National Institute for Health and Care Excellence

Final

Tinnitus: assessment and management

[L] Evidence review for psychological therapies

NICE guideline NG155

Intervention evidence review

March 2020

Final

This evidence review was developed by the National Guideline Centre

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ISBN 978-1-4731-3711-0

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1.1 Review question: What is the clinical and cost effectiveness of psychological therapies (including cognitive behavioural therapy and mindfulness based cognitive therapy)?

1.2 Introduction

While tinnitus is recognised as a physical symptom it is understood that it can have a profound emotional impact and that this is a major factor in the degree of suffering experienced.

There are a variety of different psychological therapies available currently within the NHS as interventions for a broad range of presentations. The following therapies have been applied either clinically or within a research context for people with tinnitus: cognitive behavioural therapy (CBT), mindfulness-based interventions e.g. mindfulness based cognitive therapy (MBCT) and mindfulness based stress reduction (MBSR), brief solution focused therapy, narrative therapy, acceptance and commitment therapy (ACT) and Eye Movement Desensitisation and Reprocessing (EMDR). These psychological therapies can be used with adults and can also be adapted for use with children and young people. Current practice includes psychological therapies within individual and group settings. When working with children, this often involves also working with their families and possibly schools.

CBT has been the main focus clinically and within research. Cognitive Behaviour Therapy (CBT) is based on the theory that an individual's distress arises out of an interaction between their environment and past experiences, thoughts (cognitions), behaviour and physiological experiences.

The aim of this review is to determine the clinical and cost-effectiveness of psychological therapies including cognitive behavioural therapy and mindfulness based cognitive therapy in improving psychological outcomes and the impact of tinnitus on the person.

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)	• Psychological therapies
	  ○ Cognitive Behavioural therapy (CBT)
	  ○ Mindfulness-based interventions e.g. cognitive therapy and MBSR
	  ○ Brief solution focused therapy
	  ○ Narrative therapy
	  ○ Family therapy/Systemic therapy
	  ○ Acceptance and commitment therapy (ACT)
	  ○ EMDR

Comparison(s)	• Interventions compared with each other

	• Interventions in combination with each other
	• Control group (i.e. no psychological therapy)
	• Sound therapy and sound enrichment
	  ○ sound enrichment (e.g. environmental sound, a CD or mp3 download or the radio, a smartphone App, bedside/table-top sound generators, a wearable sound generator)
	  ○ Combination hearing devices (hearing aid combined with sound generator)
	  ○ Customised sound-based therapies, e.g. amplitude modulated tones and notched noise/music
	  ○ Masking
	• Tinnitus education including coping strategies, provision of information and advice and relaxation
	• Amplification devices
	  ○ Hearing aids
	  ○ Implantable devices (including cochlear implants, bone-anchored hearing aids, bone-conduction hearing implants, bone-bridge/middle-ear devices)
	  ○ Combination device (sound generator and hearing aids)

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

Twenty-four studies were included in the review;[1, 5-7, 9, 16, 19, 21, 22, 26, 31, 33-35, 39, 46, 50, 52, 53, 55, 59, 60, 62, 64] these are summarised in Table 2 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 3).

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
Abbott 2009 [1] RCT	Intervention (n=32): Cognitive behavioural therapy (CBT) (internet-based) – intervention consisted of 10 components, presented in six modules – one module per week (intervention lasted 6 weeks). Sessions included applied relaxation training, information about noise sensitivity, sleep management. Comparison (n=24): Information only – participants read the online tinnitus information program. This program consisted of psychoeducational information minus active CBT components. Intervention was delivered over 6 weeks. Participants were provided option of completing the CBT intervention after 6 weeks.	n=56 People presenting with tinnitus for at least 3 months Age (mean): 49.6 years Gender (male to female ratio): 8.1:1 Duration of tinnitus (mean): 100 months Australia	Tinnitus distress (follow-up: post-treatment): measured using the Tinnitus Reaction Questionnaire, scale range not reported (according to literature it is 0-104) Tinnitus annoyance (follow-up: post-treatment): measured using a visual analogue scale (VAS), scale range 0-10 Tinnitus loudness (follow-up: post-treatment): measured using a visual analogue scale (VAS), scale range 0-10 Depression (follow-up: post-treatment): measured using the Depression, Anxiety and Stress Scale (DASS), scale range not reported (according to literature it is 0-120) Anxiety (follow-up: post-treatment): measured using the Depression, Anxiety and Stress Scale (DASS), scale range not reported (according to literature it is 0-120)	

Study	Intervention and comparison	Population	Outcomes	Comments
			Sleep quality (follow-up: post-treatment): measured using a visual analogue scale (VAS), scale range 0-10	
Andersson 2002[6] RCT	Intervention (n=53): Internet cognitive behavioural self-help treatment. A self-help manual was constructed using cognitive behavioural principles. Components were presented in 6 modules on a weekly basis for 6 weeks. This included applied relaxation, positive imagery, sound enrichment by means of external sounds, hearing tactics, and advice regarding noise sensitivity, controlled breathing and cognitive therapy, which was adjusted to deal with negative thoughts and beliefs relating to tinnitus, sleep management, exercises of concentration (mindfulness), and advice on physical activity. 6 weeks duration. Comparison (n=64): Waiting list control. The participants were informed that they had been randomised to a waiting-list condition and were offered the program 6 weeks later.	n=117 People presenting with tinnitus for at least 6 months, tinnitus was a severe problem for the participants Age (mean): iCBT group: 48.5 years ; WL group: 47.2 years Gender (male to female ratio): 55/62 Duration of tinnitus: iCBT group: 6.2 (5.6); WL group: 6.4 (6.8) Sweden	Tinnitus annoyance (follow-up: post-treatment): measured using a VAS, scale range 0-10 Tinnitus loudness (follow-up: post-treatment): measured using a VAS, scale range 0-10 Sleep quality (follow-up: post-treatment): measured using a VAS, scale range 0-10 Depression (follow-up: post-treatment and 1 year): measured using HADS – depression, scale range 0-21 Anxiety (follow-up: post-treatment and 1 year): measured using HADS – anxiety, scale range 0-21	
Andersson 2005[5] RCT	Intervention (n=12): Cognitive behavioural therapy (CBT) – six group sessions consisting of	n=23 People presenting with bothersome tinnitus (tinnitus that	Tinnitus distress (follow-up: 3 months): measured using the Tinnitus Reaction Questionnaire (TRQ), scale range 0-104	

Study	Intervention and comparison	Population	Outcomes	Comments
	information about tinnitus, applied relaxation (presented during four sessions), cognitive restructuring, behavioural activation, positive imagery, sound enrichment, exposure to tinnitus, advice regarding hyperacusis, hearing tactics and relapse prevention. Intervention lasted for five weeks. Comparison (n=11): Waiting-list control – participants in this group did not receive the intervention until about five weeks. Participants were then given shortened version of the version (four sessions instead of six sessions)	is audible in many acoustic environments, disturbs sleep, or is a dominating problem that affects quality of life) for at least 6 months Age (mean): 70.1 years Gender (male to female ratio): 1.1:1 Duration of tinnitus (mean): 13 years Sweden	Depression (follow-up: 3 months): measured using the Hospital Anxiety and Depression Scale (HADS) (depression subscale used), scale range not reported (according to literature it is 0-21) Anxiety (follow-up: 3 months): measured using the Hospital Anxiety and Depression Scale (HADS) (depression subscale used), scale range not reported (according to literature it is 0-21) Anxiety (follow-up: 3 months): measured using the Anxiety Sensitivity Index (ASI), scale range not reported	
Arif 2017[7] RCT	Intervention (n= 42): Mindfulness meditation: treatment plans standardised in a session format, which included the following topics: exploration, sitting meditation, meditation applied and reviewed. 5 face-to-face sessions of 40 minutes over 15 weeks Comparison (n=44): Relaxation therapy sessions split between two experienced therapists	n=86 People presenting with ‘intrusive’ tinnitus Age (mean): 53.8 years in mindfulness group;58.3 years in relaxation group Gender (male to female ratio): 1:1.2 Duration of tinnitus (range): 6 months -15 years United Kingdom	Tinnitus severity (post treatment): measured using a VAS, scale range 0-10. Tinnitus loudness (post treatment): measured using a VAS, scale range 0-10. Anxiety (post treatment): measured using HADS – Anxiety, scale range 0-21. Depression (post treatment): measured using HADS –	

Study	Intervention and comparison	Population	Outcomes	Comments
	who followed a manual. A session format was followed, including the following topics: exploration, mental skill development, cue-controlled relaxation, differential relaxation, rapid relaxation application and review of subjective findings. 5 face-to-face relaxation therapy sessions of 40 minutes over 15 weeks.		Depression, scale range 0-21. Depression and anxiety (post treatment): measured using HADS – total, scale range 0-42.	
Beukes 2018[9] RCT	Intervention (n=46): Cognitive behavioural therapy (CBT) (internet-based) - based on a CBT self-help program adapted into an 8-week program consisting of 16 recommended modules and 5 optional modules. A minimum of 10 minutes of asynchronous audiologist guidance was provided to participants. Comparison (n=46): Tinnitus information counselling – participants attended an initial appointment (60 minutes) to provide explanations about tinnitus and some basic management strategies. Participants also received additional strategies for tinnitus management, including sleep hygiene, relaxation strategies, and negative thought analysis during follow-up.	n=92 People presenting with bothersome tinnitus Age (mean): 52.96 years Gender (male to female ratio): 1.49:1 Duration of tinnitus: 6.54 years United Kingdom	Tinnitus severity (follow-up: post-treatment and 2 months): measured using Tinnitus Handicap Inventory (THI), scale range 0-100 Tinnitus distress (follow-up: post-treatment and 2 months): measured using Tinnitus Functional Index (TFI), scale range 0-100 Quality of life (follow-up: post-treatment and 2 months): measured using the Satisfaction With Life Scales (SWLS), scale range 5-35 Depression (follow-up: post-treatment and 2 months): measured using the Patient Health Questionniare-9 (PHQ-9), scale range 0-27 Anxiety (follow-up: post-treatment	

Study	Intervention and comparison	Population	Outcomes	Comments
			and 2 months): measured using the Generalised Anxiety Disorder-7 (GAD-7), scale range 0-21 Sleep (follow-up: post-treatment and 2 months): measured using the Insomnia Severity Index (ISI), scale range 0-28	
Cima 2012[16] RCT	Intervention (n=245): Specialised stepped intervention based on CBT – all participants allocated to this intervention received step 1 which consisted of multidisciplinary diagnostics and specific tinnitus retraining counselling (undertaken in a cognitive behaviour framework). Participants with mild complaints received step 1 of the intervention. Step 1 lasted for 3 months. Participants who had severe tinnitus entered step 2, consisting of three different 12-week group treatment options. Comparison (n=247): Usual care – all participants received a standard audiological intervention (step 1). Participants who had severe tinnitus entered step 2 which involved interactions with a social worker.	n=492 People presenting with subjective tinnitus Age (mean): 54.19 years Gender (male to female ratio): 1.7:1 Duration of tinnitus: <1 year – 30%; 1-5 years – 39%; >5 years – 31% Netherlands	Tinnitus severity (follow-up: 3 months and 12 months): measured using Tinnitus Questionnaire, total score ranges not reported (0-84 as indicated in literature) Quality of life (follow-up: 3 months and 12 months): measured using the Health Utilities Index (HUI) mark 3, total score ranges from -0.36-1 Tinnitus-related quality of life (follow-up: 3 months and 12 months): measured using the Tinnitus Handicap Inventory, total score ranges 0-100 Depression and anxiety (follow-up: 3 months and 12 months): measured using the Hospital Anxiety and Depression Inventory, total score ranges 0-42	
Davies 1995[19]	Intervention 1 (n=16):	n=45	Tinnitus distress (follow-up: post-	

Study	Intervention and comparison	Population	Outcomes	Comments
RCT	Cognitive behavioural therapy - intervention explored the meaning of tinnitus with the subject and identified any negative thoughts associated with emotional distress, which were then related to broader beliefs or underlying assumptions. The therapist aided this by completing a checklist with the client which listed common tinnitus complaints, associated emotions, and commonly held maladaptive beliefs about tinnitus. 6 one hour sessions with possible extension to 8 sessions. Intervention 2 (n=13): Passive relaxation training (PRT). It was explained to participants how PRT would break into the vicious cycle of "annoyance-stress-attention to noises-further annoyance" by diminishing the stress response to tinnitus annoyance. Relaxation was taught in a sitting or lying position in the office and included: progressive muscle tensing/relaxing use of pleasant visual imagery to promote mental calmness; and encouragement of relaxed diaphragmatic breathing. 6 one hour sessions with possible extension to 8 sessions. Intervention 3 (n=16): Applied Relaxation Training (ART).	People presenting with tinnitus for at least 6 months, tinnitus was a significant problem for the participants Age (mean): 56.3 years Gender (male to female ratio): 1:1.3 (completers) Duration of tinnitus (range): 6 months -6 years United Kingdom	treatment and 4 months): measured using TEQ scales – emotional distress, scale range not reported Tinnitus loudness (follow-up: post-treatment and 4 months): measured using tinnitus loudness rating, scale 1-5 Tinnitus annoyance (follow-up: post treatment and 4 months): measured using tinnitus annoyance rating, scale range not reported Anxiety (follow-up: 1 month): measured using STAI, scale ranges from 20-80 Depression (follow-up:1 month): measured using BDI, scale ranges from 0-63 Insomnia (follow-up: post-treatment and 4 months): measured using TEQ- insomnia, scale range not reported	

Study	Intervention and comparison	Population	Outcomes	Comments
	Relaxation was taught as the PRT and additionally explained that acquisition of the skill through daily practice would break into the vicious cycle of "annoyance to greater attention to greater annoyance" by enabling subjects to apply relaxation when tinnitus was annoying. 6 one hour sessions with possible extension to 8 sessions.			
Henry 1996[21] RCT	Intervention 1 (n=20): Cognitive behavioural therapy (CBT) – cognitive therapy in which participants were encouraged to learn to approach the problem of tinnitus in more adaptive and constructive way in small group sessions. Participants were trained in attention diversions strategies, imagery training (including mental imagery). Participants received a written manual containing educational material and techniques. Intervention involved one 90-minute session for six weeks. Intervention 2 (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 group 90-minute session per week for 6 weeks.	n=60 People presenting with chronic tinnitus and tinnitus distress for at least 6 months Age (mean): 64.6 years Gender (male to female ratio): 6.5:1 Duration of tinnitus: Not reported Australia	Tinnitus distress (follow-up: post-treatment and 12 months: measured using the Tinnitus Reaction Questionnaire (TRQ), scale ranges from 0-104 Tinnitus annoyance (follow-up: post-treatment and 12 months): measured using visual analogue scale range 0-4 (unclear) Tinnitus related quality of life (follow-up: post-treatment and12 months): measured using the Tinnitus Handicap 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	Included in counselling review Waiting-list control groups also received cognitive therapy after 6 weeks. 12 month follow-up results for this group were for after treatment had been completed

Study	Intervention and comparison	Population	Outcomes	Comments
	Comparison (n=20): Waiting-list control – participants were informed that their participation would be delayed.		Depression (follow-up: post-treatment and 12 months): measured using the Beck Depression Inventory (BDI), scale ranges from 0-63	
Hesser 2012[22] RCT	Intervention 1 (n=32): Internet-delivered CBT -guided, internet-delivered therapy, including structured self-help material via the internet and an identified therapist for support and guidance by email. Involved tinnitus-specific CBT techniques including applied relaxation, positive imagery, attention training, cognitive restructuring, exposure, and the use of background sounds to cope with the experience of tinnitus. Intervention was 8 weeks long. Intervention 2 (n=35): Internet-delivered ACT– guided, internet-delivered therapy, including structured self-help material via the internet and an identified therapist for support and guidance by email. Involved tinnitus-specific ACT including exercises that focused on mindfulness and distancing of internal experiences (i.e. defusion), assignments with the	n=99 People presenting with tinnitus for 6 months or more with diagnosis confirmed, participants had 'moderate to severe' tinnitus distress Age (mean): 48.5 years Gender (male to female ratio): 1.1/1 Duration of tinnitus: 8.9 months in iCBT group; 9.7months in ACT group; 9 months in control group Sweden	Tinnitus distress and severity (follow-up, post-treatment and at 1 year), measured by THI, scale range 0-100. Quality of life (follow-up, post-treatment and at 1 year), measured by Quality of Life Inventory, scale range: not reported Depression (follow-up, post-treatment and at 1 year), measured by HADS depression, scale range 0-21 Anxiety (follow-up post-treatment and at 1 year), measured by HADS-anxiety, scale range: 0-21 Sleep (follow-up, post-treatment and at 1 year), measured by Insomnia Severity Index, scale range: 0-28	It should be noted that iCBT or ACT compared to the control group was only followed up to 8 weeks, and not to 1 year, whereas iCBT versus iACT was followed up additionally to 1 year.

Study	Intervention and comparison	Population	Outcomes	Comments
	purpose of identifying personal values and goals and exercises that promoted willingness to experience tinnitus in the context of value-based behaviour change. Intervention was 8 weeks long. Comparison (n=32): Web discussion forum – confidential moderated online discussion forum that specifically targeted tinnitus-related problems. Participants were encouraged to take part in the forum, each week a therapist posted a new topic to discuss and monitored the forum. Intervention was 8 weeks long.			
Jasper 2014[26] RCT	Intervention 1 (n=41): Internet cognitive behavioural therapy (iCBT). 12 mandatory and 6 optional text modules, each covering a particular topic, including: applied relaxation, positive imagery, focus exercises, exposure to tinnitus; cognitive restructuring; avoidance behaviour. Once a week patients could communicate with the therapist via a secured online messaging system. The therapists were instructed to try to dedicate a maximum of 10 minutes per week per patient to e-mail communication. Intervention lasted 10 weeks.	n=128 People presenting with tinnitus at least mild levels of chronic tinnitus distress for at least 6 months Age (mean): iCBT 51.3(9.8); GCBT 50.2 (13.1); DF 52.1 (9) Gender (male to female ratio): ICBT 25/16; GCBT 24/199; DF 28/16 Duration of tinnitus (mean): iCBT 9.2 years, GCBT 8.4years; DF 8 years Germany	Tinnitus distress(follow-up : post-treatment): measured using mini-TQ, total score range from 0-24 Tinnitus severity (follow-up: post-treatment): measured using THI, total score range 0-100. Depression (follow-up: post treatment): measured using HADS – Depression, total score range 0-21 Anxiety (follow-up: post-treatment measured using HADS- Anxiety, total score range 0-21	

Study	Intervention and comparison	Population	Outcomes	Comments
	Intervention 2 (n=43): Group Cognitive Behavioural Therapy (GCBT). The group sizes included 5 to 12 participants and the topics included sharing experiences, discussing individual coping strategies, and demonstrating exercises. 90 minute weekly sessions for 10 weeks. Comparison (n=44): Web-based discussion forum (DF) as a control condition. A new discussion topic was presented every week. The participants were encouraged to discuss and to comment on each other's postings. The topics did not include any strategies to improve tinnitus distress but instead focused on individual experiences and attitudes concerning tinnitus.		Sleep (follow-up: post treatment): measured using ISI total score range 0-28	
Kreuzer 2012[31] RCT	Intervention (n=18): Mindfulness and body-psychotherapy-based group treatment - treatment program consisted of mindfulness, meditation, self-massage, and breathing exercises as main components by an experienced therapist. Two weekends (11 hours of treatment/weekend) with an interval of 7 weeks. A review was made at 2 weeks after each weekend and 11 and 15 weeks after the second training weekend of 2 hours each.	n=36 People presenting with chronic tinnitus for at least 6 months, participants were 'burdened' by their tinnitus Age (mean): Intervention group: 49.6 years ; control group: 51.7 years Gender (male to female ratio): Intervention group: 1:1	Tinnitus annoyance (follow-up: post-treatment): measured using numeric rating scale, scale range not reported Tinnitus severity (follow-up: post-treatment): measured using TQ, scale range 0-84. Tinnitus severity (follow-up: post-treatment): measured using THI, scale range 0-100	

Study	Intervention and comparison	Population	Outcomes	Comments
	Comparison (n=18): Waiting list control, assessed at identical time points during a waiting period of 24 weeks before they received treatment.	Germany	Tinnitus loudness (follow-up: post-treatment): measured using numeric rating scale, scale range not reported Depression (follow-up: post-treatment): measured using BDI, scale range 0-63	
Kroner-Herwig 1995[34] RCT	Intervention (n=15): Cognitive behavioural therapy (CBT) – sessions included a focus on cognition, education, analysis of stressful events and their effect on tinnitus progressive relaxation. The intervention consisted of ten 2-hour sessions, duration of intervention not reported. Comparison (n=19): Waiting-list control – following 'experimental assessment' participants were randomised to CBT or another intervention (yoga – not relevant for this evidence review) no further details reported.	n=34 People presenting with chronic idiopathic tinnitus for at least 6 months Age (mean): 47.2 years Gender (male to female ratio): 1.3:1 Duration of tinnitus (mean): 46.4 months Germany	Tinnitus annoyance (follow-up: post-treatment): measured using visual analogue scales, scale range 0-10 Tinnitus loudness (follow-up: post-treatment): measured using visual analogue scales, scale range 0-10 Sleep disturbance (follow-up: post-treatment): measured using visual analogue scales, scale range 0-10	
Kroner-Herwig 2003[33] RCT	Intervention 1 (n=56): Cognitive behavioural therapy (CBT). An outpatient cognitive-behavioural group tinnitus coping training (TCT). 11 sessions of 90-120 minutes duration. 6	n=116 People presenting with idiopathic tinnitus for at least 6 months	Tinnitus distress (follow-up: post-treatment): measured using TQ, scale range 0-84 Tinnitus severity (follow-up: post-treatment): measured using GSI	

Study	Intervention and comparison	Population	Outcomes	Comments
	to 8 patients participated in each of 7 groups was conducted. A training manual gave detailed guidelines for training delivery. Topics included education on tinnitus aetiology and maintenance; relaxation; thoughts, emotions and bodily reactions; tinnitus as a stressor; dysfunctional and functional thoughts; attention and distraction; imagery exercises; habituation exercises, withdrawal and avoidance (cognitions and behaviour); problem solving (a systematic approach); attitudes toward illness and health. Intervention 2 (n=20): Minimal contact intervention (MC-E) involved 2 group sessions, the first involved education regarding tinnitus aetiology; fears regarding tinnitus, its prognosis and consequences were discussed and, if possible, revised. Self-help strategies for coping with tinnitus (e.g., distraction, relaxed confrontation, reappraisal) A second session in which subjects were given the opportunity to discuss their progress and problems followed after a 4-week period of implementing the recommended "self-help exercises". Intervention 3 (n=20): MC-R group also received an	Age (mean): 46.8 years Gender (male to female ratio): 1:1 Duration of tinnitus (mean): 5.5 years Germany	of SCL-90R, scale range not reported Tinnitus loudness (follow-up: post-treatment): measured using diary, scale range 1-7 Depression (follow-up: post-treatment): measured using ADS, scale range 0-60	

Study	Intervention and comparison	Population	Outcomes	Comments
	educational session, where the importance of relaxation and distraction as strategies for coping with tinnitus was underlined. A second session involved audiocassettes with verbal relaxation instructions and pieces of relaxing music (30 min) selected by a music therapist. Patients were given the audiocassettes for home use and were instructed to choose the pieces of music, which suited them best. Two further meetings were used to discuss problems and progress. Comparison (n=20): Waiting list control (not further details reported).			
Li 2019 [35] RCT	Intervention (n=50): Cognitive behavioural therapy (CBT) - Intervention group received intervention twice a week. The treatment paths included three steps including cognitive restructuring, problem solving and sound treatment. Sound treatment involved hearing tests and tinnitus tests; masking treatment was applied using light music. Masking was performed for 30 minutes once a day. CBT intervention was twice a week for 6 months. Comparison (n=50):	n=100 People present with chronic subjective tinnitus for at least 3 months, participants had a negative mental mood such as fidgety and irritability Age (mean): 43.22 years Gender (male to female ratio): 1.4:1 Duration of tinnitus (mean): 2.52 years China	Tinnitus severity (follow-up: post-treatment): measured using the Tinnitus Handicap Inventory, scale range not reported (according to literature it is 0-100) Depression (follow-up: post-treatment): measured using the Symptom Checklist-90 (SCL-90) subscale for depression (F4), scale range 1-5 Anxiety (follow-up: post-treatment): measured using the Symptom Checklist-90 (SCL-90) subscale for anxiety (F5), scale	

Study	Intervention and comparison	Population	Outcomes	Comments
	Control group received the same masking intervention as the intervention group.		range 1-5	
Malouff 2010[39] RCT	Intervention (n=84): CBT self-help book – participants received a self-help book based on cognitive-behavioural principles, including educational information on tinnitus and attention control techniques. Book provides guidelines on specific exercises such as progressive muscle relaxation and personalised self-instructions. Participants were instructed to complete the book within 2 months. No further contact was made with participants until follow-up. Comparison (n=78): Waiting-list control – participants were given the CBT self-help book after 2 months. No further details reported.	n=162 People presenting with tinnitus Age (mean): 57.6 years Gender (male to female ratio): 1.3:1 Duration of tinnitus (mean): Not reported Australia	Tinnitus distress (follow-up: post-treatment): measured using Tinnitus Reaction Questionnaire (TRQ), scale range not reported (according to literature it is 0-104)	
McKenna 2017[46] RCT	Intervention (n=39): Mindfulness-based cognitive therapy (MBCT) – intervention was delivered in line with a standardised manual. There was an emphasis on sound meditation and education around the cognitive model of tinnitus and the importance of attentional processes in tinnitus. Psycho-education component which	n=75 People presenting with chronic tinnitus with psychological distress for at least 6 months Age (median): 50.0 years Gender (male to female ratio): 1.2:1	Tinnitus severity (follow-up: post-treatment and 6 months): measured using the Tinnitus Questionnaire (TQ), scale range not reported (according to literature it is 0-84) Tinnitus severity (follow-up: post-treatment and 6 months): measured using the Tinnitus	

Study	Intervention and comparison	Population	Outcomes	Comments
	focused on cognitive theory. There were eight 120-minute group sessions, delivered weekly over 8 consecutive weeks. Comparison (n=36): Relaxation training – relaxation intervention delivered in line with a standardised manual. Psycho-education component which focused on physiology of stress and tinnitus. There were eight 120-minute group sessions, delivered weekly over 8 consecutive weeks.	Duration of tinnitus (median): 56 months United Kingdom	Functional Index (TFI), scale range not reported (according to literature it is 0-100) Tinnitus loudness (follow-up: post-treatment and 6 months): measured using visual analogue scale (VAS), scale range 0-100 Depression (follow-up: post-treatment and 6 months): measured using Hospital Anxiety and Depression Scale (HADS) (depression subscale used), scale range not reported (according to literature it is 0-21) Anxiety (follow-up: post-treatment and 6 months): measured using Hospital Anxiety and Depression Scale (HADS) (anxiety subscale used), scale range not reported (according to literature it is 0-21)	
Nyenhuis 2013[50] RCT	Intervention 1 (n=71): Cognitive behavioural therapy (CBT) (group-based) - based on standardised manual, contents were presented over four two-hour meetings. All four sessions contained a progressive muscle relaxation exercise. Topics covered included: education about tinnitus, functional characteristics of the hearing system, treatment options,	n=304 People presenting with idiopathic tinnitus for 2-26 weeks Age (mean): 50.3 years Gender (male to female ratio): 1.2:1 Duration of tinnitus (mean) : 3.2 months	Tinnitus distress (follow-up: post-treatment and 9 months): measured using the Tinnitus Questionnaire (TQ) [German version], scale range not reported (according to literature it is 0-84) Depression (follow-up: post-treatment and 9 months): measured using Patient Health Questionnaire-Depression (PHQ-	

Study	Intervention and comparison	Population	Outcomes	Comments
	psychological aspects of tinnitus distress, coping by attention and distraction. Intervention lasted 3 months. Intervention 2 (n=79): Cognitive behavioural therapy (CBT) (internet-based) – participants received the CBT manual, contents were written as web pages and participants could download the progressive muscle relaxation instructions. Intervention lasted 3 months. Intervention 3 (n=77): Cognitive behavioural therapy (CBT) (bibliotherapy) – participants received the complete manual and a CD with instructions on progressive muscle relaxation. Intervention lasted 3 months. Comparison (n=77): Information only – participants were provided with an 11-page booklet that provided information on the morphological and functional characteristics of the auditory system, the potential triggers of tinnitus and medical treatment options. No further treatment was provided.	Germany	D), scale range not reported	
Philippot 2012[52]	Intervention (n=15):	n=30	Depression (follow-up: post-	

Study	Intervention and comparison	Population	Outcomes	Comments
RCT	6 weekly group sessions of Mindfulness training. A manual was constructed for each training condition. The training involved dealing with the adversity of tinnitus; focus on the theme that thoughts are not facts; the main exercise consisted of a 40 minutes sitting meditation with a sequential focus on breath, body, thoughts and the introduction of a difficult thought in the meditation; dealing with how to take care of oneself (relapse prevention) and evaluating the programme. The main exercise consisted in a 40-minute body scan. Comparison (n=15): 6 sessions of 2 and 15 hours per week of relaxation training, of which a manual was involved. The manual followed the progressive relaxation training format, including breathing training, relaxation was divided into thirteen body parts in the second session, in the third session in to eight body parts, the fourth session into four body parts and the fifth session into two body parts. The sixth session focused on mini-relaxation and on maintenance of relaxation competence.	People presenting with tinnitus in the past 6 months with significant psychological distress and impairment in everyday activities resulting from tinnitus Age (mean): 60 years Gender (male to female ratio): 1.5:1 Duration of tinnitus: Not reported Belgium	treatment and 3 month follow-up): measured by BDI, total scale range 0-63 Anxiety (follow-up: post-treatment and 3 months): measured using the Spielberger State and Trait Anxiety Inventory, total scale range 20-80	
Rief 2005[53] RCT	Intervention (n=23): Biofeedback - treatment program	n=48 People presenting with tinnitus	Tinnitus distress (follow-up: post-treatment and 6 months): measured using TQ, scale range	

Study	Intervention and comparison	Population	Outcomes	Comments
	consisting of 1 pre-assessment session, 7 treatment sessions, and a final session summarising the intervention strategies and conducting the post-assessment. All sessions lasted approximately 1 hour. The training was manual-guided and also included handouts (e.g., on the following topics: basic information on ear and the hearing system; information processes involved in tinnitus; the vicious circle of tinnitus annoyance, muscular reactivity, and selective attention; and aspects of tinnitus maintenance, modulating factors, coping strategies. Total of 8 weeks duration. Comparison (n=20): Waiting list control group who waited 8 weeks. For the same sessions as the intervention group.	for at least 6 months that participants described as 'disturbing' Age (mean): 46.8 years Gender (male to female ratio): 1:1 Duration of tinnitus (mean): 6.4 years Germany	0-84. Quality of life (health life satisfaction) (follow-up: post-treatment and 6 months): measured using questions on life satisfaction (FLZ), scale range not reported Tinnitus loudness (follow-up: post-treatment and 6 months): measured using tinnitus diary, scale range 0-10.	
Scott 1985[55] RCT	Intervention (n=12): Behavioural therapy - psychological treatment comprised relaxation training, training of self-control by distraction exercises with the aim of reducing the discomfort from tinnitus and the application of the method in situations associated with tinnitus. Intervention was delivered by ten one-hour sessions during a 2-3 week period.	n=24 People presenting with some form of hearing impairment and tinnitus grade 2 or 3 Age (mean): Men 50.6 (36-62) years; women 54.2 (36-72) years Gender (male to female ratio): 1:1.2 Duration of tinnitus: 9.4 years	Tinnitus annoyance (retrospective) (follow-up: post-treatment): measured using a diary, scale range 0-10 Tinnitus loudness (retrospective) (follow-up: post-treatment): measured using a diary, scale range 0-10 Tinnitus loudness (direct): (follow-up: post-treatment): measured	

Study	Intervention and comparison	Population	Outcomes	Comments
	Comparison (n=12): Waiting list group. After 10 weeks the group received the same as the treatment group.	Sweden	using a diary, scale range 0-10 Depression (retrospective): (follow-up: post-): measured using a diary, scale range 0-10	
Weise 2008[59] RCT	Intervention (n=63): Cognitive behavioural therapy: biofeedback-based behavioural intervention conducted by 4 trained therapists. Twelve 1 hour sessions given over 3 months. Each session included biofeedback as well as CBT elements and followed a structured manual. The biofeedback facilitated muscle relaxation and learning of control over physiological functions. Various tinnitus-specific CBT techniques found previously to be effective were included in the sessions. Comparison (n=67): Waiting list group who waited 3 months for the same sessions as the intervention group.	n=130 People presenting with tinnitus for at least 6 months, participants had serious or severe tinnitus annoyance Age (mean): 51.2 years Gender (male to female ratio): 1.3:1 Duration of tinnitus (mean): 6.4 years Germany	Tinnitus distress (follow-up: post-treatment)measured by diary. Tinnitus severity (follow-up: post treatment), measured by Tinnitus Questionnaire, scale range 0-84 Tinnitus severity (follow-up: post-treatment) measured by (Global Severity Index of the SCL-90-R), scale range not reported Tinnitus loudness: follow-up post-treatment at 3 months, measured by diary, scale range 0-10 Depression (follow-up: post-treatment), measured by (Beck Depression Inventory), scale range 0-63 Sleep (follow-up: post-treatment) measured by diary of sleep disturbance, scale range 0-10	

Study	Intervention and comparison	Population	Outcomes	Comments
Weise 2016[60] RCT	Intervention (n=62): Internet-based CBT self-help program, based on a well-established CBT self-help manual. 12 mandatory and 6 optional text modules. Mandatory modules covered strategies to reduce tinnitus-related distress (e.g., relaxation, exposure to tinnitus, or cognitive restructuring. Optional modules addressed problems potentially associated with tinnitus, such as sleep, hearing, or concentration problems. Module structure: theory and general information, exercises, worksheets and solutions for common problems. Participants downloaded text modules or spoken instructions; read the theoretical framework and conducted exercises in daily life. Once per week, patients could communicate with the therapist via a secured encrypted webpage. Therapists were instructed to spend a maximum of 10min/week per patient for e-mail correspondence. 10 weeks duration. Comparison (n=62): Control group - a confidential, moderated, online discussion forum. 10 weeks duration.	n=124 People presenting with tinnitus for at least 6 months Age (mean): 47.66 years Gender (male to female ratio): 1:1.5 Duration of tinnitus: 7.29 years Sweden	Tinnitus distress and severity: follow-up: 10 weeks), measured by THI, total score ranges 0-100 Tinnitus distress and severity: follow-up: 10 weeks), measured by mini-TQ, total score ranges 0-20 Anxiety: follow-up: 10 weeks), measured by HADS – anxiety, total score ranges 0-21 Depression: follow-up: 10 weeks), measured by HADS-depression, total score ranges 0-21 Sleep: follow-up: 10 weeks), measured by ISI, total score ranges 0-28	
Westin 2011[62] RCT	Intervention (n=22): Psychological therapy: acceptance and	n=44 People presenting with tinnitus	Tinnitus severity (follow-up: post-treatment): measured using the Tinnitus Handicap Inventory	Included in combination review

Study	Intervention and comparison	Population	Outcomes	Comments
	commitment therapy (ACT) – participants completed the ACT treatment, with individual weekly sessions. Treatment involved mindfulness and acceptance training to promote goal-directed behaviour. Comparison (n=22): Waiting-list control – participants received letter stating that they were on the waiting list for treatment. Treatment started after 10 weeks.	for at least 6 months Age (mean): 51.5 years Gender (male to female ratio): 1:1 Duration of tinnitus: 6.9 years Sweden	(THI), total score ranges from 0-100 Quality of life (follow-up: post-treatment): measured using the Quality of Life Inventory (QOLI), total score range not reported Depression (follow-up: post-treatment): measured using the Hospital Anxiety and Depression Scale (HADS) (depression subscale), total score ranges from 0-21 Anxiety (follow-up: post-treatment): measured using the Hospital Anxiety and Depression Scale (HADS) (anxiety subscale), total score ranges from 0-21 Sleep (follow-up: post-treatment): measured using the Insomnia Severity Index (ISI), total score ranges from 0-28	
Zachriat 2004[64] RCT	Intervention (n=29): Cognitive behavioural therapy (CBT) - the following interventions were included: educated on physiological and psychological factors playing a role in tinnitus; taught relaxation exercises and the use of attention distraction	n=52 People presenting with tinnitus for > 3 months Age (mean): 49.95 years Gender (male to female ratio):	Tinnitus distress (follow-up: 11 weeks/post-treatment): measuring using the Tinnitus Questionnaire (TQ), score ranges from 0-84 Tinnitus loudness (follow-up: 11 weeks/post-treatment): measured using tinnitus perception diary and	Included in combination review

Study	Intervention and comparison	Population	Outcomes	Comments
	strategies. Administered in groups of 6-8 tinnitus patients. The intervention included 11 weekly sessions. Comparison (n=23): Education - a single treatment session in which patients were informed about the physiology and psychology of tinnitus.	1.8:1 Duration of tinnitus (mean): 79 months Germany	subjective change (scale range 1-7)	

See appendix D for full evidence tables.

1.4.4 Quality assessment of clinical studies included in the evidence review

Cognitive behavioural therapy (CBT)

Table 3: Clinical evidence summary: CBT 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 CBT (95% CI)
Tinnitus severity Global Severity Index (GSI of SCL-90R)	63 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus severity in the control groups was 0.63	The mean tinnitus severity in the intervention groups was 0.09 lower (0.31 lower to 0.13 higher)
Tinnitus distress TQ/TRQ. Scale from: 0 to 84, 0-104.	103 (2 studies) post-treatment	⊕⊕⊖⊖ LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 41.28	The mean tinnitus distress in the intervention groups was 0.74 standard deviations lower (1.16 to 0.33 lower)
Tinnitus distress TRQ. Scale from: 0 to 104.	23 (1 study) 3 months	⊕⊕⊖⊖ LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 32.5	The mean tinnitus distress in the intervention groups was 22.80 lower (34.50 to 11.10 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 CBT (95% CI)
Tinnitus QoL THQ	40 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus qol in the control groups was 60.88	The mean tinnitus qol in the intervention groups was 17.16 lower (27.88 to 6.44 lower)
Tinnitus annoyance VAS. Scale from: 0 to 4, 0-10.	66 (2 studies) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus annoyance in the control groups was 3.04	The mean tinnitus annoyance in the intervention groups was 0.35 standard deviations lower (0.84 lower to 0.14 higher)
Tinnitus loudness VAS. Scale from: 0 to 4, 0-10.	129 (3 studies) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 4.47	The mean tinnitus loudness in the intervention groups was 0.27 standard deviations lower (0.64 lower to 0.09 higher)
Depression HADS. Scale from: 0 to 21.	103 (2 studies) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 13.78	The mean depression in the intervention groups was 0.21 standard deviations lower (0.62 lower to 0.2 higher)
Depression HADS. Scale from: 0 to 21.	23 (1 study) 3 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 6.4	The mean depression in the intervention groups was 3.20 lower (6.58 lower to 0.18 higher)
Anxiety HADS. Scale from: 0 to 21.	23 (1 study) 3 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 6.4	The mean anxiety in the intervention groups was 4 lower (6.21 to 1.79 lower)
Anxiety ASI	23 (1 study) 3 months	⨁⨁⊖⊖ LOW1 due to risk of bias		The mean anxiety in the control groups was 26.3	The mean anxiety in the intervention groups was 14.7 lower (21.54 to 7.86 lower)
Sleep disturbance VAS. Scale from: 0 to 10.	26 (1 study) post-	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias,		The mean sleep disturbance in the control groups was 2	The mean sleep disturbance in the intervention groups was 0.34 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 CBT (95% CI)
	treatment	imprecision			(1.98 lower to 1.3 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 4: Clinical evidence summary: CBT versus control (masking)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control (masking)	Risk difference with CBT (95% CI)
Tinnitus severity THI. Scale from: 0 to 100.	100 (1 study) post-treatment	⨁⨁⊖⊖ LOW1 due to risk of bias		The mean tinnitus severity in the control groups was 48.72	The mean tinnitus severity in the intervention groups was 12.94 lower (16.32 to 9.56 lower)
Depression Symptom Checklist-90. Scale from: 1 to 5.	100 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 2.42	The mean depression in the intervention groups was 0.3 lower (0.56 to 0.04 lower)
Anxiety Symptom Checklist-90. Scale from: 1 to 5.	100 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 2.73	The mean anxiety in the intervention groups was 0.78 lower (0.99 to 0.57 lower)

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 5: Clinical evidence summary: CBT versus information only

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Information only	Risk difference with CBT (95% CI)
Tinnitus distress TQ. Scale from: 0 to 84.	105 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 27.4	The mean tinnitus distress in the intervention groups was 7.40 lower (13.65 to 1.15 lower)
Tinnitus distress Scale from: 0 to 84.	96 (1 study) 9 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 25.2	The mean tinnitus distress in the intervention groups was 6.8 lower (13.09 to 0.51 lower)
Depression PHQ-D	105 (2 studies) post-treatment	⨁⨁⊖⊖ LOW1 due to risk of bias		The mean depression in the control groups was 5.7	The mean depression in the intervention groups was 1.00 lower (2.85 lower to 0.85 higher)
Depression PHQ-D	96 (1 study) 9 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 5.7	The mean depression in the intervention groups was 0.9 lower (2.69 lower to 0.89 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 6: Clinical evidence summary: CBT versus education

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Education	Risk difference with CBT (95% CI)
Tinnitus severity	59	⨁⊖⊖⊖		The mean tinnitus severity in	The mean tinnitus severity in the

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Education	Risk difference with CBT (95% CI)
Global Severity Index (GSI of SCL-90R)	(1 study) post-treatment	VERY LOW1,2 due to risk of bias, imprecision		the control groups was 0.53	intervention groups was 0.01 higher (0.23 lower to 0.25 higher)
Tinnitus distress TRQ. Scale from: 0 to 84, 104.	146 (3 studies) post-treatment	⨁⨁⊖⊖ LOW1 due to risk of bias		The mean tinnitus distress in the control groups was 38.01	The mean tinnitus distress in the intervention groups was 0.40 standard deviations lower (0.75 lower to 0.06 higher)
Tinnitus distress TQ. Scale from: 0 to 104.	33 (1 study) 12 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 45.94	The mean tinnitus distress in the intervention groups was 1.88 lower (16.69 lower to 12.93 higher)
Tinnitus QoL THQ	40 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus qol in the control groups was 59.34	The mean tinnitus qol in the intervention groups was 15.62 lower (26.51 to 4.73 lower)
Tinnitus QoL THQ	33 (1 study) 12 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus qol in the control groups was 55.23	The mean tinnitus qol in the intervention groups was 2.76 lower (14.69 lower to 9.17 higher)
Tinnitus loudness VAS and subjective change. Scale from: 0 to 4.	87 (2 studies) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 3.49	The mean tinnitus loudness in the intervention groups was 0.32 standard deviations lower (0.74 lower to 0.11 higher)
Tinnitus loudness Diary	106 (2 studies) 11 weeks - 6 months	⨁⨁⊖⊖ LOW1 due to risk of bias		The mean tinnitus loudness in the control groups was 4.11	The mean tinnitus loudness in the intervention groups was 0.06 lower (0.78 lower to 0.67 higher)
Tinnitus annoyance VAS. 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 0.46 lower (0.95 lower to 0.03 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Education	Risk difference with CBT (95% CI)
Tinnitus annoyance VAS. Scale from: 0 to 4.	33 (1 study) 12 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus annoyance in the control groups was 2.88	The mean tinnitus annoyance in the intervention groups was 0.63 lower (1.37 lower to 0.11 higher)
Depression BDI. Scale from: 0 to 63.	40 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW2 due to risk of bias, imprecision		The mean depression in the control groups was 11.45	The mean depression in the intervention groups was 0.45 higher (4.39 lower to 5.29 higher)
Depression BDI/ADS. Scale from: 0 to 63, 0-60.	92 (2 studies) 6-12 months	⨁⊖⊖⊖ VERY LOW2 due to risk of bias, imprecision		The mean depression in the control groups was 12.44	The mean depression in the intervention groups was 0.06 standard deviations lower (0.5 lower to 0.38 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 7: Clinical evidence summary: CBT versus relaxation

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Relaxation	Risk difference with CBT (95% CI)
Tinnitus severity Global Severity Index (GSI iof SCL-90R)	59 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus severity in the control groups was 0.75	The mean tinnitus severity in the intervention groups was 0.21 lower (0.55 lower to 0.13 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Relaxation	Risk difference with CBT (95% CI)
Tinnitus distress TQ. Scale from: 0 to 84.	59 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean distress in the control groups was 31.27	The mean tinnitus distress in the intervention groups was 7.6 lower (13.95 to 1.25 lower)
Tinnitus loudness Diary. Scale from: 1 to 7.	59 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean loudness (diary) (post treatment 6 months) in the control groups was 3.88	The mean tinnitus loudness in the intervention groups was 0.04 lower (0.93 lower to 0.85 higher)
Depression ADS	59 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 18.33	The mean depression in the intervention groups was 5.93 lower (12.11 lower to 0.25 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: CBT versus passive relaxation training

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Passive relaxation training	Risk difference with CBT (95% CI)
Tinnitus distress TEQ	21 (1 study)	⊕⊖⊖⊖ VERY LOW1,2		The mean tinnitus distress in the control groups was	The mean tinnitus distress in the intervention groups was

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Passive relaxation training	Risk difference with CBT (95% CI)
	post-treatment	due to risk of bias, imprecision		14	0.3 higher (2.2 lower to 2.8 higher)
Tinnitus distress TEQ	16 (1 study) 4 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 15.5	The mean tinnitus distress in the intervention groups was 0.2 lower (2.33 lower to 1.93 higher)
Tinnitus loudness Tinnitus loudness rating. Scale from: 1 to 5.	18 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 4	The mean tinnitus loudness in the intervention groups was 0 higher (0.72 lower to 0.72 higher)
Tinnitus loudness Tinnitus loudness rating. Scale from: 1 to 5.	16 (1 study) 4 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 4	The mean tinnitus loudness in the intervention groups was 0.03 lower (0.54 lower to 0.48 higher)
Tinnitus annoyance (most annoying)	18 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus annoyance (most annoying) in the control groups was 2.85	The mean tinnitus annoyance (most annoying) in the intervention groups was 0.75 higher (0.1 to 1.4 higher)
Tinnitus annoyance (most annoying)	16 (1 study) 4 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus annoyance (most annoying) in the control groups was 4	The mean tinnitus annoyance (most annoying) in the intervention groups was 0 higher (0.71 lower to 0.71 higher)
Depression BDI. Scale from: 0 to 63.	16 (1 study) 1 month	⨁⊖⊖⊖ VERY LOW1,2 due to risk of		The mean depression in the control groups was 11.16	The mean depression in the intervention groups was 3.36 lower

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Passive relaxation training	Risk difference with CBT (95% CI)
		bias, imprecision			(13.24 lower to 6.52 higher)
Anxiety STAI- state. Scale from: 20 to 80.	16 (1 study) 1 month	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 45.66	The mean anxiety in the intervention groups was 6.46 lower (21.31 lower to 8.39 higher)
Anxiety STAI-trait. Scale from: 20 to 80.	16 (1 study) 1 month	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 52.16	The mean anxiety in the intervention groups was 7.06 lower (18.48 lower to 4.36 higher)
Insomnia TEQ	18 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean insomnia in the control groups was 8.57	The mean insomnia in the intervention groups was 0.03 higher (2.09 lower to 2.15 higher)
Insomnia TEQ	16 (1 study) 4 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 9.33	The mean insomnia in the intervention groups was 0.13 lower (2.05 lower to 1.79 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 9: Clinical evidence summary: CBT versus applied relaxation training

Outcomes	No of	Quality of the	Relativ	Anticipated absolute effects

	Participants (studies) Follow up	evidence (GRADE)	e effect (95% CI)	Risk with Applied relaxation training	Risk difference with CBT (95% CI)
Tinnitus distress TEQ	23 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 15	The mean tinnitus distress in the intervention groups was 0.7 lower (2.64 lower to 1.24 higher)
Tinnitus distress TEQ	21 (1 study) 4 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 14.45	The mean tinnitus distress in the intervention groups was 0.85 higher (1.07 lower to 2.77 higher)
Tinnitus loudness Tinnitus loudness rating. Scale from: 1 to 5.	23 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 3.66	The mean tinnitus loudness in the intervention groups was 0.34 higher (0.35 lower to 1.03 higher)
Tinnitus loudness Tinnitus loudness rating. Scale from: 1 to 5.	21 (1 study) 4 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 4	The mean tinnitus loudness in the intervention groups was 0.3 higher (0.24 lower to 0.84 higher)
Tinnitus annoyance (most annoying)	23 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus annoyance (most annoying) in the control groups was 3.08	The mean tinnitus annoyance (most annoying) in the intervention groups was 0.52 higher (0.13 lower to 1.17 higher)
Tinnitus annoyance (most annoying)	21 (1 study) 4 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus annoyance (most annoying) in the control groups was 3.18	The mean tinnitus annoyance (most annoying) in the intervention groups was 0.82 higher (0 to 1.64 higher)
Depression BDI. Scale from: 0 to 63.	22 (1 study)	⨁⊖⊖⊖ VERY LOW1,2		The mean depression in the control groups was	The mean depression in the intervention groups was

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Applied relaxation training	Risk difference with CBT (95% CI)
	1month	due to risk of bias, imprecision		6.83	0.97 higher (4.09 lower to 6.03 higher)
Anxiety STAI-state. Scale from: 20 to 80.	22 (1 study) 1 month	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 40.41	The mean anxiety in the intervention groups was 1.21 lower (12.12 lower to 9.7 higher)
Anxiety STAI-trait. Scale from: 20 to 80.	22 (1 study) 1 month	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 44.33	The mean anxiety in the intervention groups was 0.77 higher (6.78 lower to 8.32 higher)
Insomnia TEQ	23 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean insomnia in the control groups was 8.58	The mean insomnia in the intervention groups was 0.02 higher (1.75 lower to 1.79 higher)
Insomnia TEQ	21 (1 study) 4 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean insomnia in the control groups was 9.09	The mean insomnia in the intervention groups was 0.11 higher (0.93 lower to 1.15 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 10: Clinical evidence summary: CBT-stepped intervention versus usual care

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Usual care	Risk difference with CBT-stepped intervention (95% CI)
Tinnitus severity TQ. Scale from: 0 to 84.	394 (1 study) post-treatment (step 1)	⨁⨁⨁⨁ HIGH		The mean tinnitus severity in the control groups was 45.51	The mean tinnitus severity in the intervention groups was 3.5 lower (7.4 lower to 0.4 higher)
Tinnitus severity TQ. Scale from: 0 to 84.	332 (1 study) 12 months (step 2)	⨁⨁⨁⨀ MODERATE 1 due to imprecision		The mean tinnitus severity in the control groups was 42.12	The mean tinnitus severity in the intervention groups was 8.69 lower (12.66 to 4.72 lower)
Quality of life HUI. Scale from: -0.36 to 1.	394 (1 study) post-treatment (step 1)	⨁⨁⨁⨀ MODERATE 2 due to risk of bias		The mean quality of life in the control groups was 0.64	The mean quality of life in the intervention groups was 0.02 lower (0.08 lower to 0.04 higher)
Quality of life HUI. Scale from: -0.36 to 1.	342 (1 study) 12 months (step 2)	⨁⨁⨁⨀ MODERATE 2 due to risk of bias		The mean quality of life in the control groups was 0.63	The mean quality of life in the intervention groups was 0.05 higher (0.01 to 0.11 higher)
Tinnitus-related quality of life THI. Scale from: 0 to 100.	394 (1 study) post-treatment (step 1)	⨁⨁⨁⨁ HIGH		The mean tinnitus-related quality of life in the control groups was 37.38	The mean tinnitus-related quality of life in the intervention groups was 3.13 lower (7.79 lower to 1.53 higher)
Tinnitus-related quality of life THI. Scale from: 0 to 100.	332 (1 study) 12 months	⨁⨁⨁⨀ MODERATE 1		The mean tinnitus-related quality of life in the control groups was	The mean tinnitus-related quality of life in the intervention groups was

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Usual care	Risk difference with CBT-stepped intervention (95% CI)
	(step 2)	due to imprecision		33.51	7.06 lower (11.63 to 2.49 lower)
Depression and anxiety HADS. Scale from: 0 to 42.	394 (1 study) post-treatment (step 1)	⨁⨁⨁⨁ HIGH		The mean depression and anxiety in the control groups was 12.08	The mean depression and anxiety in the intervention groups was 0.17 lower (1.82 lower to 1.48 higher)
Depression and anxiety HADS. Scale from: 0 to 42.	332 (1 study) 12 months (step 2)	⨁⨁⨁⨁ HIGH		The mean depression and anxiety in the control groups was 10.83	The mean depression and anxiety in the intervention groups was 0.61 lower (2.24 lower to 1.02 higher)

1 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.
2 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 11: Clinical evidence summary: CBT (self-help book) 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 CBT (book) (95% CI)
Tinnitus distress TRQ. Scale from: 0 to 104.	125 (1 study) 3 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 20.67	The mean tinnitus distress in the intervention groups was 5.12 lower (10.66 lower to 0.42 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 12: Clinical evidence summary: CBT (bibliotherapy) versus information only

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Information only	Risk difference with CBT-bibliotherapy (95% CI)
Tinnitus distress TQ. Scale from: 0 to 84.	109 (1 study) post-treatment	⨁⨁⊖⊖ LOW1 due to risk of bias		The mean tinnitus distress in the control groups was 27.4	The mean tinnitus distress in the intervention groups was 1.10 lower (8.37 lower to 6.17 higher)
Tinnitus distress TQ. Scale from: 0 to 84.	94 (1 study) 9 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 25.2	The mean tinnitus distress in the intervention groups was 4.40 lower (11.64 lower to 2.84 higher)
Depression PHQ-D. Scale from: 0 to 120.	109 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 5.7	The mean depression in the intervention groups was 0.70 higher (1.34 lower to 2.74 higher)
Depression PHQ-D. Scale from: 0 to 120.	94 (1 study) 9 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 5.7	The mean depression in the intervention groups was 0.80 higher (1.29 lower to 2.89 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 13: Clinical evidence summary: CBT versus control (web discussion forum)

Outcomes	No of	Quality of the	Relativ	Anticipated absolute effects

	Participants (studies) Follow up	evidence (GRADE)	e effect (95% CI)	Risk with Control (web discussion forum)	Risk difference with CBT (95% CI)
Tinnitus distress Mini-TQ. Scale from: 0 to 24.	81 (1 study) 10 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean distress in the control groups was 11.09	The mean tinnitus distress in the intervention groups was 3 lower (5.33 to 0.67 lower)
Tinnitus severity THI. Scale from: 0 to 100.	81 (1 study) 10 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean severity in the control groups was 37.46	The mean tinnitus severity in the intervention groups was 9.76 lower (18.74 to 0.78 lower)
Depression HADS. Scale from: 0 to 21.	81 (1 study) 10 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 5.88	The mean depression in the intervention groups was 1.47 lower (3.28 lower to 0.34 higher)
Anxiety HADS. Scale from: 0 to 21.	81 (1 study) 10 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 7.67	The mean anxiety in the intervention groups was 1.83 lower (3.68 lower to 0.02 higher)
Sleep ISI. Scale from: 0 to 28.	81 (1 study) 10 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean sleep in the control groups was 10.91	The mean sleep in the intervention groups was 1.88 lower (4.92 lower to 1.16 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 14: Clinical evidence summary: iCBT 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 iCBT (95% CI)
Tinnitus annoyance VAS. Scale from: 0 to 10.	84 (1 study)	⨁⊖⊖⊖ VERY LOW1,2		The mean tinnitus annoyance in the control groups was	The mean tinnitus annoyance in the intervention groups was

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 iCBT (95% CI)
	post-treatment	due to risk of bias, imprecision		5.8	0.5 lower (1.56 lower to 0.56 higher)
Tinnitus loudness VAS. Scale from: 0 to 10.	83 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 6.4	The mean tinnitus loudness in the intervention groups was 0.2 lower (1.26 lower to 0.86 higher)
Depression HADS - depression. Scale from: 0 to 21.	72 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 6	The mean depression in the intervention groups was 0.8 lower (2.76 lower to 1.16 higher)
Depression HADS - depression. Scale from: 0 to 21.	96 (1 study) 1 year	⨁⨁⊖⊖ LOW1 due to risk of bias		The mean depression in the control groups was 5.3	The mean depression in the intervention groups was 0 higher (1.56 lower to 1.56 higher)
Anxiety HADS - anxiety. Scale from: 0 to 21.	72 (1 study) post-treatment weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 6.8	The mean anxiety in the intervention groups was 0.9 lower (2.88 lower to 1.08 higher)
Anxiety HADS - anxiety. Scale from: 0 to 21.	96 (1 study) 1 year	⨁⨁⊖⊖ LOW1 due to risk of bias		The mean anxiety in the control groups was 6.4	The mean anxiety in the intervention groups was 0.3 lower (2.02 lower to 1.42 higher)
Sleep ISI. Scale from: 0 to 28.	82 (1 study) post-treatment	⨁⨁⊖⊖ LOW1 due to risk of bias		The mean sleep in the control groups was 6.7	The mean sleep in the intervention groups was 0.60 lower (0.47 lower to 1.67 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 15: Clinical evidence summary: iCBT versus information only

