2020

Is Mindfulness-Based Cognitive Therapy An Effective Treatment For Adult Patients With Tinnitus?

Ashlyn C. Smith
Philadelphia College of Osteopathic Medicine

Is Mindfulness-Based Cognitive Therapy An Effective Treatment For Adult Patients With Tinnitus?

Ashlyn C. Smith, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Suwanee, Georgia

December 13, 2019

ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not mindfulness-based cognitive therapy (MBCT) is an effective treatment for adult patients with tinnitus.

STUDY DESIGN: Systematic review of two randomized controlled trials (RCTs) published in 2012 and 2017 and one cohort study published in 2018.

DATA SOURCES: Data sources for this review are articles published in peer-reviewed journals retrieved from PubMed and Cochrane Library.

OUTCOMES MEASURED: The outcomes evaluated are tinnitus severity and tinnitus distress as determined by the Tinnitus Questionnaire (TQ) and overall negative affect as determined by the Tinnitus Psychological Impact Questionnaire (QIPA). The TQ is a patient-completed questionnaire in which 19 of the 41 questions focus on tinnitus severity or distress (McKenna L, Marks E, Hallsworth C, Schaette R. *Psychother Psychosom*. 2017;86:351-361. doi: 10.1159/000478267 and McKenna L, Marks E, Vogt F. *Ear Hearing*. 2018;39(2):359-366. doi: 10.1097/AUD.0000000000000491). The QIPA is a patient-completed questionnaire designed by Philippot, Nef, Clauw, et al. to assess tinnitus severity over the last week based on six different dimensions (*Clin Psychol Psychot*. 2012;19:411-419. doi: 10.1002/cpp.756).

RESULTS: All three studies reveal that MBCT provides statistically significant improvements in tinnitus based on the outcomes measured. Both RCTs find that MBCT is more effective than relaxation training (RT) at improving tinnitus severity with a p of 0.006 at a 6-month follow-up (McKenna L, Marks E, Hallsworth C, Schaette R. *Psychother Psychosom*. 2017;86:351-361. doi: 10.1159/000478267) and negative affect with a p of < 0.02 at a 3-month follow-up (Philippot P, Nef F, Clauw L, de Romrée M, Segal Z. *Clin Psychol Psychot*. 2012;19:411-419. doi: 10.1002/cpp.756). The cohort study further supports the effectiveness of MBCT with a decrease in tinnitus distress at both post-intervention and 6-week follow-up times having a p of < 0.001 (McKenna L, Marks E, Vogt F. *Ear Hearing*. 2018;39(2):359-366. doi: 10.1097/AUD.0000000000000491).

CONCLUSIONS: Despite all three studies indicating that MBCT is effective at reducing some of the negative effects of chronic tinnitus in adult populations, more research is necessary to adequately determine the long-term efficacy of mindfulness-based cognitive therapy in the treatment of tinnitus.

KEY WORDS: mindfulness-based cognitive therapy, tinnitus

INTRODUCTION

Tinnitus occurs when an individual perceives a sound in absence of an identifiable external stimulus. It is a symptom rather than a diagnosis and is classically referred to as having a ringing or buzzing quality; however, it may instead resemble blowing, roaring, buzzing, hissing, or a variety of other sounds. It is estimated that 45 million Americans experience tinnitus.[1] Of those individuals, 20 million are thought to experience "burdensome" chronic tinnitus.[1] Approximately 16 million of these individuals have reached out for medical care at some point in their lives.[2] Patients often seek tinnitus relief from primary care, otolaryngology, neurology, and psychiatry practices where physician assistants may work. The estimated annual US healthcare cost per patient who seeks treatment for tinnitus is $2,110.[3] Additionally, the U.S. Department of Veteran's Affairs provides roughly 1.5 billion dollars in disability to veterans annually for tinnitus.[1]

