National Institute for Health and Care Excellence

Final

Tinnitus: assessment and management

[A] Evidence review for tinnitus support

NICE guideline NG155

Intervention evidence review

March 2020

Final

This evidence review was developed by the National Guideline Centre

Disclaimer

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

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

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive. All NICE guidance is subject to regular review and may be updated or withdrawn.

ISBN 978-1-4731-3711-0

Contents

1 Tinnitus support

1.1 Review question: Is tinnitus counselling (including education, and relaxation strategies) clinically and cost effective and which is the best form of tinnitus counselling?

1.2 Introduction

People with tinnitus who seek help often do so because the tinnitus is causing some level of distress or because they believe it may be a symptom of some underlying serious disease. Support may include reassurance and tinnitus counselling. Tinnitus counselling, however, means many things to many people. Clinicians, as well as people with tinnitus, have differing perceptions about the meaning of the term. Currently, 'tinnitus counselling' may be used to describe a brief information-giving session or a series of sessions facilitated by a psychologist, or anything in between.

For the purpose of this guideline, the term 'tinnitus support' is favoured over 'tinnitus counselling' and is defined as an interactive process between the individual with tinnitus and healthcare professional. Within this, the concerns and needs of the individual are identified and explored, including difficulties associated with tinnitus and the individual's understanding of the emotions related to tinnitus. As part of this process, delivery of information about tinnitus involves a two-way discussion promoting an understanding of the tinnitus. Then, a management plan can be developed that is tailored to the individual. The individual is supported to understand why suggested strategies may be helpful and how they can go about putting these in to place. As the tinnitus support is individually focused, consideration is made with regard to the needs, age and ability of the individual to ensure that all information is made accessible to them. Where other needs are identified, for example mental health needs, the person with tinnitus may also benefit from being to be referred to other relevant services.

The provision of tinnitus support, in-line with the description above, is variable across the country. The purpose of this review is to identify whether tinnitus support and other strategies commonly used in or defined as 'tinnitus counselling' (including relaxation, education and advice) are clinically and cost effective and which is the best form of tinnitus support.

1.3 PICO table

For full details see the review protocol in appendix A.

Table 1: PICO characteristics of review question

Population	Children, young people and adults with tinnitus. Strata: Children/young people (up to 18 years) and adults
Intervention(s)	• Tinnitus counselling – education including coping strategies, provision of information and relaxation
Comparison(s)	• To each other • No active treatment/waiting list

Outcomes	• Tinnitus severity (critical) Impact of tinnitus (critical): • Tinnitus distress • Tinnitus annoyance Health related QoL (critical): • QoL (tinnitus) • QoL Tinnitus percept (important): • Tinnitus loudness Other co-occurring complaints (important): • Depression • Anxiety • Anxiety and depression • Sleep Adverse events (important): • Safety • Tolerability • Side effects
Study design	• Systematic review of RCTs • RCT • If there is an inadequate amount of RCT data, non-randomised comparative studies will be considered.

1.4 Clinical evidence

1.4.1 Included studies

Five studies were included in the review;[13, 17, 19, 22, 27] these are summarised in Table 2 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 3). All the studies identified were randomised controlled trials.

The committee recognised that there is variation in how tinnitus counselling/support interventions for tinnitus are described in practice and research. For the purpose of this review, the following categories were used to distinguish between the interventions described in the included studies:

- "Education counselling" – components of the interventions included information to people with tinnitus about the medical condition itself or interventions that can be used to manage it. Information would be delivered to participants over several sessions
- "Counselling (information)" – only information was provided to participants (e.g. provision of an information manual)

See also the study selection flow chart in appendix C, study evidence tables in appendix D, forest plots in appendix E and GRADE tables in appendix H.

1.4.2 Excluded studies

See the excluded studies list in appendix I.

1.4.3 Summary of clinical studies included in the evidence review

Table 2: Summary of studies included in the evidence review

Study	Intervention and comparison	Population	Outcomes	Comments
Dineen 1999[13] RCT	Intervention (n=28) Counselling (information) plus relaxation Information – participants received information on topics including: prevalence of tinnitus, function of the auditory system, psychology of adaptation to tinnitus and management of sleep problems. Each subject received a 60 page manual. Relaxation – 'progressive relaxation' technique (Jacobson, 1968), a relaxed breathing technique was used with the use of positive mental imagery. Two three-hour sessions provided. Comparison (n=28) Counselling (information) only – details the same as above	n=56 People presenting with tinnitus Age (mean):54.37 years Gender (male to female ratio): 2:1 Duration of tinnitus: Not reported Australia	Tinnitus loudness (follow-up:12 months): measured using a visual analogue scale, scale ranges from 0-10 Tinnitus annoyance (follow-up: 12 months): measured using a visual analogue scale, scale ranges from 0-10	Also included in the sound therapy review
Henry 1996[22] RCT	Intervention (n=20) Education counselling (*group-based intervention*) – purpose was to educate participants about tinnitus. Session topics included: the auditory system, causes of tinnitus, theories of tinnitus and medical treatments. One small	n=40 People with chronic tinnitus Age (mean): 64.6 years Gender (male to female ratio): 6.5:1	Tinnitus distress (follow-up: 12-months: measured using the Tinnitus Reaction Questionnaire (TRQ), scale ranges from 0-104 Tinnitus related quality of life (follow-up: 12 months): measured using the Tinnitus Handicap	Also included in psychological therapies review

Study	Intervention and comparison	Population	Outcomes	Comments
	group 90-minute session per week for 6 weeks. Comparison (n=20) Waiting-list control – participants were informed that their participation would be delayed	Duration of tinnitus: Not reported Australia	Questionnaire (THQ). Participants assign a number between 0 (strongly disagree) -100 (strongly agree), total score is divided by 28 (28-item questionnaire) Tinnitus loudness (follow-up: post-treatment and 12 months): measured using visual analogue scale range 0-4 Tinnitus annoyance (follow-up: post-treatment and 12 months): measured using visual analogue scale range 0-4 (unclear) Depression (follow-up: 12 months): measured using the Beck Depression Inventory (BDI), scale ranges from 0-63	
Henry 2007[17] RCT	Intervention (n=94) Educational counselling (*group-based intervention*) - group sessions based on informing participants about tinnitus and tinnitus retraining therapy (TRT). Four weekly 1.5 hour group sessions were attended; an audiologist conducted the educational presentations for each cohort of participants. Comparison 1 (n=84)	n=269 People (veterans) presenting with clinically significant tinnitus Age (mean): 61.6 years Gender (male to female ratio): 28.9:1 Duration of tinnitus: <1 year – 3%; 1-2 years – 3%; 3-5 year – 8%; 6-10 years – 14%; 10-20 years – 23%;	Tinnitus severity (follow-up: 12 months): measured using the Tinnitus Severity Index, scale ranges from 0-48.	

Study	Intervention and comparison	Population	Outcomes	Comments
	Traditional support - four weekly 1.5 hour group sessions were attended, no education was provided in the support group. Comparison 2 (n=91) No treatment – study interventions were not received. No further details reported.	>20 years – 42%; Unsure – 6% United States		
Henry 2017[19] RCT	Intervention (n=150) Education counselling (*individual-based intervention*) - Progressive tinnitus management (PTM) – consisted of five weekly sessions conducted: two with audiologist and three with a psychologist. Audiologist taught participants about sound therapy, including using sound in a personalised manner. Psychologist taught three coping strategies that are used with CBT: relaxation, planning pleasant activities and cognitive restructuring – also to specifically address individuals' tinnitus problem situations Comparison (n=150) Waiting-list control – participants were on waiting list for 6 months and were offered PTM after the 6 months as a courtesy	n=300 People (veterans) presenting with tinnitus Age (mean): 58 years Gender (male to female ratio): 19:1 Duration of tinnitus: <1 year – 1%; 1-2 years – 8%; 3-5 years – 10%; 6-10 years – 8%; 11-20 years – 11%; > 20 years – 44%; Unsure – 15% United States	Tinnitus severity (follow-up: 6 months): measured using the Tinnitus Functional Index (TFI), scale ranges from 0-100 Tinnitus related quality of life(follow up: 6 months): measured using the Tinnitus Handicap Inventory (THI), scale ranges from 0-100	
Ireland 1985[27]	Intervention 1 (n=7):	n=18	Tinnitus loudness (follow-up: 4	

Study	Intervention and comparison	Population	Outcomes	Comments
RCT (Study consisted of two stages: first stage involved randomisation whilst the second stage did not. Outcome data was reported separately for the stages, first stage results were used)	Counter-demand relaxation training (*group-based intervention*) - progressive relaxation procedure was used, participants were also instructed that they should not expect improvements in their tinnitus until after the after the fifth session. Treatment consisted of seven, weekly 1.5 hour group sessions. Intervention 2 (n=5): Neutral-demand relaxation training (*group-based intervention*) - progressive relaxation procedure was used. Treatment consisted of seven, weekly 1.5 hour group sessions. Comparison (n=6): Waiting-list control – participants informed that they could not be treated immediately and had to wait for approximately 2 months.	People presenting with subjective tinnitus Age (mean): Not reported Gender (male to female ratio): 1:1 Duration of tinnitus (months): Not reported Australia	weeks): measured by masking level required to mask the tinnitus, measured by an audiologist on a Tinnitus Synthesizer, scale 0-4. Depression (follow-up: 2 weeks): measured using the Beck Depression Inventory (BDI), scale 0-63 Anxiety (follow-up: 2 weeks): measured using the Spielberger State-Trait Anxiety Inventory (STAI)	

See appendix D for full evidence tables.

1.4.4 Quality assessment of clinical studies included in the evidence review

1.4.4.1 Education counselling versus control (group sessions)

Table 3: Clinical evidence summary: Education counselling versus control (group sessions)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control (group session)	Risk difference with Education counselling (95% CI)
Tinnitus Severity Tinnitus Severity Index (TSI). Scale from: 0 to 48.	129 (1 study) 12 months	⨁⨁⨀⨀ LOW1 due to risk of bias		The mean tinnitus severity in the control groups was 22.9	The mean tinnitus severity in the intervention groups was 0.80 lower (4.3 lower to 2.7 higher)
1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias					

1.4.4.2 Education counselling versus control (no intervention)

Table 4: Clinical evidence summary: Education counselling versus control

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control	Risk difference with Education counselling (95% CI)
Tinnitus Severity Tinnitus Severity Index (TSI). Scale from: 0 to 48.	143 (1 study) 12 months	⨁⨁⨀⨀ LOW1 due to risk of bias		The mean tinnitus severity in the control groups was 21.6	The mean tinnitus severity in the intervention groups was 0.50 higher (2.8 lower to 3.8 higher)
1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias					

1.4.4.3 Education counselling versus waiting-list control

Table 5: Clinical evidence summary: Education counselling versus waiting-list control

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Waiting-list control	Risk difference with Education counselling (95% CI)
Tinnitus distress Tinnitus Reaction Questionnaire. Scale from: 0 to 104.	40 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 46.6	The mean tinnitus distress in the intervention groups was 1.15 lower (14.84 lower to 12.54 higher)
Tinnitus distress Tinnitus Reaction Questionnaire. Scale from: 0 to 104.	31 (1 study) 12 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 46.29	The mean tinnitus distress in the intervention groups was 0.35 lower (15.58 lower to 14.88 higher)
Tinnitus severity Tinnitus Functional Index. Scale from: 0 to 100.	231 (1 study) 6 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus severity in the control groups was 0.8	The mean tinnitus severity in the intervention groups was 6.5 lower (11.19 to 1.81 lower)
Tinnitus-related quality of life Tinnitus Handicap Questionnaire. Scale from: 0 to 100.	40 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus-related quality of life in the control groups was 60.88	The mean tinnitus-related quality of life in the intervention groups was 1.54 lower (13.44 lower to 10.36 higher)
Tinnitus-related quality of life Tinnitus Handicap Inventory and Tinnitus	263 (2 studies)	⨁⊖⊖⊖ VERY		The mean tinnitus-related quality of life in the control	The mean tinnitus-related quality of life in the

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Waiting-list control	Risk difference with Education counselling (95% CI)
Handicap Questionnaire. Scale from: 0 to 100.	6-12 months	LOW1,2 due to risk of bias, imprecision		groups was 29.11	intervention groups was 5.93 lower (10.18 to 1.68 lower)
Tinnitus loudness Visual analogue scale. Scale from: 0 to 4.	40 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 3.03	The mean tinnitus loudness in the intervention groups was 0.2 lower (0.74 lower to 0.34 higher)
Tinnitus loudness Visual analogue scale. Scale from: 0 to 4.	31 (1 study) 12 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 3.35	The mean tinnitus loudness in the intervention groups was 0.18 lower (0.78 lower to 0.42 higher)
Tinnitus annoyance Visual analogue scale. Scale from: 0 to 4.	40 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus annoyance in the control groups was 2.77	The mean tinnitus annoyance in the intervention groups was 0 higher (0.47 lower to 0.47 higher)
Tinnitus annoyance Visual analogue scale. Scale from: 0 to 4.	31 (1 study) 12 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus annoyance in the control groups was 2.21	The mean tinnitus annoyance in the intervention groups was 0.67 higher (0.03 lower to 1.37 higher)
Depression Beck Depression Inventory. Scale from: 0 to 63.	40 (1 study) post-	⨁⊖⊖⊖ VERY LOW1,2		The mean depression in the control groups was 11.5	The mean depression in the intervention groups was 0.05 lower