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Information only	Risk difference with iCBT (95% CI)
Tinnitus distress TQ/TRQ. Scale from: 0 to 84, 0-104.	161 (2 studies) post-treatment	⊕⊖⊖⊖ VERY LOW1,2,3 due to risk of bias, inconsistency, imprecision		The mean tinnitus distress in the control groups was 20.68	The mean tinnitus distress in the intervention groups was 0.34 standard deviations lower (0.66 to 0.03 lower)
Tinnitus distress TQ. Scale from: 0 to 84.	93 (1 study) 9 months	⊕⊖⊖⊖ VERY LOW1,3 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 25.2	The mean tinnitus distress in the intervention groups was 5.8 lower (12.71 lower to 1.11 higher)
Tinnitus annoyance VAS. Scale from: 0 to 10.	51 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,3 due to risk of bias, imprecision		The mean tinnitus annoyance in the control groups was 3.61	The mean tinnitus annoyance in the intervention groups was 0.23 lower (1.1 lower to 0.64 higher)
Tinnitus loudness VAS. Scale from: 0 to 10.	51 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,3 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 4.48	The mean tinnitus loudness in the intervention groups was 0.1 higher (0.84 lower to 1.04 higher)
Depression DASS/PHQ-D. Scale from: not reported , 0-120.	161 (2 studies) post-treatment	⊕⊖⊖⊖ VERY LOW1,2,3 due to risk of bias, inconsistency, imprecision		The mean depression in the control groups was 4.07	The mean depression in the intervention groups was 0.05 standard deviations higher (0.26 lower to 0.36 higher)
Depression PHQ-D	93 (1 study) 9 months	⊕⊕⊖⊖ LOW1 due to risk of bias		The mean depression in the control groups was 5.7	The mean depression in the intervention groups was 0.2 higher (1.92 lower to 2.32 higher)
Anxiety DASS. Scale from: 0 to 120.	51 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,3 due to risk of bias, imprecision		The mean anxiety in the control groups was 3.09	The mean anxiety in the intervention groups was 0.7 higher (1.46 lower to 2.86 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Information only	Risk difference with iCBT (95% CI)
Sleep quality VAS. Scale from: 0 to 10.	51 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,3 due to risk of bias, imprecision		The mean sleep quality in the control groups was 4.17	The mean sleep quality in the intervention groups was 0.1 lower (1.24 lower to 1.04 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 or 2 increments because heterogeneity, I2= > 50%, p= > 0.04, unexplained by subgroup analysis.
3 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 summary: iCBT versus tinnitus information counselling

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Tinnitus information counselling	Risk difference with iCBT (95% CI)
Tinnitus severity THI. Scale from: 0 to 100.	88 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus severity in the control groups was 28.74	The mean tinnitus severity in the intervention groups was 6.41 lower (14.71 lower to 1.89 higher)
Tinnitus severity THI. Scale from: 0 to 100.	74 (1 study) 2 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus severity in the control groups was 27.11	The mean tinnitus severity in the intervention groups was 9.33 lower (17.77 to 0.89 lower)
Tinnitus distress TFI. Scale from: 0 to 100.	88 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 34.88	The mean tinnitus distress in the intervention groups was 7 lower (16.6 lower to 2.6 higher)
Tinnitus distress	74	⨁⊖⊖⊖		The mean tinnitus distress in	The mean tinnitus distress in the

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Tinnitus information counselling	Risk difference with iCBT (95% CI)
TFI. Scale from: 0 to 100.	(1 study) 2 months	VERY LOW1,2 due to risk of bias, imprecision		the control groups was 32.51	intervention groups was 9.66 lower (19.4 lower to 0.08 higher)
Quality of life SWLS. Scale from: 5 to 35.	88 (1 study) post-treatment	⊕⊕⊖⊖ LOW1 due to risk of bias		The mean quality of life in the control groups was 20.05	The mean quality of life in the intervention groups was 0.05 higher (2.16 lower to 2.26 higher)
Quality of life SWLS. Scale from: 5 to 35.	74 (1 study) 2 months	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 20.5	The mean quality of life in the intervention groups was 0.5 higher (1.78 lower to 2.78 higher)
Depression PHQ-9. Scale from: 0 to 27.	88 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 4.19	The mean depression in the intervention groups was 0.52 lower (2.14 lower to 1.1 higher)
Depression PHQ-9. Scale from: 0 to 27.	74 (1 study) 2 months	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 4.97	The mean depression in the intervention groups was 2.19 lower (3.95 to 0.43 lower)
Anxiety GAD-7. Scale from: 0 to 21.	88 (1 study) post-treatment	⊕⊕⊖⊖ LOW1 due to risk of bias		The mean anxiety in the control groups was 3.33	The mean anxiety in the intervention groups was 0.12 higher (1.43 lower to 1.67 higher)
Anxiety GAD-7. Scale from: 0 to 21.	74 (1 study) 2 months	⊕⊕⊖⊖ LOW1 due to risk of bias		The mean anxiety in the control groups was 3.42	The mean anxiety in the intervention groups was 0.09 lower (1.64 lower to 1.46 higher)
Sleep ISI. Scale from: 0 to 28.	88 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean sleep in the control groups was 9.55	The mean sleep in the intervention groups was 2.84 lower (5.42 to 0.26 lower)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Tinnitus information counselling	Risk difference with iCBT (95% CI)
Sleep ISI. Scale from: 0 to 28.	74 (1 study) 2 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean sleep in the control groups was 10.03	The mean sleep in the intervention groups was 4.34 lower (7.01 to 1.67 lower)

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 summary: iCBT versus control (web discussion forum)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control (web discussion forum)	Risk difference with iCBT (95% CI)
Tinnitus severity and distress THI. Scale from: 0 to 100.	262 (3 studies) 8-10 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus severity and distress in the control groups was 44.39	The mean tinnitus severity and distress in the intervention groups was 12.16 lower (16.37 to 7.96 lower)
Tinnitus distress Mini-TQ. Scale from: 0 to 20.	200 (2 studies) 8-10 weeks	⨁⨁⊖⊖ LOW1 due to risk of bias		The mean tinnitus distress in the control groups was 12.18	The mean tinnitus distress in the intervention groups was 4.42 lower (5.74 to 3.1 lower)
Quality of life QoLI	62 (1 study) 8 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 2.27	The mean quality of life in the intervention groups was 0.26 higher (0.5 lower to 1.02 higher)
Depression	262	⨁⊖⊖⊖		The mean depression in the control	The mean depression in the intervention

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control (web discussion forum)	Risk difference with iCBT (95% CI)
HADS. Scale from: 0 to 21.	(3 studies) 8-10 weeks	VERY LOW1,2 due to risk of bias, imprecision		groups was 6.44	groups was 1.95 lower (2.89 to 1.02 lower)
Anxiety HADS. Scale from: 0 to 21.	262 (3 studies) 8-10 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 7.43	The mean anxiety in the intervention groups was 1.66 lower (2.53 to 0.79 lower)
Sleep ISI. Scale from: 0 to 28.	262 (3 studies) 8-10 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean sleep in the control groups was 11.23	The mean sleep in the intervention groups was 2.9 lower (4.42 to 1.38 lower)

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 summary: iCBT versus iACT

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with iACT	Risk difference with iCBT (95% CI)
Tinnitus distress and severity THI. Scale from: 0 to 100.	63 (1 study) 8 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean distress and severity in the control groups was 31.94	The mean distress and severity in the intervention groups was 6.99 higher (1.64 lower to 15.62 higher)
Tinnitus distress and severity	61 (1 study)	⨁⊖⊖⊖ VERY LOW1,2		The mean distress and severity in the control groups was	The mean distress and severity in the intervention groups was

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with iACT	Risk difference with iCBT (95% CI)
THI. Scale from: 0 to 100.	12 months	due to risk of bias, imprecision		44.26	3.79 lower (14.76 lower to 7.18 higher)
Quality of life QoLI	63 (1 study) 8 weeks	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 2.12	The mean quality of life in the intervention groups was 0.41 higher (0.34 lower to 1.16 higher)
Quality of life QoLI	61 (1 study) 12 months	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 1.84	The mean quality of life in the intervention groups was 0.64 higher (0.11 lower to 1.39 higher)
Anxiety HADS. Scale from: 0 to 21.	63 (1 study) 8 weeks	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 4.21	The mean anxiety in the intervention groups was 0.46 higher (0.97 lower to 1.89 higher)
Anxiety HADS. Scale from: 0 to 21.	61 (1 study) 12 months	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 6.39	The mean anxiety in the intervention groups was 1.49 lower (3.48 lower to 0.5 higher)
Depression HADS. Scale from: 0 to 21.	63 (1 study) 8 weeks	⊕⊕⊖⊖ LOW1 due to risk of bias		The mean depression in the control groups was 3.48	The mean depression in the intervention groups was 0.11 lower (1.54 lower to 1.32 higher)
Depression HADS. Scale from: 0 to 21.	61 (1 study) 12 months	⊕⊕⊖⊖ LOW1 due to risk of bias		The mean depression in the control groups was 5.03	The mean depression in the intervention groups was 1.96 lower (3.55 to 0.37 lower)
Sleep ISI. Scale from: 0 to 28.	63 (1 study) 8 weeks	⊕⊕⊖⊖ LOW1 due to risk of bias		The mean sleep in the control groups was 3.48	The mean sleep in the intervention groups was 1.45 higher (1.62 lower to 4.52 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with iACT	Risk difference with iCBT (95% CI)
Sleep ISI. Scale from: 0 to 28.	61 (1 study) 12 months	⨁⨁⨀⨀ LOW1 due to risk of bias		The mean sleep in the control groups was 17.32	The mean sleep in the intervention groups was 5.29 lower (9.88 to 0.70 lower)

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 19: Clinical evidence summary: Biofeedback 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 Biofeedback (95% CI)
Tinnitus distress Tinnitus diary. Scale from: 0 to 84.	42 (1 study) 8 weeks	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 28.47	The mean tinnitus distress in the intervention groups was 1.33 lower (9.77 lower to 7.11 higher)
Tinnitus distress TQ. Scale from: 0 to 84.	41 (1 study) 6 months	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 28.11	The mean tinnitus distress in the intervention groups was 3.29 lower (14.15 lower to 7.57 higher)
Quality of life Health Life Satisfaction	42 (1 study) 8 weeks	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 62.68	The mean quality of life in the intervention groups was 0.54 higher (20.48 lower to 21.56 higher)
Quality of life Health Life Satisfaction	41 (1 study) 6 months	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 46.53	The mean quality of life in the intervention groups was 7.47 higher (17.67 lower to 32.61 higher)

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 Biofeedback (95% CI)
Tinnitus loudness Tinnitus diary. Scale from: 0 to 10.	42 (1 study) 8 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 4.12	The mean tinnitus loudness in the intervention groups was 0.49 lower (1.43 lower to 0.45 higher)
Tinnitus loudness Tinnitus diary. Scale from: 0 to 10.	41 (1 study) 6 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 3.87	The mean tinnitus loudness in the intervention groups was 0.17 higher (0.96 lower to 1.3 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 20: Clinical evidence summary: Biofeedback-based CBT 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 Biofeedback-based CBT (95% CI)
Tinnitus severity Global severity index of SLC-90-R	111 (1 study) 3 months	⨁⨁⨁⊖ MODERATE1 due to risk of bias		The mean tinnitus severity in the control groups was 0.76	The mean tinnitus severity in the intervention groups was 0.01 lower (0.21 lower to 0.19 higher)
Tinnitus distress TQ. Scale from: 0 to 84.	111 (1 study) 3 months	⨁⨁⨁⊖ MODERATE1 due to risk of bias		The mean tinnitus distress in the control groups was 49.54	The mean tinnitus distress in the intervention groups was 17.02 lower (22.6 to 11.44 lower)
Tinnitus distress Tinnitus diary	111 (1 study) 3 months	⨁⨁⊖⊖ LOW1,2 due to risk of bias, imprecision		The mean tinnitus distress in the control groups was 5.22	The mean tinnitus distress in the intervention groups was 1.04 lower (1.68 to 0.4 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 Biofeedback-based CBT (95% CI)
Tinnitus loudness Tinnitus diary. Scale from: 0 to 10.	111 (1 study) 3 months	⨁⨁⨀⨀ LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 5.69	The mean tinnitus loudness in the intervention groups was 1.33 lower (1.98 to 0.68 lower)
Depression BDI. Scale from: 0 to 63.	111 (1 study) 3 months	⨁⨁⨀⨀ LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 13.38	The mean depression in the intervention groups was 1.09 lower (4.16 lower to 1.98 higher)
Sleep Sleep disturbance diary. Scale from: 0 to 10.	111 (1 study) 3 months	⨁⨁⨀⨀ LOW1,2 due to risk of bias, imprecision		The mean sleep in the control groups was 4.58	The mean sleep in the intervention groups was 1.37 lower (2.28 to 0.46 lower)

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 21: Clinical evidence summary: Behavioural therapy 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 Behavioural therapy (95% CI)
Tinnitus loudness (direct) Diary. Scale from: 0 to 10.	24 (1 study) post-treatment	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus loudness (direct) in the control groups was 7.21	The mean tinnitus loudness (direct) in the intervention groups was 0.96 lower (2.49 lower to 0.57 higher)
Tinnitus loudness (retrospective) Diary. Scale from: 0 to 10.	24 (1 study) post-	⨁⨀⨀⨀ VERY LOW1,2 due to risk of		The mean tinnitus loudness (retrospective) in the control groups was	The mean tinnitus loudness (retrospective) in the intervention groups was

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 Behavioural therapy (95% CI)
	treatment	bias, imprecision		7	1.01 lower (2.80 lower to 0.78 higher)
Tinnitus annoyance (retrospective) Diary. Scale from: 0 to 10.	24 (1 study) post-treatment	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus annoyance (retrospective) in the control groups was 2.73	The mean tinnitus annoyance (retrospective) in the intervention groups was 0.55 lower (1.67 lower to 0.57 higher)
Depression (retrospective) Diary. Scale from: 0 to 10.	24 (1 study) post-treatment	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean depression (retrospective) in the control groups was 2.84	The mean depression (retrospective) in the intervention groups was 0.92 lower (1.93 lower to 0.09 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.

Mindfulness-based therapies

Table 22: Clinical evidence summary: Mindfulness-based cognitive therapy versus relaxation

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Relaxation	Risk difference with Mindfulness-based cognitive therapy (95% CI)
Tinnitus severity TQ. Scale from: 0 to 84.	68 (1 study) post-treatment	⨁⨁⨁⨀ MODERATE1 due to imprecision		The mean tinnitus severity in the control groups was 38.2	The mean tinnitus severity in the intervention groups was 6.8 lower (14.03 lower to 0.43 higher)
Tinnitus severity	62	⨁⨁⨁⨀		The mean tinnitus severity in the	The mean tinnitus severity in the

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Relaxation	Risk difference with Mindfulness-based cognitive therapy (95% CI)
TQ. Scale from: 0 to 84.	(1 study) 6 months	MODERATE1 due to imprecision		control groups was 35.6	intervention groups was 7.6 lower (16.3 lower to 1.1 higher)
Tinnitus severity TFI. Scale from: 0 to 100.	68 (1 study) post-treatment	⊕⊕⊕⊖ MODERATE1 due to imprecision		The mean tinnitus severity in the control groups was 49.2	The mean tinnitus severity in the intervention groups was 7.00 lower (16.09 to 2.09 lower)
Tinnitus severity TFI. Scale from: 0 to 100.	62 (1 study) 6 months	⊕⊕⊕⊖ MODERATE1 due to imprecision		The mean tinnitus severity in the control groups was 49	The mean tinnitus severity in the intervention groups was 11.80 lower (23.06 to 0.54 lower)
Tinnitus loudness VAS. Scale from: 0 to 100.	68 (1 study) post-treatment	⊕⊕⊕⊖ MODERATE1 due to imprecision		The mean tinnitus loudness in the control groups was 59.2	The mean tinnitus loudness in the intervention groups was 2.6 lower (13.94 lower to 8.74 higher)
Tinnitus loudness VAS. Scale from: 0 to 100.	62 (1 study) 6 months	⊕⊕⊕⊖ MODERATE1 due to imprecision		The mean tinnitus loudness in the control groups was 65.4	The mean tinnitus loudness in the intervention groups was 10.3 lower (23.79 lower to 3.19 higher)
Depression HADS. Scale from: 0 to 21.	93 (2 studies) post-treatment	⊕⊕⊕⊖ MODERATE1 due to imprecision		The mean depression in the control groups was 10.165	The mean depression in the intervention groups was 0.41 standard deviations lower (0.82 lower to 0.01 higher)
Depression HADS. Scale from: 0 to 21.	87 (2 studies) 6 months	⊕⊕⊕⊖ MODERATE1 due to imprecision		The mean depression in the control groups was 9.71	The mean depression in the intervention groups was 0.42 standard deviations lower (0.85 lower to 0.01 higher)
Anxiety HADS. Scale from: 0 to 21.	93 (2 studies) post-treatment	⊕⊕⊕⊕ HIGH		The mean anxiety in the control groups was 27.925	The mean anxiety in the intervention groups was 0.24 standard deviations lower (0.65 lower to 0.17 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Relaxation	Risk difference with Mindfulness-based cognitive therapy (95% CI)
Anxiety HADS. Scale from: 0 to 21.	87 (2 studies) 3-6 months	⨁⨁⨁⊖ MODERATE1 due to imprecision		The mean anxiety in the control groups was 27.965	The mean anxiety in the intervention groups was 0.39 standard deviations lower (0.82 lower to 0.03 higher)
1 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.					

Table 23: Clinical evidence summary: Mindfulness meditation versus relaxation therapy

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Relaxation therapy	Risk difference with Mindfulness meditation (95% CI)
Tinnitus severity VAS. Scale from: 0 to 10.	61 (1 study) 15 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus severity in the control groups was 4.41	The mean tinnitus severity in the intervention groups was 1.5 lower (2.51 to 0.49 lower)
Tinnitus loudness VAS. Scale from: 0 to 10.	61 (1 study) 15 weeks	⨁⊖⊖⊖ VERY LOW1 due to risk of bias, imprecision		The mean tinnitus loudness in the control groups was 5.11	The mean tinnitus loudness in the intervention groups was 0.64 lower (1.79 lower to 0.51 higher)
Anxiety HADS - anxiety. Scale from: 0 to 21.	61 (1 study) 15 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 5.89	The mean anxiety in the intervention groups was 1.3 lower (3.08 lower to 0.48 higher)
Depression	61	⨁⊖⊖⊖		The mean depression in the control	The mean depression in the

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Relaxation therapy	Risk difference with Mindfulness meditation (95% CI)
HADS - depression. Scale from: 0 to 21.	(1 study) 15 weeks	VERY LOW1,2 due to risk of bias, imprecision		groups was 5.15	intervention groups was 0.33 lower (2.07 lower to 1.41 higher)
Depression and anxiety HADS - total. Scale from: 0 to 42.	61 (1 study) 15 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression and anxiety in the control groups was 11.037	The mean depression and anxiety in the intervention groups was 1.63 lower (4.94 lower to 1.69 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 24: Clinical evidence summary: Mindfulness and body psychotherapy-based group treatment 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 Mindfulness and body-psychotherapy-based group treatment (95% CI)
Tinnitus severity TQ. Scale from: 0 to 84.	31 (1 study) 24 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus severity in the control groups was 33.1	The mean tinnitus severity in the intervention groups was 6.6 lower (18.18 lower to 4.98 higher)
Tinnitus severity THI. Scale from: 0 to 100	31 (1 study) 24 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of		The mean severity in the control groups was 41.3	The mean tinnitus severity in the intervention groups was 14 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 Mindfulness and body-psychotherapy-based group treatment (95% CI)
		bias, imprecision			(28.43 lower to 0.43 higher)
Tinnitus annoyance VAS. Scale from: 0 to 10.	31 (1 study) 24 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean annoyance in the control groups was 7.2	The mean tinnitus annoyance in the intervention groups was 1.8 lower (3.6 lower to 0 higher)
Tinnitus loudness VAS. Scale from: 0 to 10.	31 (1 study) 24 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean loudness in the control groups was 7	The mean tinnitus loudness in the intervention groups was 1.9 lower (3.67 to 0.13 lower)
Depression BDI. Scale from: 0 to 63.	31 (1 study) 24 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 13.3	The mean depression in the intervention groups was 5.7 lower (10.85 to 0.55 lower)

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

Acceptance and commitment therapy (ACT)

Table 25: Clinical evidence summary: iACT versus control (web discussion forum)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control (web discussion forum)	Risk difference with iACT (95% CI)
Tinnitus severity and distress	65 (1 study)	⨁⨁⊖⊖ LOW1		The mean tinnitus severity and distress in the control groups was	The mean tinnitus severity and distress in the intervention groups was

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Control (web discussion forum)	Risk difference with iACT (95% CI)
THI. Scale from: 0 to 100.	post-treatment	due to risk of bias		49.94	18 lower (25.46 to 10.54 lower)
Quality of life QoLI	65 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 2.27	The mean quality of life in the intervention groups was 0.15 lower (0.87 lower to 0.57 higher)
Depression HADS - depression. Scale from: 0 to 21.	65 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1 due to risk of bias, imprecision		The mean depression in the control groups was 4.59	The mean depression in the intervention groups was 1.11 lower (2.52 lower to 0.3 higher)
Anxiety HADS - anxiety. Scale from: 0 to 21.	65 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean anxiety in the control groups was 6.78	The mean anxiety in the intervention groups was 2.57 lower (4.15 to 0.99 lower)
Sleep ISI. Scale from: 0 to 28.	65 (1 study) post-treatment	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean sleep in the control groups was 8.48	The mean sleep in the intervention groups was 2.74 lower (5.78 lower to 0.3 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 26: Clinical evidence summary: ACT versus waiting-list control

Outcomes	No of	Quality of the	Relative	Anticipated absolute effects

	Participants (studies) Follow up	evidence (GRADE)	effect (95% CI)	Risk with Waiting-list control	Risk difference with ACT (95% CI)
Tinnitus severity THI. Scale from: 0 to 100.	44 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean tinnitus severity in the control groups was 48.29	The mean tinnitus severity in the intervention groups was 20.86 lower (32.76 to 8.96 lower)
Quality of life QoLI	44 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 1.92	The mean quality of life in the intervention groups was 0.86 higher (0.12 lower to 1.84 higher)
Depression HADS- depression. Scale from: 0 to 21.	44 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 6.2	The mean depression in the intervention groups was 3 lower (5.59 to 0.41 lower)
Anxiety HADS – anxiety. Scale from: 0 to 21.	44 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean depression in the control groups was 7.2	The mean anxiety in the intervention groups was 3.6 lower (6.27 to 0.93 lower)
Sleep ISI. Scale from: 0 to 28.	44 (1 study) post-treatment	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean sleep in the control groups was 11.8	The mean sleep in the intervention groups was 2.55 lower (5.9 lower to 0.8 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
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

One health economic study was identified with the relevant comparison and has been included in this review.[37] This is summarised in the health economic evidence profile below (Table 4) and the health economic evidence table in appendix H.

1.5.2 Excluded studies

Two economic studies relating to this review question were identified but were excluded due to methodological limitations. These are listed in appendix I, with reasons for exclusion given.

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

1.5.3 Summary of studies included in the economic evidence review

Table 27: Health economic evidence profile: Specialised care versus usual care

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Maes 2014 [37] Netherlands	Partially Applicable(a)	Potentially Serious Limitations (b)	Within trial (RCT) cost-utility analysis, with a 1yr follow up and 32% drop out rate.	£102 (c)	0.02 QALYs (d)	£7001 per QALY gained	Probability specialised care is cost effective in the base case (£20K and 30K threshold): 60% and 68%

Abbreviations: QALY: quality-adjusted life years; RCT: randomised controlled trial

(a) The analysis takes a reasonable approach however as the study is from a Dutch perspective and QALYs are derived using HUI3 the study has been judged as partially applicable.

(b) This economic analysis is based on a single trial, with a very high dropout rate. Therefore, this study has been judged to have potentially serious limitations.

(c) 2009 euros converted into GBP using the purchasing power parities[51]

(d) Utilities were derived using the Health Utilities Index Mark III

1.5.4 Health economic modelling

In order to explore the most cost-effective method of delivering psychological therapy for people who have tinnitus related distress, a threshold analysis was conducted.

Methods and inputs

The committee specified some typical psychological interventions to be evaluated. These interventions were selected on the basis that they had demonstrated evidence of clinical effectiveness in the literature. These are described in Table 28 and Table 29. The main NHS resource use involved in these interventions is staff time and this was costed using a standard national source [18] – see Table 30. Using this information, costs per patient for each intervention have been calculated – see Table 31.

Table 28: Description of psychological strategies and the staff requirement

Psychological therapy	Group Size	Frequency [(a)]	Number of clinical staff required [(b)]	Source
Supervised digital CBT	1	8 sessions: 8 weekly individual 10.9 minute phone calls	1 band 7 clinical psychologist under the supervision of band 8a principal psychologist.	Beukes (2018) and Jasper (2014) and GC[(c)]
Group CBT	8	7 sessions: 6 weekly 2 hour group sessions and a 1hr follow-up group session	2 band 7 clinical psychologists under the supervision of band 8a principal psychologist.	GC
Individual CBT	1	6 sessions: 6 weekly 1 hour individual sessions and a 1hr follow-up individual session	1 Band 7 psychologist under the supervision of band 8a principal psychologist.	GC
Group mindfulness based cognitive therapy	12	9 sessions: 8 weekly 2hr group sessions and a 1.5hr follow-up group session	2 band 7 clinical psychologists under the supervision of band 8a principal psychologist. This intervention could also be delivered by other clinical staff trained in mindfulness.	GC
Group acceptance and commitment therapy [(d)]	14	10 sessions: 10 weekly 2hr sessions	2 band 7 clinical psychologists under the supervision of band 8a principal psychologist.	NHS Worcestershire

(a) All sessions include an additional initial 1 hour individual consultation as advised by the guideline committee
(b) Many studies were not based in a UK setting and sometimes involved the provision of services by students on postgraduate degrees. In the NHS the provision of services would be from appropriately trained practitioners, and therefore the band and specialty of staff required was determined by the GC based on their clinical experience rather than the literature.
(c) The estimates for staff contact time for the digital CBT intervention varied in studies. In this costing analysis, the average has been taken of the 13.7 minutes of clinician contact time reported in Jasper (2014)[26] and the 8 minutes contact time reported in a recent UK study.[9]
(d) The time required for acceptance base therapy (ACT) has been sourced by NHS Worcestershire who provide acceptance and commitment therapy – though these sessions were not exclusively for tinnitus.

Table 29: Frequency of supervision

Psychological therapy [(a)]	Supervision sessions for whole intervention	Supervising staff	Total supervising time (hours)
Supervised digital CBT	2 sessions	8a psychologist	2
Group CBT	2 sessions	8a psychologist	2
Individual CBT	2 sessions	8a psychologist	2
Group mindfulness based cognitive therapy	2 sessions	8a psychologist	2
Group acceptance and commitment therapy	3 sessions	8a psychologist	3

(a) This was preferred over the supervision presented in the literature as many studies were not UK based and often involved students on postgraduate courses. In the NHS the provision of services would be from appropriately trained practitioners who are supervised. The assumptions for the number of supervision sessions were therefore determined by the GC based on their clinical experience. The GC based their assumption on the number of supervision sessions required according to the duration of the intervention and the number of participants involved.

Table 30: UK costs of clinical psychologists

Staff member [(a)]	Band	Cost per hour of patient contact
Clinical Psychologist	7	£53
Principal Psychologist	8a	£63

Source[s]: PSSRU (2018)

(a) The committee indicated that a band 7 clinical psychologist would be expected to deliver psychological therapies under the supervision of a band 8a principal psychologist. However, the committee explained that other trained practitioners could also deliver group mindfulness based cognitive therapies.

Table 31: Cost per patient for different psychological therapies [(a)]

Psychological Therapy	Therapy	Supervision	Total
Supervised digital CBT	£77	£29	£106
Group CBT	£172	£29	£201
Individual CBT	£371	£29	£400
Group mindfulness cognitive based therapy	£155	£19	£174
Group acceptance and commitment therapy	£151	£25	£176

(a) The costs have been calculated by calculating the total staff hours required per patient for each intervention and then multiplying by the relevant unit cost per hour for each specific staff sourced from the PSSRU.[18]

The results from Table 31 demonstrated that digital CBT is the least expensive intervention and individual CBT is the most expensive intervention. However, the committee reported that in current practice, a proportion of people with tinnitus, after an initial psychological intervention, will need to be stepped to a second-line psychological intervention. Table 32 lists the proportion of individuals that would need to be stepped up from a hypothetical population of 1000 people with tinnitus.

Table 32: Number of patients that require an additional intervention from a hypothetical (n=1000) tinnitus population

Psychological therapy strategy	Number requiring the second intervention [(a)]	Source
Supervised digital CBT stepped to individual CBT	480	Beukes, (2018)
Supervised digital CBT stepped to individual or group CBT[(b)]	480	Beukes, (2018)
Group CBT stepped to individual CBT	180	GC estimate
Individual CBT stepped to group CBT	100	GC estimate
Group mindfulness CBT based therapy stepped to individual CBT	50	GC estimate
Group acceptance and commitment therapy stepped to individual CBT	250	GC estimate

(a) Estimates of the proportion of people with tinnitus that would require a second-line intervention. These estimates were sourced from the committee's experience of current practice and a study by Beukes (2018)[11] *Sensitivity analysis has been completed to consider alternative estimates.*
(b) For this strategy it was assumed that half of those requiring a second intervention would have individual CBT and the other half would have group CBT.

Threshold analysis – base case results

Interventions are generally considered cost-effective if they cost less than £20,000 per QALY gained. The QALYs gained that would be required for an intervention to be cost effective at this threshold compared with no psychological intervention was calculated. Table 33 presents the costs of delivering psychological interventions while taking into consideration that a number of people with tinnitus will need to be stepped to second line intervention (see Table 32). Table 33 also presents the incremental QALYs that need to be generated for a particular psychological strategy to be cost-effective. The method used to calculate the incremental QALYs required was as follows:

ICER (incremental cost-effectiveness ratio) = Incremental costs ÷ Incremental QALY

Therefore: Incremental QALYs = Incremental costs ÷ ICER

At the threshold of cost effectiveness the ICER=20,000 per QALY and so

Incremental QALYs=Incremental cost ÷ 20,000.

Alongside the study by Maes(2014) study, the committee also requested that they be presented with QALY gains from RCTs exploring the clinical effectiveness of psychological interventions to help people with chronic pain. This population was chosen because the

committee were of the view that the way people experience symptoms of chronic pain are similar to the experiences people have with tinnitus. The relevant studies selected and the QALY gains achieved in those studies by the respective psychological intervention are listed in Table 34.

Table 33: Mean cost of different psychological therapy strategies and QALY gained required for the strategy to be cost effective compared to no intervention

Strategy	1st line	2nd line (a)	Both lines	QALYs required at the £20k threshold
Group mindfulness based cognitive therapy stepped up to individual CBT	£174	£20	£194	0.010
Supervised digital CBT stepped up to individual or group CBT	£106	£144	£250	0.013
Group CBT stepped up to individual CBT	£201	£72	£273	0.014
Group acceptance based therapy stepped up to individual CBT	£176	£100	£276	0.014
Supervised digital CBT stepped up to individual CBT	£106	£192	£298	0.015
Individual CBT alone	£400	£0	£400	0.020
Individual CBT stepped up to group CBT	£400	£20	£420	0.021
Sensitivity analysis				
Supervised digital CBT stepped up to individual CBT (only 25% require second-line)	£106	£100	£206	0.010
Supervised digital CBT stepped up to individual or group CBT (only 25% require second-line)	£106	£75	£181	0.009

(a) Not all patients will require a second line intervention so only a proportion will be stepped up – see Table 32 for more details.

Table 34: QALY gains achieved by adults with chronic pain after receiving psychological interventions

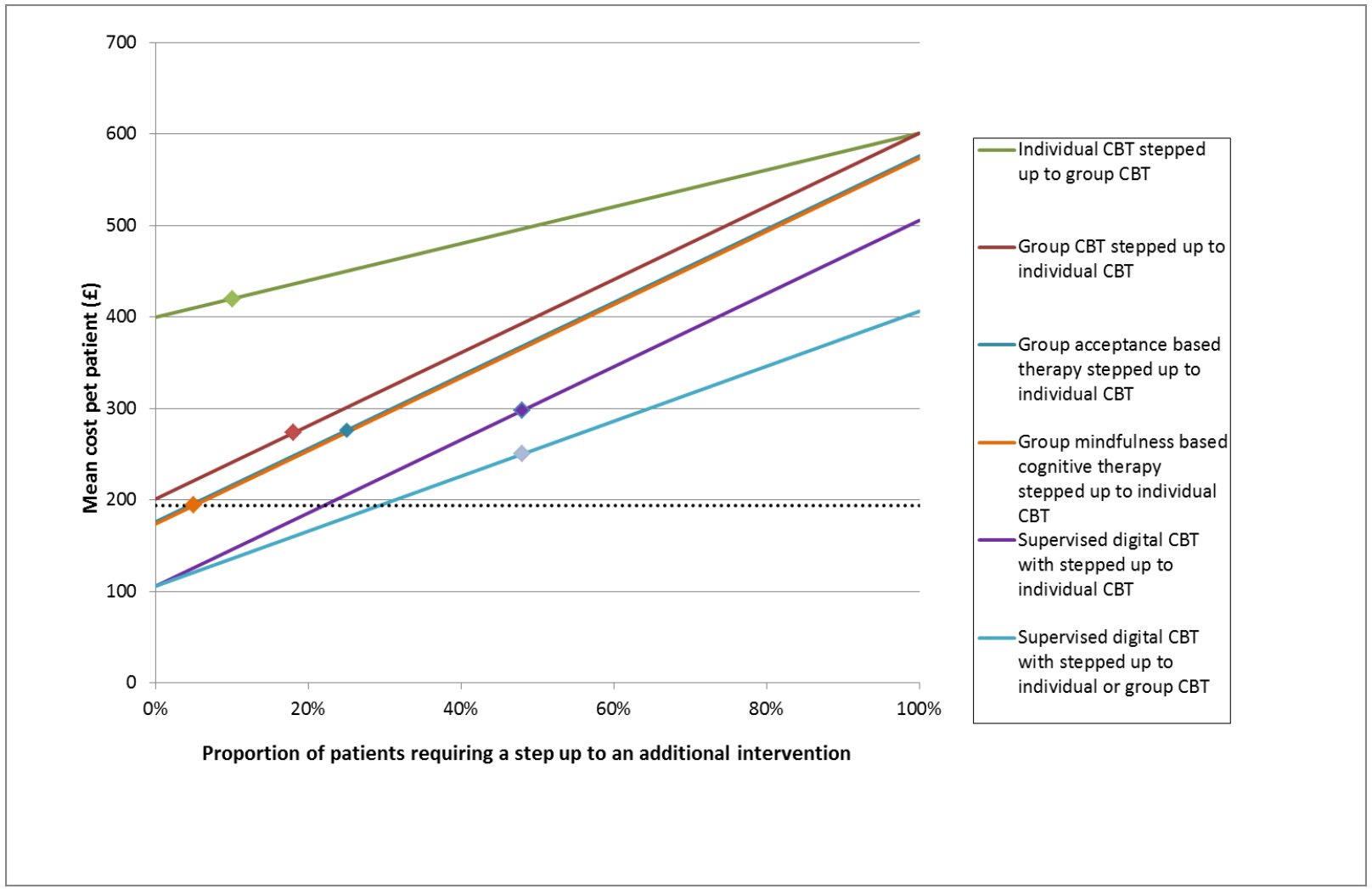
Intervention	QALY gains
Digital CBT	0.014
Group CBT	0.010
Group acceptance and commitment therapy	0.020

(a) Frisen (2017)[20]
(b) Alda (2011) [2]
(c) Luciano (2014) [36]

In order to consider how sensitive the costs were in relation to the proportion of people that require an additional intervention, a sensitivity analysis was conducted. In the sensitivity analysis the proportion requiring an additional intervention was adjusted from 0% - 100%. The results are presented in Figure 1 which also highlights the base case assumptions

(denoted as a diamond on each line), that is, how many people will be stepped to a second line intervention as described in Table 32. There is also a dotted line to illustrate the cost of the least expensive strategy in the base case.

Figure 1: Sensitivity analysis of mean cost per patient for each psychological therapy strategy
Diamonds indicate base case analysis estimates



1.6 Evidence statements

1.6.1 Clinical evidence statements

Cognitive behavioural therapy

- **CBT versus waiting-list control**

Four studies (n=173) were included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus annoyance and general quality of life. There was a clinical benefit of CBT for the outcomes tinnitus distress (at longer follow-up), tinnitus-related quality of life (post-treatment), anxiety (measured using the VAS). There was no clinical difference between CBT and waiting-list control for the outcomes tinnitus severity, tinnitus distress (post-treatment), tinnitus loudness, tinnitus annoyance, depression, anxiety (measured using the HADS) and sleep disturbance. The overall quality of the evidence was Very Low to Low due to risk of bias, inconsistency and imprecision.

- **CBT versus control (masking)**

One study (n=100) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus distress, health-related quality of life, tinnitus-related quality of life and tinnitus annoyance. There was a clinical benefit of CBT for the outcome of tinnitus severity. There was no clinical difference between CBT and masking for the outcomes of depression and anxiety. The overall quality of the evidence was Very Low to Low due to risk of bias and imprecision.

- **CBT versus information only**

One study (n=105) were included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus severity, general quality of life, tinnitus annoyance and tinnitus-related quality of life. There was no clinical difference between CBT and information only for the outcomes of tinnitus distress and depression. The overall quality of the evidence was Very Low to Low due to risk of bias and imprecision.

- **CBT versus education**

Three studies (n=163) were included in this comparison; no clinical evidence was reported for the critical outcome: health-related quality of life. There was clinical benefit of CBT for the outcomes tinnitus distress (post-treatment), tinnitus-related quality of life (post-treatment) and tinnitus annoyance (at a longer follow-up). There was no clinical difference between CBT and education for the outcomes tinnitus distress (at a longer follow-up), tinnitus-related quality of life (at a longer follow-up), tinnitus annoyance (post-treatment), tinnitus loudness ad depression. The overall quality of the evidence was Very Low to Low due to risk of bias and imprecision.

- **CBT versus relaxation**

One study (n=59) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus annoyance, general quality of life and tinnitus-related quality of life. There was a clinical benefit of CBT for the outcome of depression. There was no clinical difference between CBT and relaxation for the outcomes of tinnitus severity, tinnitus distress and tinnitus loudness. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

- **CBT versus passive relaxation training**

One study (n=18) was included in this comparison; no clinical evidence was reported for the critical outcomes tinnitus severity, general quality of life and tinnitus-related quality of life. There was a clinical benefit of CBT for the outcome of anxiety (measured using the STAI-trait). There was no clinical difference between CBT and passive relaxation training for the outcomes tinnitus annoyance, tinnitus loudness, tinnitus distress, insomnia, depression and anxiety (measured using the STAI-state). The overall quality of the evidence was Very Low due to risk of bias and imprecision.

- **CBT versus applied relaxation training**

One study (n=23) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus severity, general quality of life and tinnitus-related quality of life. There was no clinical difference between CBT and passive relaxation training for the outcomes tinnitus annoyance, tinnitus loudness, tinnitus distress, insomnia, depression and anxiety. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

- **CBT-stepped intervention versus usual care**

One study (n=394) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus distress and tinnitus annoyance. There was clinical benefit of the CBT-stepped intervention for general quality of life. There was no clinical difference between the CBT-stepped intervention and usual care for the outcomes of tinnitus severity, tinnitus-related quality of life, depression and anxiety. The overall quality of the evidence was Moderate to High due to imprecision.

- **CBT (self-help book) versus waiting-list control**

One study (n=125) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus severity, tinnitus annoyance, general quality of life and tinnitus-related quality of life. There was clinical difference between CBT (self-help books) and waiting-list control for the outcome of tinnitus distress. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

- **CBT (bibliotherapy) versus information only**

One study (n=109) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus severity, tinnitus annoyance, general quality of life and tinnitus-related quality of life. There was no clinical difference between CBT (bibliotherapy) and information only for the outcomes of tinnitus distress and depression. The overall quality of the evidence was Very Low to Low due to risk of bias and imprecision.

- **CBT versus control (web discussion forum)**

One study (n=81) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus annoyance, general quality of life and tinnitus-related quality of life. There was clinical benefit of CBT for the outcomes tinnitus severity and tinnitus distress. There was no clinical difference between CBT and the control group for the outcomes depression, anxiety and sleep. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

- **iCBT versus waiting-list control**

One study (n=72) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus severity, tinnitus distress, general quality of life and tinnitus-related quality of life. There was no clinical difference between iCBT and waiting-list control for the outcomes of tinnitus annoyance, tinnitus loudness, depression and anxiety. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

- **iCBT versus information only**

Two study (n=161) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus severity, general quality of life and tinnitus-related quality of life. There was no clinical difference between iCBT and information only for the outcomes of tinnitus distress, tinnitus annoyance, tinnitus loudness, depression, anxiety and sleep. The overall quality of the evidence was Very Low due to risk of bias, inconsistency and imprecision.

- **iCBT versus tinnitus information counselling**

One study (n=88) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus annoyance and tinnitus-related quality of life. There was clinical benefit of iCBT for tinnitus severity, tinnitus distress and sleep (at a longer follow-up). There was no clinical difference between iCBT and "tinnitus information counselling" for the outcomes for tinnitus severity, tinnitus distress and sleep (post-treatment), general quality of life, depression and anxiety (when measured post-treatment and a longer follow-up). The overall quality of the evidence was Very Low to Low due to risk of bias and imprecision.

- **iCBT versus control (web discussion forum)**

One study (n=262) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus annoyance, general quality of life and tinnitus-related quality of life. There was a clinical benefit of iCBT for the outcomes tinnitus severity and distress and tinnitus distress. There was no clinical difference between iCBT and the control group for the outcomes quality of life, depression, anxiety and sleep. The overall quality of the evidence was Very Low to Low due to risk of bias and imprecision.

- **iCBT versus iACT**

One study (n=63) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus annoyance, general quality of life and tinnitus-related quality of life. There was a clinical benefit of iCBT for the outcome of sleep. There was no clinical difference between iCBT and iACT for the outcomes tinnitus severity and distress, general quality of life, depression and anxiety. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

- **Biofeedback versus waiting-list control**

One study (n=42) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus severity, tinnitus annoyance, general quality of life and tinnitus-related quality of life. There was no clinical difference between biofeedback and waiting-list control for the outcomes tinnitus distress, general quality of life and tinnitus loudness. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

- **Biofeedback-based CBT versus waiting-list control**

One study (n=111) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus annoyance, general quality of life and tinnitus-related quality of life. There was clinical benefit of biofeedback-based CBT for the outcome of tinnitus severity (when measured using the TQ). There was no clinical difference between biofeedback-based CBT and waiting-list control for the outcomes tinnitus severity (measured using the Global Severity Index of SLC-90-R), tinnitus distress, tinnitus loudness, depression and sleep. The overall quality of the evidence was Moderate to Low due to risk of bias and imprecision.

- **Behavioural therapy versus waiting-list control**

One study (n=24) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus severity, tinnitus distress, general quality of life and tinnitus-related quality of life. There was no clinical difference between behavioural therapy and waiting-list

control for the outcomes tinnitus annoyance, tinnitus loudness and depression. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

Mindfulness-based therapies

- **Mindfulness-based cognitive therapy versus relaxation**

One study (n=68) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus distress, tinnitus annoyance, general quality of life and tinnitus-related quality of life. There was clinical benefit of tinnitus severity (when measured using the TFI). There was no clinical difference between mindfulness-based cognitive therapy and relaxation for the outcomes tinnitus severity, tinnitus loudness, depression and anxiety. The overall quality of the evidence was High to Moderate due to risk of bias and imprecision.

- **Mindfulness meditation versus relaxation therapy**

One study (n=61) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus distress, tinnitus annoyance, general quality of life and tinnitus-related quality of life. There was no clinical difference between mindfulness meditation and relaxation therapy for the outcomes tinnitus severity, tinnitus loudness, depression and anxiety. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

- **Mindfulness and body-psychotherapy-based group treatment versus waiting-list control**

One study (n=31) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus distress, general quality of life and tinnitus-related quality of life. There was clinical benefit of mindfulness and body-psychotherapy-based group treatment for the outcome tinnitus severity (measured using THI) and depression. There was no clinical difference between mindfulness and body-psychotherapy-based group treatment and waiting-list control for the outcomes tinnitus severity (measured using TQ), tinnitus annoyance and tinnitus loudness. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

Acceptance and commitment therapy

- **iACT versus control (web discussion forum)**

One study (n=65) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus annoyance, general quality of life and tinnitus-related quality of life. There was clinical benefit of iACT for the outcomes tinnitus severity and distress and anxiety. There was no clinical difference between iACT and the control group for the outcomes quality of life, depression and sleep. The overall quality of the evidence was Low to Very Low due to risk of bias and imprecision.

- **ACT versus waiting-list control**

One study (n=44) was included in this comparison; no clinical evidence was reported for the critical outcomes: tinnitus distress, tinnitus annoyance, general quality of life and tinnitus-related quality of life. There was clinical benefit of ACT for the outcomes tinnitus severity. There was no clinical difference between ACT and waiting-list for the outcomes general quality of life, depression, anxiety and sleep. The overall quality of the evidence was Very Low due to risk of bias and imprecision.

1.6.2 Health economic evidence statements

- One cost–utility analysis found that a tinnitus pathway which included group stepped CBT approach was cost effective compared with individual consultation with a support worker

when appropriate for treating bothersome tinnitus (ICER: £7001 per QALY gained). This analysis was assessed as partially applicable with potentially serious limitations.

- One original comparative cost analysis found that
    - group therapy stepped up to individual CBT was less costly than individual CBT alone for treating tinnitus (cost saving: £127-£206per patient depending on type of group intervention).
    - Internet CBT stepped up to individual CBT was less costly than individual CBT alone for treating tinnitus (cost saving: £102-£194 per patient depending on step-up rate assumed).
    - Internet CBT stepped up to individual *or group* CBT was less costly than individual CBT alone for treating tinnitus (cost saving: £150-£219 per patient depending on step-up rate assumed).
    - The results were sensitive to the success rate of the first line therapy

  This analysis was assessed as partially applicable (no QALYs) with potentially serious limitations (success rate of first line therapy is highly uncertain).

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 (QoL) (tinnitus-related) general QoL 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

Twenty-four randomised controlled trials (RCTs) were included in this review that evaluated psychological therapies for the management of tinnitus in adults. The evidence for this review was centred on cognitive behavioural therapy (CBT), mindfulness-based therapies and acceptance and commitment therapy (ACT). No evidence was identified for the use of psychological therapies in children with tinnitus.

Cognitive behavioural therapy

Different delivery forms of CBT were evaluated within sixteen studies including group CBT sessions, internet-based CBT (iCBT)/digital CBT, provision of CBT self-help book, bibliotherapy (use of CBT manual and CD for progressive muscle relaxation), biofeedback-based CBT and stepped-CBT intervention. These interventions were compared with waiting-list control, provision of information only, education, relaxation, tinnitus information counselling, control group involving a web discussion forum and usual care. Across these comparisons, the outcomes: tinnitus distress, tinnitus severity, general quality of life, tinnitus annoyance, tinnitus loudness, depression, anxiety and sleep were reported. The evidence was graded very low to high due to risk of bias, imprecision and inconsistency.

Mindfulness-based therapies

Three different types of mindfulness-based therapies were evaluated within four studies – mindfulness-based cognitive therapy (MBCT) for tinnitus, mindfulness meditation, mindfulness and body-psychotherapy-based group therapy. These interventions were

compared with relaxation (for two of the interventions: mindfulness-based cognitive therapy, mindfulness meditation) or waiting-list control. The only critical outcome reported was tinnitus severity, with the important outcomes of tinnitus loudness, tinnitus annoyance, depression and anxiety reported. The evidence was graded very low to high due to risk of bias and imprecision.

Acceptance and commitment therapy

ACT was evaluated in two studies, which investigated a standard ACT therapy or internet-based ACT. These were compared with a control of a web discussion forum or waiting-list control. Included studies reported outcome data for critical outcomes (tinnitus distress, tinnitus severity and general QoL) and important outcomes (depression, anxiety and sleep). The evidence was graded very low to low due to risk of bias and imprecision.

1.7.1.3 Benefits and harms

Cognitive behavioural therapies

Across a majority of the studies with CBT as the main intervention evaluated, there was clinical benefit of CBT in terms of tinnitus distress and tinnitus severity – two of the critical outcomes for this review. There was no clinical difference between CBT and study comparators in terms of general quality of life, tinnitus annoyance, tinnitus loudness, depression and anxiety and sleep.

CBT is widely used for different presentations but CBT used for the management of tinnitus is tailored in order to make the intervention relevant and useful for people with tinnitus. The guideline committee noted that tinnitus related CBT is not commonly used across the UK; it is currently delivered in specialist tinnitus centres. The most common form of CBT used within current practice is a diluted CBT intervention which uses CBT principles; it is delivered within audiology services in an individual format with limited supervision from psychologists. Whilst digital CBT is unavailable or where it is not suitable, group CBT should be used as the first-line psychological therapy. In current practice, the selection of group-CBT or individual-CBT is made on a case-by-case basis and mainly dependent on the availability of CBT services and individual preferences. The committee noted that some people may be hesitant about group-CBT at first but may find it a more meaningful and positive experience.

Seven studies included in this review evaluated the use of iCBT (also known as digital CBT or internet based CBT) for tinnitus, and showed that it can be effective in reducing tinnitus severity and distress. Internet-based CBT is not currently available in the UK. The committee are however optimistic that it will become available in the UK and predict that the use of digital CBT will start within specialist tinnitus centres and availability will increase over time. This optimism is primarily driven around the successful use of digital CBT for other conditions (e.g. NICE guidelines on depression in adults, CG90) and the committee are of the view that providers, working alongside clinicians with experiences in working with people with tinnitus, will take the initiative to adapt these existing tools for the tinnitus population. There are practical benefits of using digital CBT including that location is less likely to be a limiting factor as it can accessed remotely. Additionally, a more modest time commitment would be required from people with tinnitus. For healthcare professionals, digital CBT can also assist in the triaging of people with tinnitus to appropriate services.

The committee acknowledged the evidence of a CBT stepped intervention which had high quality evidence and showed clinical benefit in terms of tinnitus-related quality of life and general quality of life. The guideline committee noted the importance of tailoring interventions to the individual needs of people with tinnitus, i.e. by using a stepped approach.

Two studies evaluated the use of biofeedback interventions, reporting that some evidence of clinical benefit of biofeedback-based CBT for the outcome tinnitus severity. There was no clinical difference between the biofeedback interventions and waiting-list control for tinnitus

distress, quality of life, tinnitus loudness, depression and sleep. The committee discussed that biofeedback is rarely used within current practice; its use is largely limited to behavioural psychology settings.

Mindfulness-based therapies

Mindfulness-based therapies are not commonly used in current practice; there is very limited access to these interventions (it is mainly offered in specialist tinnitus centres). One study that evaluated MBCT for tinnitus presented evidence that showed a clinical benefit of MBCT in improving tinnitus severity. Similar to CBT interventions, there was no clinical difference between MBCT and relaxation for tinnitus loudness, depression and anxiety.

Acceptance and commitment therapy

ACT is not routinely used in current practice in the UK for tinnitus, When ACT was compared with waiting-list control and control (web discussion forum) there was reported clinical benefit of ACT (standard-ACT and iACT) in terms of tinnitus severity, distress and depression. There was no clinical difference between ACT and comparators in terms of general quality of life, depression, anxiety and sleep.

Psychological therapies for children and young people

Psychological therapies for children and young people with tinnitus are primarily offered in specialist tinnitus centres with variability in the types of psychological therapies available. The majority of the psychological therapies used with children and young people with tinnitus have CBT principles and techniques. Narrative therapy principles and techniques are also used. The committee noted that for psychological therapies to be delivered effectively in this population, healthcare professionals need to work systemically with children and young people, involving parents, carers and teachers. No evidence was identified for the clinical effectiveness of psychological therapies in children and young people with tinnitus. The guideline committee made a recommendation for further research.

The evidence identified indicates that the psychological therapies used for the management of tinnitus have limited effects on depression and anxiety. The committee noted that the inclusion and exclusion criteria used within research may be a contributing factor to this. Whilst this guideline does not address the management of depression and anxiety in people with tinnitus as these are covered by other NICE guidelines, it was acknowledged that individuals who have mental disorders tend to be excluded from studies. As a result, participants score lower on psychological outcome measures before the initiation of psychological therapies and there is minimal improvement.

The committee also noted that there was no evidence for the use of psychological therapies for people who are d/Deaf or who have a severe-to-profound hearing loss. Standard care for tinnitus in this population is not feasible, it is important that effective interventions are developed and investigated. The committee agreed that a research recommendation is made for the use of psychological therapies for this population (see Appendix J:)

After reviewing all of the evidence and the potential benefit that psychological therapies can have in improving tinnitus outcomes, the committee felt that it would be appropriate to recommend the consideration of CBT (digital CBT, group-CBT and individual-CBT), mindfulness-based therapies and ACT for people with tinnitus. The committee agreed that a stepped approach to these psychological therapies should be considered. If a person does not benefit from the first psychological intervention they try (digital CBT) or declines an intervention, an alternative intervention from the next step should be offered (group-based tinnitus psychological therapies (CBT, ACT or mindfulness-based cognitive therapy then individual-CBT).

Use of these interventions is specifically recommended in individuals with tinnitus related distress (tinnitus that is causing an impact on emotional and social well-being and day-to-day

activities). The committee decided to introduce this caveat as it was acknowledged that these interventions are generally used for severe cases of tinnitus where tinnitus cannot be managed using other interventions. Additionally, the majority of the evidence in this review evaluated psychological therapies in populations with tinnitus related distress.

1.7.2 Cost effectiveness and resource use

There was a single cost-effectiveness analysis identified in the literature conducted from a Dutch perspective.[37] This study considered group CBT in combination with other psychological strategies delivered using a stepped approach for people with moderate or severe tinnitus. This intervention was compared with individual consultations with a support worker when necessary. This cost-utility model found that group CBT stepped approach cost £7001 per QALY gained, which would be considered cost-effective at the £20,000 per QALY gained threshold from an NHS perspective. However, a key limitation of this Dutch study is that it is a cost-utility analysis of the entire tinnitus management pathway (see Appendix H) as opposed to the specific CBT component. Therefore, it is still unclear as to whether CBT for people with tinnitus would be a cost-effective intervention for the NHS to implement. Furthermore, there is no evidence that any psychological intervention for tinnitus is better than any other in terms of improving quality of life.

The comparative cost of different psychological therapy strategies

In order to explore the economic implications of the different psychological interventions available for people with tinnitus related distress, a costing analysis was presented to the committee. As there is no evidence of significant clinical differences between the strategies, the aim was to identify the lowest cost strategy for delivering psychological therapies. The results demonstrated that in scenarios where no second-line intervention was provided, digital CBT (which includes an online or internet based intervention with short weekly phone calls) was the least expensive intervention (£106) followed by the group interventions ranging from £174 - £201 per intervention per person. Individual CBT was the most expensive intervention at £400 per person. However, when an initial intervention proves ineffective, people with tinnitus are often provided with an additional intervention. When this was factored into the analysis (using the expert opinions of the committee) group mindfulness based therapy was the least expensive (£194 per person) and individual CBT remained the most expensive at £420 per person.

One important consideration for the committee was their level of uncertainty with respect to the proportion of people who will require an additional intervention. For example, the committee based their estimate of 5% of people requiring a second line intervention after receiving mindfulness based cognitive therapies on their experiences of current practice but this might not be generalizable to the entire NHS. The same could be said for the high (48%) estimate of people requiring an additional intervention after undergoing digital CBT. The estimate was derived from the study by Beukes (2018)[9] where 52% of people had a TFI score less than 25, after undergoing digital CBT. This group were considered to have achieved a significant clinical improvement in their tinnitus. However, using this source may have resulted in an overestimation of the proportion that requires a second line intervention, because a change from 50 to 30 for example on the TFI may be enough such that the person does not seek or require an additional intervention. There are also likely to be some people with tinnitus who may see a small or no reduction in their score after completing the initial intervention and decide a psychological intervention is not suitable for them. Both these cases would mean that the proportion requiring an upgrade is much smaller than the estimate that has been derived from Beukes (2018).

