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ORIGINAL PAPER

Mindfulness Based Tinnitus Stress Reduction Pilot Study

A Symptom Perception-Shift Program

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Abstract This pilot study aims to investigate whether a novel mind–body intervention, Mindfulness Based Tinnitus Stress Reduction (MBTSR), may be a beneficial treatment for chronic tinnitus. Eight tinnitus patients who had previously received Tinnitus Counseling (standard of care) at the University of California, San Francisco (UCSF) Audiology Clinic participated in the MBTSR program. The program included 8 weeks of group instruction on mindfulness practice, a 1-day retreat, supplementary readings, and home-based practice using meditation CDs. Using a pre–post intervention design, mean differences (paired *t*-tests) were calculated. Benefits were measured by a reduction in clinical symptoms, if present, and a tinnitus symptom perception shift. Tinnitus symptom activity and discomfort as well as psychological outcomes were assessed by self-report questionnaires. Both quantitative and qualitative data were gathered. Results indicate that Effect Sizes, if supported by a larger study, may be clinically significant and demonstrate a substantial decrease for items measuring perceived annoyance and perception of handicap of tinnitus. Change scores on study measures all moved in the hypothesized direction, with the exception of negligible change found for the Acting with Awareness (d=−0.05) factor of mindfulness. This pilot study provides preliminary evidence that an 8-week MBTSR program may be an effective intervention for treating chronic tinnitus and its comorbid symptoms, and may help reduce depression and phobic anxiety while improving social functioning and overall mental health. These promising findings warrant further investigation with a randomized controlled trial.

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Introduction

Interest in tinnitus and its treatment has grown in recent years, largely due to increasing awareness that tinnitus is the most common service-connected disability for veterans returning from recent military service in Iraq and Afghanistan (Department of Veterans Affairs 2010). Tinnitus is a medical term for auditory perceptions heard in the ear(s) or head, but not produced by external sound (Baguley 2002). This sound, which is often described as a ringing, buzzing, pulsing, whistling, or humming noise, can be experienced in one or both ears with varying loudness and pitch. Approximately 50 million people in the United States (25.3 % of the US population) experience tinnitus at some point in their lives (Shargorodsky et al. 2010). Around 16 million of these Americans experience tinnitus bothersome enough to consult their doctor (Shargorodsky et al. 2010). Furthermore, 2 to 3 million are so severely affected by their tinnitus that their ability to function is severely impaired (Shargorodsky et al. 2010).

Tinnitus is a symptom rather than a disease, and may develop from exposure to loud noise; a head injury; aging, outer, inner, or middle ear problems; neck or jaw disorders; cardiovascular disease; or use of prescription or non-prescription drugs (Holmes and Padgham 2009; Tyler & Baker 1983). While many theories have been proposed to explain the occurrence of tinnitus, it is a multimodal disorder that may have different causes and different pathophysiologies. This makes tinnitus difficult to treat, and oftentimes, interventions meet with only variable success (Meikle et al. 2007).

In an extensive review of the literature from 1980 to 2009, Holmes and Padgham (2009) reported on the impact

tinnitus can have on a person's life. For those who experience tinnitus bothersome enough to consult their doctor, tinnitus is most commonly associated with symptoms of anxiety, distress, sleep disturbance, and depression (Andersson et al. 2005; Lockwood et al. 2002). Disrupted sleep is the most significant complaint (Megwalu et al. 2006), affecting as many as 70 % of tinnitus patients (Andersson et al. 2005). Studies report a lifetime prevalence of 62 % for major depression, with 48 % of people with tinnitus displaying current depression (Harrop-Griffiths et al. 1987), and 45 % reporting an anxiety disorder (Zoger et al. 2001). Poor attention and concentration, interference with work, and negative impact on personal relationships are commonly reported by patients (Heller 2003; Sanchez and Stephens 1997). Almost all patients indicate that stress or tension makes their tinnitus worse (Hebert and Lupien 2007; Mazurek et al. 2010).

People with intractable cases of tinnitus are encouraged to reduce tinnitus distress by means of counseling and education (Sweetow 1986). Cognitive Behavioral Therapy (CBT) has been shown to be a helpful treatment for some (Martinez Devesa et al. 2010). CBT places its focus on reducing distress by addressing a person's maladaptive appraisal, avoidance, selective attention, and other psychological mechanisms that may be influencing distress regarding tinnitus. Paying less attention to or ignoring the tinnitus in an effort to gain more control over one's tinnitus is an emphasized goal (Folmer 2002).