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Waiting-list control	Risk difference with Education counselling (95% CI)
	treatment	due to risk of bias, imprecision			(4.64 lower to 4.54 higher)
Depression Beck Depression Inventory. Scale from: 0 to 63.	31 (1 study) 12 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 11.42	The mean depression in the intervention groups was 1.58 higher (5.02 lower to 8.18 higher)

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias.
2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

Relaxation + information versus information

Table 6: Clinical evidence summary: Relaxation + information versus information

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Information	Risk difference with Relaxation + information (95% CI)
Tinnitus annoyance Visual Analogue Scale (VAS). Scale from: 0 to 10.	38 (1 study) 12 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus annoyance in the control groups was 4.2	The mean tinnitus annoyance in the intervention groups was 0.4 lower (2.05 lower to 1.25 higher)
Tinnitus loudness Visual Analogue Scale (VAS).	38 (1 study) 12 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias,		The mean tinnitus loudness in the control groups was 5.8	The mean tinnitus loudness in the intervention groups was 1.4 lower

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Information	Risk difference with Relaxation + information (95% CI)
Scale from: 0 to 10.		imprecision			(2.87 lower to 0.07 higher)

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

1.4.4.4 Relaxation versus waiting-list control

Table 7: Clinical evidence summary: Neutral-demand relaxation versus waiting-list control

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Waiting-list control	Risk difference with Neutral-demand relaxation (95% CI)
Tinnitus loudness Scale from: 0 to 4.	11 (1 study) 4 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control group was 2.4	The mean tinnitus loudness in the intervention group was 0.4 lower (1.11 lower to 0.31 higher)
Depression Beck Depression Inventory (BDI). Scale from: 0 to 63	11 (1 study) 2 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control group was 9.3	The mean depression in the intervention group was 4.3 lower (12.44 lower to 3.84 higher)
Anxiety Spielberger State-Trait Anxiety Inventory (STAI). Scale range not reported	11 (1 study) 2 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control group was 38.8	The mean anxiety in the intervention group was 7.5 lower (18.26 lower to 3.26 higher)

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

Table 8: Clinical evidence summary: Counter-demand relaxation versus waiting-list control

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Waiting-list control	Risk difference with Counter-demand relaxation (95% CI)
Tinnitus loudness Scale from: 0 to 4.	13 (1 study) 4 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control group was 2.4	The mean tinnitus loudness in the intervention group was 0.2 lower (0.87 lower to 0.47 higher)
Depression Beck Depression Inventory (BDI). Scale from: 0 to 63	13 (1 study) 6-8 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control group was 9.3	The mean depression in the intervention group was 2 higher (5.39 lower to 9.39 higher)
Anxiety Spielberger State-Trait Anxiety Inventory (STAI). Scale range not reported	13 (1 study) 6-8 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control group was 38.8	The mean anxiety in the intervention group was 7.5 higher (4.46 lower to 19.46 higher)

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

See appendix F for full GRADE tables.

1.5 Economic evidence

1.5.1 Included studies

No relevant health economic studies were identified.

1.5.2 Excluded studies

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

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

1.6 Evidence statements

1.6.1 Clinical evidence statements

- **Education counselling versus control (group sessions)**
  One study (n=129) was included in this comparison; no clinical evidence was reported for the critical outcomes: quality of life, distress and annoyance. There was no clinical difference between education counselling and control (group sessions) for the outcome reported (tinnitus severity). The overall quality of the evidence was Low due to risk of bias.

- **Education counselling versus control (no intervention)**
  One study (n=143) was included in this comparison; no clinical evidence was reported for the critical outcomes: quality of life, distress and annoyance. There was no clinical difference between education counselling and control (no intervention) for the outcome reported (tinnitus severity). The overall quality of the evidence was Low due to risk of bias.

- **Education counselling versus waiting-list control**
  Two studies (n=263) were included in this comparison; no clinical evidence was reported for the critical outcome of annoyance. There was no clinical difference between education counselling and waiting-list control in terms of tinnitus severity, tinnitus distress, tinnitus related quality of life, tinnitus loudness, tinnitus annoyance and depression. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

- **Relaxation + information versus information**
  One study (n=38) was included in this comparison; no clinical evidence was reported for the critical outcomes: quality of life, tinnitus severity and tinnitus distress. There was no clinical difference between relaxation in combination with information and information alone for the outcomes reported (tinnitus annoyance and tinnitus loudness). The overall quality of the evidence was Very Low due to risk of bias and imprecision.

- **Neutral-demand relaxation versus waiting-list control**
  One study (n=11) was included in this comparison; no clinical evidence was reported for the critical outcomes. There was no clinical benefit of neutral-demand relaxation in terms of the outcomes of depression and anxiety. There was no clinical difference between neutral-demand relaxation and waiting-list control for the outcome of tinnitus loudness. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

- **Counter-demand relaxation versus waiting-list control**
  One study (n=13) was included in this comparison; no clinical evidence was reported for the critical outcomes. Counter-demand relaxation was less effective than waiting-list control in terms of anxiety. There was no clinical difference between counter-demand relaxation and waiting-list control for the outcomes of tinnitus loudness and depression. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

1.6.2 Health economic evidence statements

- No relevant economic evaluations were identified.

1.7 The committee's discussion of the evidence

1.7.1 Interpreting the evidence

1.7.1.1 The outcomes that matter most

Tinnitus distress, annoyance and tinnitus severity were critical outcomes as they were thought to be common factors for people with tinnitus and impact their quality of life. Quality of life (tinnitus-related) and general quality of life were also critical outcomes due to their impact on the person with tinnitus.

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

1.7.1.2 The quality of the evidence

Five randomised controlled trials (RCTs) were included in this review. Outcome data was reported for all of the critical outcomes and outcome data was reported for three of the important outcomes (tinnitus loudness, anxiety and depression).

Three RCTs evaluated "education counselling"; one compared "education counselling" with two types of control groups (group sessions and no intervention) and two studies compared education counselling to waiting-list control.

Three studies evaluated education counselling reporting outcome data for:

- tinnitus severity (measured using Tinnitus Severity Index (TSI))
- tinnitus distress (measuring using the Tinnitus Reaction Questionnaire)
- tinnitus-related quality of life (measured using the Tinnitus Handicap Questionnaire (THQ) and Tinnitus Handicap Inventory (THI)
- depression (measured using the Beck Depression Inventory (BDI)

One three-arm study evaluated "education counselling" compared with a control group which consisted of group sessions, and a control group which received no intervention. This study reported outcome data for tinnitus severity. Two studies investigated education counselling versus waiting list control and reported outcome data for tinnitus distress, tinnitus-related quality of life and depression.

The comparisons which compared "education counselling" to control groups, reported evidence that was graded low quality due to risk of bias. For the comparison of "education counselling" versus waiting-list control of the evidence was graded very low due to risk of bias and imprecision.

Two studies evaluated relaxation. Relaxation was investigated across four comparisons, as part of a combined intervention with information or relaxation only. Across the four comparisons the evidence was graded very low due to risk of bias and imprecision.

1.7.1.3 Benefits and harms

The majority of the evidence showed that there was no clinical difference between "education counselling" and control interventions (including group sessions, no intervention and waiting-list control) for the outcomes tinnitus severity, tinnitus distress, depression, tinnitus loudness and tinnitus-related quality of life, There was clinical benefit of "education counselling" in improving tinnitus annoyance when it was compared with waiting-list control. The committee noted that one of the studies included in the review used an "education counselling" intervention that consisted of providing participants with extensive levels of information about their tinnitus which was more directive and less collaborative than would be expected in current practice.

Despite the limited evidence in this evidence review and the lack of evidence for clinical effectiveness, the committee noted the importance of an interactive discussion being provided to people with tinnitus for support. It is current practice throughout the UK to offer "tinnitus counselling" for those with tinnitus. However, there is no standardised practice as to the content or mode of delivery. For some healthcare professionals it can be a brief clinician-led talk with intent to reassure that there is no significant pathology. Alternatively, it can be a longer interactive session focusing on the worries and concerns of the person with tinnitus, enabling the person to develop tinnitus strategies relevant to that person's interest and circumstances.

As tinnitus can affect an individual in different ways, effective tinnitus support through the provision of information and a discussion can explore how the tinnitus affects the individual and its impact on that individual's life and activities. This would then form the basis of the development of a management plan in which the clinician enables the person to take an active role in determining the management strategies relevant to the individual's difficulties. An early tailored interactive approach which recognises the distress, impact of tinnitus on the individual and that ensures that the individual is well-informed, will result in less distress and an increased ability of that individual to manage their tinnitus and result in fewer appointments. Anecdotally, a lay representative shared that "it can be a fantastic help to talk to someone who recognises that I face difficulties and give suggestions on strategies I can try." The committee agreed that the management plan should be shared with the relevant health, education and social care professionals to further support the person with tinnitus.

The term "tinnitus counselling" is used inconsistently and means different things to different people. Therefore the committee thought it was more helpful to focus on the mode of delivery and content and used the term "tinnitus support" rather than "tinnitus counselling" in the recommendation. The intention is that across the country, there is a standardised, and improved, level of care available to those with tinnitus from the first point of contact with the healthcare system. The committee expressed that all healthcare professionals to whom a person with tinnitus presents, including GPs, audiologist, ENT surgeons, audiovestibular physicians and psychologists should deliver the tinnitus support at all stages of the clinical pathway.

The committee discussed that it is important that healthcare professionals understand why people with longstanding tinnitus are accessing care at that point of contact, as this can inform the individual's management plan. This can involve asking the person prompting questions about lifestyle factors (for example, stress or change in mental well-being) or changes in health (for example, hearing loss).

The committee discussed that relaxation strategies are commonly used in current practice as a coping strategy for people with tinnitus. Two studies evaluated relaxation in some form, either as a stand-alone intervention or combined with information. When relaxation was combined with information there was no clinical difference between this intervention and information only for the outcomes of tinnitus annoyance and tinnitus loudness. Both outcomes were measured using a visual analogue scale (VAS). One study compared two types of relaxation (neutral-demand and counter-demand) with waiting-list control. For both

types of relaxation there was no clinical difference between relaxation and waiting-list control in terms of tinnitus loudness. There was clinical benefit of neutral-demand relaxation in terms of depression (measured using the Beck Depression Inventory) and anxiety (measured using the Spielberger State-Trait Anxiety Inventory). Contrastingly, counter-demand relaxation was less clinically effective compared to waiting-list control in terms of anxiety. There was no clinical difference between counter-demand relaxation and waiting-list control in terms of depression. The committee however discussed the applicability of counter-demand and noted that it is not commonly used for tinnitus management in current practice. The committee decided that a recommendation in favour of the use of relaxation strategies was not appropriate due to the lack of evidence and instead made a research recommendation.

1.7.2 Cost effectiveness and resource use

The purpose of the recommendation is to encourage a two way conversation where clinicians provide personalised information and give people with tinnitus an opportunity for discussion. The recommendation will result in use of staff time.

There were no economic evaluations available for this review question. The committee indicated that there was variation in practice in terms of the content and duration of tinnitus support provided to people with tinnitus. The committee did however acknowledge that the content and duration of tinnitus support would be dependent on the setting and clinicians, such as general practitioners, would be limited on time. Therefore, the committee expected duration of tinnitus support to be shorter during earlier stages of the management pathway but to increase in intensity as a person with tinnitus is referred to specialists such as audiologists and psychologists. The intensity of the tinnitus support would also vary according to the severity of a person's tinnitus.

There is a potential for this recommendation to result in added expenditure because of the variation in the way that tinnitus support is currently provided. However, the committee were of the view that tinnitus support should be a minimum level of care that all people with tinnitus should expect, as explained in the Patient experience guidelines (CG138), and therefore this potential cost increase is justified. The committee also noted that in certain cases tinnitus support could be provided in a group setting which could result in cost-savings, however as there was no evidence comparing group versus individual tinnitus support the committee did not specify how tinnitus support should be delivered.

Finally, this review also considered the role of relaxation to aid people with tinnitus. The committee agreed that tinnitus support specifically refers to the provision of information and wanted to separate this from a structured intervention such as relaxation. While there was some evidence exploring the role of relaxation for people with tinnitus, the evidence was limited and of poor quality. The committee therefore opted to make a research recommendation to explore both the clinical and cost-effectiveness of relaxation strategies for people with tinnitus.