After considering the limitations of the Beukes (2018) study, the committee agreed that 25% of people with tinnitus requiring an additional intervention after initially trying digital based CBT was a more plausible estimate, and using this assumption, the cost of digital CBT reduced to £206 per person. Mindfulness based cognitive therapy remained a slightly less

expensive intervention at £194 per person (see Figure 1). However, the committee noted, based on the level of engagement a person with tinnitus has with the digital CBT approach (i.e. completing weekly sessions and ensuring weekly phone calls with clinicians take place), clinicians would be able to appropriately identify whether a group or an individual approach would be more suitable on a case by case basis. In a scenario where 12.5% of people are stepped to individual CBT and the other 12.5% is stepped to group CBT after completing digital CBT, the cost of digital CBT is further reduced to £181, becoming the least expensive intervention. Digital CBT would be less expensive than group mindfulness based cognitive therapy even if 21% of people are triaged to individual CBT and the remaining 4% receive group CBT. In practice, the committee believed that less people would require individual CBT.

Individual CBT was the most costly strategy and the committee were of the view that there is no available evidence which would suggest individual based interventions are more clinically effective for tinnitus compared with group based interventions. Therefore, individual CBT should be considered only after other interventions have been unsuccessful (i.e. digital or group based interventions).

QALY gains from psychological therapy

An important consideration for the committee was to determine whether the interventions would achieve a large enough QALY gain compared to no psychological therapy to justify the costs. Therefore, a threshold analysis was completed to demonstrate to the committee the magnitude of QALY gain that would be required for each psychological strategy to be cost-effective at the £20,000 threshold (when using estimates from Table 32). This ranged from 0.010 (group mindfulness based cognitive therapy) to 0.021 (individual CBT). The committee considered the economic evaluation considered in the guideline review by Maes (2014) which reported 0.02 QALYs gained per person when specialised care which included group CBT was compared with usual care. The committee felt that this might be an overestimate of what could be achieved in the NHS by CBT alone. In this study, usual care included audiological diagnostics and interventions such as counselling and prescription of hearing aids and sound generators. In usual care people with tinnitus were also offered one or more consultations with a social worker up to a maximum of 10 sessions. In comparison the specialised care group received tinnitus education group sessions, tympanometry, loudness level measure (this diagnostic test has not been recommended in the tinnitus guideline), individual consultations with psychologists and weekly group sessions (for 12 weeks) for people judged by the trial as having moderate or severe tinnitus. As both the intervention and the comparator are complex interventions, it is unclear if the improved health outcomes are being generated by group CBT or due to the other differences between the interventions.

Due to the limitations of the Maes (2014) study, the committee requested that they be presented with QALY gains from RCTs exploring the clinical effectiveness of psychological interventions to help people with chronic pain. This population was chosen because the committee were of the view that the way people experience symptoms of chronic pain are similar to the experiences people have with tinnitus. The QALY gains achieved in this population ranged from 0.01 to 0.02 per person. If the psychological therapy for tinnitus could achieve this level of QALY gain then it would be considered cost effective. The committee considered this to be plausible and therefore made a consensus recommendation in favour of a stepped approach to psychological therapy.

Other considerations

While group mindfulness based cognitive therapy was the least expensive intervention (when using the assumptions in Table 32), an advantage of the digital based approach over mindfulness is that people with tinnitus can receive their intervention faster and this would help to reduce the waiting list. It could also increase participation and engagement as the sessions could be completed according to an individual's lifestyle as opposed to having to travel at a designated time. Furthermore, absences would result in increased costs per

person in the group settings compared with a digital CBT based approach where the opportunity cost due to a lack of engagement is lower as the resource requirement is a short call or an email as opposed to a 1 hour session with two psychologists for group CBT. The committee acknowledged that digital CBT approaches for tinnitus are currently only available in research. However, given there is already clinical research in this area, there was a positive outlook that if digital CBT has been successfully implemented for other conditions (e.g. NICE guidelines on depression in adults, CG90) then the same could be achieved for adults with tinnitus.

In those cases where digital CBT is not an option, the committee have recommended the use of group sessions (CBT, mindfulness based cognitive therapy and ACT) as the preferred strategy. As the clinical evidence did not conclusively demonstrate that one of these group strategies was clinically preferable to another, the committee have recommended a range of therapies so that services can adopt strategies which are easiest to implement based on their existing staff and skills and thereby limiting the resource impact.

Finally, the committee discussed the importance of psychologists delivering these therapies as specialist skills are required for interventions such as CBT and ACT. If audiologists or other healthcare practitioners were to deliver these interventions, the committee stated that they would most likely be at the same grade, band 7, but would require greater supervision than a psychologist, and therefore the cost per person for each intervention would be the same or slightly higher. A research recommendation has been made to explore the clinical and cost effectiveness of interventions delivered by non-psychologists. The only exception to the specification of the member of staff was for mindfulness based-cognitive therapy where the committee explained that appropriately trained and supervised non-psychologists could deliver the intervention without requiring extra supervision.

Overall, this recommendation is expected to be cost-neutral. Currently, there is variation in practice, with some services offering psychological therapies for people with tinnitus related distress, while other regions do not have access to the required specialists in order to offer the interventions discussed in this review. There are some tinnitus clinics that do offer psychological therapy for people with tinnitus and in some cases these can be individual CBT sessions. These clinics would achieve cost-savings by opting to offer internet or group based interventions as a first line strategy instead. There is a potential for added expenditure for those services that currently do not offer psychological services, but the committee are of the view that these services should be made available. Due to a lack of conclusive cost-effectiveness evidence, the committee have made a ‘consider’ recommendation as opposed to an ‘offer’ recommendation. However, the savings that could be made by adopting internet or group based approaches in those services that are currently offering individual based interventions would at least partially offset the added expenditure incurred by those services that have not made psychological therapies available yet.

Finally the recommendations advocating the use of psychological therapies are specifically for adults, there was no clinical evidence available for children. The committee have therefore opted to make a research recommendation to identify the most clinical and cost-effective psychological therapy for children.

1.7.3 Other factors the committee took into account

The committee discussed that psychological therapies are currently mainly delivered in clinical psychology services and some audiology services. Current access to clinical psychology services can be difficult; these recommendations may require a change in service configuration. The committee also noted that few healthcare professionals are trained in delivering psychological therapies such as CBT, more training will need to be provided and available for healthcare professionals wishing to train in delivering CBT, MBCT for tinnitus and ACT.

Multidisciplinary working is essential for the successful delivery of psychological therapies, particularly to ensure that there is appropriate supervision and audiology and psychology services should be linked. Whilst digital CBT for tinnitus is not currently available in the UK, when it becomes available multidisciplinary work should still be applied.

The committee acknowledged that psychological management of tinnitus is met with scepticism by some people with tinnitus. Some people with tinnitus might refuse this option. Despite the scepticism around psychological therapies for managing tinnitus, lay representatives reported that people with tinnitus would generally welcome increased availability of individual and group psychological therapies. Digital CBT for tinnitus will be a welcome addition to the range of interventions available and may mean that individuals have quicker access to support.

References

1. Abbott JA, Kaldo V, Klein B, Austin D, Hamilton C, Piterman L et al. A cluster randomised trial of an internet-based intervention program for tinnitus distress in an industrial setting. Cognitive Behaviour Therapy. 2009; 38(3):162-173

2. Alda M, Luciano JV, Andres E, Serrano-Blanco A, Rodero B, del Hoyo YL et al. Effectiveness of cognitive behaviour therapy for the treatment of catastrophisation in patients with fibromyalgia: a randomised controlled trial. Arthritis Research & Therapy. 2011; 13(5):R173

3. Andersson G. Clinician-supported internet-delivered psychological treatment of tinnitus. American Journal of Audiology. 2015; 24(3):299-301

4. Andersson G, Lyttkens L. A meta-analytic review of psychological treatments for tinnitus. British Journal of Audiology. 1999; 33(4):201-210

5. Andersson G, Porsaeus D, Wiklund M, Kaldo V, Larsen HC. Treatment of tinnitus in the elderly: a controlled trial of cognitive behavior therapy. International Journal of Audiology. 2005; 44(11):671-675

6. Andersson G, Strömgren T, Ström L, Lyttkens L. Randomized controlled trial of internet-based cognitive behavior therapy for distress associated with tinnitus. Psychosomatic Medicine. 2002; 64(5):810-816

7. 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

8. Beukes EW, Allen PM, Baguley DM, Manchaiah V, Andersson G. Long-term efficacy of audiologist-guided internet-based cognitive behavior therapy for tinnitus. American Journal of Audiology. 2018; 27(3S):431-447

9. Beukes EW, Andersson G, Allen PM, Manchaiah V, Baguley DM. Effectiveness of guided internet-based cognitive behavioral therapy vs face-to-face clinical care for treatment of tinnitus: A randomized clinical trial. JAMA Otolaryngology–Head & Neck Surgery. 2018; 144(12):1126-1133

10. Beukes EW, Baguley DM, Allen PM, Manchaiah V, Andersson G. Guided internet-based versus face-to-face clinical care in the management of tinnitus: study protocol for a multi-centre randomised controlled trial. Trials. 2017; 18:186

11. Beukes EW, Baguley DM, Allen PM, Manchaiah V, Andersson G. Audiologist-guided internet-based cognitive behavior therapy for adults with tinnitus in the United Kingdom: A randomized controlled trial Ear and Hearing. 2018; 39(3):423-433

12. Beukes EW, Manchaiah V, Allen PM, Baguley DM, Andersson G. Internet-based cognitive behavioural therapy for adults with tinnitus in the UK: study protocol for a randomised controlled trial. BMJ Open. 2015; 5(9):e008241

13. Beukes EW, Manchaiah V, Baguley DM, Allen PM, Andersson G. Internet-based interventions for adults with hearing loss, tinnitus and vestibular disorders: a protocol for a systematic review. Systematic Reviews. 2018; 7(1):205

14. Caffier PP, Haupt H, Scherer H, Mazurek B. Outcomes of long-term outpatient tinnitus-coping therapy: psychometric changes and value of tinnitus-control instruments. Ear and Hearing. 2006; 27(6):619-627

15. Cima RFF, Andersson G, Schmidt CJ, Henry JA. Cognitive-behavioral treatments for tinnitus: A review of the literature. Journal of the American Academy of Audiology. 2014; 25(1):29-61

16. Cima RFF, Maes IH, Joore MA, Scheyen DJWW, El Refaie A, Baguley DM et al. Specialised treatment based on cognitive behaviour therapy versus usual care for tinnitus: A randomised controlled trial. The Lancet. 2012; 379(9830):1951-1959

17. Cima RFF, van Breukelen G, Vlaeyen JWS. Tinnitus-related fear: Mediating the effects of a cognitive behavioural specialised tinnitus treatment Hearing Research. 2017; 358:86-87

18. Curtis L, Burns A. Unit costs of health and social care 2018. Canterbury. Personal Social Services Research Unit University of Kent, 2018. Available from: https://www.pssru.ac.uk/project-pages/unit-costs/unit-costs-2018/

19. Davies S, McKenna L, Hallam RS, Hallam RS. Relaxation and cognitive therapy: a controlled trial in chronic tinnitus. Psychology & Health. 1995; 10(2):129-143

20. Friesen LN, Hadjistavropoulos HD, Schneider LH, Alberts NM, Titov N, Dear BF. Examination of an internet-delivered cognitive behavioural pain management course for adults with fibromyalgia: A randomized controlled trial. Pain. 2017; 158(4):593-604

21. 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

22. Hesser H, Gustafsson T, Lunden C, Henrikson O, Fattahi K, Johnsson E et al. A randomized controlled trial of Internet-delivered cognitive behavior therapy and acceptance and commitment therapy in the treatment of tinnitus. Journal of Consulting and Clinical Psychology. 2012; 80(4):649-61

23. Hesser H, Westin VZ, Andersson G. Acceptance as a mediator in internet-delivered acceptance and commitment therapy and cognitive behavior therapy for tinnitus. Journal of Behavioral Medicine. 2014; 37(4):756-767

24. Hiller W, Haerkotter C. Does sound stimulation have additive effects on cognitive-behavioral treatment of chronic tinnitus? Behaviour Research and Therapy. 2005; 43(5):595-612

25. Jakes SC, Hallam RS, McKenna L, Hinchcliffe R. Group cognitive therapy for medical patients: an application to tinnitus. Cognitive Therapy and Research. 1992; 16(1):67-82

26. Jasper K, Weise C, Conrad I, Andersson G, Hiller W, Kleinstauber M. Internet-based guided self-help versus group cognitive behavioral therapy for chronic tinnitus: a randomized controlled trial. Psychotherapy and Psychosomatics. 2014; 83(4):234-46

27. 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

28. Kaldo V, Levin S, Widarsson J, Buhrman M, Larsen HC, Andersson G. Internet versus group cognitive-behavioral treatment of distress associated with tinnitus: a randomized controlled trial. Behavior Therapy. 2008; 39(4):348-59

29. Kallogjeri D, Piccirillo JF, Spitznagel E, Hale S, Nicklaus JE, Hardin FM et al. Cognitive training for adults with bothersome tinnitus: A randomized clinical trial. JAMA Otolaryngology - Head and Neck Surgery. 2017; 143(5):443-451

30. Kleinstauber M, Weise C, Andersson G, Probst T. Personality traits predict and moderate the outcome of Internet-based cognitive behavioural therapy for chronic tinnitus. International Journal of Audiology. 2018; 57(7):538-544

31. Kreuzer PM, Goetz M, Holl M, Schecklmann M, Landgrebe M, Staudinger S et al. Mindfulness-and body-psychotherapy-based group treatment of chronic tinnitus: a randomized controlled pilot study. BMC Complementary and Alternative Medicine. 2012; 12:235

32. Krings JG, Winel A, Kallogjeri D, Rodebaugh TL, Nicklaus J, Lenze EJ et al. A novel treatment for tinnitus and tinnitus-related cognitive difficulties using computer-based cognitive training and D-cycloserine. JAMA Otolaryngology - Head and Neck Surgery. 2015; 141(1):18-26

33. Kröner-Herwig B, Frenzel A, Fritsche G, Schilkowsky G, Esser G. The management of chronic tinnitus: comparison of an outpatient cognitive-behavioral group training to minimal-contact interventions. Journal of Psychosomatic Research. 2003; 54(4):381-389

34. Kröner-Herwig B, Hebing G, Rijn-Kalkmann U, Frenzel A, Schilkowsky G, Esser G. The management of chronic tinnitus--comparison of a cognitive-behavioural group training with yoga. Journal of Psychosomatic Research. 1995; 39(2):153-165

35. Li J, Jin J, Xi S, Zhu Q, Chen Y, Huang M et al. Clinical efficacy of cognitive behavioral therapy for chronic subjective tinnitus. American Journal of Otolaryngology. 2019; 40(2):253-256

36. Luciano JV, Guallar JA, Aguado J, Lopez-Del-Hoyo Y, Olivan B, Magallon R et al. Effectiveness of group acceptance and commitment therapy for fibromyalgia: a 6-month randomized controlled trial (EFFIGACT study). Pain. 2014; 155(4):693-702

37. Maes IH, Cima RF, Anteunis LJ, Scheijen DJ, Baguley DM, El Refaie A et al. Cost-effectiveness of specialized treatment based on cognitive behavioral therapy versus usual care for tinnitus. Otology and Neurotology. 2014; 35(5):787-795

38. Malinvaud D, Londero A, Niarra R, Peignard P, Warusfel O, Viaud-Delmon I et al. Auditory and visual 3D virtual reality therapy as a new treatment for chronic subjective tinnitus: results of a randomized controlled trial. Hearing Research. 2016; 333:127-135

39. Malouff JM, Noble W, Schutte NS, Bhullar N. The effectiveness of bibliotherapy in alleviating tinnitus-related distress. Journal of Psychosomatic Research. 2010; 68(3):245-251

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

41. Martz E, Chesney MA, Livneh H, Jelleberg C, Fuller B, Henry JA. A pilot randomized clinical trial comparing three brief group interventions for individuals with tinnitus. Global Advances in Health & Medicine. 2018; 7:2164956118783659

42. Mason JD, Rogerson D. Randomized controlled trial of client-centred hypnotherapy for the treatment of tinnitus. Clinical Otolaryngology and Allied Sciences. 1994; 19:270-271

43. Mason JD, Rogerson DR, Butler JD. Client centred hypnotherapy in the management of tinnitus--is it better than counselling? Journal of Laryngology and Otology. 1996; 110(2):117-120

44. Maudoux A, Bonnet S, Lhonneux-Ledoux F, Lefebvre P. Ericksonian hypnosis in tinnitus therapy. B-ENT. 2007; 3(Suppl 7):75-77

45. McCombie A, Gearry R, Andrews J, Mikocka-Walus A, Mulder R. Computerised cognitive behavioural therapy for psychological distress in patients with physical illnesses: A systematic review. Journal of Clinical Psychology in Medical Settings. 2015; 22(1):20-44

46. McKenna L, Marks EM, Hallsworth CA, Schaette R. Mindfulness-based cognitive therapy as a treatment for chronic tinnitus: A randomized controlled trial. Psychotherapy and Psychosomatics. 2017; 86(6):351-361

47. McKenna L, Marks EM, Vogt F. Mindfulness-based cognitive therapy for chronic tinnitus: Evaluation of benefits in a large sample of patients attending a tinnitus clinic Ear and Hearing. 2018; 39(2):359-366

48. 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

49. Nyenhuis N, Zastrutzki S, Jäger B, Kröner-Herwig B. An internet-based cognitive-behavioural training for acute tinnitus: secondary analysis of acceptance in terms of satisfaction, trial attrition and non-usage attrition. Cognitive Behaviour Therapy. 2013; 42(2):139-145

50. Nyenhuis N, Zastrutzki S, Weise C, Jäger B, Kröner-Herwig B. The efficacy of minimal contact interventions for acute tinnitus: a randomised controlled study. Cognitive Behaviour Therapy. 2013; 42(2):127-138

51. Organisation for Economic Co-operation and Development (OECD). Purchasing power parities (PPP). Available from: http://www.oecd.org/sdd/prices-ppp/ Last accessed: 14/09/2018

52. Philippot P, Nef F, Clauw L, Romrée M, Segal Z. A randomized controlled trial of mindfulness-based cognitive therapy for treating tinnitus. Clinical Psychology & Psychotherapy. 2012; 19(5):411-419

53. Rief W, Weise C, Kley N, Martin A. Psychophysiologic treatment of chronic tinnitus: a randomized clinical trial. Psychosomatic Medicine. 2005; 67(5):833-838

54. Robinson SK, Viirre ES, Bailey KA, Kindermann S, Minassian AL, Goldin PR et al. A randomized controlled trial of cognitive-behavior therapy for tinnitus. International Tinnitus Journal. 2008; 14(2):119-126

55. Scott B, Lindberg P, Lyttkens L, Melin L. Psychological treatment of tinnitus. An experimental group study. Scandinavian Audiology. 1985; 14(4):223-30

56. Thompson DM, Hall DA, Walker DM, Hoare DJ. Psychological therapy for people with tinnitus: A scoping review of treatment components. Ear and Hearing. 2017; 38(2):149-158

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

58. Weise C, Heinecke K, Rief W. Biofeedback for chronic tinnitus - Treatment guidelines and preliminary results regarding their efficacy and acceptance. Verhaltenstherapie. 2007; 17(4):220-230

59. Weise C, Heinecke K, Rief W. Biofeedback-based behavioral treatment for chronic tinnitus: results of a randomized controlled trial. Journal of Consulting and Clinical Psychology. 2008; 76(6):1046-1057

60. Weise C, Kleinstäuber M, Andersson G. Internet-delivered cognitive-behavior therapy for tinnitus: A randomized controlled trial. Psychosomatic Medicine. 2016; 78(4):501-510

61. Weise C, Martin A, Rief W. Psychophysiological treatment of chronic tinnitus - results of a randomised controlled study. Verhaltenstherapie. 2005; 15(Suppl 1):27

62. Westin VZ, Schulin M, Hesser H, Karlsson M, Noe RZ, Olofsson U et al. Acceptance and commitment therapy versus tinnitus retraining therapy in the treatment of tinnitus: a randomised controlled trial. Behaviour Research and Therapy. 2011; 49(11):737-747

63. Zachriat C, Kroner-Herwig B. The comparative effectivity of tinnitus coping training (TBT) and tinnitus retraining therapy (TRT) in a long-term comparison. Verhaltenstherapie. 2003; 13(Suppl 1):4

64. Zachriat C, Kröner-Herwig B. Treating chronic tinnitus: comparison of cognitive-behavioural and habituation-based treatments. Cognitive Behaviour Therapy. 2004; 33(4):187-198

65. Zarenoe R, Soderlund LL, Andersson G, Ledin T. Motivational interviewing as an adjunct to hearing rehabilitation for patients with tinnitus: a randomized controlled pilot trial. Journal of the American Academy of Audiology. 2016; 27(8):669-676

66. Zenner HP, Vonthein R, Zenner B, Leuchtweis R, Plontke SK, Torka W et al. Standardized tinnitus-specific individual cognitive-behavioral therapy: a controlled outcome study with 286 tinnitus patients. Hearing Research. 2013; 298:117-125

67. Zhong C, Zhong Z, Luo Q, Qiu Y, Yang Q, Liu Y. The curative effect of cognitive behavior therapy for the treatment of chronic subjective tinnitus. Journal of Clinical Otorhinolaryngology, Head, and Neck Surgery. 2014; 29(8):709-711

68. Zoeger S, Erlandsson S, Svedlund J, Holgers KM. Benefits from group psychotherapy in the treatment of severe refractory tinnitus. Audiological Medicine. 2008; 6(1):62-72

Appendices

Appendix A: Review protocols

Table 35: Review protocol: What is the clinical and cost effectiveness of psychological therapies (including cognitive behavioural therapy and mindfulness based cognitive therapy)?

ID	Field	Content
0.	PROSPERO registration number	Not registered
1.	Review title	Clinical and cost effectiveness of psychological therapies (including cognitive behavioural therapy and mindfulness based cognitive therapy)
2.	Review question	What is the clinical and cost effectiveness of psychological therapies (including cognitive behavioural therapy and mindfulness based cognitive therapy)?
3.	Objective	Cognitive Behavioural Therapy (CBT) is an approach that seeks to change the way people think about and behave in response to their tinnitus, in order to reduce the anxiety and depressive symptoms and distress associated with it. Mindfulness based cognitive therapy (MBCT) is a variant of CBT. MBCT is intended to help people establish a less distressing relationship with tinnitus through the development of acceptance based (cognitive & behavioural) strategies. The review aims to evaluate various psychological therapies in comparison or combination with each other, to other management strategies or to no psychological therapy for clinical and cost-effective outcomes.

		Recommendations might cover the inclusion of psychological therapies 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	• Cognitive Behavioural therapy (CBT) • Mindfulness-based interventions e.g. cognitive therapy and MBSR • Brief solution focused therapy • Narrative therapy • Family therapy/Systemic therapy • Acceptance and commitment therapy (ACT) • EMDR

8.	Comparator/Reference standard/Confounding factors	• Interventions compared with each other
		• Interventions in combination with each other
		• Control group (i.e. no psychological therapy)
		• Sound therapy and sound enrichment
		  ○ sound enrichment (e.g. environmental sound, a CD or mp3 download or the radio, a smartphone App, bedside/table-top sound generators, a wearable sound generator)
		  ○ Combination hearing devices (hearing aid combined with sound generator)
		  ○ Customised sound-based therapies, e.g. amplitude modulated tones and notched noise/music
		  ○ Masking
		• Tinnitus education including coping strategies, provision of information and advice and relaxation
		• Amplification devices for people with a hearing loss
		  ○ Hearing aids
		  ○ Implantable devices (including cochlear implants, bone-anchored hearing aids, bone-conduction hearing implants, bone-bridge/middle-ear devices)
		  ○ Combination device (sound generator and hearing aids)

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

		• publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
32.	Keywords	Tinnitus, psychological therapies, CBT, mindfulness
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 36: 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).[48]

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.[48]

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 37: 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 38: 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.

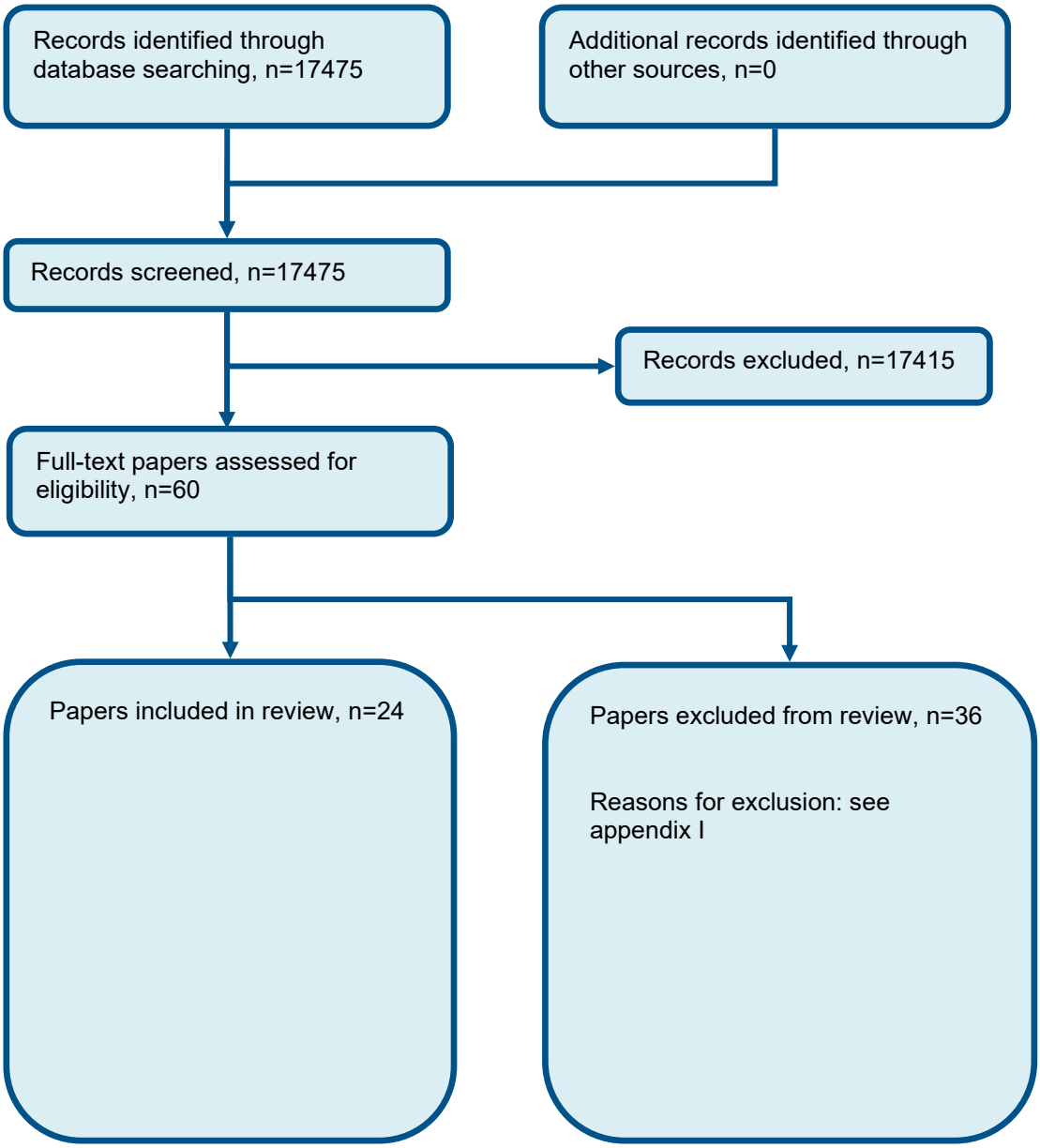
43.	(euroqol* or eq5d* or eq 5*).ti,ab.
44.	(qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
45.	(health utility* or utility score* or disutilit* or utility value*).ti,ab.
46.	(hui or hui1 or hui2 or hui3).ti,ab.
47.	(health* year* equivalent* or hye or hyes).ti,ab.
48.	discrete choice*.ti,ab.
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 2: Flow chart of clinical study selection for the review of psychological therapies



Appendix D: Clinical evidence tables

Study	Abbott 2009[1]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=56)
Countries and setting	Conducted in Australia; Setting: Internet-based intervention
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	Age between 18 and 65 years, tinnitus for at least 3 months, tinnitus diagnosed by health professional, general practitioner contact details were provided, not currently receiving psychological treatment for tinnitus, and being able to access the Internet and print instructions.
Exclusion criteria	Not reported
Recruitment/selection of patients	Participants were recruited from the Australian industrial organisations BP Australia (18 work sites) and BHP Billiton (5 work sites) from June 2006 to March 2007
Age, gender and ethnicity	Age - Mean (SD): 49.6 years. Gender (M:F): 8.1/1. Ethnicity: Not reported
Further population details	1. Mild hearing loss: Not stated / Unclear 2. People with learning disability or cognitive impairment: Not stated / Unclear 3. Profoundly deaf: Not stated / Unclear
Extra comments	Duration of tinnitus (mean): Overall - 100 months; Intervention 140.2 months; Control - 60.3 months.
Indirectness of population	No indirectness
Interventions	(n=32) Intervention 1: Cognitive behavioural therapy. Participants had an internet-delivered intervention program, inspired by previous research and theories on CBT and tinnitus. Intervention consisted of 10 components, presented in six modules, and completed at the rate of module per week. The first week of the program included a program rationale and instructions for a basic applied relaxation task. The applied relaxation training continued throughout the program modules. Participants learned two other compulsory tools: the use of positive imagery to aid relaxation and exercises to enhance ability to control where attention is directed. There were also optional modules which could be selected by participants including information and

	advice regarding noise sensitivity, sound enrichment by the mean of external sounds and improving concentration.. Duration 6 weeks. Concurrent medication/care: All modules included homework assignments and weekly diaries submitted electronically. When submitting a weekly diary, a participant was sent an e-mail from a therapist, providing assistance.. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Three psychologists or trainee psychologists). (n=24) Intervention 2: Tinnitus counselling - Provision of information. Participants allocated to this intervention were informed that they had been allocated to first read the online Tinnitus Information Program, after which they would receive the CBT tinnitus intervention. The Tinnitus Informational Program contained basic psychoeducational information minus active CBT components, presented over 6 weeks and weekly multiple-choice quizzes about participants' memory of the content of the module. Duration 6 weeks. Concurrent medication/care: Therapists contacted participants once a week to provide necessary passwords for each new module to provide minimal support regarding their tinnitus status and coping. . Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Therapists).
Funding	Academic or government funding (Grant from Australian Research Council Linkage Project and industry contribution from BP Australia)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY (INTERNET-BASED) versus PROVISION OF INFORMATION

Protocol outcome 1: Tinnitus distress
- Actual outcome for Adults: Tinnitus distress at Post-treatment; Group 1: mean 16.64 (SD 12.3); n=28, Group 2: mean 13.96 (SD 9.7); n=23; 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: 4, Reason: Lack of time, misunderstanding nature of treatment, retirement, mutual agreement between therapist and participant that program not suitable; Group 2 Number missing: 5, Reason: Lack of time, client dropped out of contact with therapist, unknown

Protocol outcome 2: Tinnitus annoyance
- Actual outcome for Adults: Tinnitus annoyance at Post-treatment; Group 1: mean 3.38 (SD 1.4); n=28, Group 2: mean 3.61 (SD 1.7); n=23; Visual analogue scale 0-10 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: 4, Reason: Lack of time, misunderstanding nature of treatment, retirement, mutual agreement between therapist and participant that program not suitable; Group 2 Number missing: 5, Reason: Lack of time, client dropped

out of contact with therapist, unknown Protocol outcome 3: Tinnitus loudness - Actual outcome for Adults: Tinnitus loudness at Post-treatment; Group 1: mean 4.58 (SD 1.7); n=28, Group 2: mean 4.48 (SD 1.7); n=23; Visual analogue scale 0-10 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: 4, Reason: Lack of time, misunderstanding nature of treatment, retirement, mutual agreement between therapist and participant that program not suitable; Group 2 Number missing: 5, Reason: Lack of time, client dropped out of contact with therapist, unknown Protocol outcome 4: Anxiety - Actual outcome for Adults: Anxiety at Post-treatment; Group 1: mean 3.79 (SD 3.8); n=28, Group 2: mean 3.09 (SD 4); n=23; Depression, Anxiety and Stress Scales 0-120 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: 4, Reason: Lack of time, misunderstanding nature of treatment, retirement, mutual agreement between therapist and participant that program not suitable; Group 2 Number missing: 5, Reason: Lack of time, client dropped out of contact with therapist, unknown Protocol outcome 5: Depression - Actual outcome for Adults: Depression at Post-treatment; Group 1: mean 4.61 (SD 5.3); n=28, Group 2: mean 2.43 (SD 4.3); n=23; Depression, Anxiety and Stress Scales 0-120 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: 4, Reason: Lack of time, misunderstanding nature of treatment, retirement, mutual agreement between therapist and participant that program not suitable; Group 2 Number missing: 5, Reason: Lack of time, client dropped out of contact with therapist, unknown Protocol outcome 6: Sleep - Actual outcome for Adults: Sleep quality at Post-treatment; Group 1: mean 4.07 (SD 1.9); n=28, Group 2: mean 4.17 (SD 2.2); n=23; Visual analogue scale 0-10 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: 4, Reason: Lack of time, misunderstanding nature of treatment, retirement, mutual agreement between therapist and participant that program not suitable; Group 2 Number missing: 5, Reason: Lack of time, client dropped out of contact with therapist, unknown
Protocol outcomes not reported by the study	Quality of life (tinnitus); Quality of life; Severity; Depression and anxiety; Safety; Tolerability; Side effects

Study	Andersson 2002[6]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=117)
Countries and setting	Conducted in Sweden; Setting: At home using the internet
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Duration of tinnitus at least 6 months and having seen a general practitioner (or ENT physician) on account of tinnitus. 'Given the nature of recruiting participants, it was not possible to obtain audiograms or measures of the tinnitus characteristics by means of tinnitus matchings. The latter have, however, questionable clinical utility.'
Stratum	Overall: Not applicable
Subgroup analysis within study	Not applicable: Not applicable
Inclusion criteria	Duration of tinnitus at least 6 months; having seen a GP or ENT physician on account of tinnitus; aged 18 to 70 years; tinnitus a severe problem; access to computer, modem, and an Internet connection and could print out the training instructions.
Exclusion criteria	Not reported
Recruitment/selection of patients	Newspaper articles in Swedish national and regional papers and on the web page of the Swedish Hard of Hearing Association.
Age, gender and ethnicity	Age - Mean (SD): CBT group: 48.5 (5.6); WL group: 47.2 (15.0). Gender (M:F): 55/62. 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=53) Intervention 1: Cognitive behavioural therapy (internet-based). Cognitive behavioural self-help treatment - internet. A self-help manual was constructed using cognitive behavioural principles. There were 10 components presented in 6 modules on a weekly basis for 6 weeks. The first week included a treatment rationale and the first step of applied relaxation (tense-relax). The second week continued the applied relaxation (relax only) and also included positive imagery, sound enrichment by means of external sounds, hearing tactics, and advice regarding noise sensitivity (which is a common problem among tinnitus patients. The latter two components were optional. Week 3 involved controlled breathing (as part of applied relaxation) and cognitive therapy, which was adjusted to deal with negative thoughts and beliefs relating to tinnitus. The module given at week 4 included differential relaxation and behavioural sleep management. In the fifth module,

	rapid relaxation was presented, as was advice regarding concentration difficulties, exercises of concentration (mindfulness), and advice on physical activity. The final module at week 6 included continued practice of applied relaxation, relapse prevention, and a summary of the contents of the treatment program. All modules involved homework assignments and weekly reports on a report web page to be submitted weekly. They were encouraged to ask questions regarding the treatment, and all queries were answered as promptly as possible by the investigators depending on their area of expertise. . Duration 6 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not stated / Unclear (Says that the queries were answered by the investigators depending on their area of expertise but does not state what this is.). (n=64) Intervention 2: Control group - i.e. no psychological therapy. Waiting list control. The participants were informed that they had been randomised to a waiting-list condition and were offered the program later on. . Duration 6 weeks. Concurrent medication/care: Not reported.. 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 (A grant from the Swedish Council for Social Research and a grant from the Swedish Hard of Hearing Association)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus I.E NO PSYCHOLOGICAL THERAPY

Protocol outcome 1: Tinnitus annoyance
- Actual outcome: VAS Annoyance at 6 weeks; Group 1: mean 5.3 Not applicable (SD 2.3); n=25, Group 2: mean 5.8 Not applicable (SD 2.2); n=59; VAS Loudness 0-10 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Very high, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 29; Group 2 Number missing: 5

Protocol outcome 2: Tinnitus loudness
- Actual outcome: VAS Loudness at 6 weeks; Group 1: mean 6.2 Not applicable (SD 2.3); n=24, Group 2: mean 6.4 Not applicable (SD 2.1); n=59; VAS Loudness 0-10 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Very high, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 29; Group 2 Number missing: 5

Protocol outcome 3: Anxiety - Actual outcome: HADS - anxiety at 6 weeks; Group 1: mean 5.9 Not applicable (SD 3.6); n=24, Group 2: mean 6.8 Not applicable (SD 4.8); n=48; HADS - anxiety 0-21 Top=High is poor outcome Risk of bias: All domain - Very high, Selection - High, Blinding - Very high, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 29, Reason: N=2 completed treatment and daily registrations but not questionnaires; N=10 failed to respond after module 1; n=8 failed to respond after module 2; n=2 failed to respond after module 3; n=5 failed to respond after module 4; n=1 failed to respond after module 5; completed treatment but not follow-up assessment.; Group 2 Number missing: 16, Reason: n=16 completed only daily registration - Actual outcome: HADS - anxiety at 1 year; Group 1: mean 6.1 Not applicable (SD 3.5); n=46, Group 2: mean 6.4 Not applicable (SD 5); n=50; HADS - anxiety 0-21 Top=High is poor outcome; Comments: At follow-up 96 were offered treatment, this second part of the trial is uncontrolled. Risk of bias: All domain - Very high, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - High, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 7; Group 2 Number missing: 14 Protocol outcome 4: Depression - Actual outcome: HADS - depression at 1 year; Group 1: mean 5.3 Not applicable (SD 3.8); n=46, Group 2: mean 5.3 Not applicable (SD 4); n=50; HADS - depression 0-21 Top=High is poor outcome; Comments: At follow-up 96 were offered treatment, this second part of the trial is uncontrolled. Risk of bias: All domain - Very high, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - High, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 7; Group 2 Number missing: 14 - Actual outcome: HADS - depression at 6 weeks; Group 1: mean 5.2 Not applicable (SD 4.1); n=24, Group 2: mean 6 Not applicable (SD 3.79); n=48; HADS - depression 0-21 Top=High is poor outcome Risk of bias: All domain - Very high, Selection - High, Blinding - Very high, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 29, Reason: N=2 completed treatment and daily registrations but not questionnaires; N=10 failed to respond after module 1; n=8 failed to respond after module 2; n=2 failed to respond after module 3; n=5 failed to respond after module 4; n=1 failed to respond after module 5; completed treatment but not follow-up assessment.; Group 2 Number missing: 16, Reason: n=16 completed only daily registration Protocol outcome 5: Sleep - Actual outcome: VAS Sleep quality at 6 weeks; Group 1: mean 7.3 Not applicable (SD 2.3); n=24, Group 2: mean 6.7 Not applicable (SD 2.1); n=58; VAS sleep quality 0-10 Top=High is good outcome Risk of bias: All domain - Very high, Selection - High, Blinding - Very high, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 29; Group 2 Number missing: 6	
Protocol outcomes not reported by the study	Tinnitus distress; Quality of life (tinnitus); Quality of life; Severity; Depression and anxiety; Safety; Tolerability; Side effects

Study	Andersson 2005[5]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=23)
Countries and setting	Conducted in Sweden; Setting: Not reported
Line of therapy	Not applicable
Duration of study	Follow up (post intervention): 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	Individuals had to have problems with their tinnitus (for example, tinnitus is audible in many acoustic environments, disturbs sleep, or is a dominating problem that affects quality of life). Duration of tinnitus for at least six months, be able to attend sessions.
Exclusion criteria	Received previous psychological treatment for tinnitus, had a depression score above 22 on the Beck Depression Inventory, a score above 2 on item 2 (hopelessness) and item 9 (suicidal ideation) or had medical reasons for not taking part in the treatment.
Recruitment/selection of patients	Advertisement (full details not reported) followed by a structured interview.
Age, gender and ethnicity	Age - Mean (SD): 70.1 (3.90) years. Gender (M:F): 1.1/1. Ethnicity: Not reported
Further population details	1. Mild hearing loss: Not stated / Unclear 2. People with learning disability or cognitive impairment: Not stated / Unclear 3. Profoundly deaf: Not stated / Unclear
Extra comments	Mean (SD) duration of tinnitus: 13 (12.5) years; 22% of the participants had been fitted with hearing aid(s) previously (25% in the intervention group, 18% in the control group)
Indirectness of population	No indirectness
Interventions	(n=12) Intervention 1: Cognitive behavioural therapy. The CBT intervention has been described elsewhere (Andersson 2001). It consisted of six weekly two hour sessions. Covered during these six sessions were information about tinnitus, applied relaxation (which is presented during four sessions), cognitive restructuring, behavioural activation, positive imagery, sound enrichment (by means of environmental sounds rather than noise generators), exposure to tinnitus, advice regarding hyperacusis, hearing tactics, and relapse prevention. All sessions were held in small groups with two therapists. Homework assignments were included in all sessions and comments on assignments were made at the beginning of each session. . Duration 5 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 (Two therapists). (n=11) Intervention 2: Control group - i.e. no psychological therapy. After 5 weeks, the waiting-list control group received the intervention. The waiting-list control group were however given four sessions instead of six group sessions.. Duration 5 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
Funding	Academic or government funding (Swedish Hard of Hearing Association)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus WAITING-LIST CONTROL Protocol outcome 1: Tinnitus distress - Actual outcome for Adults: Tinnitus distress at 3 months; Group 1: mean 9.7 (SD 5.8); n=12, Group 2: mean 32.5 (SD 19); n=11; Tinnitus Reaction Questionnaire 0-104 Top=High is poor outcome; Comments: Mean (SD) Pre-treatment: Intervention group - 16.9 (13.5); Control group - 29.4 (18.0) 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; Group 2 Number missing: 0 Protocol outcome 2: Anxiety - Actual outcome for Adults: Anxiety (HADS) at 3 months; Group 1: mean 2.7 (SD 1.4); n=12, Group 2: mean 6.7 (SD 3.5); n=11; Hospital Anxiety and Depression Scale Not reported Top=High is poor outcome; Comments: Mean (SD) Pre-treatment: Intervention group - 3.4 (1.8); Control group - 6.5 (4.0) 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; Group 2 Number missing: 0 - Actual outcome for Adults: Anxiety (ASI) at 3 months; Group 1: mean 11.6 (SD 5.1); n=12, Group 2: mean 26.3 (SD 10.5); n=11; Anxiety Sensitivity Index Not reported Top=High is poor outcome; Comments: Mean (SD) Pre-treatment: Intervention group - 12.7 (6.0); Control group - 18.9 (10.0) 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; Group 2 Number missing: 0 Protocol outcome 3: Depression - Actual outcome for Adults: Depression at 3 months; Group 1: mean 3.2 (SD 2.9); n=12, Group 2: mean 6.4 (SD 5); n=11; Hospital Anxiety and Depression Scale Not reported Top=High is poor outcome; Comments: Mean (SD) Pre-treatment: Intervention group - 4.0 (3.4); Control group - 6.1 (4.1) 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; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Severity; Tinnitus loudness; Depression and

	anxiety; Safety; Tolerability; Side effects

Study	**Arif 2017[7]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=86)
Countries and setting	Conducted in United Kingdom; Setting: University Hospital of Wales, Cardiff.
Line of therapy	Not applicable
Duration of study	Other: Open-ended
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: A pure tone audiogram and tympanogram performed for all patients. The character of tinnitus was described as buzzing, hissing, whistling and roaring.
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients with a primary complaint of intrusive tinnitus.
Exclusion criteria	Patients with tinnitus that was identified as having a treatable cause e.g. middle-ear infections; those with mild tinnitus who only required reassurance.
Recruitment/selection of patients	Recruited from tinnitus clinic, leaflets with information about the study displayed in hospital and neighbouring hospitals. ENT units referred patients to the tinnitus clinic.
Age, gender and ethnicity	Age - Mean (SD): Mindfulness group: 53.8 (11.6); relaxation group 58.3 (13.2). Gender (M:F): Mindfulness group: 41% male/59% female; relaxation group: 52% male; 48% female. 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
Extra comments	Duration of tinnitus ranged from 6 months to 15 years. Varied types of tinnitus that people complained of. None had received behavioural therapy such as tinnitus rehabilitation therapy or cognitive behavioural therapy.
Indirectness of population	No indirectness
Interventions	(n=42) Intervention 1: Mindfulness-based interventions - MBSR. Treatment plans standardised in a session format, which included the following topics: exploration, sitting meditation, meditation applied and reviewed. Content is detailed in study. . Duration 5 face to face sessions of 40 minutes over 15 weeks. Concurrent medication/care: Not applicable. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus

	non-mental health professional): Not applicable (n=44) Intervention 2: Tinnitus counselling - Relaxation strategies. Relaxation therapy sessions split between two experienced therapists who followed a manual. A session format was followed, including the following topics: exploration, mental skill development, cue-controlled relaxation, differential relaxation, rapid relaxation application and review of subjective findings. . Duration 5 face-to-face relaxation therapy sessions of 40 minutes over 15 weeks. Concurrent medication/care: Not applicable. 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: MBSR versus RELAXATION STRATEGIES

Protocol outcome 1: Severity
- Actual outcome: VAS - severity of tinnitus at 15 weeks; Group 1: mean 2.91 Not applicable (SD 2.021); n=34, Group 2: mean 4.41 Not applicable (SD 1.966); n=27; VAS 0-10 Top=High is poor outcome; Comments: Mean difference: 1.798 (95% CI -2.9906 to -0.690), p-value: 0.002
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness, Comments: Not applicable ; Baseline details: Hearing loss (% moderate to severe) in the mindfulness group: 38% compared to 73% in the relaxation group, no details of statistical significance. ; Group 1 Number missing: 8, Reason: n=5 drop-outs, n=3 who did not attend for therapy.; Group 2 Number missing: 17, Reason: n=7 drop-outs, n=10 who did not attend for therapy.

Protocol outcome 2: Tinnitus loudness
- Actual outcome: VAS - loudness of tinnitus at 15 weeks; Group 1: mean 4.47 Not applicable (SD 2.312); n=34, Group 2: mean 5.11 Not applicable (SD 2.242); n=27; VAS - loudness of tinnitus 0-10 Top=High is poor outcome; Comments: Mean difference: -0.648 (95% CI -1.867 to 0.57157, p-value: 0.292
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness, Comments: Not applicable ; Baseline details: Hearing loss (% moderate to severe) in the mindfulness group: 38% compared to 73% in the relaxation group, no details of statistical significance. ; Group 1 Number missing: 8, Reason: n=5 drop-outs, n=3 who did not attend for therapy.; Group 2 Number missing: 17, Reason: n=7 drop-outs, n=10 who did not attend for therapy.

Protocol outcome 3: Anxiety
- Actual outcome: HADS - anxiety at 15 weeks; Group 1: mean 4.59 Not applicable (SD 2.797); n=34, Group 2: mean 5.89 Not applicable (SD 4.022); n=27; HAD - anxiety 0-21 Top=High is poor outcome; Comments: Mean difference -1.0490 (95% CI -2.761 to 0.663), p-value: 0.225
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness, Comments: Not applicable ; Baseline details: Hearing loss (% moderate to severe) in the mindfulness group: 38% compared to 73% in the relaxation group, no details of statistical significance. ; Group 1 Number missing: 8, Reason: n=5 drop-outs, n=3 who did not attend for therapy.; Group 2 Number missing: 17, Reason: n=7 drop-outs, n=10 who did not attend for therapy.

	Protocol outcome 4: Depression - Actual outcome: HADS - depression at 15 weeks; Group 1: mean 4.82 Not applicable (SD 2.959); n=34, Group 2: mean 5.15 Not applicable (SD 3.78); n=27; HADS - depression 0-21 Top=High is poor outcome; Comments: Mean difference: 0.101 (95% CI -1.757 to 1.959), p-value: 0.914 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness, Comments: Not applicable ; Baseline details: Hearing loss (% moderate to severe) in the mindfulness group: 38% compared to 73% in the relaxation group, no details of statistical significance. ; Group 1 Number missing: 8, Reason: n=5 drop-outs, n=3 who did not attend for therapy.; Group 2 Number missing: 17, Reason: n=7 drop-outs, n=10 who did not attend for therapy. Protocol outcome 5: Depression and anxiety - Actual outcome: HADS - total at 15 weeks; Group 1: mean 9.4111 Not applicable (SD 5.377); n=34, Group 2: mean 11.037 Not applicable (SD 7.377); n=27; HADS -total 0-42 Top=High is poor outcome; Comments: Mean difference: -0.83838 (95% CI -4.032 to 2.355), p value = 0.601 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness, Comments: Not applicable ; Baseline details: Hearing loss (% moderate to severe) in the mindfulness group: 38% compared to 73% in the relaxation group, no details of statistical significance. ; Group 1 Number missing: 8, Reason: n=5 drop-outs, n=3 who did not attend for therapy.; Group 2 Number missing: 17, Reason: n=7 drop-outs, n=10 who did not attend for therapy.
Protocol outcomes not reported by the study	Tinnitus distress; Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Sleep; Safety; Tolerability; Side effects

Study	**Beukes 2018[9]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=92)
Countries and setting	Conducted in United Kingdom; Setting: Recruitment and treatment sites for the control group (tinnitus information counselling) were 3 hospitals in eastern England: Norfolk and Norwich University Hospitals National Health Service Foundation Trust (Norwich), Milton Keynes University Hospital National Health Service Foundation Trust (Milton Keynes) and Hinchingbrooke Health Care National Service Trust (Huntingdon).
Line of therapy	Not applicable
Duration of study	Intervention time: 8 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Not applicable

Inclusion criteria	Age of 18 years or older, regular computer and internet access, no report of any major medical or psychiatric disorder, and not undergoing any tinnitus treated.
Exclusion criteria	Not reported
Recruitment/selection of patients	Participants were examined clinically (hearing test, ear examination, and case history of symptoms) and had been referred to the local tinnitus clinical by an audiologist and/or an ear, nose, and throat specialist for bothersome tinnitus.
Age, gender and ethnicity	Age - Mean (SD): 52.96 (12.07). Gender (M:F): 1.49/1. Ethnicity: Not reported
Further population details	1. Mild hearing loss: Not stated / Unclear 2. People with learning disability or cognitive impairment: Not stated / Unclear 3. Profoundly deaf: Not stated / Unclear
Extra comments	Duration of tinnitus (mean (SD)): 5.23 (9.01) iCBT group; 7.85 (9.62) tinnitus information counselling group. Using of hearing aids: 41% iCBT; 41% information counselling group
Indirectness of population	No indirectness
Interventions	(n=46) Intervention 1: Cognitive behavioural therapy. The internet CBT (iCBT) intervention was based on a CBT self-help program originally developed in the Swedish language and adapted into an 8-week, interactive e-learning version consisting of 16 recommended modules and 5 optional modules for a UK population. To monitor progress and provide feedback on completed worksheets, a minimum of 10 minutes of asynchronous audiologist guidance using an encrypted 2-way messaging system was provide. . Duration 8 weeks. Concurrent medication/care: Participants were provided with hearing aids or combination devices regardless of group allocation.. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not applicable (Internet-based intervention). (n=46) Intervention 2: Tinnitus counselling - Education includes coping strategies. Participants received individualised face-to-face care, involving tinnitus information counselling which was generally used for the management of tinnitus in the United Kingdom. The initial appointment (60 minutes) was used to provide explanation about tinnitus and some basic management strategies. Patients received additional strategies for tinnitus management. Duration 8 weeks. Concurrent medication/care: Participants were provided with hearing aids or combination devices regardless of group allocation.. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not stated / Unclear
Funding	Academic or government funding (The study was funded by a grant from the British Society of Audiology)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: INTERNET-BASED COGNITIVE BEHAVIOURAL THERAPY (ICBT) versus

EDUCATION INCLUDING COPING STRATEGIES

Protocol outcome 1: Tinnitus distress
- Actual outcome for Adults: Tinnitus distress at 2 months; Group 1: mean 22.85 (SD 19.26); n=37, Group 2: mean 32.51 (SD 23.28); n=37; Tinnitus Functional Index 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: 9, Reason: Did not complete assessment; Group 2 Number missing: 9, Reason: Did not complete assessment
- Actual outcome for Adults: Tinnitus distress at Post-treatment; Group 1: mean 27.88 (SD 20.84); n=44, Group 2: mean 34.88 (SD 24.91); n=44; Tinnitus Functional Index 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: 2, Reason: Did not complete assessment; Group 2 Number missing: 2, Reason: Did not complete assessment

Protocol outcome 2: Quality of life
- Actual outcome for Adults: Quality of life at Post-treatment; Group 1: mean 20.1 (SD 4.96); n=44, Group 2: mean 20.05 (SD 5.61); n=44; Satisfaction With Life Scales (SWLS) 5-35 Top=High is good 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: 2, Reason: Did not complete assessment; Group 2 Number missing: 2, Reason: Did not complete assessment
- Actual outcome for Adults: Quality of life at 2 months; Group 1: mean 21 (SD 5.05); n=37, Group 2: mean 20.5 (SD 4.95); n=37; Satisfaction With Life Scales (SWLS) 5-35 Top=High is good 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: 9, Reason: Did not complete assessment; Group 2 Number missing: 9, Reason: Did not complete assessment

Protocol outcome 3: Severity
- Actual outcome for Adults: Tinnitus severity at Post-treatment; Group 1: mean 22.33 (SD 19.63); n=44, Group 2: mean 28.74 (SD 20.07); n=44; Tinnitus Handicap Inventory (THI) 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: 2, Reason: Did not complete assessment; Group 2 Number missing: 2, Reason: Did not complete assessment
- Actual outcome for Adults: Tinnitus severity at 2 months; Group 1: mean 17.78 (SD 14.77); n=37, Group 2: mean 27.11 (SD 21.62); n=37; Tinnitus Handicap Inventory 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: 9, Reason: Did not complete assessment; Group 2 Number missing: 9, Reason: Did not complete assessment

Protocol outcome 4: Anxiety - Actual outcome for Adults: Anxiety at Post-treatment; Group 1: mean 3.45 (SD 3.66); n=44, Group 2: mean 3.33 (SD 3.78); n=44; Generalised Anxiety Disorder-7 (GAD-7) 0-21 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: 2, Reason: Did not complete assessment; Group 2 Number missing: 2, Reason: Did not complete assessment - Actual outcome for Adults: Anxiety at 2 months; Group 1: mean 3.33 (SD 3.21); n=37, Group 2: mean 3.42 (SD 3.6); n=37; Generalised Anxiety Disorder-7 (GAD-7) 0-21 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: 9, Reason: Did not complete assessment; Group 2 Number missing: 9, Reason: Did not complete assessment Protocol outcome 5: Depression - Actual outcome for Adults: Depression at Post-treatment; Group 1: mean 3.67 (SD 3.64); n=44, Group 2: mean 4.19 (SD 4.08); n=44; Patient Health Questionnaire-9 (PHQ-9) 0-27 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: 2, Reason: Did not complete assessment; Group 2 Number missing: 2, Reason: Did not complete assessment - Actual outcome for Adults: Depression at 2 months; Group 1: mean 2.78 (SD 3.02); n=37, Group 2: mean 4.97 (SD 4.54); n=37; Patient Health Questionnaire-9 (PHQ-9) 0-27 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: 9, Reason: Did not complete assessment; Group 2 Number missing: 9, Reason: Did not complete assessment Protocol outcome 6: Sleep - Actual outcome for Adults: Sleep at Post-treatment; Group 1: mean 6.71 (SD 6.2); n=44, Group 2: mean 9.55 (SD 6.15); n=44; Insomnia Severity Index (ISI) 0-28 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: 2, Reason: Did not complete assessment; Group 2 Number missing: 2, Reason: Did not complete assessment - Actual outcome for Adults: Sleep at 2 months; Group 1: mean 5.69 (SD 4.64); n=37, Group 2: mean 10.03 (SD 6.88); n=37; Insomnia Severity Index (ISI) 0-28 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: 9, Reason: Did not complete assessment; Group 2 Number missing: 9, Reason: Did not complete assessment
Protocol outcomes not reported by the study	Tinnitus annoyance; Quality of life (tinnitus); Tinnitus loudness; Depression and anxiety; Safety; Tolerability; Side effects

