Sound therapy (masking) in the management of tinnitus in adults (Review)

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[**Intervention Review**]

Sound therapy (masking) in the management of tinnitus in adults

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ABSTRACT

Background

Tinnitus is described as the perception of sound or noise in the absence of real acoustic stimulation. Numerous management strategies have been tried for this potentially debilitating, heterogeneous symptom. External noise has been used as a management tool for tinnitus, in different capacities and with different philosophical intent, for over a century.

Objectives

To assess the effectiveness of sound-creating devices (including hearing aids) in the management of tinnitus in adults. Primary outcome measures were changes in the loudness or severity of tinnitus and/or impact on quality of life. Secondary outcome measures were change in pure-tone auditory thresholds and adverse effects of treatment.

Search methods

We searched the Cochrane ENT Group Trials Register; CENTRAL (2009, Issue 3); PubMed; EMBASE; CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; *m*RCT and additional sources for published and unpublished trials. The date of the most recent search was 11 September 2009.

Selection criteria

Prospective randomised controlled trials recruiting adults with persistent, distressing, subjective tinnitus of any aetiology in which the management strategy included maskers, noise-generating device and/or hearing aids, used either as the sole management tool or in combination with other strategies, including counselling.

Data collection and analysis

Two authors independently examined the 362 search results to identify studies for inclusion in the review, of which 33 were potentially relevant. Both authors extracted data independently.

Main results

Six trials (553 participants) are included in this review. Studies were varied in design, with significant heterogeneity in the evaluation of subjective tinnitus perception, with different scores, scales, tests and questionnaires as well as variance in the outcome measures used to assess the improvement in tinnitus sensation/quality of life. This precluded meta-analysis of the data. There was no long-term follow up. We assessed the risk of bias as medium in three and high in three studies. No side effects or significant morbidity were reported from the use of sound-creating devices.

Authors' conclusions

The limited data from the included studies failed to show strong evidence of the efficacy of sound therapy in tinnitus management. The absence of conclusive evidence should not be interpreted as evidence of lack of effectiveness. The lack of quality research in this area, in addition to the common use of combined approaches (hearing therapy plus counselling) in the management of tinnitus are, in part, responsible for the lack of conclusive evidence. Other combined forms of management, such as Tinnitus Retraining Therapy, have been subject to a Cochrane Review. Optimal management may involve multiple strategies.

PLAIN LANGUAGE SUMMARY

Sound therapy (masking) in the management of tinnitus in adults

Tinnitus can be described as a perception of sound that is not related to an external acoustic source. Subjective tinnitus is not heard by anyone else but the sufferer. At present no particular treatment for tinnitus has been found effective in all patients.

Sound therapy (also known as masking devices) was introduced on the principle of distraction - if sound, usually 'white noise' (similar to the noise made by an out of tune radio) is played it may be sufficient to distract a patient from hearing the noises produced by their tinnitus; the new sound will mask out the patient's tinnitus sounds.

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

Six trials (553 participants) were included in this review. Following analysis of the data, no significant change was seen in the change in loudness of tinnitus or the overall severity of tinnitus following the use of sound therapy compared to other interventions such as patient education, 'relaxation techniques', 'tinnitus coping strategies', counselling, 'tinnitus retraining' and exposure to environmental sounds.

BACKGROUND

This is one of a number of tinnitus reviews produced by the Cochrane Ear, Nose & Throat Disorders Group, which use a standard background. The following paragraphs ('Description of the condition') are based on earlier work in the following reviews and reproduced with permission: Baldo 2006; Bennett 2007; Hilton 2004; Hobson 2007; Phillips 2010.

Description of the condition

Tinnitus can be described as the perception of sound in the absence of external acoustic stimulation. For the patient it may be trivial or it may be a debilitating condition (Luxon 1993). The quality of the perceived sound can vary enormously from simple sounds such as whistling or humming to complex sounds such as music. The patient may hear a single sound or multiple sounds. Tinnitus may be perceived in one or both ears, within the head or outside the body. The symptom may be continuous or intermittent. Tinnitus is described in most cases as subjective - meaning that it cannot be heard by anyone other than the patient. While, for the patient, this perception of noise is very real, because there is no corresponding external sound it can be considered a phantom, or false, perception. Objective tinnitus is a form of tinnitus which can be detected by an examiner, either unaided or using a listening aid such as a stethoscope or microphone in the ear canal. This is much less common and usually has a definable cause such as sound generated by blood flow in or around the ear, elevated level of spontaneous otoacoustic emissions (SOAEs) or unusual

activity of the tiny muscles within the middle ear. Tinnitus may be associated with normal hearing thresholds or any degree of hearing loss and can occur at any age, with higher incidence in the age group between 50 and 70 years (Davis 2000).

It is important to distinguish between clinically significant and non-significant tinnitus (Davis 2000) and several different classifications have been proposed (Dauman 1992; McCombe 2001; Stephens 1991). Dauman, for example, makes a distinction between 'normal' (lasting less than five minutes, occurring less than once a week and experienced by most people) and 'pathological' tinnitus (lasting more than five minutes, occurring more than once a week and usually experienced by people with hearing loss). Tinnitus can also be divided into clinical tinnitus, when the sufferers are actively seeking help, and people who experience tinnitus but are well-habituated and not seeking help.

Aetiology

Almost any form of disorder involving the outer, middle or inner ear or the auditory nerve may be associated with tinnitus (Brummett 1980; Shea 1981). However, it is possible to have severe tinnitus with no evidence of any aural pathology. Conversely, tinnitus can even persist without a peripheral auditory system: unilateral tinnitus is a common presenting symptom of vestibular schwannomas (acoustic neuromas), which are rare benign tumours of the vestibulo-cochlear nerve. When these neuromas are removed by a translabyrinthine route, the cochlear nerve can be severed. Despite the effective removal of their peripheral auditory mechanisms, 60% of these patients retain their tinnitus postoperatively with no apparent change in the characteristics (Baguley 1992). This suggests the fundamental importance of the central auditory pathways in the maintenance of the symptom, irrespective of the initial mode of generation being the cochlea or the vestibulo-cochlear nerve.

Many environmental factors can also cause tinnitus, mostly related to the effect of noise on the auditory system and resultant damage to the microstructures in the cochlea. 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) and exposure to recreational and amplified music (Becher 1996; Chouard 2001; Lee 1999; Metternich 1999)

Pathophysiology

Over 50 years ago, Heller and Bergman demonstrated that if 'normal' people (within normal hearing thresholds, no significant cochlear pathology) were placed in a quiet enough environment, the vast majority of them would experience sounds inside their head. They concluded that tinnitus-like activity is a natural phenomenon perceived by many in a quiet enough environment (Heller 1953). The cochlea is active electrically in the absence of sound stimulation (resting cochlear potentials) and the different array of sounds produced internally by the body (heart contractions, head and neck joint and muscle movement, blood flow etc.) are often masked by external sounds in the environment. Removal of the masking effect of noise can lead to these sounds becoming audible.