Irreversible hearing loss, often associated with noise trauma, accounts for ninety percent of tinnitus cases.[1] Tinnitus is more commonly experienced by males than by females, by non-Hispanic whites than by other ethnicities, and by elderly patients more than by youth. There are cases in which tinnitus may be resolved by treating the underlying cause. These causes are often excess build-up of cerumen in the ear canal, temporomandibular joint misalignment, and the use of ototoxic medications such as aminoglycosides, chemotherapeutics, salicylates, quinines, and loop diuretics. There is not a gold standard of treatment for tinnitus. Chronic tinnitus patients often receive symptom management in the form of hearing aids or cochlear implants, sound-based therapies, cognitive behavioral therapy, counseling, relaxation training, and hypnosis. Some providers treat tinnitus with tricyclic antidepressants or benzodiazepines, especially in patients who have comorbid anxiety or depression.

Mindfulness-based cognitive therapy (MBCT) is being proposed as an alternative method for treating tinnitus because it has the potential to decrease the negative experience and patient distress that chronic tinnitus often causes. Since there is not currently a cure for the majority of cases of tinnitus, patients need methods to manage the negative effects it has on their daily life. Though there are many treatment options offered, success rates vary. Mindfulness training, as used in MBCT, is an approach to psychotherapy that establishes acceptance as the initial reaction to experiences that usually cause distress.

In Western medicine MBCT has recently increased in acceptance for the treatment of chronic pain and depression. Mindfulness training works by restructuring negative thoughts and judgements in relation to symptoms. Many patients who experience tinnitus avoid situations that may cause an increase in tinnitus severity; however, mindfulness training encourages patients to instead bring attention to and accept the presence of tinnitus without avoiding these situations. If successful, MBCT has the potential to improve the quality of life of patients as they may resume activities that they once found to be enjoyable before their tinnitus increased.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not mindfulness-based cognitive therapy is an effective treatment for adult patients with tinnitus.

METHODS

The criteria used for the selection of studies for this review were based on the population, interventions, comparisons, outcomes measured, and type of study. This paper analyzes a cohort study and two randomized controlled trials (RCTs). The population required for selection was adults over 18 years of age with tinnitus. The intervention analyzed was MBCT. For both of the RCTs, the comparator groups received relaxation training (RT).[4,5] No comparator was used or

required for the cohort study.[6] The outcomes evaluated are tinnitus severity[4] and tinnitus distress[6] as determined by the Tinnitus Questionnaire (TQ)[4,6] and overall negative affect based on the Tinnitus Psychological Impact Questionnaire (QIPA).[5] Study demographics are provided below in Table 1.

PubMed and Cochrane Library were the data sources used by the author for locating appropriate articles for the completion of this review. All articles have been previously published in peer-reviewed journals and all three were available on the PubMed database. Cochrane Library was also utilized to check for the presence of systemic reviews of MBCT for the treatment of tinnitus, but none were located. In order to select an article, it must have been published in the last 10 years and evaluate patient-oriented evidence that matters (POEMs). The keyword requirement included containing the terms "mindfulness-based cognitive therapy" and "tinnitus" specifically. All articles were originally published in English. The articles were selected based on availability, relevance to the clinical question proposed, and the outcome measures being patient-oriented. Due to article availability, the ten-year time frame was not specified while searching since the oldest article meeting criteria was published in 2012.

Additionally, the inclusion criteria for selection were that the study was a primary research design with cognitive therapy as an intervention. The exclusion criteria included articles using "stress reduction therapy" as interventions, systematic reviews, and articles on Cochrane without available abstracts. Two systematic reviews did populate in the initial PubMed search, but neither review analyzed multiple articles on the effect of MBCT on tinnitus. Each article selected used different statistical tests to determine significance including t-score, mean difference, p-value, number needed to treat (NNT), experimental event rate (EER), control event

rate (CER), relative benefit increase (RBI), absolute benefit increase (ABI), confidence interval (CI), and F-score.

