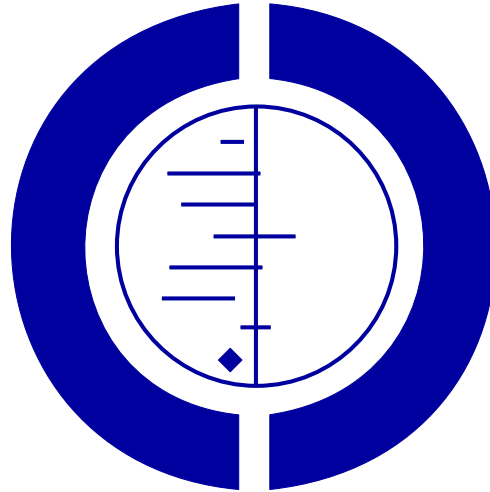


Cognitive behavioural therapy for tinnitus (Review)

Martinez Devesa P, Waddell A, Perera R, Theodoulou M



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ABSTRACT

Background

Tinnitus is an auditory perception that can be described as the experience of sound, in the ear or in the head, in the absence of external acoustic stimulation (not usually audible to anyone else). At present no specific therapy for tinnitus is acknowledged to be satisfactory in all patients.

Cognitive behavioural therapy (CBT) uses relaxation, cognitive restructuring of the thoughts and exposure to exacerbating situations in order to promote habituation and may benefit tinnitus patients, as may the treatment of associated psychological conditions.

Objectives

To assess whether cognitive behavioural therapy is effective in the management of patients suffering from tinnitus.

Search strategy

Our search included the Cochrane ENT Group Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* Issue 2, 2006), MEDLINE and EMBASE. The last search date was June 2006.

Selection criteria

Randomised controlled trials in which patients with unilateral or bilateral tinnitus as main symptom received cognitive behavioural treatment.

Data collection and analysis

One review author (PMD) assessed every report identified by the search strategy. The four review authors assessed the methodological quality, applied inclusion/exclusion criteria and extracted data.

Main results

Six trials comprising 285 participants were included.

1. Primary outcome: subjective tinnitus loudness

CBT compared to a waiting list control group: we found no significant difference (Standardised Mean Difference (SMD) 0.06 (95% CI -0.25 to 0.37)).

CBT compared to another intervention (Yoga, Education, Minimal Contact - Education and Education): we found no significant difference (SMD 0.1 (95% CI -0.22 to 0.42)).

2. Secondary outcomes

a) Depression

CBT compared to a waiting list control group: we found no significant difference in either group (SMD 0.29 (95% CI -0.04 to 0.63)).

CBT compared to another intervention (Yoga, Education and Minimal Contact - Education): we found no significant difference (SMD 0.01 (95% CI -0.43 to 0.45)).

b) Quality of life

CBT compared to a waiting list control group: we found a significant difference in favour of CBT versus the waiting list group (SMD 0.7 (95% CI 0.33 to 1.08)).

CBT compared to another intervention (Education, Minimal Contact - Education and Education): we also found a significant difference between CBT and the other intervention control group (SMD 0.64 (95% CI 0.29 to 1.00)).

There were no adverse/side effects reported in any trial.

Authors' conclusions

We did not find a significant difference in the subjective loudness of tinnitus, or in the associated depression. However we found a significant improvement in the quality of life (decrease of global tinnitus severity) of the participants, thus suggesting that cognitive behavioural therapy has an effect on the qualitative aspects of tinnitus and contributes positively to the management of tinnitus.

PLAIN LANGUAGE SUMMARY

Tinnitus can be described as the experience of sound, in the ear or in the head. Subjective tinnitus is not heard by anyone else. At present no particular treatment for tinnitus has been found effective in all patients.

Cognitive behavioural therapy was originally developed as a treatment for depression and then also used for anxiety, insomnia and chronic pain. It is a form of psychological treatment that consists of the use of relaxation, remodelling thoughts and use challenging situations to improve the patient's attitude towards tinnitus.

The objective of this review was to assess whether cognitive behavioural therapy is effective in the management of patients suffering from tinnitus.

Six trials (285 participants) are included in this review. Data analysis did not demonstrate any significant effect in the subjective loudness of tinnitus, or in the depression associated with tinnitus. We found, however a significant improvement in the quality of life (decrease of global tinnitus severity) suggesting that cognitive behavioural therapy has a positive effect on the way in which people cope with tinnitus.

Further research should use a limited number of validated questionnaires in a more consistent way and with a longer follow up to assess the long-term effect of cognitive behavioural therapy (or other intervention trials) on tinnitus.

BACKGROUND

Tinnitus is an auditory perception that can be described as the experience of sound, in the ear or in the head, in the absence of external acoustic stimulation (not heard by anyone else). The term tinnitus is derived from the Latin word 'tinnire', which means to ring or tinkle. Up to 18% of the population in industrialised countries are affected by tinnitus (Coles 1984; Coles 1995), the majority mildly. Tinnitus can be unilateral or bilateral, continuous or intermittent, low or high pitch. The types of sounds perceived vary greatly. Between 0.5% and 3% of the adult population may suffer from severe chronic tinnitus which can seriously affect their normal lives by producing mood disorders, anxiety, depression or altered sleep patterns (Andersson 2004; Coles 1984; Coles 1995; Luxon 1993).

Tinnitus is usually a subjective experience, but 'objective tinnitus' (that is, perceivable by both patient and observer) can be secondary to conditions such as temporomandibular joint dysfunction (con-

ditions affecting the jaw joint), vascular tumours and malformations (blood vessel enlargement) and contractions of the palatal muscles (muscles of the soft palate).

Prevalence

Epidemiological data reports are few. The data described by the Institute of Hearing Research (UK) in 1981 refers to a prevalence of tinnitus in 15.5% to 18.6% of 6804 participants who completed a questionnaire in four cities (MRC 1981). This is consistent with the data collected by the American Tinnitus Association (ATA) that points to a prevalence of tinnitus in 50 million Americans or about 19% (ATA 2001). Data exist for Japan, Europe and Australia and estimates suggest that tinnitus affects a similar percentage of those populations. One to two per cent of the population experiences debilitating tinnitus, severely limiting the quality of life of affected individuals (Seidman 1998). In a survey in Germany 1.5 million adults experience tinnitus as being 'considerably annoying' (Pilgramm 1999).

Aetiology

Tinnitus can occur as an isolated symptom without a recognisable cause or in association with a middle or inner ear disorder, such as sensorineural hearing loss (Vesteraager 1997), otosclerosis (Shea 1981), intoxication with certain drugs (Brummett 1980), sudden deafness and Ménière's disease (Spoendlin 1987).

Many environmental factors can also cause tinnitus. The most relevant and frequently reported are:

- Acute acoustic trauma (AAT) (for example, explosions or gunfire) (Christiansson 1993; Chung 1980; Melinek 1976; Mrena 2002; Temmel 1999);
- Airbag inflation (Saunders 1998); toy-pistols (Fleischer 1999);
- Exposure to occupational noise; 'urban noise pollution' (Alberti 1987; Axelsson 1985; Chouard 2001; Daniell 1998; Griest 1998; Kowalska 2001; McShane 1988; Neuberger 1992; Phoon 1993);
- Exposure to recreational and amplified music (Becher 1996; Chouard 2001; Lee 1999; Metternich 1999).

The consequences of such exposure can be modified in individuals (Bauer 1991; Rosenhall 1991).

Iatrogenic (treatment induced) factors causing tinnitus include drug-induced ototoxicity caused by, for example, the use of some antimicrobial and chemotherapeutic agents, quinine, aspirin overdose and platinum cytotoxics (Begg 2001; Cunha 2001; Palomar 2001; Sullivan 1988). Tinnitus is also associated with depression, although it is unclear whether tinnitus is a manifestation of depression or a factor contributing to it (Sullivan 1989).