There are several theories regarding the pathophysiological changes inside the auditory system that can lead to the generation of tinnitus. Some of those theories are related to outer hair cell damage (the cochlear motor theory - Zenner 1993), pathological changes affecting the receptor potentials of the inner hair cells (Zenner 1993), disturbances of calcium channels within the cochlea (Andersson 2005) and disturbance in cochlear neurotransmission, e.g. as a result of intensive noise exposure or ototoxic drugs (Mazurek 2007).

In the popular 'neurophysiological model' of tinnitus (Jastreboff 1990; Jastreboff 2004) it is proposed that tinnitus results from the processing of a signal generated in the auditory system at a subcortical level. One of the theories the model has suggested for the generation of tinnitus is the discordant damage between pathological outer hair cells and relatively healthy inner hair cells. The tinnitus 'signal' is processed first at the level of the limbic system. If the signal is deemed to be annoying or threatening, stimulation of the autonomic nervous system will lead to symptoms of anxiety and will put emphasis on the sound of tinnitus, which in turn will make the tinnitus sound louder, leading to further identification and annoyance and so a 'vicious cycle' develops. Tinnitus is a subjective phenomenon and the effect of tinnitus will depend mainly on the individual's experience of the symptom, rather than any objective measure of how loud it is. It is often compared with chronic pain and there are a lot of similarities in the management protocols of both conditions. Although the neurophysiological model puts emphasis on the subcritical perception by the limbic systems other psychological models emphasise the role of cortical perception, cognition, thoughts and behaviour on the development and maintenance of the tinnitus effects on quality of life (Andersson 2002; Briner 1995; Hallam 1988; Kroner-Herwigs 2003; Sullivan 1994).

The relationship between the symptom of tinnitus and the activity of the prefrontal cortex and limbic system has also been emphasised. This might suggest 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 (El Refaie 2004; Lockwood 1999; Sullivan 1989; Sullivan 1992; Sullivan 1993).

Prevalence

Epidemiological data reports are few. The largest single study was

undertaken in the UK by the Medical Research Council Institute of Hearing Research and was published in 2000 (Davis 2000). This longitudinal study of hearing questioned 48,313 people; 10.1% described tinnitus arising spontaneously and lasting for five or more minutes at a time and 5% described it as moderately or severely annoying. Only 0.5% reported tinnitus having a severe effect on their life. This is another of the paradoxes of tinnitus; the symptom is very common but the majority of people who experience it are not particularly concerned by it. Hallam 1987 explained this in his 'habituation' theory. He emphasised that the natural history of tinnitus is always towards habituation, and only negative associations with tinnitus lead to stimulation of the emotional centres in the central nervous system and delay or inhibit habituation - a theory which was further emphasised by Jastreboff and Hazell's neurophysiological model (1990). The figures from the UK are broadly consistent with data collected by the American Tinnitus Association (ATA) which suggests that tinnitus may be experienced by around 50 million Americans or 17% of the US population (ATA 2004). Data also exist for Japan, Europe and Australia (Sindhusake 2003) and estimates suggest that tinnitus affects a similar percentage of these populations, with 1% to 2% experiencing debilitating tinnitus (Seidman 1998). The Oregon Tinnitus Data Archive (Oregon 1995) contains data on the characteristics of tinnitus drawn from a sample of 1630 tinnitus patients. The age groups with the greater prevalence are those between 40 and 49 years (23.9%) and between 50 and 59 years (25.6%), findings similar to the UK figures from the Davis 2000 study. Olszewski showed in his study that the risk of tinnitus increases in patients over 55 years old who suffer from metabolic conditions and cervical spondylosis (Olszewski 2008).

Diagnosis

Firstly a patient with tinnitus may 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 musculature. Referral to a specialist is likely to involve a variety of other investigations including a full audiological test battery of pure-tone audiometry, speech audiometry, tympanometry and stapedial reflexes as well as specific tinnitus evaluation tests pitch and loudness match, minimal masking levels and residual inhibitions. Persistent, unilateral tinnitus and pulsatile tinnitus may be due to a specific disorder of the auditory pathway. Special audiological test batteries, including auditory brainstem responses and videonystagmography, which are important to ascertain any retrocochlear pathology and imaging of the cerebellopontine angle, which is important to exclude, for example, a vestibular schwannoma (acoustic neuroma) - a rare benign tumour of the vestibular nerve. Other pathologies, such as glomus tumours, meningiomas, multiple sclerosis, adenomas, vascular lesions or neurovascular abnormalities may also be detected by imaging (Marx 1999; Weissman 2000).

Treatment

There are two levels of management regarding treatment of tinnitus: i) Habituation of reaction; which aims to decrease the psychological effects of tinnitus (such as insomnia, depression and anxiety) and ii) habituation of perception, which aims to decrease the tinnitus sensation so that the sufferer will stop hearing the sounds altogether (Jastreboff 2000). At present there are different management protocols which show considerable success in achieving the first goal, although no specific therapy for tinnitus is acknowledged to be satisfactory in all patients regarding the second goal. The majority of patients who complain of tinnitus also have a significant hearing impairment. For these patients a hearing aid will be the first line of treatment. Not only will this help their hearing disability and handicap but the severity of their tinnitus may be reduced. A wide range of management protocols have been proposed for the treatment of tinnitus. Pharmacological interventions include cortisone (Koester 2004) vasodilators, benzodiazepines, lidocaine and spasmolytic drugs. The use of anticonvulsants in treating tinnitus is the subject of a forthcoming Cochrane Review (Hoekstra 2009). Antidepressants are commonly prescribed for tinnitus, however, two reviews (Baldo 2006; Robinson 2007) showed that there is no indication that tricyclic antidepressants have a direct effect on the tinnitus sensation, unless depression is caused by or associated with the tinnitus complaint. Although a number of studies have suggested that Ginkgo biloba may be of benefit in the treatment of tinnitus (Ernst 1999; Holger 1994; Rejali 2004), a Cochrane Review showed that there was no evidence that it is effective where tinnitus was the primary complaint (Hilton 2004). Hyperbaric oxygen therapy (HBOT) can improve oxygen supply to the inner ear which is suggested to result in an improvement in tinnitus, however a Cochrane Review found insufficient evidence to support this (Bennett 2007). Studies have been carried out into the effect of cognitive behavioural therapy (CBT) on tinnitus (Andersson 1999) and another Cochrane Review has shown that CBT can have an effect on the qualitative aspects of tinnitus and can improve patients' ability to manage the condition (Martinez-Devesa 2010). Other options for the management of patients with tinnitus include transcranial magnetic stimulation (Meng 2009), music therapy (Argstatter 2008), reflexology, hypnotherapy, mindfulness and traditional Chinese medicine (TCM) including acupuncture (Li 2009). This review considers the role of sound therapy devices in tinnitus.