1.7.3 Other factors the committee took into account

The committee discussed that there is variation in how tinnitus support is delivered to people with tinnitus. Following this recommendation will lead to standardisation of current practice and organisations may need to update protocols.

The committee were keen that tinnitus support takes into account the views and concerns of the person presenting with tinnitus in an interactive manner, including them in the decision making process of his/her management plan. Health professionals need to engage fully with each individual in order to offer accessible and appropriate information. They strongly felt that the inequity of tinnitus support through the country needed to be addressed. Many people with tinnitus, who may benefit from an intervention, do not currently have tinnitus support to inform and as part of their management plan.

Having been given information and having had time to digest it, and possibly search out further information, the committee believed that individuals with tinnitus would welcome the chance to discuss, on an individual basis, their tinnitus, self- management strategies and further intervention options. Being given a quick printout of information and being told to read it is unlikely to help people to the same extent. Information sharing and training in self-management techniques could potentially be group activities. A one-to-one setting may be more appropriate for developing a management plan.

The review on Patient information (evidence review B) examines what the content of information given to people should be.

The committee noted that for children, teacher of the Deaf can be helpful source of support within the education system.

References

1. Alpini D, Cesarani A, Hahn A. Tinnitus school: an educational approach to tinnitus management based on a stress-reaction tinnitus model. International Tinnitus Journal. 2007; 13(1):63-8

2. Argstatter H, Grapp M, Hutter E, Plinkert PK, Bolay HV. The effectiveness of neuro-music therapy according to the Heidelberg model compared to a single session of educational counseling as treatment for tinnitus: a controlled trial. Journal of Psychosomatic Research. 2015; 78(3):285-292

3. Argstatter H, Krick C, Plinkert P, Bolay HV. Music therapy for noisiform tinnitus. Concept development and evaluation. HNO. 2010; 58(11):1085-1093

4. Argstatter H, Plinkert P, Bolay HV. Music therapy for tinnitus patients: an interdisciplinary pilot study of the Heidelberg Model. HNO. 2007; 55(5):375-383

5. Arif M, Sadlier M, Rajenderkumar D, James J, Tahir T. A randomised controlled study of mindfulness meditation versus relaxation therapy in the management of tinnitus. Journal of Laryngology and Otology. 2017; 131(6):501-507

6. Bartnik G, Fabijanska A, Rogowski M. Experiences in the treatment of patients with tinnitus and/or hyperacusis using the habituation method. Scandinavian Audiology Supplementum. 2001; (52):187-90

7. Bauer CA, Berry JL, Brozoski TJ. The effect of tinnitus retraining therapy on chronic tinnitus: a controlled trial. Laryngoscope investigative otolaryngology. 2017; 2(4):166-177

8. Bauer CA, Brozoski TJ. Effect of tinnitus retraining therapy on the loudness and annoyance of tinnitus: a controlled trial. Ear and Hearing. 2011; 32(2):145-155

9. Beukes EW, Manchaiah V, Andersson G, Allen PM, Terlizzi PM, Baguley DM. Situationally influenced tinnitus coping strategies: a mixed methods approach Disability and Rehabilitation. 2018; 40(24):2884-2894

10. Beukes EW, Manchaiah V, Valien TE, Baguley DM, Allen PM, Andersson G. Positive experiences related to living with tinnitus: A cross-sectional survey Clinical Otolaryngology. 2018; 43(2):489-495

11. Biesinger E, Kipman U, Schätz S, Langguth B. Qigong for the treatment of tinnitus: a prospective randomized controlled study. Journal of Psychosomatic Research. 2010; 69(3):299-304

12. Cuda D, Caria A. Effectiveness of combined counseling and low-level laser stimulation in the treatment of disturbing chronic tinnitus. International Tinnitus Journal. 2008; 14(2):175-180

13. Dineen R, Doyle J, Bench J, Perry A. The influence of training on tinnitus perception: An evaluation 12 months after tinnitus management training. British Journal of Audiology. 1999; 33(1):29-51

14. Eysel-Gosepath K, Gerhards F, Schicketanz KH, Teichmann K, Benthien M. Attention diversion in tinnitus therapy. Comparison of the effects of different treatment methods. HNO. 2004; 52(5):431-439

15. Gerhards F, Brehmer D. Distraction and relaxation training in acute tinnitus : effects of a complement to otorhinolaryngological treatment. HNO. 2010; 58(5):488-496

16. Greenwell K, Sereda M, Coulson N, El Refaie A, Hoare DJ. A systematic review of techniques and effects of self-help interventions for tinnitus: Application of taxonomies from health psychology. International Journal of Audiology. 2016; 55(Suppl. 3):S79-S89

17. Henry JA, Loovis C, Montero M, Kaelin C, Anselmi KA, Coombs R et al. Randomized clinical trial: group counseling based on tinnitus retraining therapy. Journal of Rehabilitation Research and Development. 2007; 44(1):21-32

18. Henry JA, Thielman E, Zaugg T, Kaelin C, Choma C, Chang B et al. Development and field testing of a smartphone "App" for tinnitus management. International Journal of Audiology. 2017; 56(10):784-792

19. Henry JA, Thielman EJ, Zaugg TL, Kaelin C, Schmidt CJ, Griest S et al. Randomized controlled trial in clinical settings to evaluate effectiveness of coping skills education used with progressive tinnitus management. Journal of Speech Language & Hearing Research. 2017; 60(5):1378-1397

20. Henry JA, Zaugg TL, Myers PJ, Kendall CJ, Turbin MB. Principles and application of educational counseling used in progressive audiologic tinnitus management. Noise & Health. 2009; 11(42):33-48

21. Henry JA, Zaugg TL, Myers PJ, Schmidt CJ, Griest S, Legro MW et al. Pilot study to develop telehealth tinnitus management for persons with and without traumatic brain injury. Journal of Rehabilitation Research and Development. 2012; 49(7):1025-1042

22. Henry JL, Wilson PH, Henry JL, Wilson PH. The psychological management of tinnitus: comparison of a combined cognitive educational program, education alone and a waiting list control. International Tinnitus Journal. 1996; 2:9-20

23. Herraiz C, Diges I, Cobo P, Aparicio JM, Toledano A. Auditory discrimination training for tinnitus treatment: the effect of different paradigms. European Archives of Oto-Rhino-Laryngology. 2010; 267(7):1067-1074

24. Herraiz C, Diges I, Cobo P, Plaza G, Aparicio JM. Auditory discrimination therapy (ADT) for tinnitus managment: preliminary results. Acta Oto-Laryngologica. 2006; 126(Suppl 556):80-83

25. Hoare DJ, Stacey PC, Hall DA. The efficacy of auditory perceptual training for tinnitus: a systematic review. Annals of Behavioral Medicine. 2010; 40(3):313-324

26. Hoare DJ, Van Labeke N, McCormack A, Sereda M, Smith S, Al Taher H et al. Gameplay as a source of intrinsic motivation in a randomized controlled trial of auditory training for tinnitus. PloS One. 2014; 9(9):e107430

27. Ireland CE, Wilson PH, Tonkin JP, Platt-Hepworth S. An evaluation of relaxation training in the treatment of tinnitus. Behaviour Research and Therapy. 1985; 23(4):423-430

28. Jakes SC, Hallam RS, Rachman S, Hinchcliffe R. The effects of reassurance, relaxation training and distraction on chronic tinnitus sufferers. Behaviour Research and Therapy. 1986; 24(5):497-507

29. Kaldo-Sandstrom V, Larsen HC, Andersson G. Internet-based cognitive-behavioral self-help treatment of tinnitus: clinical effectiveness and predictors of outcome. American Journal of Audiology. 2004; 13(2):185-92

30. Kaldo V, Cars S, Rahnert M, Larsen HC, Andersson G. Use of a self-help book with weekly therapist contact to reduce tinnitus distress: a randomized controlled trial. Journal of Psychosomatic Research. 2007; 63(2):195-202

31. Koksoy S, Eti CM, Karatas M, Vayisoglu Y. The effects of yoga in patients suffering from subjective tinnitus. International Archives of Otorhinolaryngology. 2018; 22(1):9-13

32. Konzag TA, Rübler D, Bloching M, Bandemer-Greulich U, Fikentscher E, Frommer J. Counselling versus a self-help manual for tinnitus outpatients: a comparison of effectiveness. HNO. 2006; 54(8):599-604

33. Lee DY, Lee JY, Kim YH. Management of tinnitus in children: Review of literature and effect of counseling Auris, Nasus, Larynx. 2018; 45(4):667-672

34. Lindberg P, Scott B, Melin L, Lyttkens L. Long-term effects of psychological treatment of tinnitus. Scandinavian Audiology. 1987; 16(3):167-72

35. Lindberg P, Scott B, Melin L, Lyttkens L. Behavioural therapy in the clinical management of tinnitus. British Journal of Audiology. 1988; 22(4):265-272

36. Lindberg P, Scott B, Melin L, Lyttkens L. The psychological treatment of tinnitus: An experimental evaluation. Behaviour Research and Therapy. 1989; 27(6):593-603

37. Marks NJ, Karl H, Onisiphorou C. A controlled trial of hypnotherapy in tinnitus. Clinical Otolaryngology and Allied Sciences. 1985; 10(1):43-46

38. McFerran D, Hoare DJ, Carr S, Ray J, Stockdale D. Tinnitus services in the United Kingdom: a survey of patient experiences. BMC Health Services Research. 2018; 18:110

39. McFerran DJ, Stockdale D, Holme R, Large CH, Baguley DM. Why is there no cure for tinnitus? Frontiers in Neuroscience. 2019; 13:802

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

41. Nyenhuis N, Golm D, Kroner-Herwig B. A systematic review and meta-analysis on the efficacy of self-help interventions in tinnitus. Cognitive Behaviour Therapy. 2013; 42(2):159-169

42. Park SN, Bae SC, Kim DK, Park YS, Yeo SW, Park SY. Small-group counseling in a modified tinnitus retraining therapy for chronic tinnitus. Clinical and Experimental Otorhinolaryngology. 2013; 6(4):214-8

43. Reuther I. Qigong for the treatment of tinnitus: a prospective randomized controlled study. Chinesische Medizin. 2011; 26(3):169-172

44. Searchfield GD, Kaur M, Martin WH. Hearing aids as an adjunct to counseling: Tinnitus patients who choose amplification do better than those that don't. International Journal of Audiology. 2010; 49(8):574-579

45. Seydel C, Haupt H, Szczepek AJ, Hartmann A, Rose M, Mazurek B. Three years later: report on the state of well-being of patients with chronic tinnitus who underwent modified tinnitus retraining therapy. Audiology and Neuro-Otology. 2015; 20(1):26-38

46. Taylor JA, Hall DA, Walker DM, McMurran M, Casey A, Stockdale D et al. A psychologically informed, audiologist-delivered, manualised intervention for tinnitus: protocol for a randomised controlled feasibility trial (Tin Man study). Pilot & Feasibility Studies. 2017; 3:24

47. Tyler RS, Gogel SA, Gehringer AK. Tinnitus activities treatment. Progress in Brain Research. 2007; 166:425-34

48. Weber C, Arck P, Mazurek B, Klapp BF. Impact of a relaxation training on psychometric and immunologic parameters in tinnitus sufferers. Journal of Psychosomatic Research. 2002; 52(1):29-33

Appendices

Appendix A: Review protocols

Table 9: Review protocol: Is tinnitus counselling (including education, advice and relaxation strategies) clinically and cost effective and which is the best form of tinnitus counselling?