Mindfulness meditation stems from Buddhist philosophy and psychology and constitutes a general non-judgmental approach to life (Goleman 1988). The study of mindfulness has grown in interest over the past 30 years in the fields of medicine and psychotherapy (Ludwig and Kabat-Zinn 2008). Multiple studies have shown mindfulness to be helpful in the management of distressing symptoms as well as a broad range of chronic illnesses including a decrease in mood disturbance (Brown and Ryan 2003; Carlson et al. 2004; Chiesa and Serretti 2009; Kabat-Zinn et al. 1992; Weiss et al. 2005), a decrease in depressive relapse (Ma & Teasdale 2004; Teasdale et al. 2002), an increase in sense of well-being (Beddoe and Murphy 2004; Rosenzweig et al. 2003; Shapiro et al. 1998; Weiss et al. 2005) and a decrease in sleep disturbance (Caldwell et al. 2010; Carlson and Garland 2005). Mindfulness meditation-based treatment approaches have been successfully used in the treatment of a range of chronic conditions such as fibromyalgia (Grossman et al. 2007), chronic fatigue (Surawy et al. 2005), multiple sclerosis (Grossman et al. 2010), psoriasis (Kabat-Zinn et al. 2003), cancer (Speca et al. 2006), depression and anxiety (Brown and Ryan 2003; Carlson et al. 2004; Hofmann et al. 2010; Kabat-Zinn et al. 1992; Mason and Hargreaves 2001), depressive relapse (Ma & Teasdale 2004; Teasdale et al. 2000), PTSD (Smith et al. 2011), stress (Shapiro et al. 1998), and chronic pain (Grossman et al. 2007; Kabat-Zinn et al. 1992; Kaplan et al. 1993; Morone et al. 2008; Randolph et al. 1999).

Most probably due to the attention given to a person's thoughts and cognitions, mindfulness is often erroneously categorized as a form of CBT. While both involve an awareness of thoughts and their content, there are distinct differences between these two practices. CBT is often specifically aimed at treating symptoms such as anxiety or depression, and is a directive and structured type of psychotherapy with the goal of recognizing and correcting maladaptive ways of thinking (Beck et al. 1979). Mindfulness, on the other hand, is not a structured psychotherapy, but rather a discipline to be cultivated throughout a person's life. It involves a willful shifting of one's attention or a systematic building of awareness to bring one's attention to where the mind is at any given time. Thoughts, body sensations, and emotions are seen as mental events not to be analyzed or manipulated but rather to simply be noticed as fleeting events in the mind's field of awareness. These mental events then recede from awareness, and the mind is brought back to the present moment. Other mind–body interventions such as relaxation techniques have the goal of bringing about a state of relaxation. Mindfulness practice, in contrast to CBT and relaxation training, posits a non-striving stance towards a particular outcome: it simply allows whatever is in one's field of awareness to be witnessed without judgment.

Mindfulness Based Stress Reduction

Mindfulness Based Stress Reduction (MBSR) is a program designed by Jon Kabat-Zinn in the late 1970s at the University of Massachusetts Medical Center; Kabat-Zinn 2005). MBSR is an 8-week course teaching the principles required for exercising control of one's attention through mindfulness training, while developing skills and autonomy in mindfulness practice to be integrated into daily life (Kabat-Zinn 1982). "Mindfulness means paying attention in a particular way: On purpose, in the present moment, and nonjudgmentally" (Kabat-Zinn 1994, p.4). Practicing mindfulness is not as easy as it may seem, especially for people with tinnitus whose symptoms are often accompanied by unfounded fears that their condition may worsen, that their tinnitus may be a sign of a brain tumor, or may indicate impending or progressive hearing loss (Davis and Morgan 2008). A struggle may develop between the person and the tinnitus, which can lead to symptoms of fatigue, depression, anxiety, difficulty sleeping, and interpersonal problems, all of which can impede functioning in day-to-day life. Treatment using mindfulness-based therapies teaches a person to change his or her relationship to the tinnitus in an effort to lessen or eliminate this struggle.

Pain management treatments are of particular interest to those studying tinnitus in light of the many similarities between individuals suffering from tinnitus and those suffering

from chronic pain conditions (Møller 2000). With both conditions, there is often no single cause of the symptom, and no single medical or surgical treatment is effective; likewise, there is a wide range of psychological effects, and lifestyle and general health are particularly affected. Perceived lack of control over the symptom, problems with aspects of attention and focus, maladaptive coping strategies, catastrophic thinking, as well as the use of similar methods of treatment (e.g., cognitive coping strategies, CBT, and relaxation techniques) are common features of both chronic pain and tinnitus (Møller 2000; Tonndorf 1987). One of the first studies looking at mindfulness as a means of pain management was conducted by Kabat-Zinn, Lipworth, and Burney (1985). They studied 90 patients with chronic pain and trained them in a 10-week stress reduction and relaxation program. Results demonstrated significant reductions in present moment pain, negative body image, inhibition of activity by pain, and mood disturbances such as anxiety and depression. Significant improvements in activity level and feelings of self-esteem were also reported. These reductions and improvements, with the exception of present moment pain, were maintained 15 months post-treatment for all subjects.