Description of the intervention

Sound therapy devices were introduced on the principle of distraction; that if a level of noise, usually 'white noise' is introduced it can reduce the contrast between the tinnitus signal and background activity in the auditory system, with a decrease in the patient's perception of their tinnitus (Vernon 1977). It has long been known that appropriate external sounds can diminish or even render tinnitus inaudible. Spaulding in 1903 used a piano to match

the frequency of tinnitus in his patients - he subsequently played a note at a similar frequency, increasing the volume until the tinnitus became inaudible (Spaulding 1903). In the 1920s, Jones and Knudsen developed a portable machine which could be used as a tinnitus masker (Jones 1928). More recently, Vernon pioneered the introduction of hearing aid-like devices designed to produce noise in the ear (Vernon 1977). Initial approaches to sound therapy involved 'complete masking' whereby the masking noise is raised in intensity until the tinnitus becomes inaudible (Coles 1997).
In the early 1980s a large, complex study of sound therapy devices included white noise generators and combination hearing aids and noise generators (Hazell 1985; Stephens 1985). Further work stemming from this study showed that rather than using a volume of noise that would mask tinnitus, a low (minimally appreciable) level white noise treatment could be used to achieve down-regulation ("habituation of the disordered auditory perception"). This was based on the principle that if the patient cannot hear their tinnitus (as in complete masking) then they will not be able to habituate to it (Jastreboff 1995; McKinney 1995). Another important benefit that was suggested from using sound therapy was the concept of 'sound enrichment', in which the white noise also acts as a source of stimulation to the central auditory system to compensate for the loss of auditory stimulation arising from the cochlea in patients with hearing loss. This would prevent sensory deprivation, which is one of the theories of tinnitus generation. It is important to emphasise that sound enrichment is intended to achieve audiological masking not immediate residual inhibition. Subsequent research has refined the instruments and sought biological evidence for this theory. Low-level white noise (noise generators) is offered regularly as an element in many management protocols for tinnitus, rather than 'maskers' aimed at 'complete or partial masking' of the tinnitus in the audiological sense of the word. The effective use of noise generators involves determining the optimal volume for the device and this will depend on the philosophy behind the management protocol. Protocols aiming at partial or complete masking aim to establish a masking level that patients find more acceptable than their tinnitus (Vernon 2003). Often patients are able to achieve effective tinnitus masking at sound levels that are not very loud, however if the masking needs to be raised to an uncomfortable level to mask the tinnitus then that patient is not an ideal candidate for masking. If the philosophy is towards sound therapy and sound enrichment, then the noise generator is adjusted to a level where the patient can hear both their own tinnitus and the external noise at the same time and the adjustment seeks to establish the 'blending point'. This protocol is used in Tinnitus Retraining Therapy (Jastreboff 2000). Currently, sound therapy devices tend to be worn as in the ear or behind the ear (BTE) devices. They can output a broad spectrum of white noise or they may be focused to the frequency band of the patient's tinnitus. They may be combined with a hearing aid to augment a patient's hearing. Sound therapy devices can also take the form of CDs and music cassettes that play a similar white noise or music but through conventional stereophonic equipment. All of these forms of devices are considered in this review.

OBJECTIVES

To evaluate the effectiveness/relative effectiveness of sound-creating devices (including hearing aids) in the management of tinnitus in adults.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials.

Types of participants

Adults in whom there is a complaint of persistent, distressing, subjective tinnitus of any aetiology.

Types of interventions

Any masking or noise-generating device compared to no masking or noise-generating device.
Any masking or noise-generating device compared to any other form of tinnitus management.
Hearing aids, bone-anchored hearing aids and cochlear implants are 'noise-generating' and as such we included them in this study.
It would be difficult to construct any blinded or placebo-controlled trials due to the nature of a sound therapy devices and there is also no recommended standard of management to which sound therapy devices can be compared.

Types of outcome measures

Primary outcomes

Patients' subjective assessment of tinnitus before, during and after treatment:

- change in loudness of tinnitus;
- change in overall severity of tinnitus and/or impact on quality of life.

There are a number of validated questionnaires which provide a scale of severity of disability and handicap associated with tinnitus (e.g. the Tinnitus Handicap Inventory (Newman 1996) and the

Tinnitus Questionnaire (Hallam 1988)). Whilst the use of such validated and relatively robust assessment tools is preferable, we considered any categorical distinction between different grades of loudness and 'severity'. Where stated, we also used visual analogue scales of loudness as an outcome measure.

Secondary outcomes

- Change in thresholds on pure-tone audiometry.
- Side effects and adverse effects of treatment.

Search methods for identification of studies

We conducted systematic searches for randomised controlled trials. There were no language, publication year or publication status restrictions. The date of the last search was 11 September 2009.

Electronic searches

We searched the following databases from their inception: the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2009, Issue 3); PubMed; EMBASE; CINAHL; LILACS; KoreaMed; IndMed; PakMediNet; CAB Abstracts; Web of Science; BIOSIS Previews; CNKI; *m*RCT (Current Controlled Trials); ClinicalTrials.gov; ICTRP (International Clinical Trials Registry Platform) and Google.

We modelled subject strategies for databases on the search strategy designed for CENTRAL. Where appropriate, we combined subject strategies with adaptations of the highly sensitive search strategy designed by the Cochrane Collaboration for identifying randomised controlled trials and controlled clinical trials (as described in *The Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.1, Box 6.4.b. (Handbook 2008)). Search strategies for the major databases including CENTRAL are provided in Appendix 1.

Searching other resources

We scanned reference lists of identified studies for further trials. We searched PubMed, TRIPdatabase, NHS Evidence - ENT & Audiology, and Google to retrieve existing systematic reviews possibly relevant to this systematic review, in order to search their reference lists for additional trials. We sought abstracts from conference proceedings via the Cochrane Ear, Nose and Throat Disorders Group Trials Register, and we contacted manufacturers in order to request details of unpublished trials.

Data collection and analysis

Selection of studies

We independently selected trials for inclusion. Disagreement was resolved by consensus.

Data extraction and management

We extracted data independently and in duplicate using specially designed data extraction forms. Any differences prompted re-evaluation of the article. Extracted data included citation details, participant details (age, sex, aetiology and severity of tinnitus, concurrent management strategies (where known)), details of sound therapy devices, details of outcome and how it was assessed, and quality score.

We contacted authors for clarification and missing data information.