Study	Cima 2012[16]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=492)
Countries and setting	Conducted in Netherlands; Setting: Adelante Department of Audiology and Communication, Hoensbroek, Netherlands
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	Adults referred to the centre with a primary complaint of subjective tinnitus were eligible for inclusion.
Exclusion criteria	People who were unable to read and write in Dutch, had health issues that impaired attendance or prevented participation (e.g. terminal illness or physical disability) or had undergone treatment at the centre within 5 years before trial enrolment.
Recruitment/selection of patients	Participants were referred to the centre were invited to an off-centre baseline assessment. Participants were assessed by an otolaryngologist to rule out pathological changes that needed immediate medical care.
Age, gender and ethnicity	Age - Mean (SD): 54.19 (11.54). Gender (M:F): 1.7/1. Ethnicity: Not reported
Further population details	1. Mild hearing loss: Not stated / Unclear 2. People with learning disability or cognitive impairment: Not stated / Unclear 3. Profoundly deaf: Not stated / Unclear
Extra comments	Duration of tinnitus (overall): <1 year – 30%; 1-5 years – 39%; >5 years – 31%. Intervention use: Hearing aid - 19%; Sound generator - 19%
Indirectness of population	No indirectness
Interventions	(n=245) Intervention 1: Psychological therapies - Cognitive behavioural therapy. Two-stepped intervention based on tinnitus severity. Participants with mild tinnitus complete step 1 of the intervention only. Participants with more severe tinnitus went on to step 2. Step 1 - consisted of multidisciplinary diagnostics and specific tinnitus retraining counselling, which were undertaken in a cognitive behaviour framework (including audiological rehabilitation when necessary). Step 2 - consisted of three different 12-week group treatment (120 minutes per session) options with levels of care dependent on tinnitus severity and hearing loss. Group sessions were delivered by a clinical psychologist,

	movement therapist, physical therapist, clinical physicist in audiology, social worker and speech therapist. Group sessions included: cognitive behaviour therapy, psychoeducation, cognitive restructuring, exposure techniques, mindfulness-based elements, stress relief, attention re-directing techniques by means of movement therapy, and applied relaxation. Individual sessions were delivered if group treatment is contraindicated. . Duration Step 1: 3 months; Step 2: 12 weeks. Concurrent medication/care: n/a. Indirectness: No indirectness Further details: 1. Who is delivering the therapy: mental health professionals (psychologists and therapists) (Multidisciplinary team - including audiologists, psychologists). (n=247) Intervention 2: No intervention - No intervention. Two-stepped intervention based on tinnitus severity. Participants with mild tinnitus complete step 1 of the intervention only. Participants with more severe tinnitus went on to step 2. Participants in this group received usual care. Usual care was provided on the basis of a standardised protocol modelled in the care typically provided by secondary-care audiological centres across the Netherlands. Step 1 - was a standard audiological intervention. There was audiological diagnostics (including the potential prescription of sound generators - when specifically asked by participants - adjusted to produce a small band noise around the pitch match frequency and slightly below the tinnitus masking level), audiological rehabilitation and audiological follow-up. Step 2 - there was the intake of social work and follow-up with the social working with a maximum of nine contacts including counselling sessions, telephone contacts, extraneous appointments with third parties and house calls.. Duration Step 1: 3 months; Step 2: 12 weeks. Concurrent medication/care: n/a. Indirectness: No indirectness Further details: 1. Who is delivering the therapy:
Funding	Academic or government funding (Authors supported by a grant from the Netherlands Organisation for Health Research and Development.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: STEPPED-APPROACH COMBINATION INTERVENTION versus USUAL CARE

Protocol outcome 1: Health related quality of life
- Actual outcome for Adults: General quality of life at 3 months (post-treatment); Group 1: mean 0.62 (SD 0.285); n=200, Group 2: mean 0.64 (SD 0.294); n=194; Health Utilities Index -0.36 to 1 Top=High is good outcome
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 45, Reason: Missed measurements, dropped out, no longer affected by tinnitus, chose other health-care provide, majority (n=30) had unknown reasons; Group 2 Number missing: 53, Reason: Dropped out, not able to proceed, did not complete questionnaires, not able to complete, majority (n=18) had unknown reasons

- Actual outcome for Adults: Health-related quality of life at 12 months; Group 1: mean 0.681 (SD 0.25); n=171, Group 2: mean 0.631 (SD 0.279); n=161; Health Utilities Index -0.36 to 1 Top=High is good outcome
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 74, Reason: Missed measurements in addition to reasons highlighted for the time-point of 3 months; Group 2 Number missing: 86, Reason: Missed measurements in addition to reasons highlighted for the time-point of 3 months

Protocol outcome 2: Tinnitus-related quality of life
- Actual outcome for Adults: Tinnitus-related quality of life at 3 months (post-treatment); Group 1: mean 34.25 (SD 23.44); n=200, Group 2: mean 37.38 (SD 23.74); n=194; Tinnitus Handicap Inventory 0-100 Top=High is poor outcome
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 45, Reason: Missed measurements, dropped out, no longer affected by tinnitus, chose other health-care provide, majority (n=30) had unknown reasons; Group 2 Number missing: 53, Reason: Dropped out, not able to proceed, did not complete questionnaires, not able to complete, majority (n=18) had unknown reasons
- Actual outcome for Adults: Tinnitus-related quality of life at 12 months; Group 1: mean 26.45 (SD 18.81); n=171, Group 2: mean 33.51 (SD 23.25); n=161; Tinnitus Handicap Inventory 0-100 Top=High is poor outcome
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 74, Reason: Missed measurements in addition to reasons highlighted for the time-point of 3 months; Group 2 Number missing: 86, Reason: Missed measurements in addition to reasons highlighted for the time-point of 3 months

Protocol outcome 3: Severity
- Actual outcome for Adults: Tinnitus severity at 12 months; Group 1: mean 33.43 (SD 16.89); n=171, Group 2: mean 42.12 (SD 19.81); n=161; Tinnitus Questionnaire 0-84 Top=High is poor outcome
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 74, Reason: Missed measurements in addition to reasons highlighted for the time-point of 3 months; Group 2 Number missing: 86, Reason: Missed measurements in addition to reasons highlighted for the time-point of 3 months
- Actual outcome for Adults: Tinnitus severity at 3 months (post-treatment); Group 1: mean 42.01 (SD 19.81); n=200, Group 2: mean 45.51 (SD 19.65); n=194; Tinnitus Questionnaire 0-84 Top=High is poor outcome
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 45, Reason: Missed measurements, dropped out, no longer affected by tinnitus, chose other health-care provide, majority (n=30) had unknown reasons; Group 2 Number missing: 53, Reason: Dropped out, not able to proceed, did not complete questionnaires, not able to complete, majority (n=18) had unknown reasons

Protocol outcome 4: Depression and anxiety
- Actual outcome for Adults: Depression and anxiety (negative effect) at 12 months; Group 1: mean 10.22 (SD 7.01); n=171, Group 2: mean 10.83 (SD 8.03); n=161; Hospital Anxiety and Depression Inventory 0-42 Top=High is poor outcome
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 74, Reason: Missed measurements in addition to reasons highlighted for the time-

point of 3 months; Group 2 Number missing: 86, Reason: Missed measurements in addition to reasons highlighted for the time-point of 3 months - Actual outcome for Adults: Depression and anxiety (negative effect) at 3 months (post-treatment) ; Group 1: mean 11.91 (SD 7.96); n=200, Group 2: mean 12.08 (SD 8.75); n=194; Hospital Anxiety and Depression Inventory 0-42 Top=High is poor outcome Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 45, Reason: Missed measurements, dropped out, no longer affected by tinnitus, chose other health-care provide, majority (n=30) had unknown reasons; Group 2 Number missing: 53, Reason: Dropped out, not able to proceed, did not complete questionnaires, not able to complete, majority (n=18) had unknown reasons	
Protocol outcomes not reported by the study	Tinnitus distress; Tinnitus annoyance; Tinnitus loudness; Depression; Anxiety; Sleep; Adverse events

Study	**Davies 1995[19]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=45)
Countries and setting	Conducted in United Kingdom; Setting: Specialist (mainly tertiary referral) neuro-otology clinic
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 4 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Participants were attending a specialist clinic with certain requirements that would ensure diagnosis of tinnitus by professional.
Stratum	Overall: Not applicable
Subgroup analysis within study	Not applicable
Inclusion criteria	All referrals to the psychology service were screened on the basis of the following criteria: tinnitus was a significant problem to the client and also the main problem; duration of complaint was at least 6 months; able and willing to attend the hospital for therapy; able to complete questionnaires without difficulty.
Exclusion criteria	Presence of major psychiatric disorder; previous psychological help in the department.
Recruitment/selection of patients	Selected from outpatients attending a specialist (mainly tertiary referral) neuro-otology clinic.
Age, gender and ethnicity	Age - Mean (range): 56.3 (28-73). Gender (M:F): 13/17 (completers). 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=16) Intervention 1: Cognitive behavioural therapy. Individual Cognitive Therapy (ICT) explored the meaning of tinnitus with the subject and identified any negative thoughts associated with emotional distress, which were then related to broader beliefs or underlying assumptions. The therapist aided this by completing a checklist with the client which listed common tinnitus complaints, associated emotions, and commonly held maladaptive beliefs about tinnitus. The participants completed a diary on antecedents, beliefs and consequences and recent incidents formed the basis for cognitive analysis. Maladaptive beliefs about tinnitus were disputed using a Socratic form of questioning. Behavioural experiments to test out beliefs were employed where appropriate. . Duration 6 one hour sessions with possible extension to 8. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Qualified clinical psychologist). (n=13) Intervention 2: Tinnitus counselling - Relaxation strategies. Passive relaxation training (PRT). It was explained to participants how PRT would break into the vicious cycle of "annoyance-stress-attention to noises-further annoyance" by diminishing the stress response to tinnitus annoyance. Relaxation was taught in a sitting or lying position in the office and included: progressive muscle tensing/relaxing; use of pleasant visual imagery to promote mental calmness; and encouragement of relaxed diaphragmatic breathing. Participants received an audiocassette to practice at home at least once per day for 20-30 minutes. Progress was monitored, problems were dealt with, further practice was given in each session, and subjects were encouraged to apply their relaxation skill in their daily life. However, no instructions were given to apply relaxation in any specific way to their tinnitus distress/annoyance and discussion of relaxation as a specific coping technique was avoided. . Duration 6 one hour sessions with possible extension to 8. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Qualified clinical psychologist). (n=16) Intervention 3: Tinnitus counselling - Relaxation strategies. Applied Relaxation Training (ART). Relaxation was taught as the PRT and additionally explained that acquisition of the skill through daily practice would break into the vicious cycle of "annoyance to greater attention to greater annoyance" by enabling subjects to apply relaxation when tinnitus was annoying. Moments of greatest annoyance/distress were recorded in a daily diary in which subjects identified antecedents and consequents of these moments. Subjects were instructed in the following techniques in order to apply relaxation to tinnitus annoyance as a method of coping with it: 1. "When relaxed, focus on the noises and float with them rather than tense up or fight them." 2. "When relaxed and listening to the noises, search for more pleasant interpretations such as 'wind in trees' rather than 'piercing whistle.'" 3. "When tinnitus is especially distressing, apply relaxation at these times to counteract the learned tendency to tense up to the noise."

	Treatment sessions were used to help subjects identify and record their annoyance and distress so that relaxation could be applied. These distressing situations were also rehearsed in imagination and subjects practiced 'relaxing away' their negative emotional responses. A hierarchy of situations was constructed and the least distressing was presented once the subject had learned to relax moderately well. Each situation was imagined for 10-20 seconds, the subject then took a breath, paused said "relax" (or "calm", "take it easy" etc) and then relaxed the muscles of the body while breathing out. The scene was rehearsed several times before moving up this hierarchy.. Duration 6 one hour sessions with possible extension to 8. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Qualified clinical psychologist).
Funding	Other (The Locally Organised Research Scheme)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus RELAXATION STRATEGIES

Protocol outcome 1: Tinnitus distress
- Actual outcome: Emotional distress - PRT at Post-treatment; Group 1: mean 14.3 Not reported (SD 1.4); n=11, Group 2: mean 14 Not reported (SD 3.8); n=7; TEQ scales - emotional distress Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 5; Group 2 Number missing: 6
- Actual outcome: Emotional distress - PRT at 4 months follow-up; Group 1: mean 15.3 Not reported (SD 2.1); n=10, Group 2: mean 15.5 Not reported (SD 2.1); n=6; TEQ scales - emotional distress Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 7

Protocol outcome 2: Tinnitus loudness
- Actual outcome: Tinnitus loudness ratings - PRT at Post-treatment; Group 1: mean 4 Not reported (SD 0.66); n=11, Group 2: mean 4 Not reported (SD 0.81); n=7; Tinnitus Loudness rating 1-5 extremely quiet, quiet, moderate, loud, extremely loud Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 5; Group 2 Number missing: 6
- Actual outcome: Tinnitus loudness ratings - PRT at 4 month follow-up; Group 1: mean 4.3 Not reported (SD 0.48); n=10, Group 2: mean 4.33 Not reported (SD 0.51); n=6; Tinnitus loudness rating 1-5 extremely quiet, quiet, moderate, loud, extremely loud Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low,

Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 7

Protocol outcome 3: Anxiety
- Actual outcome: Anxiety - PRT at 1 month follow-up; Group 1: mean 39.2 Not reported (SD 11.7); n=10, Group 2: mean 45.66 Not reported (SD 16.2); n=7; STAI (STAI-state) Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 7
- Actual outcome: Anxiety - PRT at 1 month follow-up; Group 1: mean 45.1 Not reported (SD 8.9); n=10, Group 2: mean 52.16 Not reported (SD 12.5); n=7; STAI (STAI-trait) Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 7

Protocol outcome 4: Depression
- Actual outcome: Depression - PRT at 1 month follow-up; Group 1: mean 7.8 Not reported (SD 7); n=10, Group 2: mean 11.16 Not reported (SD 11.1); n=6; BDI 0-63 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 7

Protocol outcome 5: Sleep
- Actual outcome: Insomnia - PRT at post-treatment; Group 1: mean 8.6 Not reported (SD 2.3); n=11, Group 2: mean 8.57 Not reported (SD 2.2); n=7; TEQ - insomnia Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 5; Group 2 Number missing: 6
- Actual outcome: Insomnia - PRT at 4 month follow-up; Group 1: mean 9.2 Not reported (SD 1.5); n=10, Group 2: mean 9.33 Not reported (SD 2.1); n=6; TEQ - insomnia Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 7

Protocol outcome 6: Tinnitus annoyance
- Actual outcome: Tinnitus annoyance - PRT at post-treatment; Group 1: mean 3.6 Not reported (SD 0.69); n=11, Group 2: mean 2.85 Not reported (SD

0.69); n=7; Tinnitus annoyance rating Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 5; Group 2 Number missing: 6
- Actual outcome: Tinnitus annoyance - PRT at 4 month follow-up; Group 1: mean 4 Not reported (SD 0.81); n=10, Group 2: mean 4 Not reported (SD 0.63); n=6; Tinnitus annoyance rating Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 7

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus RELAXATION STRATEGIES

Protocol outcome 1: Tinnitus distress
- Actual outcome: Emotional distress - ART at Post-treatment; Group 1: mean 14.3 Not reported (SD 1.4); n=11, Group 2: mean 15 Not reported (SD 3.1); n=12; TEQ - emotional distress Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 5; Group 2 Number missing: 4
- Actual outcome: Emotional distress - ART at 4 months follow-up; Group 1: mean 15.3 Not reported (SD 2.1); n=10, Group 2: mean 14.45 Not reported (SD 2.4); n=11
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 5

Protocol outcome 2: Tinnitus loudness
- Actual outcome: Tinnitus loudness ratings - ART at Post-treatment; Group 1: mean 4 Not reported (SD 0.66); n=11, Group 2: mean 3.66 Not reported (SD 1); n=12; Tinnitus loudness rating 1-5 extremely quiet, quiet, moderate, loud, extremely loud Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 5; Group 2 Number missing: 4
- Actual outcome: Tinnitus loudness ratings - ART at 4 month follow-up; Group 1: mean 4.3 Not applicable (SD 0.48); n=10, Group 2: mean 4 Not applicable (SD 0.77); n=11; Tinnitus loudness rating 0-10 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 5

Protocol outcome 3: Anxiety
- Actual outcome: Anxiety - ART at 1 month follow-up; Group 1: mean 39.2 Not reported (SD 11.7); n=10, Group 2: mean 40.41 Not reported (SD 14.4); n=12; STAI (STAI-state) Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 4
- Actual outcome: Anxiety - ART at 1 month follow-up; Group 1: mean 45.1 Not reported (SD 8.9); n=10, Group 2: mean 44.33 Not reported (SD 9.1); n=12; STAI (STAI-trait) Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 4

Protocol outcome 4: Depression
- Actual outcome: Depression - ART at 1 month follow-up; Group 1: mean 7.8 Not reported (SD 7); n=10, Group 2: mean 6.83 Not reported (SD 4.6); n=12; BDI 0-63 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 4

Protocol outcome 5: Sleep
- Actual outcome: Insomnia - ART at post-treatment; Group 1: mean 8.6 Not reported (SD 2.3); n=11, Group 2: mean 8.58 Not reported (SD 2); n=12; TEQ - insomnia Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 5; Group 2 Number missing: 4
- Actual outcome: Insomnia - ART at 4 month follow-up; Group 1: mean 9.2 Not reported (SD 1.5); n=10, Group 2: mean 9.09 Not reported (SD 0.8); n=11; TEQ - insomnia Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 5; Group 2 Number missing: 5

Protocol outcome 6: Tinnitus annoyance
- Actual outcome: Tinnitus annoyance - ART at Post-treatment; Group 1: mean 3.6 Not reported (SD 0.69); n=11, Group 2: mean 3.08 Not reported (SD 0.9); n=12; Tinnitus annoyance rating Not reported Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 5; Group 2 Number missing: 4

- Actual outcome: Tinnitus annoyance - ART at 4 months follow-up; Group 1: mean 4 Not reported (SD 0.81); n=10, Group 2: mean 3.18 Not reported (SD 1.1); n=11; Tinnitus annoyance rating Not reported Top=High is poor outcome Risk of bias: All domain - Very high, Selection - High, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Differences were not statistically significant; Group 1 Number missing: 6; Group 2 Number missing: 5	
Protocol outcomes not reported by the study	Quality of life (tinnitus); Quality of life; Severity; Depression and anxiety; Safety; Tolerability; Side effects

Study	**Henry 1996[21]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=60)
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: Cognitive behavioural therapy. Intervention involved one 90-minute small group (5-7 participants) session per week for six weeks. Participants were encouraged to learn to approach the problem of tinnitus in more adaptive and constructive ways, and to regard their reaction to tinnitus as potentially manageable and subject to modification. They were trained in attention diversion strategies in order to achieve this goal (e.g. guided exercises whereby they practiced re-focusing attention from internal stimuli to external stimuli). Imagery training also formed a further component of the intervention. Mental imagery was presented as an important part of behaviour which is closely related to attention diversion. Additionally, participants were trained in cognitive restructuring. Participants were provided with information about tinnitus and received a written treatment manual which covered the attention diversion strategies, imagery techniques, thought management skills. They were also supplied with audio-cassettes of attention diversion and imagery exercise for use in home practice of the techniques. 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): Mental health professional (A clinical psychologist). (n=20) Intervention 2: Tinnitus counselling - Provision of information (education). 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 3: Control group - i.e. no psychological therapy. 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):
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus INFORMATION/EDUCATION

Protocol outcome 1: Tinnitus distress
- Actual outcome for Adults: Tinnitus distress at Post-treatment; Group 1: mean 34.35 (SD 19.95); n=20, Group 2: mean 45.45 (SD 22.28); n=20; 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 - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0
- Actual outcome for Adults: Tinnitus distress at 12 months; Group 1: mean 44.06 (SD 21.81); n=16, Group 2: mean 45.94 (SD 21.56); n=17; 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 - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 4, Reason: Not reported; Group 2 Number missing: 3, Reason: Not reported

Protocol outcome 2: Tinnitus annoyance
- Actual outcome for Adults: Tinnitus annoyance at Post-treatment; Group 1: mean 2.31 (SD 0.91); n=20, Group 2: mean 2.77 (SD 0.64); 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; Group 2 Number missing: 0
- Actual outcome for Adults: Tinnitus annoyance at 12 months; Group 1: mean 2.25 (SD 1.06); n=16, Group 2: mean 2.88 (SD 1.11); n=17; 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: 4, Reason: Not reported; Group 2 Number missing: 3, 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 43.72 (SD 15.46); n=20, Group 2: mean 59.34 (SD 19.44); n=20; Tinnitus Handicap Questionnaire (THQ) Not reported 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; Group 2 Number missing: 0
- Actual outcome for Adults: Tinnitus-related quality of life at 12 months; Group 1: mean 52.47 (SD 16.14); n=16, Group 2: mean 55.23 (SD 18.8); n=17; Tinnitus Handicap Questionnaire (THQ) Not reported 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: 4, Reason: Not reported; Group 2 Number missing: 3, Reason: Not reported

Protocol outcome 4: Tinnitus loudness

- Actual outcome for Adults: Tinnitus loudness at Post-treatment; Group 1: mean 2.76 (SD 1.07); n=20, Group 2: mean 2.83 (SD 0.73); 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; Group 2 Number missing: 0
- Actual outcome for Adults: Tinnitus loudness at 12 months; Group 1: mean 2.75 (SD 0.85); n=16, Group 2: mean 3.17 (SD 0.95); n=17; 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: 4, Reason: Not reported; Group 2 Number missing: 3, Reason: Not reported

Protocol outcome 5: Depression
- Actual outcome for Adults: Depression at Post-treatment; Group 1: mean 11.9 (SD 6.94); n=20, Group 2: mean 11.45 (SD 8.58); n=20; Beck Depression Inventory (BDI) 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; Group 2 Number missing: 0
- Actual outcome for Adults: Depression at 12 months; Group 1: mean 11 (SD 7.61); n=16, Group 2: mean 13 (SD 9.57); n=17; Beck Depression Inventory (BDI) 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: 4, Reason: Not reported; Group 2 Number missing: 3, Reason: Not reported

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

Protocol outcome 1: Tinnitus distress
- Actual outcome for Adults: Tinnitus distress at Post-treatment; Group 1: mean 34.35 (SD 19.95); n=20, Group 2: mean 46.6 (SD 21.89); n=20; 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 - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 2: Tinnitus annoyance
- Actual outcome for Adults: Tinnitus annoyance at Post-treatment; Group 1: mean 2.31 (SD 0.91); n=20, Group 2: mean 2.77 (SD 0.86); 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; Group 2 Number missing: 0

Protocol outcome 3: Quality of life (tinnitus)
- Actual outcome for Adults: Tinnitus-related quality of life at Post-treatment; Group 1: mean 43.72 (SD 15.46); n=20, Group 2: mean 60.88 (SD 18.95); n=20; Tinnitus Handicap Questionnaire (THQ) Not reported 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; Group 2 Number missing: 0 Protocol outcome 4: Tinnitus loudness - Actual outcome for Adults: Tinnitus loudness at Post-treatment; Group 1: mean 2.76 (SD 1.07); 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; Group 2 Number missing: 0 Protocol outcome 5: Depression - Actual outcome for Adults: Depression at Post-treatment; Group 1: mean 11.9 (SD 6.94); n=20, Group 2: mean 11.5 (SD 6.01); n=20; Beck Depression Inventory (BDI) 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; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Quality of life; Severity; Anxiety; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	**Hesser 2012** [22]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=99)
Countries and setting	Conducted in Sweden; Setting: Self-help provided via the internet.
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: The participants had to have tinnitus for more than 6 months and diagnosis had to be confirmed by an ENT specialist or audiological physician.
Stratum	Overall: Not applicable
Subgroup analysis within study	Not applicable: Not applicable
Inclusion criteria	Had to have tinnitus for more than 6 months, confirmed by ENT specialist or audiological physician; at least 18 years old; a resident of Sweden; have moderate to severe tinnitus distress (defined as a total score of >/=38 on the Tinnitus Handicap Inventory (THI); had to be able to read and write sufficiently well to be able to work with text-based material, have the time to complete treatment (2 hours per week for 8 weeks) and have access to a computer with an Internet connection.

Exclusion criteria	Severe medical or psychiatric condition; presented with an imminent suicide risk; had an ongoing treatment for tinnitus; or had previously received the treatments that were offered in the present trial.
Recruitment/selection of patients	Advertisements in Swedish media and from a waiting list on the Internet where individuals could report interest in taking part in upcoming Internet-based treatment studies on tinnitus.
Age, gender and ethnicity	Age - Mean (SD): 48.5 (14.7) years. Gender (M:F): 46/43. Ethnicity: Not reported
Further population details	1. Mild hearing loss: Not stated / Unclear 2. People with learning disability or cognitive impairment: Not stated / Unclear 3. Profoundly deaf: Not stated / Unclear
Extra comments	Tinnitus severity grade: n(%): Grade 1: CBT 1(3.1); ACT 1(2.9); Control 2(6.3); Grade 2: CBT 25 (78.1); ACT 29 (82.9); Control 23 (71.9); Grade 3: CBT 6 (18.8); ACT5 (14.3); control 7 (21.9). Tinnitus distress duration months, mean (SD): CBT: 8.9 (5.5); A 9.7 (9.5); 9 (9.2).
Indirectness of population	No indirectness: Not applicable
Interventions	(n=32) Intervention 1: Cognitive behavioural therapy. Guided internet-delivered therapy, including structured self-help material presented via the Internet and an identified therapist who provided support and guidance of therapeutic activities. Communication with participants was handled in a secure encrypted web page, where both the therapist and participant could post messages online. All online communication was asynchronous (not at same time). Treatments consisted primarily of text- and picture-based self-help material. The CBT self-help material was based on a shortened version of a published self-help manual (Kaldo & Andersson, 2004). A modified manual as used, the text was divided into eight modules and key ingredients of treatment were retained and approved by the original authors of the manual. Tinnitus-specific CBT techniques included applied relaxation, positive imagery, attention training, cognitive restructuring, exposure, and the use of background sounds to cope with the experience of tinnitus. Additionally participants could work on specific problems that are commonly experienced by individuals with tinnitus, including noise sensitivity, hearing problems and sleep problems, using traditional cognitive and behavioural interventions (e.g., sleep restriction, problem solving, hearing tactics). . Duration Outcome measures were competed at pre-treatment (approx. 2 weeks prior to start of treatment, post-treatment (approx. 8 weeks from start of treatment), and 1- year follow-up. Concurrent medication/care: Not reported. . Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (One licensed psychologist who had experience of treating tinnitus and six clinical psychology MSc students who had completed their training.). Comments: This was an internet asynchronous intervention, rather than face-to-face contact with therapist. (n=35) Intervention 2: Acceptance and commitment therapy. Guided internet-delivered therapy, including structured self-help material presented via the Internet and an identified therapist who provided support and guidance of therapeutic activities. Communication with participant was handled in a secure encrypted web

	page, where both the therapist and participant could post messages online. All online communication was asynchronous (not at same time). Treatments consisted primarily of text- and picture-based self-help material. ACT seeks to promote health and value-based behaviour change by reducing an individual's effort to control or avoid internal experiences through the means of acceptance-based strategies. Targeting acceptance of tinnitus-related experiences, the therapeutic techniques used in the ACT condition were part of the previously developed and tested protocol used in the ACT condition were part of the previously developed and tested protocol used in face-to-face psychotherapy for tinnitus distress. The author of the face-to-face protocol was involved in adapting and approving the final treatment. Exercises and homework assignments in the self-help manual were similar to those used in the original protocol. It was divided into 8 modules of various experiential exercises and assignments to illustrate key concepts of the ACT model. Specific ACT interventions included exercises that focused on mindfulness and distancing of internal experiences (i.e., defusion), assignments with the purpose of identifying personal values and goals, and exercises that promoted willingness to experience tinnitus in the context of value-based behaviour change. Duration Outcome measures were completed at pre-treatment (approx. 2 weeks prior to start of treatment, post-treatment (approx. 8 weeks from start of treatment), and 1- year follow-up. . Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (One licensed psychologist who had experience of treating tinnitus and six clinical psychology MSc students who had completed their training.). Comments: This was an internet asynchronous intervention, rather than face-to-face contact with therapist. (n=32) Intervention 3: Control group - i.e. no psychological therapy. Participants were invited to join in a confidential moderated online discussion forum that specifically targeted tinnitus-related problems. They were encouraged to take part by posting messages online. Therapists monitored the forum, and each week a therapist posted a new topic for the participants to discuss. . Duration Outcome measures were competed at pre-treatment (approx. 2 weeks prior to start of treatment, post-treatment (approx. 8 weeks from start of treatment), and 1- year follow-up. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (One licensed psychologist who had experience of treating tinnitus and six clinical psychology MSc students who had completed their training). Comments: 53% actively took part by posting messages in the forum but participants could just read it without being active.
Funding	Academic or government funding (Study funded by grant from Swedish Council for Working Life and Social Research; preparation of paper sponsored in part by grant from Swedish Research Council (HEAD Linneaus grant).)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY (INTERNET) versus	

ACCEPTANCE AND COMMITMENT THERAPY (INTERNET)

Protocol outcome 1: Tinnitus distress
- Actual outcome: THI (measuring distress and severity) at 8 weeks after treatment; Group 1: mean 38.93 Not applicable (SD 19.72); n=30, Group 2: mean 31.94 Not applicable (SD 14.54); n=33; THI 0-100 Top=High is poor outcome
Risk of bias: All domain – Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness, Comments: Possibly indirect as the THI measures tinnitus distress and severity rather than just one outcome but is a combination of two of our critical outcome so is very relevant.; Group 1 Number missing: 2, Reason: Discontinued participation ; Group 2 Number missing: 2, Reason: Discontinued participation
- Actual outcome: THI (measuring distress and severity) at 1- year follow-up; Group 1: mean 40.47 Not applicable (SD 21.45); n=30, Group 2: mean 44.26 Not applicable (SD 22.25); n=31; THI 0-100 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness, Comments: Possibly indirect as the THI measures tinnitus distress and severity rather than just one outcome but is a combination of two of our critical outcome so is very relevant.; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 4, Reason: Discontinued participation in treatment

Protocol outcome 2: Quality of life
- Actual outcome: QoLI - the Quality of Life Inventory at 8 weeks after treatment; Group 1: mean 2.53 Not applicable (SD 1.55); n=30, Group 2: mean 2.12 Not applicable (SD 1.47); n=33; Quality of Life Inventory Not reported Top=Unclear
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 0, Reason: N/A
- Actual outcome: QoLI - the Quality of Life Inventory at 1-year follow-up; Group 1: mean 2.48 Not applicable (SD 1); n=30, Group 2: mean 1.84 Not applicable (SD 1.87); n=31; Quality of Life Inventory Not reported Top=Unclear
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 4, Reason: Discontinued participation in treatment

Protocol outcome 3: Anxiety
- Actual outcome: HADS - anxiety at 1-year follow-up; Group 1: mean 4.9 Not applicable. (SD 3.51); n=30, Group 2: mean 6.39 Not applicable. (SD 4.37); n=31; HADS - anxiety 0-21 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 4, Reason: Discontinued participation in treatment
- Actual outcome: HADS - anxiety at 8 weeks after treatment; Group 1: mean 4.67 Not applicable (SD 3.37); n=30, Group 2: mean 4.21 Not applicable (SD 2.25); n=33; HADS -anxiety 0-21 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 2, Reason: Discontinued participation in treatment;

Group 2 Number missing: 0, Reason: N/A

Protocol outcome 4: Depression
- Actual outcome: HADS - depression at 8 weeks after treatment; Group 1: mean 3.37 Not applicable (SD 3.25); n=30, Group 2: mean 3.48 Not applicable (SD 2.43); n=33; HADS - depression 0-21 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 0, Reason: N/A
- Actual outcome: HADS - depression at 1-year follow-up; Group 1: mean 3.07 Not applicable (SD 2.95); n=30, Group 2: mean 5.03 Not applicable (SD 3.36); n=31; HADS - depression 0-21 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 4, Reason: Discontinued participation in treatment

Protocol outcome 5: Sleep
- Actual outcome: ISI - Insomnia Severity Index at 1-year follow-up; Group 1: mean 12.03 Not applicable (SD 8.39); n=30, Group 2: mean 17.32 Not applicable (SD 9.85); n=31; ISI - Insomnia Severity Index 0-28 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 4, Reason: Discontinued participation in treatment
- Actual outcome: ISI - Insomnia Severity Index at 8 weeks after treatment; Group 1: mean 9.93 Not applicable (SD 6.85); n=30, Group 2: mean 8.48 Not applicable (SD 5.43); n=33; ISI - Insomnia Severity Index 0-28 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 0, Reason: N/A

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus I.E NO PSYCHOLOGICAL THERAPY

Protocol outcome 1: Tinnitus distress
- Actual outcome: THI (measuring distress and severity) at 8 weeks after treatment; Group 1: mean 38.93 Not applicable (SD 19.72); n=30, Group 2: mean 49.94 Not applicable (SD 16.09); n=32; THI 0-100 Top=High is poor outcome; Comments: Classification of tinnitus in THI: no handicap (0-16), mild handicap (18-36), moderate handicap (38-56) and severe handicap (58-100).
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness, Comments: Possibly indirect as the THI measures tinnitus distress and severity rather than just one outcome but is a combination of two of our critical outcome so is very relevant.; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 0, Reason: N/A

Protocol outcome 2: Quality of life
- Actual outcome: QoLI - the Quality of Life Inventory at 8 weeks after treatment; Group 1: mean 2.53 Not applicable (SD 1.55); n=30, Group 2: mean 2.27 Not applicable (SD 1.5); n=32; Quality of Life Inventory Not reported Top=Unclear
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2, Reason: Discontinued participation ; Group 2 Number missing: 2, Reason: Discontinued participation

Protocol outcome 3: Anxiety
- Actual outcome: HADS - anxiety at 8 weeks after treatment; Group 1: mean 4.67 Not applicable (SD 3.37); n=30, Group 2: mean 6.78 Not applicable (SD 3.98); n=32; HADS- anxiety 0-21 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness; Group 1 Number missing: 2, Reason: Discontinued participation ; Group 2 Number missing: 2, Reason: Discontinued participation

Protocol outcome 4: Depression
- Actual outcome: HADS - depression at 8 weeks after treatment; Group 1: mean 3.37 Not applicable (SD 3.25); n=30, Group 2: mean 6.78 Not applicable (SD 3.98); n=32; HADS - depression 0-21 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness; Group 1 Number missing: 2, Reason: Discontinued participation ; Group 2 Number missing: 2, Reason: Discontinued participation

Protocol outcome 5: Sleep
- Actual outcome: ISI - Insomnia Severity Index at 8 weeks after treatment; Group 1: mean 9.93 Not applicable (SD 6.85); n=30, Group 2: mean 11.22 Not applicable (SD 6.97); n=32; ISI - Insomnia Severity Index 0-28 Top=High is poor outcome
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Comments - ; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2, Reason: Discontinued participation ; Group 2 Number missing: 2, Reason: Discontinued participation

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACCEPTANCE AND COMMITMENT THERAPY versus I.E NO PSYCHOLOGICAL THERAPY

Protocol outcome 1: Tinnitus distress
- Actual outcome: THI (measuring distress and severity) at 8 weeks after treatment; Group 1: mean 31.94 Not applicable (SD 14.54); n=33, Group 2: mean 49.94 Not applicable (SD 16.09); n=32; THI 0-100 Top=High is poor outcome; Comments: Classification of tinnitus in THI: no handicap (0-16), mild handicap (18-36), moderate handicap (38-56) and severe handicap (58-100).
Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness, Comments: Possibly indirect as the THI measures tinnitus distress and severity rather than just one outcome but is a combination of two of our critical outcome so is very relevant; Group 1 Number missing: 2, Reason:

Discontinued participation in treatment; Group 2 Number missing: 0, Reason: N/A Protocol outcome 2: Quality of life - Actual outcome: QoLI - the Quality of Life Inventory at 8 weeks after treatment; Group 1: mean 2.12 Not applicable (SD 1.47); n=33, Group 2: mean 2.27 Not applicable (SD 1.5); n=32; Quality of Life Inventory Not reported Top=Unclear; Comments: Could not find the range for the QoLI online. Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 0, Reason: N/A Protocol outcome 3: Anxiety - Actual outcome: HADS - anxiety at 8 weeks after treatment; Group 1: mean 4.21 Not applicable (SD 2.25); n=33, Group 2: mean 6.78 Not applicable (SD 3.98); n=32; HADS - anxiety 0-21 Top=High is poor outcome Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 0, Reason: N/A Protocol outcome 4: Depression - Actual outcome: HADS - depression at 8 weeks after treatment; Group 1: mean 3.48 Not applicable (SD 2.43); n=33, Group 2: mean 4.59 Not applicable (SD 3.29); n=32; HADS- depression 0-21 Top=High is poor outcome Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 0, Reason: N/A Protocol outcome 5: Sleep - Actual outcome: ISI - Insomnia Severity Index at 8 weeks after treatment; Group 1: mean 8.48 Not applicable (SD 5.43); n=33, Group 2: mean 11.22 Not applicable (SD 6.97); n=32; ISI - Insomnia Severity Index 0-28 Top=High is poor outcome Risk of bias: All domain - Very high, Selection - Low, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2, Reason: Discontinued participation in treatment; Group 2 Number missing: 0, Reason: N/A	
Protocol outcomes not reported by the study	Tinnitus annoyance; Quality of life (tinnitus); Severity; Tinnitus loudness; Depression and anxiety; Safety; Tolerability; Side effects

Study	**Jasper 2014[26]**
Study type	RCT (Patient randomised; Parallel)

Number of studies (number of participants)	1 (n=128)
Countries and setting	Conducted in Germany; Setting: University Outpatient Clinic for Psychotherapy in Mainz
Line of therapy	Not applicable
Duration of study	Intervention time: 10 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Assessed by THI, mini-TQ and tinnitus duration of >/= 6 months
Stratum	Overall: Not applicable
Subgroup analysis within study	Not applicable
Inclusion criteria	Age >/=18 years; score of >/=18 on the Tinnitus Handicap Inventory (THI) or a score of >/=8 on the Mini-Tinnitus Questionnaire (mini-TQ); a tinnitus duration of >/=6 months; tinnitus as the primary problem (not e.g. as a consequence of morbus Meniere); consenting to be randomised; internet access; willingness and ability to attend the weekly group sessions; no anticipated absence of > 2 weeks during the course of the study
Exclusion criteria	Had CBT for tinnitus within the last 2 years; ongoing psychological tinnitus treatment; major medical or psychiatric condition; acute suicidality.
Recruitment/selection of patients	Recruited from a waiting list for tinnitus treatment at the University Outpatient Clinic for Psychotherapy in Mainz, as well as via the German Tinnitus Association, tinnitus self-help groups, and the public media. Also flyers were placed in pharmacies and the private practices of ear, nose and throat practitioners.
Age, gender and ethnicity	Age - Mean (SD): iCBT 51.3 (9.8); GCBT 50.2 (13.1); DF 52.1 (9). Gender (M:F): iCBT 25/16; GCBT 24/19; DF 28/16. 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
Extra comments	.
Indirectness of population	No indirectness
Interventions	(n=41) Intervention 1: Cognitive behavioural therapy. Internet CBT. Based on German version of the Swedish treatment manual developed by Kaldo and Anderson (2004). 12 mandatory and 6 optional text modules, each covering a particular topic, including: applied relaxation, positive imagery, focus exercises, exposure to tinnitus; cognitive restructuring; avoidance behaviour. Each module included general information suggestions for exercising, worksheets, and solutions for common problems. The structure was: download the text modules; reading general information; exercising in daily life. Once a week patients could communicate with the therapist via a secured online messaging system. The therapists were instructed to try to dedicate a maximum of 10 minutes per week per patient to e-mail communication.. Duration 10 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness

	Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Master's level clinical psychologists, who were either certified CB therapists or in the second year of their CBT training). (n=43) Intervention 2: Cognitive behavioural therapy. Group CBT. The treatment was strictly manualised; the group sizes included 5 to 12 participants; Sharing experiences, discussing individual coping strategies, and demonstrating exercises were important components of the treatment. To facilitate understanding and practice, the participants were given handouts and encouraged to complete homework assignments. . Duration 90 minute weekly sessions for 10 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Master's level clinical psychologists, who were either certified CB therapists or in the second year of their CBT training). (n=44) Intervention 3: Control group - i.e. no psychological therapy. Web-based DF. In order to control nonspecific professional support and counselling would be helpful in the treatment of tinnitus. In order to control for nonspecific effects such as increased attention or empathy, a DF was included as a control condition. A new discussion topic was presented every week. The participants were encouraged to discuss and to comment on each other's postings. The topics did not include any strategies to improve tinnitus distress but instead focused on individual experiences and attitudes concerning tinnitus. The forum was closely monitored to make sure postings were appropriate. Duration Not reported. Concurrent medication/care: Not reported. 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: COGNITIVE BEHAVIOURAL THERAPY - ICBT versus I.E NO PSYCHOLOGICAL THERAPY

Protocol outcome 1: Tinnitus distress
- Actual outcome: Mini-TQ at post-treatment; Group 1: mean 7.44 Not applicable (SD 5.3); n=38, Group 2: mean 11.09 Not applicable (SD 5.77); n=43; Mini-TQ 0-24 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No significant differences; Group 1 Number missing: 3; Group 2 Number missing: 1

Protocol outcome 2: Severity

- Actual outcome: THI at post-treatment; Group 1: mean 26.67 Not applicable (SD 20.75); n=38, Group 2: mean 37.46 Not applicable (SD 18.94); n=43; THI 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness; Baseline details: No significant differences; Group 1 Number missing: 3; Group 2 Number missing: 1

Protocol outcome 3: Anxiety
- Actual outcome: HADS -anxiety at Post-treatment; Group 1: mean 5.44 Not applicable (SD 3.23); n=38, Group 2: mean 7.67 Not applicable (SD 4.68); n=43; HADS - anxiety 0-21 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No significant differences; Group 1 Number missing: 3; Group 2 Number missing: 1

Protocol outcome 4: Depression
- Actual outcome: HADS -depression at post-treatment; Group 1: mean 4.41 Not applicable (SD 3.92); n=38, Group 2: mean 5.88 Not applicable (SD 4.41); n=43; HADS - depression 0-21 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No significant differences; Group 1 Number missing: 3; Group 2 Number missing: 1

Protocol outcome 5: Sleep
- Actual outcome: ISI at post-treatment; Group 1: mean 8.7 Not applicable (SD 5.8); n=38, Group 2: mean 10.91 Not applicable (SD 7.21); n=43; ISI 0-28 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No significant differences; Group 1 Number missing: 3; Group 2 Number missing: 1

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY - GCBT versus I.E NO PSYCHOLOGICAL THERAPY

Protocol outcome 1: Tinnitus distress
- Actual outcome: Mini-TQ at post-treatment; Group 1: mean 8.09 Not applicable (SD 4.93); n=38, Group 2: mean 11.09 Not applicable (SD 5.77); n=43; Mini-TQ 0-24 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No significant differences; Group 1 Number missing: 3; Group 2 Number missing: 1

Protocol outcome 2: Severity

- Actual outcome: THI at post-treatment; Group 1: mean 27.7 Not applicable (SD 21.93); n=38, Group 2: mean 37.46 Not applicable (SD 18.94); n=43; THI 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No significant differences; Group 1 Number missing: 3; Group 2 Number missing: 1 Protocol outcome 3: Anxiety - Actual outcome: HADS -anxiety at Post-treatment; Group 1: mean 5.84 Not applicable (SD 3.82); n=38, Group 2: mean 7.67 Not applicable (SD 4.68); n=43; HADS - anxiety 0-21 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No significant differences; Group 1 Number missing: 3; Group 2 Number missing: 1 Protocol outcome 4: Depression - Actual outcome: HADS -depression at post-treatment; Group 1: mean 4.41 Not applicable (SD 3.92); n=38, Group 2: mean 5.88 Not applicable (SD 4.41); n=43; HADS - depression 0-21 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No significant differences; Group 1 Number missing: 3; Group 2 Number missing: 1 Protocol outcome 5: Sleep - Actual outcome: ISI at post-treatment; Group 1: mean 9.03 Not applicable (SD 6.75); n=38, Group 2: mean 10.91 Not applicable (SD 7.21); n=43; ISI 0-28 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No significant differences; Group 1 Number missing: 3; Group 2 Number missing: 1	
Protocol outcomes not reported by the study	Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Tinnitus loudness; Depression and anxiety; Safety; Tolerability; Side effects

Study	**Kreuzer 2012[31]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=36)
Countries and setting	Conducted in Germany; Setting: Therapeutic meetings held in Aachen, Germany

Line of therapy	Not applicable
Duration of study	Intervention + follow up: 24 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: People had chronic tinnitus (duration ≥6 months). Tinnitus assessments included the German versions of the Tinnitus Handicap Inventory, the Tinnitus Questionnaire, the Beck Depression Inventory, several tinnitus numeric rating scales (loudness, discomfort, annoyance, distractibility, unpleasantness) at baseline.
Stratum	Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged 18 to 80 years and located in north-western part of Germany or Belgium and able to understand German language; individual burden caused by subjective tinnitus for at least 6 months
Exclusion criteria	Communicational problems; any instable medical conditions.
Recruitment/selection of patients	Clients were recruited by direct referral from a local ENT physician and by an advertisement in the newsletter of the German Tinnitus League.
Age, gender and ethnicity	Age - Mean (SD): Intervention group: 49.6 (8.8); control group: 51.7 (16.0). Gender (M:F): Intervention group: 11/7; control group: 8/10. 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=18) Intervention 1: Mindfulness-based interventions - MBSR. Treatment program consisted of mindfulness, meditation, self-massage, and breathing exercises as main components by an experienced therapist. The treatment included 1. meditation elements 2. imagination exercises 3. self-massage and individualised gentle movement exercises of the body 4. exercises aiming at directing moment-to-moment awareness of body- and self-perception and 5. breathing exercises with emphasis on expiration in order to reduce muscle tension and increase relaxation. . Duration Two weekends (11 hours of treatment/weekend) with an interval of 7 weeks. A review was made at 2 weeks after each weekend and 11 and 15 weeks after the second training weekend of 2 hours each. . Concurrent medication/care: Not applicable. . Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not applicable (Expert therapist but did not differ by group as other group was waiting list control.). (n=18) Intervention 2: Control group - i.e. no psychological therapy. Waiting list control. Duration Assessed at the identical time points during a waiting period of 24 weeks before they received treatment. Concurrent medication/care: Not applicable. Indirectness:

	No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not applicable
Funding	Study funded by industry (Grant from the Bundesverband der Innungskrankenkassen (IKK), Association of Health Insurances)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: MBSR versus I.E NO PSYCHOLOGICAL THERAPY

Protocol outcome 1: Tinnitus annoyance
- Actual outcome: Annoyance at 24 weeks; Group 1: mean 5.4 Not applicable (SD 2.6); n=15, Group 2: mean 7.2 Not applicable (SD 2.5); n=16; Numeric rating scale Not reported Top=Unclear; Comments: Week 24 vs baseline intervention group: t=-1.5; p=0.154; control group t=-0.4; p=0.683. Intervention versus control group (df=31): t=2.1: p=0.045
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Baseline details: All baseline demographic and clinical characteristics were comparable, with no statistically significant differences.; Blinding details: Data assessment and analysis took place at the University of Regensburg, Regensburg, Germany.; Group 1 Number missing: 3; Group 2 Number missing: 2

Protocol outcome 2: Severity
- Actual outcome: Tinnitus questionnaire at 24 weeks; Group 1: mean 26.5 Not applicable (SD 16.3); n=15, Group 2: mean 33.1 Not applicable (SD 16.6); n=16; Tinnitus questionnaire 0-84 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, Subgroups - Low; Indirectness of outcome: No indirectness ; Baseline details: All baseline demographic and clinical characteristics were comparable, with no statistically significant differences.; Blinding details: Data assessment and analysis took place at the University of Regensburg, Regensburg, Germany.; Group 1 Number missing: 3; Group 2 Number missing: 2
- Actual outcome: Tinnitus Handicap Inventory at 24 weeks; Group 1: mean 27.3 Not applicable (SD 19.9); n=15, Group 2: mean 41.3 Not applicable (SD 21.1); n=16; THI 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, Subgroups - Low; Indirectness of outcome: No indirectness ; Baseline details: All baseline demographic and clinical characteristics were comparable, with no statistically significant differences.; Blinding details: Data assessment and analysis took place at the University of Regensburg, Regensburg, Germany.; Group 1 Number missing: 3; Group 2 Number missing: 2

Protocol outcome 3: Tinnitus loudness
- Actual outcome: Loudness at 24 weeks; Group 1: mean 5.1 Not applicable. (SD 2.7); n=15, Group 2: mean 7 Not applicable. (SD 2.3); n=16; Numeric rating scale Not reported Top=Unclear
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness; Baseline details: All baseline demographic and clinical characteristics were comparable,

with no statistically significant differences.; Blinding details: Data assessment and analysis took place at the University of Regensburg, Regensburg, Germany.; Group 1 Number missing: 3; Group 2 Number missing: 2 Protocol outcome 4: Depression - Actual outcome: Beck Depression Inventory at 24 weeks; Group 1: mean 7.6 Not applicable (SD 5.7); n=15, Group 2: mean 13.3 Not applicable (SD 8.7); n=16; Beck Depression Inventory 0-63 Top=High is poor outcome; Comments: Intervention vs control group t=2.2; p=0.035. Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low; Indirectness of outcome: No indirectness ; Baseline details: All baseline demographic and clinical characteristics were comparable, with no statistically significant differences; Blinding details: Data assessment and analysis took place at the University of Regensburg, Regensburg, Germany; Group 1 Number missing: 3; Group 2 Number missing: 2	
Protocol outcomes not reported by the study	Tinnitus distress; Quality of life (tinnitus); Quality of life; Anxiety; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	**Kröner-Herwig 1995[34]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=34)
Countries and setting	Conducted in Germany; Setting: Not reported
Line of therapy	Not applicable
Duration of study	Not clear
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	(1) duration of tinnitus >6 months; (2) impairment due to tinnitus >4 on a 10-point rating scale (3) hearing ability good enough to allow communication in a group setting (4) no treatable organic pathology (5) no psychopathologic disorder (6) no current psychotherapy (7) medical examination completed (8) willingness to participate in the assessment and in at least 8 of 10 treatment sessions
Exclusion criteria	Not reported
Recruitment/selection of patients	People with tinnitus were recruited through a newspaper announcement which informed potential participants of the opportunity to take part in a research study on non-medical treatment approaches to chronic tinnitus.

Age, gender and ethnicity	Age - Mean (SD): 47.2 years. Gender (M:F): 1.3/1. Ethnicity: Not reported
Further population details	1. Mild hearing loss: Not stated / Unclear 2. People with learning disability or cognitive impairment: Not stated / Unclear 3. Profoundly deaf: Not stated / Unclear
Extra comments	Duration of tinnitus (mean): 46.4 months
Indirectness of population	No indirectness
Interventions	(n=15) Intervention 1: Cognitive behavioural therapy. This intervention group participating in ten 2 hour sessions. The first session focused on education (morphological and functional characteristics of the hearing system; illness model of tinnitus as disorganised spontaneous activity in the hearing system; importance of stress/ways of controlling tinnitus; coping not 'healing' as the goal of training. Progressive relaxation was one main element in sessions 2-10. Sessions 3-6 focused on analysing stressful events and their effect on tinnitus. From sessions 5-10 directing tinnitus to and from tinnitus was demonstrated as a means of coping with tinnitus. Sessions 5-10 focused on cognition, i.e. trying to change dysfunctional irrational self-statements, catastrophising thoughts and beliefs relating to tinnitus. In session 10 the maintenance of acquired coping skills after training was a topic of discussion. . Duration Not reported. 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 (Graduate students of clinical psychology). (n=19) Intervention 2: Control group - i.e. no psychological therapy. Following ‘experimental assessment’ participants were randomised to CBT or another intervention (yoga – not relevant for this evidence review) - no further details reported. Duration Not reported. 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):
Funding	Funding not stated

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

Protocol outcome 1: Tinnitus annoyance
- Actual outcome for Adults: Tinnitus annoyance at Post-treatment; Group 1: mean 3.12 (SD 1.976); n=10, Group 2: mean 3.3 (SD 1.5); n=16; 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: 5, Reason: Drop-outs; Group 2 Number missing: 3, Reason: Drop-outs

Protocol outcome 2: Tinnitus loudness

- Actual outcome for Adults: Tinnitus loudness at Post-treatment; Group 1: mean 4 (SD 2.145); n=10, Group 2: mean 5.5 (SD 1.9); n=16; 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: 5, Reason: Drop-outs; Group 2 Number missing: 3, Reason: Drop-outs Protocol outcome 3: Sleep - Actual outcome for Adults: Sleep disturbance at Post-treatment; Group 1: mean 1.66 (SD 1.752); n=10, Group 2: mean 2 (SD 2.5); n=16; 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: 5, Reason: Drop-outs; Group 2 Number missing: 3, Reason: Drop-outs	
Protocol outcomes not reported by the study	Tinnitus distress; Quality of life (tinnitus); Quality of life; Severity; Anxiety; Depression; Depression and anxiety; Safety; Tolerability; Side effects

Study	**Kröner-Herwig 2003[33]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=116)
Countries and setting	Conducted in Germany; Setting: Not reported.
Line of therapy	Not applicable
Duration of study	Not clear
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Duration of tinnitus exceeded 6 months and they had a medical diagnosis of "idiopathic tinnitus".
Stratum	Overall: Not applicable
Subgroup analysis within study	Not applicable: Not applicable
Inclusion criteria	Aged between 18 and 65 years; duration of tinnitus exceeded 6 months and their medical diagnosis was "idiopathic tinnitus" (excluding patients with Morbus Meniere); tinnitus had to be currently their main health problem. Subjective annoyance by tinnitus had to reach an average rating >/=40 on nine scales (rating 0-100) assessing disruptive effects of tinnitus.
Exclusion criteria	If hearing loss prevented them from participating in communication within groups and if they were currently in psychotherapeutic treatment.