A few studies have recently begun to look at meditation-based treatments for chronic tinnitus (Philippot et al. 2011; Sadlier et al. 2008). In a pilot study conducted in Wales by Sadlier et al. (2008), a combination of CBT and mindfulness training over four 1-h sessions was used to treat 25 individuals with chronic tinnitus. Split into two groups, the treatment group received CBT and Mindfulness Meditation practice, while the second group (control group) waited 3 months and was then treated with the same intervention. Significant reductions in tinnitus severity post-treatment were reported for both groups, with 80 % of patients reporting that they were better or much better at 4- and 6-month follow-ups. A second randomized controlled trial conducted by Philippot et al. (2011) examined the relative effectiveness of two psychological interventions, mindfulness training and relaxation training, for treating tinnitus in 25 participants. All subjects were first offered a single session of psychoeducation regarding tinnitus, followed by six weekly sessions of either mindfulness or relaxation training with each session lasting 2 h and 15 min. Results indicated that psychoeducation, followed by mindfulness training, appeared to be an effective intervention for chronic tinnitus with a reduction in negative emotions, rumination and psychological difficulties of living with tinnitus. These benefits were enhanced or at least maintained by mindfulness training over time, as compared to relaxation training where there was an erosion of these benefits over the follow-up.

The following pilot study aims to test the feasibility of a novel mind–body intervention, Mindfulness Based Tinnitus Stress Reduction (MBTSR), as a possible tinnitus intervention, to address limitations mentioned in previous studies, and to determine whether conducting a larger randomized controlled trial is warranted. Although mindfulness-based training has been used with tinnitus patients in recent studies, the present study is the first to introduce the 8-week MBTSR program with a 7-hday-long mindfulness retreat based on conjecture that longer training would provide participants the full benefits of the intervention (Philippot et al. 2011; Sadlier et al. 2008). Furthermore, this study aims to facilitate a tinnitus perception shift in its participants. For the purposes of this study, a tinnitus perception shift is defined as a person's attitude towards the reality of living with chronic tinnitus changing from one of struggle to one of acceptance.

Method

Participants

Subjects were recruited from the University of California, San Francisco (UCSF) Audiology Clinic database of past patients (approximately 700) who had been seen for Tinnitus Counseling (TC) at least 6 months prior to enrollment in the study (refer to Fig. 1 for a recruitment flow chart). All patients who present at the UCSF Audiology Clinic with a complaint of tinnitus may choose to participate in TC. After receiving clearance from a physician to determine if the cause of the tinnitus is medically treatable, or if the tinnitus is a symptom of a significant health issue that needs to be addressed, patients meet individually with an audiologist for approximately 90 min. During the visit, patients are presented with tinnitus education and options for management. The provider shares information on possible causes and ways to minimize stress, and outlines some of the myriad of management tools and treatments that are currently available; referrals are also made to other healthcare providers, if indicated. Patients are also given time to talk about their personal experience with tinnitus and to ask questions.

A total of 514 patients met the inclusion criteria per chart review, from which 75 names were randomly chosen and mailed recruitment letters (see Table 1 for a list of Inclusion/Exclusion Criteria). An additional 20 names were randomly chosen and mailed letters to meet recruitment goals. Randomization was performed by computer-generated random allocations sequence by simple randomization. Of the 95 letters sent out, 19 patients (20 %) responded with interest. Of the 19 patients, 13 (68 %) potential subjects attended a 30-min individual interview. This interview served as an orientation to the MBTSR program, described the nature and time requirements of the intervention, and confirmed whether the inclusion criteria were met. Three patients excluded themselves after the orientation, two reporting scheduling conflicts interfering with attendance and one stating a lack of interest. Ten subjects (77 %) met inclusion criteria, consents were signed, and pre-test measures were administered immediately following the interview. Two