Table 1: Demographics of included studies

Study	Type	# Pts	Age (years)	Inclusion Criteria	Exclusion Criteria	W/D	Intervention
McKenna[4] (2017)	RCT	75	>18 Median of 50	Patients who were 18 years or older, report tinnitus of more than 6-month duration, report clinical levels of psychological distress, have completed medical investigations for tinnitus, and have sufficient hearing and grasp of the English language in order to participate in group discussion	Patients with current comorbid severe physical or mental illness, current risk factors of active suicidal ideation or self-harm, or who have current substance dependence	13 at 6 months	Mindfulness-based cognitive therapy vs relaxation training Both groups received eight 120-min. group sessions delivered over 8 consecutive weeks
Philippot[5] (2012)	RCT	30	35-79	Patients with tinnitus within the last 6 months, have had a medical check-up by a physician specializing in hearing disorders, have sufficient hearing capacity to follow instructions in group sessions, and who report significant psychological distress and impairment in everyday activities resulting from tinnitus	Patients with tinnitus resulting from an organic condition that could benefit from medical intervention, those who use a tinnitus masking apparatus, use of psychotherapy or psychological intervention during the study, and patients with borderline or antisocial personality disorder	5	Mindfulness-based cognitive therapy vs relaxation training Groups were initially given psycho-education about tinnitus, received no treatment for 2.5 months, then attended 6 weekly group therapy sessions
McKenna[6] (2018)	Cohort	205	27-83	Patients over 18 years old who have chronic tinnitus present for more than 3 months that is associated with psychological distress, agree to take part in group therapy (engage in home practice and attend all sessions of treatment), and have sufficient hearing and grasp of the English language to participate in group discussion	Patients who report active suicidal ideation or deliberate self-harm, current comorbid severe mental health problems, or current alcohol or substance abuse	23 at the end of therapy	Mindfulness-based cognitive therapy 8 weeks of group therapy including psycho-education about tinnitus and specific education on the cognitive behavioral model

OUTCOMES MEASURED

The outcomes evaluated are tinnitus severity[4] and tinnitus distress[6] as determined by the TQ[4,6] and overall negative affect based on the QIPA.[5] The TQ is a patient-completed evaluation that quantifies tinnitus distress or severity based on the effect of tinnitus on emotional disturbance, intrusiveness, auditory perceptual difficulties, sleep disturbance, and somatic complaints.[4,6] Of the 41 questions on the TQ, 19 questions are focused on tinnitus severity or distress.[4,6] Two of the articles used in this review utilized the TQ for monitoring outcomes but referenced the outcome of interest as tinnitus severity[4] in one article and as tinnitus distress[6] in the other. The QIPA is a patient-completed questionnaire designed by Philippot, Nef, Clauw, et al. to assess tinnitus severity over the last week based on six different dimensions.[5] The dimension of emphasis for this review is the extent to which tinnitus triggered negative emotions, which the authors further classified into frustration and negative affect.[5] This review focused specifically on the effect of MBCT and RT on negative affect.[5]

RESULTS

Each article used different statistics to represent their results. Since tinnitus is often chronic, desirable treatments should provide long-term results. In order to analyze the longevity of results, statistics are provided from each study for baseline to follow-up results. In both RCTs, gender was considered prior to randomization to prevent this factor as a confounding variable.[4,6] McKenna, Marks, Hallsworth, et al. also stratified for age before randomization was completed.[4] All three studies focused on adult patient populations with tinnitus described as causing "psychological distress" per the inclusion criteria.[4-6] One RCT and the cohort study were completed within a British ear, nose, and throat (ENT) hospital.[4,6] The other RCT was conducted in a university psychology department.[5] In both RCTs there was a statistically significant

difference in favor of MBCT over RT based on the results at the time of follow-up as compared to preintervention.[4,5]

