias towards ENT/audiological components of the patient journey. I see very little that recognises and reflects activities, services or aspects of care that happen in primary care. This section seems to start with the assumption that patients have already been diagnosed with a subjective tinnitus, and that patients have undergone an appropriate medical work-up. Diagnosis of tinnitus precedes assessing the nature of the tinnitus, and this essential first step (often undertaken at GP level) is missing from the draft scope.	Thank you for your comment. We have not specified the setting as it may vary between different regions and we expect that many of the areas listed in the scope will be performed in primary care. Due to the importance of having primary care input we are trying to recruit two GPs onto the guideline committee.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NIHR Nottingham Biomedical Research Centre	3	General	It is unclear whether the draft scope acknowledges clinically important subtypes of tinnitus are to be considered. These include pulsatile tinnitus caused by vascular problems and clicking tinnitus caused by middle ear myoclonus. Appropriate assessment and management strategies for these specific forms of tinnitus are missing.	Thank you for your comment. Depending on the individual question the guideline committee will decide whether pulsatile tinnitus, clicking tinnitus or any other types will be stratified separately in the review.
NIHR Nottingham Biomedical Research Centre	3	61 - 62	Why does the guideline implicitly exclude groups with a treatment-related tinnitus? This could be tinnitus associated with a failed surgery or ototoxicity. There are many such cases, and so these represent a significant NHS caseload.	Thank you for your comment. We are not planning to exclude these patients. Those with iatrogenic tinnitus due to failed surgery, for example, will still have the same management strategies as idiopathic tinnitus.
NIHR Nottingham Biomedical Research Centre	3	57, 64	On line 57 "learning disability" and on line 64 "cognitive difficulties". The choice of terminology seems unnecessarily inconsistent. Do you mean "learning disabilities" in both places?	Thank you for your comment. We have changed the wording to "learning disability and cognitive impairment".
NIHR Nottingham Biomedical Research Centre	3	61	To define children over 5 seems reasonable given that this is the UK school age.	Thank you for your comment. We have removed 'over 5' in response to other stakeholder comments to ensure that those under 5 are also covered by the guideline.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NIHR Nottingham Biomedical Research Centre	3	75	This statement is factually incorrect because at present, there are no objective tests of tinnitus. Tinnitus is the perception of a sound which is only heard by the patient. Tinnitus sound matching tests are quantitative in that they attempt to characterise tinnitus according to a numerical value such as loudness in dB or pitch in kHz. But both of these tests are subjective because they rely wholly on the self-reported perception by the patient. Note on Line 188, the draft scope admits that tinnitus loudness' is subjective!	Thank you for your comment, we have deleted 'objective' from the scope.
NIHR Nottingham Biomedical Research Centre	3	76	Further investigations excludes CT venography and MR venography which can be important for assessing pulsatile tinnitus.	Thank you for your comment. These have not been excluded as they will be included in imaging. Please note that the terminology 'imaging' has superseded 'radiological investigations' in the scope.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NIHR Nottingham Biomedical Research Centre	4	81 - 94	The list of management strategies for tinnitus does raise a number of important questions: First about why these and not other therapeutic approaches? Second about potential ambiguity of interpretation and overlap between strategies. • Choice of terminology describing 'self-management' can be interpreted in a range of different ways. Presumably this is referring to 'clinician-supported activities' within the NHS? And does not include 'self help' strategies initiated by the patient outside the NHS? Clarification would be welcomed. • Hearing aids are explicitly mentioned, but implantable devices for hearing are not. These may be beneficial for those who are profoundly deaf, and yet they are missing from the list. See also comment #13. • Choice of terminology describing 'tinnitus reprogramming devices' can be interpreted in a range of different ways. Presumably this refers only to devices where the marketing claims make explicit reference to such mode of	Thank you for your comment. **Self – help** Self-help is taken to mean measures that are initiated by patients themselves. As we have limited time to produce the guideline we have not prioritised this area for inclusion in the scope. **Implantable devices** Implantable devices are not included in the scopebecause we are only considering devices which are being offered because of a patient's tinnitus. Patients with severe or profound hearing loss will be offered these devices regardless of whether they have tinnitus or not. We have included hearing aids in the scope for people with hearing loss and tinnitus who are not offered hearing aids for their hearing loss alone. **Tinnitus re-programming devices** We have changed the terminology to 'tinnitus neuromodulation devices' as this is a better understood term.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			therapeutic action. Clarification would be welcomed. • Choice of terminology describing 'psychological therapies' and 'counselling' can be interpreted in a range of different ways. Does the former specifically refer to therapies delivered within psychology (such as CBT, mindfulness, acceptance and commitment therapy)? Does the latter specifically refer to client-centred counselling? Clarification would be welcomed. • Gingko biloba is not a prescribed medication. Should it not therefore be considered as a form of 'self help' initiated by the patient outside the NHS? And excluded from the list? Clarification would be welcomed. • There is a dubious distinction between antidepressants and anxiolytics. Would a single question here not suffice asking about prescriptions of licensed medications?	**Psychological therapies and counselling** One of the research questions will look at what psychological therapies and counselling approaches are effective as we recognise that there are a variety of approaches. The guideline committee will decide on the details of the interventions included when developing the protocols for the evidence review. **Ginkgo biloba** We have removed ginkgo biloba from the scope. . **Anxiety and depression** We have removed anxiety and depression from the management part of the scope. We will cross refer to other NICE guidelines as appropriate.
NIHR Nottingham	4	102	Choice of terminology describing 'managing the underlying health conditions causing tinnitus' can be	Thank you for your comment. We have to prioritise our work to the time available and are therefore unable

