

A randomised controlled study of mindfulness meditation versus relaxation therapy in the management of tinnitus

M ARIF¹, M SADLIER², D RAJENDERKUMAR³, J JAMES⁴, T TAHIR⁵

¹Department of ENT, Glangwili Hospital, Carmarthen, ²Department of Physiotherapy, University Hospital of Wales, Cardiff, ³Welsh Hearing Institute, University Hospital of Wales, Cardiff, ⁴Department of Physiotherapy, Whitchurch Hospital, Cardiff and Vale University Health Board, and ⁵Department of Liaison Psychiatry, University Hospital of Wales, Cardiff, UK

Abstract

Objective: Psychotherapeutic interventions have been adopted effectively in the management of tinnitus for a long time. This study compared mindfulness meditation and relaxation therapy for management of tinnitus.

Methods: In this randomised controlled trial, patients were recruited for five sessions of mindfulness meditation or five sessions of relaxation therapy. Patients' responses were evaluated using the Tinnitus Reaction Questionnaire as a primary outcome measure, and the Hospital Anxiety and Depression Scale, visual analogue scale and a health status indicator as secondary outcome measures.

Results: A total of 86 patients were recruited. Thirty-four patients completed mindfulness meditation and 27 patients completed relaxation therapy. Statistically significant improvement was seen in all outcome measures except the health status indicator in both treatment groups. The change in treatment scores was greater in the mindfulness meditation group than in the relaxation therapy group.

Conclusion: This study suggests that although both mindfulness meditation and relaxation therapy are effective in the management of tinnitus, mindfulness meditation is superior to relaxation therapy.

Key words: Meditation; Relaxation Therapy; Tinnitus

Introduction

Tinnitus is described as the perception of sound in the ears or head. McFadden defined tinnitus as 'a conscious experience of sound that originates in the head of its owner, without an external acoustic source'.¹

The prevalence of tinnitus varies from 10 to 30 per cent.^{2–4} Approximately 10–15 per cent of the population suffers from prolonged spontaneous tinnitus,^{5,6} and 2–5 per cent will have significant psychological problems.² Although it can be evident in children, tinnitus is more commonly associated with advancing age and is often linked to hearing loss. Tinnitus prevalence is the same in men and women; however, women tend to describe more complex sounds.

Whilst tinnitus is clinically heterogeneous in terms of its nature and how it affects different people,⁷ the majority of tinnitus sufferers adjust reasonably well to their tinnitus. Most see tinnitus as a minor annoyance rather than a major problem.⁸ However, a substantial minority suffer tinnitus-related distress.⁹

The overall economic impact of tinnitus remains unknown, although untreated severe tinnitus is likely

to be associated with substantial economic costs for society.¹⁰

Patient-specific treatment remains problematic given the uncertainty of the neural basis for tinnitus, the influence of the emotional brain on reactivity to the tinnitus signal and the heterogeneous nature of tinnitus.¹¹ The variability in presentation makes it difficult to match the patient to an active treatment or provide reassurance.¹² Uncertainty and paucity of evidence add to the dilemma faced by a clinician.

The pathogenesis of tinnitus is not well understood. Many types of peripheral injuries have been understood to induce tinnitus, including damage to the cochlea by intense sound or ototoxic medications. To clarify the pathogenesis of tinnitus, there is a need to understand the rebalancing of excitatory and inhibitory signalling mechanisms that occur after a peripheral injury.¹³ A prominent current hypothesis for tinnitus development suggests that tinnitus may result from a maladaptation of the central auditory system to dysfunction associated with a prior peripheral injury.¹⁴ One of the mechanisms by which this occurs is a decrease in inhibitory

neurotransmission. The major structures that play a role in transmitting neural activity through the ascending central auditory system include: the cochlear nucleus and superior olivary complex in the pons-medulla region, the inferior colliculus of the midbrain, the medial geniculate nucleus of the thalamus, and the auditory cortex.

Several treatments are used for the management of tinnitus, including sound therapy,¹⁵ tinnitus retraining therapy,¹⁶ counselling,¹⁷ cognitive behavioural therapy,^{18,19} acceptance commitment therapy²⁰ and mindfulness-based tinnitus stress reduction.²¹ Some of these therapies integrate aspects of others, which makes it difficult to evaluate their impact. At present, no specific therapy for tinnitus is acknowledged to be satisfactory in all patients.²² Treatment is mainly focused on reducing the tinnitus sound and the distress associated with tinnitus.