Compliance varied greatly among the studies. In the RCT by McKenna, Marks, Hallsworth, et al. the MBCT groups received printed literature while the RT groups did not and both groups were instructed to complete and record daily practice.[4] Both the RT and MBCT groups indicated that they did practice their skills, but the MBCT group had a mean practice time of 1,315 minutes with a standard deviation of 548 minutes compared to a mean practice time of 815 minutes with a standard deviation of 506 minutes in the RT group.[4] Patients in this study attended an average of 6.9 of the 8 sessions provided.[4] For the other RCT, patients were dropped from the study if they missed three or more of the six sessions.[5] Three of thirty participants were dropped for this reason and two others dropped after the first training session, but there is no further data provided on the compliance of the subjects for this study.[5] In the cohort study, 188 of the initial 205 patients who started MBCT completed therapy, but only 182 of these patients completed their questionnaires posttreatment.[6] It is indicated that merely 82 patients completed the questionnaires at the 6-week follow-up.[6] Long-term compliance is uncertain due to significant loss to follow-up in this cohort study.[6]

Overall, there is very little analysis in these articles of the potential safety of using MBCT. In one of the RCTs, there were 6 individuals noted to have “significant deterioration” in the study, three of whom were in the MBCT group.[4] Since there were only 39 patients in the MBCT group, this estimates the number needed to harm (NNH) to be 13 patients.[4] The specific side effects experienced were not discussed. This same RCT found that there was a number needed to treat (NNT) of 6.7 patients at post-treatment and 11 patients at follow-up in order to attain clinically significant improvements in tinnitus severity.[4] A clinically significant

improvement was defined as a decrease of at least 11 points on the TQ based on unpublished data.[4] The adjusted mean difference at both post-treatment and at 6-month follow-up times was also statistically significant between the MBCT and RT groups.[4] The patients in the MBCT had a post-treatment adjusted mean difference of -6.3 points ($p < 0.016$) and an adjusted mean difference of -7.2 points ($p < 0.006$) at the 6-month follow-up. The confidence intervals (CI) for both time frames were not precise due to having a greater than ten-point range.[4]

The treatment groups in the RCT by McKenna, Marks, Hallsworth, et al. were equivalent regarding clinical characteristics and demographics except the length of time which patients have experienced tinnitus.[4] After randomization, patients allocated to the MBCT groups were noted to have an increased duration of tinnitus experience as compared to the RT groups.[4] There is also a difference in the percent of patients with hearing loss in the MBCT groups (74%) versus the RT groups (53%) and in patients who used aids for their hearing loss (31% of the MBCT patients versus 19% of the RT patients).[4] This difference was not statistically significant, but it is notable due to the fact that hearing aids and cochlear implants are alternative treatments for tinnitus.[4] In the RCT by Philippot, Nef, Clauw, et al., this potentially confounding variable was eliminated by making the use of these devices meet exclusion criteria.[5]

Table 2: Effect of MBCT vs RT on Tinnitus Severity from the RCT by McKenna et al.

Time	Adjusted Mean Difference (95% CI)	*p*	EER	CER	RBI	ABI	NNT	NNH
Post- Treatment	-6.3 (-11.34 to -1.)	0.016	0.44	0.59	0.34	0.15	6.7	13
6-Month Follow-Up	-7.2 (-12.3 to -2.1)	0.006	0.53	0.62	0.17	0.09	11	

The RCT by Philippot, Nef, Clauw, et al. analyzed outcomes using 2 x 2 ANOVAs to compare the treatment groups at different time points.[5] The QIPA scores were taken at baseline, which was defined as before psychoeducation, at pre-training, at post-training, and at a 3-month follow-up.[5] Negative affect is indicated to be one of two components of negative emotion with

frustration being the other component.[5] Unfortunately, the two components are not differentiated between in the authors' table of results, but negative affect is referenced separately from frustration in the discussion portion of the article's results.[5] From baseline to the 3-month follow-up, the F-score was calculated to be 8.36 with $p < 0.01$, indicating that there was a statistically significant difference between the use of MBCT and RT in the treatment of negative affect caused by tinnitus.[5] However, during this time frame the patients also received psychoeducation.[5] When analyzing results of only MBCT versus RT on negative affect, it is important to consider the pretraining to 3-month follow-up results.[5] During this time, there is still a statistically significant difference between the effectiveness of MBCT and RT with a *F*-score of 6.11 and a *p*-value of < 0.02.[5] Of note, statistics are not numerically provided for a pre- to post-training comparison, but the authors state that there is not a statistically significant difference between MBCT and RT for this interval.[5] These results indicate that MBCT may have more longevity as a potential treatment than RT despite initial treatment outcomes being similar.[5]