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Biomedical Research Centre			interpreted in a range of different ways. Clarification would be welcomed. Hearing loss itself is one of the most important and common underlying health conditions causing tinnitus and so probably doesn't need to be listed as a separate point in this subsection. There are numerous surgical and non-surgical (device) strategies for managing hearing loss and all of these may have a secondary benefit for tinnitus. Hearing aids are a good case in point, but they alone have been elevated to a prominent status, at line 84. I'm not sure why.	to cover management of underlying health conditions, of which tinnitus may only be a part. Hearing aids are included in the scope as there is the possibility of prescribing these for people with hearing loss and tinnitus who are not offered hearing aids for their hearing loss alone. We have not included other assistive listening devices, such as cochlear implants, as we are only considering devices which are being offered because of a patient's tinnitus. Patients with severe or profound hearing loss will be offered these devices regardless of whether they have tinnitus or not.
NIHR Nottingham Biomedical Research Centre	5	77	Specific consideration is to be given to people with tinnitus and hyperacusis. While this is to be welcomed, the draft scope must consider how the clinical condition 'hyperacusis' is to be diagnosed and assessed. There is no practical consensus, and guidelines on this would be welcomed by the profession. Will the diagnosis and assessment of hyperacusis be included under the subheading 'Further investigations – assessing hearing?' We	Thank you for your comment. This guideline is focusing on tinnitus and therefore we will not be looking at diagnosis and management of hyperacusis. However, when reviewing the data on tinnitus, particularly the management of tinnitus, we will consider what management options are available for those with tinnitus and hyperacusis. We recognise that the inclusion of hyperacusis as a group to be given specific consideration may cause confusion so moved