Mindfulness meditation

Dr Jon Kabat Zinn introduced mindfulness meditation to the Western world in the 1970s. He defined mindfulness meditation as ‘paying attention in the present moment and non-judgementally’. It is a technique designed to help one purposely pay attention to the present experience, without judgement or taking ownership of the many thoughts and emotional reactions that can become attached to a situation or stimulus. A desensitisation programme based on this would be ideally suited to tinnitus sufferers.²³ This approach is more metacognitive than cognitive in that it is not concerned with trying to analyse the problem from within. It works based on what Wilson refers to as classical conditioning.²⁴ If one learns to be less reactive to a perceived threat then the vigilance towards that threat should diminish. The approach facilitates the ‘what if I did nothing option’ in the face of tinnitus, or, as Hebb’s axiom puts it: ‘nerves that fire together wire together, nerves that fire apart soon depart’.²⁵

Studies examining the effects of mindfulness training on morbidity and mortality outcomes are beginning to emerge.²⁶ There are accumulating data supporting the notion that mindfulness meditation may ameliorate physiological changes that accompany chronic mental and emotional stress, improving the cortisol secretion profile and providing beneficial anatomical changes in the brain.²²

Relaxation therapy

Relaxation exercises have been used for a wide variety of conditions including anxiety, pain and tinnitus.^{27,28} The relaxation treatment procedure used in this study was based on the work of Lars-Goran Ost²⁸ and served as the control treatment. The treatment aimed to offer a way of coping with tinnitus-related stress.

Materials and methods

This was an open-ended randomised controlled trial comparing mindfulness meditation with relaxation

training, with no difference in the duration of intervention in both arms. Ethical approval for the project was obtained (research ethics committee reference: 11/WA/198).

Patients with a primary complaint of intrusive tinnitus were recruited from the tinnitus clinic held at the University Hospital of Wales, Cardiff. Leaflets comprising information about the study were displayed in the University Hospital of Wales and the neighbouring districts’ general hospitals. Colleagues at the ENT units from these hospitals were also asked to refer patients to the tinnitus clinic.

Those patients identified as having tinnitus caused by certain treatable conditions such as middle-ear infections, and those with mild tinnitus who needed only reassurance, were excluded from the study. Tinnitus was considered to be mild if it was not troublesome and if patients scored in the single digits on the Tinnitus Reaction Questionnaire.

Study population

Patients underwent a thorough history, relevant examinations and appropriate investigations where necessary. A pure tone audiogram and tympanogram were performed for all patients. Those patients with unilateral hearing loss underwent magnetic resonance imaging or computed tomography scanning.

The type and the duration of tinnitus were not considered as criteria for inclusion or exclusion from the study. Adults with intrusive tinnitus, aged over 18 years, who had not responded to other treatments such as hearing aids, maskers, background music or reassurance, or patients who did not want to try these treatments, were recruited for the study. Patients with psychiatric disorders severe enough to require treatment were excluded. Those who were undergoing litigation or legal matters related to auditory disorders, those unwilling to consider mindfulness meditation or relaxation therapy, and those who had problems communicating in English were also excluded.

Participants who satisfied the above criteria were given written information with brief descriptions of relaxation therapy and mindfulness meditation. The purpose of the research and the potential benefits were also explained. Participants were given the opportunity to ask any questions related to the study at this point. Participants had two weeks to decide whether to participate in the study.

After completing an informed consent form, participants were randomly allocated to one of two groups using sealed envelopes prepared by a person not involved in the trial.