Recruitment/selection of patients	Recruitment by newspaper announcements, informing the public of the research project.
Age, gender and ethnicity	Age - Mean (SD): 46.8 (11.15). Gender (M:F): 46:49. 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=56) Intervention 1: Cognitive behavioural therapy. An outpatient cognitive-behavioural group tinnitus coping training (TCT). 11 sessions of 90-120 minutes duration. 6 to 8 patients participated in each of 7 groups conducted. A training manual gave detailed guidelines for training delivery. Topics were: session 1: education on tinnitus etiology and maintenance; training rationale; relaxation; session 2: thoughts, emotions and bodily reactions (introduction to the ABC Model sensu Ellis); session 3: tinnitus as a stressor (using the ABC Model); dysfunctional and functional thoughts; relaxation; Session 4: attention and distraction; Session 5: changing the emotional context of tinnitus (imagery exercises); habituation exercises; Session 6: withdrawal and avoidance (cognitions and behaviour); relaxation; Session 7: relaxation; operant mechanisms in disability maintenance; Session 8: relaxation; factors of tinnitus exacerbation; coping; Session 9: problem solving (a systematic approach); Session 10: attitudes toward illness and health; Session 11: review of training and maintenance of skills. . Duration 11 sessions. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Post-graduate psychologists.). (n=20) Intervention 2: Tinnitus counselling - Education including coping strategies. Minimal contact intervention (MC-E) 2 group sessions, the first involved education regarding tinnitus etiology (neuroacoustical processes and an introduction to the psychological model of tinnitus disability). Fears regarding tinnitus, its prognosis and consequences were discussed and, if possible, revised. Self-help strategies for coping with tinnitus (e.g., distraction, relaxed confrontation, reappraisal) were deduced from the model and recommended for use. A second session in which subjects were given the opportunity to discuss their progress and problems followed after a 4-week period of implementing the recommended "self-help exercises". Duration 2 sessions. Concurrent medication/care: Not reported. 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 3: Tinnitus counselling - Relaxation strategies. MC-R group also received an educational session, where the importance of relaxation and distraction as strategies for coping with tinnitus was underlined. A second session involved audiocassettes with verbal relaxation instructions and pieces of relaxing music (30 min) selected by a music therapist. Patients were given the audiocassettes for home use and were instructed to choose the pieces of music, which suited them best. Two further meetings were used to discuss problems and progress. . Duration 4 sessions. Concurrent medication/care: Not reported. 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 4: Control group i.e. no psychological therapy. Waiting list. . Duration Not applicable. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not stated / Unclear
Funding	Academic or government funding (Grant from the German Ministry of Research and Technology)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus EDUCATION INCLUDING COPING STRATEGIES

Protocol outcome 1: Tinnitus distress
- Actual outcome: Tinnitus distress (TQ) at post-treatment; Group 1: mean 23.67 Not applicable (SD 13.67); n=43, Group 2: mean 30.94 Not applicable (SD 18.88); n=16; TQ 0-84 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Significant difference for the duration of tinnitus and significant differences in subjective loudness of tinnitus, and in the GSI of SCL-90R. Loudness shows the highest baseline score in WC, and GSI is highest in MC-R.; Group 1 Number missing: 13; Group 2 Number missing: 4

Protocol outcome 2: Severity
- Actual outcome: Tinnitus severity (GSI of SCL-90R) at post-treatment; Group 1: mean 0.54 Not applicable (SD 0.46); n=43, Group 2: mean 0.53 Not applicable (SD 0.4); n=16
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Significant difference for the duration of tinnitus and significant differences in subjective loudness of tinnitus, and in the GSI of SCL-90R. Loudness shows the highest baseline score in WC, and GSI is highest in MC-R.; Group 1 Number missing: 13; Group 2 Number missing: 4

Protocol outcome 3: Tinnitus loudness
- Actual outcome: Tinnitus loudness (diary) at post-treatment; Group 1: mean 3.84 Not applicable (SD 1.65); n=43, Group 2: mean 3.75 Not applicable (SD 1.6); n=16; diary 1-7 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Significant difference for the duration of tinnitus and significant differences in subjective loudness of tinnitus, and in the GSI of SCL-90R. Loudness shows the highest baseline score in WC, and GSI is highest in MC-R.; Group 1 Number missing: 13; Group 2 Number missing: 4

Protocol outcome 4: Depression
- Actual outcome: Depression (ADS) at post-treatment; Group 1: mean 12.4 Not applicable (SD 7.77); n=43, Group 2: mean 11.87 Not applicable (SD 9.35); n=16; ADS 0-60 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Significant difference for the duration of tinnitus and significant differences in subjective loudness of tinnitus, and in the GSI of SCL-90R. Loudness shows the highest baseline score in WC, and GSI is highest in MC-R.; Group 1 Number missing: 13; Group 2 Number missing: 4

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus RELAXATION STRATEGIES

Protocol outcome 1: Tinnitus distress
- Actual outcome: Tinnitus distress (TQ) at post-treatment; Group 1: mean 23.67 Not applicable (SD 13.67); n=43, Group 2: mean 31.27 Not applicable (SD 9.92); n=16; TQ 0-84 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Significant difference for the duration of tinnitus and significant differences in subjective loudness of tinnitus, and in the GSI of SCL-90R. Loudness shows the highest baseline score in WC, and GSI is highest in MC-R.; Group 1 Number missing: 13; Group 2 Number missing: 4

Protocol outcome 2: Severity
- Actual outcome: Tinnitus severity (GSI of SCL-90R) at post-treatment; Group 1: mean 0.54 Not applicable (SD 0.46); n=43, Group 2: mean 0.75 Not applicable (SD 0.63); n=16

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Significant difference for the duration of tinnitus and significant differences in subjective loudness of tinnitus, and in the GSI of SCL-90R. Loudness shows the highest baseline score in WC, and GSI is highest in MC-R.; Group 1 Number missing: 13; Group 2 Number missing: 4

Protocol outcome 3: Tinnitus loudness
- Actual outcome: Tinnitus loudness (diary) at post-treatment; Group 1: mean 3.84 Not applicable (SD 1.65); n=43, Group 2: mean 3.88 Not applicable (SD 1.55); n=16; Diary 1-7 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Significant difference for the duration of tinnitus and significant differences in subjective loudness of tinnitus, and in the GSI of SCL-90R. Loudness shows the highest baseline score in WC, and GSI is highest in MC-R.; Group 1 Number missing: 13; Group 2 Number missing: 4

Protocol outcome 4: Depression

- Actual outcome: Depression (ADS) at post-treatment; Group 1: mean 12.4 Not applicable (SD 7.77); n=43, Group 2: mean 18.33 Not applicable (SD 11.69); n=16; ADS 0-60 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Significant difference for the duration of tinnitus and significant differences in subjective loudness of tinnitus, and in the GSI of SCL-90R. Loudness shows the highest baseline score in WC, and GSI is highest in MC-R.; Group 1 Number missing: 13; Group 2 Number missing: 4

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus I.E NO PSYCHOLOGICAL THERAPY

Protocol outcome 1: Tinnitus distress
- Actual outcome: Tinnitus distress (TQ) at post-treatment; Group 1: mean 23.67 Not applicable (SD 13.67); n=43, Group 2: mean 35.95 Not applicable (SD 14.24); n=20; TQ 0-84 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness; Baseline details: Significant difference for the duration of tinnitus and significant differences in subjective loudness of tinnitus, and in the GSI of SCL-90R. Loudness shows the highest baseline score in WC, and GSI is highest in MC-R.; Group 1 Number missing: 13; Group 2 Number missing: 0

Protocol outcome 2: Severity
- Actual outcome: Tinnitus severity (GSI of SCL-90R) at post-treatment; Group 1: mean 0.54 Not applicable (SD 0.46); n=43, Group 2: mean 0.63 Not applicable (SD 0.4); n=20
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Significant difference for the duration of tinnitus and significant differences in subjective loudness of tinnitus, and in the GSI of SCL-90R. Loudness shows the highest baseline score in WC, and GSI is highest in MC-R.; Group 1 Number missing: 13; Group 2 Number missing: 0

Protocol outcome 3: Tinnitus loudness
- Actual outcome: Tinnitus loudness (diary) at post-treatment; Group 1: mean 4.73 Not applicable (SD 1.51); n=43, Group 2: mean 4.88 Not applicable (SD 1.73); n=20
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Significant difference for the duration of tinnitus and significant differences in subjective loudness of tinnitus, and in the GSI of SCL-90R. Loudness shows the highest baseline score in WC, and GSI is highest in MC-R.; Group 1 Number missing: 13; Group 2 Number missing: 0

Protocol outcome 4: Depression
- Actual outcome: Depression (ADS) at post-treatment; Group 1: mean 12.4 Not applicable (SD 7.77); n=43, Group 2: mean 16.05 Not applicable (SD 10.62); n=20; ADS 0-60 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Significant difference for the duration of tinnitus and significant differences in subjective loudness of tinnitus, and in the GSI of SCL-90R. Loudness shows the highest baseline score in WC, and GSI is highest in MC-R.; Group 1 Number missing: 13; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Anxiety; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	**Li 2019[35]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=100)
Countries and setting	Conducted in China; Setting: Not reported
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	The patients had persistent tinnitus or had nocturnal tinnitus symptoms for >3 months, and had the negative mental mood, such as fidgety and irritability.
Exclusion criteria	i) obvious local and systemic acute inflammation; ii) tumor history; iii) obvious metabolic diseases; iv) obvious systemic immune diseases; v) serious medical illness; vi) ear surgery related to diseases.
Recruitment/selection of patients	Chronic subjective tinnitus patients receiving treatment from September 2013 to March 2016
Age, gender and ethnicity	Age - Mean (SD): 43.22 (4.32) years. Gender (M:F): 59/41. 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
Extra comments	Duration of tinnitus: intervention group - 2.59 years; control group - 2.47 years
Indirectness of population	No indirectness
Interventions	(n=50) Intervention 1: Cognitive behavioural therapy. Intervention group received intervention twice a week. The treatment paths included three steps including cognitive restructuring, problem solving and sound

	treatment. 1) Cognitive restructuring: firstly the doctors and nurses obtained the trust and cooperation of patients, listening to worries and concerns; 2) Problem solving: patients were encouraged to actively participate in recreational activities in spare time, patients were guided to dilute the focus on tinnitus; 3) Sound treatment: participants received the same masking intervention as the control group.. 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): Non-mental health professional (Doctors and nurses). (n=50) Intervention 2: Control group - i.e. no psychological therapy. Control group received masking therapy and sound treatment using TinniTest tinnitus treatment system as follows: i) The tinnitus information, hearing test results, tinnitus test results and sound treatment course of each patient were recorded. ii) The tinnitus test was performed, which included tinnitus sound type, frequency and loudness test. iii) After completion of hearing test and tinnitus test, the masking treatment program was generated based on the accurate testing and matching data. Sounds were overlaid by appropriate light music, and were directly output to the Tinni Test masker. Masking was performed for 30 minutes once a day.. 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): Non-mental health professional (Doctors and nurses).
Funding	-- (Health Planning Committee Fund of Shanghai Changning District)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus CONTROL GROUP

Protocol outcome 1: Severity
- Actual outcome for Adults: Tinnitus severity at 6 months; Group 1: mean 35.78 (SD 8.21); n=50, Group 2: mean 48.72 (SD 9.04); n=50; Tinnitus Handicap Inventory 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; Group 2 Number missing: 0

Protocol outcome 2: Anxiety
- Actual outcome for Adults: Anxiety at 6 months; Group 1: mean 1.95 (SD 0.56); n=50, Group 2: mean 2.73 (SD 0.53); n=50; Symptom Checklist-90, F5 subscale - anxiety component 1-5 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; Group 2 Number missing: 0

Protocol outcome 3: Depression
- Actual outcome for Adults: Depression at 6 months; Group 1: mean 2.12 (SD 0.63); n=50, Group 2: mean 2.42 (SD 0.71); n=50; Symptom Checklist-90,

F4 subscale - depression component 1-5 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; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Tinnitus distress; Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Tinnitus loudness; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	**Malouff 2010[39]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=162)
Countries and setting	Conducted in Australia; Setting: Home-based intervention
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	Individuals had some symptoms of tinnitus as assessed by items on the Tinnitus Severity Scale.
Exclusion criteria	No exclusion criteria used (explicitly reported)
Recruitment/selection of patients	Participants were recruited from throughout Australia through postings on tinnitus support Web pages, announcements at in-person tinnitus support groups, postings in audiology practices, and media releases.
Age, gender and ethnicity	Age - Mean (SD): 57.6 years. Gender (M:F): 1.3/1. Ethnicity: Not reported
Further population details	1. Mild hearing loss: Not stated / Unclear 2. People with learning disability or cognitive impairment: Not stated / Unclear 3. Profoundly deaf: Not stated / Unclear
Extra comments	Duration of tinnitus not reported.
Indirectness of population	No indirectness
Interventions	(n=84) Intervention 1: Cognitive behavioural therapy. Participants in the intervention group received a self-help book (Tinnitus: A Self-Management Guide for the Ringing in Your Ears). The self-help book is based on cognitive-behavioural principles, including educational information on tinnitus, cognitive reappraisal and

	restructuring, relaxation and stress management techniques, attention control techniques, use of self-instruction, making lifestyle changes, and maintaining gains. The book provides guidelines for specific exercises such as progressive muscle relaxation and personalising self-instructions. Participants were asked to complete the book within 2 months, one chapter every 5 days. Duration 8 weeks. Concurrent medication/care: Accompanying the book was a brief letter asking participants to read the book and to follow the suggestions contained in it during the subsequent 6 weeks. No specific directions were provided in the letter and no further contact was made with participants until the time of post-assessment. . 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=78) Intervention 2: Control group i.e. no psychological therapy. After two months, participants in the waiting-list group received the CBT self-help books. Duration 8 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
Funding	Academic or government funding (Grant from the American Tinnitus Association)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY (SELF-HELP BOOK) versus WAITING-LIST CONTROL Protocol outcome 1: Tinnitus distress - Actual outcome for Adults: Tinnitus distress at Post-treatment; Group 1: mean 15.55 (SD 15.02); n=55, Group 2: mean 20.67 (SD 16.51); n=70; Tinnitus Reaction Questionnaire 0-104 Top=High is poor outcome Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 29, Reason: No reasons for loss were ascertained; Group 2 Number missing: 8, Reason: No reasons for loss were ascertained	
Protocol outcomes not reported by the study	Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Severity; Tinnitus loudness; Anxiety; Depression; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	**McKenna 2017[46]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=75)

Countries and setting	Conducted in United Kingdom; Setting: Royal National Throat, Nose and Ear Hospital, London, UK
Line of therapy	Not applicable
Duration of study	Follow up (post intervention): 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	(1) aged 18 years or over; (2) reported tinnitus of more than 6 months' duration; (3) reported clinical levels of psychological distress (Clinical Outcomes in Routine Evaluation - Non-Risk, CORE-NR score >10); (4) completed medical investigations for tinnitus; and (5) sufficient command of English and hearing levels allowing participation in group discussions.
Exclusion criteria	(1) current comorbid, severe physical or mental illness (2) current risk factors of active suicidal ideation or self-harm; (3) current substance dependence
Recruitment/selection of patients	Consecutive referrals to the clinical psychology department were screened for eligibility between January 2013 and March 2015
Age, gender and ethnicity	Age - Median (IQR): 50 (16) years. Gender (M:F): 1.2/1. Ethnicity: 80% White, 7% Black, Other 13%
Further population details	1. Mild hearing loss: Mild hearing loss (64% of participants had hearing loss). 2. People with learning disability or cognitive impairment: Not stated / Unclear 3. Profoundly deaf: Not stated / Unclear
Extra comments	Duration of tinnitus (median/(IQR)): 56 (104) months. Hearing loss aided: 25%; Not hearing loss aided: 39%; Hearing loss aid - not applicable: 36%
Indirectness of population	No indirectness
Interventions	(n=39) Intervention 1: Mindfulness-based interventions - Cognitive therapy. Mindfulness based cognitive therapy (MBCT) was delivered in line with a manual. MBCT included an emphasis on sound meditation and education around the cognitive model of tinnitus, and the importance of attentional processes in tinnitus. Included formal experiential exercises (meditation), discussion, and psycho-education within the group. Psycho-education focused on cognitive theory. Intervention consisted of eight 120-minute group sessions, delivered weekly over 8 consecutive weeks. Duration 8 weeks. Concurrent medication/care: Participants were asked to complete daily formal practices (supported by audio guides) and to begin to apply their practice of mindfulness to daily life. Participants received supporting literature. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Two clinical psychologists). (n=36) Intervention 2: Tinnitus counselling - Relaxation strategies. Relaxation therapy (RT) was delivered in

	line with a manual. RT was based on standardised interventions for relaxation, adapted to create an 8-week course for comparability to MBCT. Included formal experiential exercises (relaxation), discussion, and psycho-education within the group. Psycho-education focused on the physiology of stress and tinnitus. Intervention consisted of eight 120-minute group sessions, delivered weekly over 8 consecutive weeks. Duration 8 weeks. Concurrent medication/care: Participants were asked to complete daily formal practices (supported by audio guides) and to begin to apply their practice of relaxation to daily life. Participants did not receive supporting literature. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not stated/Unclear
Funding	Academic or government funding (British Tinnitus Association)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: MINDFULNESS-BASED COGNITIVE THERAPY versus RELAXATION STRATEGIES

Protocol outcome 1: Severity
- Actual outcome for Adults: Tinnitus severity (TQ) at Post-treatment; Group 1: mean 31.4 (SD 16.1); n=36, Group 2: mean 38.2 (SD 14.3); n=32; Tinnitus Questionnaire 0-82 Top=High is poor outcome
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Could not be contacted; Group 2 Number missing: 4, Reason: Could not be contacted
- Actual outcome for Adults: Tinnitus severity (TFI) at Post-treatment; Group 1: mean 42.2 (SD 19.2); n=36, Group 2: mean 49.2 (SD 19); n=32; Tinnitus Functional Index 0-100 Top=High is poor outcome
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Could not be contacted; Group 2 Number missing: 4, Reason: Could not be contacted
- Actual outcome for Adults: Tinnitus severity (TQ) at 6 months; Group 1: mean 28 (SD 18.1); n=34, Group 2: mean 35.6 (SD 16.8); n=28
Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Could not be contacted; Group 2 Number missing: 8, Reason: Could not be contacted
- Actual outcome for Adults: Tinnitus severity (TFI) at 6 months; Group 1: mean 37.2 (SD 24.1); n=34, Group 2: mean 49 (SD 21.1); n=28; Tinnitus Functional Index 0-100 Top=High is poor outcome
Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Could not be contacted; Group 2 Number missing: 8, Reason: Could not be contacted

Protocol outcome 2: Tinnitus loudness

- Actual outcome for Adults: Tinnitus loudness at Post-treatment; Group 1: mean 56.6 (SD 25.2); n=36, Group 2: mean 59.2 (SD 22.5); n=32; Visual analogue scale 0-10 Top=High is poor outcome Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Could not be contacted; Group 2 Number missing: 4, Reason: Could not be contacted - Actual outcome for Adults: Tinnitus loudness at 6 months; Group 1: mean 55.1 (SD 29.9); n=34, Group 2: mean 65.4 (SD 24.3); n=28; Visual analogue scale 0-10 Top=High is poor outcome Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Could not be contacted; Group 2 Number missing: 8, Reason: Could not be contacted Protocol outcome 3: Anxiety - Actual outcome for Adults: Anxiety at Post-treatment; Group 1: mean 9.2 (SD 3.8); n=36, Group 2: mean 10.1 (SD 3.9); n=32; Hospital Anxiety and Depression Scale 0-21 Top=High is poor outcome Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Could not be contacted; Group 2 Number missing: 4, Reason: Could not be contacted - Actual outcome for Adults: Anxiety at 6 months; Group 1: mean 9 (SD 3.8); n=34, Group 2: mean 10.2 (SD 3.7); n=28; Hospital Anxiety and Depression Scale 0-21 Top=High is poor outcome Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Could not be contacted; Group 2 Number missing: 8, Reason: Could not be contacted Protocol outcome 4: Depression - Actual outcome for Adults: Depression at Post-treatment; Group 1: mean 6.2 (SD 3.1); n=36, Group 2: mean 7.5 (SD 3.8); n=32; Hospital Anxiety and Depression Scale 0-21 Top=High is poor outcome Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 3, Reason: Could not be contacted; Group 2 Number missing: 4, Reason: Could not be contacted - Actual outcome for Adults: Depression at 6 months; Group 1: mean 5.6 (SD 3.6); n=34, Group 2: mean 7.5 (SD 4.2); n=28; Hospital Anxiety and Depression Scale 0-21 Top=High is poor outcome Risk of bias: All domain - High, Selection - Low, Blinding - Low, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5, Reason: Could not be contacted; Group 2 Number missing: 8, Reason: Could not be contacted
Protocol outcomes not reported by the study	Tinnitus distress; Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	Nyenhuis 2013[50]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=304)
Countries and setting	Conducted in Germany; Setting: Two study centres in the southern region of Lower Saxony
Line of therapy	Not applicable
Duration of study	Follow up (post intervention): 9 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	Participant experienced idiopathic tinnitus for 2 to 26 weeks, was between 18 and 75 years old and was not receiving any other tinnitus-related psychological treatment.
Exclusion criteria	Not reported - based on inclusion criteria
Recruitment/selection of patients	Participants were recruited via newspapers, radio announcements, ENT offices and outpatient clinics. A standardised telephone interview was performed with each participant to check the inclusion criteria and to provide information about the study procedures and treatments.
Age, gender and ethnicity	Age - Mean (SD): 50.3 years. Gender (M:F): 1.2/1. Ethnicity: Not reported
Further population details	1. Mild hearing loss: Not stated / Unclear 2. People with learning disability or cognitive impairment: Not stated / Unclear 3. Profoundly deaf: Not stated / Unclear
Extra comments	Mean duration of tinnitus: Intervention group - 3.2 months; Comparison group - 3.2 months.
Indirectness of population	No indirectness
Interventions	(n=71) Intervention 1: Cognitive behavioural therapy. CBT was based on a manual (full details below). The contents were presented in four two-hour meetings. All four sessions contained a progressive muscle relaxation (PMR) exercise. The first session was based on chapters 1-5. At the end of the session, the subjects received a PMR CD and the information booklet, but not the full self-management manual. The second session was based on chapter 6 and participants were asked to practice attention diversion at home. The third session was based on chapter 7 and the homework was to record one's thoughts on tinnitus and to find alternative beliefs. Chapters 8 and 9 were presented in the fourth session. . Duration 3 months. Concurrent medication/care: Chapter 1 & 2 - education regarding the aetiology of tinnitus, Chapter 3 - the morphological and functional characteristics of the hearing system, Chapter 4 - treatment options, Chapter 5 - the

	psychological aspects of tinnitus distress (vicious circle of thoughts, emotions, bodily functions), Chapter 6 - coping by attention and distraction, Chapter 7 - dysfunctional and functional thoughts - tinnitus as a stressor, Chapter 8 - stress management and relaxation, Chapter 9 - a review of training and maintenance of skills. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Three psychologists). (n=77) Intervention 2: Tinnitus counselling - Provision of information. Participants received an 11-page booklet that provided information on the morphological and functional characteristics of the auditory system, the potential triggers of tinnitus and medical treatment options. No treatment recommendation were given and all information was avoided that could instill optimistic or pessimistic thoughts about the prognosis of tinnitus. Participants received no further treatment.. Duration 3 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 (n=79) Intervention 3: Cognitive behavioural therapy. Participants received 67-page CBT manual contents were written as web pages and participants could download the progressive muscle relaxation instructions as an MP3-data file in order to use it offline. Duration 3 months. Concurrent medication/care: Chapter 1 & 2 - education regarding the aetiology of tinnitus, Chapter 3 - the morphological and functional characteristics of the hearing system, Chapter 4 - treatment options, Chapter 5 - the psychological aspects of tinnitus distress (vicious circle of thoughts, emotions, bodily functions), Chapter 6 - coping by attention and distraction, Chapter 7 - dysfunctional and functional thoughts - tinnitus as a stressor, Chapter 8 - stress management and relaxation, Chapter 9 - a review of training and maintenance of skills. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not applicable (n=77) Intervention 4: Cognitive behavioural therapy. Intervention consisted of the complete manual and a CD with instructions on progressive muscle relaxation (PMR). This was a self-management strategy with no therapeutic contact. . Duration 3 months. Concurrent medication/care: Chapter 1 & 2 - education regarding the aetiology of tinnitus, Chapter 3 - the morphological and functional characteristics of the hearing system, Chapter 4 - treatment options, Chapter 5 - the psychological aspects of tinnitus distress (vicious circle of thoughts, emotions, bodily functions), Chapter 6 - coping by attention and distraction, Chapter 7 - dysfunctional and functional thoughts - tinnitus as a stressor, Chapter 8 - stress management and relaxation, Chapter 9 - a review of training and maintenance of skills. 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 (Grant from the Federal Ministry of Research and Education, Germany)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY (GROUP) versus PROVISION OF INFORMATION

Protocol outcome 1: Tinnitus distress
- Actual outcome for Adults: Tinnitus distress at 3 months (post-intervention); Group 1: mean 20.8 (SD 14.7); n=47, Group 2: mean 27.4 (SD 18); n=58; Tinnitus questionnaire [German] 0-84 (seen in literature) 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: 24, Reason: Not reported; Group 2 Number missing: 19, Reason: Not reported
- Actual outcome for Adults: Tinnitus distress at 9 months; Group 1: mean 18.4 (SD 11.6); n=47, Group 2: mean 25.2 (SD 19.1); n=49; Tinnitus questionnaire [German] 0-84 (seen in literature) 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: 24, Reason: Not reported; Group 2 Number missing: 28, Reason: Not reported

Protocol outcome 2: Depression
- Actual outcome for Adults: Depression at 9 months; Group 1: mean 4.8 (SD 3.8); n=47, Group 2: mean 5.7 (SD 5.1); n=49; Patient Health Questionnaire-Depression Not reported 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: 24, Reason: Not reported; Group 2 Number missing: 28, Reason: Not reported
- Actual outcome for Adults: Depression at 3 months (post-intervention); Group 1: mean 4.7 (SD 4.8); n=47, Group 2: mean 5.7 (SD 4.8); n=58; Patient Health Questionnaire-Depression Not reported 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: 24, Reason: Not reported; Group 2 Number missing: 19, Reason: Not reported

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY (INTERNET) versus PROVISION OF INFORMATION

Protocol outcome 1: Tinnitus distress
- Actual outcome for Adults: Tinnitus distress at 3 months (post-intervention); Group 1: mean 17.6 (SD 12.7); n=52, Group 2: mean 27.4 (SD 18); n=58; Tinnitus Questionnaire (TQ) [German version] 0-84 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: 27, Reason: Not reported; Group 2 Number missing: 19, Reason: Not

reported
- Actual outcome for Adults: Tinnitus distress at 9 months; Group 1: mean 19.4 (SD 14.8); n=44, Group 2: mean 25.2 (SD 19.1); n=49; Tinnitus Questionnaire (TQ) [German version] 0-84 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: 35, Reason: Not reported; Group 2 Number missing: 28, Reason: Not reported

Protocol outcome 2: Depression
- Actual outcome for Adults: Depression at 9 months; Group 1: mean 5.9 (SD 5.3); n=44, Group 2: mean 5.7 (SD 5.1); n=49; Patient Health Questionnaire-Depression (PHQ-D) 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; Indirectness of outcome: No indirectness ; Group 1 Number missing: 35, Reason: Not reported; Group 2 Number missing: 28, Reason: Not reported
- Actual outcome for Adults: Depression at 3 months (post-intervention); Group 1: mean 5.1 (SD 4.5); n=52, Group 2: mean 5.7 (SD 4.8); n=58; Patient Health Questionnaire-Depression (PHQ-D) 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; Indirectness of outcome: No indirectness ; Group 1 Number missing: 27, Reason: Not reported; Group 2 Number missing: 19, Reason: Not reported

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY (BIBLIOTHERAPY) versus PROVISION OF INFORMATION

Protocol outcome 1: Tinnitus distress
- Actual outcome for Adults: Tinnitus distress at 3 months (post-intervention); Group 1: mean 26.3 (SD 20.4); n=51, Group 2: mean 27.4 (SD 18); n=58; Tinnitus Questionnaire 0-84 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: 19, Reason: Not reported
- Actual outcome for Adults: Tinnitus distress at 9 months; Group 1: mean 20.8 (SD 16.7); n=45, Group 2: mean 25.2 (SD 19.1); n=49; Tinnitus Questionnaire 0-84 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: 32, Reason: Not reported; Group 2 Number missing: 28, Reason: Not reported

Protocol outcome 2: Depression
- Actual outcome for Adults: Depression at 3 months (post-intervention); Group 1: mean 6.4 (SD 5.9); n=51, Group 2: mean 5.7 (SD 4.8); n=58; Patient Health Questionnaire-Depression (PHQ-D) Not reported 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: 19, Reason: Not reported - Actual outcome for Adults: Depression at 9 months; Group 1: mean 6.5 (SD 5.2); n=45, Group 2: mean 5.7 (SD 5.1); n=49; Patient Health Questionnaire-Depression (PHQ-D) Not reported 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: 32, Reason: Not reported; Group 2 Number missing: 28, Reason: Not reported	
Protocol outcomes not reported by the study	Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Severity; Tinnitus loudness; Anxiety; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	**Philippot 2012[52]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=30)
Countries and setting	Conducted in Belgium; Setting: University Psychology Department.
Line of therapy	Not applicable
Duration of study	Follow up (post intervention): 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: tinnitus experienced within the past 6 months and a medical check-up by a physician specialised in hearing disorders.
Stratum	Overall: Not applicable
Subgroup analysis within study	Not applicable: Not applicable
Inclusion criteria	Tinnitus experienced within the past 6 months; a medical check-up by a physician specialised in hearing disorders; sufficient hearing capacity to follow instructions delivered during group sessions; and significant psychological distress and impairment in everyday activities resulting from tinnitus (measured by the Tinnitus Psychological Impact Questionnaire (QIPA: Philippot, Clauw & de Romeree unpublished data).
Exclusion criteria	Tinnitus resulting from an organic condition that could benefit from a medical intervention; use of tinnitus masking apparatus; other psychotherapy or psychological intervention during the study; borderline or antisocial personality disorder.
Recruitment/selection of patients	Advertised in local newspapers as a controlled clinical trial aimed at reducing the psychological distress resulting from tinnitus.

Age, gender and ethnicity	Age - Mean (SD): 60 (11.53) for those who completed entire protocol. Gender (M:F): 18/12. 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
Extra comments	. Eligible participants were invited to a screening interview that consisted of an anamnesis of the tinnitus and resulting psychological difficulties, a full diagnosis on the Axis I of the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (APA 1994) as determined in a semi-structured interview conducted by a clinical psychologist.
Indirectness of population	No indirectness
Interventions	(n=15) Intervention 1: Mindfulness-based interventions - Cognitive therapy. 6 weekly group sessions of Mindfulness training. A manual was constructed for each training condition. The mindfulness training manual was derived from Segal, Williams & Teasdale (2002). The original manual, designed for the treatment of depression relapse, was adapted in the following ways. The content relative to psychoeducation of depression relapse was deleted, as the treatment target was the psychological consequences of tinnitus; the number of sessions was reduced from 8 to 6; the first four sessions were very similar to the original programme: comprising exactly the same exercises but 1) referred to dealing with the adversity of tinnitus rather than with depression relapse and b) did not present the psychoeducative part of the session. The fifth session of the programme merged aspects of sessions 5 and 6 of the original programme, focusing mostly on the theme that thoughts are not facts. The main exercise consisted of a 40 minutes sitting meditation with a sequential focus on breath, body, thoughts and finally the introduction of a difficult thought in the meditation. The sixth session of the programme merged aspects of sessions 7 and 8 of the original programme dealing with how to take care of oneself (relapse prevention) and evaluating the programme. The main exercise consisted in a 40-minute body scan. Duration 6 weeks, each session was 2 hours 15 minutes. Concurrent medication/care: Psychoeducation was given to both groups 2.5 months prior to intervention. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Two PhD level psychotherapists with at least 3 years of practice in mindfulness and in relaxation training and with a formal training in mindfulness-based cognitive therapy. Both alternated teaching of relaxation and mindfulness sessions. An observer was present in the group to rate the extent to which the manual content and treatment procedures were adhered to. Weekly briefing sessions gathered observers and instructors to coordinate the intervention and ensure treatment homogeneity and integrity.). (n=15) Intervention 2: Tinnitus counselling - Relaxation strategies. 6 sessions of 2 and 15 hours per week of relaxation training, of which a manual was constructed. The manual followed the progressive relaxation training of Jacobson (1957) adapted by Van Rillaer (1997). The first session consisted of breathing training, the second session taught Jacobson relaxation and was divided into thirteen body parts, the third session in to

	eight body parts, the fourth session into four body parts and the fifth session into two body parts. The sixth session focused on mini-relaxation and on maintenance of relaxation competence. . Duration 6 sessions of 2 hours 15 minutes session. . Concurrent medication/care: Psychoeducation for 2.5 months prior to the intervention. . Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Two PhD level psychotherapists with at least 3 years of practice in mindfulness and in relaxation training and with a formal training in mindfulness-based cognitive therapy. Both alternated teaching of relaxation and mindfulness sessions. An observer was present in the group to rate the extent to which the manual content and treatment procedures were adhered to. Weekly briefing sessions gathered observers and instructors to coordinate the intervention and ensure treatment homogeneity and integrity.).
Funding	Academic or government funding (Grant from the Fonds National de la Recherche Scientifique de Belgique (grant no. 8.4505.00).)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE THERAPY versus RELAXATION STRATEGIES

Protocol outcome 1: Anxiety
- Actual outcome: Spielberger State and Trait Anxiety Inventory at 6 weeks; Group 1: mean 42.85 Not applicable (SD 12.77); n=13, Group 2: mean 45.75 Not applicable (SD 7.72); n=12; STAI 20-80 Top=High is poor outcome; Comments: The baseline data for the STAI, mean (SD): mindfulness group: 39.84 (9.76) versus the relaxation group: 43.83 (6.63).
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Mindfulness group: 39.84 (9.76) versus relaxation group 13.08 (9.80) ; Group 1 Number missing: 2, Reason: Dropped out of first session or missed three training sessions.; Group 2 Number missing: 3, Reason: Dropped out of first session or missed three training sessions.
- Actual outcome: Spielberger State and Trait Anxiety Inventory at 3 months follow-up; Group 1: mean 40.46 Not applicable (SD 6.63); n=13, Group 2: mean 45.73 Not applicable (SD 10.47); n=12; STAI 20-80 Top=High is poor outcome; Comments: The baseline data for the STAI, mean (SD): mindfulness group: 39.84 (9.76) versus the relaxation group: 43.83 (6.63).
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Mindfulness group: 39.84 (9.76) versus relaxation group 13.08 (9.80) ; Group 1 Number missing: 2, Reason: Dropped out of first session or missed three training sessions.; Group 2 Number missing: 3, Reason: Dropped out of first session or missed three training sessions.

Protocol outcome 2: Depression
- Actual outcome: Beck Depression Index (BDI) at 6 weeks; Group 1: mean 8.84 Not applicable (SD 9.43); n=13, Group 2: mean 12.83 Not applicable (SD 5.36); n=12; BDI 0-63 Top=High is poor outcome; Comments: BDI at baseline: mindfulness group, mean (SD): 9.00 (5.65) versus relaxation group 13.08 (9.80)

Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Mindfulness group: 39.84 (9.76) versus relaxation group 13.08 (9.80) ; Group 1 Number missing: 2, Reason: Dropped out of first session or missed three training sessions.; Group 2 Number missing: 3, Reason: Dropped out of first session or missed three training sessions. - Actual outcome: Beck Depression Inventory (BDI) at 3 months follow-up; Group 1: mean 9.38 Not applicable (SD 10.44); n=13, Group 2: mean 11.92 Not applicable (SD 7.23); n=12; Comments: BDI at baseline: mindfulness group, mean (SD): 9.00 (5.65) versus relaxation group 13.08 (9.80) Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Mindfulness group: 39.84 (9.76) versus relaxation group 13.08 (9.80) ; Group 1 Number missing: 2, Reason: Dropped out of first session or missed three training sessions.; Group 2 Number missing: 3, Reason: Dropped out of first session or missed three training sessions.	
Protocol outcomes not reported by the study	Tinnitus distress; Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Severity; Tinnitus loudness; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	**Rief 2005[53]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=48)
Countries and setting	Conducted in Germany; Setting: The psychotherapy outpatient clinic at the University of Marburg, Germany.
Line of therapy	1st line
Duration of study	Intervention + follow up: 8 weeks treatment or 8 weeks waiting then 8 weeks treatment with 6 months follow-up.
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Persisting tinnitus for at least 6 months and participants said tinnitus was disturbing.
Stratum	Overall: Not reported.
Subgroup analysis within study	Not applicable:
Inclusion criteria	Participants rated their tinnitus annoyance on a visual analogue scale from 0 to 10 and those with >3 were included.
Exclusion criteria	Not reported.
Recruitment/selection of patients	ENT-offices, website of a tinnitus self-help group and local newspapers.
Age, gender and ethnicity	Age - Mean (SD): 45.5 (12.8%) in the intervention group and 48 (15.3%) in the waiting list group. . Gender

	(M:F): Intervention group 59.1%/40.9% and waiting list group 40%/60%. 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
Extra comments	Illness duration was 4.5 (5.3) years in the intervention group and 8.3 (7.7) years in the waiting list group, but this difference was found to be non-significant. Illness severity on a scale of 0 to 10 showed a mean of 6.5 (1.7) in the intervention group and 5.9 (1.6) in the waiting list group, this was also non-significant. .
Indirectness of population	No indirectness
Interventions	(n=23) Intervention 1: Cognitive behavioural therapy (Biofeedback). Treatment program consisting of 1 pre-assessment session, 7 treatment sessions, and a final session summarising the intervention strategies and conducting the post-assessment. All sessions lasted approximately 1 hour. The training was manual-guided and also included handouts (e.g., on the following topics: basic information on ear and the hearing system; information processes involved in tinnitus; the vicious circle of tinnitus annoyance, muscular reactivity, and selective attention; and aspects of tinnitus maintenance, modulating factors, coping strategies, etc... Duration 8 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Therapists were 5 graduate students under supervision of experienced psychotherapists.). (n=20) Intervention 2: Control group - i.e. no psychological therapy. Waiting list control group. Duration 8 weeks. Concurrent medication/care: Not reported. 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: COGNITIVE BEHAVIOURAL THERAPY (BIOFEEDBACK) versus I.E NO PSYCHOLOGICAL THERAPY

Protocol outcome 1: Tinnitus distress
- Actual outcome: Tinnitus distress at 8 weeks; Group 1: mean 27.14 Not applicable (SD 13.3); n=22, Group 2: mean 28.47 Not applicable (SD 14.5); n=20; TQ total score - tinnitus distress 0-84 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 1, Reason: Discontinued intervention; Group 2 Number missing: 0
- Actual outcome: Tinnitus distress at 6 months; Group 1: mean 24.82 Not applicable (SD 17.9); n=22, Group 2: mean 28.11 Not applicable (SD 17.5); n=19;

TQ total score - tinnitus distress 0-84 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 1, Reason: Discontinued intervention; Group 2 Number missing: 1, Reason: Discontinued intervention Protocol outcome 2: Quality of life - Actual outcome: Health life satisfaction at 6 months; Group 1: mean 54 Not applicable (SD 35.4); n=22, Group 2: mean 46.53 Not applicable (SD 45.2); n=19 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 1, Reason: Discontinued intervention; Group 2 Number missing: 1, Reason: Discontinued intervention - Actual outcome: Health life satisfaction at 8 weeks; Group 1: mean 63.22 Not applicable (SD 36.4); n=22, Group 2: mean 62.68 Not applicable (SD 33.1); n=20 Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 1, Reason: Discontinued intervention; Group 2 Number missing: 0 Protocol outcome 3: Tinnitus loudness - Actual outcome: Tinnitus loudness at 8 weeks; Group 1: mean 3.63 Not applicable (SD 1.3); n=22, Group 2: mean 4.12 Not applicable (SD 1.76); n=20; Tinnitus diary 0-10 Top=High is poor outcome; Comments: For 1 week before treatment, 1 week at the end of treatment, and 1 week at follow-up, patients filled in a tinnitus diary rating the subjective loudness of their tinnitus. They rated this three times per day. Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 1, Reason: Discontinued intervention; Group 2 Number missing: 0 - Actual outcome: Tinnitus loudness at 6 months; Group 1: mean 4.04 Not applicable (SD 2); n=22, Group 2: mean 3.87 Not applicable (SD 1.7); n=19; Tinnitus loudness diary 0-10 Top=High is poor outcome; Comments: For 1 week before treatment, 1 week at the end of treatment, and 1 week at follow-up, patients filled in a tinnitus diary rating the subjective loudness of their tinnitus. They rated this three times per day. Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 1, Reason: Discontinued intervention; Group 2 Number missing: 1, Reason: Discontinued intervention
Protocol outcomes not reported by the study	Tinnitus annoyance; Quality of life (tinnitus); Severity; Anxiety; Depression; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	**Scott 1985[55]**
Study type	RCT (Patient randomised; Parallel)

Number of studies (number of participants)	1 (n=24)
Countries and setting	Conducted in Sweden; Setting: Department of Audiology of the University Hospital, Uppsala.
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 10 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: The patients underwent a cochleo-vestibular investigation comprising tone audiogram, speech audiogram, stapedius reflex threshold, stapedius reflex decay, brainstem response audiometry and electronystagmography. None of the patients had had tinnitus for less than one year.
Stratum	Overall: Not applicable
Subgroup analysis within study	Not applicable
Inclusion criteria	Not reported but all had some form of hearing impairment. All patients had tinnitus of grade 2 or 3.
Exclusion criteria	Not reported
Recruitment/selection of patients	Patients referred to the Department of Audiology of the University Hospital, Uppsala.
Age, gender and ethnicity	Age - Mean (range): Men 50.6 (36-62) years; women 54.2 (36-72) years. Gender (M:F): 11/13. 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
Extra comments	All had some form of hearing impairment.
Indirectness of population	No indirectness
Interventions	(n=12) Intervention 1: Cognitive behavioural therapy (behavioural therapy). The psychological treatment comprised relaxation training, training of self-control by distraction exercises with the aim of reducing the discomfort from tinnitus and the application of the method in situations associated with tinnitus. The participant firstly had an interview to assess what significance the tinnitus had on the patient's life, i.e. a behavioural analysis. When the aim of the treatment had been discussed with the patient, relaxation training was given with exercises in progressive relaxation. The patients were instructed to practise relaxation between sessions. Specific problems in relaxing were discussed from the reported results of the practising. Between each session the same items that had been introduced in the treatment session were practised as often as possible. Emphasis was placed on independent training throughout the training programme, as this was a prerequisite for the use of the method in real-life situations. The next step was training in conditioned relaxation. To be able to relax on cue, the patient associated a relaxed state with slow, relaxed breathing and the word "relax". The training was then focused on quick relaxation i.e. the patient was to put himself in a state of deep relaxation by silently saying the cue word and taking a few deep breaths. The treatment then continued with training of

	distraction with the help of exercises to relocate attention. The aim of this perceptual restructuring was that the patients, by self-suggestion, should transfer their attention from their tinnitus to something unrelated to this phenomenon. The perceptual restructuring began with a presentation by the therapist of a situation associated with tinnitus, when their attention was focused on the tinnitus, quick relaxation was introduced. When relaxed they were instructed to imagine themselves in a pleasant situation, incompatible with tinnitus, and afterwards to report the effects on the tinnitus. Step-by-step the patient practised with imagined situations associated with increasing tinnitus discomfort. When the patient became more skilled, the therapist gradually decreased the instructions. The third, main part of therapy was the application of the method in the patient's daily life. The same exercises were used as previously, except that now training took place in real situations. At first the therapist accompanied the patient and helped him or her to apply the self-control technique. Finally, the patients were instructed to use the technique on their own. Duration 10 one-hour sessions during a 2-3 week period. . Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Psychologist with similar training in behaviour therapy). Comments: None of the patients had previously undergone any form of behaviour therapy. A few patients had brief contacts with a psychologist but otherwise they had no experience of psychotherapy. (n=12) Intervention 2: Control group - i.e. no psychological therapy. Waiting list group. After 10 weeks the group received the same as the treatment group. . Duration 10 weeks waiting then the same as the treatment group.. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Not applicable (No treatment until 10 weeks and then the same psychologists as the treatment group.).
Funding	Other (Bank of Sweden Tercentenary Foundation, grant no. 83/16:1)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY (BEHAVIOURAL THERAPY) versus I.E NO PSYCHOLOGICAL THERAPY

Protocol outcome 1: Tinnitus annoyance
- Actual outcome: Irritation: retrospective at Post-treatment; Group 1: mean 2.18 Not reported (SD 1.43); n=12, Group 2: mean 2.73 Not reported (SD 1.37); n=12; VAS 1-10 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No differences between the groups for baseline demographics; Group 1 Number missing: 0; Group 2 Number missing: 2

Protocol outcome 2: Tinnitus loudness - Actual outcome: Subjective tinnitus loudness: direct at Post-treatment; Group 1: mean 6.25 Not reported (SD 2.02); n=12, Group 2: mean 7.21 Not reported (SD 1.81); n=12; VAS 1-10 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No differences between the groups for baseline demographics; Group 1 Number missing: 0; Group 2 Number missing: 2 - Actual outcome: Subjective tinnitus loudness: retrospective at Post-treatment; Group 1: mean 5.99 Not reported (SD 2.44); n=12, Group 2: mean 7 Not reported (SD 2.01); n=12; VAS 1-10 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No differences between the groups for baseline demographics; Group 1 Number missing: 0; Group 2 Number missing: 2 Protocol outcome 3: Depression - Actual outcome: Depression: retrospective at Post-treatment; Group 1: mean 1.92 Not reported (SD 1.17); n=12, Group 2: mean 2.84 Not reported (SD 1.34); n=12; VAS 1-10 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: No differences between the groups for baseline demographics; Group 1 Number missing: 0; Group 2 Number missing: 2	
Protocol outcomes not reported by the study	Tinnitus distress; Quality of life (tinnitus); Quality of life; Severity; Anxiety; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Study	**Weise 2008[59]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=130)
Countries and setting	Conducted in Germany; Setting: Outpatient treatment centre for psychological interventions at the University of Marburg between January 2005 and November 2007
Line of therapy	Not applicable
Duration of study	Follow up (post intervention): 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Duration of tinnitus and tinnitus annoyance assessed using the 12 questions of the mini-TQ. This then established those who had tinnitus for more than 6 months with serious or severe annoyance.

Stratum	Overall: Not applicable
Subgroup analysis within study	Not applicable
Inclusion criteria	Have tinnitus for more than 6 months (chronic tinnitus); have serious or severe tinnitus annoyance (total score of at least 47 in the Tinnitus Questionnaire; Goebel & Hiller, 1998); and be between 16 and 75 years of age.
Exclusion criteria	Patients with a mild degree of annoyance, or with tinnitus following Meniere's disease, as well as patients with psychosis or seriously disabling brain damage (e.g. craniocerebral injury or dementia) were excluded.
Recruitment/selection of patients	Newspaper articles and an article on the website of the German Tinnitus Association (Deutsche Tinnitus-Liga e. V.).
Age, gender and ethnicity	Age - Mean (SD): 49.46 (11.83) IG; 52.93 (11.92) WLG. Gender (M:F): 29/23 in IG group; 33/26 in WLG. 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
Extra comments	Duration of tinnitus 5.74 (5.19) in the intervention group and 7.05 (8.25) in the waiting list group; illness severity: 7.21 (1.50) in the intervention group and 7.31 (1.34) in the waiting list group
Indirectness of population	No indirectness
Interventions	(n=63) Intervention 1: Cognitive behavioural therapy. Biofeedback-based behavioural intervention. Individual therapy sessions conducted by 4 trained therapists. Each session contained biofeedback as well as CBT elements and followed a structured manual (Weise, heineck, & Rief, 2007). The biofeedback component followed the intervention guidelines of Flor and Schwartz (2003). EMG biofeedback in all sessions facilitated muscle relaxation and the learning of control over physiological functions. Training included relaxation training, threshold training, and quick shifts between tension and relaxation. The fifth session onward several training units were provided without feedback or delayed feedback to improve self efficacy. Homework was to transfer the learned self-control skills into everyday life. The other main component of the treatment was a collection of tinnitus-specific CBT techniques that were found effective in previous studies. First session provided information about tinnitus, hearing, and possible causes and to explain the treatment rationale. Sessions 2 and 3 focused on the influence of stress on tinnitus maintenance and severity. The importance of cognitions and emotions in relation to tinnitus explained and demonstrated in sessions 4-8. Coping strategies and alternative cognitions were developed. Sessions 8-10 practiced directing attention toward and away from their tinnitus. Session 11 focused on avoidance behaviour in social situations.. Duration Twelve 1 hour sessions over 3 months. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (4 therapists). (n=67) Intervention 2: Control group - i.e. no psychological therapy. Waiting list group. Duration 3 months.

	Concurrent medication/care: Not reported. 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 (German Research Foundation Grant Ri574/12-1)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus I.E NO PSYCHOLOGICAL THERAPY

Protocol outcome 1: Tinnitus distress
- Actual outcome: Tinnitus Questionnaire (TQ) total score at 3 months; Group 1: mean 32.52 Not reported (SD 15.96); n=52, Group 2: mean 49.54 Not reported (SD 13.75); n=59; TQ 0-84 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low, Comments - ; Indirectness of outcome: No indirectness ; Baseline details: No statistically significant differences; Group 1 Number missing: 11; Group 2 Number missing: 4
- Actual outcome: Diary: distress at 3 months; Group 1: mean 4.18 Not reported (SD 1.65); n=52, Group 2: mean 5.22 Not reported (SD 1.78); n=59; VAS 0-10 Top=High is poor outcome
Risk of bias: All domain - ; Indirectness of outcome: No indirectness

Protocol outcome 2: Severity
- Actual outcome: Global Severity Index of the SCL-90-R at 3 months; Group 1: mean 0.75 Not reported (SD 0.56); n=52, Group 2: mean 0.76 Not reported (SD 0.5); n=59
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low, Comments - ; Indirectness of outcome: No indirectness ; Baseline details: No statistically significant differences; Group 1 Number missing: 11; Group 2 Number missing: 4

Protocol outcome 3: Tinnitus loudness
- Actual outcome: Diary: loudness at 3 months; Group 1: mean 4.36 Not reported (SD 1.82); n=52, Group 2: mean 5.69 Not reported (SD 1.68); n=59; VAS 0-10 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low, Comments - ; Indirectness of outcome: No indirectness ; Baseline details: No statistically significant differences; Group 1 Number missing: 11; Group 2 Number missing: 4

Protocol outcome 4: Depression
- Actual outcome: Beck Depression Index at 3 months; Group 1: mean 12.29 Not reported (SD 8.91); n=52, Group 2: mean 13.38 Not reported (SD 7.38); n=59; BDI 0-63 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low, Comments - ; Indirectness of outcome: No indirectness ; Baseline details: No statistically significant differences; Group 1 Number missing: 11; Group 2 Number missing: 4 Protocol outcome 5: Sleep - Actual outcome: Diary: sleep disturbance at 3 months; Group 1: mean 3.21 (SD 2.2); n=52, Group 2: mean 4.58 (SD 2.71); n=59; VAS 0-10 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, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low, Comments - ; Indirectness of outcome: No indirectness ; Baseline details: No statistically significant differences; Group 1 Number missing: 11; Group 2 Number missing: 4	
Protocol outcomes not reported by the study	Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Anxiety; Depression and anxiety; Safety; Tolerability; Side effects

Study	**Weise 2016[60]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=124)
Countries and setting	Conducted in Sweden; Setting: At home on computer.
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 1 year
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: THI and Mini TQ used and tinnitus confirmed by ENT.
Stratum	Overall: Not applicable
Subgroup analysis within study	Not applicable: Not applicable
Inclusion criteria	Aged 18 or more; subjective tinnitus (confirmed by an ENT specialist) with a duration of at least 6 months, present for most times of the day; total score of 38 or higher on THI or of 13 or higher on the Mini-Tinnitus Questionnaire; no tinnitus-specific psychological tinnitus treatment within the last 2 years; tinnitus as the primary problem and not only a consequence of a medical disease, as determined by ENT specialist; access to computer with internet connection; sufficient reading and writing skills; capacity of minimum 2 hours' time per week for a period of 10 weeks to complete the treatment.
Exclusion criteria	Medical or psychiatric condition; acute suicidality.
Recruitment/selection of patients	Articles on several health-related websites, public media and self-help groups.

Age, gender and ethnicity	Age - Mean (SD): iCBT group: 47.81 (12.26) range 18-67; DF group: 47.51 (14.07) range 20-83. Gender (M:F): iCBT group: 25/37; DF group: 25/37. 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
Extra comments	.
Indirectness of population	No indirectness
Interventions	(n=62) Intervention 1: Cognitive behavioural therapy. Internet-based CBT self-help program, based on a well-established CBT self-help manual. 12 mandatory and 6 optional text module. Mandatory modules covered strategies to reduce tinnitus-related distress (e.g., relaxation, exposure to tinnitus, or cognitive restructuring. Optional modules addressed problems potentially associated with tinnitus, such as sleep, hearing, or concentration problems. Module structure: theory and general information, exercises, worksheets and solutions for common problems. Participants downloaded text modules or spoken instructions; read the theoretical framework and conducted exercises in daily life. Once per week, patients could communicate with the therapist via a secured encrypted webpage. Therapists were instructed to spend a maximum of 10min/week per patient for e-mail correspondence. . Duration 10 weeks. Concurrent medication/care: Not applicable. . 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=62) Intervention 2: Control group - i.e. no psychological therapy. A confidential, moderated, online discussion forum. Participants were invited to discuss tinnitus-related topics with other participants of the discussion forum. Every week, the therapists posted a new discussion topic, which was related to tinnitus (e.g., representation of tinnitus in public media), but did not target strategies to improve tinnitus-related distress. If patients came up with treatment-related topics by themselves, they were free to discuss them. Therapists monitored postings to assure their appropriateness. . Duration 10 weeks. Concurrent medication/care: Not applicable.. 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 (Grant from Swedish Research Council (HEAD Linnaeus Grant No. 349-2007-8654).)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus I.E NO PSYCHOLOGICAL THERAPY

Protocol outcome 1: Severity
- Actual outcome: THI - to assess tinnitus-related distress and severity at 10 weeks; Group 1: mean 32.56 Not applicable (SD 16.5); n=58, Group 2: mean 45.77 Not applicable (SD 15.06); n=61; THI 0-100 Top=High is poor outcome; Comments: Hedges g (95% CI):
0.83 (0.47-1.20)
Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness, Comments: Possible indirectness as it is measuring distress and severity within the THI, whereas our outcomes were individual. ; Group 1 Number missing: 4, Reason: n=3 discontinued participation in iCBT and n=1 did not start iCBT treatment; Group 2 Number missing: 1, Reason: Discontinued participation in DF
- Actual outcome: THI - to assess tinnitus-related distress and severity at 1 year; Group 1: mean 29.14 Not applicable (SD 19.87); n=55. Only the treatment arm was reported in the 1 year follow-up.

Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness, Comments: Possible indirectness as it is measuring distress and severity within the THI, whereas our outcomes were individual. ; Group 1 Number missing: 4, Reason: n=3 discontinued participation in iCBT and n=1 did not start iCBT treatment; Group 2 Number missing: 1, Reason: Discontinued participation in DF
- Actual outcome: Mini-TQ - to assess tinnitus-related distress and severity at 10 weeks; Group 1: mean 8.51 Not applicable. (SD 4.47); n=58, Group 2: mean 13.26 Not applicable. (SD 4.27); n=61; Mini-TQ 0-20 Top=High is poor outcome; Comments: Hedges g (95% CI): 1.08 (0.71 to 1.64)
Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness, Comments: Possible indirectness as it is measuring distress and severity within the Mini-TQ, whereas our outcomes were individual. ; Group 1 Number missing: 4, Reason: n=3 discontinued participation in iCBT and n=1 did not start iCBT treatment; Group 2 Number missing: 1, Reason: Discontinued participation in DF
- Actual outcome: Mini-TQ - to assess tinnitus-related distress and severity at 1 year; Group 1: mean 7.76 Not applicable (SD 5.29); n=55,
Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness, Comments: Possible indirectness as it is measuring distress and severity within the Mini-TQ, whereas our outcomes were individual. ; Group 1 Number missing: 4, Reason: n=3 discontinued participation in iCBT and n=1 did not start iCBT treatment; Group 2 Number missing: 1, Reason: Discontinued participation in DF

Protocol outcome 2: Anxiety
- Actual outcome: HADS Anxiety at 10 weeks; Group 1: mean 6.65 Not applicable (SD 3.4); n=58, Group 2: mean 7.84 Not applicable (SD 3.32); n=61; HADS - Anxiety 0-21 Top=High is poor outcome; Comments: Hedges g 0.35 (0.00 to 0.71)
Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 4, Reason: n=3 discontinued participation in iCBT and n=1 did not start iCBT treatment; Group 2 Number missing: 1, Reason: Discontinued participation in DF
- Actual outcome: HADS Anxiety at 1 year; Group 1: mean 6.34 Not applicable (SD 3.52); n=55. Only the treatment arm was reported in the 1 year follow-up.
Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 4, Reason: n=3 discontinued participation in iCBT and n=1 did not start iCBT treatment; Group 2 Number missing: 1, Reason: Discontinued participation in DF

Protocol outcome 3: Depression - Actual outcome: HADS Depression at 10 weeks; Group 1: mean 5.27 Not applicable (SD 3.72); n=58, Group 2: mean 6.66 Not applicable (SD 3.98); n=61; HADS depression 0-21 Top=High is poor outcome Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 4, Reason: n=3 discontinued participation in iCBT and n=1 did not start iCBT treatment; Group 2 Number missing: 1, Reason: Discontinued participation in DF - Actual outcome: HADS Depression at 1 year; Group 1: mean 5.3 Not applicable (SD 4.08); n=55. Only the treatment arm was reported in the 1 year follow-up. Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 4, Reason: n=3 discontinued participation in iCBT and n=1 did not start iCBT treatment; Group 2 Number missing: 1, Reason: Discontinued participation in DF Protocol outcome 4: Sleep - Actual outcome: ISI - insomnia severity index at 10 weeks; Group 1: mean 7.67 Not applicable (SD 5.4); n=58, Group 2: mean 11.56 Not applicable (SD 6.36); n=61; ISI 0-28 Top=High is poor outcome; Comments: Hedges g (95% CI): 0.66 (0.30 to 1.02) Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness; Group 1 Number missing: 4, Reason: n=3 discontinued participation in iCBT and n=1 did not start iCBT treatment; Group 2 Number missing: 1, Reason: Discontinued participation in DF - Actual outcome: ISI - insomnia severity index at 1 year; Group 1: mean 9.34 Not applicable (SD 5.92); n=55. Only the treatment arm was reported in the 1 year follow-up. Risk of bias: All domain - Very high, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 4, Reason: n=3 discontinued participation in iCBT and n=1 did not start iCBT treatment; Group 2 Number missing: 1, Reason: Discontinued participation in DF	
Protocol outcomes not reported by the study	Tinnitus distress; Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Tinnitus loudness; Depression and anxiety; Safety; Tolerability; Side effects

Study	**Westin 2011[62]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=44)
Countries and setting	Conducted in Sweden; Setting: Three audiological departments in Sweden
Line of therapy	Not applicable

Duration of study	Intervention + follow up: 10 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Adults
Subgroup analysis within study	Not applicable
Inclusion criteria	Participants needed (a) to have tinnitus as their primary problem (b) to be ≥18 years old, (c) to have a score of ≥30 on the Tinnitus Handicap Inventory (THI), (d) a duration of tinnitus of ≥6 months, (e) not to suffer from a severe psychiatric disorder, (f) not to have previously received a psychological or sound-generator treatment for tinnitus (g) not be in need of immediate medical consultation and (h) have hearing thresholds which would allow for the use of wearable sound generators (i.e., in severe hearing loss the sound stimulation may not be heard or need to be so loud that the person would have problems hearing conversations)
Exclusion criteria	Based on inclusion criteria. No further details reported.
Recruitment/selection of patients	Participants were recruited from three different audiology departments and via advertisements and articles in newspapers over the course of 17 months. All were registered as regular patients within the public health care system and diagnostic assessments and treatments were provided within that system.
Age, gender and ethnicity	Age - Mean (SD): 51.5 years. Gender (M:F): 1/1. Ethnicity: Not reported
Further population details	1. Mild hearing loss: Not stated / Unclear 2. People with learning disability or cognitive impairment: Not stated / Unclear 3. Profoundly deaf: Not stated / Unclear
Extra comments	Mean duration of tinnitus: 7.7 years (ACT group 6.77 years, waiting-list control group 7.11 years
Indirectness of population	No indirectness
Interventions	(n=22) Intervention 1: Acceptance and commitment therapy. Acceptance and commitment therapy (ACT) intervention was delivered in an individual format using a treatment manual developed according to ACT treatment principles as outlined by Hayes, Strosahl, and Wilson 1999. All participants in the ACT condition received weekly sessions. A maximum of 10 sessions was offered and the average number of treatment sessions was 8.38 sessions. The sessions were set to be 60 minutes, with exception for session two, which was set to 75 minutes. The first sessions contained evaluating the patients' current coping strategies in relation to tinnitus, examining costs and benefits and the introduction to mindfulness. The treatment further consisted of mindfulness and acceptance training to promote goal-directed behaviours in valued life-domains. The mindfulness exercises involved approaching the tinnitus sound and related reactions in a non-judgmental way. Other treatment components included working with values, and life goals, changing tinnitus related behavioural patterns, and psychoeducation regarding tinnitus. . Duration 18 months. Concurrent medication/care: Each session ended with a homework assignment such as daily ACT-ratings. . Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (Eight therapists delivered the intervention. Six

	were master program students and two were clinical psychologists). (n=22) Intervention 2: Control group - i.e. no psychological therapy. Participants in the waiting-list control group received a written confirmation that they were included in the study, and received information about when their treatment would start. Treatment started after 10 weeks. Participants received CBT either in an individual, self-help or a group format. . Duration 10 weeks. Concurrent medication/care: Some participants declined treatment after time on the waiting-list, no further details reported. 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 (Grants from the Medical Research Council of Southeast Sweden and the Swedish Council for Working Life and Social Research.)