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			would recommend that it is not. And instead added as a separate subheading in its own right. In doing so, its worth considering whether the scope is really concerned with hyperacusis (which includes a major psychological component) or 'decreased sound tolerance' (which does not).	it to 'equality considerations' and have broadened this to include 'sound sensitivities, such as hyperacusis (intolerance to every day sounds that cause significant distress and affects day-to-day activities)'.
NIHR Nottingham Biomedical Research Centre	6	149 - 160	Questions pertaining to 'Further investigations' For questions 2.1 to 2.6, it would seem more appropriate to ask 'What are the indications, clinical and cost effectiveness and risks of ….'	Thank you for your comment. The indications are covered by question 1.1. The guideline committee will decide on the most important outcome measures, such as risks, when developing the protocols for the evidence review.
NIHR Nottingham Biomedical Research Centre	6	142 - 145	Questions 1.1 and 1.2 need to capture clinical activities at all stages of the NHS pathway including primary care onwards. This is important.	Thank you for your comment. This question is not limited to any specific part of the patient pathway.
NIHR Nottingham Biomedical Research Centre	6	155	The question about ultrasound seems very spurious.	Thank you for your comment. A question on ultrasound is intended to cover investigation of pulsatile tinnitus.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NIHR Nottingham Biomedical Research Centre	7	168	'sound generators' is duplicated in Questions 3.4 and 3.5. I think this is an error.	Thank you for your comment We have rewritten the questions to make this clearer.
NIHR Nottingham Biomedical Research Centre	7	189	Tinnitus severity merely expresses the magnitude of complaining. It does not explain the dimension of complaint on which severity should be assessed. This means that there are limitations with this construct as a main outcome, in the way it is current phrased. In most instances, when researchers have used 'tinnitus severity' they are actually referring to 'the impact of tinnitus' as reported by the patient. It would be advisable to use this alternative wording: **Change in the impact of tinnitus** See: Hall DA, Haider H, Szczepek AJ, Lau P, Rabau S, Jones-Diette J, Londero A, Edvall NK, Cederroth CR, Mielczarek M, Fuller T, Batuecas-Caletrio A, Brueggemen P, Thompson DM, Norena A, Cima RF, Mehta RL, Mazurek B. Systematic review of outcome domains and instruments used in clinical trials of	Thank you. We have amended the list of outcomes to include the change in subjective perception of tinnitus and change in the impact of tinnitus. This list is not comprehensive; outcomes will be discussed by the guideline committee.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			tinnitus treatments in adults. Trials. 2016 Jun 1;17(1):270.	
RCP	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We would like to endorse the response submitted by the British Association of Audiovestibular Physicians (BAAP).	Thank you for your comment.
Royal College of General Practitioners	All		The consultation draft seems comprehensive and sensible. JW have always had tinnitus and had some deafness late on in life, JW was 50 years old before she went to her GP and OPC and got a hearing aid to help her hearing in certain situations. She was very surprised and a bit upset when she heard "normally". JW own view is that non- medication, explanation and putting up with the tinnitus if not intrusive is the best outcome but that there is no good literature for people on this. JW would have liked a leaflet re options and best management, as for her no active management is	Thank you for your comment. We will be looking at provision of information. The guideline committee will discuss the possibility of no active management as part of their decision-making.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			best as it is just a part of her. That is something about heterogeneity and variations of normal.	
Royal College of General Practitioners	4	91 - 94	Medications. These are usually suggested by NICE but it would useful to know effectiveness rates when would they be stopped, can they be taken intermittently, what are the serious interactions and side effects as people age or take other medications? This area needs expanding for GPs to give best views and patients to take them away in discussing therapy. Most guidelines do not nuance for reality of older people or those with long-term medications in prescribing and this could be stepped up here, please.	Thank you for your comment. We hope to ascertain the clinical and cost-effectiveness of these drugs for managing tinnitus. The guideline committee will take your comments into consideration when discussing the evidence review.
Royal College of General Practitioners	7	174 - 175	A systematuc review identified 15 articles showing a high prevalence of psychiatric disorders in tinnitus-affected patients, and nine showing a high correlation between the presence of a psychiatric disorder and tinnitus-related annoyance and severity. The prevalence of psychiatric disorders, especially anxiety and depression, is high in tinnitus patients, and the	Thank you for your comment and reference. The guideline committee will keep this information in mind when they are developing the guideline.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			presence of these disorders correlates with tinnitus-related annoyance and severity. Pinto, P., Marcelos, C., Mezzasalma, M., Osterne, F., De Melo Tavares de Lima, M., & Nardi, A. (2014). Tinnitus and its association with psychiatric disorders: Systematic review. The Journal of Laryngology & Otology, 128(8), 660-664. doi:10.1017/S0022215114001030	
Royal College of Nursing	General	General	The Royal College of Nursing (RCN) welcomes proposals to develop guidance on assessment and management of tinnitus. The RCN invited members who work in ear, nose and throat and maxillofacial nursing to review the document on its behalf. The comments below reflect the views of our reviewers.	Thank you for your comment.
Royal College of Nursing	9	159	*Key issues and questions*: There should be clear guidance on the parameters when to request MRI Internal Auditory Maetus (IAM) for unilateral tinnitus, for example the minimum time from the onset of symptoms - for example 3 or 6 months).	Thank you for your comment. The indications are covered by question 1.1. The guideline committee will consider these points when discussing the relevant questions.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			Should there be a core requirement of ear examination and audiogram before requesting imaging? Also suggest the guidance needs to clarify - should these scans be requested in secondary care only?	
The Tinnitus Clinic	6/7	162 - 184	In order to address each of these, there will need to be an agreed outline of what the treatment is under each of the 3.x . There are different types of counselling, CBT pathways, sound therapies etc	Thank you for your comment. The guideline committee will specify the different types of interventions at the protocol development stage.
The Tinnitus Clinic	1	15	Tinnitus is a symptom or series of symptoms. Sounds plus anxiety, sleeplessness, irritability, withdrawal from social interaction, mental health deterioration, depression.	Thank you for your comment. We have added the following sentence to cover this: 'Tinnitus can be associated with problems with concentration, listening, anxiety and depression, all of which may have an impact on the person's activities of daily living and social interactions.'
The Tinnitus Clinic	1	25	Cost of treatment £750m does this mean assessment and treatment? Does it cover primary and secondary care?	Thank you for your comment. Please refer to the following study to see what was included in the cost estimate: https://bmchealthservres.biomedcentral.com/track/pdf/