ID	Field	Content
0.	PROSPERO registration number	Not registered
1.	Review title	The clinical and cost effectiveness of “tinnitus counselling” (including education, advice and relaxation strategies) and the best form of “tinnitus counselling”
2.	Review question	Is tinnitus counselling (including education, advice and relaxation strategies) clinically and cost effective and which is the best form of tinnitus counselling?
3.	Objective	“Tinnitus counselling” is aimed at helping the person with tinnitus learn more about their condition and how to cope with it. Hearing therapists, audiologists, psychologists, specialist teachers of the deaf (working with children or young people) or doctors can carry out the treatment. The review aims to evaluate “tinnitus counselling” types in comparison with each other, or to no counselling for clinical and cost-effective outcomes. Recommendations might cover the inclusion of counselling as part of a package of care for people with tinnitus.
4.	Searches	The following databases will be searched: • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic

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

8.	Comparator/Reference standard/Confounding factors	• To different types of “tinnitus counselling” • No active treatment/waiting list
9.	Types of study to be included	• Systematic reviews • RCTs • If there is an inadequate amount of RCT data, non-randomised comparative studies will be considered
10.	Other exclusion criteria	• Non-English language studies • Studies will only be included if they report one or more of the outcomes listed above. • Descriptive (non-comparative) studies will be excluded
11.	Context	N/A
12.	Primary outcomes (critical outcomes)	• Tinnitus severity Impact of tinnitus: • Tinnitus distress • Tinnitus annoyance Health related QoL: • QoL (tinnitus) • QoL
13.	Secondary outcomes (important outcomes)	Tinnitus percept: • Tinnitus loudness Other co-occurring complaints: • Depression • Anxiety • Anxiety and depression • Sleep Adverse events: • Safety • Tolerability • Side effects
14.	Data extraction (selection and coding)	EndNote will be used for reference management, sifting, citations and

		bibliographies. Titles and/or abstracts of studies retrieved using the search strategy and those from additional sources will be screened for inclusion. The full text of potentially eligible studies will be retrieved and will be assessed for eligibility in line with the criteria outlined above. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. An in-house developed database; EviBase, will be used for data extraction. A standardised form is followed to extract data from studies (see Developing NICE guidelines: the manual section 6.4) and for undertaking assessment of study quality. Summary evidence tables will be produced including information on: study setting; study population and participant demographics and baseline characteristics; details of the intervention and control interventions; study methodology' recruitment and missing data rates; outcomes and times of measurement; critical appraisal ratings. A second reviewer will quality assure the extracted data. Discrepancies will be identified and resolved through discussion (with a third reviewer where necessary).
15.	Risk of bias (quality) assessment	Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual. For Intervention reviews the following checklist will be used according to study design being assessed: • Systematic reviews: Risk of Bias in Systematic Reviews (ROBIS) • Randomised Controlled Trial: Cochrane RoB (2.0) Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.

16.	Strategy for data synthesis	Where possible, data will be meta-analysed. Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5) to combine the data given in all studies for each of the outcomes stated above. A fixed effect meta-analysis, with weighted mean differences for continuous outcomes and risk ratios for binary outcomes will be used, and 95% confidence intervals will be calculated for each outcome. Heterogeneity between the studies in effect measures will be assessed using the I^2 statistic and visually inspected. We will consider an I^2 value greater than 50% indicative of substantial heterogeneity. Sensitivity analyses will be conducted based on pre-specified subgroups using stratified meta-analysis to explore the heterogeneity in effect estimates. If this does not explain the heterogeneity, the results will be presented using random-effects. GRADE pro will be used to assess the quality of each outcome, taking into account individual study quality and the meta-analysis results. The 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) will be appraised for each outcome. Publication bias is tested for when there are more than 5 studies for an outcome. Other bias will only be taken into consideration in the quality assessment if it is apparent. Where meta-analysis is not possible, data will be presented and quality assessed individually per outcome. If sufficient data is available to make a network of treatments, WinBUGS will be used for network meta-analysis.
17.	Analysis of sub-groups	• Profoundly deaf • People with learning disability or cognitive impairment • Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional) • Mild hearing loss

18.	Type and method of review	☒ Intervention ☐ Diagnostic ☐ Prognostic ☐ Qualitative ☐ Epidemiologic ☐ Service Delivery ☐ Other (please specify)		
19.	Language	English		
20.	Country	England		
21.	Anticipated or actual start date	29/05/18		
22.	Anticipated completion date	11/03/20		
23.	Stage of review at time of this submission	Review stage	Started	Completed
		Preliminary searches	☐	☑
		Piloting of the study selection process	☐	☑
		Formal screening of search results against eligibility criteria	☐	☑
		Data extraction	☐	☑
		Risk of bias (quality) assessment	☐	☑
		Data analysis	☐	☑

24.	Named contact	5a. Named contact National Guideline Centre 5b Named contact e-mail Tinnitus@nice.org.uk 5e Organisational affiliation of the review National Institute for Health and Care Excellence (NICE) and the National Guideline Centre
25.	Review team members	From the National Guideline Centre: • Dr Jenny Hill [Guideline lead] • Ms Sedina Lewis/Ms Julie Neilson [Senior systematic reviewers] • Dr Richard Clubbe [Systematic reviewer] • Mr David Wonderling [Health economist lead] • Mr Emtiyaz Chowdhury [Health economist] • Ms Jill Cobb [Information specialist] • Dr Giulia Zuodar [Project manager]
26.	Funding sources/sponsor	This systematic review is being completed by the National Guideline Centre which receives funding from NICE.
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: [NICE guideline webpage].

29.	Other registration details	N/A
30.	Reference/URL for published protocol	N/A
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
32.	Keywords	Tinnitus, tinnitus counselling, education, information, relaxation, coping strategies
33.	Details of existing review of same topic by same authors	N/A
34.	Current review status	☐ Ongoing ☒ Completed but not published ☐ Completed and published ☐ Completed, published and being updated ☐ Discontinued
35..	Additional information	N/A
36.	Details of final publication	www.nice.org.uk

Table 10: Health economic review protocol

Review question	All questions – health economic evidence
Objectives	To identify health economic studies relevant to any of the review questions.
Search criteria	• Populations, interventions and comparators must be as specified in the clinical review protocol above. • Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis). • Studies must not be a letter, editorial or commentary, or a review of health

	economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English.
Search strategy	A health economic study search will be undertaken using population-specific terms and a health economic study filter – see appendix B below.
Review strategy	Studies not meeting any of the search criteria above will be excluded. Studies published before 2003, abstract-only studies and studies from non-OECD countries or the USA will also be excluded. Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014).[40] **Inclusion and exclusion criteria** • If a study is rated as both 'Directly applicable' and with 'Minor limitations' then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile. • If a study is rated as either 'Not applicable' or with 'Very serious limitations' then it will usually be excluded from the guideline. If it is excluded then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile. • If a study is rated as 'Partially applicable', with 'Potentially serious limitations' or both then there is discretion over whether it should be included. **Where there is discretion** The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below. The health economist will be guided by the following hierarchies. *Setting:* • UK NHS (most applicable). • OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden). • OECD countries with predominantly private health insurance systems (for example, Switzerland). • Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations. *Health economic study type:* • Cost–utility analysis (most applicable). • Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis). • Comparative cost analysis. • Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations. *Year of analysis:*

	• The more recent the study, the more applicable it will be. • Studies published in 2003 or later but that depend on unit costs and resource data entirely or predominantly from before 2003 will be rated as 'Not applicable'. • Studies published before 2003 will be excluded before being assessed for applicability and methodological limitations. *Quality and relevance of effectiveness data used in the health economic analysis:* • The more closely the clinical effectiveness data used in the health economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

Appendix B: Literature search strategies

The literature searches for this review are detailed below and complied with the methodology outlined in Developing NICE guidelines: the manual.[40]

For more detailed information, please see the Methodology Review.

B.1 Clinical search literature search strategy

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

Table 11: Database date parameters and filters used

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

Medline (Ovid) search terms

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

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

Embase (Ovid) search terms

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

Cochrane Library (Wiley) search terms

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

CINAHL (EBSCO) search terms

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

PsycINFO (ProQuest) search terms

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

B.2 Health Economics literature search strategy

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

Table 12: Database date parameters and filters used

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

Medline (Ovid) search terms

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

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

Embase (Ovid) search terms

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

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

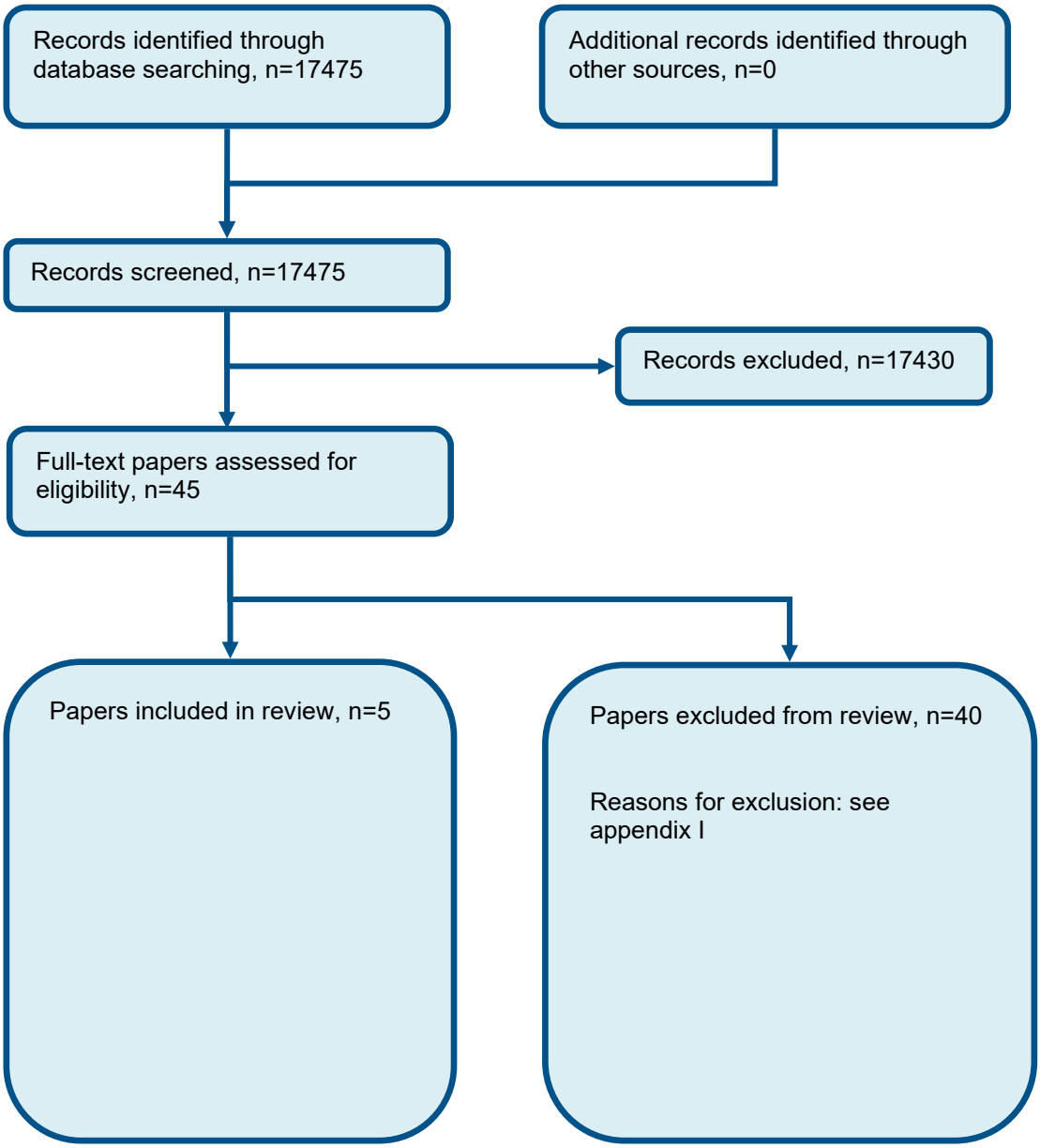
43.	(euroqol* or eq5d* or eq 5*).ti,ab.
44.	(qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
45.	(health utility* or utility score* or disutilit* or utility value*).ti,ab.
46.	(hui or hui1 or hui2 or hui3).ti,ab.
47.	(health* year* equivalent* or hye or hyes).ti,ab.
48.	discrete choice*.ti,ab.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

NHS EED and HTA (CRD) search terms

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

Appendix C: Clinical evidence selection

Figure 1: Flow chart of clinical study selection for the review of tinnitus counselling



Appendix D: Clinical evidence tables

Study	Dineen 1999[13]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=56)
Countries and setting	Conducted in Australia; Setting: Speech and Hearing Clinic of the School of Communication Sciences, La Trobe University, Melbourne
Line of therapy	Not applicable
Duration of study	Follow up (post intervention): 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	Subjects with tinnitus, no other details reported
Exclusion criteria	Not reported
Recruitment/selection of patients	Subjects who responded to community announcements, via newspapers and radio, of the tinnitus research and management programme were assessed.
Age, gender and ethnicity	Age - Mean (SD): 54.37 (13.86). Gender (M:F): 2/1. Ethnicity: Not reported
Further population details	1. Mild hearing loss: Not applicable 2. People with learning disability or cognitive impairment: Not applicable 3. Profoundly deaf: Not applicable
Indirectness of population	No indirectness
Interventions	(n=28) Intervention 1: Tinnitus counselling - Relaxation. Two three-hour sessions provided - subjects received training in a 'progressive relaxation' technique, a relaxed breathing technique, and the use of positive mental imagery. Subjects were supplied with an audiocassette that guided them through the relaxation process and were encouraged to regularly practice the relaxation techniques. Practice was given at both sessions of the tinnitus management training. All subjects received the same information programme, namely information on: prevalence of tinnitus, function of the auditory system, contemporary theories of tinnitus generation, tinnitus related pathologies, pharmacological and dietary influences on tinnitus, psychology of adaptation to

	tinnitus, role of hearing aids, the use of cognitive and environmental sound-masking strategies in tinnitus management, management of sleep problems and the influence of stress on tinnitus perception. Each subject received a 60 page manual: 'Tinnitus: How to live with it' (Dineen et al., 1995), which gave written details of the topics. . Duration Unclear. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not stated (n=28) Intervention 2: Tinnitus counselling - Education including coping strategies. All subjects received the same information programme, namely information on: prevalence of tinnitus, function of the auditory system, contemporary theories of tinnitus generation, tinnitus related pathologies, pharmacological and dietary influences on tinnitus, psychology of adaptation to tinnitus, role of hearing aids, the use of cognitive and environmental sound-masking strategies in tinnitus management, management of sleep problems and the influence of stress on tinnitus perception. Each subject received a 60 page manual: 'Tinnitus: How to live with it' (Dineen et al., 1995), which gave written details of the topics.. Duration Unclear. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not stated
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: RELAXATION + INFORMATION versus INFORMATION ONLY