Treatment programme

Mindfulness meditation was used in an attempt to uncouple or neutralise the sensory signal of tinnitus from the interpretative and behavioural response, thereby preventing a weak signal having a powerful conditioned response. The relaxation procedure used

TABLE I
MINDFULNESS MEDITATION SESSION FORMAT

Session	Topic	Contents
1	Exploration	<ul style="list-style-type: none"> – In-session exercise – Information gathering – Exploration of patient’s model of tinnitus – Homework: read material on mindfulness meditation
2	Sitting meditation	<ul style="list-style-type: none"> – In-session exercise: sitting meditation, slow low-volume diaphragmatic breathing – Homework: listen to meditation CD for 20 min/day & 5 min/night
3	Meditation applied	<ul style="list-style-type: none"> – Feedback on homework & acceptance – In-session exercise: how to apply meditation
4	Meditation applied (continued)	<ul style="list-style-type: none"> – Feedback on homework & insight gained regarding avoidance behaviour & reassurance checking – In-session exercise: concept of breath as creating space that facilitates different perception & choice of response – Homework: continued use of CD & its application
5	Review	<ul style="list-style-type: none"> – In-session exercise: review of internal locus of control via behavioural work, progress on use of meditation in given situations – Emphasis on meditation as way of life

CD = compact disc; min = minutes

in this study was based on the work of Lars-Goran Ost²⁸ and served as the control treatment.

Each treatment programme was standardised, following the session plans outlined in Tables I and II. Each patient had 5 face-to-face sessions of 40 minutes of relaxation therapy or mindfulness meditation treatment over a period of 15 weeks. The meditation was conducted by a single experienced therapist, whilst the relaxation therapy arm was split between two experienced therapists who followed a manual. The five mindfulness meditation sessions involved in-session exercises and homework (Table I). The five relaxation therapy sessions consisted of applied relaxation training (Table II).²⁸

Outcome measures

The pre- and post-assessment measures were completed at recruitment and at the end of the five treatment sessions respectively. Tinnitus-related severity, handicap and psychological effects were measured by self-report questionnaires. The primary outcome measure was the Tinnitus Reaction Questionnaire. The secondary measures used were the Hospital Anxiety and Depression Scale, a visual analogue scale (VAS) and a Health State Thermometer.

TABLE II
RELAXATION THERAPY SESSION FORMAT

Session	Topic	Contents
1	Exploration	<ul style="list-style-type: none"> – Information gathering – Exploration of patient’s understanding of tinnitus – Explanation of relaxation response & psychological reaction – Brief explanation of neural plasticity of brain – Rationale of treatment – Emphasis on patient compliance – In-session exercise: release-only relaxation – Home-based practice twice daily: duration of 15–20 min/session
2	Mental skill development	<ul style="list-style-type: none"> – Feedback on session 1: respond to patient’s questions where appropriate – In-session exercise involving release-only relaxation & visualisation – Home-based practice twice daily: duration 15–20 min/session
3	Cue-controlled relaxation	<ul style="list-style-type: none"> – Feedback from sessions 1 & 2 – In-session exercise, focusing on breathing & establishing a form of conditioning between a self-instruction to ‘relax’ & respiratory pattern, for 20–30 repetitions – Home-based practice twice daily: duration of 15–20 min/session
4	Differential relaxation	<ul style="list-style-type: none"> – Feedback from home-based relaxation – In-session exercise, aiming to relax patient whilst they are engaged in everyday activities – Patient taught how to avoid unnecessary tension in muscle groups not required for specific activities – Recognition of unnecessary tension is flagged up – Home-based practice twice daily: duration 15–20 min/session
5	Rapid relaxation application & review of subjective findings	<ul style="list-style-type: none"> – Feedback from home-based practice – In-session introduction to mini practice that reduces relaxation time to 60–90 seconds – Again, the word ‘relax’ is cued to respiration, repeated 2–3 times: duration of 60–90 seconds, practised 15–20 times/day with an identified ‘trigger’

Min = minutes

Tinnitus Reaction Questionnaire. The Tinnitus Reaction Questionnaire is a 26-item self-report, psychometrically validated questionnaire, that covers various elements of personal and social handicap associated with tinnitus.²⁹ The items within the scale can be divided into four subcategories: general distress,

TABLE III
PATIENTS' DEMOGRAPHICS

Parameter	Mindfulness group	Relaxation group
Patients (<i>n</i>)	34	27
Age (mean (SD); years)	53.8 (11.6)	58.3 (13.2)
Sex (% female)	59	48
Tinnitus duration (mean (SD); years)	5.2 (4.9)	6.5 (4.4)
Localisation (% bilateral)	65	78
Hearing loss (% moderate to severe)	38	73

SD = standard deviation

interference with activities, distress severity and avoidance activities. The Tinnitus Reaction Questionnaire is easy to complete and interpret, and has high internal consistency and high test–retest reliability.²⁹

Hospital Anxiety and Depression Scale. This scale was used to measure the emotional state of the patients. It is a 14-item questionnaire divided into 2 subscales for anxiety and depression.³⁰ For tinnitus patients, internal consistency was reported as $\alpha = 0.83$ for anxiety and $\alpha = 0.88$ for depression.³¹

Visual analogue scale. This was used to measure the severity and the loudness of tinnitus, the sensitivity to loud sounds, and the awareness of tinnitus. A scale of 0 to 10 was used, where 0 reflected no distress and 10 reflected most distressed.