Pathophysiology

There are several theories of the pathophysiology of tinnitus:

One theory suggests that tinnitus is caused by excessive or abnormal spontaneous activity in the auditory system and in related cerebral areas (Jastreboff 1994; Kaltenbach 2000; Lockwood 1999; Moller 1997). Lockwood proposed that the perception of tinnitus arises not in the ears but in the brain (Lockwood 1999). Experimentally delivered audiometric pure tones presented to subjects with tinnitus activate changes in cerebral blood flow in more portions of the brains of tinnitus patients than in controls when assessed with Positron Emission Tomography (PET). This suggests that 'abnormal connections' in the central auditory system may play a role in tinnitus perception.

A separate, but not incompatible, hypothesis suggests a genetic origin for tinnitus (Gingrass 1993; Laubert 1986; Snow 1993). The genetic causes of hearing loss have been reviewed by Willems (Willems 2000).

In the 'neurophysiological model for tinnitus' (Jastreboff 1990) it is proposed that tinnitus results from the abnormal processing of a signal generated in the auditory system. This abnormal processing

occurs before the signal is perceived centrally. This may result in 'feedback', whereby the annoyance created by the tinnitus causes the individual to focus increasingly on the noise, which in turn exacerbates the annoyance and so a 'vicious cycle' develops. In this model tinnitus could therefore result from continuous firing of cochlear fibres to the brain, from hyperactivity of cochlear hair cells or from permanent damage to these cells being translated neurally into a 'phantom' sound-like signal that the brain 'believes' it is hearing. For this reason tinnitus may be compared to chronic pain of central origin - a sort of 'auditory pain' (Briner 1995; Sullivan 1994).

In all these models of tinnitus generation and perception, the relationship between the symptom of tinnitus and the activity of the prefrontal cortex and limbic system has been emphasised. The limbic system mediates emotions. It can be of great importance in understanding why the sensation of tinnitus is in many cases so distressing for the patient. It also suggests why, when symptoms are severe, tinnitus can be associated with major depression, anxiety and other psychosomatic and/or psychological disturbances, leading to a progressive deterioration of quality of life (Lockwood 1999; Sullivan 1989; Sullivan 1992; Sullivan 1993).

Diagnosis

Initially, a patient complaining of tinnitus may simply undergo a basic clinical assessment. This will include the relevant otological, general and family history, and an examination focusing on the ears, teeth and neck and scalp muscles. Referral to a specialist may involve a variety of other investigations including audiological tests and radiology. Persistent, unilateral tinnitus may be due to a specific disorder of the auditory pathway and imaging of the cerebellopontine angle (brainstem) is important to exclude for example, a vestibular schwannoma (acoustic neuroma) - a benign tumour of the cochleo-vestibular nerve. This is the commonest tumour of the cerebellopontine angle, with an incidence of 1.4 per 100,000 of the population (Anderson 2000; Dawes 2000). Other lesions, such as glomus tumours, meningiomas, adenomas, vascular lesions or neuro-vascular conflicts may also be detected by imaging (Marx 1999; Weissman 2000).

Treatment

At present no specific therapy for tinnitus is acknowledged to be satisfactory in all patients.

Many patients who complain of tinnitus and who also have a significant hearing impairment will benefit from a hearing aid. Not only will this help their hearing disability, but also the severity of their tinnitus may be reduced.

A recent review (Waddell 2003) showed that the use of tricyclic antidepressants improved tinnitus related disability in people with or without depression and chronic tinnitus (Bayar 2001; Dobie 1993). Other pharmacological agents used in the treatment of tinnitus with less beneficial results include: antiepileptics (Simpson 1999), baclofen (skeletal muscle relaxant and central nervous

system depressant) (Westerberg 1996), benzodiazepines (sedative) (Johnson 1993), cinnarizine (a cerebral vasodilator and vestibular sedative) (Podoshin 1991), nicotinamide (vitamin B group) (Hulshof 1987) and zinc (Paaske 1991).

Ginkgo biloba for tinnitus has been the subject of a number of studies (Drew 2001; Ernst 1999; Holger 1994; Rejali 2004) and a recent Cochrane review (Hilton 2004). Lidocaine and tocainide (local anaesthetics and antiarrhythmics that act by stabilising hair cell membrane and cochlear nerve fibres) (Hulshof 1985; Lenarz 1986) have also been used in the treatment of tinnitus with no significant benefit but with reported adverse reactions (gastrointestinal upset, dizziness, mouth dryness, rash and tremor).

Other interventions include acupuncture (Park 2000), electromagnetic stimulation (Dobie 1986; Fiedler 1998; Roland 1993), hypnosis (Artias 1993; Mason 1996), low power laser (Mirz 1999), psychotherapy (Andersson 1999), tinnitus masking devices ('white noise generators') and biofeedback.

In recent years increasing attention has been given to the method known as Tinnitus Retraining Therapy (TRT). This is a therapeutic process that uses a combination of low level, broad-band noise and counselling to achieve 'habituation'. The aim of the treatment is to redirect the brain's 'attentional focus' away from the tinnitus signal.

Cognitive behavioural therapy

Cognitive behavioural therapy (CBT) is a structured, time-limited psychological therapy. It is usually offered on an outpatient basis with between eight and 24 weekly sessions. It involves the patient using behavioural and cognitive tasks to modify their response to thoughts and situations.

Cognitive behavioural therapy is based on the principle that core beliefs, usually developed in childhood and often arising from a specific incident, provide a pattern of assumptions. Specific mood states or events similar to the original or critical incident can set up thought patterns which reinforce the core beliefs. These patterns influence behavioural and emotional responses giving rise to symptoms, which may be cognitive, behavioural or somatic.

Tinnitus may be conceived as a failure to adapt to a stimulus (Hallam 1984) and in that sense may be considered to be analogous to anxiety states.

Cognitive behavioural therapy involves collaborative empiricism (Beck 1979) in which patient and therapist view the patient's fearful thoughts as hypotheses to be critically examined and tested. This is achieved by (a) generating an understanding of the link between thoughts and feelings arising from an event and using this information to understand the core beliefs and (b) modifying these cognitions and the behavioural and cognitive responses by which they are normally maintained. Education, discussion of evidence for and against the beliefs, imagery modification, attentional manipulations, exposure to feared stimuli and relaxation techniques

are used in the therapy. Behavioural and cognitive assignments which test beliefs are used. The potential pitfalls and obstacles are identified and achievable goals are set so that a successful and therefore therapeutic outcome is experienced.

Originally developed as a treatment for depression, there are now a wide range of psychological conditions for which cognitive behavioural therapy has an evidence based rationale including anxiety, insomnia and chronic pain (Hawton 1989). The use of relaxation, cognitive restructuring of the thoughts and exposure to exacerbating situations in order to promote habituation may benefit tinnitus patients, as may the treatment of associated psychological conditions.

OBJECTIVES

To assess whether cognitive behaviour therapy is effective in the management of patients suffering from tinnitus. As the symptoms of tinnitus are very subjective for the great majority of patients, we aim to evaluate subjective improvement in the perception of this symptom.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomised controlled trials.

Types of participants

Patients with unilateral or bilateral tinnitus as main symptom, not necessarily associated with hearing loss. We will exclude patients with pulsatile tinnitus and other somatic sounds, delusional auditory hallucinations and patients undergoing concurrent psychotherapeutic interventions.

Types of intervention

Cognitive behavioural therapy (of variable intensity and duration, within a group or individually, by a qualified practitioner) versus no treatment or other treatments.

Types of outcome measures

Primary outcome measure

Subjective tinnitus loudness (measured on a numeric scale).

Secondary outcome measures

Subjective and objective improvement of the symptoms of depression and mood disturbances associated with tinnitus.

Evaluation of quality of life for patients (Tinnitus Handicap Questionnaire or other validated assessment method).

Adverse effects (i.e. worsening of symptoms, suicidal tendencies, negative thoughts)

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Ear, Nose and Throat Disorders Group methods used in reviews.

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* Issue 2, 2006), MEDLINE (1950 to June 2006) and EMBASE (1974 to June 2006). The date of the last search was June 2006.

The following databases were also searched: CINAHL (1982 to June 2006), AMED (1985 to June 2006), LILACS, KOREAMED, INDMED, SIGLE, Cambridge Scientific Abstracts, *mRCT* (metadatabase of controlled trials), the National Research Register and ISI Web of Science.