Protocol outcome 1: Tinnitus annoyance
- Actual outcome for Adults: Tinnitus annoyance at 12 months; Group 1: mean 3.9 (SD 2.9); n=21, Group 2: mean 4.3 (SD 2.3); n=17; Visual analogue scale 0-10 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 7, Reason: Not reported; Group 2 Number missing: 11, Reason: Not reported

Protocol outcome 2: Tinnitus loudness
- Actual outcome for Adults: Tinnitus loudness at 12 months; Group 1: mean 4.4 (SD 2.7); n=21, Group 2: mean 5.8 (SD 1.9); n=17; Visual analogue scale 0-10 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 7, Reason: Not reported; Group 2 Number missing: 11, Reason: Not reported

Protocol outcomes not reported by the study	Tinnitus distress; Quality of life (tinnitus); Quality of life; Severity; Anxiety; Depression; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	**Henry 1996[22]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=40)
Countries and setting	Conducted in Australia; Setting: Veterans Hospital out-patients clinic in Australia
Line of therapy	Not applicable
Duration of study	Intervention time: 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	(1) a primary complaint of chronic tinnitus (i.e. duration greater than six months), (2) the tinnitus has been assessed by both an otolaryngologist and an audiologist, (3) traditional medical and audiological treatments were not recommended, or had been attempted and had failed, (4) no provision of a hearing aid, masker or tinnitus suppressive medication within the previous six months, (5) a demonstrated level of distress associated with tinnitus as indicated by a total score of at least 17 points on the Tinnitus Reaction Questionnaire (TRQ), (6) able to read and speak English, (7) willing to participate in a research-oriented treatment program.
Exclusion criteria	Not reported
Recruitment/selection of patients	Patients who were primarily referred by audiologists and/or otolaryngologists at a Veterans Hospital out-patients clinic
Age, gender and ethnicity	Age - Mean (range): 64.6 (33-77) years. Gender (M:F): 6.5/1. Ethnicity: Not reported
Further population details	1. Mild hearing loss: Not applicable 2. People with learning disability or cognitive impairment: Not applicable 3. Profoundly deaf: Not applicable
Indirectness of population	No indirectness
Interventions	(n=20) Intervention 1: Tinnitus counselling - Provision of information and advice. Treatment was conducted in small groups of 5-7 subjects - one 90-minute session per week for six weeks. The aim of the intervention was solely to educate subjects about tinnitus. Material was presented in a written treatment manual. The sessions

	were didactic in nature and followed a sequence of specific topics each week. Topics covered were: the auditory system, language and speech, and the nature of tinnitus, audiological assessment, causes of tinnitus, theories of tinnitus and medical treatments, audiological treatments, history of tinnitus and details of the Australian Tinnitus Association. Subjects of this education-only program were not instructed in any active coping skills.. Duration 6 weeks. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not stated / Unclear (n=20) Intervention 2: No tinnitus counselling . Subjects assigned to waiting-list control were informed that due to present demands and limited facilities their participation in the program would be delayed. Subjects were assured that they would be treated when further groups were scheduled. Waiting-list subjects received treatment (cognitive coping skills/education) immediately following the post-treatment assessment.. Duration 6 weeks. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not applicable
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INFORMATION versus WAITING-LIST CONTROL

Protocol outcome 1: Tinnitus distress
- Actual outcome for Adults: Tinnitus distress at Post-treatment; Group 1: mean 45.45 (SD 22.28); n=20, Group 2: mean 46.6 (SD 21.89); n=20; Tinnitus Reaction Questionnaire 0-104 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Not reported; Group 2 Number missing: 0, Reason: Not reported
- Actual outcome for Adults: Tinnitus distress at 12 months; Group 1: mean 45.94 (SD 21.56); n=17, Group 2: mean 46.29 (SD 21.5); n=14; Tinnitus Reaction Questionnaire (TRQ) 0-104 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Not reported; Group 2 Number missing: 6, Reason: Not reported

Protocol outcome 2: Tinnitus annoyance
- Actual outcome for Adults: Tinnitus annoyance at Post-treatment; Group 1: mean 2.77 (SD 0.64); n=17, Group 2: mean 2.77 (SD 0.86); n=14; Visual analogue scale 0-4 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Not reported; Group 2 Number missing: 0, Reason: Not reported

- Actual outcome for Adults: Tinnitus annoyance at 12 months; Group 1: mean 2.88 (SD 1.11); n=17, Group 2: mean 2.21 (SD 0.89); n=14; Visual analogue scale 0-4 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Not reported; Group 2 Number missing: 6, Reason: Not reported

Protocol outcome 3: Quality of life (tinnitus)
- Actual outcome for Adults: Tinnitus-related quality of life at Post-treatment; Group 1: mean 59.34 (SD 19.44); n=20, Group 2: mean 60.88 (SD 18.95); n=20; Tinnitus Handicap Questionnaire 0-100 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Not reported; Group 2 Number missing: 0, Reason: Not reported
- Actual outcome for Adults: Tinnitus-related quality of life at 12 months; Group 1: mean 55.23 (SD 18.8); n=17, Group 2: mean 55.91 (SD 17.03); n=14; Tinnitus Handicaps Questionnaire (THQ) Unclear Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Not reported; Group 2 Number missing: 6, Reason: Not reported

Protocol outcome 4: Tinnitus loudness
- Actual outcome for Adults: Tinnitus loudness at Post-treatment; Group 1: mean 2.83 (SD 0.73); n=20, Group 2: mean 3.03 (SD 0.99); n=20; Visual analogue scale 0-4 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Not reported; Group 2 Number missing: 0, Reason: Not reported
- Actual outcome for Adults: Tinnitus loudness at 12 months; Group 1: mean 3.17 (SD 0.95); n=17, Group 2: mean 3.35 (SD 0.74); n=14; Visual analogue scale 0-4 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Not reported; Group 2 Number missing: 6, Reason: Not reported

Protocol outcome 5: Depression
- Actual outcome for Adults: Depression at Post-treatment; Group 1: mean 11.45 (SD 8.58); n=20, Group 2: mean 11.5 (SD 6.01); n=20; Beck Depression Inventory 0-63 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Not reported; Group 2 Number missing: 0, Reason: Not reported
- Actual outcome for Adults: Depression at 12 months; Group 1: mean 13 (SD 9.57); n=17, Group 2: mean 11.42 (SD 9.14); n=14; Beck Depression

Inventory 0-63 Top=High is poor outcome Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Not reported; Group 2 Number missing: 6, Reason: Not reported	
Protocol outcomes not reported by the study	Quality of life; Severity; Anxiety; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	**Henry 2007**[17]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=269)
Countries and setting	Conducted in USA; Setting: Seattle/Tacoma area, United States
Line of therapy	Not applicable
Duration of study	Follow up (post intervention): 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	Callers were considered potential candidates, regardless of age or medical condition, if they (1) had clinically significant tinnitus, i.e. if their tinnitus was sufficiently bothersome to warrant intervention; (2) were willing and able to complete all study requirements; and (3) attended an open-house, where they received further information about the study.
Exclusion criteria	Not reported
Recruitment/selection of patients	Subjects were recruited from the Seattle/Tacoma area via local newspaper and radio advertisements and flyers posted at the Seattle and American Lake VAMCs. Approximately 750 veterans responded to the advertisements by telephoning the project coordinator, who asked them four scripted questions: (1) Do you have tinnitus that is constant? (2) Does tinnitus affect your sleep? (3) Does tinnitus affect your reading or concentration? and (4) On a scale of 1to 10, how much has tinnitus annoyed you in the last month (1 being not at all,10 being as much as you can imagine)? Callers were invited to an open house event, interested candidates were asked to sign informed consent forms and complete baseline questionnaires.
Age, gender and ethnicity	Age: Not reported. Gender (M:F): 28.9/1. Ethnicity: Not reported

Further population details	1. Mild hearing loss: No mild hearing loss 2. People with learning disability or cognitive impairment: People without learning disability or cognitive impairment 3. Profoundly deaf: Not profoundly deaf
Extra comments	Duration of tinnitus: <1 year – 3%; 1-2 years – 3%; 3-5 year – 8%; 6-10 years – 14%; 10-20 years – 23%; >20 years – 42%; Unsure – 6%
Indirectness of population	No indirectness
Interventions	(n=94) Intervention 1: Tinnitus counselling - Provision of information and advice. Subjects in the educational counselling group attended four weekly sessions. Each session lasted 1.5 hours, including 15 minutes for general discussion. One of three study audiologists conducted the educational presentations for each cohort of subjects. Session 1 included an introduction into tinnitus retraining therapy (TRT), basic anatomy and physiology of ear and auditory pathways and "selective" listening. Session 2 included educating participants about the misconceptions around tinnitus. Session 3 included information about the use of sound therapy in TRT and the TRT "neurophysiological model". Session 4 included a detailed description of hyperacusis, "neural networks" and how stress is related to tinnitus.. Duration Unclear. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Non-mental health professional (n=84) Intervention 2: No tinnitus counselling . Participants attended four weekly 1.5 hour discussion-type group sessions. Sessions were moderated by the project coordinator. No education was provided in the support group. Duration Unclear. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Non-mental health professional (n=91) Intervention 3: No tinnitus counselling. Participants did not receive any study intervention.. Duration Unclear. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not applicable
Funding	Academic or government funding (Veterans Health Administration and the VA Rehabilitation Research and Development Service)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: EDUCATION COUNSELLING versus TRADITIONAL SUPPORT (CONTROL GROUP)

Protocol outcome 1: Severity
- Actual outcome for Adults: Tinnitus severity at 12 months; Group 1: mean 22.1 (SD 11); n=68, Group 2: mean 22.9 (SD 9.3); n=61; Tinnitus Severity

Index 0-48 Top=High is poor outcome Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 26, Reason: Not reported; Group 2 Number missing: 23, Reason: Not reported RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: EDUCATION COUNSELLING versus CONTROL GROUP Protocol outcome 1: Severity - Actual outcome for Adults: Tinnitus severity at 12 months; Group 1: mean 22.1 (SD 11); n=68, Group 2: mean 21.6 (SD 8.9); n=75; Tinnitus Severity Index 0-48 Top=High is poor outcome Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 26, Reason: Not reported; Group 2 Number missing: 15, Reason: Not reported	
Protocol outcomes not reported by the study	Tinnitus distress; Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Tinnitus loudness; Anxiety; Depression; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	**Henry 2017[19]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=300)
Countries and setting	Conducted in USA; Setting: Memphis VAMC (Tennessee) and VA Connecticut HealthcareSystem (West Haven) Memphis VAMC
Line of therapy	Not applicable
Duration of study	Intervention time: 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	Requirements for participation included the following:(a)using the THS, patients identified at least one tinnitus-specific problem they were experiencing; (b) they wanted to attend a series of workshops to learn coping skills to deal with one or more tinnitus-specific problems identified on the THS (so as to be as consistent as possible with normal clinical procedures,no minimum score on the THS was required); and (c) they understood that the coping skills taught in the workshops would not help with any hearing problems