Health State Thermometer. This was used as a generic measure to characterise current health state. It consisted of a VAS ranging from 0 to 100, wherein 0 indicated that the patient was in the worst state of health and 100 indicated that the patient was in the best state of health.

Results

Demographics

Eighty-six patients were recruited for the study, with 42 in the mindfulness meditation group and 44 in the relaxation therapy group. Amongst the 61 patients who completed treatment (34 for mindfulness meditation and 27 for relaxation therapy), there was a slight preponderance of females (55 per cent overall; 59 per cent in the mindfulness meditation group and 48 per cent in the relaxation therapy group). In the mindfulness meditation group, there were five dropouts and three patients who did not attend for therapy. In the relaxation therapy group, there were 7 dropouts and 10 patients who did not attend for therapy (Figure 1). The reasons for not completing the study varied from being too busy to attend, moving out of area, wanting no further treatment, having no time to attend for treatment, not being convinced of treatment benefits and the emergence of other medical problems.

The duration of tinnitus ranged from 6 months to 15 years. The type of tinnitus that patients complained of

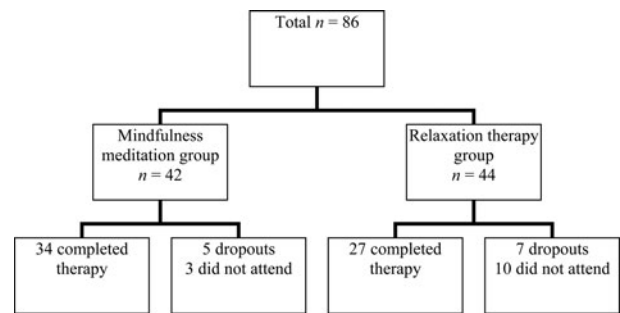


FIG. 1

Summary of patients recruited.

also varied. None of the patients recruited had received any behavioural therapy such as tinnitus rehabilitation therapy or cognitive behavioural therapy. Some of the patients had other medical concerns including hypertension, ischaemic heart disease, diabetes mellitus and hyperlipidaemia.

The mean age (standard deviation (SD)) of patients was 53.8 (11.6) years in the mindfulness meditation group and 58.3 (13.2) years in the relaxation therapy group, with a range of 25 to 80 years (Table III). The character of tinnitus was described as buzzing, hissing, whistling and roaring. There were no participants with severe or profound deafness. These variables were not statistically significant.

Outcome measures

The difference between the pre- and post-treatment scores was calculated for all of the measures (Table IV). Those differences were checked using the Shapiro–Wilk test and were all normally distributed. The variances of the differences between the two groups were checked using the variance ratio test and all were found to be equivalent. Each pair of differences (one for each group) was subsequently evaluated using the paired *t*-test for independent samples with equal variances.

The mean difference in scores (post- vs pre-treatment change) was greater in the mindfulness meditation group than in the relaxation therapy group for all outcome measures except the health status indicator.

Although a difference in Tinnitus Reaction Questionnaire scores was apparent in both groups, the difference was statistically significant for the mindfulness meditation group only. Mindfulness meditation and relaxation therapy showed pre-intervention mean scores (SDs) of 39.40 (15.412) and 41.77 (17.709) respectively, and post-intervention mean scores (SDs) of 15.06 (13.124) and 19.59 (13.151). The mean difference between the two groups was 8.24 in favour of the mindfulness meditation group (95 per cent confidence interval (CI) = $-16.4, -0.1$; $p = 0.047$).

The only other measure showing a statistically significant improvement between the two groups was the tinnitus severity, with mean difference (standard error of the difference) of 1.798 (0.553) in favour of the mindfulness meditation group (95 per cent CI = $-2.906, -0.69$; $p = 0.002$).