There are limitations to the generalizability of results for this RCT. The authors note that the 30-patient population has a higher education level than the general public.[5] Standard mindfulness training lasts for eight weeks or eight sessions, as seen in both of the other studies,[4,6] but the participants in this study only completed six sessions.[5] The participants also did not receive follow-up therapy or printed materials that may have refreshed skills and improved long-term results.[5] These factors plus the very small sample size prevent reliable extrapolation of results.

Table 3: Efficacy of MBCT vs RT on Negative Affect from the RCT by Philippot et al.

Time Frame	*F*	*p*	Effect Size as Cohen's *d* for Mindfulness Group
Pretraining to 3-Month Follow-Up	6.11	< 0.02	0.75
Baseline to 3-Month Follow-Up	8.36	< 0.01	1.44

In the cohort study, there is a statistically significant difference in the tinnitus distress experienced from preintervention to postintervention as well as from preintervention to the 6-week follow-up after using MBCT to treat tinnitus.[6] The mean differences are -12.08 and -11.80 respectively, both of which have a $p < 0.001$ and a moderately large effect size based on the provided Cohen's *d* score.[6] The control event rate (CER) is based on the reliable improvement in scores based on a reduction from preintervention to a future time point when a difference of at least 11.21 points is identified in TQ scores.[6] Fifty percent of patients achieved reliable improvement from preintervention to postintervention and 52.8% reached reliable improvement using MBCT at the 6-week follow-up.[6] It is important to note that while the initial study size was larger than past studies, only approximately 82 of the initial 205 patients in this study completed the 6-week follow-up questionnaires.[6] Each of the missing data points were treated as missing at random and were corrected for with multiple imputation.[6] This method of analysis does not necessarily represent the actual experience of the patients who were lost to follow-up.

Most of the patients had evidence of improvement in their tinnitus distress through MBCT based on their responses on the TQ.[6] Since many of these patients have failed prior treatments, these results seem to be very promising and indicate that MBCT may be an effective treatment for refractory tinnitus.[6] Another strength of this study is the methods used to provide MBCT. Between January 2008 and April 2014, 16 separate groups of patients completed MBCT from three therapists who closely adhered to a treatment manual.[6] This makes the MBCT model used in this study very replicable for future studies.[6]

Table 4: Effect of MBCT on Tinnitus Distress from the Cohort Study by McKenna et al.

Time Frame	Mean Difference (SE)	*t*	*p*	Cohen's *d*	CER
Pre- to Post-Intervention	- 12.08 (0.81)	-14.96	< 0.001	0.72	50.0%
Preintervention to 6-Week Follow-Up	- 11.80 (0.78)	-15.13	< 0.001	0.73	52.8%

DISCUSSION

Since MBCT requires active participation, it is impossible to blind both the recipients of care and the providers.[4,5] In both RCTs there were relatively small sample sizes evaluated.[4,5] The sample studied in the cohort study is more reflective of actual patients suffering from tinnitus, but there was significant loss to follow-up in this study.[6] For each of the studies, there is only self-reported outcome measures assessed and a lack of objective findings, further limiting analysis of successful treatment.[4-6] No outliers were noted in the studies.