Assessment of risk of bias in included studies

The criteria for quality assessment were based on the recommendations of the *Cochrane Handbook for Systematic Reviews of Interventions*. The criteria for consideration were:

1. the quality of randomisation process and allocation concealment;
2. the potential for selection bias after allocation to the study group;
3. whether there is blinding of outcome assessors to the participants' study group;
4. the quality of outcome assessment and the adequacy, development and standardisation of the questionnaires and of the rating or scoring schemes used in the trials.

Studies were graded as A, B or C for their overall methodological quality:

Grade A: low risk of bias in all parameters considered;

Grade B: medium risk of bias in only one parameter;

Grade C: medium risk of bias in more than one parameter, or high risk of bias in one parameter.

We planned to use study quality in a sensitivity analysis.

Data synthesis

We analysed data on an intention-to-treat basis. For dichotomous data, we planned to express the estimate of effect of an intervention as an odds ratio (OR) with 95% confidence intervals (CI). We also planned to calculate number needed to treat (NNT). For continuous outcomes, we planned to use mean differences (MD) and 95% CIs to summarise the data for each group. For fixed-effect studies we planned to transform data to binary outcome to determine an odds ratio.

We had planned to assess clinical heterogeneity by examining type of participants (e.g. cause of tinnitus), intervention type and outcome in each study. We planned to perform meta-analysis on studies of low heterogeneity with the same outcome measure(s) but

due to the heterogeneity of studies and disparate outcome measures this was not possible.

Subgroup analysis and investigation of heterogeneity

We planned to perform subgroup analyses on trials involving different types of sound therapy devices, e.g. pure-tone versus white noise.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

Results of the search

We identified 362 study reports using the combined searches. The authors scrutinised the search results and identified 33 trials that appeared to address the subject and eligibility criteria of the review. We obtained the full text of these articles and analysed them for eligibility.

The study by Pritchard (Pritchard 1987) was an abstract only with no further data available for extraction. Five of the studies identified presented results of other papers which have been included in the final analysis and so those studies have been added as subreferences of the main studies (Dineen 1999; Goebel 1999; Hazell 1985; Henry 2006). The trial by Caffier et al (Caffier 2006) was primarily a randomised study to evaluate tinnitus coping therapy with a control group. The intervention consisted of counselling, auditory training, muscle relaxation and provision of broadband noise generators. A second group of patients were provided with the components of tinnitus coping without the noise generators and although this study initially appeared eligible for inclusion, the second control group were not randomised and so we excluded the study. We rejected the remaining trials, after careful analysis of the full texts, as not relevant to this review. See: 'Characteristics of included studies' and 'Characteristics of excluded studies'.

Included studies

The six included studies were varied in design, with significant heterogeneity in the evaluation of subjective tinnitus perception with different scores, scales, tests and questionnaires used across studies.

Dineen 1999

Ninety-six patients (36 female and 60 male) with ages ranging from 22 to 87 (mean = 54.37; SD = 13.86) were recruited. The subjects had a detailed medical history taken and were assessed by means of the revised Ways of Coping Check List (WCCL-R), the Derogatis Stress Profile (DSP), the Tinnitus Reaction Questionnaire (TRQ), and 10-point visual analogue scales of tinnitus loudness, annoyance and general coping ability. Audiometry was assessed using pure-tone audiometry, tinnitus frequency matching, tinnitus intensity matching and minimal masking levels. The subjects were randomly allocated to four groups: 1) information only, 2) information plus long-term, low-level white noise, 3) information plus relaxation, and 4) information plus relaxation plus long-term, low-level white noise. Information consisted of general pathophysiological information on tinnitus as well as information on coping strategies and stress reduction techniques. Sound therapy was provided with custom-made Starkey devices providing stable wide-band noise with as wide a frequency range as possible. Relaxation involved a relaxed breathing technique and the use of positive mental imagery.

Goebel 1999

This study investigated the efficacy of broad-band noise with Tinnitus Retraining Therapy and tinnitus coping therapy. The 52 patients (mean age = 44) in the study had chronic, decompensated tinnitus with scores ranging from 40 to 70 on the German Tinnitus Questionnaire. The patients had been referred for inpatient behavioural psychotherapy and whilst awaiting admission were assigned randomly to one of four groups: 1) noise generators (Viennatone Silent Star), 2) Tinnitus Retraining Therapy, defined by a combination of tinnitus coping therapy and noise generation, 3) tinnitus coping therapy alone, and 4) no treatment. The patients remained in these groups for four months. Patients were excluded if they had Ménière's disease, acoustic neuroma, otosclerosis, severe general health problems or psychoses. Tinnitus severity was measured with the German Tinnitus Questionnaire (an instrument developed by the main author and described by him as having high validity and reliability) and a visual analogue score of tinnitus annoyance.

Mehlum 1984

Forty-five patients were enrolled in this cross-over study of whom 34 completed the protocol (10 female and 24 male) with ages ranging from 21 to 80 years (average age = 49). Patients were randomly assigned to four groups: 1) 'tinnitus maskers', 2) 'tinnitus instruments' (combined maskers and hearing aids), 3) hearing aids, and 4) exposure to 'environmental sounds'. Following assignment to a group, the subjects proceeded sequentially through each of the four methods. All patients underwent baseline audiometry.

Hazell 1985

One hundred and fifty-three patients enrolled in the randomised arm of this multi-centre trial (76 female and 77 male). Ages are quoted in strata with two patients aged younger than 20, 10 patients aged over 70 and the majority aged between 50 and 69. This study is a three-centre study investigating the effectiveness of sound therapy devices, combination instruments and hearing aids in the management of tinnitus. The study protocol differed at the three centres. Two of the centres (University College Hospital,

London and General Hospital, Nottingham) assigned patients to sound therapy devices or hearing aids according to pre-existing management strategies and protocols. One centre (Royal National Throat Nose and Ear Hospital (RNTNE)) randomly allocated patients to counselling or one of two types of sound therapy device if the patient had no deafness, or to a hearing aid, sound therapy device or combination instrument if the patient had hearing problems. Patients were followed up for two evaluation periods separated by six months.

Henry 2006

This study recruited 800 US military veterans via advertisements. Following screening 172 candidates were enrolled into the study; those not eligible were not convinced that their tinnitus was sufficiently severe or they were not motivated to comply with the study requirements. One hundred and twenty-three patients started treatment in the study (six female and 117 male). The mean age in the sound therapy group was 61 (SD 9.6) and in the tinnitus retraining group it was 58.7 (SD 10.5). Baseline audiometry was performed and the Tinnitus Handicap Inventory (THI), Tinnitus Handicap Questionnaire (THQ) and Tinnitus Severity Index (TSI) were administered. A further 49 subjects were excluded at this stage - their tinnitus was not judged severe enough for inclusion. Candidates were quasi-randomly assigned to a sound therapy device or Tinnitus Retraining Therapy group. Both groups used a combination of noise generators, hearing aids and combination instruments. Audiometry and questionnaires were evaluated at 3, 6, 12 and 18 months.