TABLE IV
QUESTIONNAIRE RESULTS

Outcome measure	Therapy group	Patients (n)	Score (mean (SD))	Post-intervention mindfulness & relaxation mean difference (p-value)	95% CI
HADS – total	– Pre-intervention	Mindfulness 41	13.341 (8.392)	–0.83838 (0.601)	–4.032, 2.355
		Relaxation 44	13.613 (6.221)		
– Post-intervention	Mindfulness 34	9.411 (5.377)			
	Relaxation 27	11.037 (7.377)			
HADS – anxiety	– Pre-intervention	Mindfulness 42	7.02 (4.314)	–1.0490 (0.225)	–2.761, 0.663
		Relaxation 44	7.45 (3.507)		
– Post-intervention	Mindfulness 34	4.59 (2.797)			
	Relaxation 27	5.89 (4.022)			
HADS – depression	– Pre-intervention	Mindfulness 41	6.39 (4.358)	0.101 (0.914)	–1.757, 1.959
		Relaxation 44	6.16 (2.980)		
– Post-intervention	Mindfulness 34	4.82 (2.959)			
	Relaxation 27	5.15 (3.780)			
Tinnitus Reaction Questionnaire	– Pre-intervention	Mindfulness 41	39.40 (15.412)	–8.23747 (0.047)	–16.375, –0.0996
		Relaxation 44	41.77 (17.709)		
– Post-intervention	Mindfulness 34	15.06 (13.124)			
	Relaxation 27	19.59 (13.151)			
VAS – severity of tinnitus	– Pre-intervention	Mindfulness 41	6.00 (2.000)	1.798 (0.002)	–2.906, –0.690
		Relaxation 44	6.23 (2.112)		
– Post-intervention	Mindfulness 34	2.91 (2.021)			
	Relaxation 27	4.41 (1.966)			
VAS – loudness of tinnitus	– Pre-intervention	Mindfulness 41	6.86 (2.102)	–0.648 (0.292)	–1.867, 0.57157
		Relaxation 44	6.91 (2.078)		
– Post-intervention	Mindfulness 34	4.47 (2.312)			
	Relaxation 27	5.11 (2.242)			
VAS – sensitivity to loud sounds	– Pre-intervention	Mindfulness 41	6.43 (2.490)	–0.858 (0.270)	–1.867, –0.571
		Relaxation 44	6.61 (2.608)		
– Post-intervention	Mindfulness 34	4.18 (2.634)			
	Relaxation 27	5.04 (2.426)			
VAS – awareness of tinnitus	– Pre-intervention	Mindfulness 41	69.76 (26.868)	–9.479 (0.239)	–25.417, 6.458
		Relaxation 44	72.40 (24.901)		
– Post-intervention	Mindfulness 34	35.76 (28.250)			
	Relaxation 27	48.96 (27.157)			
Health status indicator	– Pre-intervention	Mindfulness 41	75.17 (16.070)	–1.736 (0.745)	–12.377, 8.904
		Relaxation 44	72.05 (19.922)		
– Post-intervention	Mindfulness 34	75.32 (14.785)			
	Relaxation 27	76.59 (15.579)			

SD = standard deviation; CI = confidence interval; HADS = Hospital Anxiety and Depression Scale; VAS = visual analogue scale

Total Hospital Anxiety and Depression Scale mean scores (SDs) were 13.341 (8.392) and 13.613 (6.221) for the mindfulness meditation and relaxation therapy groups respectively. The post-intervention scores (SDs) were 9.411 (5.377) and 11.037 (7.377) respectively. The mean difference (standard error) was 0.838 (1.595) (95 per cent CI = –4.032, 2.355; $p = 0.601$). The Hospital Anxiety and Depression Scale anxiety and depression scores with mean differences are summarised in Table IV.

The only measure that showed no improvement following either mindfulness meditation or relaxation therapy was the overall health status indicator. The

mindfulness meditation group had pre- and post-treatment mean scores (SDs) of 75.174 (16.070) and 75.32 (14.4785), respectively. The relaxation therapy group had pre- and post-treatment mean scores (SDs) of 72.05 (19.922) and 76.59 (15.579), respectively.