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

Protocol outcome 1: Quality of life
- Actual outcome for Adults: Quality of life at 10 weeks (post-treatment); Group 1: mean 2.78 (SD 1.53); n=22, Group 2: mean 1.92 (SD 1.77); n=22; Quality of Life Inventory (QOLI) Not reported 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; Group 2 Number missing: 0

Protocol outcome 2: Severity
- Actual outcome for Adults: Tinnitus severity at 10 weeks (post-treatment); Group 1: mean 27.43 (SD 19.18); n=22, Group 2: mean 48.29 (SD 21.04); n=22; Tinnitus Handicap Inventory (THI) 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; Group 2 Number missing: 0

Protocol outcome 3: Depression
- Actual outcome for Adults: Depression at 10 weeks (post-treatment); Group 1: mean 3.2 (SD 3.47); n=22, Group 2: mean 6.2 (SD 5.13); n=22; Hospital Anxiety and Depression Scale (HADS) (depression subscale) 0-21 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; Group 2 Number missing: 0

Protocol outcome 4: Anxiety
- Actual outcome for Adults: Anxiety at 10 weeks (post-treatment); Group 1: mean 3.6 (SD 3.14); n=22, Group 2: mean 7.2 (SD 5.57); n=22; Hospital Anxiety and Depression Scale (HADS) (anxiety subscale) 0-21 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; Group 2 Number missing: 0 Protocol outcome 5: Sleep - Actual outcome for Adults: Sleep at 10 weeks (post-treatment); Group 1: mean 9.25 (SD 5.17); n=22, Group 2: mean 11.8 (SD 6.14); n=22; Insomnia Severity Index (ISI) 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; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Tinnitus distress; Tinnitus annoyance; Quality of life (tinnitus); Tinnitus loudness; Depression and anxiety; Safety; Tolerability; Side effects

Study	**Zachriat 2004[64]**
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=52)
Countries and setting	Conducted in Germany; Setting: Therapy and Counselling Centre of the Department of Clinical Psychology and Psychotherapy at the University of Gottingen.
Line of therapy	Not applicable
Duration of study	Intervention time: 11 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: All patients were diagnosed by their physicians as suffering from tinnitus without a treatable organic disease.
Stratum	Overall: Not reported
Subgroup analysis within study	Not applicable
Inclusion criteria	Tinnitus for a period of more than 3 months; absence of treatable organic causes of tinnitus; absence of Morbus Meniere; hearing capacity sufficient for communication within groups; tinnitus disability score >/= 25 (see tinnitus questionnaire (TQ)); no ongoing psychotherapy or masker treatment.
Exclusion criteria	Not reported
Recruitment/selection of patients	Newspaper announcements about the research project.
Age, gender and ethnicity	Age - Mean (SD): 53.8 (11.8) in TCT group; 51.6 (11.0) in HT group; 46.1 (10.6) in EDU group. Gender (M:F): 16/11 in TCT group; 20/10 in HT group; 14/6 in EDU group . 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
Extra comments	Tinnitus duration in months, mean (SD): TCT group 68.5 (61.9); HT group 65.4 (64.3); EDU group: 90.2 (79.0). Hearing deficit: TCT group 50%; HT group 35.7%; EDU group: 45%.
Indirectness of population	No indirectness
Interventions	(n=29) Intervention 1: Cognitive behavioural therapy. Cognitive-behavioural tinnitus coping training (TCT). Administered in groups of 6-8 tinnitus patients. After a first (psychoeducational) session and a subsequent intermission of 4 weeks to test for effect of education alone, TCT continued. Treatment was given in adherence to a detailed training manual (Kroner Herwig 1997). The following interventions were included: educated on physiological and psychological factors playing a role in tinnitus; taught relaxation exercises and the use of attention distraction strategies. Also trained to identify cognitive processes (e.g. automatic thoughts regarding tinnitus, worrying, catastrophising) and emotional responses (e.g. depression, anger, helplessness, fear) relating to tinnitus and to modify them. Avoidance behaviour was analysed and cognitive-behavioural coping techniques were introduced in order to learn how to cope with tinnitus as a stressor and to cope with stress as an exacerbator of tinnitus. Attitudes towards illness and health, and their influence on dealing with tinnitus were explored. Finally coping with relapse was discussed. . Duration 11 weekly sessions of 90-120 minutes. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (5 therapists were postgraduate female psychologists, who were intensively schooled in delivering the training in strict adherence to the manuals. Regular supervision took place.). (n=23) Intervention 2: Tinnitus counselling - Education including coping strategies. EDU consisted of a single treatment session in which patients were informed about the physiology and psychology of tinnitus. The content of this session was, in main parts, identical to the first session of TCT. The educational part of HT (session 1) also corresponded closely to the educational contents of EDU. They were encouraged to use the information to improve their coping with tinnitus. . Duration 1 session. Concurrent medication/care: Not reported. Indirectness: No indirectness Further details: 1. Who is delivering therapy (mental health professional (psychologists and therapists) versus non-mental health professional): Mental health professional (5 therapists were postgraduate female psychologists, who were intensively schooled in delivering the training in strict adherence to the manuals. Regular supervision took place.).
Funding	Other (Grant from the Geers Foundation. The noise generators were donated by Hansaton, the batteries by Energiser and support in fitting noise generators by Reuter Acoustics.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: COGNITIVE BEHAVIOURAL THERAPY versus EDUCATION INCLUDING COPING STRATEGIES Protocol outcome 1: Tinnitus distress - Actual outcome: Tinnitus questionnaire (TQ) at 11 weeks; Group 1: mean 33.9 Not reported (SD 16.2); n=27, Group 2: mean 37.65 Not reported (SD 14.19); n=20; TQ 0-84 Top=High is poor outcome Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Higher number of males in the EDU group (74% compared to 59.3%) in the TCT group and tinnitus duration in months, mean (SD) higher in EDU group 90.2 (79) than the TCT group 68.5 (61.9). No details on the statistical significance at baseline. ; Group 1 Number missing: 2, Reason: Dropouts; Group 2 Number missing: 3, Reason: Dropouts Protocol outcome 2: Tinnitus loudness - Actual outcome: Subjective loudness - tinnitus perception diary at 11 weeks; Group 1: mean 4.18 Not reported (SD 1.74); n=27, Group 2: mean 4.47 Not reported (SD 2.2); n=20; Comments: Baseline values were 4.93 (1.34) in the TCT group versus 4.93 (2.02) in the EDU group Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - High, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Higher number of males in the EDU group (74% compared to 59.3%) in the TCT group and tinnitus duration in months, mean (SD) higher in EDU group 90.2 (79) than the TCT group 68.5 (61.9). No details on the statistical significance at baseline. ; Group 1 Number missing: 2, Reason: Dropouts; Group 2 Number missing: 3, Reason: Dropouts - Actual outcome: Subjective loudness (SSR) at 11 weeks; Group 1: mean 3.7 Not reported (SD 1); n=27, Group 2: mean 4.15 Not reported (SD 0.49); n=20; Subjective change (SSR) Loudness 1-7 (1 very much improved, 4 no change 7 exacerbated). Top=High is poor outcome Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low, Crossover - Low, Subgroups - Low, Other 1 - Low, Other 2 - Low, Other 3 - Low; Indirectness of outcome: No indirectness ; Baseline details: Higher number of males in the EDU group (74% compared to 59.3%) in the TCT group and tinnitus duration in months, mean (SD) higher in EDU group 90.2 (79) than the TCT group 68.5 (61.9). No details on the statistical significance at baseline. ; Group 1 Number missing: 2, Reason: Dropouts; Group 2 Number missing: 3, Reason: Dropouts	
Protocol outcomes not reported by the study	Tinnitus annoyance; Quality of life (tinnitus); Quality of life; Severity; Anxiety; Depression; Depression and anxiety; Sleep; Safety; Tolerability; Side effects

Appendix E: Forest plots

Cognitive behavioural therapy

E.1 CBT versus waiting-list control

Figure 3: Tinnitus severity (post-treatment); GSI, scale not reported

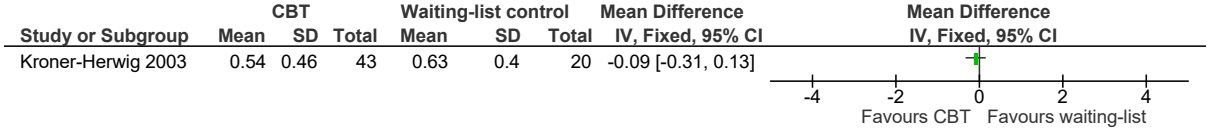
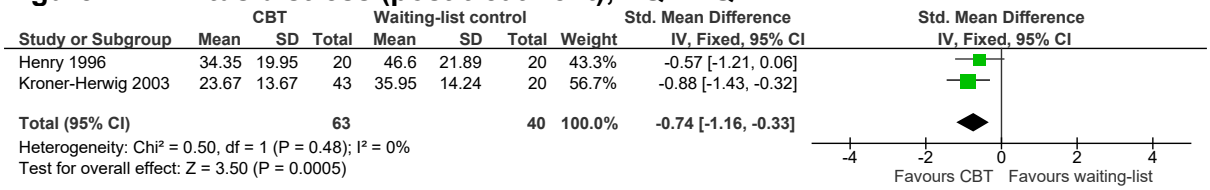


Figure 4: Tinnitus distress (post-treatment); TQ/TRQ



Scales: Henry 1996 (TRQ) – 0-104; Kroner-Herwig 2003 (TQ) – 0-84

Figure 5: Tinnitus distress (3 months); TRQ, scale 0-104

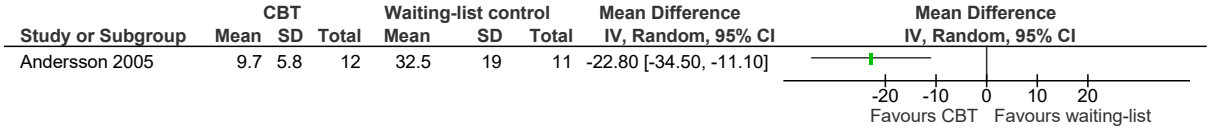


Figure 6: Tinnitus QoL (post-treatment); THQ, scale not reported

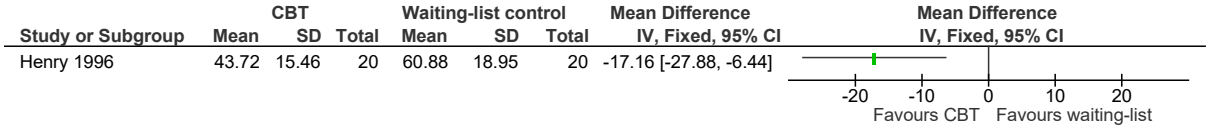
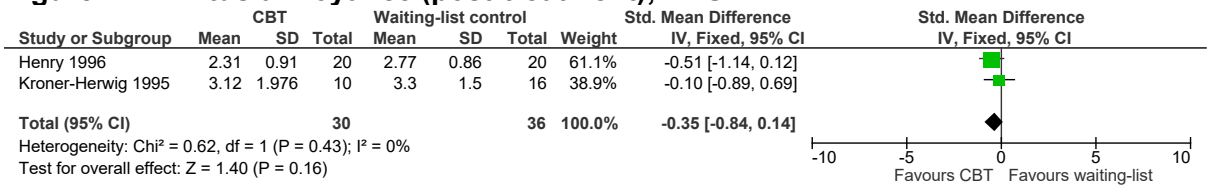
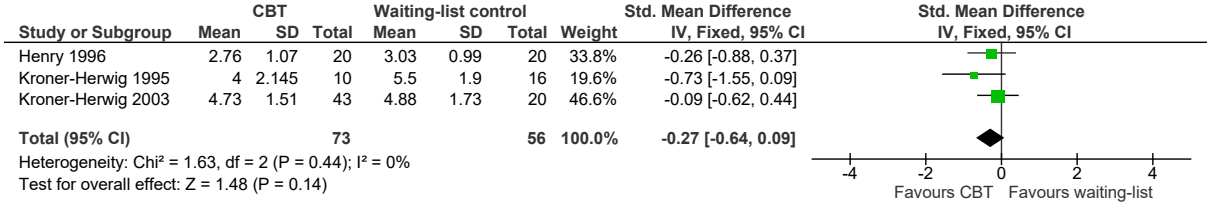


Figure 7: Tinnitus annoyance (post-treatment); VAS



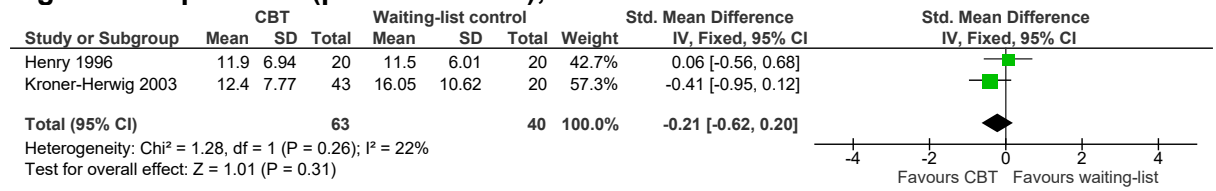
Scales: Henry 1996 – 0-4; Kroner-Herwig 1995 – 0-10

Figure 8: Tinnitus loudness (post-treatment); VAS



Scales: Henry 1996 – 0-4 (unclear); Kroner-Herwig 1995 – 0-10; Kroner-Herwig 2003 – 1-7

Figure 9: Depression (post-treatment);BDI/ADS



Scales: Henry 1996 (BDI) – 0-63; Kroner-Herwig 2003 (ADS) – 0-60

Figure 10: Depression (3 months); HADS, scale 0-21

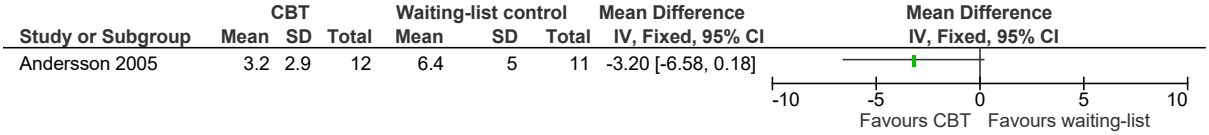


Figure 11: Anxiety (3 months); ASI, scale not reported

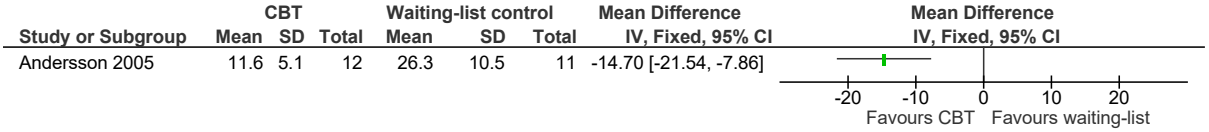


Figure 12: Anxiety (HADS) (3 months); HADS, scale 0-21

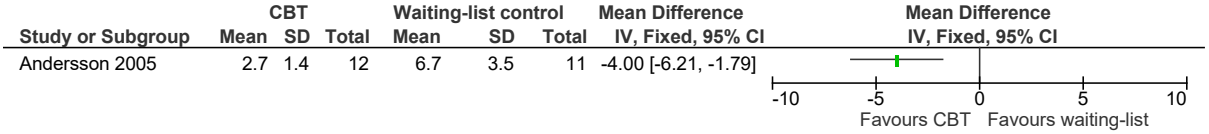
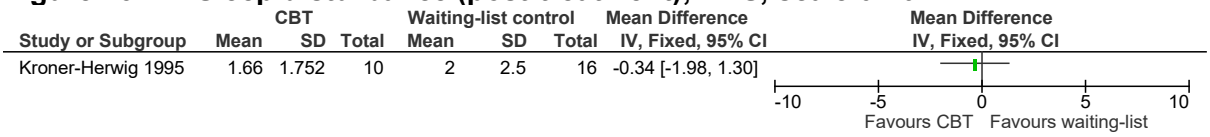


Figure 13: Sleep disturbance (post-treatment); VAS, scale 0-10



E.2 CBT versus control (masking)

Figure 14: Tinnitus severity (post-treatment); THI, scale 0-100

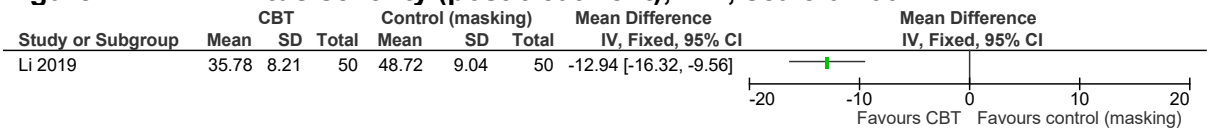


Figure 15: Depression (post-treatment); SCL-90 depression, subscale 1-5

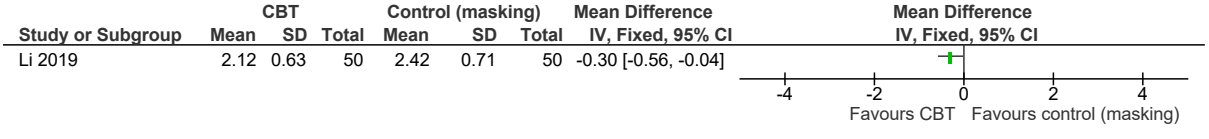
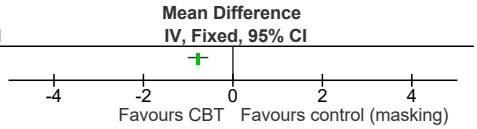


Figure 16: Anxiety (post-treatment); SCL-90 anxiety, subscale 1-5

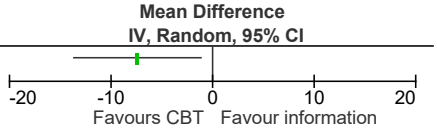
Study or Subgroup	CBT Mean	CBT SD	CBT Total	Control (masking) Mean	Control (masking) SD	Control (masking) Total	Mean Difference IV, Fixed, 95% CI
Li 2019	1.95	0.56	50	2.73	0.53	50	-0.78 [-0.99, -0.57]



E.3 CBT versus information only

Figure 17: Tinnitus distress (post-treatment); TQ, scale 0-84

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Information only Mean	Information only SD	Information only Total	Mean Difference IV, Random, 95% CI
Nyenhuis 2013	20	14.7	47	27.4	18	58	-7.40 [-13.65, -1.15]



Scale

Figure 18: Tinnitus distress (9 months); TQ, scale 0-84

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Information only Mean	Information only SD	Information only Total	Mean Difference IV, Fixed, 95% CI
Nyenhuis 2013	18.4	11.6	47	25.2	19.1	49	-6.80 [-13.09, -0.51]

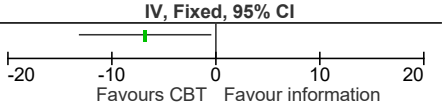


Figure 19: Depression (post-treatment); PHQ-D, scale not reported

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Information only Mean	Information only SD	Information only Total	Mean Difference IV, Fixed, 95% CI
Nyenhuis 2013	4.7	4.8	47	5.7	4.8	58	-1.00 [-2.85, 0.85]

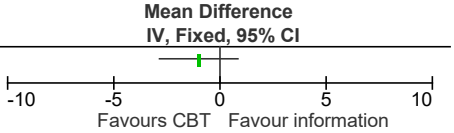
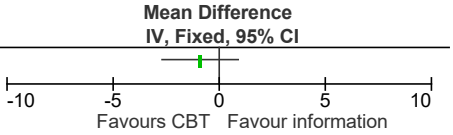


Figure 20: Depression (9 months); PHQ-D, scale not reported

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Information only Mean	Information only SD	Information only Total	Mean Difference IV, Fixed, 95% CI
Nyenhuis 2013	4.8	3.8	47	5.7	5.1	49	-0.90 [-2.69, 0.89]



E.4 CBT versus education

Figure 21: Tinnitus severity (Global Severity Index) (post-treatment)

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Education Mean	Education SD	Education Total	Mean Difference IV, Fixed, 95% CI
Kroner-Herwig 2003	0.54	0.46	43	0.53	0.4	16	0.01 [-0.23, 0.25]

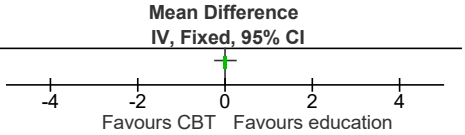
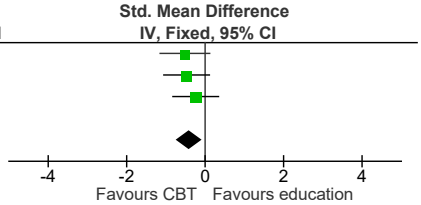


Figure 22: Tinnitus distress (post-treatment); TRQ/TQ

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Education Mean	Education SD	Education Total	Weight	Std. Mean Difference IV, Fixed, 95% CI
Henry 1996	34.35	19.95	20	45.45	22.28	20	29.7%	-0.51 [-1.15, 0.12]
Kroner-Herwig 2003	23.67	13.67	43	30.94	18.88	16	35.1%	-0.47 [-1.05, 0.11]
Zachriat 2004	33.9	16.2	27	37.65	14.19	20	35.1%	-0.24 [-0.82, 0.34]
Total (95% CI)			**90**			**56**	**100.0%**	**-0.40 [-0.75, -0.06]**

Heterogeneity: Chi² = 0.48, df = 2 (P = 0.79); I² = 0%
Test for overall effect: Z = 2.29 (P = 0.02)



Scales: Henry 1996 (TRQ) – 0-104; Kroner-Herwig 2003 and Zachriat 2004 (TQ) – 0-84

Figure 23: Tinnitus distress (12 months); TRQ, scale 0-104

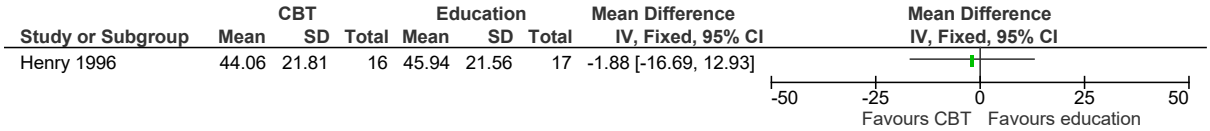


Figure 24: Tinnitus QoL (post-treatment); THQ, scale unclear

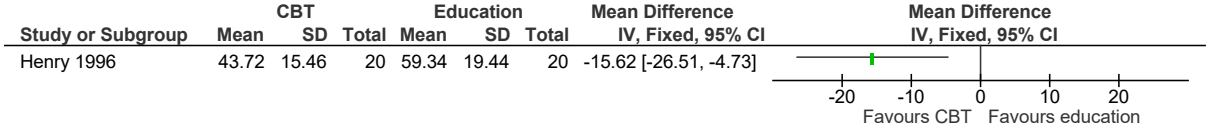


Figure 25: Tinnitus QoL (12 months); THQ, scale unclear

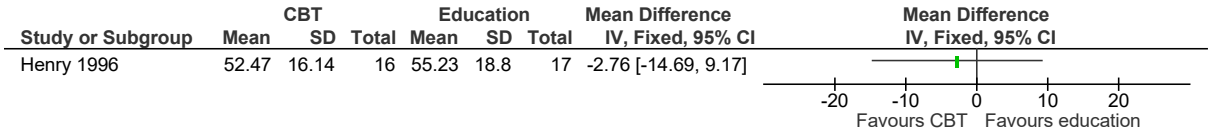
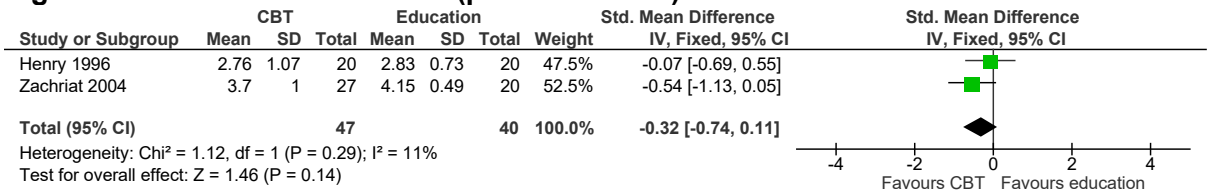


Figure 26: Tinnitus loudness (post-treatment)



Scales: Henry 1996 (VAS) – 0-4; Zachriat 2004 (subjective change) – 1-7

Figure 27: Tinnitus loudness (diary) (post-treatment)

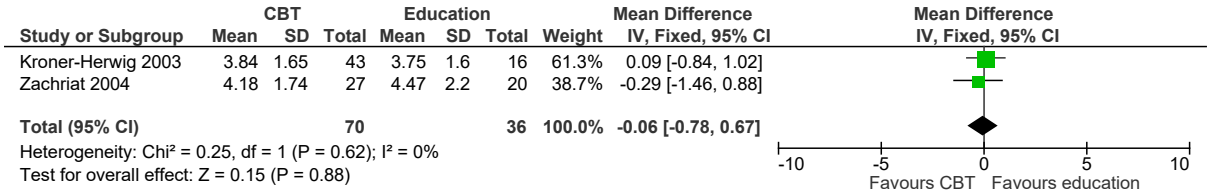


Figure 28: Tinnitus annoyance (post-treatment); VAS, scale 0-4 (unclear)

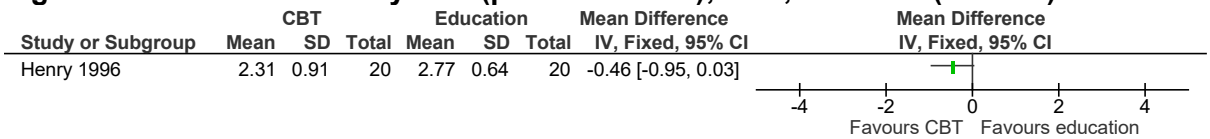


Figure 29: Tinnitus annoyance (12 months); VAS, scale 0-4 (unclear)

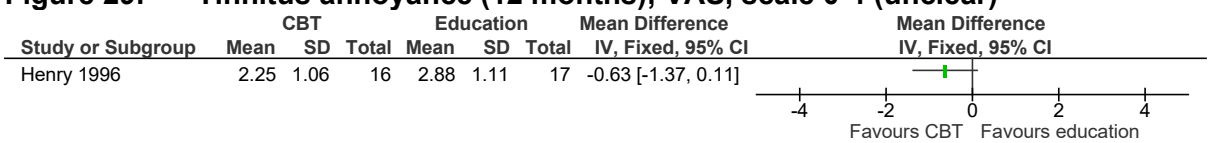


Figure 30: Depression (post-treatment); BDI, scale 0-63

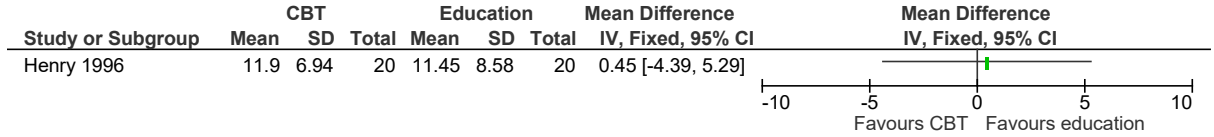
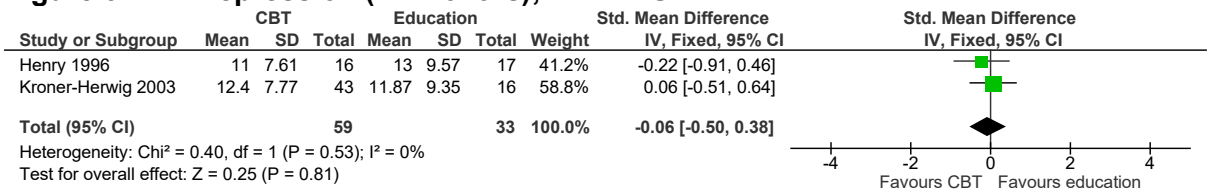


Figure 31: Depression (12 months); BDI/ADS



Scales: Henry 1996 (BDI) – 0-63; Kroner-Herwig 2003 (ADS) – 0-60

E.5 CBT versus relaxation

Figure 32: Tinnitus severity (post-treatment); Global Severity Index, scale not reported

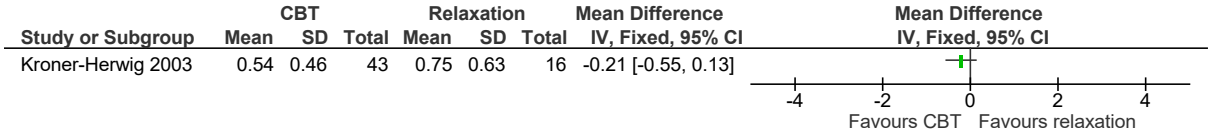


Figure 33: Tinnitus distress (post-treatment); TQ, scale 0-84

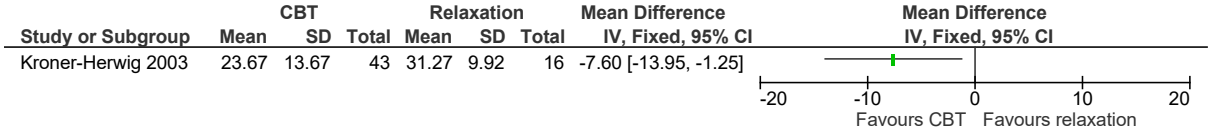


Figure 34: Tinnitus loudness (post-treatment); diary, scale 1-7

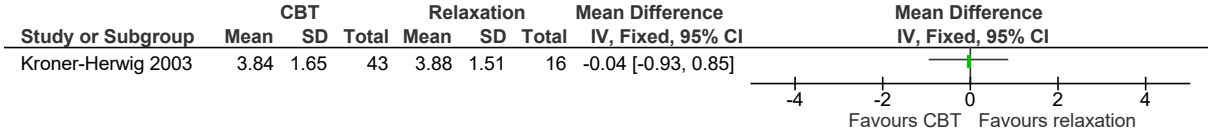
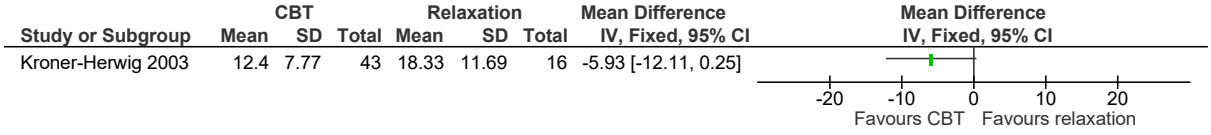


Figure 35: Depression (post-treatment); ADS, scale 0-60



E.6 CBT versus passive relaxation training

Figure 36: Tinnitus distress (post-treatment); TEQ, scale not reported

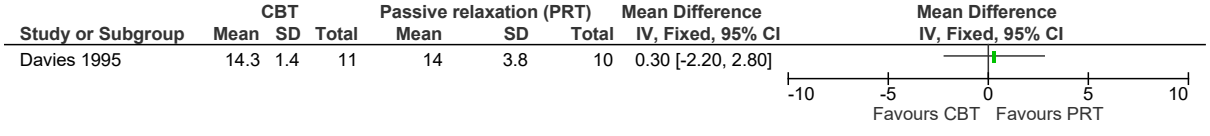


Figure 37: Tinnitus distress (4 months); TEQ, scale not reported

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Passive relaxation (PRT) Mean	PRT SD	PRT Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	15.3	2.1	10	15.5	2.1	6	-0.20 [-2.33, 1.93]

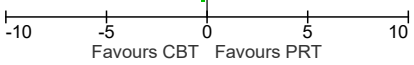


Figure 38: Tinnitus loudness (post-treatment); tinnitus loudness rating, scale 1-5

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Passive relaxation (PRT) Mean	PRT SD	PRT Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	4	0.66	11	4	0.81	7	0.00 [-0.72, 0.72]

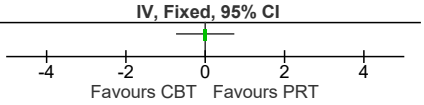


Figure 39: Tinnitus loudness (4 months); tinnitus loudness rating, scale 1-5

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Passive relaxation (PRT) Mean	PRT SD	PRT Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	4.3	0.48	10	4.33	0.51	6	-0.03 [-0.54, 0.48]

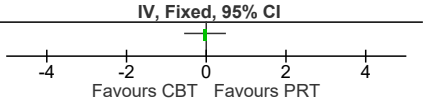


Figure 40: Tinnitus annoyance (post-treatment); annoyance rating, scale not reported

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Passive relaxation (PRT) Mean	PRT SD	PRT Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	3.6	0.69	11	2.85	0.69	7	0.75 [0.10, 1.40]

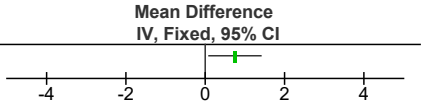


Figure 41: Tinnitus annoyance (4 months); annoyance rating, scale not reported

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Passive relaxation (PRT) Mean	PRT SD	PRT Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	4	0.81	10	4	0.63	6	0.00 [-0.71, 0.71]

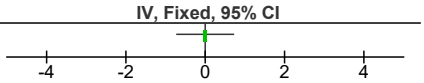


Figure 42: Depression (1 month); BDI, 0-63

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Passive relaxation (PRT) Mean	PRT SD	PRT Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	7.8	7	10	11.16	11.1	6	-3.36 [-13.24, 6.52]

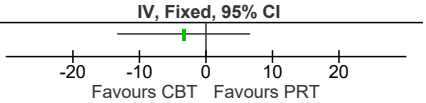


Figure 43: Anxiety (1 month); STAI-state, scale 20-80

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Passive relaxation (PRT) Mean	PRT SD	PRT Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	39.2	11.7	10	45.66	16.2	6	-6.46 [-21.31, 8.39]

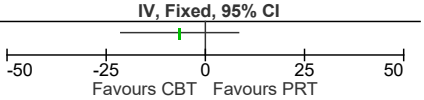


Figure 44: Anxiety (1 month); STAI-trait, scale 20-80

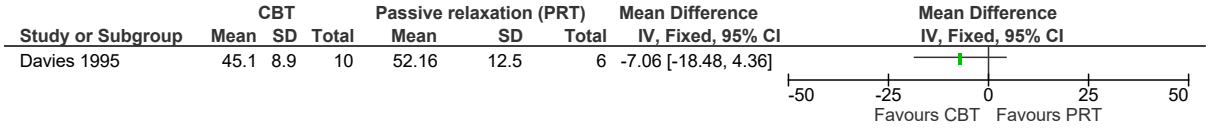


Figure 45: Insomnia (post-treatment); TEQ, scale not reported

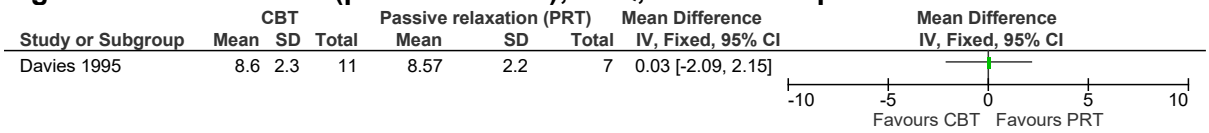
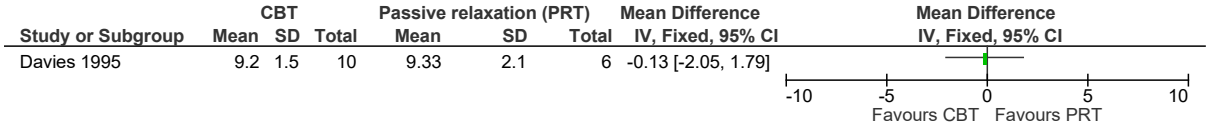


Figure 46: Insomnia (4 months); TEQ, scale not reported



E.7 CBT versus applied relaxation training

Figure 47: Tinnitus distress (post-treatment);TEQ, scale not reported

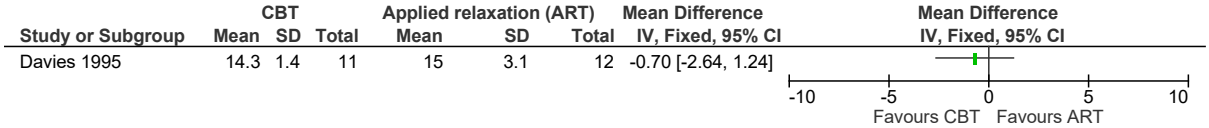


Figure 48: Tinnitus distress (4 months);TEQ, scale not reported

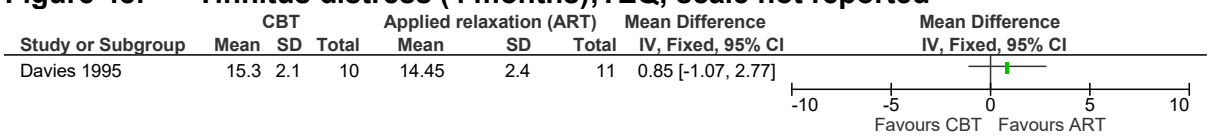


Figure 49: Tinnitus loudness (post-treatment); tinnitus loudness rating, scale 1-5

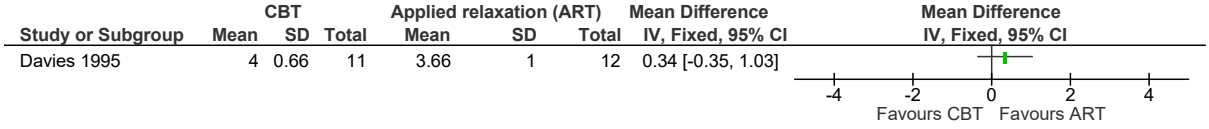


Figure 50: Tinnitus loudness (4 months); tinnitus loudness rating, scale 1-5

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Applied relaxation (ART) Mean	ART SD	ART Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	4.3	0.48	10	4	0.77	11	0.30 [-0.24, 0.84]

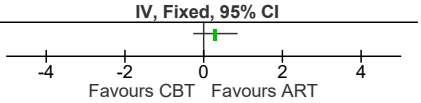


Figure 51: Tinnitus annoyance (post-treatment); annoyance rating, scale not reported

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Applied relaxation (ART) Mean	ART SD	ART Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	3.6	0.69	11	3.08	0.9	12	0.52 [-0.13, 1.17]

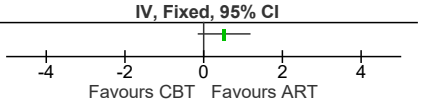


Figure 52: Tinnitus annoyance (4 months); annoyance rating, scale not reported

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Applied relaxation (ART) Mean	ART SD	ART Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	4	0.81	10	3.18	1.1	11	0.82 [-0.00, 1.64]

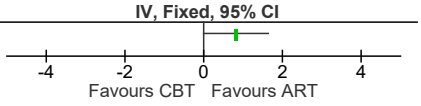


Figure 53: Depression (1 month); BDI, 0-63

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Applied relaxation (ART) Mean	ART SD	ART Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	7.8	7	10	6.83	4.6	12	0.97 [-4.09, 6.03]

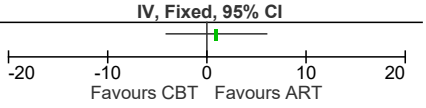


Figure 54: Anxiety (1 month); STAI-state, scale 20-80

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Applied relaxation (ART) Mean	ART SD	ART Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	39.2	11.7	10	40.41	14.4	12	-1.21 [-12.12, 9.70]

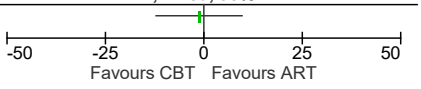


Figure 55: Anxiety (1 month); STAI-trait, scale 20-80

Study or Subgroup	CBT Mean	CBT SD	CBT Total	Applied relaxation (ART) Mean	ART SD	ART Total	Mean Difference IV, Fixed, 95% CI
Davies 1995	45.1	8.9	10	44.33	9.1	12	0.77 [-6.78, 8.32]

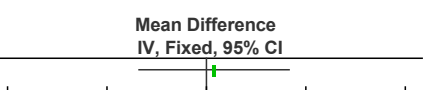


Figure 56: Insomnia (post-treatment);TEQ, scale not reported

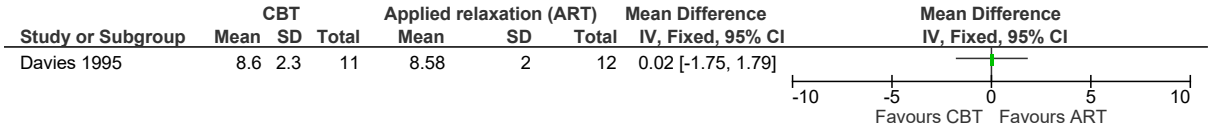
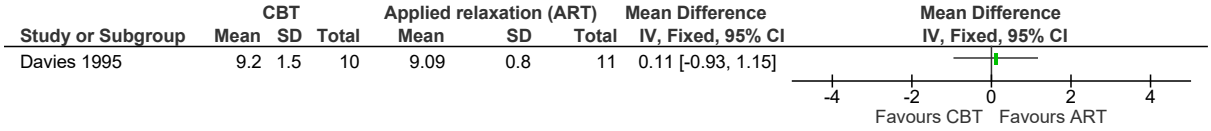


Figure 57: Insomnia (4 months);TEQ, scale not reported



Source: <Insert Source text here>

E.8 CBT-stepped intervention versus usual care

Figure 58: Tinnitus severity (post-treatment) (step 1); TQ, scale 0-84

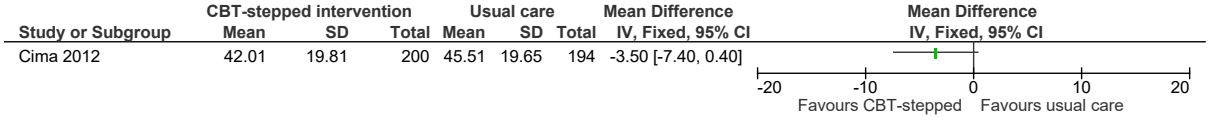


Figure 59: Tinnitus severity (12 months) (step 2); TQ, scale 0-84

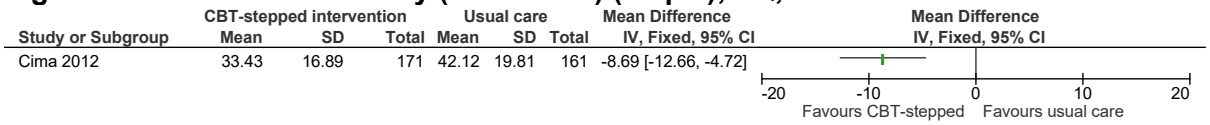


Figure 60: Quality of life (post-treatment) (step 1); HUI, scale -0.36-1

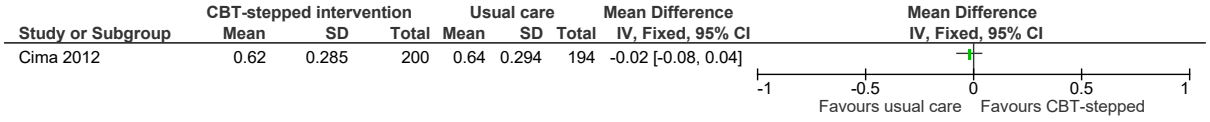


Figure 61: Quality of life (12 months) (step 2); HUI, scale -0.36-1

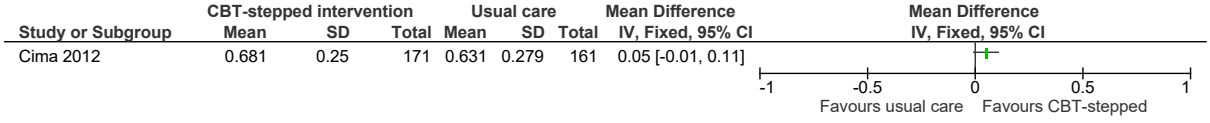


Figure 62: Tinnitus-related quality of life (post-treatment) (step 1); THI, scale 0-100

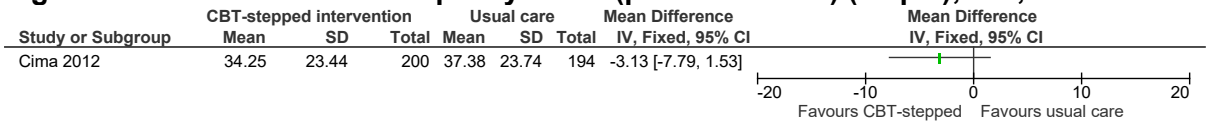


Figure 63: Tinnitus-related quality of life (12 months) (step 2); THI, scale 0-100

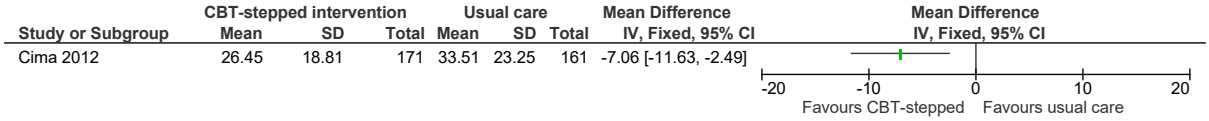


Figure 64: Depression and anxiety (post-treatment) (step 1); HADS, scale 0-42

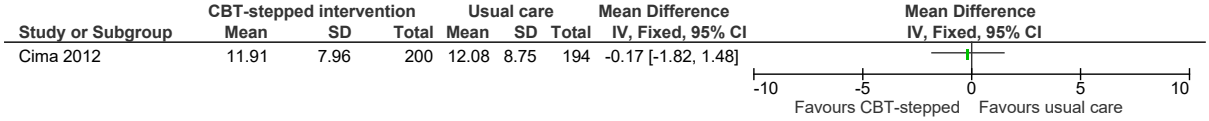
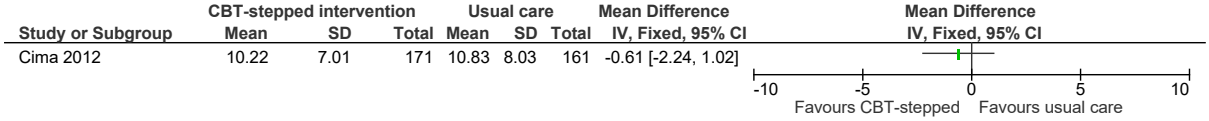
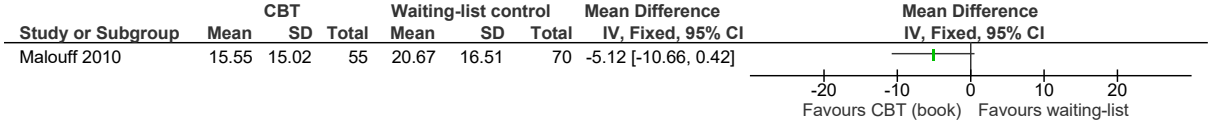


Figure 65: Depression and anxiety (12 months) (step 2); HADS, scale 0-42



E.9 CBT (self-help book) versus waiting-list control

Figure 66: Tinnitus distress (3 months); TRQ, scale 0-104



E.10 CBT (bibliotherapy/self-help) versus information only

Figure 67: Tinnitus distress (post-treatment); TQ, scale 0-84

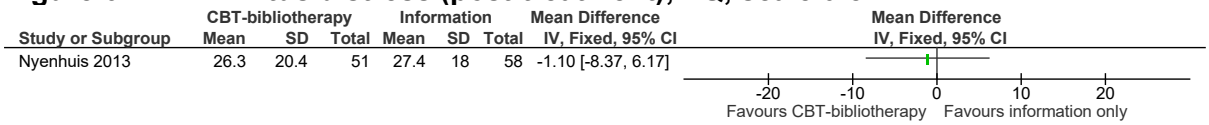


Figure 68: Tinnitus distress (9 months); TQ, scale 0-84

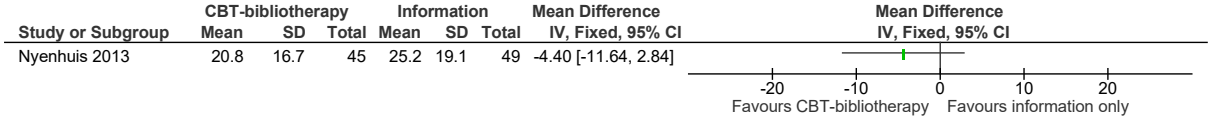


Figure 69: Depression (post-treatment); PHQ-D, scale not reported

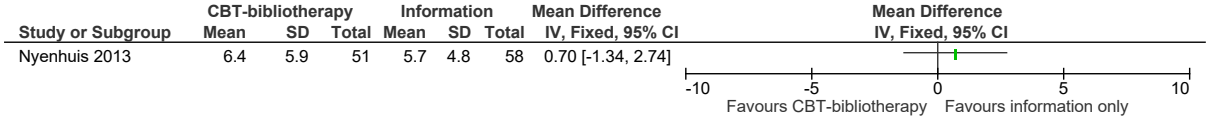
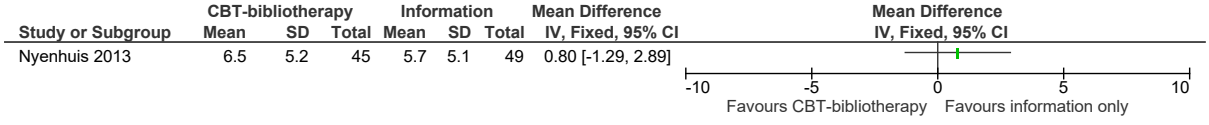


Figure 70: Depression (9 months); PHQ-D, scale not reported



E.11 CBT versus control (web discussion forum)

Figure 71: Tinnitus distress (post-treatment); Mini-TQ, scale 0-24

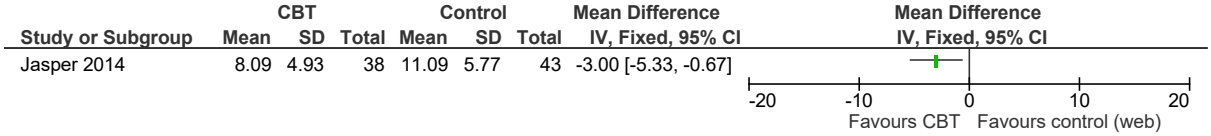


Figure 72: Tinnitus severity (post-treatment); THI, scale 0-100

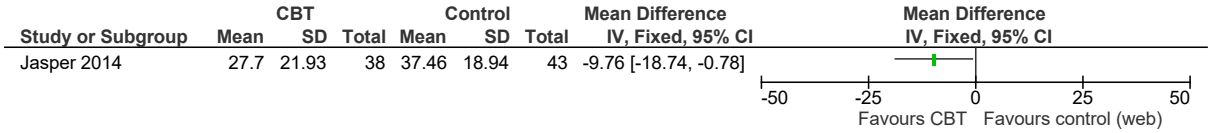


Figure 73: Depression (post-treatment); HADS, scale 0-21

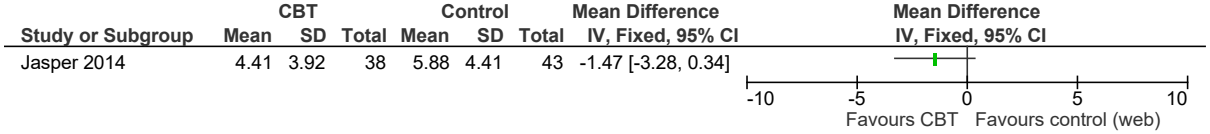


Figure 74: Anxiety (post-treatment); HADS, scale 0-21

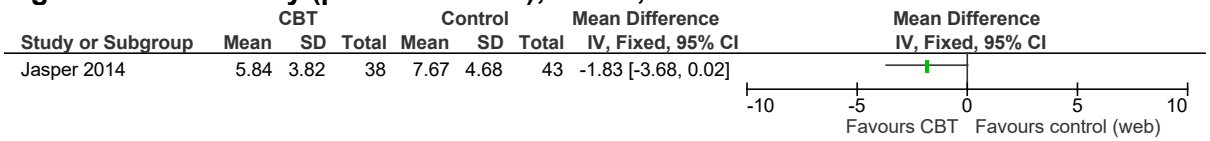
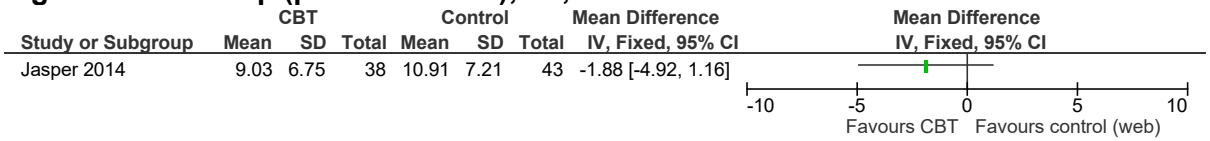


Figure 75: Sleep (post-treatment); ISI, scale 0-28



E.12 iCBT versus waiting-list control

Figure 76: Tinnitus annoyance (post-treatment); VAS, scale 0-10

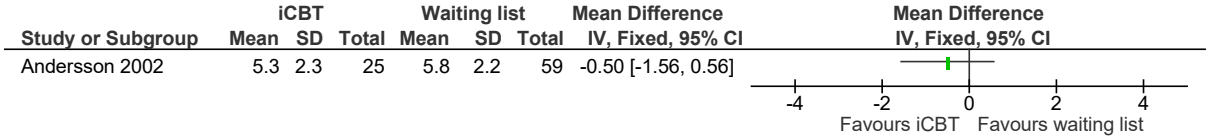


Figure 77: Tinnitus loudness (post-treatment); VAS, scale 0-10

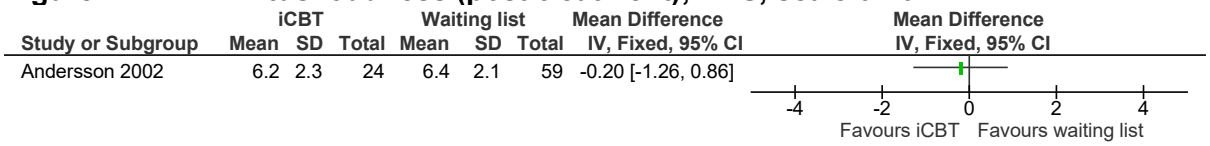


Figure 78: Depression (post-treatment); HADS, scale 0-21

Study or Subgroup	iCBT Mean	iCBT SD	iCBT Total	Waiting list Mean	Waiting list SD	Waiting list Total	Mean Difference IV, Fixed, 95% CI
Andersson 2002	5.2	4.1	24	6	3.79	48	-0.80 [-2.76, 1.16]

