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Mindfulness-Based Cognitive Therapy as a Treatment for Chronic Tinnitus: A Randomized Controlled Trial

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Tinnitus · Mindfulness-based cognitive therapy · Relaxation

Abstract
Background: Tinnitus is experienced by up to 15% of the population and can lead to significant disability and distress. There is rarely a medical or surgical target and psychological therapies are recommended. We investigated whether mindfulness-based cognitive therapy (MBCT) could offer an effective new therapy for tinnitus. ***Methods:*** This single-site randomized controlled trial compared MBCT to intensive relaxation training (RT) for chronic, distressing tinnitus in adults. Both treatments involved 8 weekly, 120-min sessions focused on either relaxation (RT) or mindfulness meditation (MBCT). Assessments were completed at baseline and at treatment commencement 8 weeks later. The primary outcomes were tinnitus severity (Tinnitus Questionnaire) and psychological distress (Clinical Outcomes in Routine Evaluation – Non-Risk, CORE-NR), 16 weeks after baseline. The analysis utilized a modified intention-to-treat approach. ***Results:*** A total of 75 patients were randomly allocated to MBCT (n = 39) or RT (n = 36). Both groups showed significant reductions in tinnitus severity and loudness, psychological distress, anxiety, depression, and disability. MBCT led to a significantly greater reduction in tinnitus severity than RT, with a mean difference of 6.3 (95% CI 1.3–11.4, p = 0.016). Effects persisted 6 months later, with a mean difference of 7.2 (95% CI 2.1–2.3, p = 0.006) and a standardized effect size of 0.56 (95% CI 0.16–0.96). Treatment was effective regardless of initial tinnitus severity, duration, or hearing loss. ***Conclusions:*** MBCT is effective in reducing tinnitus severity in chronic tinnitus patients compared to intensive RT. It also reduces psychological distress and disability. Future studies should explore the generalizability of this approach and how outcome relates to different aspects of the intervention.

Introduction

Persistent tinnitus is experienced by 10–15% of the population [1]. Approximately half report at least moderate annoyance and 1–2% report significant distress and disability. Insomnia, anxiety, depression, hearing problems, and cognitive processing difficulties are common [1].

There is rarely a medical or surgical solution to tinnitus and the clinical challenge is to relieve associated distress. Tinnitus is affected by cognitive, behavioural, and

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neuronal factors. The natural history of tinnitus involves habituation; simply waiting for treatment can reduce distress [2]. Habituation is facilitated by reducing stress arousal and minimizing the emotional significance of tinnitus. The strongest evidence for treatment is for cognitive behavioural therapy (CBT) [3, 4], and a stepped-care approach combining CBT and tinnitus retraining therapy is supported [5].

Recent developments in CBT incorporate mindfulness and "acceptance-based" approaches. Mindfulness involves bringing a certain quality of attention to present moment experience [6]. Standard programmes include mindfulness-based stress reduction (MBSR) or mindfulness-based cognitive therapy (MBCT); the latter more closely aligns with psychological theory. MBCT reduces relapse rates in recurrent depression [7] and mindfulness therapies are advocated in a range of medical settings [6], including chronic pain [8], a condition that has similarities to tinnitus [9].

Meta-analyses of mindfulness-based therapy across conditions report effects equal to cognitive and behavioural therapies [10]. In the treatment of long-term medical conditions, mindfulness-based therapies (excluding MBCT) have some evidence [11]. Applications of mindfulness to tinnitus are in their infancy, and as yet there have been just 7 relevant studies published, of which only 2 are randomized controlled trials [12, 13]. These trials have indicated potential benefits of mindfulness, but both have reported on small sample sizes only, and neither adhered to the standardized (and thus replicable) MBCT or MBSR protocols advised in the psychological and medical literature.

Mechanisms of mindfulness may include the self-regulation of attention towards the present moment, characterized by curiosity, openness, and acceptance [14, 15]. By fostering a non-judgmental focus in the present moment, mindfulness may reduce negative cognitions which are known to be associated with anxiety, depression, and tinnitus severity [16]. MBCT may improve cognitive and metacognitive awareness (awareness of the link between negative thinking and negative emotional states). This could allow individuals to establish a different relationship with negative experiences, whereby they are less emotionally destructive [15]. Distressed tinnitus patients often attempt to avoid or escape environments which they fear may increase their tinnitus or awareness of tinnitus (i.e., particularly noisy or quiet places, or by keeping busy to distract from tinnitus). Such behaviours are associated with anxiety and tinnitus severity and related distress [17, 18]. MBCT targets avoidance by encouraging exposure to and acceptance of tinnitus. Tinnitus acceptance mediates between initial tinnitus distress and later depression, quality of life, and distress [19]. By reducing avoidance and enhancing acceptance, mindfulness is likely to lead to significant benefits in tinnitus patients.

There is growing interest in mindfulness in audiology [20]. This growth is taking place in the context of a nascent evidence base, indicating an urgent need for rigorous controlled trials. We developed an intervention based on a standard 8-week MBCT protocol, adapted for tinnitus, an important issue in a field where mindfulness-based interventions vary widely. A pre-post study found that this was effective in reducing tinnitus severity, improving psychological well-being, and acceptance in chronic tinnitus patients [unpubl. data].

A randomized controlled trial was developed to establish whether MBCT is an effective treatment for tinnitus, and whether it is more effective than an existing treatment delivered at equivalent intensity (relaxation training, RT). MBCT was therefore compared to both a pre-treatment waiting period and to an active control condition (RT). We hypothesized that MBCT would lead to a greater reduction in tinnitus severity, psychological distress, functional disability, avoidance, and negative cognitions and a greater increase in tinnitus acceptance than RT by the end of treatment, and in comparison to a waiting period. Psychological treatment does not directly target tinnitus volume, so we hypothesized that this would remain unchanged.