In the United States, mindfulness-based cognitive therapy is covered by most insurance plans that offer mental health and group therapy coverage when a patient has a prior diagnosis of anxiety or depression.[7] Fortunately, in 2008 the Mental Health Parity and Addiction Equity Act became a federal law that requires mental health coverage to at least equal that of traditional medical and surgical coverage.[8] In 2014 the Affordable Care Act required most health insurance plans for individuals and small groups to cover mental health services, which makes therapy services more accessible than in the recent past.[9] There are still limitations that American patients with tinnitus will face to receiving MBCT. Tinnitus patients may or may not have comorbid anxiety or depression, but these diagnoses are often required for insurance coverage.[7] While estimates are not available for the cost of MBCT for the treatment of tinnitus specifically, the uninsured out-of-pocket cost at the University of Iowa for MBCT for treating depression is $315 for an initial intake session and $1083 for the eight group sessions.[7] An additional barrier to care is that not every therapist has been trained in mindfulness techniques.

CONCLUSIONS

This review of three recent studies indicates that, yes, there does seem to be promise in utilizing MBCT for treating adult patients with tinnitus. The statistics provided indicate that there

is a significant improvement in tinnitus severity, distress, and related negative affect following MBCT.[4-6] Additionally, both RCTs demonstrated more efficacy from MBCT than from RT, which is an established treatment for tinnitus.[4,5] Nevertheless, further research is necessary due to the small sample sizes studied and the significant loss to follow-up.[4-6] Since many of the patients in these studies have failed prior treatments, these results show potential for patients with tinnitus that may be refractory to other treatment modalities.

In future studies it would be beneficial to have a larger sample size, consistent follow-up times with better participation, and 8 consistent sessions with equal take-home education materials given to both groups. While provider and patient blinding is not possible, future studies should emphasize blinding of the statisticians for unbiased data analysis. Using a comparison treatment other than RT may provide data that further supports the efficacy of MBCT. Finally, a study designed in an outpatient clinical setting in the United States may make future results more generalizable to the population of U.S. adults suffering from chronic tinnitus and may encourage insurance companies to cover MBCT for this new indication.

REFERENCES

1. Impact of tinnitus. American Tinnitus Association. https://www.ata.org/understanding-facts/impact-tinnitus. Published 2018. Accessed September 29, 2019.
2. Hearing loss & tinnitus statistics. Hearing Health Foundation. https://hearinghealthfoundation.org/hearing-loss-tinnitus-statistics. Accessed September 29, 2019.
3. Goldstein E, Ho C, Hanna R, Elinger C, Yaremchuk KL, Seidman MD, Jesse MT. Cost of care for subjective tinnitus in relation to patient satisfaction. *Otology and Neurotology*. 2015;152(3):518-523. doi: 10.1177/0194599814566179.
4. McKenna L, Marks E, Hallsworth C, Schaette R. Mindfulness-based cognitive therapy as a treatment for chronic tinnitus: A randomized control trial. *Psychother Psychosom*. 2017;86:351-361. doi: 10.1159/000478267.
5. Philippot P, Nef F, Clauw L, de Romrée M, Segal Z. A randomized controlled trial of mindfulness-based cognitive therapy for treating tinnitus. *Clin Psychol Psychot*. 2012;19:411-419. doi: 10.1002/cpp.756.
6. McKenna L, Marks E, Vogt F. Mindfulness-based cognitive therapy for chronic tinnitus: Evaluation of benefits in a large sample of patients attending a tinnitus clinic. *Ear Hearing*. 2018;39(2):359-366. doi: 10.1097/AUD.0000000000000491.
7. Mindfulness-based cognitive therapy (MBCT) for prevention of depression relapse. University of Iowa Hospitals and Clinics. https://uihc.org/mindfulness-based-cognitive-therapy-mbct-prevention-depression-relapse. Accessed December 10, 2019.
8. The mental health parity and addiction equity act (MHPAEA). Centers for Medicare & Medicaid Services. https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/mhpaea_factsheet. Published October 27, 2016. Accessed December 10, 2019.
9. Beronio K, Po R, Skopec L, Glied S. Affordable care act expands mental health and substance use disorder benefits and federal parity protections for 62 million Americans. U.S. Department of Health & Human Services. https://aspe.hhs.gov/report/affordable-care-act-expands-mental-health-and-substance-use-disorder-benefits-and-federal-parity-protections-62-million-americans. Published February 20, 2013. Accessed December 10, 2019.