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				10.1186/s12913-017-2527-2?site=bmchealthservres.biomedcentral.com
The Tinnitus Clinic	2	33	Remove psychological interventions – this inclusion of one specific implies it is more importnant than other treatments	Thank you for your comment. The scope wording is intended to convey that access to psychological interventions may be even more variable than other treatments.
The Tinnitus Clinic	2	34	This guideline aims to reduce unwarranted variation in assessment and management of tinnitus. – perhaps consider rewording to read positively…"This guideline aims to provide evidence based models to achieve consistent assessment and management in tinnitus across the NHS	Thank you for your comment. We have changed this to 'this guideline aims to standardise assessment and management of tinnitus'.
The Tinnitus Clinic	3	57	Should cognitive decline also be considered under inequality, appreciate this is under specific consideration in line 63/64	Thank you for your comment. We have changed the wording to "learning disability and cognitive impairment". Equalities issues relating to these groups will be considered across the whole guideline. These groups have been removed from the 'specific groups' section and listed in the equality considerations sections to make this clearer.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
The Tinnitus Clinic	3	61	Tinnitus for children up to 18 is treated differently to adults. Reasons: manufacturers of specialist devices aim at the adult market and devices are not passed for use with children. There is already guidance for children which was created by Dr Veronica Kennedy and others very recently. Could this be referred to rather than having a very large scope of work for this guidance?	Thank you for your comment. Children have been included in the guideline as a separate group as they may have different needs to adults and therefore will require different treatment. The practice guidance mentioned has a limited tinnitus evidence base drawing on other disciplines for its references e.g. mental health.
The Tinnitus Clinic	3	73	Would suggest splitting the assessment into 2 - first check that there are no symptoms or potential medical issues that need checking; then assess (you should not assess until all other symptoms and concerns are checked and cleared up)	Thank you for your comment. We will discuss this when developing recommendations.
The Tinnitus Clinic	3	79	Under the further investigations are areas such as linme80 which is an assessment which should be undertaken before the assessment.	Thank you for your comment. We think that identification of symptoms and features that need further investigation is required first. Please note that the order of areas within the scope do not necessarily reflect the patient pathway.
The Tinnitus Clinic	3	81	Anything which is related to managing tinnitus should have a minimum level of evidence required and a target group for the treatment as one treatment does	Thank you for your comment. The guideline committee will decide on populations and evidence levels for each review at the protocol stage of development.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			not fit all. Even if something has been done as custom and practice within the NHS guidance should be given on ensuring evidence is gathered or in place for what is done	Recommendations will be made following a thorough search and robust review of the evidence in line with the protocol. Depending on the evidence available the guideline committee may decide to make different recommendations for particular groups. Research recommendations may be made if it is felt necessary.
The Tinnitus Clinic	3	81	Include specialist devices and treatments such as Acoustic CR Neuromodulation and Levo Therapy for Tinnitus	Thank you for your comment. These may be included under sound based therapies. The strategies to be included will be considered by the guideline committee when developing the protocols for the evidence review.
The Tinnitus Clinic	3	103	Anxiety and depression caused by tinnitus is a symptom of tinnitus and should be treated in a holistic fashion alongside the specific treatment for best results.	Thank you for your comment. We acknowledge that anxiety and depression can be associated with tinnitus and need to be treated. We will consider these in our reviews in relation to the outcomes of treatments and the guideline will cover identification of depression / anxiety and signpost to existing NICE guidelines on management of depression and anxiety, as these are co-morbid conditions.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
The Tinnitus Clinic	6	141	Assessing tinnitus – there are different types of tinnitus. Can the guidance be clear about which type is being discussed, against the treatment and symptoms for each which might require referral.	Thank you for your comment. Where appropriate we will specify the types of tinnitus in the recommendations.
The Tinnitus Clinic	6	151	The scope as it stands states that anxiety and depression will not be addressed in this guidance. Yet this question is about assessing the psychological impact – the two statements are inconsistent	Thank you for your comment. We acknowledge that anxiety and depression can be associated with tinnitus and need to be treated. We have removed drugs to treat anxiety and depression from the scope. We will consider anxiety and depression in our reviews in relation to the outcomes of treatments and the guideline will cover identification of depression / anxiety and signpost to existing NICE guidelines on management of depression and anxiety.
The Tinnitus Clinic	7	188 193	This should be a positive change in each of these areas. Where a score is mentioned, an internationally validated questionnaire should be proposed.	Thank you for your comment. The guideline committee will keep this information in mind when they are developing the guideline.
The Tinnitus Clinic	8	207	There is recent device on the market called Levo Therapy for Tinnitus which has shown positive effect in a trial run by Dr James Henry at the Veterans Association in USA and published in November American Journal of Audiology. This therapy is used at	Thank you for your comment. We have amended the scope to include the term 'tinnitus neuromodulation devices' instead of 'reprogramming devices', which may cover this device. The guideline committee will