Methods

Study Design and Participants

This was a 2-group randomized controlled trial, conducted at the Royal National Throat, Nose and Ear Hospital, London, UK. Adult patients were recruited between January 2013 and March 2015. Consecutive referrals to the clinical psychology department were screened for eligibility. Inclusion criteria were (1) aged 18 years or over; (2) reported tinnitus of more than 6 months' duration; (3) reported clinical levels of psychological distress (Clinical Outcomes in Routine Evaluation – Non-Risk, CORE-NR score >10); (4) completed medical investigations for tinnitus; and (5) sufficient command of English and hearing levels allowing participation in group discussions. Exclusion criteria were (1) current, comorbid, severe physical or mental illness; (2) current risk factors of active suicidal ideation or self-harm; (3) current substance dependence.

Ethical Considerations

To manage the ethical implications of random allocation to different treatment conditions, all patients provided full, informed consent. Those opting out of the study were offered standard care with no additional delay, and since both treatments are "active,"

no patient was denied help. After completing the study, all participants could opt to choose the alternative intervention. There were no changes to the trial design following its commencement.

Randomization and Masking

Randomization was done in cohort groups of 15–19 participants, to ensure a group size of 6–10. Anonymized details were sent to an independent researcher at the Ear Institute (UCL, London, UK). They were randomly allocated to RT or MBCT by computer. Randomization was stratified by age and gender, conducted independently for each cohort group to ensure later allocation sequence was not affected. Allocations were sent to the trial clinical psychologists (L.M. and E.M.M.) who informed participants 4 weeks prior to commencing treatment. It was not possible to mask the participants or clinicians to allocation, although participants were masked to the content of the alternative treatment. Independent statisticians analysing the results were masked to group for the initial analyses. The work was conducted at the Royal National Throat, Nose and Ear Hospital, London, UK. Ethical approval was given by the UK NHS research committee and the trial was registered with Clinical Trials.gov (NCT02059447).

Procedures

Eligibility assessment involved a 1-hour interview with a clinical psychologist and completion of a screening questionnaire: Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM). Following consent participants completed a battery of outcome questionnaires at baseline, 8 weeks prior to treatment. An 8-week waiting period without intervention followed. Outcome questionnaires were completed at 4 additional time points after baseline: 8 weeks (pre-treatment), 16 weeks (post-treatment), 20 weeks (1-month follow-up), and 40 weeks (6-month follow-up). Follow-up was completed by December 2015.

Both interventions consisted of eight 120-min group sessions, delivered weekly over 8 consecutive weeks. Groups were run on the same day with counterbalancing of morning/afternoon delivery. Two clinical psychologists were involved in the study; both had qualifications in CBT, expertise in RT, and teacher training in mindfulness-based approaches from Bangor University. Treatment fidelity and procedural adherence was assessed through weekly briefing sessions between the clinicians and regular supervision with accredited mindfulness supervisors.

Both MBCT and RT were structured programmes, delivered in line with manuals (details in Supplementary Text; for all online suppl. material, see www.karger.com/doi/10.1159/000478267). MBCT was based on the protocol for depression [14], with tinnitus-related modifications that included a greater emphasis on sound meditation and education around the cognitive model of tinnitus [21], and the importance of attentional processes in tinnitus. RT was based on standardized interventions for relaxation [22], adapted to create an 8-week course for comparability to MBCT. Both groups had a similar framework, involving formal experiential exercises (either relaxation or meditation), discussion, and psycho-education within the group. Psycho-education in RT focused on the physiology of stress and tinnitus, and in MBCT it focused on cognitive theory. Both groups were asked to complete equivalent amounts of daily formal practice (supported by audio guides) and to begin to apply their practice of either mindfulness or relaxation to daily life. In line with advised protocols, MBCT participants received supporting literature but RT participants did not.

Outcomes

The primary outcomes were change from pre- to post-treatment in tinnitus severity and psychological distress. The Tinnitus Questionnaire (TQ) assesses self-reported tinnitus severity with 41 items on a 3-point scale. The scale has high test-retest reliability and internal consistency [23]. Reliable change was calculated as 11 points [unpubl. data]. CORE-OM [24] is a pan-diagnostic measure of psychological distress with items scored on a 5-point scale, and the mean of all scores multiplied by 10. It has good reliability and validity. The most useful scoring method for assessing clinical change uses the 28 non-risk items (CORE-NR) [25]. A mean score over 10 is clinically important, and reliable change is indicated by a change in score >5.

Secondary outcomes included additional time points: effect of waiting period (change from baseline to pre-treatment) and long-term effects (change from pre-treatment to 1-month and 6-month follow-ups), and the following measures:

Perceived Tinnitus Loudness was measured with a 10-cm Visual Analogue Scale (VAS), a standard measure for subjective tinnitus loudness [3].

The Tinnitus Functional Index (TFI) [26], has limited reliability and validity in research samples [27], but was included following a call from the tinnitus community to develop a consensual measure of tinnitus impact. It has 8 separate subscales and the total score can be used.

The Hospital Anxiety and Depression Scale (HADS) [28] measures anxiety and depression. Fourteen items are scored from 0 to 3. The scale has good psychometric properties that are maintained in tinnitus populations [29].

The Tinnitus Catastrophizing Scale (TCS) [16] assesses thoughts and feelings about tinnitus using a 13-item scale. Internal consistency is good, and convergent validity with the TQ is high ($r = 0.74$) [16].

The Tinnitus Fear Avoidance Scale (T-FAS) measured tinnitus-related fearful cognitions and behaviours around tinnitus. Internal consistency is good [17].

The Tinnitus Acceptance Questionnaire (TAQ) [19] is a 12-item questionnaire assessing acceptance versus experiential avoidance of tinnitus. The total score has good test-retest reliability and the subscales ("tinnitus willingness" and "activity engagement") both have good internal consistency ($\alpha = 0.70$ and $\alpha = 0.91$).

The Mindful Attention Awareness Scale (MAAS) [30] measures dispositional mindfulness in daily life with 15 items on a 6-point scale. In clinical populations reliability levels are high (>0.8) [30].

