

Mindfulness-based Therapy
For the Treatment of Chronic Tinnitus:
A Randomized Controlled Pilot Study

Peter M Kreuzer, MD ; Monika Goetz, MS; Maria Holl; Martin Schecklmann, PhD; Michael Landgrebe, MD; Susanne Staudinger, MA; Berthold Langguth, MD;

Department of Psychiatry and Psychotherapy

University of Regensburg

Universitaetsstrasse 84

93053 Regensburg

Regensburg, Germany

Phone: +49-(0)941-941-1256

Fax: +49-(0)941-941-1255

Correspondence to: peter.kreuzer@medbo.de

Keywords: subjective tinnitus, mindfulness-based therapy, somatoform disorders, self-management

Figures: 2

Tables: 1

Financial Disclosure: MH has written a book describing the methods of the applied behavioral techniques. The study has been financially supported by a grant from the Bundesverband der Innungskrankenkassen (IKK), Association of Health Insurances. The other authors have no conflicts of interest or disclosures to declare in relation to this article.

Abstract

Background: Tinnitus, the perception of sound in absence of an external acoustic source, impairs the quality of life in 2% of the population. Since causal treatment options are scarce most therapeutic attempts aim at developing and strengthening individual coping and habituation strategies. Therapeutic interventions that incorporate training in mindfulness meditation have become increasingly popular in the treatment of stress-related disorders. Here we conducted a randomized controlled clinical study to investigate the efficacy of a specific mindfulness-based therapy program in patients suffering from chronic tinnitus.

Methods: Thirty-six patients were enrolled in the study. Treatment was performed as group therapy at two training weekends which were separated by an interval of 7 weeks (eleven hours/weekend) and in four further two-hour sessions (week 2, 9, 18 and 22). Patients were randomized to receive treatment either immediately or after waiting time, which served as control condition. The primary study outcome was the change in Tinnitus complaints as measured by the German Version of the Tinnitus Questionnaire (TQ).

Results: ANOVA testing for primary outcome showed a significant interaction effect time by group ($F=8.311$; $df=1$; $p=0.007$). Post hoc t-tests indicated an amelioration of TQ scores from baseline to week 9 in both groups (intervention group: $T=6.174$; $df=17$; $p<0.001$; control group: $T=2.494$; $df=17$; $p=0.023$), but intervention group improved more than control group.

Conclusion: Mindfulness-based therapy represents a promising new approach for the treatment of tinnitus and merits further evaluation in clinical studies with larger sample sizes.

The study is registered with clinicaltrials.gov (NCT01540357).

Introduction

Tinnitus is defined as the perception of sound in the absence of an external sound source. About one in 10 adults is affected by chronic tinnitus, 20-30 percent of them dealing with considerable effects on daily living [1]. Severe tinnitus is frequently related to comorbidities such as insomnia [2], somatoform disorders, depression [3] or anxiety [4, 5]. Treatment options are scarce up to now [6]. Best evidence is available for cognitive behavioral therapy which aims to facilitate habituation by improving individual tinnitus coping strategies [6-8].

Mindfulness-based approaches use meditation techniques and yoga-like elements, and have been introduced in clinical medicine about thirty years ago [9]. They have demonstrated efficacy in the treatment of a variety of stress related disorders [10, 11] such as anxiety and mood disorders [12] or chronic pain [13, 14]. Very recently mindfulness-based cognitive therapy has been proposed for the treatment of tinnitus [15].

In the present randomized waiting-list-controlled study we investigated a specific manualized mindfulness-based therapeutic approach (Tinnitus Atemtherapie/TAT) [16] consisting of meditation, self massage, and breathing exercises. These components are intended to help patients to use their inner resources for increasing self-responsibility and self-efficacy and for supporting acceptance.

Methods

Thirty-six patients with chronic tinnitus (duration \geq 6 months) were randomized to an experimental group or a waiting list control group of 18 subjects each after giving written, informed consent to the study. The experimental group was treated with the mindfulness-based therapy; the control group was assessed at identical time points during a waiting period of 24 weeks before they received treatment. Demographical and clinical characteristics of the enrolled patients are provided in table 1.