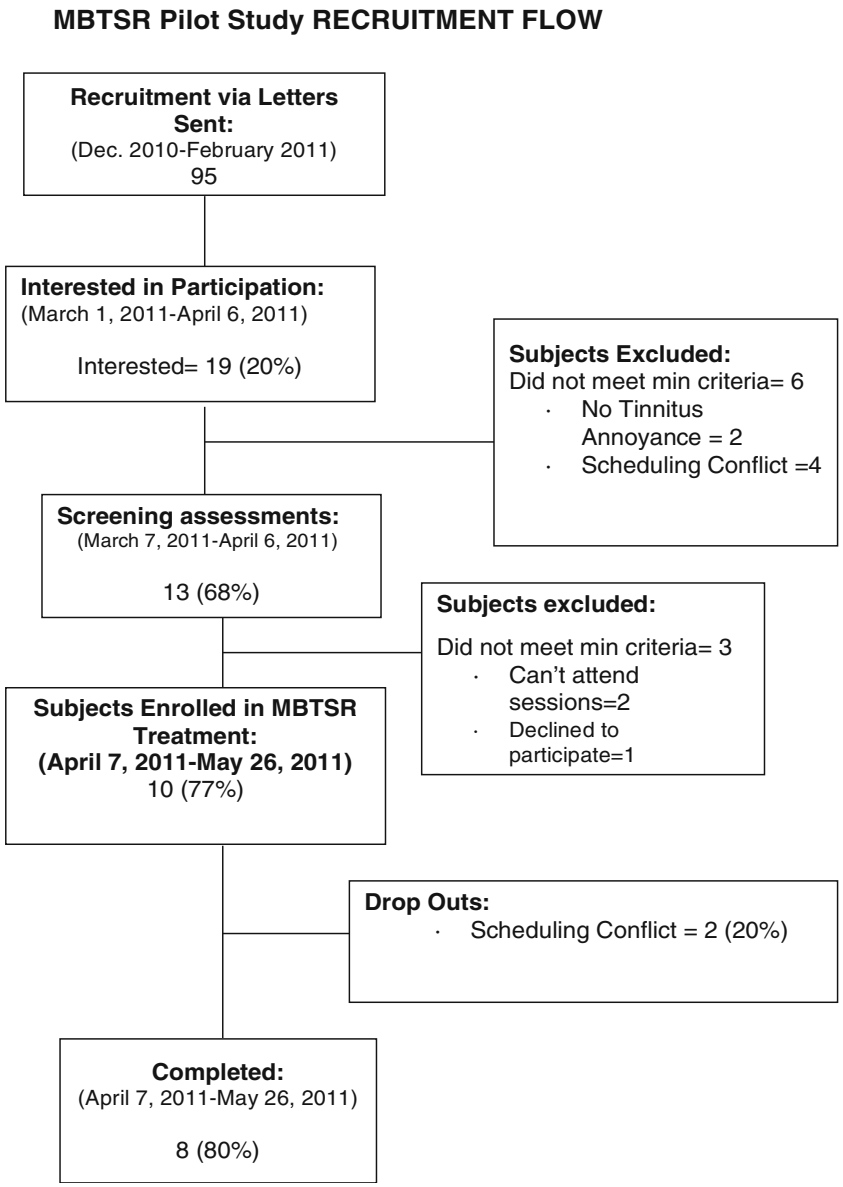

Fig. 1 Recruitment flow chart displaying the recruitment, selection, and retention of subjects from commencement to completion of the MBTSR pilot study

participants discontinued the program, one in the third week, the other in the fourth week, reporting unanticipated work and scheduling conflicts. All participants agreed not to partake in any new tinnitus treatment during the length of the study.

Eight participants (80 %) completed the MBTSR program (defined as attendance of six or more of the eight MBTSR classes). The average age of participants was 58 years (38–70, SD=±19). Six (75 %) of the participants were male, and two (25 %) were female. The study protocol was approved and procedures were followed throughout the study in accordance with the UCSF Institutional Review Board.

Intervention

The MBTSR class ran from April 2011 through May 2011. While taught in a similar 8-week format as MBSR (Kabat-Zinn 1982, 2005), the MBTSR course includes significant programmatic modifications designed to address participants' unique experience with tinnitus. The most fundamental change was the reshaping and reorientation of MBSR into a program whose central focus addresses psychoeducation related to the often co-occurring disorders (e.g., sleep disorder, anxiety, depression) common in people with tinnitus. Additional class-time was focused on guided mindfulness practices emphasizing awareness of sound and tinnitus perception, education about sleep and sleep hygiene, explaining the circular and complex connection between stress in daily life and tinnitus exacerbation, increasing relaxation and awareness skills, and increasing an overall sense of well-being as it relates to living with tinnitus. The additional class time was added to improve the participant's understanding of the relationship among tinnitus and the