CENTRAL was searched using the following terms:

- #1 TINNITUS single term (MeSH)
- #2 TINNIT*
- #3 EAR* NEAR BUZZ* OR EAR* NEAR RING* OR EAR* NEAR ROAR* OR EAR* NEAR CLICK* OR EAR* NEAR PULS*
- #4 #1 OR #2 OR #3
- #5 BEHAVIOR THERAPY explode all trees (MeSH)
- #6 COGNIT* AND BEHAV*
- #7 (COGNIT* OR BEHAV* OR CONDITIONING OR RELAXATION OR DESENSITI*) AND (THERAP* OR PSYCHOTHERAP* OR TRAIN* OR RETRAIN* OR TREATMENT* OR MODIFICATION*)
- #8 DESENSITI* NEAR PSYCHOLOG*
- #9 IMPLOSIVE NEAR THERAP*
- #10 #5 OR #6 OR #7 OR #8 OR #9
- #11 #4 AND #10

Search strategies for MEDLINE + CINAHL, EMBASE and PsycINFO, based on the above strategy, are presented in Table 01. These strategies were combined with the first two sections of the highly sensitive search strategy designed by The Cochrane Collaboration for identifying randomised controlled trials and controlled clinical trials in MEDLINE and EMBASE.

References of retrieved articles from electronic searches were searched. A search for existing meta-analyses and non-Cochrane systematic reviews was performed and their reference lists scanned for additional trials. Authors of published trials and other experts in the field were contacted. There were no language, publication year or publication status restrictions on searching.

METHODS OF THE REVIEW

One review author (PMD) assessed every report identified by the search strategy described above for relevance to this review. The

criteria for selection at this stage were simple and broad, so as not to miss any relevant study, and were:

- 1) randomisation;
- 2) diagnosis of tinnitus;
- 3) comparison between cognitive behavioural therapy and other treatment or no treatment.

Four review authors, blinded to decisions made each other, decided which trials fit the inclusion criteria and graded their methodological quality. Any disagreement was resolved by discussion between the review authors. Authors were contacted if necessary for clarification.

Quality assessment

The criteria for quality assessment were based on the recommendations of the Cochrane Reviewers' Handbook, version 4.2.1, Section 6 (updated Dec. 2003). The quality of selected studies was assessed for the following characteristics:

Adequacy of the randomisation process and of allocation concealment:

- A - Adequate (e.g. centralised randomisation by a central office)
- B - Unclear (e.g. apparently adequate concealment but without other information in trial)
- C - Inadequate (e.g. alterations in method or any allocation that could be potentially transparent)

Attrition bias:

- A - Adequate (trials where an intention-to-treat analysis is possible and drop out rate was less than 20% in all groups)
- B - Unclear (trials where drop out rate was more than 20% or great heterogeneity in drop out rate between groups was observed)
- C - Inadequate (lack of reporting on drop out rate and intention-to-treat analysis is not possible)

Detection bias:

Blinding of investigators who assessed the outcomes of interventions is relevant to this research, in that the outcome measures have great subjective components (severity of tinnitus and/or associated depression). For the purpose of this review, it will also be important to evaluate the adequacy, the development and the standardisation of the questionnaires used in the trials. For this reason adequacy of studies will be classified as:

- A - Adequate (trials in which blinding of investigators assessing outcomes was adequate; the utilisation of questionnaires was clearly shown; the questionnaires used were well known and/or standardised)
- B - Unclear (trials in which blinding of investigators is not adequately described and/or the utilisation of questionnaires was not clearly shown; the questionnaires used were not well known and/or not standardised)
- C - Inadequate (trials in which blinding of investigators was clearly not performed)

Studies were graded A, B or C for their overall methodological quality. Study quality was used in a sensitivity analysis.

Data extraction

The authors extracted data independently on to standardised data forms. Studies that have incomplete or ambiguous reporting of data were clarified by discussion between the authors.

Data analysis

Data analysis was intention-to-treat. For dichotomous data we would calculate the odds ratio (OR) and number needed to treat (NNT). For continuous data, the standardised mean difference (SMD) was calculated.

A pooled statistical analysis of treatment effects proceeded only in the absence of significant clinical or statistical heterogeneity. When obtaining the outcome of change we used the correlation obtained from Zachriat 2004 (complete data set, correlation = 0.69) to model the outcomes for those studies that reported measures at baseline and endpoint only.

The main analysis was an examination of severity (subjective loudness) of tinnitus and its effect on depression and quality of life, during and after the period of treatment.

We also planned to collect and analyse data on any adverse reactions due to treatment.

DESCRIPTION OF STUDIES

See tables of 'Characteristics of included studies' and 'Characteristics of excluded studies'.

Twenty-one studies were identified following our search, from which six studies (comprising 285 participants) met our inclusion criteria. Most of the studies compared cognitive behavioural therapy to a waiting list control and/or other intervention/s, namely educational, yoga or other psychotherapeutic treatment, in two to four study arms. The assessment tools used in these five studies varied greatly, but could be divided in three main groups: (1) audiological, (2) psychometric questionnaires and well-being scales (such as Tinnitus Questionnaire and Tinnitus Handicap Questionnaire) and (3) subjective score in a tinnitus diary (loudness, tinnitus awareness and tinnitus control etc.). Cognitive behavioural therapy treatment consisted of six to 11 group sessions (six to eight individuals) of 60 to 120 minutes duration, with a qualified psychologist or student psychologists under supervision (Rief 2005). Self-report questionnaires and diaries (between eight and 12) were used to measure outcomes at pre-, post-treatment and follow-up periods (i.e. 3, 6, 12 and 18/21 months). Report of patients lost during treatment and follow up was good with total drop out varying from 4.65% to 21.66%, which would be more than adequate for these types of trials.

All studies aimed to report results at baseline (pre-treatment), post-treatment and at follow-up periods that varied from three to 18

months, however after the initial treatment, the waiting list groups also received CBT thus invalidating the follow-up comparisons for the purpose of this review. One study (Kröner-Herwig 2003) collected follow-up data on the treatment group only (CBT) as their hypothesis was that the treatment effect would be maintained. In this trial, the Tinnitus Questionnaire score (quality of life) was maintained at six months and deteriorated slightly but not significantly at 12 months follow up.

METHODOLOGICAL QUALITY

Allocation bias

Six studies (comprising 285 participants) met our inclusion criteria. Of these, two (Kröner-Herwig 1995; Henry 1996) did not explain the method of randomisation. Allocation concealment was adequate in most studies, only one study (Kröner-Herwig 1995) divided the treatment group into two arms to have a more balanced four arm study (comparing them to yoga and waiting list control), however this was taken into account when extracting data from this study, using a combined mean and standard deviations.

The inclusion/exclusion criteria were clearly defined in all studies. The participants' demographics were comparable throughout all the studies with the exception of a male preponderance (86%) in one study (Henry 1996).

Attrition bias

An acceptable drop out rate was considered in this review to be no more than 20%. Two studies (Kröner-Herwig 1995; Henry 1996) had a drop out just above this limit at 21.66% and 20.93%, however this was well accounted for in these trials and affected also other trial arms which were not involved in our data extraction and calculations.

Detection bias

A large number of self-reported questionnaires and diaries (eight to 12) were used as main assessment outcomes of the treatments imparted in these trials. The adequacy and validation of these questionnaires was generally poor. We used the Tinnitus Questionnaire (Hallam 1988; used in Kröner-Herwig 2003 and Zachriat 2004), the Tinnitus Handicap Questionnaire (Kuk 1990; used in Henry 1996) and the Tinnitus Reaction Questionnaire (Wilson 1991; used in Andersson 2005) as standardised and validated instruments to measure global tinnitus severity and its effect on quality of life, and the also validated Beck Depression Inventory (Beck 1961; Beck 1988 and used in Henry 1996) and when not available a modified Centre for Epidemiological Studies Depression Scale (CES-D, German translation ADS; Radloff 1977; used in Kröner-Herwig 2003), the Depression scale ("Depressivitäts Skala"; Zerssen 1975; used in Kröner-Herwig 1995) and the Hospital Anxiety and Depression Scale-depression subscale (Zigmond 1983; used in Andersson 2005) to provide a measure of depression of the participants before and after their intervention.