The applied mindfulness based therapy has been developed and manualized by MH [16]. Shortly it consists of (1) meditation elements, (2) imagination exercises, (3) self-massage and individualized gentle movement exercises of the body, (4) exercises aiming at directing moment-to-moment awareness to body- and self- perception and (5) breathing exercises with emphasis on expiration in order to reduce muscle tension and increase relaxation. Participants were taught the therapeutic modules at two weekends (11 hours of treatment/weekend) with an interval of 7 weeks. Two weeks after each weekend and 11 and 15 weeks after the second training weekend patients gathered for a review meeting of 2 hours duration each. Patients were strongly encouraged to perform regularly

self exercises and were instructed to contact and motivate each other by mutual phone calls at least once a week.

Tinnitus characteristics were assessed before treatment (baseline), at week 7 (end of second training weekend), at week 9 and week 24 (figure 1). Tinnitus assessments included the German versions of the Tinnitus Handicap Inventory [17], the tinnitus questionnaire [18], the Beck Depression Inventory [19], several tinnitus numeric rating scales (loudness, discomfort, annoyance, distractibility, unpleasantness) [20]. Prospective assessment of treatment effects was performed using standardized procedures as established in the Tinnitus Research Initiative (TRI) database [20]. Data management was conducted according to the Data Handling Plan (TRI-DHP Version 06, May 9th, 2011). Data analysis was conducted according to the Standard Operating Procedure (TRI-SA Version 01, May 9th, 2011), thereby following a study-specific Statistical Analysis Plan (SAP-002). All documents are to be found under <http://database.tinnitusresearch.org/>.

According to the intention to treat principle we inserted precedent or subsequent TQ scores if data were incomplete (last observation carried forward and backward method). Primary outcome was the change in TQ scores from baseline to week 9. For this purpose, we conducted an analysis of variance (ANOVA) with the within-subjects factor time (screening and week 9) and the between-subjects factor group (intervention vs. control group). Secondary outcome measures included chi-square tests for the variables group and treatment response which was defined as amelioration of at least 5 points in the TQ [21]. In addition, we conducted an additional ANOVA with the factor group and time, this time including four measurement time points (screening, week7, week 9, and week 24). For THI, the numeric rating scales and BDI we performed identical ANOVAs.

Results

The groups did not differ significantly in demographical or clinical characteristics as shown in table 1.

Three participants did not complete the study procedures. One patient refused participation after being randomized into the waiting list group; two patients did not return the follow-up-questionnaires after having participated in the meetings without giving further explanation.

ANOVA testing for primary outcome demonstrated a significant interaction effect time by group ($F=8.3$; $df=1,34$; $p=0.007$). Post hoc t-tests indicated an amelioration of TQ scores from baseline to week 9 in both groups (intervention group: $T=6.2$; $df=17$; $p<0.001$; control group: $T=2.5$; $df=17$; $p=0.023$) (figure 2), but intervention group bettered at a higher rate than control group (baseline:

T=0.7; df=34; p=0.512; week 9: T=2.4; df=34; p=0.022; d=0.799). Responder rate was higher in the intervention group (16 out of 18 responders) in contrast to the control group (8 out of 18 responders; $\chi^2=8.0$; df=1; p=0.005)

ANOVA with four measurement time points showed a significant interaction effect time by group (F=3.1; df=3,103; p=0.032). Post hoc tests indicated a significant amelioration at week 7, week 9, and week 24 in contrast to baseline for the intervention group (all Ts>3.7; df=17; all ps<0.002) and at week 9 and 24 for the control group in contrast to baseline (all Ts>2.5; df=17; all ps<0.023). Groups differed at week 7 (T=1.6; df=34; p=0.058) and 9 (see primary outcome), but not at week 24. Concordant effects were also found for THI (F=6.1; df=3,102; p<0.001) and BDI (F=6.0; df=3,99; p<0.001). Numeric rating scales did not show significant interaction effects (all Fs<2.3; all ps>0.087).