Study	Henry 2017[19]
	identified on the THS.
Exclusion criteria	Not reported
Recruitment/selection of patients	The two study sites were selected on the basis of having psychologists available to join the study team who were trained in and experienced with CBT.
Age, gender and ethnicity	Age - Mean (SD): 58 (13) years. Gender (M:F): 19/1. Ethnicity:
Further population details	1. Mild hearing loss: No mild hearing loss 2. People with learning disability or cognitive impairment: People without learning disability or cognitive impairment 3. Profoundly deaf: Not profoundly deaf
Extra comments	Duration of tinnitus: <1 year – 1%; 1-2 years – 8%; 3-5 years – 10%; 6-10 years – 8%; 11-20 years – 11%; > 20 years – 44%; Unsure – 15%
Indirectness of population	No indirectness
Interventions	(n=150) Intervention 1: Tinnitus counselling - Education including coping strategies. Five weekly workshops were conducted: two with an audiologist and three with a psychologist. In a typical schedule, an audiologist conducted Workshops1 and 3 and a psychologist conducted Workshops 2, 4, and 5. The audiologist taught participants reasonable expectations for using sound as therapy and provided a structured framework for creating personalized plans for using sound to address specific tinnitus problem situations identified by each participant. The psychologist taught three coping techniques that are used with CBT: relaxation, planning pleasant activities, and cognitive restructuring—also to specifically address individuals' tinnitus problem situations. If a participant required services beyond Level 3, then a Level4 interdisciplinary evaluation was offered. PTM Level 4 normally involves a psychologist and an audiologist each conducting an in-depth evaluation of the patient's tinnitus-specific needs. If, after the Level 4 evaluation, the clinicians and patient agree that individualised support is desired and appropriate, then Level 5 individualised support is initiated. Level 5 involves one-on-one sessions that focus on barriers to enacting the Level 3 skills and provision of ongoing support to incorporate the use of the skills in daily life. Duration Unclear. Concurrent medication/care: If a study participant failed to attend a scheduled workshop, he or she was mailed a DVD with the workshop presentation that was missed. The participant was instructed to view the video and complete any tasks described within the presentation before his or her next scheduled workshop if possible. The RA followed up with the participant to determine whether the video had been viewed. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (n=150) Intervention 2: No counselling . Details not reported. Duration 6 months. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not applicable

Study	Henry 2017[19]
Funding	Academic or government funding (Veteran Affairs Rehabilitation Research & Development Service (Grant C7213R and C9247S))
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: EDUCATION COUNSELLING versus WAITING-LIST CONTROL Protocol outcome 1: Quality of life (tinnitus) - Actual outcome for Adults: Tinnitus-related quality of life at 6 months; Group 1: mean -4.3 (SD 17.8); n=111, Group 2: mean 2.3 (SD 17.2); n=121; Tinnitus Handicap Inventory 0-100 Top=High is poor outcome Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 39, Reason: Did not attend workshops; Group 2 Number missing: 29, Reason: Did not attend workshops Protocol outcome 2: Severity - Actual outcome for Adults: Tinnitus severity at 6 months; Group 1: mean -5.7 (SD 18.8); n=112, Group 2: mean 0.8 (SD 17.5); n=119; Tinnitus Functional Index (TF) 0-100 Top=High is poor outcome Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 38, Reason: Did not attend workshops; Group 2 Number missing: 31, Reason: Did not attend workshops	
Protocol outcomes not reported by the study	Tinnitus distress; Tinnitus annoyance; Quality of life; Tinnitus loudness; Anxiety; Depression; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	Ireland 1985[27]
Study type	RCT (randomised; Parallel)
Number of studies (number of participants)	(n=18)
Countries and setting	Conducted in Australia; Setting: University Psychology Clinic, exact location not reported.
Line of therapy	Not applicable
Duration of study	Follow up (post intervention): 2-4 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Not applicable

Inclusion criteria	People complaining of subjective tinnitus, for whom other traditional treatments were either not recommended or had failed.
Exclusion criteria	Not reported
Recruitment/selection of patients	Patients referred to the University Psychology Clinic by otolaryngologists, following assessment by an audiologist.
Age, gender and ethnicity	Age – Mean (range): 55.9 (28-76) years. Gender (M:F): 1/1. Ethnicity: Not reported
Further population details	1. Mild hearing loss: No mild hearing loss 2. People with learning disability or cognitive impairment: People without learning disability or cognitive impairment 3. Profoundly deaf: Not profoundly deaf
Extra comments	Mean duration of tinnitus was 5.3 years (range = 7 months to 20 years)
Indirectness of population	No indirectness
Interventions	(n=7) Intervention 1: Tinnitus counselling - Relaxation. Treatment consisted of seven, weekly 1.5 hour sessions and was conducted in groups of 4-7 participants. Treatment was conducted at the University Psychology Clinic. One therapist, a final-year graduate student in clinical psychology conducted all the treatment sessions. A progressive relaxation procedure outlined was used, consisting of learning to sequentially tense and relax various groups of muscles while at the same time paying close attention to breathing and saying the cue word 'relax'. Emphasis was placed upon regular home practice of the procedures. Participants in the counter-demand group were instructed that after the fifth session they will begin to experience dramatic improvement in their tinnitus and in general feelings of well-being. However, during the first 5 weeks, improvement is not expected. These instructions were given during the initial treatment session and were repeated during the second and third session. . Duration 7 weeks. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (n=5) Intervention 2: Tinnitus counselling - Relaxation. Treatment consisted of seven, weekly 1.5 hour sessions and was conducted in groups of 4-7 participants. Treatment was conducted at the University Psychology Clinic. One therapist, a final-year graduate student in clinical psychology conducted all the treatment sessions. A progressive relaxation procedure outlined was used, consisting of learning to sequentially tense and relax various groups of muscles while at the same time paying close attention to breathing and saying the cue word 'relax'. Emphasis was placed upon regular home practice of the procedures. Participants received no demand instructions.. Duration 7 weeks. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional

	(n=6) Intervention 3: No tinnitus counselling. Participants who were assigned to the waiting-list condition were informed that, due to present demands, they could not be treated until new groups were commenced in approximately 2 months. Participants received group relaxation training immediately following the post-treatment assessment period. Duration 7 weeks. Concurrent medication/care: N/A. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not applicable
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: RELAXATION (COUNTER-DEMAND) versus WAITING-LIST CONTROL

Protocol outcome 1: Tinnitus loudness
- Actual outcome for Adults: Tinnitus loudness at 4 weeks; Group 1: mean 2.2 (SD 0.5); n=7, Group 2: mean 2.4 (SD 0.7); n=6; Not reported 0-4 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Study consisted of two stages: first stage involved randomisation whilst the second stage did not. Outcome data was reported separately for the stages, first stage results were used. However, overall missing data information is reported, unclear at which stage in the trial participants withdrew from the study. ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Not reported; Group 2 Number missing: 0, Reason: Not reported

Protocol outcome 2: Anxiety
- Actual outcome for Adults: Anxiety at 2 weeks; Group 1: mean 46.3 (SD 12.1); n=7, Group 2: mean 38.8 (SD 9.9); n=6; Spielberger State-Trait Anxiety Inventory (STAI) Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Study consisted of two stages: first stage involved randomisation whilst the second stage did not. Outcome data was reported separately for the stages, first stage results were used. However, overall missing data information is reported, unclear at which stage in the trial participants withdrew from the study. ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Not reported; Group 2 Number missing: 0, Reason: Not reported

Protocol outcome 3: Depression
- Actual outcome for Adults: Depression at 2 weeks; Group 1: mean 11.3 (SD 4.6); n=7, Group 2: mean 9.3 (SD 8.2); n=6; Beck Depression Inventory (BDI) Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Study consisted of two stages: first stage involved randomisation whilst the second stage did not. Outcome data was reported separately for the stages, first stage results were used. However, overall missing data information is reported, unclear at which stage in the trial participants

withdrew from the study. ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Not reported; Group 2 Number missing: 0, Reason: Not reported

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: RELAXATION (NEUTRAL-DEMAND) versus WAITING-LIST CONTROL

Protocol outcome 1: Tinnitus loudness
- Actual outcome for Adults: Tinnitus loudness at 4 weeks; Group 1: mean 2 (SD 0.5); n=5, Group 2: mean 2.4 (SD 0.7); n=6; Not reported 0.4 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Study consisted of two stages: first stage involved randomisation whilst the second stage did not. Outcome data was reported separately for the stages, first stage results were used. However, overall missing data information is reported, unclear at which stage in the trial participants withdrew from the study. ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Not reported; Group 2 Number missing: 0, Reason: Not reported

Protocol outcome 2: Anxiety
- Actual outcome for Adults: Anxiety at 2 weeks; Group 1: mean 31.3 (SD 8.3); n=5, Group 2: mean 38.8 (SD 9.9); n=6; Spielberger State-Trait Anxiety Inventory (STAI) Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Study consisted of two stages: first stage involved randomisation whilst the second stage did not. Outcome data was reported separately for the stages, first stage results were used. However, overall missing data information is reported, unclear at which stage in the trial participants withdrew from the study. ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Not reported; Group 2 Number missing: 0, Reason: Not reported

Protocol outcome 3: Depression
- Actual outcome for Adults: Depression at 2 weeks; Group 1: mean 5 (SD 5.5); n=5, Group 2: mean 9.3 (SD 8.2); n=6; Beck Depression Inventory Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - Study consisted of two stages: first stage involved randomisation whilst the second stage did not. Outcome data was reported separately for the stages, first stage results were used. However, overall missing data information is reported, unclear at which stage in the trial participants withdrew from the study. ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0, Reason: Not reported; Group 2 Number missing: 0, Reason: Not reported

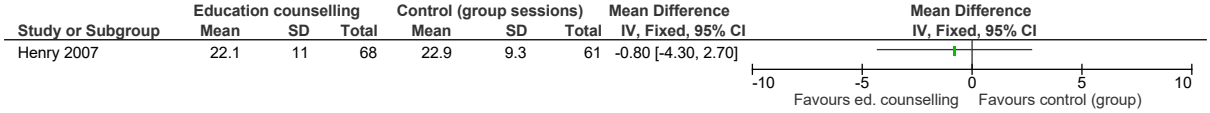
Protocol outcomes not reported by the study	Tinnitus distress; Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Severity; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Appendix E: Forest plots

E.1 Education counselling versus control

E.1.1 Education counselling versus control (group session)

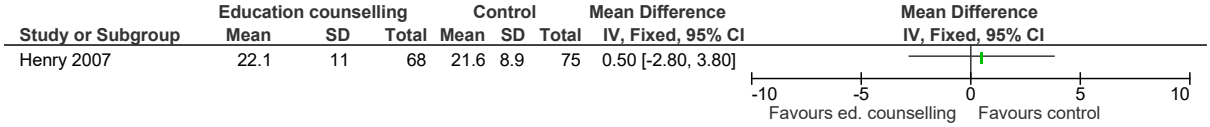
Figure 2: Tinnitus severity (12 months); TSI, scale 0-48



TSI = tinnitus severity index

E.1.2 Education counselling versus control (no interventions)

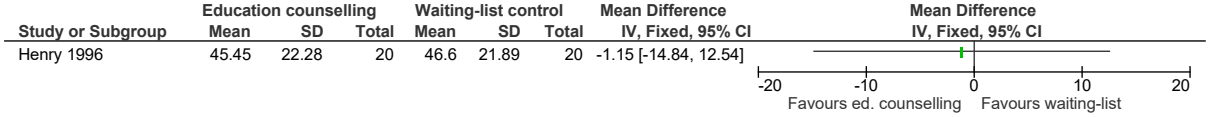
Figure 3: Tinnitus severity (12 months); TSI, scale 0-48



TSI = tinnitus severity index

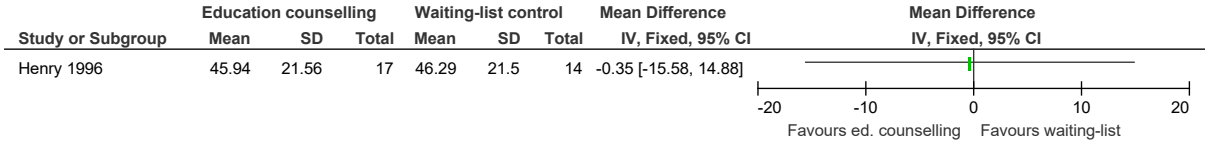
E.1.3 Education counselling versus waiting-list control