Table 1 List of inclusion/exclusion criteria

Inclusion criteria	
Subject characteristics	
	Age ≥18 years
	English-speaking
	Duration of subjective chronic tinnitus ≥6 months
	Moderate to strong tinnitus annoyance (minimum THI score of ≥20 per chart review)
Exclusion criteria	
Subject characteristics	
	Age ≥18 years
	Non-English-speaking
	>40 dB hearing loss [a]
	Duration of chronic subjective tinnitus <6 months
	Severe depression and/or anxiety (as measured by the HADS)
	Recent (within 3 months) history of alcohol or drug abuse or dependence other than tobacco or caffeine
	No recent (within 3 months) start of new tinnitus treatment
	History of psychotic disorders or dementia
	THI score <20
	Currently undergoing litigation or legal matters related to auditory disorders

[a]Exclusion of subjects with bilateral Moderate or above hearing loss (>40 dB loss aided) was set to ensure that all participants would be able to hear and understand spoken English in a group setting

comorbid symptoms. The program also aims to foster the recognition of early warning signs of tinnitus exacerbation, teaching skills to come back to present, moment-by-moment awareness whenever the mind starts to dwell in the past or future, and teaching how to access inner resources through the acquisition of mindfulness skills. In class and home-practice mindfulness exercises emphasized becoming aware of the tinnitus sensation, observing it with a certain spaciousness and affectionate curiosity instead of reacting in habitual ways. Participants were instructed to practice mindfulness throughout their day when tinnitus is perceived to be loud and troubling, including while eating meals, before sleeping, during social interactions, and during periods of quiet.

Similar to the original MBSR program, the MBTSR course introduces participants to mindfulness practice in the form of sitting meditation, body awareness, mindful movement, as well as informal mindfulness practices of daily life (e.g., eating, communicating, working). In accordance with the non-goal setting that is inherent in mindfulness, participants were encouraged to let go of decreasing tinnitus as the "goal" of the program. Instead, participants were encouraged to develop a mindful outlook on their lives as a whole. Between sessions, participants were asked to practice at home for 30 min/day, 6 days/week, aided by meditation CDs made by the course instructor. At the start of the program, each participant was supplied with a copy of *Full Catastrophe Living* (Kabat-Zinn 2005), and a participant manual. Between classes, participants were instructed to enhance their participation through readings from the course materials.

Participant and instructor manuals were created specifically for the study. The MBTSR manual was derived from Kabat-Zinn's (1982, 2005) MBSR curriculum, with weekly sessions following a similar format, with classes lasting 150 min. Classes began with a 40-min meditation practice, followed by a review of the previous week's homework, presentation and discussion of the theme of that particular session, and concluding with a brief experiential exercise and a review of the homework for the following week. The seventh and eighth sessions were slightly modified from the standard session format; in order to emphasize self-reliance in the meditative practice, participants were given fewer instructions and less guidance during exercises. Similar to MBSR, between the sixth and seventh weeks of the program, participants attended a 7-h retreat. During the day-long retreat, participants experienced various meditations (i.e., awareness of the breath, sitting, walking meditations) bringing moment-to-moment awareness to body sensations, thoughts, and emotions as they arise. The retreat provided participants with the opportunity to practice in a continuous group setting the skills they had cultivated over the past 6 weeks. The day ended with a group discussion of participants' individual experience with the practice, where they were encouraged to reflect on what they had learned.

At the end of the eighth and final MBTSR class, participants were asked to anonymously complete a 12-item Post-Intervention Feedback Form (PIFF) developed for the study. Finally, participants were provided with a packet of post-assessment measures along with a self-addressed stamped envelope, and were asked to mail the completed forms back

to the Clinic. Pre- and post-outcome data was received and included in analysis from all eight study participants.

Outcome Measures

Pre-assessment measures were individually administered to participants at the UCSF Audiology Clinic immediately after consents were signed, no earlier than 2 weeks prior to the start of the intervention. Post-assessment measures were filled out at home and mailed back to the Clinic by participants no more than 2 weeks after the intervention's completion.

Tinnitus symptom activity and handicap as well as psychological outcomes were assessed by self-report questionnaires. Both quantitative and qualitative data were gathered. The primary outcome measure was the Tinnitus Handicap Inventory (THI), a 25-question self-report measure that can be used to quantify the perceived impact of tinnitus on daily living (Newman et al. 1996). The measure is brief, useful in a busy health care setting, easy to administer and interpret, broad in scope, and psychometrically robust. The THI is grouped into emotional, functional, and catastrophic subscales. The total scales yield excellent internal consistency reliability (Cronbach's alpha=0.93). Convergent validity was assessed using another measure of perceived tinnitus handicap (Tinnitus Handicap Questionnaire). Construct validity was assessed using the Beck Depression Inventory, Modified Somatic Perception Questionnaire, symptom rating scales (annoyance, sleep disruption, depression, and concentration), and perceived tinnitus pitch and loudness judgments.