Discussion

The most important result of this pilot study is that the patients receiving thirty hours of mindfulness-based therapy achieved a remarkable clinical improvement of tinnitus, as reflected by a highly significant reduction in the primary outcome measure (TQ score baseline vs. week 9) in comparison to the waiting list control group. Very recently first results from a randomized controlled study investigating mindfulness-based therapy in tinnitus patients have been presented [15]. Notably, in this study neither mindfulness-based therapy nor relaxation training as control condition did exert an immediate effect on tinnitus symptoms. This might at least in part be due to the large effect already yielded by preceding psycho-education [15]. However, during the follow-up period mindfulness-based treatment was superior to relaxation therapy [15].

In contrast to this study [15] progresses tended to stagnate in our study. Clearly, mindfulness-based therapy depends on practice behavior [15]. Thus, the retrogressive effects in our study point to a reduced training maintenance at follow-up and indicate the relevance of boosting sessions for stabilizing treatment effects.

A pronounced long-lasting effect has also been observed in a randomized controlled study treating chronic tinnitus with a five-weeks-lasting training program with Qigong [22]. Notably, Qigong had been trained in sessions of 2 hours weekly and one could question the time schedule of two weekends of intensive training of up to 11 hours in our study. Possibly a longer-lasting and repetitive training process would enhance longer-lasting effects through incorporation of the exercises in daily routine.

Mindfulness-based therapeutic approaches have demonstrated beneficial effects in other stress-related disorders such as chronic pain [13, 23] or anxiety [12]. With effect sizes of 0.37 for pain scores [23] and between 0.24 to 0.47 on anxiety scores in patients with chronic medical diseases [10] the effects of mindfulness based therapies were smaller in those studies when compared to the effect size of 0.80 in our study. (However caution is warranted in such comparisons, since further data from larger samples will be needed before the effect size of mindfulness-based therapy in tinnitus can be reliably estimated.)

Future studies should also address by which mechanisms mindfulness-based therapy exerts its beneficial effects on tinnitus. A significant increase in alpha power through meditation has been revealed by electroencephalographic [24] and magnetencephalographic [25] studies. Alpha power in sensory areas is considered as an indicator of inhibitory function [26] and an increase of alpha activity by neurobiofeedback or transcranial magnetic stimulation has been shown to result in reduced tinnitus perception [27, 28]. Thus it is tempting to speculate that the beneficial effects of mindfulness based therapy may be mediated by an increase in alpha power.

Moreover brain areas which are known to be involved in tinnitus such as the left hippocampus [29], the posterior cingulate cortex [30], the temporo-parietal junction [31], and the cerebellum [32] have recently been shown to be altered by mindfulness meditation [33].

We are well aware about the limiting factors of the conducted pilot study such as small sample size, inherent problems of waiting list control conditions [34] and the fact that treatment effects may depend on the instructor, which might limit generalization of the results. Nevertheless our pilot data indicate the promise of mindfulness-based therapy in the treatment of tinnitus and warrant further investigation of its clinical and neurobiological effects in larger studies.

Acknowledgements:

The authors have been supported by a grant from the Tinnitus Research Initiative (TRI) to the Tinnitus Research Initiative Database. M. Holl has been financially supported by a grant from the Bundesverband der Innungskrankenkassen (IKK).