The Work and Social Adjustment Scale (WSAS) [31] is a widely used measure of impaired functioning. Five items are rated on a 9-point scale, and total scores over 10 suggest significant functional impairment. Internal consistency ranges from 0.7 to 0.94 and test-retest correlation is good (0.73).

Demographic information was collected at assessment. Records were taken for number of sessions attended and minutes of practice per week to assess treatment adherence. Treatment satisfaction was assessed using two 11-point Likert scales assessing perceived "usefulness" and "relevance" of treatment 16 weeks after baseline. Potential adverse events, identified as significant deterioration in mood or tinnitus severity, were recorded by the trial therapists and treated appropriately.

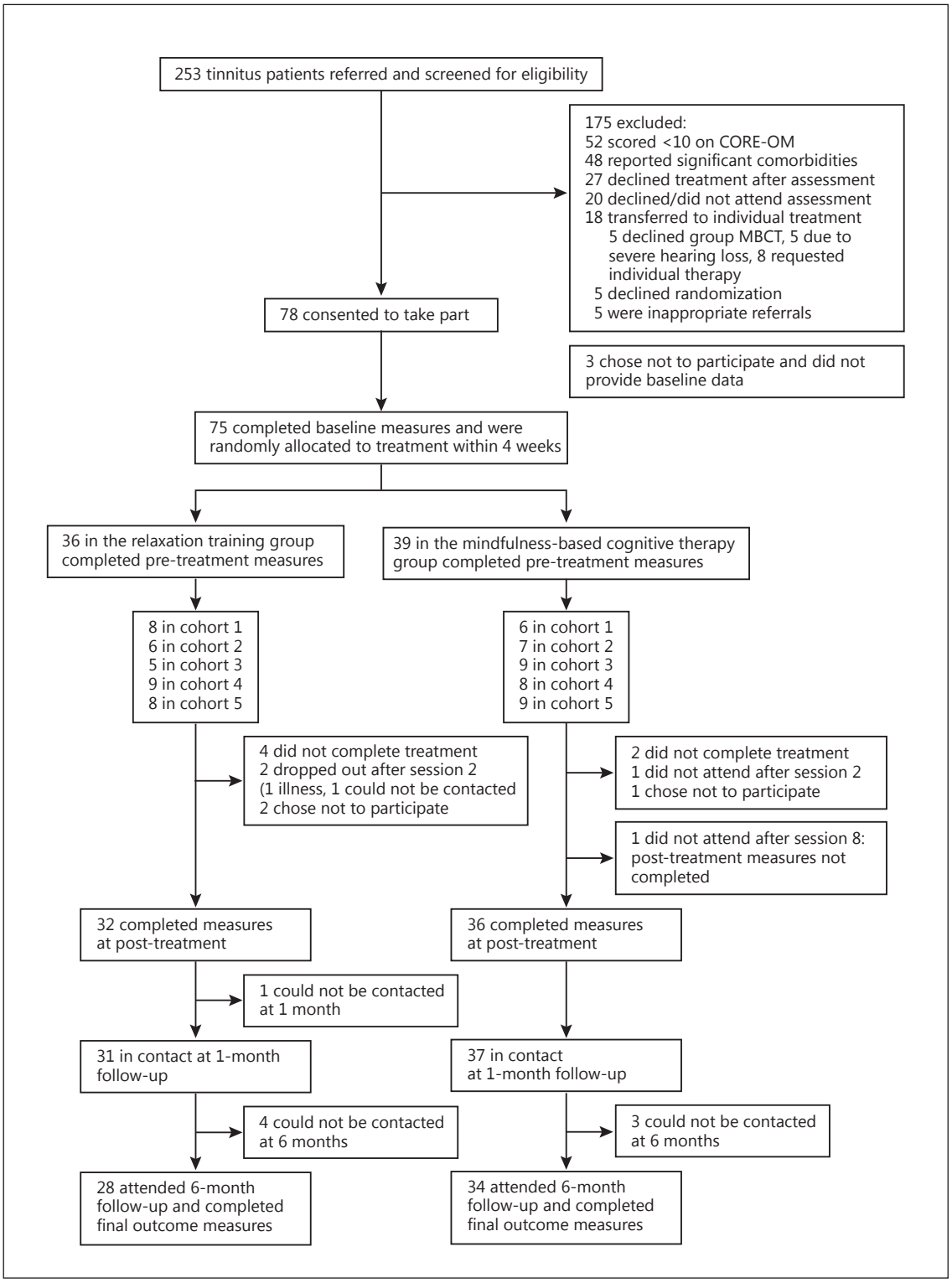

Fig. 1. CONSORT diagram: profile of enrolment and flow through the randomized controlled trial of mindfulness-based cognitive therapy versus relaxation training for tinnitus.

Statistical Analyses

A pilot study [unpubl. data] suggested that the standardized effect size corresponding to a reliable reduction in TQ is 11 points (standardized effect size 0.8; SD 12 points). A sample size of 74 was sufficient to give 80% power, allowing for 20% loss to follow-up, an inter-class correlation coefficient of 0.07 to account for clustering within groups, with an average of 7 participants per group, and a baseline to outcome correlation of 0.4.

The statistical analysis plan was agreed upon before completion of data collection. We used a modified intention-to-treat approach; all patients allocated to treatment were included. Drop-out rates were small and similar between groups. Analyses were conducted under the assumption that missing data were missing at random. Missing data points were systematically inputted based on recommendations for each questionnaire manual, whereby the mean of an individual scale was used to replace a missing data point only if no more than 20% of that individual scale was missing. In the rare cases where more than 20% of a scale was missing then missing data points were imputed as the last observation carried forward (see online suppl. Table 1). To check the dependence of our conclusions on the intention-to-treat assumption, primary analyses were repeated for completers only. None of the results changed materially when only complete cases were analysed.