Davis 2007

Forty-two patients were recruited into this study but seven were subsequently excluded from analysis because their pre-treatment levels of tinnitus-related disturbance were not clinically significant, as determined by a Tinnitus Reaction Questionnaire (TRQ). Thirty-five patients with moderate to severe levels of tinnitus-related stress were subsequently included in this study (nine female and 26 male) with ages ranging from 22 to 87 (mean = 61.3 years; SD 8.9). Pure-tone audiograms were used to assess for hearing thresholds and tinnitus severity were assessed using the tinnitus reaction questionnaire (TRQ). Patients were randomised and allocated into one of two groups. Group one used a method of sound therapy using individually modified acoustic stimulation applied in intermittent perception throughout. Patients in group two started with complete covering of the tinnitus perception initially, followed later by intermittent perception. Both groups had equal times for educational and counselling intervention as part of the management plan. Evaluation of intervention occurred at two, four, six and 12 months after commencing treatment.

Risk of bias in included studies

Dineen 1999: overall grade B

Although the subjects were randomly allocated, no mention is made in the text of the process of randomisation or allocation concealment. We have contacted the author for clarification but no further information is available at this time. The four groups were conducted in the same timeframe so that subjects each received the same therapeutic group time but the groups did differ in the number and type of management strategies provided. Of the initial pool of 96 patients, 72 attended the four group sessions. Questionnaires were sent to the 25 non-attenders and 12 were returned. Reasons for non-attendance included death, relocation, in hospital, on holiday, lack of time off work, tinnitus no longer a problem and lack of transport. The only noted difference between attenders and non-attenders was that the non-attenders reported fewer emotion-regulation strategies, which the authors suggest implies that the non-attenders experienced a lower level of emotional reaction to their tinnitus. No significant differences were found between the four management groups at 12-month follow up as regards gender, age or any of the psychological or audiological variables. The uneven rate of decline in the number of subjects in each management group led to reduced statistical power of the study and so a decision was made to condense the four groups to two - those exposed to sound therapy (groups 2 and 4) and those who were not (groups 1 and 3).

Goebel 1999: overall grade C

Although the paper states that patients were randomly assigned to the four groups, no method of randomisation or allocation concealment was described. The subjects were all awaiting inpatient behavioural psychotherapy for their symptoms, and as such had numerous psychiatric comorbidities. Twenty-six of the subjects had major depression and 20 had anxiety disorders so the applicability of this study to other populations needs to be considered carefully. Following inpatient treatment, a further subset of patients were assigned to noise generation or tinnitus coping strategies but we have excluded these data from the analysis because of the possible confounding variable of the inpatient psychological treatment.

Mehlum 1984: overall grade C

The study states that patients were randomly assigned to the treatment groups but no details of the randomisation process are given.

Hazell 1985: overall grade B

We have excluded the University College Hospital, London and General Hospital, Nottingham data because they were not randomised. The paper presents the outcome data for the three arms of the study and so only the randomised (Royal National Throat Nose and Ear Hospital) data are included in this review. Although the paper states that subjects are assigned randomly, no details of the randomisation or allocation concealment process are given. One hundred and fifty-three patients enrolled in the RNTNE arm of trial but only 50 reached the second evaluation session. There is a significant risk of bias with an attrition rate of 67%.

Henry 2006: overall grade C

The randomisation process of this study is quasi-randomised with patients assigned to the two groups alternately and this obviously increases the risk of selection bias. Tinnitus retraining patients

received more counselling time than the sound therapy group (5.4 versus 4 hours) and the counselling was more structured for the former group. In the results analysis the authors present changes in the means and in addition they calculate effect sizes for each of the groups, but there is no reference in the text as to how this has been performed and it is also unclear whether the statistically significant P values apply to the means or the calculated effect sizes.

Davis 2007: overall grade B

This is a well-designed study with a clear, well adhered to methodological protocol. Patients were randomised into two groups and although the method of randomisation was mentioned, no information was given about blinding and concealment. No power calculation was given. There was no counselling only group because the authors stated that "...As the previous study incorporated a counselling-only control group (Davis 2001), it was not considered necessary to repeat such a control group in the current clinical trial." No placebo (no treatment) group existed due to ethical considerations.

Effects of interventions

Dineen 1999

Primary outcome measure: patients' subjective assessment of tinnitus

The majority of subjects reported improvement in most of the subjective measures of tinnitus perception (visual analogue scales and the Tinnitus Reaction Questionnaire (TRQ)). There were relative decreases of 41.5% for visual acuity scale of tinnitus loudness, 64.6% for visual acuity scale of tinnitus annoyance, 24.6% for visual acuity scale of tinnitus coping, 73.9% for TRQ and 30.8% for change awareness. These are quoted in the paper as relative percentage change with no other data given and no confidence intervals quoted. Much of this improvement occurred in the first three months of the management programme. Both the sound therapy and control groups reported significant decline in tinnitus annoyance and reduction in the reaction to tinnitus but there was no significant difference between the TRQ scores at initial assessment and 12-month follow up. There was no significant difference in coping ability between the two groups at initial assessment or 12-month follow up. The results of the study show that tinnitus management training has a significant influence on the level of habituation to tinnitus, however none of the three forms of management training compared in this study (information, relaxation or sound therapy) were found to be more effective than the others in facilitating change in the level of habituation to tinnitus (Dineen 1999).

Secondary outcome measures

The audiological measures of tinnitus remained stable over the 12-month period of the study.

Goebel 1999

Primary outcome measure: patients' subjective assessment of tinnitus

No significant difference was seen between the groups with respect to a visual analogue score of tinnitus annoyance. The Tinnitus Questionnaire dropped from 56 (SD 9) to 55 (SD 13) in the noise generation group; this was not significant. The score remained unchanged (54 (SD 8)) in the waiting list control group and dropped statistically significantly from 47 (SD 9) to 39 (SD 12) and 51 (SD 15) to 41 (SD 12) in the tinnitus retraining and tinnitus control groups respectively (Goebel 1999).

Secondary outcome measures

None noted in study.

Mehlum 1984

Primary outcome measure: patients' subjective assessment of tinnitus

The trial's outcome measures were largely subjective. Patients were asked to detail their duration of instrument use, under what conditions they used the device and the effect that the instrument had in controlling their symptoms. Following completion of the trial, subjects were given the option of selecting a trial instrument for continued use. Seven chose a combination of unilateral or bilateral hearing aids, 12 chose sound-generating devices and nine combined instruments, whereas seven opted to 'live with it', choosing no further treatment for their tinnitus. The paper does not present a breakdown of users' comments for individual devices but states that no method was found to be more efficacious than another. Tinnitus outcome instruments are assessed in this trial (Mehlum 1984).