Literature

1. Andersson G, Baguley D, McKenna L: *Tinnitus: A Multidisciplinary Approach*. London: Whurr; 2005.
2. Cronlein T, Langguth B, Geisler P, Hajak G: **Tinnitus and insomnia**. *Prog Brain Res* 2007, **166**:227-233.
3. Langguth B, Landgrebe M, Kleinjung T, Sand GP, Hajak G: **Tinnitus and depression**. *World J Biol Psychiatry* 2011.
4. Langguth B: **A review of tinnitus symptoms beyond 'ringing in the ears': a call to action**. *Curr Med Res Opin* 2011, **27**(8):1635-1643.
5. Krog NH, Engdahl B, Tambs K: **The association between tinnitus and mental health in a general population sample: results from the HUNT Study**. *J Psychosom Res*, **69**(3):289-298.
6. Hoare DJ, Kowalkowski VL, Kang S, Hall DA: **Systematic review and meta-analyses of randomized controlled trials examining tinnitus management**. *Laryngoscope* 2011, **121**(7):1555-1564.
7. Hesser H, Westin V, Hayes SC, Andersson G: **Clients' in-session acceptance and cognitive defusion behaviors in acceptance-based treatment of tinnitus distress**. *Behav Res Ther* 2009, **47**(6):523-528.
8. Martinez-Devesa P, Perera R, Theodoulou M, Waddell A: **Cognitive behavioural therapy for tinnitus**. *Cochrane Database Syst Rev* 2010(9):CD005233.
9. Kabat-Zinn J: **An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: theoretical considerations and preliminary results**. *Gen Hosp Psychiatry* 1982, **4**(1):33-47.
10. Bohlmeijer E, Prenger R, Taal E, Cuijpers P: **The effects of mindfulness-based stress reduction therapy on mental health of adults with a chronic medical disease: a meta-analysis**. *J Psychosom Res* 2010, **68**(6):539-544.
11. Chiesa A, Serretti A: **Mindfulness-based stress reduction for stress management in healthy people: a review and meta-analysis**. *J Altern Complement Med* 2009, **15**(5):593-600.
12. Hofmann SG, Sawyer AT, Witt AA, Oh D: **The effect of mindfulness-based therapy on anxiety and depression: A meta-analytic review**. *J Consult Clin Psychol* 2010, **78**(2):169-183.
13. Morone NE, Greco CM, Weiner DK: **Mindfulness meditation for the treatment of chronic low back pain in older adults: a randomized controlled pilot study**. *Pain* 2008, **134**(3):310-319.
14. Wong SY, Chan FW, Wong RL, Chu MC, Kitty Lam YY, Mercer SW, Ma SH: **Comparing the effectiveness of mindfulness-based stress reduction and multidisciplinary intervention programs for chronic pain: a randomized comparative trial**. *Clin J Pain* 2011, **27**(8):724-734.
15. Philippot P, Nef F, Clauw L, Romree M, Segal Z: **A Randomized Controlled Trial of Mindfulness-Based Cognitive Therapy for Treating Tinnitus**. *Clin Psychol Psychother* 2011.
16. Holl M: *Die Tinnitus-Atemtherapie: So gehen Sie aktiv gegen Ihr Ohrgeräusch vor*. . Hannover: Schluetersche; 2011.
17. Kleinjung T, Fischer B, Langguth B, Sand P, Hajak G, Dvorakova J, Eichhammer P: **Validation of the German-Version Tinnitus Handicap Inventory (THI)**. . *Psychiatr Prax* 2007, **34**:140-142.
18. Goebel G, Hiller W: **[The tinnitus questionnaire. A standard instrument for grading the degree of tinnitus. Results of a multicenter study with the tinnitus questionnaire]**. *HNO* 1994, **42**(3):166-172.
19. Beck AT, Steer RA: **Internal consistencies of the original and revised Beck Depression Inventory**. *J Clin Psychol* 1984, **40**(6):1365-1367.