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			sleep and should be included as a specialist product due to its wide range of treatment groups and ease of prescribing.	consider which interventions to include when developing the protocols for the reviews.
The Tinnitus Clinic	9	216	The provision of evidence based information is vital at first appointment. Can the guidance point to this or propose a model for the evidence (to educate and inform the patient)	Thank you for your comment. We are planning to make recommendations on provision of information.
University Hospitals Coventry & Warwickshire NHS Trust	General	General	The draft scope does not cover using relaxation techniques as an option in the management of Tinnitus. As relaxation techniques can be taught and used independently of any counselling or psychological therapies this may need to be considered as a separate management strategy, although it can be used in conjunction with devices, informational counselling and psychological intervention.	Thank you for your comment. Relaxation techniques may be included under self-management, which has been moved to the 'providing information' area of the scope'. This will be explored with the guideline committee at the development stage of the guideline.
University of Nottingham	6-7	161-184	In addition to effectiveness and cost-effectiveness, indications and risks should be assessed as well.	Thank you for your comment. The indications are covered by question 1.1. The guideline committee will decide on the most important outcome measures, such as risks, when developing the protocols for the evidence review.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University of Nottingham	1	20 - 21	It states that 'Tinnitus occurs in approximately 6 million people in the UK (10% of the population).' According to the new studies tinnitus affects up to 30% of adult population and about 20% of people experience clinically significant tinnitus. Please see: McCormack A, Edmondson-Jones M, Somerset S, Hall D, 2016. A systematic review of the reporting of tinnitus prevalence and severity. Hear Res, 337: 70-9.	Thank you for your comment. We have changed the figure to that reported by NHS England in its Commissioning Services for People with Hearing Loss: A Framework for Clinical Commissioning Groups document, available at:https://www.england.nhs.uk/wp-content/uploads/2016/07/HLCF.pdf.
University of Nottingham	1	19	It is stated that: 'Research on possible new treatments continues.' Given into account that evidence on efficacy of current treatments and management options is lacking this sentence should be: 'Research on existing and possible new treatments continues.'	Thank you for your comment this has been amended in the scope.
University of Nottingham	2	41 - 42	Primary and secondary care is mentioned, however there is no mention of tertiary care (as defined in Department of Health, 2009. Provision of services for adults with tinnitus. A Good Practice Guide. London: Central Office of Information). As it was stated that the whole tinnitus management pathway should be taken into consideration this should be added. Otherwise there might be a risk that centres identifying as 'tertiary care' might assume the guideline is not applicable to them.	Thank you for your comment, we have changed this to 'Healthcare professionals providing NHS-commissioned services' so that all relevant settings are covered.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University of Nottingham	3	60 - 64	Treatment related disabilities should be added to this section, including failed surgery and ototoxicity.	Thank you for your comment. Potential harms of treatments for tinnitus will be discussed when selecting the outcome measures for the relevant reviews and taken into account when making recommendations.
University of Nottingham	3	57, 64	People with 'learning disabilities' are mentioned, later people with 'cognitive difficulties' are mentioned as well. Definitions for both should be included. Also, would a better term be 'cognitive disabilities' rather than 'cognitive difficulties'?	Thank you for your comment. We have changed the wording to "learning disability and cognitive impairment". We have used the term 'cognitive impairment' to cover people with any medical issue which affects their cognitive ability.
University of Nottingham	3	63	Hyperacusis is mentioned, however no definition or ways to diagnose hyperacusis are mentioned. This should be added if hyperacusis is to be included.	Thank you for your comment. We have added a definition of hyperacusis to the scope 'hyperacusis (intolerance to everyday sounds that causes significant distress and affects day-to-day activities)'. This guideline is focusing on tinnitus and therefore we will not be looking at diagnosis and management of hyperacusis. However, when reviewing the data on tinnitus, particularly the management of tinnitus, we will consider what management options are available for those with tinnitus and hyperacusis. We recognise that the inclusion of hyperacusis as a group to be