Linear mixed models were used for all analyses accounting for repeated measurements. A random effect for participant was included, and for each outcome, age, gender, duration of tinnitus, and presence of hearing loss were included as covariates. Difference between treatments is reported as a mean difference, adjusted for pre-treatment score in each group. Owing to the cohort structure of the trial, a sensitivity analysis was performed with an additional random effect term included for treatment cohort. This increased the Akaike information criterion, without changing the outcomes, so analysis proceeded without a random effect for cohort.

All analyses were carried out in RStudio, using the lme4 package (v1.1-10) for linear mixed modelling. Effect sizes are reported as standardized mean differences (using baseline standard deviation of scale). All planned analyses were parametric unless there was clear evidence of deviation from a normal distribution. Differences between groups at baseline were assessed using *t* tests or the Mann-Whitney U test, chosen appropriately according to the distribution of the data. The Fisher exact test was used for analysis of categorical variables and differences in reliable change.

Role of the Funding Source

The study sponsor did not play a role in the study design, data collection, analysis, interpretation, or write-up. L.M. and E.M.M. had full access to data and were responsible for final submission. R.S. had access to anonymized baseline information for randomization. R.S. and C.A.H. had access to anonymized data for analyses.

Table 1. Demographic characteristics

	Overall	RT	MBCT
Age[a], years	50 (16)	53 (14)	47 (17)
Female sex	34 (45)	16 (44)	18 (46)
Time since tinnitus onset, months[a]	56 (104)	34 (72)	96 (108)
Education			
No qualifications	3 (4)	1 (3)	2 (5)
School level	26 (35)	14 (39)	12 (31)
Higher education	40 (53)	17 (47)	23 (59)
Not given	6 (8)	4 (11)	2 (5)
Ethnic origin			
White	60 (80)	27 (74)	33 (85)
Black	5 (7)	4 (11)	1 (3)
Other	10 (13)	5 (15)	5 (13)
Hearing loss			
No	27 (36)	17 (47)	10 (26)
Yes	48 (64)	19 (53)	29 (74)
Hearing loss aided?			
No	29 (39)	12 (33)	17 (44)
Yes	19 (25)	7 (19)	12 (31)
Not applicable	27 (36)	17 (47)	10 (26)
Other audiovestibular conditions			
No	66 (88)	31 (86)	35 (90)
Yes	9 (12)	5 (14)	4 (10)
Other health conditions			
No	22 (29)	8 (22)	14 (36)
Yes	53 (71)	28 (78)	25 (64)
Previous tinnitus treatments			
No	40 (53)	20 (54)	20 (51)
Yes	35 (47)	16 (44)	19 (49)
Completed trial treatment			
No	6 (8)	4 (11)	2 (5)
Yes	69 (92)	32 (89)	37 (95)
Sessions attended[b]	6.9 (1.9)	6.6 (2.2)	7.1 (1.7)
"Usefulness"[b]	8.25 (1.55)	7.89 (1.55)	8.56 (1.50)
"Relevance"[b]	8.36 (1.46)	8.07 (1.71)	8.60 (1.19)

Values are *n* (%) unless otherwise indicated. RT, relaxation therapy; MBCT, mindfulness-based cognitive therapy. [a] Values are median (IQR). [b] Values are mean (SD).

Results

Between January 2013 and March 2015, 253 participants were screened for eligibility. A total of 175 were excluded (52 reported levels of psychological distress below eligibility criteria, 48 reported significant comorbidities, 52 declined participation, 18 required individual therapy, and 5 were inappropriate referrals). Consent was given by 78 although 3 then chose not to participate. Thus, 75 participants were randomly allocated to treatment (36 to RT, 39 to MBCT). Attrition from therapy was low (8%) and not significantly different between groups (odds ratio 2.29, 95% CI 0.30–26.9); 4 withdrew from RT, and 2 from MBCT. Figure 1 shows the trial profile.

Table 2. Primary outcomes: tinnitus severity (TQ) and psychological distress (CORE-NR)

	RT, mean (SD)	MBCT, mean (SD)	Adjusted mean difference (95% CI)	*p*	Effect size (95% CI)
TQ					
Baseline	51 (12.8)	49.5 (13)			
Pre-treatment	48.1 (14.1)	47.7 (13.8)	–1 (–6.2 to 4.1)	0.696	–0.08 (–0.48 to 0.32)
Post-treatment	38.2 (14.3)	31.4 (16.1)	–6.3 (–11.5 to –1.2)	0.016	–0.49 (–0.89 to –0.09)
1-month follow-up	36.2 (15.9)	30.9 (16.8)	–4.8 (–10 to 0.3)	0.065	–0.38 (–0.78 to 0.02)
6-month follow-up	35.6 (16.8)	28 (18.1)	–7.2 (–12.3 to –2.1)	0.006	–0.56 (–0.96 to –0.16)
CORE-NR					
Baseline	20.2 (5.5)	18.1 (5)			
Pre-treatment	17.6 (7)	16.6 (5.7)	–1.1 (–3.6 to 1.3)	0.371	–0.21 (–0.67 to 0.25)
Post-treatment	14.1 (7.4)	12.3 (6.2)	–0.7 (–3.2 to 1.7)	0.555	–0.14 (–0.6 to 0.32)
1-month follow-up	14.2 (7.8)	13 (6.2)	–0.2 (–2.6 to 2.3)	0.887	–0.03 (–0.5 to 0.43)
6-month follow-up	14.3 (8)	12 (5.8)	–1.3 (–3.8 to 1.2)	0.303	–0.24 (–0.71 to 0.22)

RT, relaxation therapy; MBCT, mindfulness-based cognitive therapy; TQ, Tinnitus Questionnaire; CORE-NR, Clinical Outcomes in Routine Evaluation – Non-Risk.

Baseline clinical characteristics and demographics were equivalent between groups (Table 1), excepting median tinnitus duration, which was greater in the MBCT group (p = 0.04). Tinnitus was problematic overall (mean TQ score of 50) and chronic (median duration 56 months). Psychological distress was high (mean CORE-NR score of 19.1). Thirty-five (47%) participants had previously tried treatments for tinnitus. The complexity of the client group was reflected by 48 (64%) reporting hearing loss, 9 (12%) reporting other audiovestibular conditions, and 53 (71%) reporting other health problems. Binary logistic regression found that no baseline characteristics were predictive of drop-out.