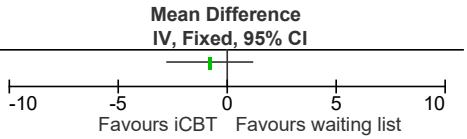


Figure 79: Depression (1 year); HADS, scale 0-21

Study or Subgroup	iCBT Mean	iCBT SD	iCBT Total	Waiting list Mean	Waiting list SD	Waiting list Total	Mean Difference IV, Fixed, 95% CI
Andersson 2002	5.3	3.8	46	5.3	4	50	0.00 [-1.56, 1.56]

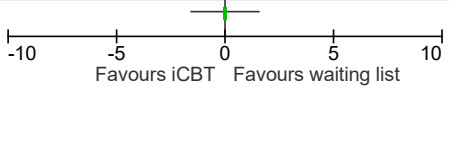


Figure 80: Anxiety (post-treatment); HADS, scale 0-21

Study or Subgroup	iCBT Mean	iCBT SD	iCBT Total	Waiting list Mean	Waiting list SD	Waiting list Total	Mean Difference IV, Fixed, 95% CI
Andersson 2002	5.9	3.6	24	6.8	4.8	48	-0.90 [-2.88, 1.08]

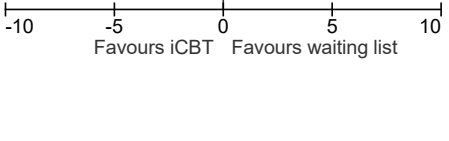


Figure 81: Anxiety (1 year); HADS, scale 0-21

Study or Subgroup	iCBT Mean	iCBT SD	iCBT Total	Waiting list Mean	Waiting list SD	Waiting list Total	Mean Difference IV, Fixed, 95% CI
Andersson 2002	6.1	3.5	46	6.4	5	50	-0.30 [-2.02, 1.42]

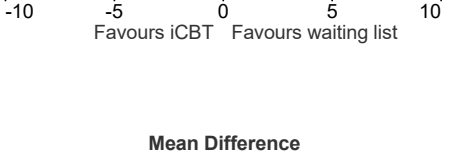


Figure 82: Sleep (post-treatment), VAS, scale 0-10

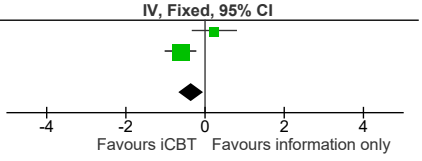
Study or Subgroup	iCBT Mean	iCBT SD	iCBT Total	Waiting list Mean	Waiting list SD	Waiting list Total	Mean Difference IV, Fixed, 95% CI
Andersson 2002	7.3	2.3	24	6.7	2.1	58	0.60 [-0.47, 1.67]

E.13 iCBT versus information only

Figure 83: Tinnitus distress (post-treatment); TQ/TRQ, scale 0-84

Study or Subgroup	Internet-based CBT Mean	Internet-based CBT SD	Internet-based CBT Total	Information only Mean	Information only SD	Information only Total	Weight	Std. Mean Difference IV, Fixed, 95% CI
Abbott 2009	16.64	12.3	28	13.96	9.7	23	32.4%	0.24 [-0.32, 0.79]
Nyenhuis 2013	17.6	12.7	52	27.4	18	58	67.6%	-0.62 [-1.00, -0.24]
Total (95% CI)			**80**			**81**	**100.0%**	**-0.34 [-0.66, -0.03]**

Heterogeneity: Chi² = 6.18, df = 1 (P = 0.01); I² = 84%
Test for overall effect: Z = 2.13 (P = 0.03)



Scales: Abbott 2009 (TRQ) – 0-104; Nyenhuis 2013 (TQ) – 0-84

Figure 84: Tinnitus distress (9 months); TQ, scale 0-84

Study or Subgroup	Internet-based CBT Mean	Internet-based CBT SD	Internet-based CBT Total	Information only Mean	Information only SD	Information only Total	Mean Difference IV, Fixed, 95% CI
Nyenhuis 2013	19.4	14.8	44	25.2	19.1	49	-5.80 [-12.71, 1.11]

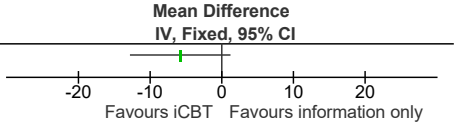


Figure 85: Tinnitus annoyance (post-treatment); VAS, scale 0-10

Study or Subgroup	Internet-based CBT Mean	SD	Total	Information only Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Abbott 2009	3.38	1.4	28	3.61	1.7	23	-0.23 [-1.10, 0.64]

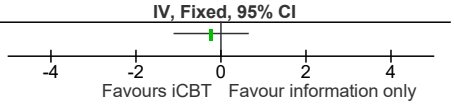


Figure 86: Tinnitus loudness (post-treatment); VAS, scale 0-10

Study or Subgroup	Internet-based CBT Mean	SD	Total	Information only Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Abbott 2009	4.58	1.7	28	4.48	1.7	23	0.10 [-0.84, 1.04]

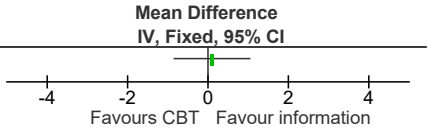
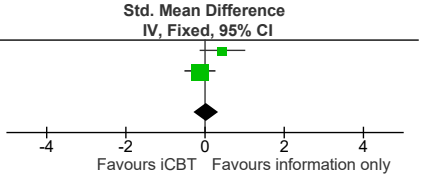


Figure 87: Depression (post-treatment); PHQ-D/DASS

Study or Subgroup	Internet-based CBT Mean	SD	Total	Information only Mean	SD	Total	Weight	Std. Mean Difference IV, Fixed, 95% CI
Abbott 2009	4.61	5.3	28	2.43	4.3	23	31.0%	0.44 [-0.12, 1.00]
Nyenhuis 2013	5.1	4.5	52	5.7	4.8	58	69.0%	-0.13 [-0.50, 0.25]
Total (95% CI)			**80**			**81**	**100.0%**	**0.05 [-0.26, 0.36]**

Heterogeneity: Chi² = 2.74, df = 1 (P = 0.10); I² = 63%
Test for overall effect: Z = 0.30 (P = 0.76)



Scales: Abbott 2009 (DASS) – 0-120; Nyenhuis 2013 (PHQ-D), scale not reported

Figure 88: Depression (9 months); PHQ-D, scale not reported

Study or Subgroup	Internet-based CBT Mean	SD	Total	Information only Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Nyenhuis 2013	5.9	5.3	44	5.7	5.1	49	0.20 [-1.92, 2.32]

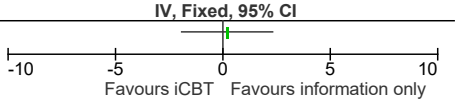


Figure 89: Anxiety (post-treatment); DASS, scale 0-120

Study or Subgroup	Internet-based CBT Mean	SD	Total	Information only Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Abbott 2009	3.79	3.8	28	3.09	4	23	0.70 [-1.46, 2.86]

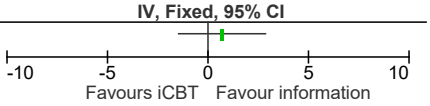
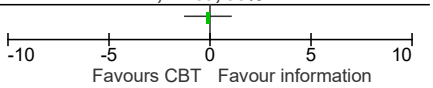


Figure 90: Sleep (post-treatment); VAS, scale 0-10

Study or Subgroup	Internet-based CBT Mean	SD	Total	Information only Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Abbott 2009	4.07	1.9	28	4.17	2.2	23	-0.10 [-1.24, 1.04]



E.14 iCBT versus tinnitus information counselling

Figure 91: Tinnitus severity (post-treatment); THI, scale 0-100

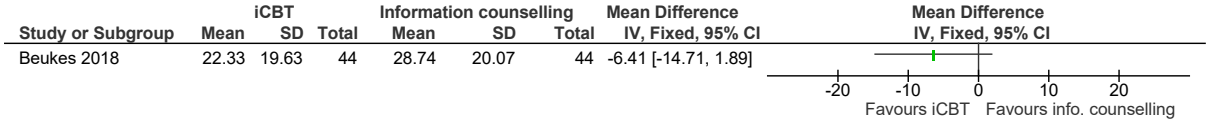


Figure 92: Tinnitus severity (2 months); THI, scale 0-100

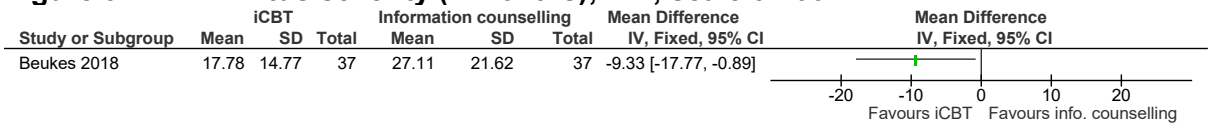


Figure 93: Tinnitus distress (post-treatment); TFI, scale 0-100

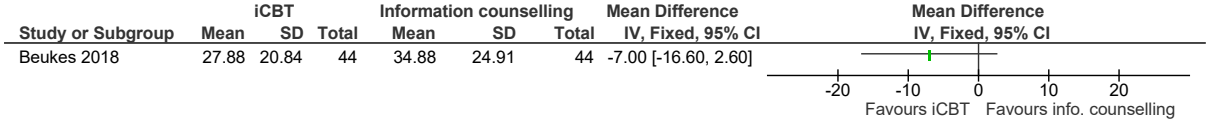


Figure 94: Tinnitus distress (2 months); TFI, scale 0-100

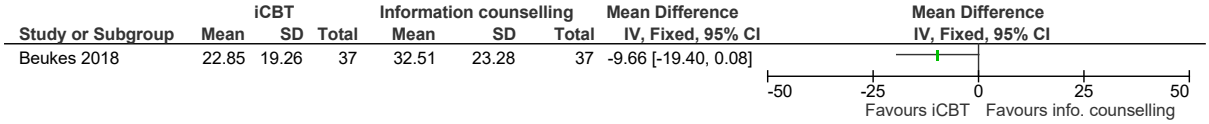


Figure 95: Quality of life (post-treatment); SWLS (Satisfaction With Life Scales, scale 5-35

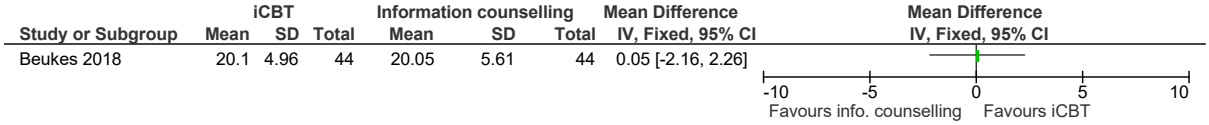


Figure 96: Quality of life (2 months); SWLS (Satisfaction With Life Scales, scale 5-35

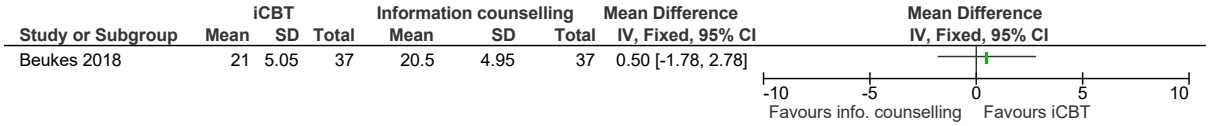


Figure 97: Depression (post-treatment); PHQ-9, scale 0-27

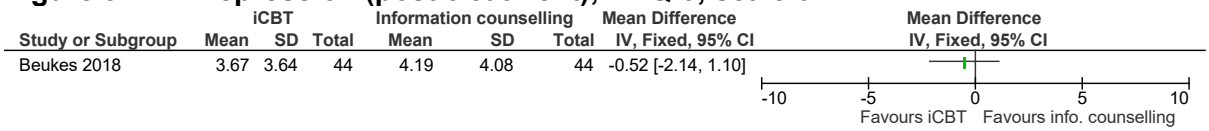


Figure 98: Depression (2 months); PHQ-9, scale 0-27

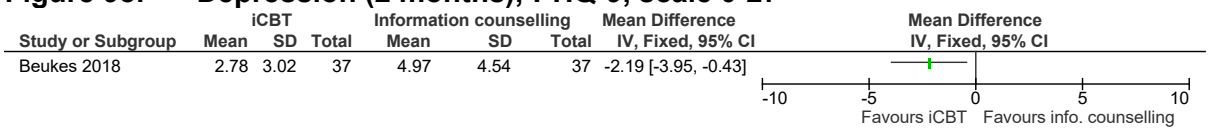


Figure 99: Anxiety (post-treatment); GAD-7, scale 0-21

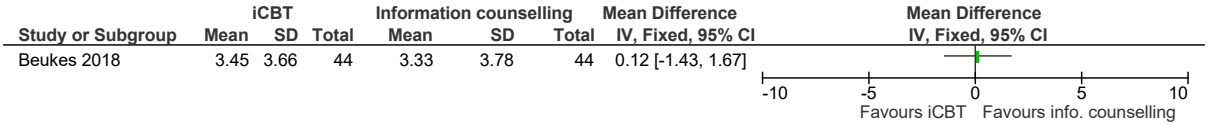


Figure 100: Anxiety (2 months); GAD-7, scale 0-21

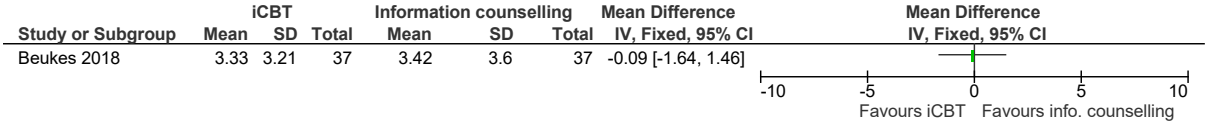


Figure 101: Sleep (post-treatment); ISI, scale 0-28

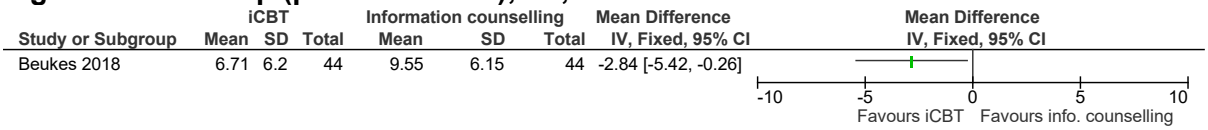
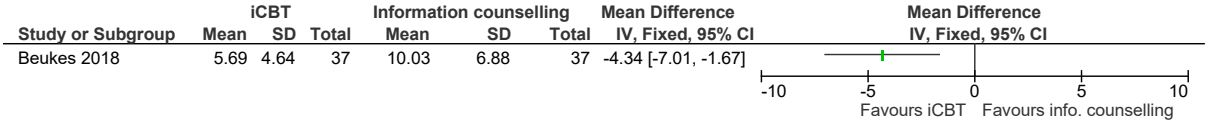


Figure 102: Sleep (2 months); ISI, scale 0-28



E.15 iCBT versus control (web discussion forum)

Figure 103: Tinnitus severity and distress (8-10 weeks); THI, scale 0-100

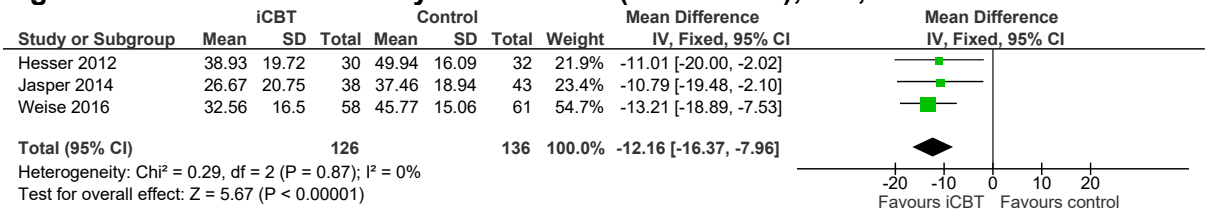


Figure 104: Tinnitus distress (8-10 weeks); Mini-TQ, scale 0-20

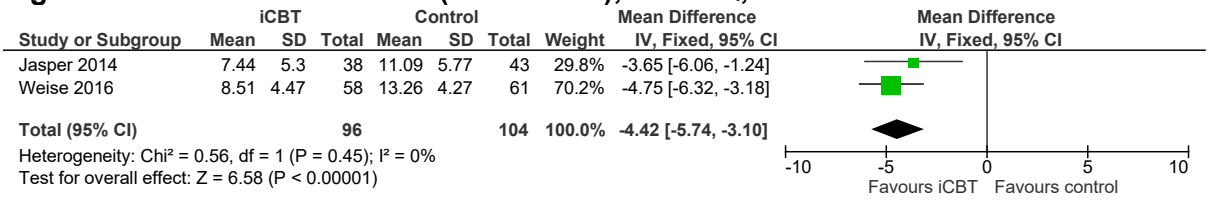


Figure 105: Quality of life (8 weeks); QoLI, scale not reported

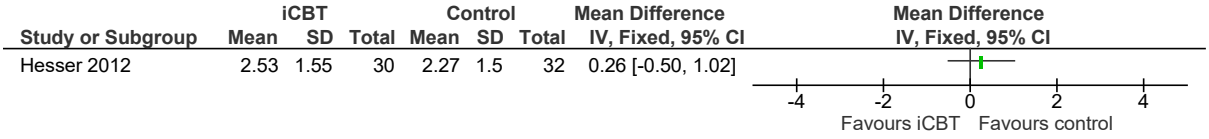


Figure 106: Depression (8-10 weeks); HADS, scale 0-21

Study or Subgroup	iCBT Mean	iCBT SD	iCBT Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Fixed, 95% CI
Hesser 2012	3.37	3.25	30	6.78	3.98	32	26.8%	-3.41 [-5.21, -1.61]
Jasper 2014	4.41	3.72	38	5.88	4.41	43	27.8%	-1.47 [-3.24, 0.30]
Weise 2016	5.27	3.72	58	6.66	3.98	61	45.5%	-1.39 [-2.77, -0.01]
Total (95% CI)			**126**			**136**	**100.0%**	**-1.95 [-2.89, -1.02]**

Heterogeneity: Chi² = 3.43, df = 2 (P = 0.18); I² = 42%
Test for overall effect: Z = 4.10 (P < 0.0001)

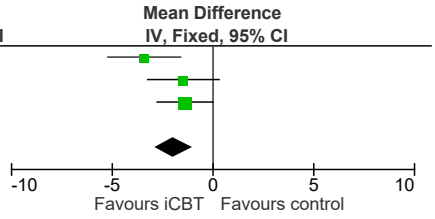


Figure 107: Anxiety (8-10 weeks); HADS, scale 0-21

Study or Subgroup	iCBT Mean	iCBT SD	iCBT Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Fixed, 95% CI
Hesser 2012	4.67	3.37	30	6.78	3.98	32	22.7%	-2.11 [-3.94, -0.28]
Jasper 2014	5.44	3.23	38	7.67	4.68	43	25.3%	-2.23 [-3.97, -0.49]
Weise 2016	6.65	3.4	58	7.84	3.32	61	52.1%	-1.19 [-2.40, 0.02]
Total (95% CI)			**126**			**136**	**100.0%**	**-1.66 [-2.53, -0.79]**

Heterogeneity: Chi² = 1.23, df = 2 (P = 0.54); I² = 0%
Test for overall effect: Z = 3.73 (P = 0.0002)

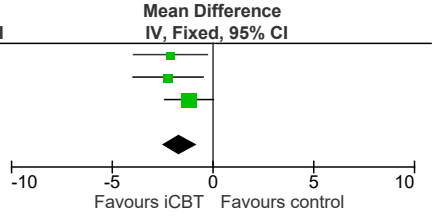
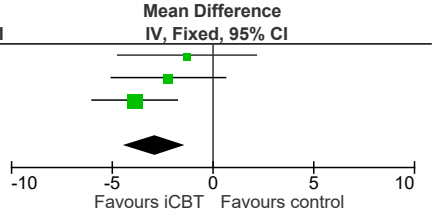


Figure 108: Sleep (8-10 weeks), ISI, scale 0-28

Study or Subgroup	iCBT Mean	iCBT SD	iCBT Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Fixed, 95% CI
Hesser 2012	9.93	6.85	30	11.22	6.97	32	19.5%	-1.29 [-4.73, 2.15]
Jasper 2014	8.7	5.8	38	10.91	7.21	43	28.8%	-2.21 [-5.05, 0.63]
Weise 2016	7.67	5.4	58	11.56	6.36	61	51.7%	-3.89 [-6.01, -1.77]
Total (95% CI)			**126**			**136**	**100.0%**	**-2.90 [-4.42, -1.38]**

Heterogeneity: Chi² = 1.91, df = 2 (P = 0.39); I² = 0%
Test for overall effect: Z = 3.73 (P = 0.0002)



E.16 iCBT versus iACT

Figure 109: Tinnitus distress and severity (8 weeks);THI, scale 0-100

Study or Subgroup	iCBT Mean	iCBT SD	iCBT Total	iACT Mean	iACT SD	iACT Total	Mean Difference IV, Fixed, 95% CI
Hesser 2012	38.93	19.72	30	31.94	14.54	33	6.99 [-1.64, 15.62]

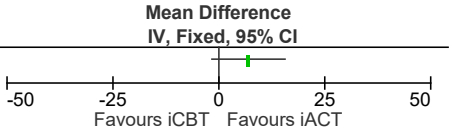


Figure 110: Tinnitus distress and severity (12 months); THI, scale 0-100

Study or Subgroup	iCBT Mean	iCBT SD	iCBT Total	iACT Mean	iACT SD	iACT Total	Mean Difference IV, Fixed, 95% CI
Hesser 2012	40.47	21.45	30	44.26	22.25	31	-3.79 [-14.76, 7.18]

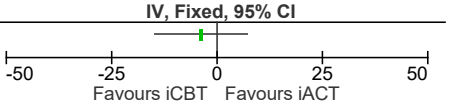


Figure 111: Quality of life (8 weeks); QoLI, scale not reported

Study or Subgroup	iCBT Mean	iCBT SD	iCBT Total	iACT Mean	iACT SD	iACT Total	Mean Difference IV, Fixed, 95% CI
Hesser 2012	2.53	1.55	30	2.12	1.47	33	0.41 [-0.34, 1.16]

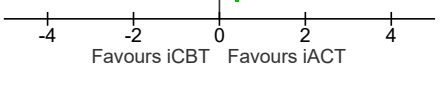


Figure 112: Quality of life (12 months) QoLI, scale not reported

Study or Subgroup	iCBT Mean	iCBT SD	iCBT Total	iACT Mean	iACT SD	iACT Total	Mean Difference IV, Fixed, 95% CI
Hesser 2012	2.48	1	30	1.84	1.87	31	0.64 [-0.11, 1.39]

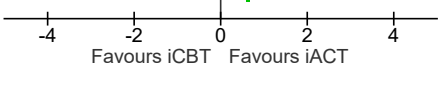


Figure 113: Anxiety (8 weeks); HADS, scale 0-21

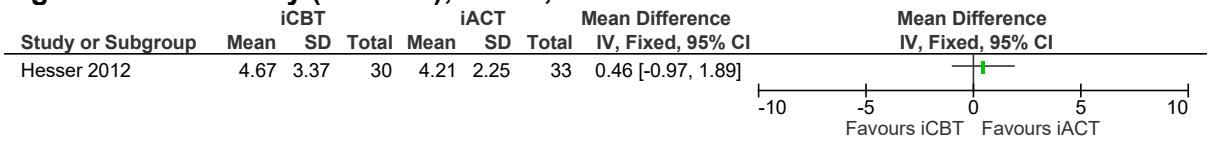


Figure 114: Anxiety (12 months); HADS, scale 0-21

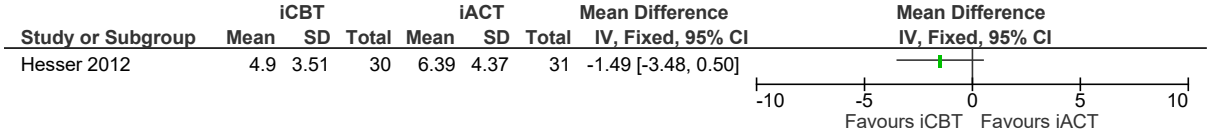


Figure 115: Depression (8 weeks); HADS, scale 0-21

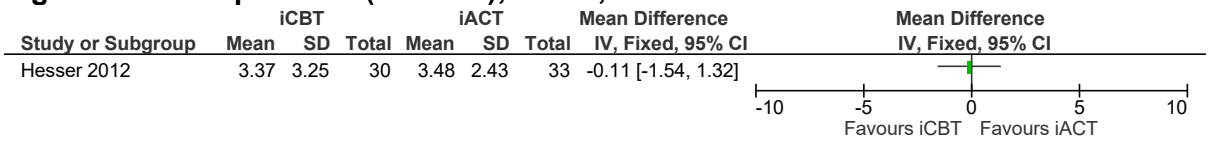


Figure 116: Depression (12 months); HADS, scale 0-21

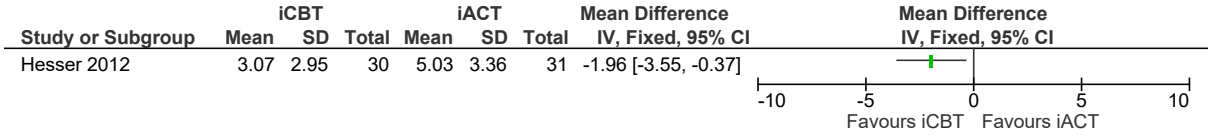


Figure 117: Sleep (8 weeks); ISI, scale 0-28

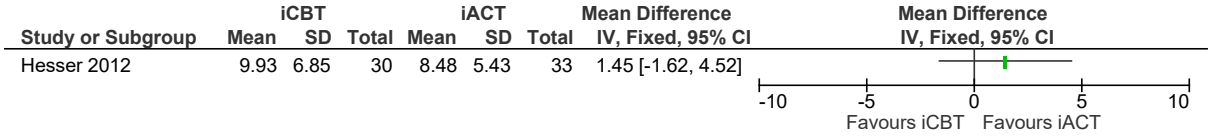
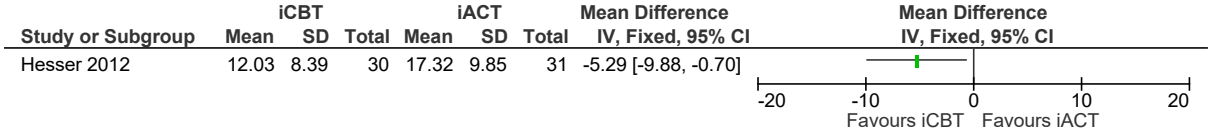


Figure 118: Sleep (12 months); ISI, scale 0-28



E.17 Biofeedback versus waiting-list control

Figure 119: Tinnitus distress (8 weeks); Tinnitus diary, scale not reported

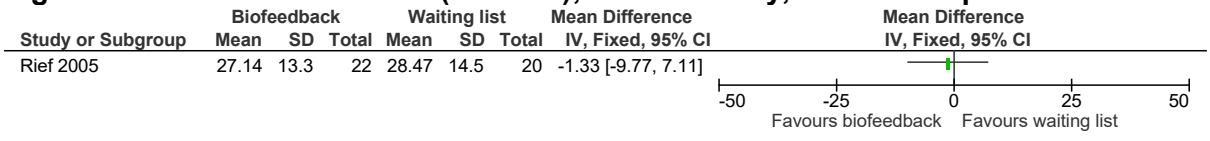


Figure 120: Tinnitus distress (6 months); TQ, scale 0-84

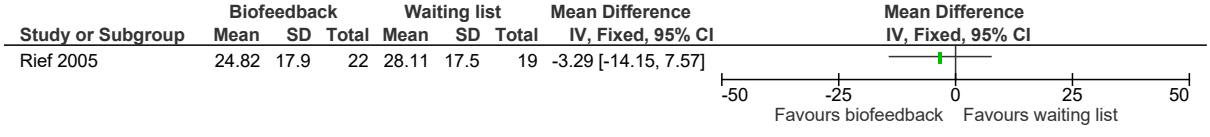


Figure 121: Quality of life (8 weeks); Health Life Satisfaction, scale not reported

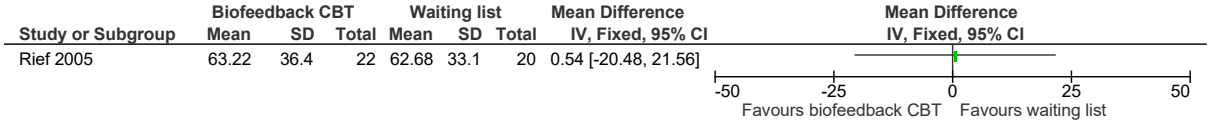


Figure 122: Quality of life (6 months); Health Life Satisfaction, scale not reported

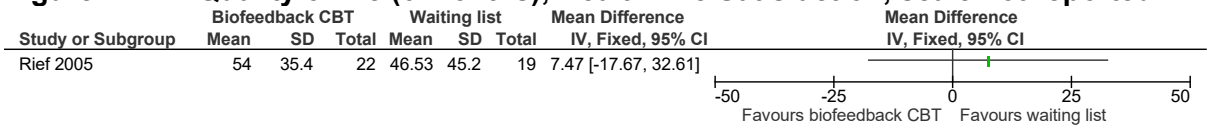


Figure 123: Tinnitus loudness (8 weeks); Tinnitus diary, scale 0-10

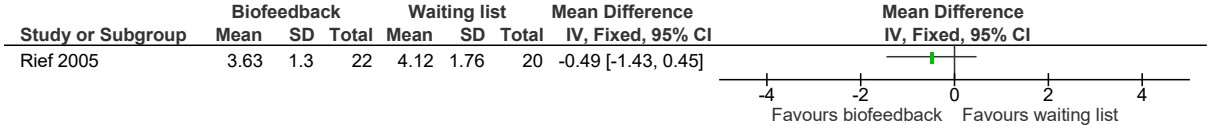
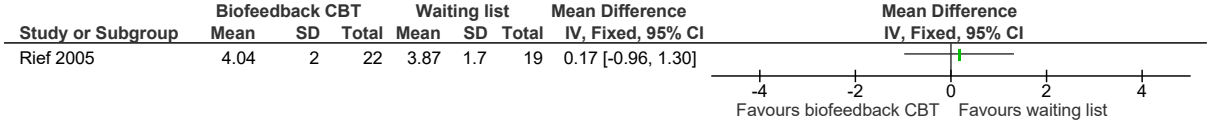


Figure 124: Tinnitus loudness (6 months); Tinnitus diary, scale 0-10



E.18 Biofeedback-based CBT versus waiting-list control

Figure 125: Tinnitus severity (3 months); Global Severity Index of SLC-90-R, scale not reported

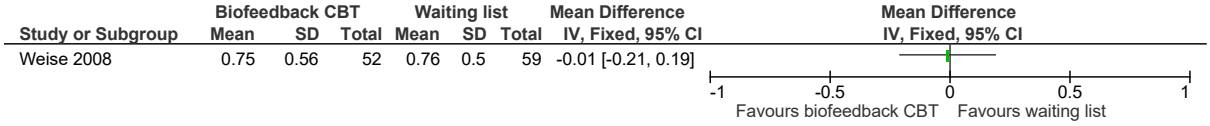


Figure 126: Tinnitus distress (3 months); TQ, scale 0-84

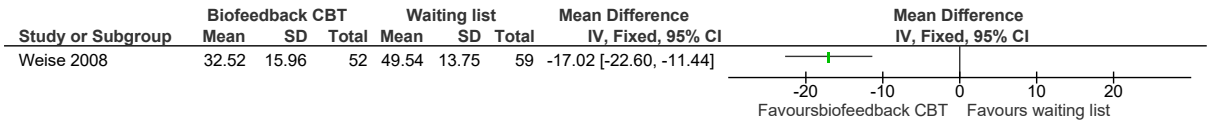


Figure 127: Tinnitus distress (3 months); Tinnitus diary, scale not reported

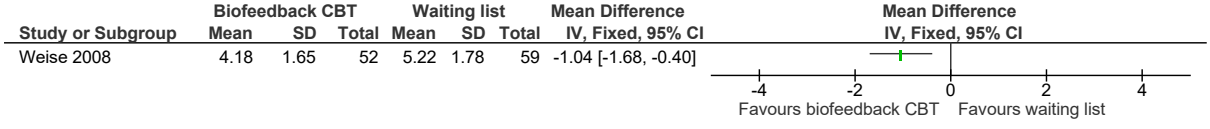


Figure 128: Tinnitus loudness (3 months); Tinnitus diary, scale 0-10

Study or Subgroup	Biofeedback CBT Mean	SD	Total	Waiting list Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Weise 2008	4.36	1.82	52	5.69	1.68	59	-1.33 [-1.98, -0.68]

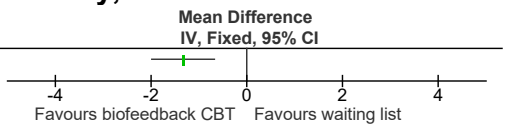


Figure 129: Depression (3 months); BDI, scale 0-63

Study or Subgroup	Biofeedback CBT Mean	SD	Total	Waiting list Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Weise 2008	12.29	8.91	52	13.38	7.38	59	-1.09 [-4.16, 1.98]

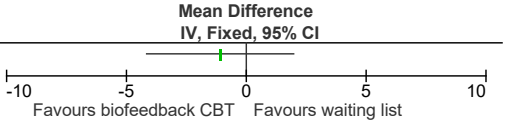
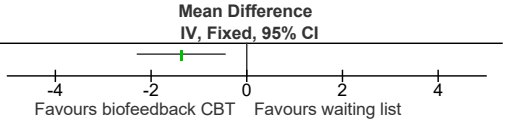


Figure 130: Sleep (3 months); Sleep disturbance diary, scale 0-10

Study or Subgroup	Biofeedback CBT Mean	SD	Total	Waiting list Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Weise 2008	3.21	2.2	52	4.58	2.71	59	-1.37 [-2.28, -0.46]



E.19 Behavioural therapy versus waiting-list control

Figure 131: Tinnitus loudness (direct) (post-treatment); Diary, scale 0-10

Study or Subgroup	Behavioural therapy Mean	SD	Total	Waiting-list control Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Scott 1985	6.25	2.02	12	7.21	1.81	12	-0.96 [-2.49, 0.57]

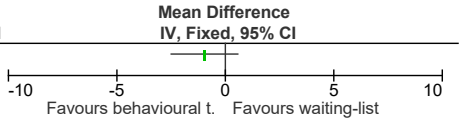


Figure 132: Tinnitus loudness (retrospective) (post-treatment); Diary, scale 0-10

Study or Subgroup	Behavioural therapy Mean	SD	Total	Waiting-list control Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Scott 1985	5.99	2.44	12	7	2.01	12	-1.01 [-2.80, 0.78]

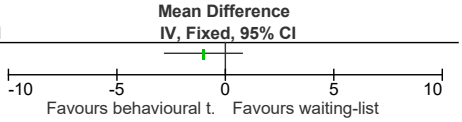
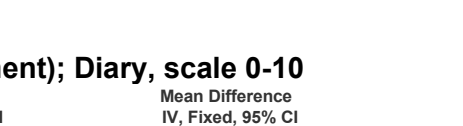


Figure 133: Tinnitus annoyance (retrospective) (post-treatment); Diary, scale 0-10 (unclear)

Study or Subgroup	Behavioural therapy Mean	SD	Total	Waiting-list control Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Scott 1985	2.18	1.43	12	2.73	1.37	12	-0.55 [-1.67, 0.57]

Figure 134: Depression (retrospective) (post-treatment); Diary, scale 0-10

Study or Subgroup	Behavioural therapy Mean	SD	Total	Waiting-list control Mean	SD	Total	Mean Difference IV, Fixed, 95% CI
Scott 1985	1.92	1.17	12	2.84	1.34	12	-0.92 [-1.93, 0.09]



Mindfulness-based therapies

E.20 Mindfulness-based cognitive therapy versus relaxation

Figure 135: Tinnitus severity (post-treatment); TQ, scale 0-84

Study or Subgroup	MBCT Mean	MBCT SD	MBCT Total	Relaxation Mean	Relaxation SD	Relaxation Total	Mean Difference IV, Fixed, 95% CI
McKenna 2017	31.4	16.1	36	38.2	14.3	32	-6.80 [-14.03, 0.43]

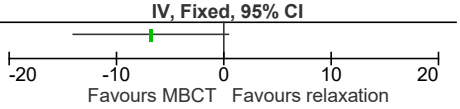


Figure 136: Tinnitus severity (6 months); TQ, scale 0-84

Study or Subgroup	MBCT Mean	MBCT SD	MBCT Total	Relaxation Mean	Relaxation SD	Relaxation Total	Mean Difference IV, Fixed, 95% CI
McKenna 2017	28	18.1	34	35.6	16.8	28	-7.60 [-16.30, 1.10]

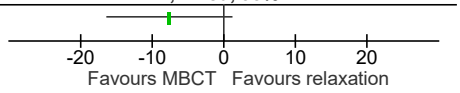


Figure 137: Tinnitus severity (post-treatment); TFI, scale 0-100

Study or Subgroup	MBCT Mean	MBCT SD	MBCT Total	Relaxation Mean	Relaxation SD	Relaxation Total	Mean Difference IV, Fixed, 95% CI
McKenna 2017	42.2	19.2	36	49.2	19	32	-7.00 [-16.09, 2.09]

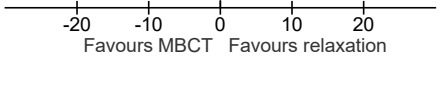


Figure 138: Tinnitus severity (6 months); TFI, scale 0-100

Study or Subgroup	MBCT Mean	MBCT SD	MBCT Total	Relaxation Mean	Relaxation SD	Relaxation Total	Mean Difference IV, Fixed, 95% CI
McKenna 2017	37.2	24.1	34	49	21.1	28	-11.80 [-23.06, -0.54]

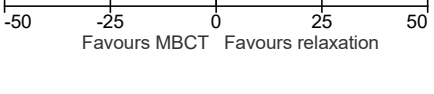


Figure 139: Tinnitus loudness (post-treatment); VAS, scale 0-100

Study or Subgroup	MBCT Mean	MBCT SD	MBCT Total	Relaxation Mean	Relaxation SD	Relaxation Total	Mean Difference IV, Fixed, 95% CI
McKenna 2017	56.6	25.2	36	59.2	22.5	32	-2.60 [-13.94, 8.74]

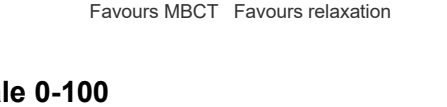


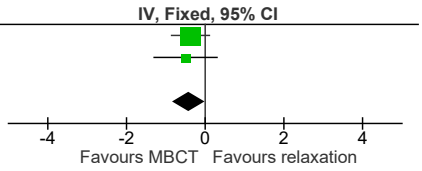
Figure 140: Tinnitus loudness (6 months); VAS, scale 0-100

Study or Subgroup	MBCT Mean	MBCT SD	MBCT Total	Relaxation Mean	Relaxation SD	Relaxation Total	Mean Difference IV, Fixed, 95% CI
McKenna 2017	55.1	29.9	34	65.4	24.3	28	-10.30 [-23.79, 3.19]

Figure 141: Depression (post-treatment); HADS/BDI

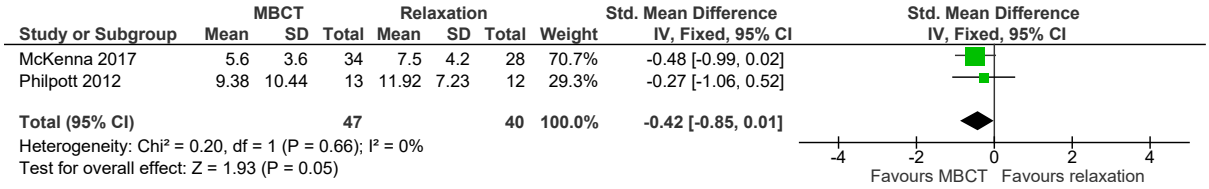
Study or Subgroup	MBCT Mean	MBCT SD	MBCT Total	Relaxation Mean	Relaxation SD	Relaxation Total	Weight	Std. Mean Difference IV, Fixed, 95% CI
McKenna 2017	6.2	3.1	36	7.5	3.8	32	73.4%	-0.37 [-0.85, 0.11]
Philpott 2012	8.84	9.43	13	12.83	5.36	12	26.6%	-0.50 [-1.30, 0.30]
Total (95% CI)			**49**			**44**	**100.0%**	**-0.41 [-0.82, 0.01]**

Heterogeneity: Chi² = 0.07, df = 1 (P = 0.79); I² = 0%
Test for overall effect: Z = 1.93 (P = 0.05)



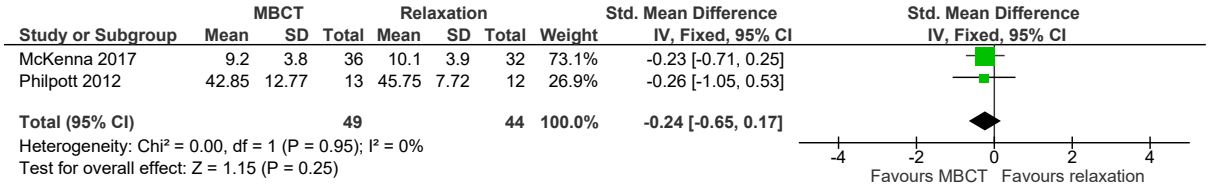
Scales: McKenna 2017 (HADS) – 0-21; Philpott 2012 (BDI) – 0-63

Figure 142: Depression (6 months); HADS/BDI



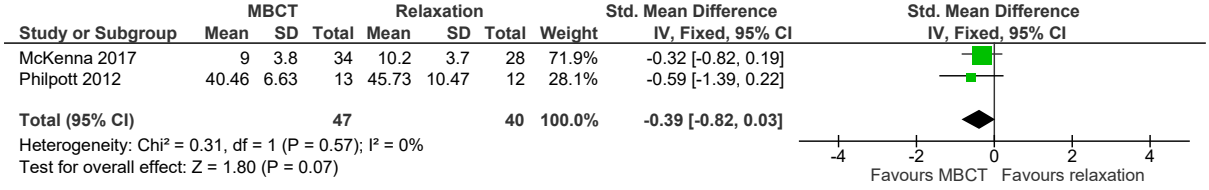
Scales: McKenna 2017 (HADS) – 0-21; Philpott 2012 (BDI) – 0-63

Figure 143: Anxiety (post-treatment); HADS/STRAI



Scales: McKenna 2017 (HADS) – 0-21; Philpott 2012 (STRAI) – 20-80

Figure 144: Anxiety (3-6 months); HADS/STRAI



Scales: McKenna 2017 (HADS) – 0-21; Philpott 2012 (STRAI) – 20-80

E.21 Mindfulness meditation versus relaxation therapy

Figure 145: Tinnitus severity (post-treatment), VAS, scale 0-10

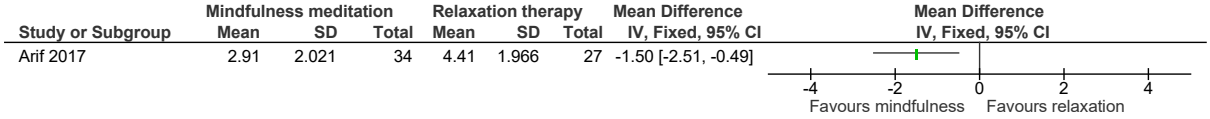


Figure 146: Tinnitus loudness (post-treatment), VAS, scale 0-10

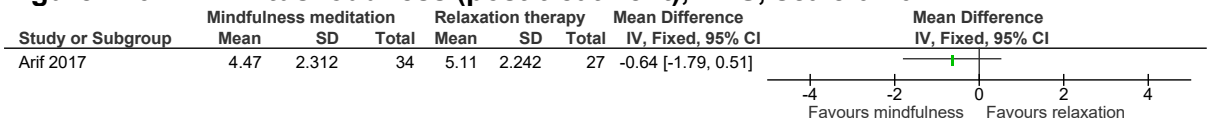


Figure 147: Anxiety (post-treatment), HADS, scale 0-21

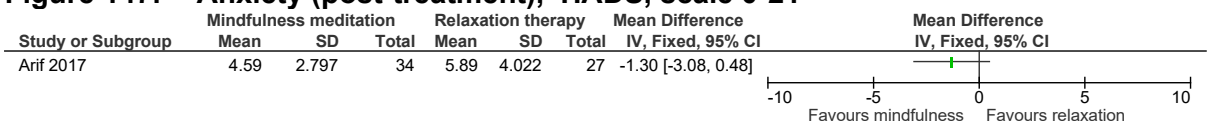


Figure 148: Depression (post-treatment); HADS, scale 0-21

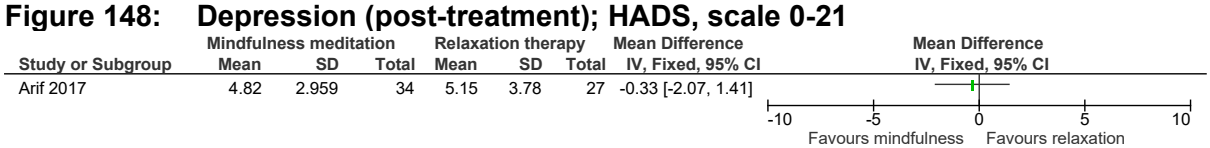
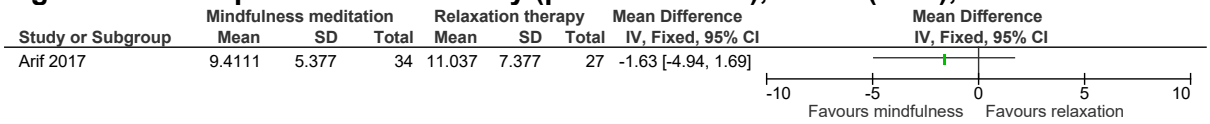


Figure 149: Depression and anxiety (post-treatment), HADS (total), scale 0-42



E.22 Mindfulness and body-psychotherapy-based group treatment versus waiting-list control

Figure 150: Tinnitus severity (post-treatment); TQ, scale 0-84

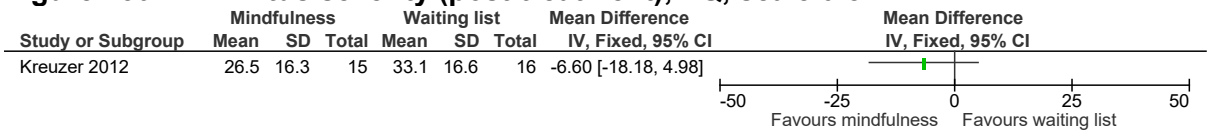


Figure 151: Tinnitus severity (post-treatment); THI, scale 0-100

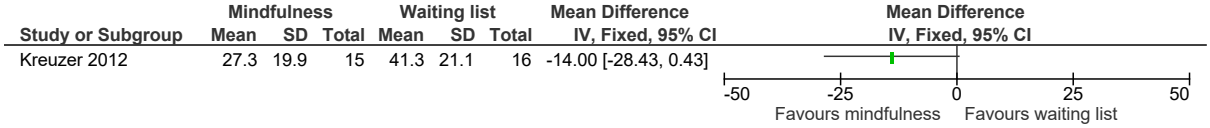


Figure 152: Tinnitus annoyance (post-treatment); VAS, scale not reported

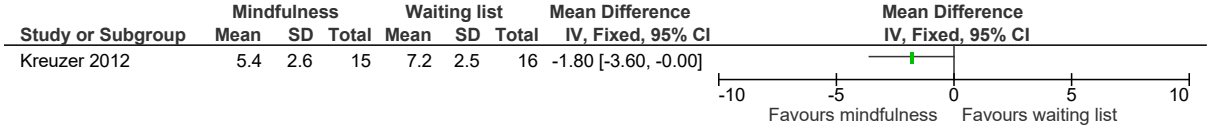


Figure 153: Tinnitus loudness (post-treatment); VAS, scale not reported

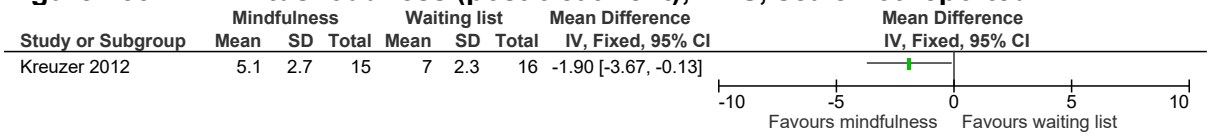
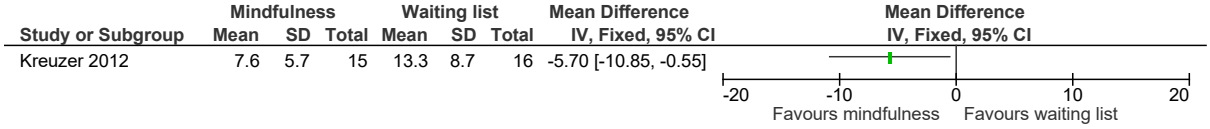


Figure 154: Depression (post-treatment); BDI, scale 0-62



Acceptance and commitment therapy

E.23 iACT versus control (web discussion forum)

Figure 155: Tinnitus severity and distress (post-treatment); THI, scale 0-100

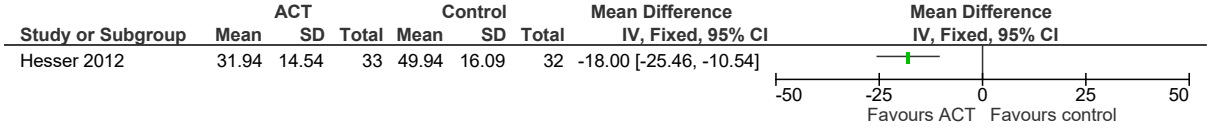


Figure 156: Quality of life (post-treatment); QoLI, scale not reported

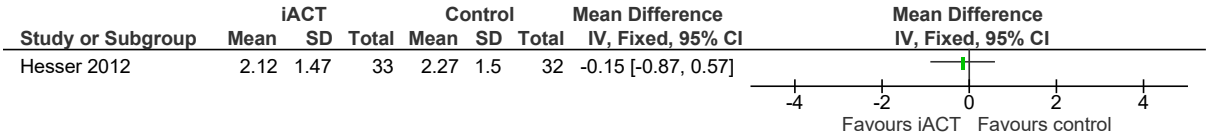


Figure 157: Depression (post-treatment); HADS, scale 0-21

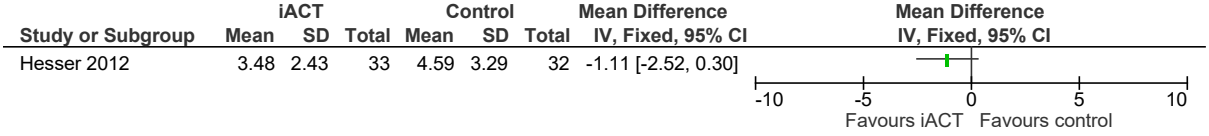


Figure 158: Anxiety (post-treatment); HADS, scale 0-21

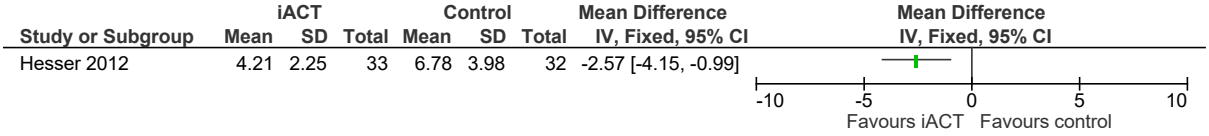
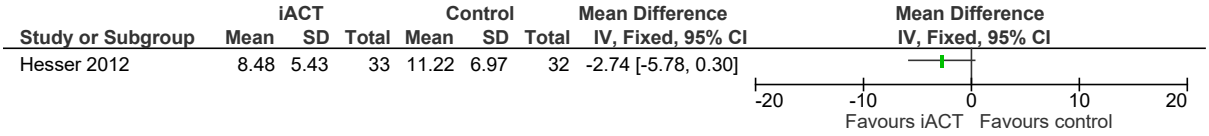


Figure 159: Sleep (post-treatment); ISI, scale 0-28



E.24 ACT versus waiting-list control

Figure 160: Tinnitus severity (post-treatment); THI, scale 0-100

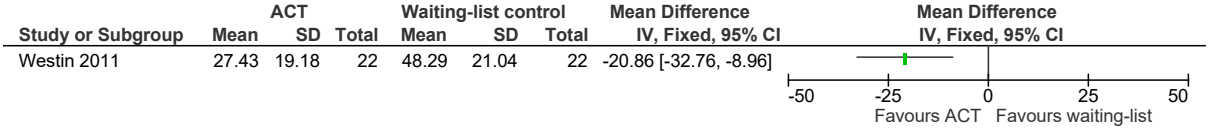


Figure 161: Quality of life (post-treatment); QoLI, scale not reported

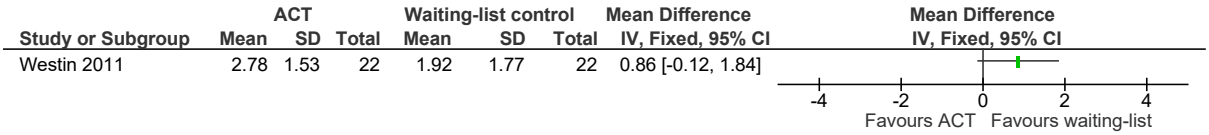


Figure 162: Depression (post-treatment); HADS, scale 0-21

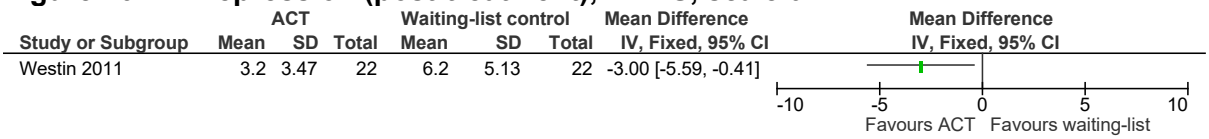


Figure 163: Anxiety (post-treatment); HADS, scale 0-21

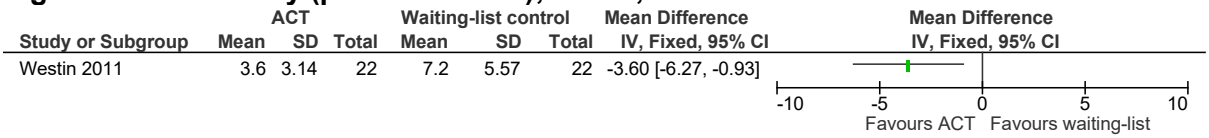
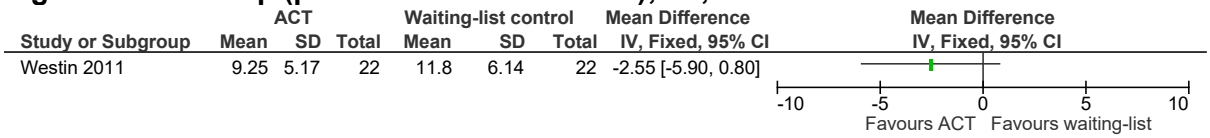


Figure 164: Sleep (post-treatment-10 weeks); ISI, 0-28



Appendix F: GRADE tables

Table 39: Clinical evidence profile: CBT versus waiting-list control

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	CBT	Waiting-list control	Relative (95% CI)	Absolute		
Tinnitus severity (follow-up post-treatment; measured with: Global Severity Index (GSI of SCL-90R); Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	43	20	-	MD 0.09 lower (0.31 lower to 0.13 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus distress (follow-up post-treatment; measured with: TQ/TRQ; range of scores: 0-84, 0-104; Better indicated by lower values)												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	63	40	-	SMD 0.74 lower (1.16 to 0.33 lower)	⊕⊕OO LOW	CRITICAL
Tinnitus distress (follow-up 3 months; measured with: TRQ; range of scores: 0-104; Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	12	11	-	MD 22.80 lower (34.50 to 11.10 lower)	⊕⊕OO LOW	CRITICAL
Tinnitus QoL (follow-up post-treatment; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	20	20	-	MD 17.16 lower (27.88 to 6.44 lower)	⊕OOO VERY LOW	CRITICAL
Tinnitus annoyance (follow-up post-treatment; measured with: VAS; range of scores: 0-4, 0-10; Better indicated by lower values)												