With regards to the assessment of subjective loudness experienced by the participants this was our only primary outcome and it was reported in five of the six studies using numeric visual analogue scales.

Overall quality of the studies was generally good (see 'Characteristics of included studies' table). One study (Rief 2005) was of higher quality than the rest with regards to allocation concealment. All studies had adequate randomisation and ascertainment. All outcomes reported by the studies were subjective as there was no blinding to intervention, so the possibility of bias is present. However this is typical in trials with this type of intervention (CBT).

RESULTS

Six trials comprising 285 participants were included in this review.

We established in our protocol that there would be a primary outcome measure: (1) subjective tinnitus loudness, and two secondary outcome measures: (2) subjective and objective improvement of the symptoms of depression and mood disturbances associated with tinnitus, and (3) evaluation of quality of life for patients (Tinnitus Handicap Questionnaire or other validated assessment method).

The selected control groups for comparison were first a waiting list group (participants did not receive any intervention) and then another intervention (when available) carried out in another arm of the trial (i.e. Yoga in Kröner-Herwig 1995, Education in Henry 1996, Minimal Contact - Education in Kröner-Herwig 2003, Education in Zachriat 2004).

All the data extracted were continuous and were therefore analysed using Standardised Mean Difference (SMD), a 95% Confidence Interval (CI) and visually represented in a forest plot.

The Kröner-Herwig 1995 trial reported two CBT arms separately. We pooled the results (Means and SD) for these two to obtain a single measure to use in our comparisons.

1. Primary outcome: subjective tinnitus loudness

Five trials (262 participants) reported subjective loudness pre- and post-treatment on numeric visual analogue scales (VAS), the scores ranging from 0 to 10 points (Kröner-Herwig 1995), 0 to 4 points (Henry 1996), 1 to 7 points (Kröner-Herwig 2003; Zachriat 2004) or 0 to 10 points (Rief 2005).

Four studies (171 participants) compared CBT to a waiting list control group.

After pooling these studies we found no significant difference between treatment (cognitive behavioural therapy) and a waiting list control group: SMD 0.06 (95% CI -0.25 to 0.37).

Four studies (164 participants) compared CBT to another intervention (Yoga in Kröner-Herwig 1995, Education in Henry 1996,

Minimal Contact - Education in Kröner-Herwig 2003 and Education in Zachriat 2004). After pooling these studies we found no significant difference between treatment (cognitive behavioural therapy) and other intervention control group: SMD 0.1 (95% CI -0.22 to 0.42).

Secondary outcomes

2. Depression

Four trials (196 participants) assessed changes in depression scores pre- and post-treatment on itemised scales ranging from 0 to 100 points ("Depressivitäts Skala"; Kröner-Herwig 1995), 0 to 63 points (Beck Depression Inventory; Henry 1996), 0 to 60 points (ADS-German version of the CES-D; Kröner-Herwig 2003) and 0 to 21 points (Hospital Anxiety and Depression Scale-depression; Andersson 2005).

Four studies (152 participants) compared CBT to a waiting list control group, using a Depression scale ("Depressivitäts Skala", Kröner-Herwig 1995), the Beck Depression Inventory (Henry 1996), the ADS (German version of the CES-D, Kröner-Herwig 2003) and the HADS-depression scale (Andersson 2005). After analysing these studies together, there was no significant difference in either group: SMD 0.29 (95% CI -0.04 to 0.63).

Three studies (117 participants), compared CBT to another intervention (Yoga in Kröner-Herwig 1995, Education in Henry 1996, and Minimal Contact - Education in Kröner-Herwig 2003). We found no significant difference between treatment (cognitive behavioural therapy) and the other intervention control group: SMD 0.01 (95% CI -0.43 to 0.45).

3. Quality of life

This was assessed in four trials (219 participants) using the Tinnitus Handicap Questionnaire (THQ) in one of them (Henry 1996), the Tinnitus Questionnaire (TQ) in two (Kröner-Herwig 2003; Zachriat 2004), and the Tinnitus Reaction Questionnaire in the final one (Andersson 2005).

Three studies (126 participants) compared CBT to a waiting list control group.

After pooling these studies, data analysis supports a significant difference in favour of the treatment group (CBT) versus the waiting list group: SMD 0.70 (95% CI 0.33 to 1.08). This was also highlighted in the individual trials results.

Three studies (146 participants) compared CBT to another intervention (Education in Henry 1996, Minimal Contact - Education in Kröner-Herwig 2003 and Education in Zachriat 2004). After pooling these studies we also found a significant difference between treatment (cognitive behavioural therapy) versus other intervention control group: SMD 0.64 (95% CI 0.29 to 1.00).

Adverse effects

There were no adverse/side effects reported in any trial.

DISCUSSION

The objective of this review was to assess whether cognitive behavioural therapy was effective in the management of patients suffering from tinnitus. As tinnitus itself is usually a subjective experience, our aim throughout the review was to look at subjective improvement in tinnitus and its effect on mood (depression) and overall quality of life.

Six of twenty-one identified trials provided us with enough information to fulfil our objective. One trial was excluded as the number of participants in each group was not available and further attempts to obtain extra information were unsuccessful (Henry 1998).

A large number of assessment tools (eight to 12) were used in each individual trial, so they generated an even larger list of outcome variables when some subsections of questionnaires or diaries were analysed independently.

The adequacy and validation of the questionnaires used was generally poor. We used the Tinnitus Questionnaire (Hallam 1988) and the Tinnitus Handicap Questionnaire (Kuk 1990) as standardised and validated instruments to measure global tinnitus severity and its effect on quality of life, and the also validated Beck Depression Inventory (Beck 1961; Beck 1988) and when not available, the validated Centre for Epidemiological Studies Depression Scale (CES-D, German translation ADS, Radloff 1977) and the Depression scale ("Depressivitäts Skala", Zerssen 1975), to provide a measure of depression of the participants before and after their intervention.

In the data analysis we found no significant change in subjective loudness of tinnitus, however we found a significant improvement in the quality of life (decrease of global tinnitus severity) of the participants, thus suggesting that cognitive behavioural therapy has an effect on the qualitative aspects of tinnitus and contributes positively to the management of tinnitus. This effect was observed for both comparisons of CBT versus waiting list and versus other interventions.

Regarding depression we found no significant effect of CBT in the trials that used depression as study tools. In one of these trials, there were no significant intra- and inter-group changes found, with low baseline scores in the depression scale (Kröner-Herwig 2003); the authors of this trial believe this left little room for improvement and subsequently had little overall effect.

Cognitive behavioural therapy was developed as a treatment for depression and has been consistently effective with this population (Gelder 2000). Perhaps depression is only a significant comorbidity of the 'severe' tinnitus sufferers, and as a small group in

general, the inclusion of these 'severe' tinnitus sufferers with other not so severe in a trial, fails to show any overall significant effect.

Finally the lack of follow up found in the trials prevents us from drawing any conclusions about the long-term effect of this intervention for tinnitus, especially on quality of life where there was an initial significant effect and it would be interesting to see if this effect was maintained.

AUTHORS' CONCLUSIONS

Implications for practice

1. Cognitive behavioural therapy for tinnitus is effective for improving the quality of life (or reducing the global severity of tinnitus).
2. There is a lack of available evidence of the effect of this intervention on subjective loudness of tinnitus or on the depression associated with it.

Implications for research

1. A consensus should be reached to use a limited number of validated questionnaires, in a more consistent way, for future research in this area.
2. Longer follow up is necessary to assess the long-term effect of cognitive behavioural therapy, or other intervention trials, on tinnitus.

POTENTIAL CONFLICT OF INTEREST

None known.