Effects on Tinnitus Severity

Both groups showed a significant reduction in tinnitus severity (TQ) pre- to post-treatment, but this was significantly greater in MBCT (mean = 31.4, SD = 16.1), with the adjusted mean score in the MBCT group 6.3 points (95% CI 1.3–11.4, p = 0.016) lower than in RT (mean = 38.2, SD = 14.3) and a standardized effect size of 0.49 (95% CI 0.09–0.89) (Table 2). At the 1-month follow-up, the mean score in MBCT was essentially unchanged, and had declined by 2 points in RT; the adjusted mean difference was 4.8 points (95% CI –0.3 to 10, p = 0.065) lower in the MBCT group, and this did not quite reach significance. By the 6-month follow-up, the adjusted mean score in MBCT (mean = 23, SD –18.1) was 7.2 points (95% CI 2.1–12.3, p = 0.006) lower than RT (mean = 35.6, SD = 16.8), with a standardized effect size of 0.56 (95% CI 0.16–0.96) (see online suppl. Fig. 1a).

Clinically significant, reliable change required a reduction of at least 11 points on the TQ. Post-treatment, reliable change was observed in 59% of participants in the MBCT group and 44% in the RT group. The number needed to treat (NNT) was 6.9. Considering only reliable change, the difference between treatments was not significant (odds ratio 1.8, 95% CI 0.72–4.49). At the 6-month follow-up, reliable change was observed in 62% of the MBCT and in 53% of the RT group (odds ratio 1.43, 95% CI 0.57–3.59); the NNT was 11.4.

Effects on Psychological Distress

Both groups showed a significant reduction in psychological distress (CORE-NR) pre- to post-treatment. Post-treatment, in MBCT (mean = 12.3, SD = 6.2), the mean decrease was 4.3 points (95% CI 2.5–6.1), and in RT (mean = 14.1, SD = 7.4), the mean decrease was 3.6 points (95% CI 2.1–5.0). There was no significant difference between the groups' post-treatment scores: adjusted mean difference –0.7 points (95% CI –3.2 to 1.7, p = 0.5). This pattern was sustained over time, and by 6 months, the mean reduction in MBCT (mean = 12, SD = 5.8) was 4.6 points (95% CI 2.7–6.6), and in RT (mean = 14.3, SD = 8), the mean reduction was 3.3 points (95% CI 1.5–5.2). The adjusted mean difference between the groups was –1.3 points (95% CI –3.8 to 1.2, p = 0.2) (online suppl. Fig. 1b).

A reduction of >5 indicates reliable change on the CORE (item 23). At post-treatment, this was observed in 49% of participants in the MBCT group and 28% in the RT group. The NNT was 4.8, and the odds ratio was 2.47

(95% CI 0.94–6.47). At the 6-month follow-up, the proportion of participants experiencing reliable change in the MBCT and RT groups was 49 and 31%, respectively. This gives an NNT of 5.5 and an odds ratio of 2.16 (95% CI 0.84–5.57), which is not significant.

Effects on Secondary Outcomes

Table 3 shows the secondary outcomes over time. The mean subjective tinnitus loudness (VAS) was significantly lower after treatment in both groups. Post-treatment scores for MBCT (mean = 56.6, SD = 25.2) represented a mean decrease of 14 points (95% CI 8.1–19.9) and in RT (mean = 59.2, SD = 22.5) a decrease of 12 points (95% CI 5.7–18.7). There were no significant differences between groups. At 6 months, a trend suggested that MBCT (mean = 55.1, SD = 29.9), led to a greater reduction in tinnitus loudness than RT (mean = 65.4, SD = 24.3): adjusted mean difference, 9.6 points (95% CI –19.7 to 0.5, p = 0.063). Variability in responses suggests that this may be an unreliable indicator of difference. The impact of tinnitus (TFI) was significantly lower after treatment in both groups but not significantly different (p = 0.2), with a mean decrease of 18.4 in MBCT (mean = 42.2, SD = 19.2) and 13.6 in RT (mean = 49.2, SD = 19). By 6 months, the mean TFI score was unchanged in RT (mean = 49, SD = 21.1) but had decreased in MBCT (mean = 37.2, SD = 24.1), and this difference became significant (p = 0.01).

There were significant changes in measures of cognition, behaviour, and acceptance related to tinnitus. Both groups showed a significant reduction in tinnitus catastrophizing (TCS). Post-treatment this was significantly greater in MBCT (mean = 16.5, SD = 11.5) compared to RT (mean = 23.7, SD = 13.3): adjusted mean difference 4.6 (95% CI 0.50–8.6, p = 0.029). At 1 month, the mean score decreased slightly in the RT group, but in MBCT was essentially unchanged; at this point the groups were not significantly different (p = 0.123). However, by 6 months, the TCS scores were again significantly lower in MBCT (mean = 15.1, SD = 12.4) compared to RT (mean = 22.3, SD = 13.3): adjusted mean difference of 4.6 points. The same pattern was seen in reported avoidance behaviours (T-FAS), with both groups reporting significantly reduced avoidance behaviour post-treatment. This decrease was significantly greater in MBCT (mean = 38.4, SD = 13.3) compared to RT (mean = 45, SD = 13.5): adjusted mean difference 5.2 points (95% CI 0.7–9.7). At 1 month, the groups were not different, but by 6 months, T-FAS scores were significantly lower in MBCT (mean = 37.1, SD = 13.2) compared to RT (mean = 43, SD = 14.9): adjusted mean difference 4.5 points. Both groups showed a significant increase in tinnitus acceptance (TAQ) post-treatment, but this was significantly greater in MBCT (mean = 42.8, SD = 12.4) compared to RT (mean = 36.8, SD = 9.8): adjusted mean difference 4.7 points (95% CI 0.9–8.5, p = 0.015). At 1 month, the mean score decreased slightly in the RT group, but was essentially unchanged in MBCT, so the groups were not significantly different. At 6 months, a further increase in acceptance was observed in the MBCT group (mean = 45.3, SD = 13.7) but not in RT (mean = 37, SD = 11.8): adjusted mean difference 7 points (95% CI 3.2–10.7, $p < 0.001$).