In addition to tinnitus symptom impact on daily living, secondary outcome assessments were used to measure change in tinnitus awareness, mindfulness, Health-Related Quality of Life (HRQoL), and other comorbid symptoms such as anxiety and depression, if they existed. The secondary outcome measures included a Tinnitus Visual Analogue Scale (VAS), Percent of Awareness Scale (PAS), SF-36 Health Survey (SF-36), the Symptom Checklist-90-Revised (SCL-90-R), Hospital Anxiety and Depression Scale (HADS), and the Five-Facet Mindfulness Questionnaire (FFMQ).

The Tinnitus VAS is a collection of straight lines 100 mm in length anchored at the end with extremes (e.g., not bothersome, extremely bothersome) of the tinnitus sensation, feeling or response. This method of measuring distress has been recommended for use in research (Axelsson et al. 1993).

The PAS is a measure created for the purposes of this study. It asks subjects to estimate the percent of time that they are aware of the tinnitus sensation during waking hours.

The HADS (Zigmond and Snaith 1983) was chosen as a measure of self-reported depression and anxiety. As compared to the Beck Depression Inventory and State Trait Anxiety Inventory, the HADS is a 14-item questionnaire and does not tend to overburden or exhaust patients while filling it out. The HADS is a more discrete measure that controls for complaints better explained by the somatic problem than does the BDI or STAI (Herrmann 1997).

The SCL-90-R is used to assess psychological distress SCL-90-R is a 90-item questionnaire measuring psychological distress over the past week (Derogatis 1983). Reliability and validity of the measure is found to be high. The Global Severity Index (GSI) is used as a measure of overall psychological distress. The SCL-90-R has been used in several previous MBSR studies to measure psychological status (Kabat-Zinn et al. 1985, 1987, 1992; Kaplan et al. 1993; Majumdar et al. 2002; Miller et al. 1995).

The Five-Facet Mindfulness Questionnaire (FFMQ) (Baer et al. 2006) is a 39-item inventory assessing five facets of mindfulness: observing, describing, acting with awareness, nonjudging of inner experience, and nonreactivity to inner experience. The FFMQ has been shown to have strong psychometric characteristics, including adequate to good internal consistencies for all facets and significant correlations in predicted directions with a variety of other constructs (Baer et al. 2006, 2008).

The SF-36® Health Survey (Version 1) is a 36-item generic self-report outcome measure designed to examine a person's perceived health status. It takes approximately 5–10 min to administer. It is easy to use, acceptable to patients, and fulfills stringent criteria of reliability and validity (Brazier et al. 1992).

The PIFF is a paper-and-pencil qualitative measure created for the purposes of this study. The PIFF asks participants with open ended and directed questions about the MBTSR intervention's usefulness, satisfaction, relevance, applicability, participant satisfaction with the training, and suggestions on how to improve the program.

Instructor

The weekly meetings were facilitated by a licensed clinical psychologist trained to teach MBSR and who specializes in the psychological impact of deafness and hearing difficulty as it relates to a person's well-being. To ensure that the meditation program was properly implemented throughout the study, weekly supervision was provided by an experienced MBSR-certified instructor. The instructor was involved in subject recruitment, facilitating groups, data collection, and authoring the current paper.

Statistical Analysis

Changes to each measure across time (pre-treatment to post-treatment) following the 8-week MBTSR intervention were assessed with paired sample *t*-tests. Treatment effect sizes were calculated using Cohen's *d* statistic (Cohen 1977). Effect Size (ES) using Cohen's *d* statistic rather than levels of significance (*t*-test) were reported due to the small sample size. We defined ES under 0.3 as small, around 0.5 as moderate and around 0.8 or higher as large (Hojat and Xu 2004).

Results

Change scores across all study measures moved in the hypothesized direction with the exception of scores measuring Acting with Awareness on the FFMQ that showed negligible ES change (d=−0.05). Table 2 is a chart including pre- and post-treatment mean change scores with ES.

Perceived Tinnitus Annoyance, Awareness, and Handicap

Results indicate that ESs may be clinically significant and demonstrate a substantial decrease for items measuring tinnitus annoyance and the perceived impact on daily living (VAS d=0.99; THI d=0.69) and moderate reduction in the percent time participants were aware of tinnitus (PAS d=0.64).

Health-Related Quality of Life

Results indicate that ESs may be clinically significant and demonstrate a substantial increase for items measuring Social Functioning (d=−0.70), and a moderate overall increase in Mental Health (d=−0.62). A moderate increase was seen for Vitality (d=−0.46). Change for items measuring Physical Functioning, Physical Health, Bodily Pain, and Role Limitations due to Physical Functioning all fell within the negligible range for change from pre- to post-test.