20. Landgrebe M, Zeman F, Koller M, Eberl Y, Mohr M, Reiter J, Staudinger S, Hajak G, Langguth B: **The Tinnitus Research Initiative (TRI) database: a new approach for delineation of tinnitus subtypes and generation of predictors for treatment outcome.** *BMC Med Inform Decis Mak* 2010, **10**:42.
21. Kleinjung T, Eichhammer P, Landgrebe M, Sand P, Hajak G, Steffens T, Strutz J, Langguth B: **Combined temporal and prefrontal transcranial magnetic stimulation for tinnitus treatment: a pilot study.** *Otolaryngol Head Neck Surg* 2008, **138**(4):497-501.
22. Biesinger E, Kipman U, Schatz S, Langguth B: **Qigong for the treatment of tinnitus: a prospective randomized controlled study.** *J Psychosom Res* 2010, **69**(3):299-304.
23. Veehof MM, Oskam MJ, Schreurs KM, Bohlmeijer ET: **Acceptance-based interventions for the treatment of chronic pain: a systematic review and meta-analysis.** *Pain* 2011, **152**(3):533-542.
24. Chiesa A, Serretti A: **Mindfulness based cognitive therapy for psychiatric disorders: a systematic review and meta-analysis.** *Psychiatry Res* 2011, **187**(3):441-453.
25. Kerr CE, Jones SR, Wan Q, Pritchett DL, Wasserman RH, Wexler A, Villanueva JJ, Shaw JR, Lazar SW, Kaptchuk TJ *et al*: **Effects of mindfulness meditation training on anticipatory alpha modulation in primary somatosensory cortex.** *Brain Res Bull* 2011, **85**(3-4):96-103.
26. Weisz N, Dohrmann K, Elbert T: **The relevance of spontaneous activity for the coding of the tinnitus sensation.** *Prog Brain Res* 2007, **166**:61-70.
27. Dohrmann K, Weisz N, Schlee W, Hartmann T, Elbert T: **Neurofeedback for treating tinnitus.** *Prog Brain Res* 2007, **166**:473-485.
28. Weisz N, Langguth B: **[Cortical plasticity and changes in tinnitus: treatment options].** *HNO* 2010, **58**(10):983-989.
29. Landgrebe M, Langguth B, Rosengarth K, Braun S, Koch A, Kleinjung T, May A, de Ridder D, Hajak G: **Structural brain changes in tinnitus: grey matter decrease in auditory and non-auditory brain areas.** *Neuroimage* 2009, **46**(1):213-218.
30. Vanneste S, Plazier M, der Loo E, de Heyning PV, Congedo M, De Ridder D: **The neural correlates of tinnitus-related distress.** *Neuroimage* 2010, **52**(2):470-480.
31. Giraud AL, Chery-Croze S, Fischer G, Fischer C, Vighetto A, Gregoire MC, Lavenne F, Collet L: **A selective imaging of tinnitus.** *Neuroreport* 1999, **10**(1):1-5.
32. Lanting CP, de Kleine E, van Dijk P: **Neural activity underlying tinnitus generation: results from PET and fMRI.** *Hear Res* 2009, **255**(1-2):1-13.
33. Holzel BK, Ott U, Hempel H, Hackl A, Wolf K, Stark R, Vaitl D: **Differential engagement of anterior cingulate and adjacent medial frontal cortex in adept meditators and non-meditators.** *Neurosci Lett* 2007, **421**(1):16-21.
34. Tyler RS, Oleson J, Noble W, Coelho C, Ji H: **Clinical trials for tinnitus: study populations, designs, measurement variables, and data analysis.** *Prog Brain Res* 2007, **166**:499-509.