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				given specific consideration may cause confusion so have moved it to 'equality considerations' and have broadened this to include 'sound sensitivities, such as hyperacusis'.
University of Nottingham	3	68	No distinction between types of tinnitus (i.e. subjective vs objective) have been made. If the intention is to only consider subjective tinnitus then this should be explicit.	Thank you for your comment. We are planning to include both.
University of Nottingham	3	72	General history taking should be added, with clear indication of essential elements, including those that are diagnostic, and those that are descriptive, and explicit distinction between these	Thank you for your comment. We agree that good history taking is important, and we are looking at symptoms and features that need further investigation and specialist treatment. We are unable to cover all areas of tinnitus diagnosis and management and so have prioritised the areas where we feel that a review of the clinical and cost effectiveness evidence is most valuable.
University of Nottingham	3	75	Tinnitus sound matching is a subjective not an objective test of tinnitus. It does provide a numerical value at the end but it is based on patient's report, therefore is defined as subjective. Please, see also	Thank you for your comment, we have deleted 'objective' from the scope.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			page 7 line 188 where one of the main aoutcome measures is stated as 'subjective tinnitus loudness'.	
University of Nottingham	3	76	Blood testing should be added, with indication as to method and target conditions	Thank you for your comment. Blood tests are not included as the results would not affect management of the tinnitus. We are unable to cover all areas of tinnitus diagnosis and management and so have prioritised the areas where we feel that a review of the clinical and cost effectiveness evidence is most valuable.
University of Nottingham	3	77	Assessing hyperacusis should be added as it was stated that specific considerations will be given to people with tinnitus and hyperacusis.	Thank you for your comment. The focus of this guideline is on tinnitus and therefore we won't be looking at assessment of hyperacusis. However, the guideline committee will consider how suitable different treatments are for patients with hyperacusis. We recognise that the inclusion of hyperacusis as a group to be given specific consideration may cause confusion so have moved it to 'equality considerations' and have broadened this to include 'sound sensitivities, such as hyperacusis (intolerance to every day sounds that cause significant distress and affects day-to-day activities)'.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University of Nottingham	4	81 - 94	Cochlear implants should be added to the list, especially that profound hearing loss is mentioned as one of the populations needing consideration. While cochlear implants are currently recommended by NICE for improving speech understanding (National Institute for Health and Clinical Excellence. (2009). Cochlear implants for children and adults with severe to profound deafness. In: NICE technology appraisal guidance 166.), they have also been suggested as a potential treatment for tinnitus in profoundly deaf patients due to their suppressive effect on tinnitus (Tyler RS, Rubinstein J, Pan T, Chang SA, Gogel SA, Gehringer A, et al. (2008). Electrical stimulation of the cochlea to reduce tinnitus. Semin Hear, 29, 326-332).	Cochlear implants are not included in the scope because we are only considering devices which are being offered because of a patient's tinnitus. Patients with severe or profound hearing loss will be offered these devices regardless of whether they have tinnitus or not. We have included hearing aids in the scope as there is the possibility of prescribing these for patients with tinnitus and hearing loss whose hearing loss alone didn't require a hearing aid.
University of Nottingham	4	91 - 94	The distinction between antidepressants and anxiolytics is neither clear in practice, nor helpful with regard to tinnitus	Thank you for your comment. We have removed antidepressants and anxiolytics from the scope. The guideline will cover identification of depression and anxiety and signpost to existing NICE guidelines on management of depression and anxiety, as these are co-morbid conditions.
University of Nottingham	4	80	Magnetic Resonance Venography (MRV) should be added, specifically in the case of pulsatile tinnitus	Thank you for your comment. This will be covered under imaging. The guideline committee will decide on