Mindfulness

Results indicate that ESs may be clinically significant and demonstrate a substantial increase for items measuring the mindfulness factor of Non-Judging (d=−1.29) (FFMQ). Moderate levels of change were suggested by an increase in Observing (d=−0.46), Reactivity to Inner Experience (d=−0.52), and Describe (d=−0.57) items as measured by the FFMQ. Negligible ES change was found for the Acting with Awareness (d=−0.05) factor of mindfulness.

Psychological Symptomatology

Results indicate that ESs on the SCL-90-R may be clinically significant and demonstrate a moderate decrease for items measuring Depression (d=0.52), Phobic Anxiety (d=0.62), and Somatization (d=0.58). A small to moderate decrease in Anxiety (d=0.41) was found. Only negligible change was seen for items related to scales for Obsessive–Compulsive, Psychoticism, Paranoid Ideation, and Hostility.

Anxiety and Depression

Changes from pre-treatment to post-treatment on depression and anxiety scales indicated a small ES (HADS d=0.30)

Table 2 Pre- and post-intervention score differences with effect sizes

Measure	Pre-MBTSR Mean (SD)	Post-MBTSR Mean (SD)	Effect size (Cohen's d)[a]
THI	50.63 (15.22)	39 (21.8)	0.69
VAS	59 (24.87)	36.88 (24.26)	0.99
Tinnitus awareness	60 (33.7)	41.25 (32.49)	0.64
FFMQ			
Non-judge	28 (5.09)	32.25 (6.94)	−1.29
Observing	30.13 (5.64)	31.75 (3.92)	−0.46
Non-reactivity	20.38 (4.81)	23 (9.44)	−0.52
Describe	29.75 (5.78)	32.38 (5.53)	−0.57
Acting with awareness	28 (6.57)	27.75 (4.4)	−0.05
SF-36			
Social functioning	39.5 (10.35)	49 (46.3)	−0.70
Mental health	44.78 (11.21)	49.33 (9.32)	−0.62
Vitality	50.83 (9.1)	53.78 (6.94)	−0.46
HADS	15.5 (6.46)	13.38 (7.23)	0.30
SCL-90-R			
Depression	66.5 (12.3)	56.38 (24.44)	0.52
Phobic anxiety	65.38 (13.31)	50.39 (21.77)	0.62
Somatization	60.13 (14.75)	49.89 (23.5)	0.58
Anxiety	63.38 (12.57)	54.88 (23.95)	0.41

[a]Effect Size (ES) rather than levels of significance were reported due to a small sample size

Qualitative Results

Participants were asked at the end of the eighth and final MBTSR class to complete a 12-item PIFF developed for the study. The PIFF uses open-ended and directed questions to ask participants about the MBTSR intervention's usefulness, relevance, and applicability, their satisfaction with the training, and suggestions for how the program may be improved. A tinnitus perception shift, a reduction in psychological distress, increased mindfulness, and improvement in general functioning can be surmised from participant comments.

Tinnitus Perception Shift

Participants reported a sense that attitudes and beliefs about experiencing chronic tinnitus shifted, including one participant who noted feeling increased tolerance, acceptance, and courage to live with chronic tinnitus. This perception shift can be seen in the following comment:

> Tinnitus doesn't seem like a terrible curse anymore. It's sometimes annoying now but not insurmountable.

Participants expressed a newfound ability to deal with tinnitus in more adaptive and effective ways following the training:

> I can see it (tinnitus) now as just another sensation, typically unpleasant, rarely neutral, never pleasant, but I try to be aware without judging.

Another participant wrote:

> Each and every day I think about you saying that there are pleasant, unpleasant, and neutral moments. I smile every time I remember this and I remember you saying it. Sometimes, I ask myself is this an unpleasant or neutral experience? 99.9 % of the time the answer is it is a neutral experience.

Changes in perception or attitude about tinnitus are expressed in comments such as:

> I am taking a more relaxed approach overall and just allowing tinnitus to be there.

Change in Psychological Distress

Participants from our study reported an improvement in the amount and quality of their sleep post-intervention, with one participant mentioning a reduction in sleep-inducing medications:

> I am sleeping in a more regular pattern now. When I take medication to sleep, I'm taking half instead of the full dose.