Figure 4: Tinnitus distress (post-treatment); TRQ, scale 0-104



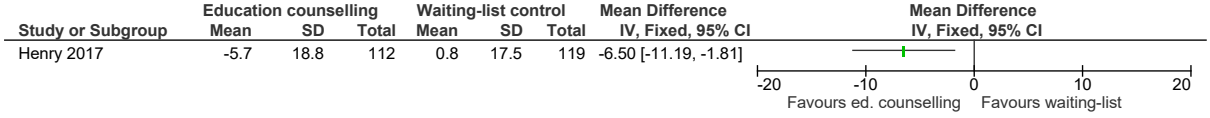
TRQ = tinnitus reaction questionnaire

Figure 5: Tinnitus distress (12 months); TRQ, scale 0-104



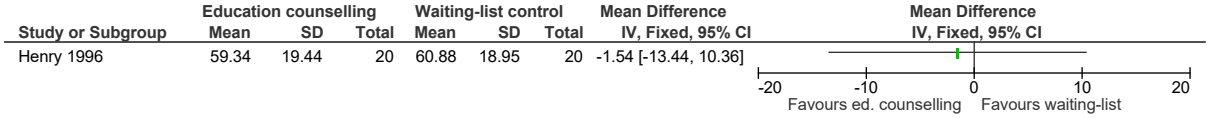
TRQ = tinnitus reaction questionnaire

Figure 6: Tinnitus severity (6 months); TFI, scale 0-100



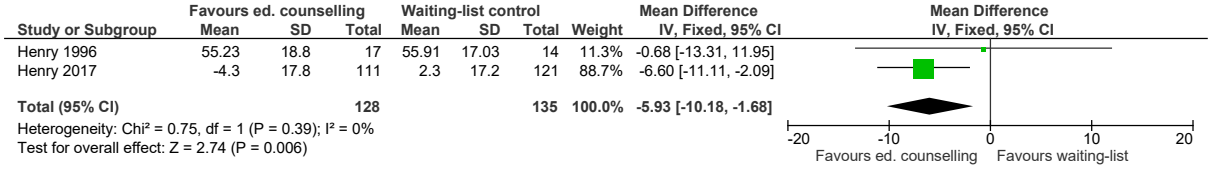
TFI = tinnitus functional index

Figure 7: Tinnitus-related quality of life (post-treatment); THQ, scale 0-100



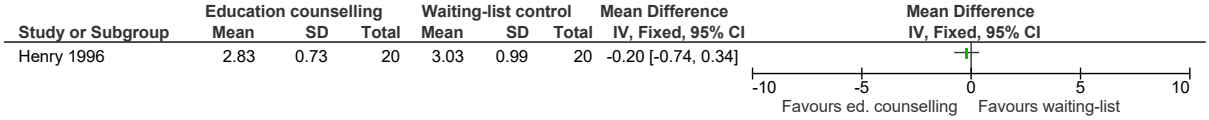
THQ = tinnitus handicap questionnaire

Figure 8: Tinnitus-related quality of life (6-12 months); THI and THQ, scale 0-100



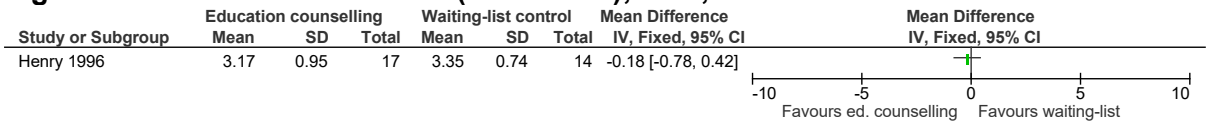
THI = tinnitus handicap inventory; THQ = tinnitus handicap questionnaire

Figure 9: Tinnitus loudness (post-treatment); VAS, scale 0-4



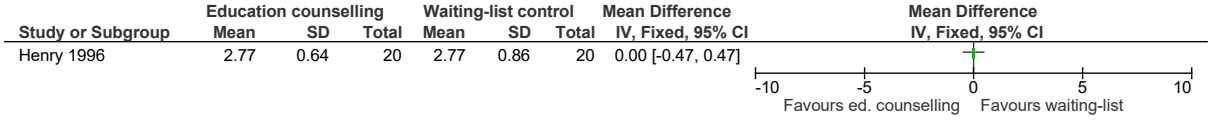
VAS = visual analogue scale

Figure 10: Tinnitus loudness (12 months); VAS, scale 0-4



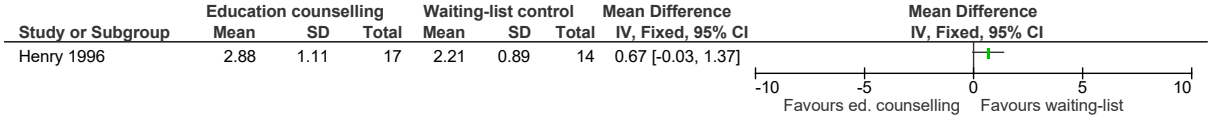
VAS = visual analogue scale

Figure 11: Tinnitus annoyance (post-treatment); VAS, scale 0-4



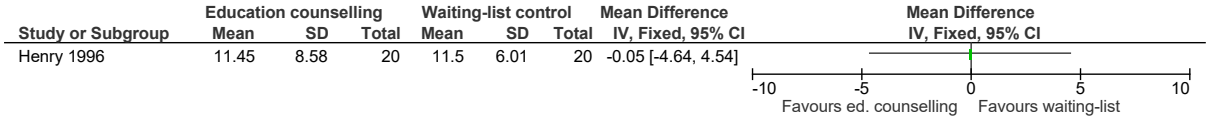
VAS = visual analogue scale

Figure 12: Tinnitus annoyance (12 months); VAS, scale 0-4



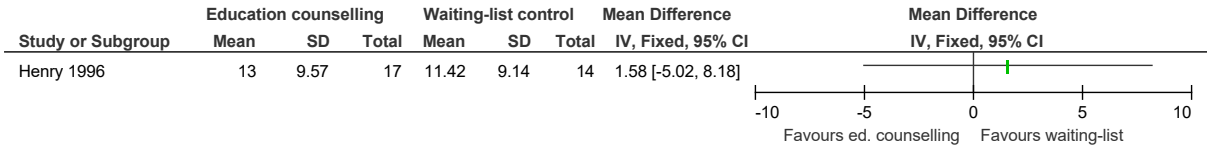
VAS = visual analogue scale

Figure 13: Depression (post-treatment); BDI, scale 0-63



BDI = Beck Depression Inventory

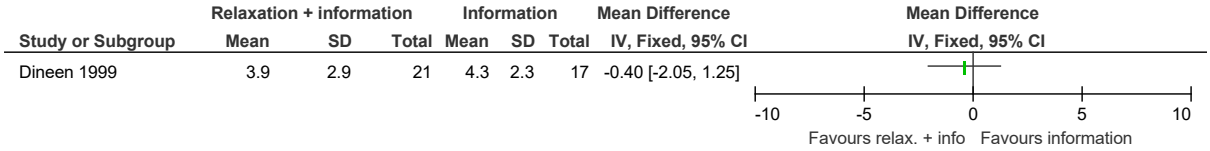
Figure 14: Depression (12 months); BDI, scale 0-63



BDI = Beck Depression Inventory

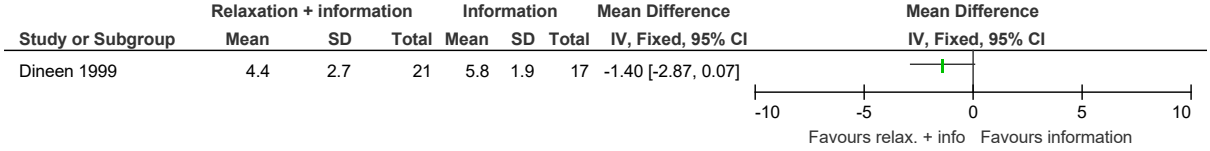
E.2 Relaxation + counselling (information) versus counselling (information)

Figure 15: Tinnitus annoyance (12 months); VAS, scale range 0-10



VAS = visual analogue scale

Figure 16: Tinnitus loudness (12 months); VAS, scale range 0-10



VAS = visual analogue scale

E.3 Relaxation versus waiting-list control

E.3.1 Neutral-demand (ND) relaxation versus waiting-list control

Figure 17: Tinnitus loudness (1-4 weeks); scale range 0-4

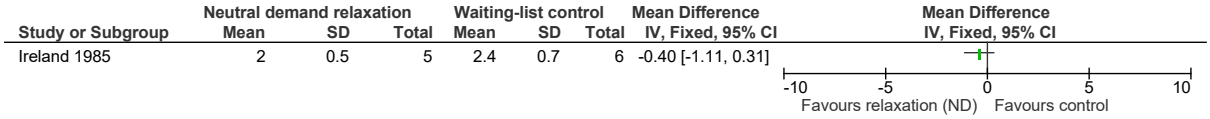
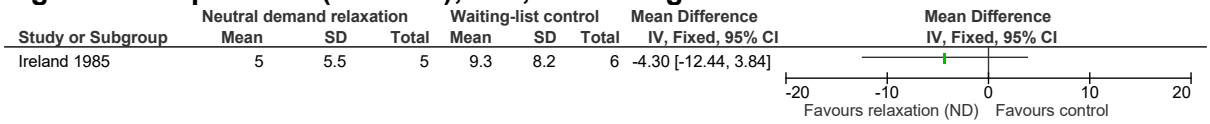
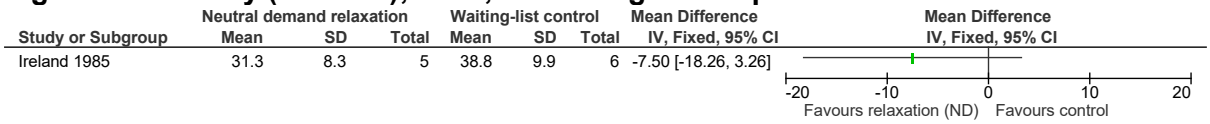


Figure 18: Depression (2 weeks); BDI, scale range 0-63



BDI = Beck Depression Inventory

Figure 19: Anxiety (2 weeks); STAI, scale range not reported



STAI = Spielberger State-Trait Anxiety Inventory

E.3.2 Counter-demand (CD) relaxation versus waiting-list control

Figure 20: Tinnitus loudness (1-4 weeks); scale range 0-4

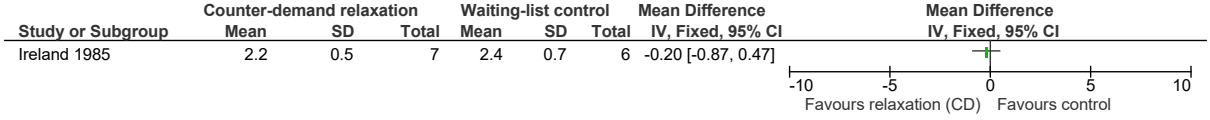
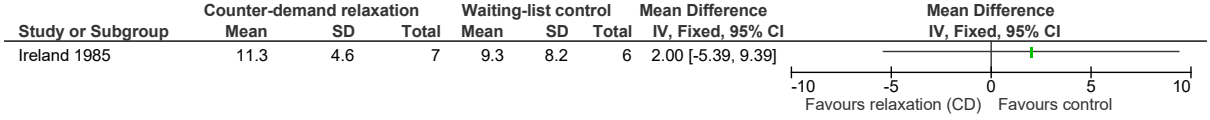
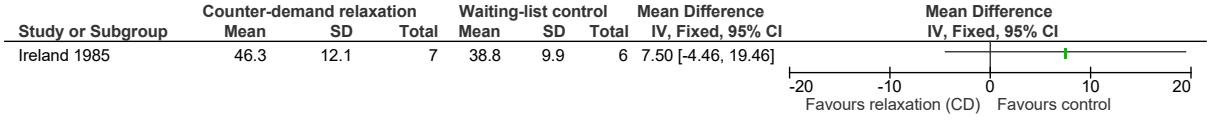


Figure 21: Depression (2 weeks); BDI, scale range 0-63



BDI = Beck Depression Inventory

Figure 22: Anxiety (2 weeks); STAI, scale range not reported



STAI = Spielberger State-Trait Anxiety Inventory

Appendix F: GRADE tables

Table 13: Clinical evidence profile: Education counselling versus control (group sessions)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Education counselling	Control (group sessions)	Relative (95% CI)	Absolute		
Tinnitus severity (follow-up 12 months; measured with: Tinnitus Severity Index (TSI); range of scores: 0-48; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	68	61	-	MD 0.80 lower (4.3 lower to 2.7 higher)	⊕⊕OO LOW	CRITICAL

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

Table 14: Clinical evidence profile: Education counselling versus control (no intervention)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Education counselling	Control	Relative (95% CI)	Absolute		
Tinnitus severity (follow-up 12 months; measured with: Tinnitus Severity Index (TSI); range of scores: 0-48; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	68	75	-	MD 0.50 higher (2.8 lower to 3.8 higher)	⊕⊕OO LOW	CRITICAL

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

Table 15: Clinical evidence profile: Education counselling versus waiting-list control

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Education counselling	Waiting-list control	Relative (95% CI)	Absolute		
Tinnitus distress (follow-up post-treatment; measured with: Tinnitus Reaction Questionnaire; range of scores: 0-104; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	20	20	-	MD 1.15 lower (14.84 lower to 12.54 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus distress (follow-up 12 months; measured with: Tinnitus Reaction Questionnaire; range of scores: 0-104; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	17	14	-	MD 0.35 lower (15.58 lower to 14.88 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus severity (follow-up 6 months; measured with: Tinnitus Functional Index; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	112	119	-	MD 6.5 lower (11.19 to 1.81 lower)	⊕OOO VERY LOW	CRITICAL
Tinnitus-related quality of life (follow-up post-treatment; measured with: Tinnitus Handicap Questionnaire; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	20	20	-	MD 1.54 lower (13.44 lower to 10.36 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus-related quality of life (follow-up 6-12 months; measured with: Tinnitus Handicap Inventory and Tinnitus Handicap Questionnaire; range of scores: 0-100; Better indicated by lower values)												
2	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	128	135	-	MD 5.93 lower (10.18 to 1.68 lower)	⊕OOO VERY	CRITICAL