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the individual interventions to be included at the protocol stage.
University of Nottingham	4	82	Self-management should be defined and which management options are considered self-management. Would it only cover options that are clinician supported and available on the NHS in contrast to self-help which would represent options that clinicians can signpost to but are not available on the NHS?	Thank you for your comment. In the scope self-management refers to strategies provided by healthcare professionals in collaboration with patients. The strategies to be included will be considered with the guideline committee at the protocol development stage. Self-help is taken to mean measures that are initiated by patients themselves. As we have limited time to produce the guideline we have not prioritised this area for inclusion in the scope.
University of Nottingham	4	85	Sound generators are listed. What is defined as sound generators? Would that include all devices that are used for tinnitus management and that are generating sound (i.e. BTE sound generators, bedside sound generators, mobile applications etc.)?	Thank you for your comment. Yes these all may be included under the umbrella of sound generators. The guideline committee will decide on which interventions will be included when developing the protocols for the evidence review.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University of Nottingham	4	86	What is meant by 'tinnitus reprogramming'? This is not clear and it is not clear which management options would be considered under this definition.	Thank you for your comment we have amended the terminology to 'tinnitus neuromodulation devices'.
University of Nottingham	4	92	Gingko biloba is not a prescription medication: if this is in scope then consider supplements (zinc, magnesium) and vitamins (B12 specifically)	Thank you for your comment. Because of limited time available we have picked prioritised only those interventions most commonly used or where we feel that a review of the clinical and cost effectiveness evidence is most valuable. We have removed ginkgo biloba from the scope. As the guideline can only cover a limited number of topics for evidence reviews, based on stakeholder feedback we do not consider that complementary therapies should be prioritised over other topics in the scope. .
University of Nottingham	4	102	'Managing underlying health conditions causing tinnitus' is stated as the area that will not be covered by this guidelines. However, hearing loss, stapedectomy, vestibular schwannoma, Meniere's Disease are underlying health conditions and their management would be important to include in this guidelines.	Thank you for your comment. We have to prioritise our work to the time available and are therefore unable to cover management of underlying health conditions, of which tinnitus may only be a part.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University of Nottingham	6	142 - 145	The scope states that the guideline would cover the whole tinnitus management pathway, therefore those questions would be relevant to all stages of the pathway, including GP referral to audiology/ENT. Was this intentional or specific parts of the pathway are meant here? This should be clarified.	Thank you for your comment. This question is not limited to any specific part of the patient pathway.
University of Nottingham	6	146 - 147	'Assessing tinnitus' should be clarified. It is not clear if it means percept itself, its impact, or something else.	Thank you for your comment. The guideline committee will work on the details of the question when developing the protocols for the evidence review.
University of Nottingham	6	155 - 156	We are not sure how ultrasound can be used to investigate the cause of tinnitus. This question should be removed.	Thank you for your comment. A question on ultrasound is intended to cover investigation of pulsatile tinnitus.
University of Nottingham	6	159 - 160	The omission of surgical techniques for treating tinnitus is anomalous, particularly as there may be substantial benefits for a suitable patient. Please consider stapedectomy, stenting for pulsatile tinnitus, cochlear implants	Thank you for your comment. Stapedectomy is a surgical treatment for hearing loss not tinnitus and therefore will not be included in this guideline. Pulsatile tinnitus can be due to a variety of causes and the surgical option is dependent on surgical opinion and individual patient. Cochlear implants are not included in the scope because we are only considering devices which are being offered because of a patient's tinnitus. Patients with severe or profound hearing loss will be