Secondary outcome measures

No significant changes were seen in auditory thresholds as a result of device use.

Hazell 1985

Primary outcome measure: patients' subjective assessment of tinnitus

The authors evaluated sound therapy effectiveness by means of a unique questionnaire: 'the masker effectiveness questionnaire', a measure of psychoneurotic pathology, the Crown Crisp Experiential Index, audiometry, tinnitus loudness levels and thresholds. In addition a Semantic Differential Score was calculated, which is a means of subjectively scoring various features of tinnitus on a 1 to 7 scale. In response to the question "was the masking effect helpful?" there was a significant improvement in the sound therapy versus the control groups. There were no significant differences between the results of treatment with hearing aids, sound therapy devices or combination instruments in respect to the degree of masking, the presence and duration of partial and complete residual inhibition and long-term effects on hearing and tinnitus. The authors state that hearing aids were used for longer hours than the other instruments, and were more likely to be used all the time than the other instruments. Maskers were more likely to be used in the evening. Hearing aids were more likely to improve hearing while in use and maskers to make it worse. A reduction in anxiety using the Crown Crisp experiential index was noted but the significance of this can be related to several factors. Using the semantic differential for the subset of patients with normal hearing the control subjects appear to have improved more, or at least as much, as those in the two sound therapy groups. In those patients with hearing impairment no significant change was found as to the amount of time that the tinnitus was present. Annoyance was reduced in both the sound therapy and combination instrument groups and sleep disturbance was reduced in the sound therapy group (Hazell 1985).

Secondary outcome measures

The paper shows a small deterioration in hearing over the course of the study in patients using hearing aids, masking devices and combined instruments, but the authors interpret this as reflecting a deterioration due to underlying pathology rather than damage due to the instruments. The authors do suggest that all wearers are kept under review and undergo serial audiometry.

Henry 2006

Primary outcome measure: patients' subjective assessment of tinnitus

The authors subdivided patients into those whose baseline questionnaires categorised their tinnitus subjectively as 'moderate', 'big' and 'very big'. These subjective categories do correspond to increasing severity with the outcome instruments used. The data analysis looked at changes in the baseline in the Tinnitus Handicap Inventory (THI), Tinnitus Handicap Questionnaire (THQ) and Tinnitus Severity Index (TSI) for the three severity groups at 3, 6, 12 and 18 months. For patients with 'moderate' problems sound therapy resulted in a statistically significant improvement in the THQ at six months but tinnitus retraining appeared to offer superior results. For patients who described their tinnitus as a 'big' problem, there was an across the board significant improvement in the three instruments at all time points except three months, which is comparable to the tinnitus retraining group. Looking at the effect sizes, for sound therapy these ranged from 0.18 to 0.59 in the 'moderate' group and did not show a systematic improvement over time. For those with a 'big' problem, the effect sizes for sound therapy ranged from 0.46 to 0.86 and whereas the THI and TSI improved over time the THQ effect size remained unchanged. For those with a 'very big' problem the effect of sound therapy seemed greater at three months, with a trend of effect sizes becoming progressively smaller through 18 months. Based on effect size both groups showed considerable improvement overall but whereas the benefits of sound therapy tended to remain constant over time, the effect of tinnitus retraining improved incrementally (Henry 2006).

Secondary outcome measures

None and no mention of the audiometry.

Davis 2007

Primary outcome measures: patients' subjective assessment of tinnitus

The study showed a statistically significant improvement in the tinnitus reaction questionnaire (TRQ) scores after two months of treatment and overall after 12 months in the two study groups. The authors reported a smaller improvement after four and six months of treatment though it did not reach statistical significance. A similar pattern was observed from the results of the visual analogue scale (VAS). Overall 91% of patients across the two groups reported an improvement in the TRQ scores of at least 40%. There was no statistically significant difference between the two study groups.

Secondary outcome measures

Minimum masking level: 70% of patients had a reduction of at least 5 dB HL after six months of treatment. The overall significance of the 5 dB HL threshold is unclear. There was no significant difference between the two study groups.

Loudness discomfort levels (LDLs): 78% of patients exhibiting decrease in sound tolerance prior to intervention (defined by the authors as LDLs < 85 dB HL) showed improvement of at least 5

dB HL. Again the significance of the 5 dB HL step was unclear. There was no statistically significant difference between the two groups (Davis 2007).

DISCUSSION

Summary of main results

There is no evidence from the available literature that a significant change in loudness of tinnitus or the overall severity of tinnitus can be achieved following the use of sound-generating (masking) devices as a sole intervention (i.e. there is no significant habituation of perception). The Hazell study (Hazell 1985) reported that users found sound therapy devices subjectively helpful and reported lower levels of tinnitus annoyance with their use but found no significant difference between sound therapy devices, hearing aids or combination instruments. The study by Henry (Henry 2006) did find decreased scores on the Tinnitus Handicap Questionnaire at six months but this was less than the effect seen for Tinnitus Retraining Therapy and across the board the latter intervention appeared more efficacious. It is important to mention that Tinnitus Retraining Therapy protocols often include noise generators as an integral element of the rehabilitation process. The study by Davis et al (Davis 2007) showed a general improvement in the Tinnitus Reaction Questionnaire (TRQ) after treatment, though this was an improvement due to the combined use of sound therapy and counselling, so the singular effect of sound therapy cannot be measured and the numbers of patients involved in the trial was relatively small.

Overall completeness and applicability of evidence

The evidence to support (or refute) the use of sound-generating devices in the management of tinnitus is not complete. No long-term data were presented by any of these studies and so it is impossible to state whether the effect of sound therapy is maintained after its use. The fact that most tinnitus rehabilitation protocols use combined approaches, which most of the time include an element of counselling combined with masking/noise generators/sound enrichment, further complicates the process of extracting evidence for or against the effectiveness and value of each individual method in the overall result of the management process. This was also the opinion expressed in systematic reviews by McKenna and Irwin (McKenna 2008), who found difficulties in extracting the benefits from sound therapy from the general psychological benefit of the rehabilitation process. Similar findings were expressed by Noble et al (Noble 2008). The lack of adverse events in conjunction with the complex and limited evidence of benefit should not preclude the use of noise-generating devices in the management of tinnitus.

Quality of the evidence

The quality of the studies in the review was generally low and there was marked methodological heterogeneity with numerous measures used for the assessment of tinnitus severity and outcome. In addition, there was marked heterogeneity in the intervention with different devices used in the different studies. The degree of heterogeneity precluded meta-analysis of the data. The lack of an established universal tool for pre- and post-management assessment of tinnitus outcome measures has been a long-recognised problem in tinnitus research.