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* Indicates the major publication for the study

T A B L E S**Characteristics of included studies**

Study	Andersson 2005
Methods	Randomised controlled trial.
Participants	23 (of 37 initially recruited) participants (12 male), mean age 70.1 years (range 65-79), allocated to two groups: CBT (12 patients) and waiting list control (11 patients). Inclusion criteria were: (1) patient should have problems with their tinnitus; (2) duration of tinnitus for at least 6 months; and (3) being able to attend the sessions, including walking up the stairs to attend the sessions. Exclusion criteria were: (1) previous psychological treatment for tinnitus; (2) depression score above 22 on BDI; (3) a score above 2 on item 2 (hopelessness) and item 9 (suicidal ideation); or (4) had medical reasons for not taking part in the treatment.
Interventions	Two groups: (1) A treatment group of CBT (12 patients); and (2) a waiting list control group (11 patients).
Outcomes	Four outcome measures: (1) The Tinnitus Reaction Questionnaire (TRQ); (2) the Hospital Anxiety and Depression Scale (HADS); (3) the Anxiety Severity Index (ASI); and (4) a Visual Analogue Scale for tinnitus annoyance, loudness and quality of sleep. Comparisons were made at pre- and post-treatment points. Also at 3 months follow up the outcomes were compared, but at this point the data were non-experimental, as the waiting list group had also received CBT after the post-treatment observations.
Notes	There were no drop-outs. Outcomes were measured pre- and post-treatment (6 weeks), then the waiting list group received the same treatment, so follow-up results at three months cannot be used.
Allocation concealment	B – Unclear

Study **Henry 1996**

Methods Randomised controlled trial.

Characteristics of included studies (Continued)

Participants	60 (of 65 initially recruited) patients (52 male, mean age 64 years) allocated to three groups: 20 patients in each group. Inclusion criteria were: (1) chronic tinnitus of greater than six months duration; (2) tinnitus assessed by both otolaryngologist and audiologist; (3) traditional treatments not recommended or had failed; (4) no hearing aid, masker or medication for tinnitus in the previous six months; (5) at least 17 points on the TRQ; (6) English literacy; and (7) willingness to participate in a research program.
Interventions	Three experimental conditions: (1) combined cognitive educational program; (2) education alone (both treatments involved a 90-minute session per week for six weeks, given by the same clinical psychologists, in groups of 5 to 7 subjects); and (3) a waiting-list control.
Outcomes	Self report questionnaires administered at pre-treatment, post-treatment and 12 months follow-up: TRQ, THQ, TEQ, TCQ, TCSQ, TKQ, BDI, LCB and a Self Monitoring of Tinnitus record, including: loudness, notice and bother by tinnitus.
Notes	The number of patients that were lost to the 12-month follow up was 13 (4 in the Cognitive Education, 3 in the Education alone and 6 in the waiting list group). Total drop-out at 12-month follow up = 13/60 = 21.66%. There were no adverse effects reported.
Allocation concealment	B – Unclear

Study **Kröner-Herwig 1995**

Methods	Randomised controlled trial. Randomisation by drawing code numbers from a basket with the total sample.
Participants	43 (of 52 initially recruited) patients (60.5% male, mean age 48 years) allocated to four groups. Inclusion criteria were: (1) duration of tinnitus greater than six months; (2) impairment due to tinnitus >4 on a 10-point rating scale; (3) hearing ability adequate for communication purposes; (4) no treatable organic or psychological pathology; (5) no current psychotherapy; (6) completed medical examination; and (7) willingness to participate in the assessment and at least 8 to 10 treatment sessions.
Interventions	Four experimental groups: (1) Tinnitus Coping Training 1 (TCT1 = 7 patients); (2) Tinnitus Coping Training 2 (TCT2 = 8 patients); (3) Yoga Training (9 patients); and (4) a waiting list control (WLC = 19 patients). Each treatment group (TCT1, TCT2, yoga) consisted of ten 2-hourly sessions, each group was conducted by a different qualified professional.
Outcomes	The outcome measures included: (1) Audiological: Tinnitus Sensation Level (TSL), Tinnitus Masking Level (TML); (2) Self-monitoring tinnitus diary: subjective loudness, tinnitus discomfort, sleep disturbance, interference with activity, control of tinnitus and hours per day of tinnitus ignored; and (3) Self report questionnaires: TQ, and well-being variables: depression, mood and symptoms. All assessments were completed at pre-treatment, post-treatment and 3 months follow up (the latter one except for audiological outcomes).

Characteristics of included studies (Continued)

Notes The number of patients that were lost was 9 (3 in TCT1, 2 in TCT2t, 1 in yoga and 3 in the WLC). Total drop-out = $9/43 = 20.93\%$. There were no adverse effects reported.

Allocation concealment B – Unclear

Study Kröner-Herwig 2003

Methods Randomised controlled trial. Randomisation by drawing code numbers from the total sample and the sequential assignment to the treatment conditions until a pre-set number of subjects was reached.

Participants 95 (of 116 initially recruited) patients (51.6% female, mean age 46.8 years) allocated to four groups.

Inclusion criteria were:

- (1) age between 18 and 65 years;
- (2) duration of tinnitus greater than six months;
- (3) medical diagnosis of 'idiopathic' (unknown) tinnitus;
- (4) tinnitus being their main health problem, with subjective annoyance rating of >40 (out 100) on nine scales assessing disruptive effects of tinnitus.

Exclusion criteria were:

- (1) Ménière's disease;
- (2) hearing loss preventing from participating in communication within groups; and
- (3) current psychotherapeutic treatment.

Interventions Four experimental groups: (1) Tinnitus Coping Training (TCT = 43 patients); (2) Minimal Contact - Education (MC-E = 16 patients); (3) Minimal Contact - Relaxation (MC-R = 16 patients); and (4) a waiting list control (WLC = 20 patients).

TCT comprised 11 sessions of 90 to 120 minutes duration, each group consisted of 6 to 8 patients and was conducted by two qualified psychologists.

MC-E comprised of two group sessions (of education and self-help strategies for coping with tinnitus) 4 weeks apart while 'self-help exercises' were undertaken.

MC-R consisted of an educational session in relaxation and distraction, followed by a second session where patients received audiocassettes with relaxing music and instructions, then a further 2 sessions to discuss progress. Patients in MC-E and MC-R were told they could join in TCT after post-treatment assessment.

All assessments were completed at pre-treatment, post-treatment 6 and 12 months follow up.

Outcomes The outcome measures included:

- (1) Self-monitoring tinnitus diary (during 2 weeks period at pre-, post-treatment and 6 months follow up): loudness, tinnitus awareness and subjective control of tinnitus;
- (2) Psychometric questionnaires: TQ (only instrument used at 12 month follow up), TDQ, a German coping inventory (COPE), SCL-90R and a German depression scale (ADS), a questionnaire of subjective change in tinnitus-related variables (loudness, disability, awareness, control, ignoring) and general well-being variables: physical well-being, activities, mood and stress coping). All assessments were completed at pre-treatment, post-treatment and 6 months follow-up, Tinnitus Questionnaire was the only assessment used at 12 months follow up;
- (3) Audiological variables (tinnitus masking level, tinnitus sensation level) are only measured in the pre-treatment period.

Notes The number of patients that was lost was 21 (13 in the TCT group, 4 in MC-E and MC-R each). Total drop-out = $21/95 = 22.1\%$. There were no adverse effects reported.

Allocation concealment B – Unclear

Study Rief 2005

Methods Randomised controlled trial. Randomisation by a list of random sequence.