											LOW	
Tinnitus loudness (follow-up post-treatment; measured with: Visual analogue scale; range of scores: 0-4; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	20	20	-	MD 0.2 lower (0.74 lower to 0.34 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus loudness (follow-up 12 months; measured with: Visual analogue scale; range of scores: 0-4; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	17	14	-	MD 0.18 lower (0.78 lower to 0.42 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus annoyance (follow-up post-treatment; measured with: Visual analogue scale; range of scores: 0-4; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	20	20	-	MD 0 higher (0.47 lower to 0.47 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus annoyance (follow-up 12 months; measured with: Visual analogue scale; range of scores: 0-4; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	17	14	-	MD 0.67 higher (0.03 lower to 1.37 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up post-treatment; measured with: Beck Depression Inventory; range of scores: 0-63; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	20	20	-	MD 0.05 lower (4.64 lower to 4.54 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up 12 months; measured with: Beck Depression Inventory; range of scores: 0-63; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	17	14	-	MD 1.58 higher (5.02 lower to 8.18 higher)	⊕OOO VERY LOW	IMPORTANT

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 16: Clinical evidence profile: Relaxation + counselling (information) versus counselling (information) only

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Relaxation + information	Information	Relative (95% CI)	Absolute		
Tinnitus annoyance (follow-up 12 months; measured with: Visual Analogue Scale (VAS); range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	21	17	-	MD 0.4 lower (2.05 lower to 1.25 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus loudness (follow-up 12 months; measured with: Visual Analogue Scale (VAS); range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	21	17	-	MD 1.4 lower (2.87 lower to 0.07 higher)	⊕OOO VERY LOW	IMPORTANT

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 17: Clinical evidence profile: Neutral-demand relaxation versus waiting-list control

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Neutral-demand relaxation	Waiting-list control	Relative (95% CI)	Absolute		

Tinnitus loudness (follow-up 4 weeks; range of scores: 0-4; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	5	6	-	MD 0.4 lower (1.11 lower to 0.31 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up 2 weeks; measured with: Beck Depression Inventory; range of scores: 0-63; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	5	6	-	MD 4.3 lower (12.44 lower to 3.84 higher)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up 2 weeks; measured with: Spielberger State-Trait Anxiety Inventory (STAI) ; Better indicated by lower values)												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	5	6	-	MD 7.5 lower (18.26 lower to 3.26 higher)	⊕OOO VERY LOW	IMPORTANT

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 18: Clinical evidence profile: Counter-demand relaxation versus waiting-list control

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Counter-demand relaxation**	**Waiting-list control**	**Relative (95% CI)**	**Absolute**		
Tinnitus loudness (follow-up 4 weeks; range of scores: 0-4; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	7	6	-	MD 0.2 lower (0.87 lower to 0.47 higher)	⊕OOO VERY LOW	IMPORTANT

Depression (follow-up 2 weeks; measured with: Beck Depression Inventory; range of scores: 0-63; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	7	6	-	MD 2 higher (5.39 lower to 9.39 higher)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up 2 weeks; measured with: Spielberger State-Trait Anxiety Inventory (STAI); Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	7	6	-	MD 7.5 higher (4.46 lower to 19.46 higher)	⊕OOO VERY LOW	IMPORTANT

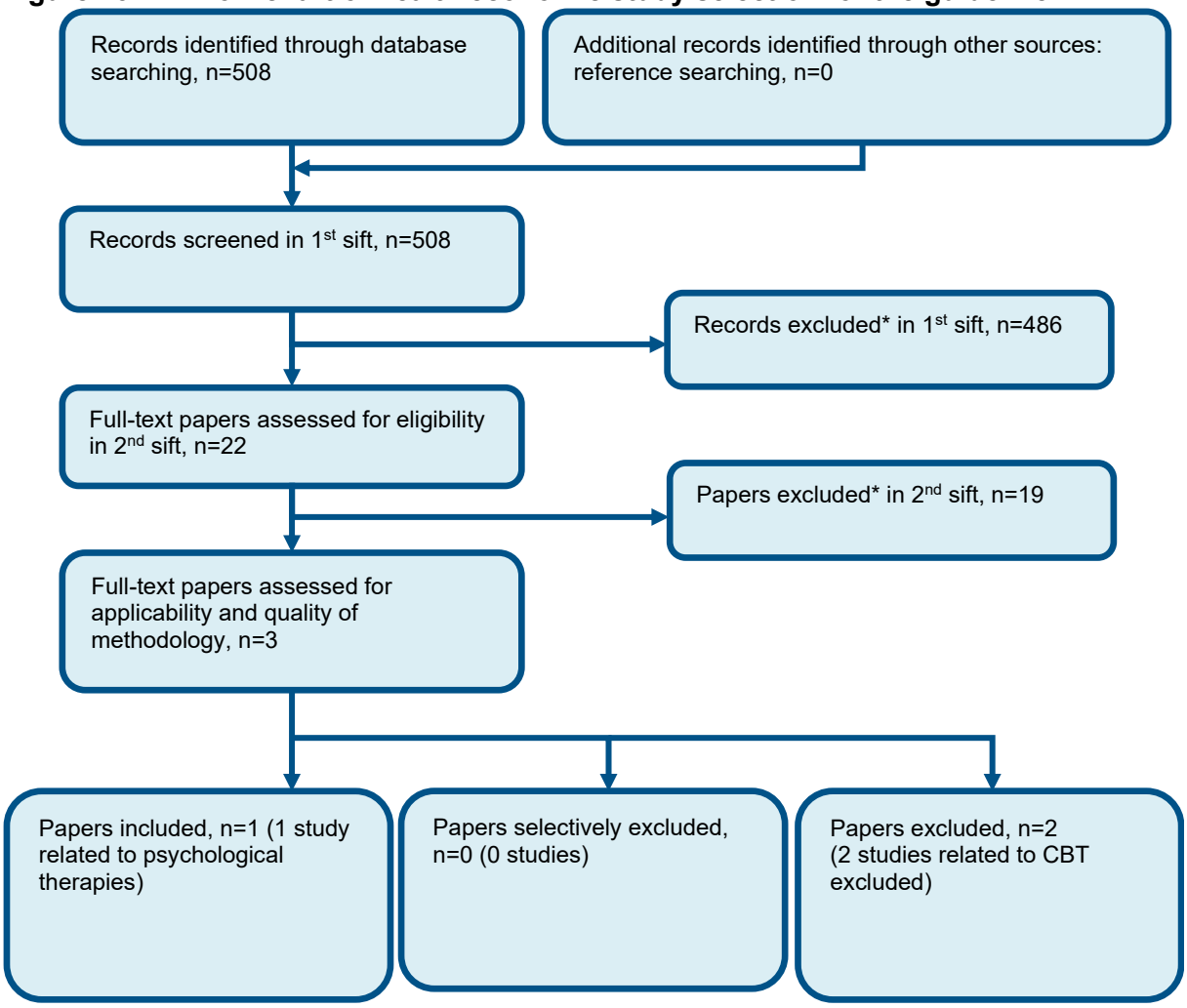
[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

/

Appendix G: Health economic evidence selection

Figure 23: Flow chart of health economic study selection for the guideline



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

Appendix H: Excluded studies

H.1 Excluded clinical studies

Table 19: Studies excluded from the clinical review

Study	Exclusion reason
Alpini 2007[1]	Incorrect study design: narrative
Argstatter 2007[4]	Incorrect interventions: music therapy
Argstatter 2010[3]	Incorrect interventions: music therapy
Argstatter 2015[2]	Incorrect interventions: neuro-music therapy
Arif 2017[5]	Inappropriate comparison: relaxation versus mindfulness
Bartnik 2001[6]	Incorrect interventions: tinnitus retraining therapy
Bauer 2011[8]	Incorrect interventions: tinnitus retraining therapy
Bauer 2017[7]	Incorrect interventions: tinnitus retraining therapy
Beukes 2018[10]	No relevant outcome data
Beukes 2018[9]	Incorrect study design: study protocol
Biesinger 2010[11]	Incorrect interventions: Qigong training therapy
Cuda 2008[12]	Incorrect comparison: Low-level laser stimulation treatment versus control (both arms received combined counselling with muscle relaxation and hypnotherapy techniques)
Eysel-Gosepath 2004[14]	Non-English
Gerhards 2010[15]	Non-English
Greenwell 2016[16]	Incorrect study design. Incorrect interventions: systematic review of psychological therapies
Henry 2009[20]	Incorrect study design: narrative
Henry 2012[21]	Incorrect stratum. Incorrect study design: non-randomised study
Henry 2017[18]	No relevant outcome data.
Herraiz 2006[24]	No relevant outcome data
Herraiz 2010[23]	Incorrect comparison: participants randomised to intervention groups based on frequency of tinnitus pitch
Hoare 2010[25]	Incorrect study design: systematic review
Hoare 2014[26]	Incorrect interventions: frequency discrimination training
Jakes 1986[28]	No relevant outcome data: results for randomised groups were combined
Kaldo 2007[30]	Incorrect interventions: CBT-based self-help book
Kaldo-Sandstrom 2004[29]	Incorrect interventions: CBT intervention
Koksoy 2018[31]	Incorrect interventions: yoga therapy
Konzag 2006[32]	Non-English
Lee 2018[33]	Incorrect study design: systematic review
Lindberg 1987[34]	No relevant outcome data: results for randomised groups were combined
Lindberg 1988[35]	Incorrect study design: non-randomised study
Lindberg 1989[36]	No relevant outcome data
Marks 1985[37]	Incorrect interventions: hypnotherapy
Nyenhuis 2013[41]	Incorrect study design: systematic review
Park 2013[42]	Incorrect interventions: tinnitus retraining therapy-modified counselling in combination with pharmacological agents

Study	Exclusion reason
Reuther 2011[43]	Non-English
Searchfield 2010[44]	Incorrect interventions: hearing aids in combination with hearing aids
Seydel 2015[45]	Incorrect interventions: modified tinnitus retraining therapy
Taylor 2017[46]	Incorrect study design: study protocol
Tyler 2007[47]	Incorrect study design: narrative
Weber 2002[48]	Incorrect study design: non-randomised study

H.2 Excluded health economic studies

None.

Appendix I: Research recommendations

I.1 Relaxation strategies for children, young people and adults

Research question: Are relaxation strategies clinically and cost effective for the management of tinnitus for children, young people and adults?

Why this is important:

The use of relaxation strategies is widespread in tinnitus management. Practice is variable with many services simply recommending or signposting rather than actually providing instructions in relaxation. This is in the face of mixed evidence regarding the benefits of relaxation in tinnitus management; overall the evidence is not favourable but there are methodological weaknesses in some studies. A carefully controlled study into the benefits of relaxation will therefore add a meaningful contribution to the evidence base.

Criteria for selecting high-priority research recommendations:

PICO question	**Population:** Children, young people and adults with tinnitus. **Intervention(s):** Relaxation programmes, including combinations of progressive muscle relaxation, relaxation without muscle tension, relaxing breathing and relaxing imagery, delivered in clinic. **Comparison:** No active treatment/waiting list, coping strategies, provision of information and advice. **Outcome(s):** • Tinnitus severity (critical) impact of tinnitus: -(critical) • Tinnitus Distress • Tinnitus Annoyance • Health related QoL: (critical) • QoL (EQ-5D) Tinnitus percept: • Tinnitus Loudness (important) Other co-occurring complaints (important) • Depression • Anxiety • Anxiety and depression • Sleep Adverse events (important) • Safety • Tolerability • Side effects
Importance to patients or the population	This research has the potential to improve in current practice. Relaxation is routinely used to support the management of tinnitus and improve quality of life. Increased understanding of optimal strategies will

	standardise care and improve patient outcomes.
Relevance to NICE guidance	Research in this area would allow a practice recommendation to be made on the use or not of relaxation in tinnitus care and management in future NICE guidance.
Relevance to the NHS	Relaxation is routinely used to support tinnitus management. Increased knowledge of this would improve and standardise care. Many services currently recommend relaxation, but do not provide it. This research recommendation should focus on the provision of relaxation, which could have potential cost implications for the NHS.
National priorities	N/A
Current evidence base	The body of evidence for relaxation is mixed regarding its benefits in tinnitus management. Overall the evidence is not favourable but there are methodological weaknesses in some studies with studies being conducted up to 30 years ago. A carefully controlled study into the benefits of relaxation will therefore add a meaningful contribution to the evidence base.
Equality	N/A
Study design	Randomised control trials.
Feasibility	No feasibility issues.
Other comments	No other comments.
Importance	Medium: the research is relevant to the recommendations in the guideline, but the research recommendations are not key to future updates.