Both groups showed similar reductions in disability (WSAS) post-treatment and at all time points. By 6 months, a mean improvement of 5.9 points was observed in the MBCT group (mean = 11.8, SD = 10; 95% CI 3.8–8.6), and a mean of 5.2 points was seen in the RT group (mean = 14, SD = 10.2; 95% CI 2.5–7.8). Both groups showed a reduction in mean anxiety (HADS-A) and depression (HADS-D) pre- to post-treatment and at 1 and 6 months (see Table 3). After adjusting for pre-treatment scores, there was no significant difference between the groups' scores at either time point.

Both groups showed significant increases in mindfulness pre- to post-treatment, but it was significantly greater in MBCT (mean = 3.8, SD = 0.8) than RT (mean = 3.7, SD = 0.8): adjusted mean difference 0.3 (95% CI 0.0–0.60, p = 0.038). At 1 month, increased mindfulness in the RT group made the groups equivalent. By 6 months, increases in MBCT (mean = 4.1, SD = 1) and decreases in RT (mean = 3.8, SD = 0.9) meant that MBCT had significantly greater mindfulness: adjusted mean difference 0.3 points (95% CI 0.0–0.6, p = 0.025).

Effect of Waiting Period

During the waiting period, there was a small reduction in tinnitus severity (2.3 points overall), corresponding to a standardized effect size of 0.18 (95% CI 0.06–0.31). There were small improvements in a number of secondary outcomes (VAS, CORE, TCS, HADS-anxiety), but none were significantly different between groups (see online suppl. Table 2).

Practice and Acceptability

The number of minutes of practice recorded in the participant diaries over the 8-week treatment period was high, indicating good adherence. It was substantially different between groups. The mean practice times (in minutes) were significantly greater in the MBCT (mean = 1,315, SD = 548) than in the RT group (mean = 815, SD = 506), probably reflecting differences in the treat-

Table 3. Effect of treatment on secondary outcomes

	RT, mean (SD)	MBCT, mean (SD)	Adjusted mean difference (95% CI)	*p*	Effect size (95% CI)
VAS					
Baseline	74.2 (20)	76.3 (20.2)			
Pre-treatment	71.4 (18.9)	70.6 (20.3)	2.9 (–7.2 to 12.9)	0.577	0.14 (–0.36 to 0.65)
Post-treatment	59.2 (22.5)	56.6 (25.2)	–1.8 (–11.9 to 8.2)	0.721	–0.09 (–0.59 to 0.41)
1-month follow-up	63.4 (23.5)	57.7 (26.9)	–4.9 (–15 to 5.1)	0.338	–0.25 (–0.75 to 0.26)
6-month follow-up	65.4 (24.3)	55.1 (29.9)	–9.6 (–19.7 to 0.5)	0.063	–0.48 (–0.98 to 0.02)
TFI					
Baseline	66.5 (16.7)	63.2 (15.1)			
Pre-treatment	62.8 (15.8)	60.6 (16)	–1.1 (–8.5 to 6.2)	0.76	–0.07 (–0.54 to 0.39)
Post-treatment	49.2 (19)	42.2 (19.2)	–4.8 (–12.2 to 2.5)	0.199	–0.3 (–0.77 to 0.16)
1-month follow-up	49.7 (21)	42.5 (21.5)	–5.1 (–12.5 to 2.2)	0.173	–0.32 (–0.79 to 0.14)
6-month follow-up	49 (21.1)	37.2 (24.1)	–9.6 (–17 to –2.3)	0.011	–0.61 (–1.07 to –0.14)
TCS					
Baseline	32.2 (11)	30 (10.2)			
Pre-treatment	30.1 (12.5)	27.5 (10.9)	0.3 (–3.7 to 4.4)	0.867	0.03 (–0.35 to 0.42)
Post-treatment	23.7 (13.3)	16.5 (11.5)	–4.6 (–8.6 to –0.5)	0.029	–0.43 (–0.82 to –0.05)
1-month follow-up	22.7 (14)	16.8 (13.3)	–3.2 (–7.3 to 0.9)	0.123	–0.3 (–0.69 to 0.08)
6-month follow-up	22.3 (13.3)	15.1 (12.4)	–4.6 (–8.7 to –0.5)	0.028	–0.43 (–0.82 to –0.05)
TFAS					
Baseline	50 (11.7)	48.6 (12.3)			
Pre-treatment	49.1 (13.8)	47.7 (10.9)	0 (–4.5 to 4.5)	0.992	0 (–0.38 to 0.37)
Post-treatment	45 (13.5)	38.4 (13.3)	–5.2 (–9.7 to –0.7)	0.023	–0.44 (–0.81 to –0.06)
1-month follow-up	42.6 (15.4)	38.6 (13.6)	–2.6 (–7.1 to 1.8)	0.251	–0.22 (–0.59 to 0.15)
6-month follow-up	43 (14.9)	37.1 (13.2)	–4.5 (–9 to 0)	0.05	–0.38 (–0.75 to 0)
TAQ					
Baseline	29.4 (11.5)	32 (11.6)			
Pre-treatment	31.9 (11.4)	33.3 (10.3)	1.2 (–2.7 to 5.1)	0.542	0.1 (–0.23 to 0.44)
Post-treatment	36.8 (9.8)	42.8 (12.4)	4.7 (0.8 to 8.6)	0.019	0.41 (0.07 to 0.74)
1-month follow-up	37.7 (11.7)	42.6 (13)	3.6 (–0.3 to 7.5)	0.073	0.31 (–0.03 to 0.65)
6-month follow-up	37 (11.8)	45.3 (13.7)	7 (3.1 to 10.9)	0.001	0.6 (0.26 to 0.94)
HADS-A					
Baseline	13.1 (3.6)	12.6 (3.3)			
Pre-treatment	12.3 (4.1)	12.4 (3.6)	–0.7 (–2.2 to 0.9)	0.406	–0.19 (–0.64 to 0.26)
Post-treatment	10.1 (3.9)	9.2 (3.8)	–1 (–2.6 to 0.5)	0.196	–0.3 (–0.74 to 0.15)
1-month follow-up	10 (4.2)	9.7 (3.8)	–0.4 (–1.9 to 1.2)	0.647	–0.1 (–0.55 to 0.34)
6-month follow-up	10.2 (3.7)	9 (3.8)	–1.3 (–2.8 to 0.2)	0.098	–0.38 (–0.83 to 0.07)
HADS-D					
Baseline	9.3 (4.1)	8.9 (3.6)			
Pre-treatment	9 (3.7)	8.4 (3.3)	0.2 (–1.1 to 1.6)	0.757	0.06 (–0.3 to 0.41)
Post-treatment	7.5 (3.8)	6.2 (3.1)	–0.6 (–2 to 0.7)	0.35	–0.17 (–0.52 to 0.19)
1-month follow-up	7.6 (4.2)	6.5 (3.3)	–0.4 (–1.8 to 0.9)	0.546	–0.11 (–0.46 to 0.25)
6-month follow-up	7.5 (4.2)	5.6 (3.6)	–1.3 (–2.6 to 0.1)	0.069	–0.33 (–0.69 to 0.02)
WSAS					
Baseline	20 (10.1)	18.2 (9.5)			
Pre-treatment	19.2 (10.2)	17.7 (9.5)	–0.3 (–3.3 to 2.8)	0.858	–0.03 (–0.34 to 0.28)
Post-treatment	15.4 (9.8)	12.6 (8.5)	–1.2 (–4.3 to 1.8)	0.423	–0.13 (–0.44 to 0.18)
1-month follow-up	13.7 (9.7)	13.3 (9.5)	1.2 (–1.9 to 4.2)	0.459	0.12 (–0.19 to 0.43)
6-month follow-up	14 (10.2)	11.8 (10)	–0.7 (–3.8 to 2.3)	0.647	–0.07 (–0.39 to 0.24)
MAAS					
Baseline	3.5 (0.9)	3.6 (0.9)			
Pre-treatment	3.6 (0.9)	3.5 (0.9)	0.2 (–0.1 to 0.5)	0.118	0.27 (–0.07 to 0.6)
Post-treatment	3.7 (0.8)	3.9 (0.8)	0.3 (0 to 0.6)	0.038	0.35 (0.02 to 0.69)
1-month follow-up	3.9 (1)	4 (0.9)	0.2 (–0.1 to 0.5)	0.302	0.18 (–0.16 to 0.51)
6-month follow-up	3.8 (0.9)	4.1 (1)	0.3 (0 to 0.6)	0.025	0.38 (0.05 to 0.72)