Characteristics of included studies (Continued)

Participants	43 (of 48 initially recruited) patients (46.75% female, mean age 46.75 years) allocated to two groups. Inclusion criteria were: (1) duration of tinnitus greater than six months; (2) and participants agreed that the tinnitus was disturbing, with a subjective annoyance rating of >3 (on a visual analogue scale from 0 to 10).
Interventions	Two experimental groups: (1) Psychophysiological-oriented intervention (23 patients); and (2) a waiting list control (WLC = 20 patients). The psychophysiological-oriented intervention comprised 9 sessions of 60 minutes duration conducted by five supervised graduate student psychologists. All assessments were completed at pre-treatment, post-treatment (8 weeks) and 6 months follow up.
Outcomes	The outcome measures included: (1) Psychometric questionnaires: TQ, STI, IDCL, SCL-90R, Self-efficacy; (2) Tinnitus diary (3 times a day, during 1 week period at pre-, post-treatment and 6 months follow up): subjective loudness, tinnitus awareness and subjective control of tinnitus. All assessments were completed at pre-treatment, post-treatment and 6 months follow up.
Notes	The number of patients that were lost at the pos-treatment point was 1 (in the intervention group), and 1 more drop out (in the control group) occurred at the first follow-up point. Total drop-out = 2/43 = 4.65%. There were no adverse effects reported.
Allocation concealment	A – Adequate

Study Zachriat 2004

Methods	Randomised controlled trial. Randomisation by throwing dice.
Participants	77 (of 83 initially recruited) patients (66.6% male, mean age 53.8 years) allocated to three groups. Inclusion criteria were: (1) duration of tinnitus greater than three months; (2) absence of a treatable organic cause of tinnitus; (3) absence of Ménière's disease; (4) hearing capacity for communication within groups; (5) tinnitus disability score >25 on TQ; (6) no ongoing psychotherapy or masker treatment.
Interventions	Three experimental groups: (1) Tinnitus Coping Training (TCT = 29 patients); (2) Habituation-based treatment (HT = 31 patients); and (3) Educational intervention (EDU = 23 patients). TCT comprised 11 sessions of 90 to 120 minutes duration, each group consisted of 6 to 8 patients. There was a 4 week recess between the first and second session of TCT and HT to assess the effect of education alone, and then TCT and HT continued. HT was conducted in 5 sessions of 90 to 120 minutes (spaced over 6 months) to a group of 6 to 8 patients, where education, noise generator and counselling was conducted. Education consisted in a single session informing about the physiology and psychology of tinnitus. This session was identical to the first session for TCT and very similar to the HT one. Patients in EDU group were also offered a further treatment after 15 weeks should they wish. All groups were conducted by 5 qualified psychologist therapists. Assessments were carried out at seven measurement periods, at pre-treatment, post-treatment, 6, 12 and 18 (21 for TCT) months follow up.
Outcomes	The outcome measures included:

- (1) Self-monitoring tinnitus diary (three times per day during 1 week period): loudness, hours of tinnitus awareness and subjective control of tinnitus;
- (2) Psychometric questionnaires: TQ, Tinnitus Coping Questionnaire, QCC, QDC, JQ, a German questionnaire in changes in well-being and adaptive behaviour (VEV), SSR, SCL-90R and Minimal Diagnostic Interview of Psychological Disorders (DSM-III-R).

Most variables were assessed at pre- and post-treatment periods. The TQ was the only one applied at every time period.

Objective tinnitus parameters (pitch masking and masking measurements) were excluded from the study.

Notes The number of patients that were lost before the post-treatment period was 6 (2 in the TCT group, 1 in HT group and 3 in EDU group). A further 2 drop-outs (one in TCT and one in HT group) occurred at 18 months follow up (21 months for the TCT group). Total drop-out = 8/77 = 10.38%. There were no adverse effects reported.

Allocation concealment B – Unclear

TRQ = Tinnitus Reaction Questionnaire, THQ = Tinnitus Handicap Questionnaire, TEQ = Tinnitus Effect Questionnaire, TCQ = Tinnitus Cognitions Questionnaire, TCSQ = Tinnitus Coping Strategies Questionnaire, TKQ = Tinnitus Knowledge Questionnaire, BDI = Beck Depression Inventory, LCB = Locus of Control of Behavior Scale, ATQ = Automatic Thoughts Questionnaire, TQ = Tinnitus Questionnaire, TDQ = Tinnitus Disability Questionnaire, SCL-90R = Symptom Checklist, QCC = Questionnaire of Catastrophizing Cognitions, QDC = Questionnaire of Dysfunctional Cognitions, JQ = Jastreboff Questionnaire, SSR = Questionnaire of Subjective Success, STI = Structured Tinnitus Review, IDCL = International Diagnostic Check-List, QS = Quality Score, R = Randomisation, DB = Double Blind, W = Withdrawals

Characteristics of excluded studies

Study	Reason for exclusion
Andersson 2002	ALLOCATION: Randomised PARTICIPANTS: High drop out (51% in the CBT group)
Davies 1995	ALLOCATION: Randomised PARTICIPANTS: High drop out (43.33%)
Delb 2002	ALLOCATION: Not randomised
Goebel 2000	ALLOCATION: Randomised PARTICIPANTS: Patients with tinnitus INTERVENTION: Not CBT
Henry 1998	ALLOCATION: Randomised PARTICIPANTS: Patients with tinnitus. INTERVENTION: CBT OUTCOME: No usable data. No primary outcome
Hiller 2004	ALLOCATION: Inadequate randomisation, as patients with severe tinnitus (Tinnitus Questionnaire score >40) were allocated to CBT and those with lower scores to the Tinnitus Education group. The randomisation was then done for receiving (or not) noise generators.
Jakes 1986	ALLOCATION: Not randomised
Jakes 1992	ALLOCATION: Randomised PARTICIPANTS: High drop out (44.8%)
Kröner-Herwig 1999	ALLOCATION: Randomised PARTICIPANTS: High drop out (39.53%)
Lindberg 1987	ALLOCATION: Not randomised
Lindberg 1988	ALLOCATION: Not randomised
Lindberg 1989	ALLOCATION: Randomised PARTICIPANTS: Patients with tinnitus.

Characteristics of excluded studies (Continued)

	INTERVENTIONS: Not CBT
Scott 1985	ALLOCATION: Randomised PARTICIPANTS: Patients with tinnitus. INTERVENTIONS: Not CBT
Wise 1998	ALLOCATION: Randomised PARTICIPANTS: Patients with tinnitus. INTERVENTIONS: Not CBT

Characteristics of ongoing studies

Study	Robinson 2001
Trial name or title	Cognitive Behavioral Therapy and SSRI Use in Tinnitus
Participants	69 (38 male). Inclusion criteria: (1) no treatable cause for tinnitus; (2) no psychosis or dementia; (3) reported distress from tinnitus and (4) >18 years age.
Interventions	Two groups: (1) CBT; (2) Control group.
Outcomes	(1) Tinnitus symptoms: THI, ITHQ, TRQ, TEQ. (2) Psychological Symptoms: BDI, HRSD, SCL-90R. (3) Measures of internal focus: MSPQ, PSCS. (4) Functional measures: quality of well-being scale. All assessments at pre-treatment, 8, 16 and 52 weeks.
Starting date	2005
Contact information	Shannon K Robinson, MD. University of California, San Diego. E-mail: skrobinson@ucsd.edu
Notes	THI = Tinnitus Handicap Inventory, ITHQ = Iowa Tinnitus Handicap Questionnaire, TRQ = Tinnitus Reaction Questionnaire, TEQ = Tinnitus Effect Questionnaire, BDI = Beck Depression Inventory, HRSD = Hamilton Rating Scale of Depression, SCL-90R = Symptom Check List 90R, MSPQ = Modified Somatic Perception Questionnaire, PSCS = Private Self Consciousness Scale.