2	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	36	-	SMD 0.35 lower (0.84 lower to 0.14 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus loudness (follow-up post-treatment; measured with: VAS; range of scores: 0-4, 0-10; Better indicated by lower values)												
3	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	73	56	-	SMD 0.27 lower (0.64 lower to 0.09 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up post-treatment; measured with: BDI/ADS; range of scores: 0-63, 0-60; Better indicated by lower values)												
2	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	63	40	-	SMD 0.21 lower (0.62 lower to 0.2 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up 3 months; measured with: HADS; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	12	11	-	MD 3.20 lower (6.58 lower to 0.18 higher)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up 3 months; measured with: HADS; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	12	11	-	MD 4 lower (6.21 to 1.79 lower)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up 3 months; measured with: ASI; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	12	11	-	MD 14.7 lower (21.54 to 7.86 lower)	⊕⊕OO LOW	IMPORTANT
Sleep disturbance (follow-up post-treatment; measured with: 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	10	16	-	MD 0.34 lower (1.98 lower to 1.3 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 40: Clinical evidence profile: CBT versus control (masking)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	CBT	Control (masking)	Relative (95% CI)	Absolute		
Tinnitus severity (follow-up post-treatment; measured with: Tinnitus Handicap Inventory; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	50	50	-	MD 12.94 lower (16.32 to 9.56 lower)	⊕⊕OO LOW	CRITICAL
Depression (follow-up post-treatment; measured with: Symptom Checklist-90; range of scores: 1-5; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	50	-	MD 0.3 lower (0.56 to 0.04 lower)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up post-treatment; measured with: Symptom Checklist-90; range of scores: 1-5; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	50	50	-	MD 0.78 lower (0.99 to 0.57 lower)	⊕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 41: Clinical evidence profile: CBT versus information only

Quality assessment	No of patients	Effect	Quality	Importance

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	CBT	Information only	Relative (95% CI)	Absolute		
Tinnitus distress (follow-up post-treatment; measured with: TQ; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	47	58	-	MD 7.40 lower (13.65 to 1.15 lower)	⊕OOO VERY LOW	CRITICAL
Tinnitus distress (follow-up 9 months; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	47	49	-	MD 6.8 lower (13.09 to 0.51 lower)	⊕OOO VERY LOW	CRITICAL
Depression (follow-up post-treatment; measured with: PHQ-D; Better indicated by lower values)												
2	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	47	58	-	MD 1.00 lower (2.85 lower to 0.85 higher)	⊕⊕OO LOW	IMPORTANT
Depression (follow-up 9 months; measured with: PHQ-D; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	47	49	-	MD 0.9 lower (2.69 lower to 0.89 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 42: Clinical evidence profile: CBT versus education

Quality assessment							No of patients		Effect		Quality	Importance
No of	Design	Risk of	Inconsistency	Indirectness	Imprecision	Other	CBT	Education	Relative (95%	Absolute		

studies		bias				considerations			CI)			
Tinnitus severity (follow-up post-treatment; measured with: Global Severity Index (GSI of SCL-90R); Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	43	16	-	MD 0.01 higher (0.23 lower to 0.25 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus distress (follow-up post-treatment; measured with: TQ/TRQ; range of scores: 0-84, 0-104; Better indicated by lower values)												
3	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	90	56	-	SMD 0.40 lower (0.75 lower to 0.06 higher)	⊕⊕OO LOW	CRITICAL
Tinnitus distress (follow-up 12 months; measured with: TRQ; range of scores: 0-104; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	16	17	-	MD 1.88 lower (16.69 lower to 12.93 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus QoL (follow-up post-treatment; measured with: THQ; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	20	20	-	MD 15.62 lower (26.51 to 4.73 lower)	⊕OOO VERY LOW	CRITICAL
Tinnitus QoL (follow-up 12 months; measured with: THQ; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	16	17	-	MD 2.76 lower (14.69 lower to 9.17 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus loudness (follow-up post-treatment; measured with: VAS and subjective change; range of scores: 0-4; Better indicated by lower values)												
2	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	47	40	-	SMD 0.32 lower (0.74 lower to 0.11 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus loudness (follow-up 11 weeks - 6 months; measured with: Diary; Better indicated by lower values)												

2	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	70	36	-	MD 0.06 lower (0.78 lower to 0.67 higher)	⊕⊕OO LOW	IMPORTANT
Tinnitus annoyance (follow-up post-treatment; measured with: VAS; 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 0.46 lower (0.95 lower to 0.03 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus annoyance (follow-up 12 months; measured with: VAS; 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	16	17	-	MD 0.63 lower (1.37 lower to 0.11 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up post-treatment; measured with: BDI; range of scores: 0-63; Better indicated by lower values)												
1	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness	very serious[2]	none	20	20	-	MD 0.45 higher (4.39 lower to 5.29 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up 6-12 months; measured with: BDI/ADS; range of scores: 0-63, 0-60; Better indicated by lower values)												
2	randomised trials	very serious[2]	no serious inconsistency	no serious indirectness	serious[2]	none	59	33	-	SMD 0.06 lower (0.5 lower to 0.38 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 43: Clinical evidence profile: CBT versus relaxation

Quality assessment							No of patients		Effect		Quality	Importance
No of	Design	Risk of	Inconsistency	Indirectness	Imprecision	Other	CBT	Relaxation	Relative (95%	Absolute		

studies		bias				considerations			CI)			
Tinnitus severity (follow-up post-treatment; measured with: Global Severity Index (GSI of SCL-90R; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	43	16	-	MD 0.21 lower (0.55 lower to 0.13 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus distress (follow-up post-treatment; measured with: TQ; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	43	16	-	MD 7.6 lower (13.95 to 1.25 lower)	⊕OOO VERY LOW	CRITICAL
Tinnitus loudness (follow-up post-treatment; measured with: Diary; range of scores: 1-7; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	43	16	-	MD 0.04 lower (0.93 lower to 0.85 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up post-treatment; measured with: ADS; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	43	16	-	MD 5.93 lower (12.11 lower to 0.25 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 44: Clinical evidence profile: CBT versus passive relaxation training

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**CBT**	**Passive relaxation training**	**Relative (95%**	**Absolute**		

									CI)			
Tinnitus distress (follow-up post-treatment; measured with: TEQ; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	11	10	-	MD 0.3 higher (2.2 lower to 2.8 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus distress (follow-up 4 months; measured with: TEQ; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10	6	-	MD 0.2 lower (2.33 lower to 1.93 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus loudness (follow-up post-treatment; measured with: Tinnitus loudness rating; range of scores: 1-5; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	11	7	-	MD 0 higher (0.72 lower to 0.72 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus loudness (follow-up 4 months; measured with: Tinnitus loudness rating; range of scores: 1-5; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	10	6	-	MD 0.03 lower (0.54 lower to 0.48 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus annoyance (most annoying) (follow-up post-treatment; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	11	7	-	MD 0.75 higher (0.1 to 1.4 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus annoyance (most annoying) (follow-up 4 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10	6	-	MD 0 higher (0.71 lower to 0.71 higher)	⊕OOO VERY LOW	IMPORTANT

Depression (follow-up 1 month; measured with: BDI; 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	10	6	-	MD 3.36 lower (13.24 lower to 6.52 higher)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up 1 month; measured with: STAI- state; range of scores: 20-80; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10	6	-	MD 6.46 lower (21.31 lower to 8.39 higher)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up 1 month; measured with: STAI-trait; range of scores: 20-80; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	10	6	-	MD 7.06 lower (18.48 lower to 4.36 higher)	⊕OOO VERY LOW	IMPORTANT
Insomnia (follow-up post-treatment; measured with: TEQ; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	11	7	-	MD 0.03 higher (2.09 lower to 2.15 higher)	⊕OOO VERY LOW	IMPORTANT
Insomnia (follow-up 4 months; measured with: TEQ; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10	6	-	MD 0.13 lower (2.05 lower to 1.79 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 45: Clinical evidence profile: CBT versus applied relaxation training

Quality assessment	No of patients	Effect	Quality	Importance

No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**CBT**	**Applied relaxation training**	**Relative (95% CI)**	**Absolute**			
Tinnitus distress (follow-up post-treatment; measured with: TEQ; Better indicated by lower values)													
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	11	12	-	MD 0.7 lower (2.64 lower to 1.24 higher)	⊕OOO VERY LOW	CRITICAL	
Tinnitus distress (follow-up 4 months; measured with: TEQ; Better indicated by lower values)													
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	10	11	-	MD 0.85 higher (1.07 lower to 2.77 higher)	⊕OOO VERY LOW	IMPORTANT	
Tinnitus loudness (follow-up post-treatment; measured with: Tinnitus loudness rating; range of scores: 1-5; Better indicated by lower values)													
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	11	12	-	MD 0.34 higher (0.35 lower to 1.03 higher)	⊕OOO VERY LOW	IMPORTANT	
Tinnitus loudness (follow-up 4 months; measured with: Tinnitus loudness rating; range of scores: 1-5; Better indicated by lower values)													
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	10	11	-	MD 0.3 higher (0.24 lower to 0.84 higher)	⊕OOO VERY LOW	IMPORTANT	
Tinnitus annoyance (most annoying) (follow-up post-treatment; Better indicated by lower values)													
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	11	12	-	MD 0.52 higher (0.13 lower to 1.17 higher)	⊕OOO VERY LOW	IMPORTANT	
Tinnitus annoyance (most annoying) (follow-up 4 months; Better indicated by lower values)													

1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	10	11	-	MD 0.82 higher (0 to 1.64 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up 1month; measured with: BDI; 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	10	12	-	MD 0.97 higher (4.09 lower to 6.03 higher)	⊕OOO VERY LOW	
Anxiety (follow-up 1 month; measured with: STAI-state; range of scores: 20-80; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10	12	-	MD 1.21 lower (12.12 lower to 9.7 higher)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up 1 month; measured with: STAI-trait; range of scores: 20-80; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10	12	-	MD 0.77 higher (6.78 lower to 8.32 higher)	⊕OOO VERY LOW	IMPORTANT
Insomnia (follow-up post-treatment; measured with: TEQ; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	11	12	-	MD 0.02 higher (1.75 lower to 1.79 higher)	⊕OOO VERY LOW	IMPORTANT
Insomnia (follow-up 4 months; measured with: TEQ; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	10	11	-	MD 0.11 higher (0.93 lower to 1.15 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 46: Clinical evidence profile: CBT-stepped intervention versus usual care

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	CBT-stepped intervention	Usual care	Relative (95% CI)	Absolute		
Tinnitus severity (follow-up post-treatment (step 1); measured with: Tinnitus Questionnaire; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	200	194	-	MD 3.5 lower (7.4 lower to 0.4 higher)	⊕⊕⊕⊕ HIGH	CRITICAL
Tinnitus severity (follow-up 12 months (step 2); measured with: Tinnitus Questionnaire; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	171	161	-	MD 8.69 lower (12.66 to 4.72 lower)	⊕⊕⊕O MODERATE	CRITICAL
Quality of life (follow-up post-treatment (step 1); measured with: Health Utilities Index; range of scores: -0.36-1; Better indicated by higher values)												
1	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	no serious imprecision	none	200	194	-	MD 0.02 lower (0.08 lower to 0.04 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of life (follow-up 12 months (step 2); measured with: Health Utilities Index; range of scores: -0.36-1; Better indicated by lower values)												
1	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	no serious imprecision	none	171	171	-	MD 0.05 higher (0.01 to 0.11 higher)	⊕⊕⊕O MODERATE	CRITICAL
Tinnitus-related quality of life (follow-up post-treatment (step 1); measured with: Tinnitus Handicap Inventory; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	200	194	-	MD 3.13 lower (7.79 lower to 1.53 higher)	⊕⊕⊕⊕ HIGH	CRITICAL
Tinnitus-related quality of life (follow-up 12 months (step 2); measured with: Tinnitus Handicap Inventory; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	171	161	-	MD 7.06 lower (11.63 to 2.49 lower)	⊕⊕⊕O MODERATE	CRITICAL

Depression and anxiety (follow-up post-treatment (step 1); measured with: Hospital Anxiety and Depression Inventory; range of scores: 0-42; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	200	194	-	MD 0.17 lower (1.82 lower to 1.48 higher)	⊕⊕⊕⊕ HIGH	IMPORTANT
Depression and anxiety (follow-up 12 months (step 2); measured with: Hospital Anxiety and Depression Inventory; range of scores: 0-42; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	171	161	-	MD 0.61 lower (2.24 lower to 1.02 higher)	⊕⊕⊕⊕ HIGH	IMPORTANT

[1] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.
[2] 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 47: Clinical evidence profile: CBT (self-help book) versus waiting-list control

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**CBT (book)**	**Waiting-list control**	**Relative (95% CI)**	**Absolute**		
Tinnitus distress (follow-up 3 months; measured with: TRQ; range of scores: 0-104; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	55	70	-	MD 5.12 lower (10.66 lower to 0.42 higher)	⊕OOO VERY 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
[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs

Table 48: Clinical evidence profile: CBT (bibliotherapy) versus information only

Quality assessment							No of patients		Effect		Quality	Importance
No of	**Design**	**Risk of**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**CBT-**	**Information**	**Relative (95%**	**Absolute**		

studies		bias				considerations	bibliotherapy	only	CI)			
Tinnitus distress (follow-up post-treatment; measured with: TQ; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	51	58	-	MD 1.10 lower (8.37 lower to 6.17 higher)	⊕⊕OO LOW	CRITICAL
Tinnitus distress (follow-up 9 months; measured with: TQ; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	45	49	-	MD 4.40 lower (11.64 lower to 2.84 higher)	⊕OOO VERY LOW	CRITICAL
Depression (follow-up post-treatment; measured with: PHQ-D; range of scores: 0-120; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	51	58	-	MD 0.70 higher (1.34 lower to 2.74 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up 9 months; measured with: PHQ-D; range of scores: 0-120; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	45	49	-	MD 0.80 higher (1.29 lower to 2.89 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 49: Clinical evidence profile: CBT versus control (web discussion forum)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**CBT**	**Control (web discussion forum)**	**Relative (95% CI)**	**Absolute**		
Tinnitus distress (follow-up mean 10 weeks; measured with: Mini-TQ; range of scores: 0-24; Better indicated by lower values)												

1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	38	43	-	MD 3 lower (5.33 to 0.67 lower)	⊕OOO VERY LOW	CRITICAL
Tinnitus severity (follow-up mean 10 weeks; measured with: THI; 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	38	43	-	MD 9.76 lower (18.74 to 0.78 lower)	⊕OOO VERY LOW	CRITICAL
Depression (follow-up mean 10 weeks; measured with: HADS; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[1]	none	38	43	-	MD 1.47 lower (3.28 lower to 0.34 higher)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up mean 10 weeks; measured with: HADS; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	38	43	-	MD 1.83 lower (3.68 lower to 0.02 higher)	⊕OOO VERY LOW	IMPORTANT
Sleep (ISI) (follow-up mean 10 weeks; measured with: ISI; range of scores: 0-28; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	38	43	-	MD 1.88 lower (4.92 lower to 1.16 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 50: Clinical evidence profile: iCBT versus waiting-list control

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**iCBT**	**Waiting-list control**	**Relative (95%**	**Absolute**		

									CI)			
Tinnitus annoyance (follow-up post-treatment; measured with: VAS; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious	none	25	59	-	MD 0.5 lower (1.56 lower to 0.56 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus loudness (follow-up post-treatment; measured with: VAS; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	24	59	-	MD 0.2 lower (1.26 lower to 0.86 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up post-treatment; measured with: HADS - depression; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	24	48	-	MD 0.8 lower (2.76 lower to 1.16 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up 1 year; measured with: HADS - depression; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	46	50	-	MD 0 higher (1.56 lower to 1.56 higher)	⊕⊕OO LOW	IMPORTANT
Anxiety (follow-up post-treatment; measured with: HADS - anxiety; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	24	48	-	MD 0.9 lower (2.88 lower to 1.08 higher)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up 1 year; measured with: HADS - anxiety ; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	46	50	-	MD 0.3 lower (2.02 lower to 1.42 higher)	⊕⊕OO LOW	IMPORTANT
Sleep (follow-up post-treatment; measured with: ISI; range of scores: 0-28; Better indicated by lower values)												

1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	24	58	-	MD 0.60 lower (0.47 lower to 1.67 higher)	⊕⊕OO 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 51: Clinical evidence profile: iCBT versus information only

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	iCBT	Information only	Relative (95% CI)	Absolute		
Tinnitus distress (follow-up post-treatment; measured with: TQ/TRQ; range of scores: 0-84, 0-104; Better indicated by lower values)												
1	randomised trials	very serious[1]	serious[2]	no serious indirectness	serious[3]	none	80	81	-	SMD 0.34 lower (0.66 to 0.03 lower)	⊕OOO VERY LOW	CRITICAL
Tinnitus distress (follow-up 9 months; measured with: TQ; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	44	49	-	MD 5.8 lower (12.71 lower to 1.11 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus annoyance (follow-up post-treatment; measured with: VAS; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	28	23	-	MD 0.23 lower (1.1 lower to 0.64 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus loudness (follow-up post-treatment; measured with: VAS; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	28	23	-	MD 0.1 higher (0.84 lower to 1.04 higher)	⊕OOO VERY LOW	CRITICAL

Depression (follow-up post-treatment; measured with: DASS/PHQ-D; range of scores: - 0-120, not reported; Better indicated by lower values)												
2	randomised trials	very serious[1]	serious[2]	no serious indirectness	serious[3]	none	80	81	-	SMD 0.05 higher (0.26 lower to 0.36 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up 9 months; measured with: PHQ-D; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	44	49	-	MD 0.2 higher (1.92 lower to 2.32 higher)	⊕⊕OO LOW	IMPORTANT
Anxiety (follow-up post-treatment; measured with: DASS; range of scores: 0-120; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	28	23	-	MD 0.7 higher (1.46 lower to 2.86 higher)	⊕OOO VERY LOW	IMPORTANT
Sleep quality (follow-up post-treatment; measured with: 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[3]	none	28	23	-	MD 0.1 lower (1.24 lower to 1.04 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 or 2 increments because heterogeneity, I2= > 50%, p= > 0.04, unexplained by subgroup analysis.

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

Table 52: Clinical evidence profile: iCBT versus tinnitus information counselling

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**iCBT**	**Tinnitus information counselling**	**Relative (95% CI)**	**Absolute**		

Tinnitus severity (follow-up post-treatment; measured with: Tinnitus Handicap Inventory; 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	44	44	-	MD 6.41 lower (14.71 lower to 1.89 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus severity (follow-up 2 months; measured with: Tinnitus Handicap Inventory; 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	37	37	-	MD 9.33 lower (17.77 to 0.89 lower)	⊕OOO VERY LOW	CRITICAL
Tinnitus distress (follow-up post-treatment; 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	44	44	-	MD 7 lower (16.6 lower to 2.6 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus distress (follow-up 2 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	37	37	-	MD 9.66 lower (19.4 lower to 0.08 higher)	⊕OOO VERY LOW	CRITICAL
Quality of life (follow-up post-treatment; measured with: Satisfaction With Life Scales; range of scores: 5-35; Better indicated by higher values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	44	44	-	MD 0.05 higher (2.16 lower to 2.26 higher)	⊕⊕OO LOW	CRITICAL
Quality of life (follow-up 2 months; measured with: Satisfaction With Life Scales; range of scores: 5-35; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	37	37	-	MD 0.5 higher (1.78 lower to 2.78 higher)	⊕OOO VERY LOW	CRITICAL
Depression (follow-up post-treatment; measured with: Patient Health Questionnaire-9; range of scores: 0-27; Better indicated by lower values)												
1	randomised	very	no serious	no serious	serious[2]	none	44	44	-	MD 0.52 lower (2.14	⊕OOO VERY	IMPORTANT

	trials	serious[1]	inconsistency	indirectness						lower to 1.1 higher)	LOW	
Depression (follow-up 2 months; measured with: Patient Health Questionnaire-9; range of scores: 0-27; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	37	37	-	MD 2.19 lower (3.95 to 0.43 lower)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up post-treatment; measured with: Generalised Anxiety Disorder-7; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	44	44	-	MD 0.12 higher (1.43 lower to 1.67 higher)	⊕⊕OO LOW	IMPORTANT
Anxiety (follow-up 2 months; measured with: Generalised Anxiety Disorder-7; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	37	37	-	MD 0.09 lower (1.64 lower to 1.46 higher)	⊕⊕OO LOW	IMPORTANT
Sleep (follow-up post-treatment; measured with: Insomnia Severity Index; range of scores: 0-28; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	44	44	-	MD 2.84 lower (5.42 to 0.26 lower)	⊕OOO VERY LOW	IMPORTANT
Sleep (follow-up 2 months; measured with: Insomnia Severity Index; range of scores: 0-28; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	37	37	-	MD 4.34 lower (7.01 to 1.67 lower)	⊕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 53: Clinical evidence profile: iCBT versus control (web discussion forum)

Quality assessment	No of patients	Effect	Quality	Importance

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	iCBT	Control (web discussion forum)	Relative (95% CI)	Absolute		
Tinnitus severity and distress (follow-up 8-10 weeks; measured with: THI; range of scores: 0-100; Better indicated by lower values)												
3	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	126	136	-	MD 12.16 lower (16.37 to 7.96 lower)	⊕OOO VERY LOW	CRITICAL
Tinnitus distress (follow-up 8-10 weeks; measured with: Mini-TQ; range of scores: 0-20; Better indicated by lower values)												
2	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	96	104	-	MD 4.42 lower (5.74 to 3.1 lower)	⊕⊕OO LOW	CRITICAL
Quality of life (follow-up 8 weeks; measured with: QoLI; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	32	-	MD 0.26 higher (0.5 lower to 1.02 higher)	⊕OOO VERY LOW	CRITICAL
Depression (follow-up 8-10 weeks; measured with: HADS; range of scores: 0-21; Better indicated by lower values)												
3	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	126	136	-	MD 1.95 lower (2.89 to 1.02 lower)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up 8-10 weeks; measured with: HADS; range of scores: 0-21; Better indicated by lower values)												
3	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	126	136	-	MD 1.66 lower (2.53 to 0.79 lower)	⊕OOO VERY LOW	IMPORTANT
Sleep (follow-up 8-10 weeks; measured with: ISI; range of scores: 0-28; Better indicated by lower values)												
3	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	126	136	-	MD 2.9 lower (4.42 to 1.38 lower)	⊕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 54: Clinical evidence profile: iCBT versus iACT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	iCBT	iACT	Relative (95% CI)	Absolute		
Tinnitus distress and severity (follow-up 8 weeks; measured with: THI; 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	30	33	-	MD 6.99 higher (1.64 lower to 15.62 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus distress and severity (follow-up 12 months; measured with: THI; 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	30	31	-	MD 3.79 lower (14.76 lower to 7.18 higher)	⊕OOO VERY LOW	CRITICAL
Quality of life (follow-up 8 weeks; measured with: QoLI; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	33	-	MD 0.41 higher (0.34 lower to 1.16 higher)	⊕OOO VERY LOW	CRITICAL
Quality of life (follow-up 12 months; measured with: QoLI; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	31	-	MD 0.64 higher (0.11 lower to 1.39 higher)	⊕OOO VERY LOW	CRITICAL
Anxiety (follow-up 8 weeks; measured with: HADS; range of scores: 0-21; Better indicated by lower values)												

1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	33	-	MD 0.46 higher (0.97 lower to 1.89 higher)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up 12 months; measured with: HADS; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	30	31	-	MD 1.49 lower (3.48 lower to 0.5 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up 8 weeks; measured with: HADS; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	30	33	-	MD 0.11 lower (1.54 lower to 1.32 higher)	⊕⊕OO LOW	IMPORTANT
Depression (follow-up 12 months; measured with: HADS; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	30	31	-	MD 1.96 lower (3.55 to 0.37 lower)	⊕⊕OO LOW	IMPORTANT
Sleep (follow-up 8 weeks; measured with: ISI; range of scores: 0-28; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	30	33	-	MD 1.45 higher (1.62 lower to 4.52 higher)	⊕⊕OO LOW	IMPORTANT
Sleep (follow-up 12 months; measured with: ISI; range of scores: 0-28; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	30	31	-	MD 5.29 lower (9.88 to 0.7 lower)	⊕⊕OO 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 55: Clinical evidence profile: Biofeedback versus waiting-list control

Quality assessment							No of patients		Effect	Quality	Importance

No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Biofeedback**	**Waiting-list control**	**Relative (95% CI)**	**Absolute**		
Tinnitus distress (follow-up 8 weeks; measured with: Tinnitus diary; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	20	-	MD 1.33 lower (9.77 lower to 7.11 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus distress (follow-up 6 months; measured with: TQ; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	19	-	MD 3.29 lower (14.15 lower to 7.57 higher)	⊕OOO VERY LOW	CRITICAL
Quality of life (follow-up 6 months; measured with: Health Life Satisfaction; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	19	-	MD 7.47 higher (17.67 lower to 32.61 higher)	⊕OOO VERY LOW	CRITICAL
Quality of life (follow-up 8 weeks; measured with: Health Life Satisfaction; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	22	20	-	MD 0.54 higher (20.48 lower to 21.56 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus loudness (follow-up 8 weeks; measured with: Tinnitus diary; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	20	-	MD 0.49 lower (1.43 lower to 0.45 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus loudness (follow-up 6 months; measured with: Tinnitus diary; 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	22	19	-	MD 0.17 higher (0.96 lower to 1.3 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 56: Clinical evidence profile: Biofeedback-based CBT versus waiting-list control

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Biofeedback-based CBT**	**Waiting-list control**	**Relative (95% CI)**	**Absolute**		
Tinnitus severity (follow-up 3 months; measured with: Global severity index of SLC-90-R; Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	52	59	-	MD 0.01 lower (0.21 lower to 0.19 higher)	⊕⊕⊕O MODERATE	CRITICAL
Tinnitus distress (follow-up 3 months; measured with: TQ; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	52	59	-	MD 17.02 lower (22.6 to 11.44 lower)	⊕⊕⊕O MODERATE	CRITICAL
Tinnitus distress (follow-up 3 months; measured with: Tinnitus diary; Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	52	59	-	MD 1.04 lower (1.68 to 0.4 lower)	⊕⊕OO LOW	CRITICAL
Tinnitus loudness (follow-up 3 months; measured with: Tinnitus diary; range of scores: 0-10; Better indicated by lower values)												
1	randomised	serious[1]	no serious	no serious	serious[2]	none	52	59	-	MD 1.33 lower (1.98	⊕⊕OO	IMPORTANT

	trials		inconsistency	indirectness						to 0.68 lower)	LOW	
Depression (follow-up 3 months; measured with: BDI; range of scores: 0-63; Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	52	59	-	MD 1.09 lower (4.16 lower to 1.98 higher)	⊕⊕OO LOW	IMPORTANT
Sleep (follow-up 3 months; measured with: Sleep disturbance diary; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	52	59	-	MD 1.37 lower (2.28 to 0.46 lower)	⊕⊕OO 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 57: Clinical evidence profile: Behavioural therapy versus waiting-list control

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Behavioural therapy**	**Waiting-list control**	**Relative (95% CI)**	**Absolute**		
Tinnitus loudness (direct) (follow-up post-treatment; measured with: Diary; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	12	12	-	MD 0.96 lower (2.49 lower to 0.57 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus loudness (retrospective) (follow-up post-treatment; measured with: Diary; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	12	12	-	MD 1.01 lower (2.80 lower to 0.78 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus annoyance (retrospective) (follow-up post-treatment; measured with: Diary; range of scores: 0-10; Better indicated by lower values)												

1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	12	12	-	MD 0.55 lower (1.67 lower to 0.57 higher)	⊕OOO VERY LOW	IMPORTANT
Depression (retrospective) (follow-up post-treatment; measured with: Diary; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	12	12	-	MD 0.92 lower (1.93 lower to 0.09 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.

Mindfulness-based therapies

Table 58: Clinical evidence profile: Mindfulness-based cognitive therapy versus relaxation

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Mindfulness-based cognitive therapy**	**Relaxation**	**Relative (95% CI)**	**Absolute**		
Tinnitus severity (follow-up post-treatment; measured with: TQ; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	36	32	-	MD 6.8 lower (14.03 lower to 0.43 higher)	⊕⊕⊕O MODERATE	CRITICAL
Tinnitus severity (follow-up 6 months; measured with: TQ; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	34	28	-	MD 7.6 lower (16.3 lower to 1.1 higher)	⊕⊕⊕O MODERATE	CRITICAL

Tinnitus severity (follow-up post-treatment; measured with: TFI; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	36	32	-	MD 7.00 lower (16.09 lower to 2.09 higher)	⊕⊕⊕O MODERATE	CRITICAL
Tinnitus severity (follow-up 6 months; measured with: TFI; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	34	28	-	MD 11.80 lower (23.06 to 0.54 lower)	⊕⊕⊕O MODERATE	CRITICAL
Tinnitus loudness (follow-up post-treatment; measured with: VAS; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	36	32	-	MD 2.6 lower (13.94 lower to 8.74 higher)	⊕⊕⊕O MODERATE	IMPORTANT
Tinnitus loudness (follow-up 6 months; measured with: VAS; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	34	28	-	MD 10.3 lower (23.79 lower to 3.19 higher)	⊕⊕⊕O MODERATE	IMPORTANT
Depression (follow-up post-treatment; measured with: HADS/ BDI; range of scores: 0-21, 0-63; Better indicated by lower values)												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	49	44	-	SMD 0.41 lower (0.82 lower to 0.01 higher)	⊕⊕⊕O MODERATE	IMPORTANT
Depression (follow-up 6 months; measured with: HADS/BDI; range of scores: 0-21, 0-63; Better indicated by lower values)												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	47	40	-	SMD 0.42 lower (0.85 lower to 0.01 higher)	⊕⊕⊕O MODERATE	IMPORTANT
Anxiety (follow-up post-treatment; measured with: HADS/STRAI; range of scores: 0-21, 20-80; Better indicated by lower values)												
2	randomised	no serious	no serious	no serious	no serious	none	49	44	-	SMD 0.24 lower (0.65 lower to 0.17	⊕⊕⊕⊕	IMPORTANT

	trials	risk of bias	inconsistency	indirectness	imprecision					higher)	HIGH	
Anxiety (follow-up 3-6 months; measured with: HADS/ STRAI; range of scores: 0-21, 20-80; Better indicated by lower values)												
2	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[1]	none	47	40	-	SMD 0.39 lower (0.82 lower to 0.03 higher)	⊕⊕⊕O MODERATE	IMPORTANT

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

Table 59: Clinical evidence profile: Mindfulness meditation versus relaxation therapy

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Mindfulness meditation**	**Relaxation therapy**	**Relative (95% CI)**	**Absolute**		
Tinnitus severity (follow-up mean 15 weeks; measured with: VAS; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	34	27	-	MD 1.5 lower (2.51 to 0.49 lower)	⊕OOO VERY LOW	CRITICAL
Tinnitus loudness (follow-up mean 15 weeks; measured with: VAS; range of scores: 0-10; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[1]	none	34	27	-	MD 0.64 lower (1.79 lower to 0.51 higher)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up mean 15 weeks; measured with: HADS - anxiety; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	34	27	-	MD 1.3 lower (3.08 lower to 0.48 higher)	⊕OOO VERY LOW	IMPORTANT

Depression (follow-up mean 15 weeks; measured with: HADS - depression; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	34	27	-	MD 0.33 lower (2.07 lower to 1.41 higher)	⊕OOO VERY LOW	IMPORTANT
Depression and anxiety (follow-up mean 15 weeks; measured with: HADS - total; range of scores: 0-42; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	34	27	-	MD 1.63 lower (4.94 lower to 1.69 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 60: Clinical evidence profile: Mindfulness and body psychotherapy-based group treatment versus waiting-list control

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Mindfulness and body-psychotherapy-based group treatment**	**Waiting-list control**	**Relative (95% CI)**	**Absolute**		
Tinnitus severity (follow-up post-treatment; measured with: TQ; range of scores: 0-84; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	15	16	-	MD 6.6 lower (18.18 lower to 4.98 higher)	⊕OOO VERY LOW	CRITICAL
Tinnitus severity (follow-up post-treatment; measured with: THI; range of scores: 0-1--; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	15	16	-	MD 14 lower (28.43 lower to 0.43 higher)	⊕OOO VERY LOW	CRITICAL

Tinnitus annoyance (follow-up post-treatment; measured with: VAS; range of scores: 0-10; Better indicated by lower values)											
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	15	16	-	MD 1.8 lower (3.6 lower to 0 higher)	⊕OOO VERY LOW	IMPORTANT
Tinnitus loudness (follow-up post-treatment; measured with: VAS; range of scores: 0-10; Better indicated by lower values)											
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	15	16	-	MD 1.9 lower (3.67 to 0.13 lower)	⊕OOO VERY LOW	IMPORTANT
Depression (follow-up post-treatment; measured with: BDI; range of scores: 0-63; Better indicated by lower values)											
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	15	16	-	MD 5.7 lower (10.85 to 0.55 lower)	⊕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

Acceptance and commitment therapy (ACT)

Table 61: Clinical evidence profile: iACT versus control (web discussion forum)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**iACT**	**Control (web discussion forum)**	**Relative (95% CI)**	**Absolute**		
Tinnitus severity and distress (follow-up post-treatment; measured with: THI; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	33	32	-	MD 18 lower (25.46 to 10.54 lower)	⊕⊕OO LOW	CRITICAL
Quality of life (follow-up post-treatment; measured with: QoLI; Better indicated by higher values)												

1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	33	32	-	MD 0.15 lower (0.87 lower to 0.57 higher)	⊕OOO VERY LOW	CRITICAL
Depression (follow-up post-treatment; measured with: HADS - depression; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[1]	none	33	32	-	MD 1.11 lower (2.52 lower to 0.3 higher)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up post-treatment; measured with: HADS - anxiety; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	33	32	-	MD 2.57 lower (4.15 to 0.99 lower)	⊕OOO VERY LOW	IMPORTANT
Sleep (follow-up post-treatment; measured with: ISI; range of scores: 0-28; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	33	32	-	MD 2.74 lower (5.78 lower to 0.3 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 62: Clinical evidence profile: ACT versus waiting-list control

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**ACT**	**Waiting-list Control**	**Relative (95% CI)**	**Absolute**		
Tinnitus severity (follow-up post-treatment; measured with: THI; 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	22	22	-	MD 20.86 lower (32.76 to 8.96 lower)	⊕OOO VERY	CRITICAL

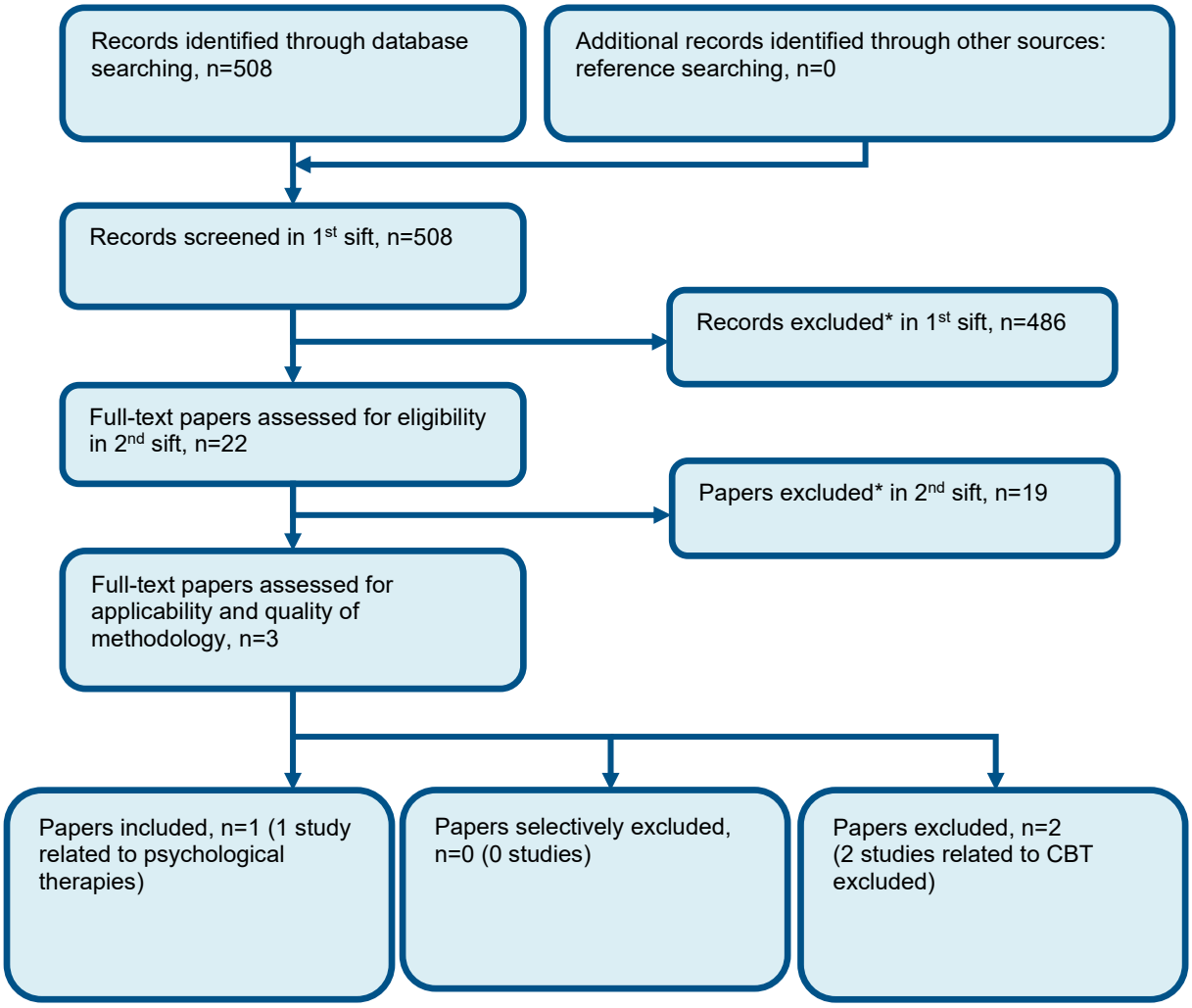
											LOW	
Quality of life ((follow-up post-treatment; measured with: QoLI; Better indicated by higher values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	22	-	MD 0.86 higher (0.12 lower to 1.84 higher)	⊕OOO VERY LOW	CRITICAL
Depression (follow-up post-treatment; measured with: HADS- depression; range of scores: 0-21; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	22	-	MD 3 lower (5.59 to 0.41 lower)	⊕OOO VERY LOW	IMPORTANT
Anxiety (follow-up post-treatment; measured with: HADS - anxiety; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	22	-	MD 3.6 lower (6.27 to 0.93 lower)	⊕OOO VERY LOW	IMPORTANT
Sleep ((follow-up post-treatment ; measured with: ISI; range of scores: 0-28; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	22	22	-	MD 2.55 lower (5.9 lower to 0.8 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 165 Flow chart of health economic study selection for the guideline



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

Appendix H: Health economic evidence tables

Study	Maes 2014[37]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: Cost-utility analysis **Study design:** Within trial analysis (RCT) **Approach to analysis:** Mean costs and mean QALYs compared over the duration of the study period (1 year) with multiple imputations. **Perspective:** Netherlands provider perspective(a) **Time horizon/Follow-up** 1 year **Treatment effect duration:** 1 year **Discounting:** Costs = NR Outcomes = NR	**Population:** Adults referred to audiological centre with subjective tinnitus complaints **Patient characteristics:** Mean age: 54.2 N = 492 Drop out = 160 (32.5%) **Intervention 1 (n=247):** Usual care: treatment currently applied in Netherlands audiological centres for Tinnitus patients. Stepped approach (1) Audiologic diagnostics and intervention (counselling, prescription of hearing aid/sound generator) (2) One or more consultations with social worker (maximum of 10) **Intervention 2 (n=245):** Specialised care: multidisciplinary and more tailored care (1) Same as (1) in intervention 1 but also includes a more intensive audiological examination (including tympanometry and loudness level	**Total costs (mean per patient):** Intervention 1: £2595 Intervention 2: £2694 Incremental (2−1): £102 (95% CI: -£223 to £431) **Currency & cost year:** 2009 euros (presented here as 2009 UK pounds(b)) **Cost components incorporated:** Diagnostic tests, hearing aids (including cost of fitting), cost of CBT/education/relaxation, GP costs, hospital costs, other health professional costs, prescribed medication	**QALYs (mean per patient):** Intervention 1: 0.62 Intervention 2: 0.64 Incremental (2−1): 0.02 (95% CI: -0.028 to 0.055; p=NR)	**ICER (Intervention 2 versus Intervention 1):** £7001 per QALY gained **Analysis of uncertainty:** Sensitivity analyses were conducted on the approach to missing data a) Imputation using predicted values from mixed multi-level regression: ICER of £6160 per QALY gained. b) Complete case analysis: ICER of £6742 per QALY gained. Probability Intervention 2 cost effective in the base case (£20K and 30K threshold): 60% and 68%

	measure), Tinnitus Education Group session and an individual consultation with psychologist (2) Based on scores from tinnitus questionnaire, separated to mild, moderate and severe. • Mild receive no additional care. • Moderate – severe receives 'Program A' 12 weekly group sessions. • Severe receive 'Program B' two group sessions a week for 12 weeks. Program A and B comprise of CBT/education/relaxation techniques/attention diversion			

Data sources

Health outcome: Health-related quality of life reported directly from patients **Quality-of-life weights:** Health Utilities Index Mark III. **Cost sources:** Hearing aid unit costs from 'GIP databank 2009', cost of fitting from Dutch Association of Hearing Aid Dispensers, unit costs of health care from Dutch guideline for cost research list, salary costs are average from Dutch audiology centres for each relevant profession.

Comments

Source of funding: Netherlands Organisation for Health Research and Development. **Limitations:** The study does not include children (an inclusion criterion is 18≥). Utility weights are not derived from NICE reference case (EQ5D) and the study was from a Dutch perspective. The study was only conducted over 1 year. Nonetheless, as the costs are approximately similar in both intervention and the second intervention derives more QALYs it would be expected that this intervention is still more cost-effective over a longer time horizon. There was a large dropout in the study (32%) and therefore it is difficult to predict how the ICER would be effected if the profile of participants dropping out are those who would derive less QALYs from this new intervention. The study has attempted to deal with this by conducting a regression analysis to input missing data however as these are estimated using participants in the study it does not fully address the potential systematic difference between the participants in the study for the full time horizon and those who drop out. Finally as step 1 is different in both groups, the study could be perceived to be a cost-utility analysis of the entire tinnitus management pathway as oppose to CBT alone, this was one of the key reasons the study was downgraded for both applicability and quality.

Overall applicability:[(c)] Partially applicable **Overall quality:**[(d)] Potentially serious limitations

Abbreviations: RCT: Randomised control trials. EQ-5D: Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER: incremental cost-effectiveness ratio; NR: not reported; QALYs: quality-adjusted life years

(a) The study also presented a societal perspective but only provider perspective has been presented here.

(b) Converted using 2009 purchasing power parities [51]

(c) Directly applicable / Partially applicable / Not applicable

(d) Minor limitations / Potentially serious limitations / Very serious limitations

Appendix I: Excluded studies

I.1 Excluded clinical studies

Table 63: Studies excluded from the clinical review

Study	Exclusion reason
Andersson 1999[4]	Incorrect study design: non-randomised study
Andersson 2015[3]	Incorrect study design: literature review
Beukes 2015[12]	Incorrect study design: study protocol
Beukes 2017[10]	Incorrect study design: study protocol
Beukes 2018[11]	No relevant outcome data
Beukes 2018 [13]	Incorrect study design: non-randomised study
Beukes 2018[8]	Incorrect study design: non-randomised study
Caffier 2006[14]	No relevant outcome data
Cima 2014[15]	Incorrect study design: systematic review including non-randomised studies
Cima 2017[17]	Incorrect study design: secondary analysis of an RCT with no relevant outcome data
Hesser 2014[23]	No relevant outcomes
Hiller 2005 [24]	Incorrect study design: non-randomised study
Jakes 1992[25]	No relevant outcomes
Kaldo 2008[28]	Incorrect comparison: two types of CBT
Kallogjeri 2017[29]	Incorrect population: control group in study is people without tinnitus
Kleinstauber 2018[30]	Incorrect study design: non-randomised study
Krings 2015[32]	Incorrect intervention: pharmacological intervention
Malinvaud 2016[38]	Incorrect comparison: CBT versus auditory and visual 3D virtual reality therapy
Marks 2019[40]	Incorrect study design: non-randomised study
Martz 2018[41]	No relevant outcome data
Mason 1994[42]	Incorrect study design; incorrect intervention: hypnotherapy
Mason 1996[43]	Incorrect comparison: counselling versus hypnotherapy
Maudoux 2007[44]	Incorrect study design: non-randomised study
McCombie 2015[45]	Incorrect population: people with physical illnesses (tinnitus not a specific population within study)
McKenna 2018[47]	Incorrect study design: non-randomised study
Nyenhuis 2013[49]	Incorrect study design: secondary analysis of an RCT with no relevant outcome data
Robinson 2008[54]	Data not extractable
Thompson 2017[56]	Incorrect study design: non-randomised study
Tyler 2007[57]	Incorrect study design: narrative article
Weise 2005[61]	Not English Language
Weise 2007[58]	Not English language

Zachriat 2003[63]	Not available
Zarenoe 2016[65]	Incorrect intervention: included in combination review
Zenner 2013[66]	Incorrect study design: non-randomised study
Zhong 2014[67]	Not English Language
Zoeger 2008[68]	Incorrect study design: non-randomised study

I.2 Excluded health economic studies

Table 64: Studies excluded from the health economic review

Reference	Reason for exclusion
Kaldo 2007[27]	This study was assessed as partially applicable with very serious limitations as the authors only include resource use rather than costs.
Kaldo 2008 [28]	This study was assessed as partially applicable with very serious limitations as the authors only include resource use rather than costs.

Appendix J: Research recommendations

Cognitive behavioural therapy (CBT) for adults with tinnitus delivered by appropriately trained healthcare professionals other than psychologists

Research question: What is the clinical and cost effectiveness of CBT for adults with tinnitus delivered by appropriately trained healthcare professionals other than psychologists (for example, audiologists)?

Why this is important:

CBT is a psychological therapy that is usually delivered to individuals with tinnitus by psychologists. However, individuals who present with tinnitus commonly see non-psychologists (e.g. audiologists) and there are many more non-psychologists than psychologists working in the tinnitus field. Costs could be reduced and access to CBT could be improved if appropriately trained non-psychologists were able to deliver CBT. There is currently insufficient evidence to recommend this.

Criteria for selecting high-priority research recommendations:

PICO question	**Population**: Adults (aged over 18 years old) presenting with tinnitus
	
	Intervention(s): CBT (individual, group and digital) delivered by non-psychologists (e.g. audiologists).
	
	Comparison:
	• CBT delivered by psychologists
	• Sound therapy and sound enrichment
	  ○ sound enrichment (e.g. environmental sound, a CD or mp3 download or the radio, a smartphone App, bedside/table-top sound generators, a wearable sound generator)
	  ○ Combination hearing devices (hearing aid combined with sound generator)
	  ○ Customised sound-based therapies, e.g. amplitude modulated tones, notched noise/music
	  ○ Masking
	• Tinnitus support, intervention involving the following components:
	  ○ Discussion of experience of tinnitus, including any concerns and its impact with individuals presenting with tinnitus. This discussion occurs between the person with tinnitus or their family members or carers and healthcare professional.
	  ○ A management plan is also developed to include information and opportunities for discussion about different management options
	• Amplification devices for those with a hearing loss
	  ○ Hearing aids
	  ○ Implantable devices (including cochlear implants, bone-anchored hearing aids, bone-conduction hearing implants, bone-bridge/middle-ear devices)
	  ○ Combination device (sound generator and hearing aids)
	
	• No psychological therapy
	
	Outcome(s):

	• Tinnitus severity (critical)- measured using validated questionnaires Impact of tinnitus, measured using validated questionnaires:(critical) • Tinnitus Distress • Tinnitus Annoyance Health related QoL, measured using validated questionnaires: (critical) • QoL (EQ-5D) Tinnitus percept, measured using validated questionnaires: • Tinnitus Loudness (important) Other co-occurring complaints, measured using validated questionnaires (important) • Depression • Anxiety • Anxiety and depression • Sleep NHS costs and cost effectiveness
Importance to patients or the population	There is evidence that CBT is helpful in the management of tinnitus. The evidence comes from studies where the therapy is delivered by psychologists. There are, however, very few psychologists working in the field. Most people complaining of tinnitus will be managed by other health care professionals, usually audiologists. CBT is not a part of the routine training of audiologists and few have taken additional training. This means that a lot of people seeking help for tinnitus are unable to access this successful management option. The situation is analogous to the historic lack of access to CBT for mental health problems. If CBT for tinnitus can be successfully delivered by audiologists with appropriate training and supervision, then people complaining of tinnitus will be able to access treatment. Demonstration of cost effectiveness is crucial and trials will need to consider the supervision level required by non-psychologists and psychologists to provide a cost- effective service.
Relevance to NICE guidance	Evidence in this area may mean that future NICE guidance recommends that CBT is carried out by suitably trained professionals, other than psychologists, allowing wider access to this intervention.
Relevance to the NHS	If CBT delivered by audiologists is shown to be cost- effective, audiologists delivering tinnitus services would need additional training. If CBT by audiologists is not shown to be effective, strategic planning would be required to allow for increased inclusion of psychologists in tinnitus services.
National priorities	None.
Current evidence base	One UK based RCT (Beukes 2018)[9]; the CBT intervention was delivered by audiologists with supervision from a psychologist. However, this study was an internet-delivered approach which is not available clinically. It exists only for use in research and is therefore not applicable to the question. There is no evidence that considers face-to-face CBT delivered by audiologists. CBT has been shown to be effective for tinnitus when carried out by psychologists but access to psychology services are limited in most

	parts of the country.
Equality	None.
Study design	Randomised controlled trial examining cost effectiveness outcomes. It may be possible to have a single blinding in the RCT. In theory participant might be blinded to the profession of the therapists. However the accessibility of professional profiles on social media and institutional websites may limit this.
Feasibility	The study is feasible and could be carried out in a reasonable timescale.
Other comments	None.
Importance	High: the research is essential to inform future updates of key recommendations in the guideline.

J.1 Psychological therapies for children and young people

Research question: What is the clinical and cost effectiveness of psychological therapies for children and young people who have tinnitus-related distress?

Why this is important:

The clinical and cost effectiveness of psychological therapies has been a focus of research in the management of tinnitus for adults and this has been used to determine the current guidelines. Currently there is no research looking at this for children and recommendations are limited in not being able to recommend specific psychological approaches. This will be important for children with tinnitus and their families so that they are able to receive the best care, and for care providers so that they can provide the most clinical and cost effective care.

Criteria for selecting high-priority research recommendations:

PICO question	**Population:** Children and young people presenting with tinnitus
	
	Intervention(s):
	• Psychological therapies
	  ○ Cognitive Behavioural therapy (CBT)
	  ○ Mindfulness-based interventions e.g. Cognitive therapy and MBSR
	  ○ Brief solution focused therapy
	  ○ Narrative therapy
	  ○ Family therapy/Systemic therapy
	
	Comparison:
	• Interventions compared with each other
	• Interventions in combination with each other
	• Sound therapy and sound enrichment
	  ○ sound enrichment (e.g. environmental sound, a CD or mp3 download or the radio, a smartphone App, bedside/table-top sound generators, a wearable sound generator)
	  ○ Combination hearing devices (hearing aid combined with sound generator)
	  ○ Customised sound-based therapies
	  ○ Masking
	• Tinnitus support, intervention involving the following components:
	  ○ Discussion of experience of tinnitus, including any concerns and its impact with individuals presenting with tinnitus. This

	discussion occurs between the person with tinnitus or their family members or carers and healthcare professional. o A management plan is also developed to include information and opportunities for discussion about different management options • Amplification devices for those with hearing loss o Hearing aids o Implantable devices (including cochlear implants, bone-anchored hearing aids, bone-conduction hearing implants, bone-bridge/middle-ear devices) o Combination device (sound generator and hearing aids) • No psychological therapy • Waiting-list control **Outcome(s):** • Tinnitus severity (critical) Impact of tinnitus:(critical) • Tinnitus Distress • Tinnitus Annoyance Health related QoL (critical): • QoL (EQ-5D) Tinnitus percept: • Tinnitus Loudness (important) Other co-occurring complaints (important) • Depression • Anxiety • Anxiety and depression • Sleep
Importance to patients or the population	The question is important to children, young people and their families who experience tinnitus distress as there are few management options available for children and young people.
Relevance to NICE guidance	The answer to this question would inform future NICE guidance as to the clinical and cost effectiveness of psychological therapies for children and young people.
Relevance to the NHS	There is no practice in the UK for children and young people as there is no evidence of clinical or cost effectiveness. There is a need for evidence to inform future recommendations.
National priorities	There is Department of Health/NHS England guidance on 'Improving mental health services for young people': 'Future in mind**.** Promoting, protecting and improving our children and young people's mental health and wellbeing (2015)' (https://www.gov.uk/government/publications/improving-mental-health-services-for-young-people). This is the report of the work of the Children and Young People's Mental Health Taskforce.
Current evidence base	No evidence was identified that evaluated the use of psychological therapies for children and young people with tinnitus.
Equality	Currently, research has only been carried out with adults and therefore this question will address equality issues in being able to make recommendations for children and young people. Research should consider children of different ages and abilities.

Study design	Randomised control trial with a good quality control group. A robust qualitative study could be an alternative.
Feasibility	There are few providers of psychological services for children with tinnitus.
Other comments	Any intervention for tinnitus for children and young people should consist of the systematic working of healthcare professionals with children and young people and their parents, carers and teachers.
Importance	High: the research is essential to inform future updates of key recommendations in the guideline.

J.2 Psychological therapies for people who are d/Deaf or who have a severe-to-profound hearing loss

Research question: What is the clinical and cost effectiveness of psychological therapies for people who are d/Deaf or who have a severe-to-profound hearing loss and tinnitus-related distress?

Why this is important:

Psychological therapies, also known as “talking therapies”, may be difficult to access for those who have a severe-to-profound hearing loss particularly those who communicate through British Sign Language and/or rely on lip reading despite amplification. This question seeks to identify the effective types or delivery modes of psychological therapies for such individuals.

Criteria for selecting high-priority research recommendations:

PICO question	**Population:** Children, young people and adults presenting with tinnitus-related distress who are d/Deaf or who have a severe-to-profound hearing loss including those who communicate by British Sign Language (BSL)
	
	Intervention(s):
	• Psychological therapies
	  ○ Cognitive Behavioural therapy (CBT)
	  ○ Mindfulness-based interventions e.g., Cognitive therapy and MBSR
	  ○ Brief solution focused therapy
	  ○ Narrative therapy
	  ○ Family therapy/Systemic therapy
	
	Comparison:
	• Interventions compared with each other
	• Interventions in combination with each other
	• Sound therapy
	  ○ Combination hearing devices (hearing aid combined with sound generator)
	  ○ Customised sound-based therapies
	• Tinnitus support including coping strategies, provision of information and advice and relaxation
	• Amplification devices for those with hearing loss

	○ Hearing aids ○ Implantable devices (including cochlear implants, bone-anchored hearing aids, bone-conduction hearing implants, bone-bridge/middle-ear devices) ○ Combination device (sound generator and hearing aids) • No psychological therapy • Waiting-list control **Outcome(s):** • Tinnitus severity (critical) Impact of tinnitus:(critical) • Tinnitus Distress • Tinnitus Annoyance Health related QoL (critical): • QoL (EQ-5D) Tinnitus percept: • Tinnitus Loudness (important) Other co-occurring complaints (important) • Depression • Anxiety • Anxiety and depression • Sleep
Importance to patients or the population	There is currently very limited research into how to manage tinnitus in people who are D/deaf and therefore no clinical evidence or guidance on how to do so. Tinnitus is co-morbid with hearing loss and so understanding how to manage tinnitus within this population should be a priority, as standard care is not feasible for people who are D/deaf.
Relevance to NICE guidance	It would help to ensure future guidance is relevant to a key group for whom tinnitus is an issue and who are identified as such within the equality impact assessment.
Relevance to the NHS	This may impact on strategic delivery or service delivery depending on findings. In the SignHealth Report of 2014, ‘Sick of it: how the health service is failing deaf people’(https://www.signhealth.org.uk/health-information/sick-of-it-report/), it was pointed out that deaf people have worse health and lower life expectancy than people who are not deaf. It is important to find evidence to help reduce this inequality.
National priorities	N/A
Current evidence base	No evidence was identified that evaluated psychological therapies in people presenting with tinnitus-related distress who are d/Deaf or who have a severe-to-profound hearing loss
Equality	This research recommendation addresses people with who are d/Deaf or who have a severe-to-profound hearing loss, a group that needs special consideration.
Study design	Randomised controlled trial or well-designed prospective or retrospective cohort study.
Feasibility	Limited availability to mental health services for those who communicate by BSL. Those who do not use BSL, interpreter will be needed.

Other comments	Psychological therapies could be delivered by BSL.
Importance	Low: the research is of interest and will fill existing evidence gaps.