Potential biases in the review process

We carried out this review in duplicate to minimise bias. After discussion there were no conflicts in the authors' opinions. The search process we used was robust and the term tinnitus is internationally recognised. We feel that although the included studies all had varied degrees of potential bias, this was minimal in the review process.

Agreements and disagreements with other studies or reviews

All studies and reviews demonstrate either no or limited improvement in tinnitus perception. The improvement in the impact on life with noise generators did not reach strong statistical values and was complicated by the combined nature of the protocols, when noise generators were used in combination with counselling and other forms of intervention. No adverse outcomes or adverse sequelae from using sound-generating (masking) devices have been reported.

AUTHORS' CONCLUSIONS

Implications for practice

The limited data from the included studies show that sound therapy on its own is of unproven benefit in the treatment of tinnitus, although the effect may be better than placebo and we have not thus far been able to demonstrate any substantial risks of sound therapy. The use of hearing aids in tinnitus management will always be associated with an improvement in hearing handicap and quality of life, and that makes the decision as to how much it affects tinnitus handicap on its own very complicated.

No side effects or significant morbidity have been reported from the use of this intervention. It is also important to emphasise that the lack of strong proven evidence in this report does not necessarily mean a lack of clinical efficacy of sound therapy in the management of tinnitus.

Implications for research

Future research should be based on a consensus as to the most appropriate outcome measures of tinnitus. At this time there is a serious lack of standardised outcome assessments. The included studies in this review utilised over 10 different outcome instruments. It would seem appropriate that this be a validated questionnaire but changes in the acoustic/audiological characteristics of tinnitus could be described in addition.

Long-term follow up of patients would provide information about the effectiveness of sound-generating devices following the discontinuation of their use.

It is not known whether the effects of sound therapy are dependent on the aetiology of tinnitus and further research could elucidate this.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Davis 2007

Methods	Randomised controlled trial
Participants	35 subjects with a predominantly moderate to severe level of tinnitus-related distress before treatment were randomly allocated into 1 of 2 treatment groups, corresponding to the 2 stage-based variations of the Neuromonics Tinnitus Treatment
Interventions	This study evaluates the use of the Neuronomics Tinnitus Treatment - a protocol that incorporates the principle of systematic desensitisation utilising a 12-month structured rehabilitation programme
Outcomes	The principal outcome measure was the Tinnitus Reaction Questionnaire (TRQ). Pure-tone audiometry with minimal masking level (MML) and loudness discomfort level (LDL) were also used. These were recorded at 2, 4, 6 and 12 months after instigation of treatment
Notes	-

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C

Dineen 1999

Methods	Randomised controlled trial
Participants	96 patients (36 female and 60 male)
Interventions	Four groups: 1) information only, 2) information plus long-term, low-level white noise (masking), 3) information plus relaxation and 4) information plus relaxation plus long-term, low-level white noise
Outcomes	Ways of Coping Check List (WCCL-R), the Derogatis Stress Profile (DSP), the Tinnitus Reaction Questionnaire (TRQ), and 10-point visual analogue scales of tinnitus loudness, annoyance and general coping ability. Audiometry was assessed using pure-tone audiometry, tinnitus frequency matching, tinnitus intensity matching and minimal masking levels
Notes	-

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B

Goebel 1999

Methods	Randomised controlled trial
Participants	52 patients with chronic, decompensated tinnitus
Interventions	Four groups: 1) noise generators (Viennatone Silent Star), 2) Tinnitus Retraining Therapy, defined by a combination of tinnitus coping therapy and noise generation, 3) tinnitus coping therapy alone, and 4) no treatment
Outcomes	Tinnitus severity was measured with the German Tinnitus Questionnaire (an instrument developed by the main author and described by him as having high validity and reliability) and a visual analogue score of tinnitus annoyance
Notes	-

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	C

Hazell 1985

Methods	Randomised controlled trial
Participants	153 patients
Interventions	Allocation randomly to counselling or one of 2 types of masker, if the patient had no deafness, or to a hearing aid, masking device or combination instrument if the patient had hearing problems
Outcomes	Crown Crisp Experiential Index (a measure of psychoneurotic pathology), audiometry, tinnitus loudness levels and thresholds. In addition a Semantic Differential Score is calculated which is a means of subjectively scoring various features of tinnitus on a 1 to 7 scale
Notes	-

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B

Henry 2006

Methods	Randomised controlled trial
Participants	172 military veterans
Interventions	Tinnitus masking or Tinnitus Retraining Therapy

Henry 2006 (*Continued*)

Outcomes	Audiometry, Tinnitus Handicap Inventory (THI), Tinnitus Handicap Questionnaire (THQ) and Tinnitus Severity Index (TSI) were administered
Notes	-

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C

Mehlum 1984

Methods	Randomised controlled, cross-over trial
Participants	45 patients
Interventions	Four groups: 1) tinnitus maskers, 2) tinnitus instruments (combined maskers and hearing aids), 3) hearing aids, and 4) exposure to 'environmental sounds'
Outcomes	Patients were asked to detail their duration of instrument use, under what conditions they used the device and the effect that the instrument had in controlling their symptoms
Notes	-

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	C

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Al-Jassim 1987	ALLOCATION: Non-randomised
Al-Jassim 1988	ALLOCATION: Non-randomised
Attias 1993	ALLOCATION: Non-randomised

(*Continued*)

Caffier 2006	ALLOCATION: Non-randomised
Coles 1984	ALLOCATION: Non-randomised
Delb 2002	ALLOCATION: Non-randomised
Erlandsson 1987	ALLOCATION: Non-randomised
Eysel-Gosepath 2004	ALLOCATION: Randomised controlled trial PARTICIPANTS: Adults with persistent, distressing, subjective tinnitus of any aetiology INTERVENTION: Treatment did not utilise masking techniques but TRT
Feldman 1971	ALLOCATION: Non-randomised
Feldman 1981	ALLOCATION: Non-randomised
Franz 2003	ALLOCATION: Non-randomised
Goldstein 2005	This study evaluates the use of UltraQuiet - a new form of high-frequency bone conduction therapy. As such it is not a noise-generating device per se and so has been excluded from this review
Hazell 1981	ALLOCATION: Non-randomised
Jakes 1987	ALLOCATION: Non-randomised
Jastreboff 1994	ALLOCATION: Non-randomised
Kiessling 1980	ALLOCATION: No mention made of randomisation
Kitajima 1987	ALLOCATION: Non-randomised
Ohkwara 1995	ALLOCATION: Non-randomised
Pritchard 1987	Abstract of meeting presentation - no further data available

(*Continued*)