RT, relaxation therapy; MBCT, mindfulness-based cognitive therapy; VAS, Visual Analogue Scale (tinnitus loudness); TCS, Tinnitus Catastrophizing Scale; T-FAS, Tinnitus Fear Avoidance Scale; TAQ, Tinnitus Acceptance Questionnaire; HADS-A, Hospital Anxiety and Depression Scale – Anxiety; HADS-D, Hospital Anxiety and Depression Scale – Depression; WSAS, Work and Social Adjustment Scale (functioning); MAAS, Mindful Attention Awareness Scale; TFI, Tinnitus Functional Index (tinnitus impact).

ment methodology. Within each group, no significant correlation was found between reduction in tinnitus severity and practice time during treatment. Both groups rated both treatments equivalently highly on scales of "usefulness" (mean = 8.2, SD = 1.5) and "relevance" (mean = 8.4, SD = 1.5). Both groups attended the majority of treatment sessions (mean = 6.9, SD = 1.9), demonstrating good adherence and engagement (Table 1).

Adverse Events and Non-Responders

We recorded 2 adverse events (1 in each group). One MBCT participant reported significant depression at 6 months, and 1 RT participant reported significant anxiety at the 6-month follow-up. Following discussion with each individual, neither event was considered to be related to the intervention; the changes were associated with changing life circumstances. To assess for negative side effects of psychotherapy, data were analysed for significant deterioration or lack of significant change on the primary outcomes. A total of 3 participants in each group showed significant deterioration (see online suppl. Table 3).

Discussion

This study clearly shows that MBCT is more effective in reducing tinnitus severity than both a waiting period and an active treatment of equal intensity (RT). After receiving 8 weeks of treatment, patients in the MBCT group reported significantly less severe tinnitus, with a moderate effect size (standardized mean difference = 0.59). Both MBCT and RT were additionally associated with reductions in self-reported tinnitus loudness, psychological distress, depression and anxiety, and impairments in functioning and tinnitus impact, which was also significantly lower in MBCT after 6 months. Recent meta-analyses of therapy for tinnitus report outcomes that compare favourably with ours [3, 4, 32], also reporting moderate effects on tinnitus severity and small effects on psychological distress when compared to active controls. Unlike our study, these meta-analyses do not report any reduction in subjective tinnitus loudness.

Reliable change in tinnitus distress was seen in a large proportion of the MBCT group (59% post-treatment increasing to 62% at 6 months), with an NNT of 6.9. This was not statistically different between groups, and is probably due to insufficient power for this particular analysis, but it demonstrates the clinically important effect of MBCT for tinnitus. Benefits were found regardless of initial tinnitus severity, duration, and associated hearing loss, within a group of patients with clinical levels of psychological distress. This supports our hypothesis that MBCT is a successful treatment for distressed tinnitus patients who are likely to present to clinical services. However, 48 (27%) of participants were excluded due to physical and mental health comorbidities, which limits generalizability somewhat. Further research could explore whether MBCT might also apply in more complex cases (our own clinical experience suggests that this is the case).