ADDITIONAL TABLES

Table 01. SEARCH STRATEGIES

MEDLINE (DataStar)	EMBASE (DataStar)	PsycINFO (DataStar)
1. TINNITUS.DE.	1. TINNITUS.DE.	1. TINNITUS.DE.
2. TINNIT\$2.TI,AB.	2. TINNIT\$2.TI,AB.	2. TINNIT\$2.TI,AB.
3. (EAR\$1 NEAR (BUZZ\$4 OR RING\$4 OR ROAR\$4 OR CLICK\$4 OR PULS\$4)).TI,AB.	3. (EAR\$1 NEAR (BUZZ\$4 OR RING\$4 OR ROAR\$4 OR CLICK\$4 OR PULS\$4)).TI,AB.	3. (EAR\$1 NEAR (BUZZ\$4 OR RING\$4 OR ROAR\$4 OR CLICK\$4 OR PULS\$4)).TI,AB.
4. 1 OR 2 OR 3	4. 1 OR 2 OR 3	4. 1 OR 2 OR 3
5. BEHAVIOR-THERAPY#.DE.	5. COGNIT\$3 AND BEHAV\$6.TI,AB.	5. BEHAVIOR-THERAPY#.DE.
6. COGNIT\$3 AND BEHAV\$6.TI,AB.	6. DESENSITI\$6 AND	6. COGNITIVE-TECHNIQUES#.DE.
7. (COGNIT\$3 OR BEHAV\$6 OR		7. COGNITIVE-BEHAVIOR-

Table 01. SEARCH STRATEGIES (Continued)

MEDLINE (DataStar)	EMBASE (DataStar)	PsycINFO (DataStar)
CONDITIONING OR RELAXATION OR DESENSITI\$6 AND (THERAPY OR THERAPIES OR THERAPEUTIC\$4 OR PSYCHOTHERAP\$3 OR TRAIN\$3 OR RETRAIN\$3 OR TREATMENT\$1 OR MODIFICATION\$1).TI,AB. 8. DESENSITI\$6 AND PSYCHOLOG\$6.TI,AB. 9. IMPLOSIVE NEAR THERAP\$9.TI,AB. 10. 5 OR 6 OR 7 OR 8 OR 9 11. 4 AND 10	PSYCHOLOG\$6.TI,AB. 7. IMPLOSIVE NEAR THERAP\$9.TI,AB. 8. (COGNIT\$3 OR BEHAV\$6 OR CONDITIONING OR RELAXATION OR DESENSITI\$6) AND (THERAPY OR THERAPIES OR THERAPEUTIC\$4 OR PSYCHOTHERAP\$3 OR TRAIN\$3 OR RETRAIN\$3 OR TREATMENT\$1 OR MODIFICATION\$1).TI,AB. 9. PSYCHOTHERAPY#.DE. 10. 5 OR 6 OR 7 OR 8 OR 9 11. 4 AND 10	THERAPY.DE. 8. COGNIT\$3 AND BEHAV\$6.TI,AB. 9. (COGNIT\$3 OR BEHAV\$6 OR CONDITIONING OR RELAXATION OR DESENSITI\$6) AND (THERAPY OR THERAPIES OR THERAPEUTIC\$4 OR PSYCHOTHERAP\$3 OR TRAIN\$3 OR RETRAIN\$3 OR TREATMENT\$1 OR MODIFICATION\$1).TI,AB. 10. DESENSITI\$6 AND PSYCHOLOG\$6.TI,AB. 11. IMPLOSIVE NEAR THERAP\$9.TI,AB. 12. 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 13. 4 AND 12

ANALYSES

Comparison 01. Cognitive Behavioural Therapy versus control (waiting list): Subjective loudness score.

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Improvement on subjective loudness score pre- and post-treatment.	4	171	Standardised Mean Difference (Random) 95% CI	0.06 [-0.25, 0.37]

Comparison 02. Cognitive Behavioural Therapy versus control (waiting list): Depression score.

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
02 Improvement on depression score pre- and post-treatment.	4	152	Standardised Mean Difference (Random) 95% CI	0.29 [-0.04, 0.63]

Comparison 03. Cognitive Behavioural Therapy versus control (waiting list): Quality of life score.

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
03 Improvement on quality of life score pre- and post-treatment.	3	126	Standardised Mean Difference (Random) 95% CI	0.70 [0.33, 1.08]

Comparison 04. Cognitive Behavioural Therapy versus control (other intervention): Subjective loudness score.

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Improvement on subjective loudness score pre- and post-treatment.	4	164	Standardised Mean Difference (Random) 95% CI	0.10 [-0.22, 0.42]

Comparison 05. Cognitive Behavioural Therapy versus control (other intervention): Depression score.

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
02 Improvement on depression score pre- and post-treatment.	3	117	Standardised Mean Difference (Random) 95% CI	0.01 [-0.43, 0.45]

Comparison 06. Cognitive Behavioural Therapy versus control (other intervention): Quality of life score.

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
03 Improvement on quality of life score pre- and post-treatment.	3	146	Standardised Mean Difference (Random) 95% CI	0.64 [0.29, 1.00]

COVER SHEET

Title	Cognitive behavioural therapy for tinnitus
Authors	Martinez Devesa P, Waddell A, Perera R, Theodoulou M
Contribution of author(s)	All authors contributed to the drafting of the protocol. PMD carried out the search and the three authors selected the included studies, carried out data extraction and contributed to the final text of the review. RP contributed to the statistical methods and the assessment of inclusion/exclusion criteria.
Issue protocol first published	2005/2
Review first published	2007/1
Date of most recent amendment	15 November 2006
Date of most recent SUBSTANTIVE amendment	14 November 2006
What's New	Information not supplied by author
Date new studies sought but none found	Information not supplied by author
Date new studies found but not yet included/excluded	Information not supplied by author
Date new studies found and included/excluded	Information not supplied by author
Date authors' conclusions section amended	Information not supplied by author
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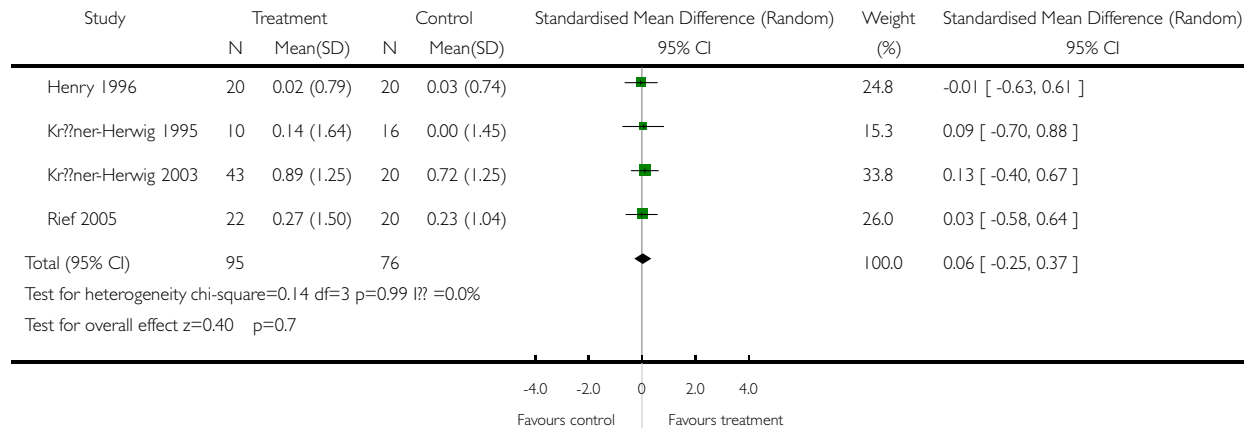
GRAPHS AND OTHER TABLES

Analysis 01.01. Comparison 01 Cognitive Behavioural Therapy versus control (waiting list): Subjective loudness score., Outcome 01 Improvement on subjective loudness score pre- and post-treatment.

Review: Cognitive behavioural therapy for tinnitus

Comparison: 01 Cognitive Behavioural Therapy versus control (waiting list): Subjective loudness score.

Outcome: 01 Improvement on subjective loudness score pre- and post-treatment.