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				offered these devices regardless of whether they have tinnitus or not. The guideline committee will decide at protocol development stage which interventions will be included for review questions.
University of Nottingham	7	167 - 171	Sound generators are repeated twice in two consecutive questions. We assume that question 3.5 considers people without hearing loss. This should be clarified.	Thank you for your commentWe have rewritten the questions to make this clearer. The guideline committee will define the population at the protocol development stage.
University of Nottingham	7	185	The list of main outcomes should include '**tinnitus intrusiveness'**. The global tinnitus community has recently been involved in a project to identify how sound-, psychology- and drug-based tinnitus treatments should be commonly assessed before and after treatment. There now exist recommendations for a minimum standard of outcomes selected on the basis that they are: i) directly relevant to patients with tinnitus, to the healthcare professionals giving the treatment, and to the researchers designing the trial, ii)	Thank you for your comment. We will consider the best outcomes to use for each review question when developing the protocols. We have amended the list of outcomes to include the change in subjective perception of tinnitus and change in the impact of tinnitus. This list is not comprehensive; outcomes will be discussed by the guideline committee.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			directly relevant to how the treatment is supposed to be working, and iii) are expected to be very sensitive to change during the treatment. **Sound based treatments:** tinnitus intrusiveness, ability to ignore, concentration, quality of sleep, sense of control **Psychology-based treatments:** tinnitus intrusiveness, tinnitus acceptance, mood (including feelings of anxiety and depression), negative thoughts and beliefs, sense of control **Drug-based treatments:** tinnitus intrusiveness, tinnitus loudness See: http://tinnet.tinnitusresearch.net/index.php/recommendations See: Hall DA, Haider H, Kikidis D, Mielczarek M, Mazurek B, Szczepek AJ, Cederroth CR. Toward a Global Consensus on Outcome Measures for Clinical Trials in Tinnitus: Report From the First International Meeting of the COMiT Initiative,	

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			November 14, 2014, Amsterdam, The Netherlands Trends Hear. 2015 Jan-Dec; 19: 2331216515580272. The draft scope would therefore be well advised to consider these in their list of outcomes, especially '**tinnitus intrusiveness'** which was recommended irrespective of the type of tinnitus treatment in question.	
University of Nottingham	7	189	Tinnitus severity merely expresses the magnitude of complaining. It does not explain the dimension of complaint on which severity should be assessed. This means that there are limitations with this construct as a main outcome, in the way it is current phrased. In most instances, when researchers have used 'tinnitus severity' they are actually referring to 'the impact of tinnitus' as reported by the patient. It would be advisable to use this alternative wording: Change in the impact of tinnitus See: Hall DA, Haider H, Szczepek AJ, Lau P, Rabau S, Jones-Diette J, Londero A, Edvall NK, Cederroth	Thank you for your comment. We have amended the list of outcomes to include the change in subjective perception of tinnitus and change in the impact of tinnitus. This list is not comprehensive; outcomes will be discussed by the guideline committee.

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			CR, Mielczarek M, Fuller T, Batuecas-Caletrio A, Brueggemen P, Thompson DM, Norena A, Cima RF, Mehta RL, Mazurek B. Systematic review of outcome domains and instruments used in clinical trials of tinnitus treatments in adults. Trials. 2016 Jun 1;17(1):270.	
University of Nottingham	7	193	If sleep is listed as a main outcome measure, it should also be considered under assessment and management.	Thank you for your comment. Sleep may be included under self-management strategies, which has been moved to the 'providing information' area of the scope.'This will be explored with the guideline committee during the development stage of the guideline.
University of Nottingham	8	210	Tinnitus NICE clinical knowledge summary was updated in March, therefore the date should be 2017 not 2010.	Thank you for your comment, we have updated this.

No tobacco link declared.

Registered stakeholders

Tinnitus

Consultation on draft scope
Stakeholder comments table

23/11/2017 to 21/12/2017

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.