We note that there was a difference between measures of tinnitus severity, with differences on the TQ apparent at the end of treatment, but differences in the TFI emerging only at 6 months. This probably reflects less responsiveness to change of the TFI in research samples [27], although both show that MBCT is superior to RT in reducing tinnitus severity.

As expected, MBCT generated greater reductions in negative cognition and avoidance behaviour and greater increases in tinnitus acceptance and mindfulness than RT. Such changes emerged more quickly in MBCT and were then sustained and even increased over 6 months. Such changes are clinically relevant as negative cognition, avoidance, and acceptance correlate with tinnitus severity, distress, and handicap [16–18]. Interestingly, the RT group also showed increased mindfulness, and we postulate that the process of increased attention to physical tension and applied relaxation skills are in part captured by the MAAS scale.

Contrary to our hypothesis, both treatments led to a significant reduction in subjective tinnitus loudness on the VAS. Reduction in self-reported tinnitus loudness is often not found in tinnitus intervention studies, and our observation may relate to the phrasing of the question.

A common pattern of change across measures found group differences post-treatment that disappeared at 1 month but re-emerged at 6 months. This pattern suggests that MBCT may lead to faster improvements that are stable and then grow in the longer term, however, whilst RT leads to slower changes that continue for the following month. However, in the longer term, whilst MBCT is associated with growing benefits, the gains from RT plateau or deteriorate. This supports an earlier study which found that benefits of psycho-education are enhanced by MBCT but not by RT [12]. It indicates that MBCT can lead to more lasting improvement than RT. This may be related to the greater cognitive and behavioural changes seen in MBCT.

The low attrition rate (11% in RT and 5% in MBCT) demonstrates the acceptability of this approach. It compares favourably with attrition from CBT [5], and is reflected by participants' high ratings of its "relevance" and

"usefulness." Participants receiving MBCT reported practising for longer periods at home, despite both groups being given similar practice demands and audio guides to support this. We posit that MBCT practices are more engaging, and that this could be an important part of the treatment effect. Within each group, however, the duration of practice was not associated with outcome.

Very few participants showed non-response or deterioration, which is encouraging in terms of generalizability, but the low numbers mean that analyses could not be conducted to identify whether specific patient characteristics may contraindicate this therapy. This is a limitation of randomized controlled trials which prevents the development of clear guidelines for treating individual patients, particularly those with complex presentations [33]. Future studies should explore associations with patient characteristics and response to MBCT, particularly in the longer term. Future research could also consider the use of systematic patient feedback throughout treatment, particularly using specific measures that can assess deterioration or non-response, a method that can also lead to improved recovery rates [34].

The use of the standardized 8-week MBCT protocol has not been studied in this population before. Although previous studies have found benefits of mindfulness in tinnitus, there are only 2 controlled trials [12, 13], and both reported on small sample sizes and non-standardized treatment protocols. To our knowledge, no previous randomized controlled trial of this scale has properly investigated a standardized and replicable MBCT intervention in chronic tinnitus with a sample size that offers adequate statistical power.

Strengths of our study are the inclusion of participants who would commonly be seen in tinnitus clinics, because although some complex cases were excluded, all participants reported clinical levels of psychological distress, and many had co-morbidities such as hearing loss, hyperacusis, balance problems, Ménière's disease, and migraine. This demonstrates that MBCT is relevant to patients with varied audiovestibular presentations. Other strengths are the sample size – the largest to date in a trial of MBCT in this population – and low attrition rates. The comparison of MBCT to a credible treatment control that required similar levels of participant engagement in skills practice, and outwardly similar processes of being relatively quiet and still with tinnitus, is compelling, suggesting that group differences are likely to be due to specific aspects of MBCT. Through comparison with RT we feel that active ingredients of MBCT go beyond simple exposure (i.e., minimizing avoidance by sitting quietly with tinnitus), and appears to target specific domains of catastrophic thinking, fear avoidance, and acceptance, with associated changes in mindfulness.

There are a number of limitations to the study. MBCT is a complex, multicomponent, group-based intervention, and future studies should attempt to delineate the active elements of treatment, preferably using a standard, replicable protocol. We are also investigating processes of change with mediation analyses and using qualitative analysis to explore how therapeutic alliance, group dynamic, and other aspects of therapy may affect experiences and outcomes. The delivery of treatment within a specialist outpatient clinic and via clinical psychologists could limit generalizability of findings. With few psychology services available in audiology and increasing delivery of mindfulness via non-psychotherapeutically trained professionals [35], it is important that future studies explore MBCT delivered in general audiology settings through other health care professionals, preferably using standardized intervention protocols such as the one described here.

We did not control for all potential confounding factors that could affect tinnitus symptoms, such as the use of hearing aids, masking devices, or psychotropic medication. We did, however, request that participants inform us of any changes to their medical care throughout the duration of the trial, and none were reported. Another limitation is the lack of an objective audiological measure of tinnitus loudness and reliance on self-report measures. The MBCT group received supporting literature, but the RT group did not. It is possible that this additional input could have added to the positive effects of MBCT, particularly considering the impact that psycho-education has on tinnitus [12]. However, we note that this difference reflects the underlying differences in the interventions themselves, as MBCT recommends supporting literature [14] and RT does not [22].

Our study offers clear evidence that MBCT is an effective treatment for tinnitus, using a standard and replicable approach that could be adopted widely for tinnitus management in a field where clinical interventions are limited [5]. Mindfulness is already being explored by the audiology community [20]. Our study adds more support to the use of MBCT as a further route for patient benefit.

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Disclosure Statement

The authors declare that they have no conflicts of interest.

Author Contributions

L.M. (chief investigator) and E.M.M. designed the study and were granted funding; they adapted the clinical interventions for tinnitus and conducted the group therapies. R.S. conducted randomization. C.A.H. and R.S. conducted data analysis. All authors contributed to data interpretation and write-up, and approved the final draft of this paper.

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