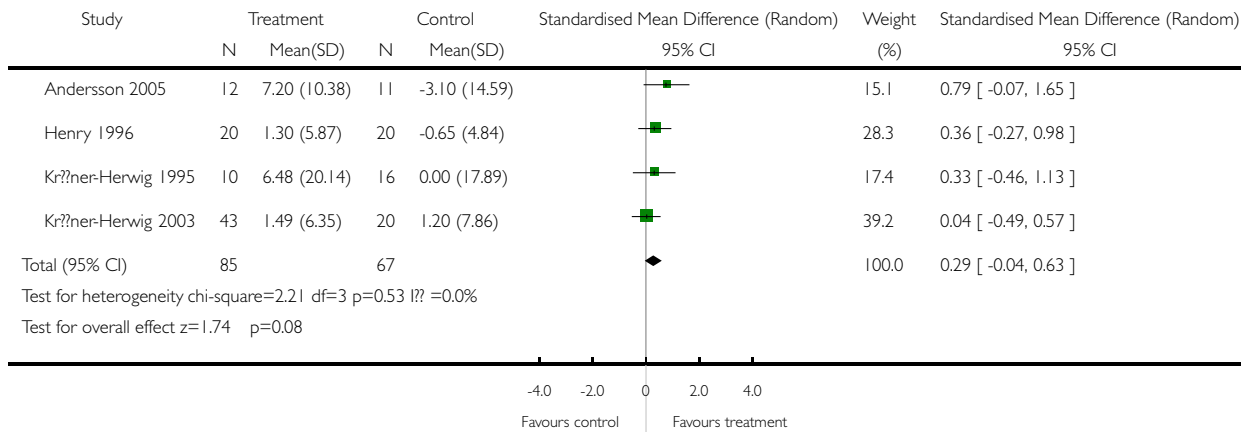


Analysis 02.02. Comparison 02 Cognitive Behavioural Therapy versus control (waiting list): Depression score., Outcome 02 Improvement on depression score pre- and post-treatment.

Review: Cognitive behavioural therapy for tinnitus

Comparison: 02 Cognitive Behavioural Therapy versus control (waiting list): Depression score.

Outcome: 02 Improvement on depression score pre- and post-treatment.

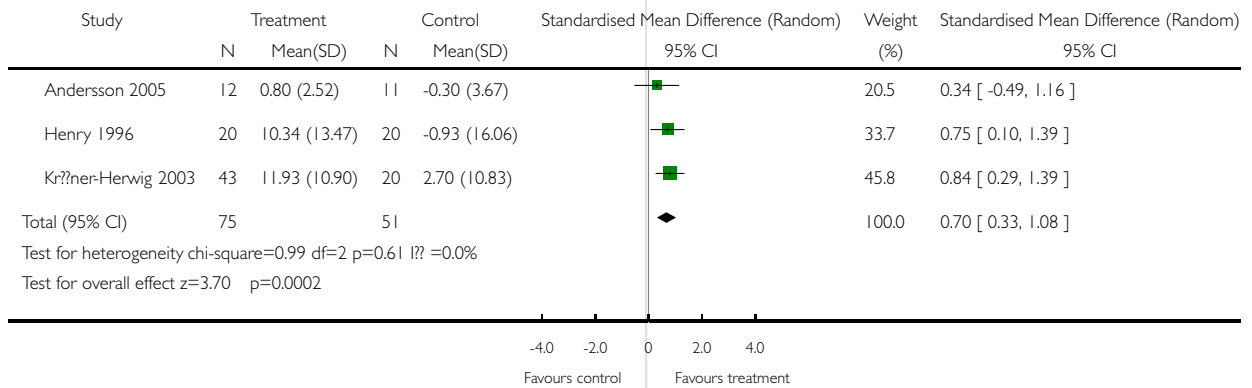


Analysis 03.03. Comparison 03 Cognitive Behavioural Therapy versus control (waiting list): Quality of life score., Outcome 03 Improvement on quality of life score pre- and post-treatment.

Review: Cognitive behavioural therapy for tinnitus

Comparison: 03 Cognitive Behavioural Therapy versus control (waiting list): Quality of life score.

Outcome: 03 Improvement on quality of life score pre- and post-treatment.

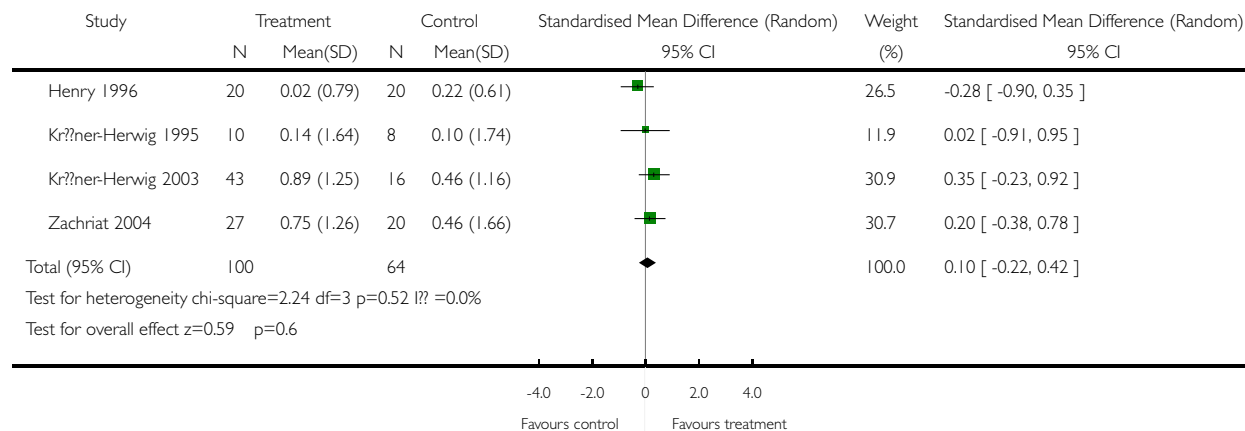


Analysis 04.01. Comparison 04 Cognitive Behavioural Therapy versus control (other intervention): Subjective loudness score., Outcome 01 Improvement on subjective loudness score pre- and post-treatment.

Review: Cognitive behavioural therapy for tinnitus

Comparison: 04 Cognitive Behavioural Therapy versus control (other intervention): Subjective loudness score.

Outcome: 01 Improvement on subjective loudness score pre- and post-treatment.

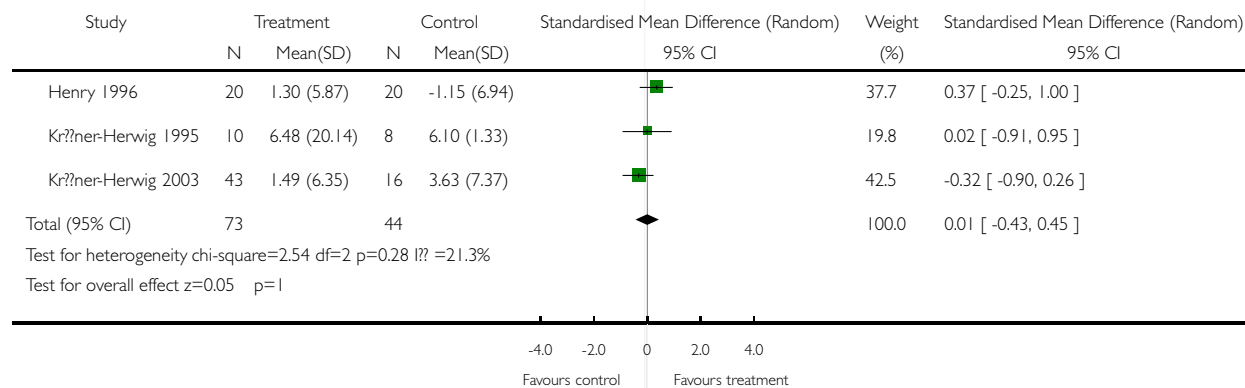


Analysis 05.02. Comparison 05 Cognitive Behavioural Therapy versus control (other intervention): Depression score., Outcome 02 Improvement on depression score pre- and post-treatment.

Review: Cognitive behavioural therapy for tinnitus

Comparison: 05 Cognitive Behavioural Therapy versus control (other intervention): Depression score.

Outcome: 02 Improvement on depression score pre- and post-treatment.



Analysis 06.03. Comparison 06 Cognitive Behavioural Therapy versus control (other intervention): Quality of life score., Outcome 03 Improvement on quality of life score pre- and post-treatment.

Review: Cognitive behavioural therapy for tinnitus

Comparison: 06 Cognitive Behavioural Therapy versus control (other intervention): Quality of life score.

Outcome: 03 Improvement on quality of life score pre- and post-treatment.