The mean (SD) scores for all the outcome measures with differences between the two groups are summarised in Table IV.

Discussion

To our knowledge, this is the first trial comparing mindfulness meditation with relaxation therapy for the management of chronic tinnitus. Our study shows

a significant improvement in patients' symptoms for both therapies as recorded after five sessions of either therapy.

Successful management of tinnitus involves guiding the patient towards habituation, thereby reducing the negative effect that tinnitus has on the patient's health, lessening their suffering and allowing them to lead a normal life. Although this study comprised only a small sample, we established that both interventions were effective for the management of chronic tinnitus. However, some statistically significant results suggest that mindfulness meditation is better than relaxation therapy for reducing the severity of tinnitus, with improvements also recorded in terms of the loudness and the awareness of tinnitus, and the sensitivity to loud sounds. Importantly, the primary outcome measure, the Tinnitus Reaction Questionnaire, suggested a statistically significant improvement with mindfulness meditation in terms of the distress associated with chronic tinnitus. This study adds to the growing literature supporting mindfulness meditation in the management of other chronic conditions such as chronic pain, anxiety, stress and depression.

These two modes of treatment have not been compared previously, although both treatments have been used effectively for the management of tinnitus in the past.^{7,31–33}

We used a number of outcome measures, which showed consistency in results for improvement in most domains. The primary outcome measure, the Tinnitus Reaction Questionnaire, was designed to determine the psychological distress and impact of tinnitus, whereas the other scales show the impact of tinnitus on the sufferer's life. Changes in the awareness and the severity of tinnitus associated with mindfulness have been reported previously by Gans *et al.*²¹ Patients receiving relaxation therapy also showed improvement on the VAS, but with no statistically significant improvement recorded for any of the measures.

A comparison between mindfulness meditation and relaxation therapy on the Hospital Anxiety and Depression Scale revealed similar improvements for these therapies, with a reduction in patients' distress and an improvement in the patients' state of mind. The only measure which indicated little benefit was the health status indicator. Previous studies on mindfulness meditation have recorded improvements in health status when investigating patients' general wellbeing and quality of life.²³

Similar previous studies have also shown a benefit of mindfulness meditation in patients with tinnitus.^{33,34} In the study by Philippot *et al.*, the benefit of mindfulness increased with practice.³³ The sample size of these studies was much smaller than in our study, and none of these studies compared mindfulness meditation with relaxation therapy.

The strengths of this study are the comparatively large size of randomised samples in the controlled trial, the clearly defined protocols for the two

interventions and the use of experienced therapists in a clinical sample.

There were no differences observed between the two groups in terms of patients' age or sex, or tinnitus duration.

The main aim of tinnitus treatment is to help guide the patient towards habituation. Such treatment teaches a person to change their relationship with tinnitus in order to minimise their suffering, and provides a practical, simple and easy-to-learn technique that can be used in their daily life.

- **A randomised controlled trial was conducted to investigate mindfulness meditation versus relaxation therapy as tinnitus treatments**
- **A total of 86 patients were recruited for the study; 61 patients completed treatment**
- **Each patient received five sessions of mindfulness meditation or relaxation therapy**
- **Results of primary and secondary outcome measures were analysed pre- and post-therapy**
- **There were improvements in outcome measures for both treatments**
- **Mindfulness meditation appeared more effective than relaxation therapy**

Ideally, we would have liked to follow up both groups for 12 months after treatment, to evaluate if the improvements were sustained. However, a previous study using a similar approach did show sustained improvement at three to six months' follow up.²³ Our findings strengthen the evidence that mindfulness meditation is an effective treatment for the management of tinnitus. However, at present only a few centres offer mindfulness meditation for tinnitus, particularly at the primary and secondary care levels.

Conclusion

For tinnitus management to be successful, we must provide patients with strategies that will allow them to reduce their symptoms and help them to habituate to their tinnitus. Both mindfulness meditation and relaxation therapy have been shown to be effective in reducing the suffering, and would eventually lead to habituation. In this study, mindfulness meditation appears to have been more effective than relaxation therapy.

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Address for correspondence:
Mr Mohamed Arif,
Department of ENT,
Glangwili Hospital,
Carmarthen SA31 2AF, Wales, UK

E-mail: arif9164@gmail.com

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