Figure 1: Structure and Time Course of the Study

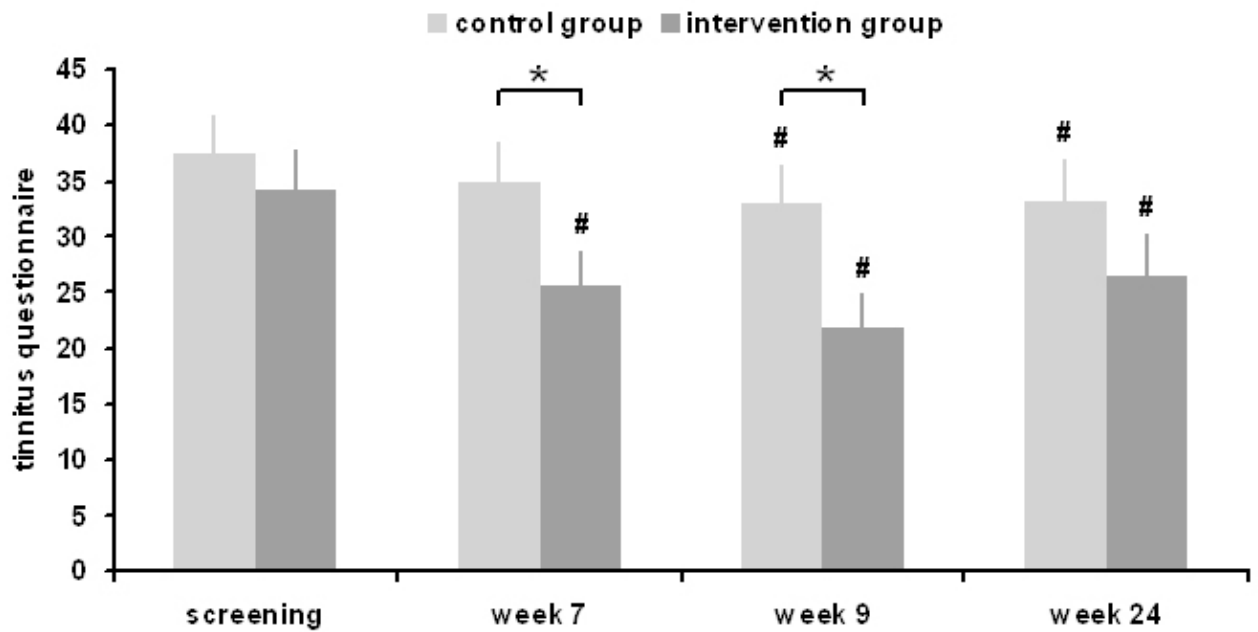


Figure 2: Primary Outcome Tinnitus Questionnaire in control and intervention groups (mean ± standard deviation, * p<0.05 group contrast, # p<0.05 contrasts against screening)

Table 1: Sample Characteristics and statistical parameters (mean \pm standard deviation)

	Intervention group	Control group	Statistics
n	18	18	
gender (male/ female)	11/7	8/10	$\chi^2=1.003$; df=1; p=0.317
age	49.6 \pm 8.8	51.7 \pm 16.0	T=0.487; df=34; p=0.629
tinnitus duration	100.5 \pm 119.1	142.3 \pm 116.2	T=1.053; df=33; p=0.300
number of previous treatments	3.4 \pm 2.0	3.7 \pm 2.1	T=0.454; df=33; p=0.653
laterality (left, both/central, right)	6, 6, 5	8, 3, 7	$\chi^2=1.592$; df=2; p=0.451
questionnaires			
TF	34.1 \pm 15.8	37.4 \pm 14.9	T=0.663; df=34; p=0.512
THI	41.0 \pm 20.4	45.9 \pm 17.7	T=0.768; df=34; p=0.448
BDI	11.1 \pm 8.1	11.8 \pm 7.0	T=0.264; df=34; p=0.793
numeric rating scales			
loudness	5.7 \pm 2.5	6.5 \pm 2.2	T=0.992; df=34; p=0.328
annoyance	37.0 \pm 37.3	33.1 \pm 23.9	T=0.369; df=33; p=0.714
discomfort	6.9 \pm 2.8	7.3 \pm 2.3	T=0.529; df=34; p=0.600
distractibility	6.2 \pm 2.7	6.4 \pm 2.7	T=0.247; df=34; p=0.806
unpleasantness	5.9 \pm 2.8	7.1 \pm 2.2	T=1.4; df=34; p=0.169
other (no, yes)			
temporomandibular joint disorder	12, 5	14, 4	$\chi^2=0.237$; df=1; p=0.627
neck pain	7, 10	6, 12	$\chi^2=0.230$; df=1; p=0.631
other pain	10, 6	10, 8	$\chi^2=0.169$; df=1; p=0.681
influence of neck movement	12, 4	9, 9	$\chi^2=2.242$; df=1; p=0.134
psychiatric comorbidity	12, 5	14, 4	$\chi^2=0.237$; df=1; p=0.627