Vernon 1978	ALLOCATION: Non-randomised
Watanabe 1997	ALLOCATION: Cohort study, non-randomised

TRT = Tinnitus Retraining Therapy

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. Search strategies

CENTRAL	PubMed	EMBASE (Ovid)
#1 TINNITUS single term (MeSH) #2 tinnit* #3 ear* NEAR (buzz* OR ring* OR roar* OR click* OR pulsat* OR pulse*) #4 #1 OR #2 OR #3 #5 PERCEPTUAL MASKING single term (MeSH) #6 ACOUSTIC STIMULATION single term (MeSH) #7 NEUROPHYSIOLOGY [is] single term (MeSH) #8 PSYCHOACOUSTICS single term (MeSH) #9 mask* OR sound NEXT therap* OR sound NEXT pillow* OR tinnitus NEXT instrument* OR sound NEXT effect* OR sound NEAR device* OR acoustic* NEAR stimulat* OR auditor* NEAR stimulat* OR noise* NEAR generat* OR white NEXT noise OR audio NEXT frequenc* #10 tinnitech* OR starkey* OR ultraquiet* OR mitigation NEXT system* OR control NEXT instrument* OR TCI OR relief NEXT device* OR TRD OR hisonic* #11 #5 OR #6 OR #7 OR #8 OR #9 OR #10 #12 #4 AND #11	#1 "Tinnitus"[Mesh] #2 tinnit* [tiab] #3 (ear* [ti] AND (buzz* [ti] OR ring* [ti] OR roar* [ti] OR click* [ti] OR pulsat* [ti] OR pulse*[ti])) #4 #1 OR #2 OR #3 #5 "Perceptual Masking"[Mesh] #6 "ACOUSTIC STIMULATION"[Mesh] #7 "Neurophysiology/ instrumentation"[Mesh] #8 "PSYCHOACOUSTICS"[Mesh] #9 mask [tiab] AND therapy* [tiab] #10 sound [tiab] AND (therap* [tiab] OR pillow [tiab] OR effect* [tiab] OR device*[tiab]) #11 ((acoustic [tiab] or auditor* [tiab]) AND stimulat* [tiab]) #12 "Tinnitus instrument" [tiab] #13 Noise [tiab] AND generat* [tiab] #14 "white noise" [tiab] #15 audio [tiab] AND frequen* [tiab] #16 (tinnitech* [tiab] OR starkey* [tiab] OR ultraquiet* [tiab] OR TCI [tiab] OR TRD [tiab] OR hisonic* [tiab]) #17 mitigation [tiab] AND system* [tiab] #18 control [tiab] AND instrument* [tiab] #19 relief [tiab] AND device [tiab] #20 #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 #21 #4 AND #20	1 Tinnitus/ 2 tinnit*.tw. 3 (ear* and (buzz* or ring* or roar* or click* or pulsat* or pulse*)).ti. 4 auditory masking/ 5 auditory rehabilitation/ 6 auditory stimulation/ 7 white noise/ 8 Electrostimulation/ 9 (mask and therapy*).tw. 10 (sound and (therap* or pillow or effect* or device*)).tw. 11 ((acoustic or auditor*) and stimulat*).tw. 12 (tinnitus and instrument).tw. 13 (Noise and generat*).tw. 14 (white and noise).tw. 15 (audio and frequen*).tw. 16 (tinnitech* or starkey* or ultraquiet* or TCI or TRD or hisonic*).tw. 17 (mitigation and system*).tw. 18 (control and instrument*).tw. 19 (relief and device).tw. 20 1 or 3 or 2 21 11 or 7 or 17 or 18 or 16 or 13 or 6 or 9 or 12 or 14 or 15 or 8 or 4 or 10 or 19 or 5 22 21 and 20
Web of Science	**BIOSIS Previews/ CAB Abstracts (Ovid)**	**CINAHL (EBSCO)**

(*Continued*)

#1 TS=tinnit* #2 TS=(mask and therapy*) #3 TS=(sound and (therap* or pillow or effect* or device*)) #4 TS=((acoustic or auditor*) and stimulat*) #5 TS=(tinnitus and instrument) #6 TS=(Noise and generat*) #7 TS=(white and noise) #8 TS=(audio and frequen*) #9 TS=(tinnitech* or starkey* or ultraquiet* or TCI or TRD or hisonic*) #10 TS=(mitigation and system*) #11 TS=(control and instrument*) #12 TS=(relief and device) #13 #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 #14 #13 AND #1	1 tinnit*.tw. 2 (ear* and (buzz* or ring* or roar* or click* or pulsat* or pulse*)).ti. 3 (mask and therapy*).tw. 4 (sound and (therap* or pillow or effect* or device*)).tw. 5 ((acoustic or auditor*) and stimulat*).tw. 6 (tinnitus and instrument).tw. 7 (Noise and generat*).tw. 8 (white and noise).tw. 9 (audio and frequen*).tw. 10 (tinnitech* or starkey* or ultraquiet* or TCI or TRD or hisonic*).tw. 11 (mitigation and system*).tw. 12 (control and instrument*).tw. 13 (relief and device).tw. 14 1 or 2 15 6 or 11 or 3 or 7 or 9 or 12 or 8 or 4 or 13 or 10 or 5 16 15 and 14	S1 (MH "Tinnitus") S2 TX tinnit* S3 TI ear and TI ((buzz* or ring* or roar* or click* or pulsat* or pulse*)) S4 S1 OR S2 OR S3 S5 TX mask and therapy* S6 TX ((acoustic or auditor*) and stimulat*) S7 TX (sound and (therap* or pillow or effect* or device*)) S8 TX (tinnitus and instrument) S9 TX (Noise and generat*) S10 TX (white and noise) S11 TX (audio and frequen*) S12 TX (tinnitech* or starkey* or ultraquiet* or TCI or TRD or hisonic*) S13 TX (mitigation and system*) S14 TX (control and instrument*) S15 TX (relief and device) S16 (MH "Perceptual Masking") S17 (MH "ACOUSTIC STIMULATION") S18 S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 S19 S4 AND S18

HISTORY

Protocol first published: Issue 1, 2007

Review first published: Issue 12, 2010

Date	Event	Description
4 November 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

Jonathan Hobson: Corresponding author, searching, data extraction and co-drafting of review.

Edward Chisholm: Searching, data extraction and co-drafting of review.

Amr El Refaie: Co-drafting review.

DECLARATIONS OF INTEREST

None known.

INDEX TERMS

Medical Subject Headings (MeSH)

*Hearing Aids; *Perceptual Masking; *Sound; Acoustic Stimulation [methods]; Quality of Life; Randomized Controlled Trials as Topic; Tinnitus [*therapy]

MeSH check words

Adult; Humans