This same participant went on to state:

> In one of our sessions, you said when going to sleep, "Just let go." Man oh man, has that helped me. I'm a planner, and I used to plan out the next day as I was laying in bed waiting to go to sleep. Bad idea. Now when I go to bed, I just monitor my breathing or go into choice-less awareness mode. I absolutely refuse to follow any goofy thoughts my thinking mind brings up. I just let go. Next thing I know it is morning. Fantastic

Participants remarked that they noticed a positive change in symptoms of depression. One wrote:

> I can go into the ringing without going towards depression.

A change in symptoms of anxiety was expressed by a participant who contacted the instructor about 2 weeks after completing the 8-week program and recounted the following experience:

> We had a power failure last night just before I was going to bed, which meant my white noise generators would not work. And, because I'm getting ready to put my house on the market, my battery-powered white noise generators are in storage. Before our study I would have gone into a complete panic thinking about going to bed without white noise. I would have broken into a cold sweat. But because of our sit-down meditation in which we breathe into the ringing, I knew I could handle silence in bed. Thank you, the study saved me from having a panic attack. Whew, close call.

Another participant wrote about the impermanent nature of body sensations from one moment to the next:

> It [tinnitus] does not impact me emotionally since I experience it as a sensation that will come and go.

Increased Mindfulness in Daily Life

Participants mentioned an increased mindfulness in daily life. One participant stated:

> I have begun to meditate regularly. I have combined the learnings from the MBTSR class with other work.

Another wrote:

> I'm more mindful in daily life. I concentrate on breathing while waiting in line at the store.

Changes in Lifestyle

Comments made by participants demonstrating changes in lifestyle are seen in the following statements:

> I have begun to meditate regularly. I have combined the learnings from the MBTSR with my work.
> I'm more mindful in my daily life. I concentrate on breathing while waiting in line at the store.
> I am making sure I allocate time for meditation. I am being mindful as much of the time as I can.
> The stress reduction aspect is very useful. Regardless of the tinnitus, it is been very useful to learn to meditate and being mindful in nearly everything I do.

Improved General Functioning

Participants also reported that the training contributed to better self-care practices and brought relief from fear in daily activities.

> I am trying to relax more, sleep better and longer. I watch what food I eat and try to take a walk or other exercise each day.
> I am less afraid to be inside of a room or a building.

Importance of Ongoing Mindfulness Practice

Participants recognized that to experience ongoing benefits, they would need to continue the mindfulness meditation practice:

> The retreat was a very good experience and well worth the day spent. Follow-up will be important to see if we can continue the practice.

Change in Body Perception

Participants indicate that they have become more aware of their bodies with an increased tolerance, acceptance, and courage to deal with the effects of chronic tinnitus on their health and well-being:

> I have realized that my body deserves love and care. It is valuable to view myself as a custodian of my body. I treat it better and appreciate it more now.

During a group discussion at the close of the all-day retreat, one participant in the group relayed to the class that he has always hated his body and thought of it as an "enemy." When he developed tinnitus in 1997, his anger only grew. He began to contemplate suicide, seeing no other way out. He stated in the group that in the previous 6 weeks of the MBTSR program, he learned how to "relate differently" to his tinnitus, and had come to realize that it is just a "body sensation" that does not require him to attach such angry thoughts and sad emotions to it (or any thoughts and emotions to it, for that matter). He stated that because of his experience with the MBTSR class he now can "just be" with the sensation moment to moment, and experience it as a bare sensation, not something that is destroying his life.

Role of the Group Facilitator

The group facilitator was well received by the participants. She was found to be both supportive and knowledgeable.

Discussion

The present study highlights the potential benefit of MBTSR as an intervention for chronic tinnitus. Quantitative results indicated that there was moderate to large improvement with respect to reduced tinnitus annoyance and awareness, increased mindfulness (specifically for non-judging of inner experience or refraining from evaluations of one's cognitions, sensations, and emotions), reduction in mood disturbance (primarily for depression, phobic anxiety, and somatization), and meaningful improvements in patient well-being and quality of life. A comparison of the quantitative and qualitative data demonstrates the cross-validity of participants' responses regarding certain aspects of functioning, including enhanced well-being and reduced depression, anxiety, somatization, and sleep difficulty.

Qualitative findings from the PIFF and participant comments also suggest that within this small group there was a reduction in the need for sleep medication, change in how participants experienced and accepted their bodies, and a marked shift in their perception of tinnitus. Across the board, subjects expressed that they had a positive experience with the intervention, and noticed a positive change in their day-to-day lives. No adverse events were reported, and participants felt that MBTSR was safe and accessible for people with chronic tinnitus.

The small number of participants, lack of an active control group, use of only subjective endpoints for measurement, and the absence of follow-up data all impede generalizability and preclude any definitive statement about effectiveness of MBTSR at this time. The time required for involvement in the MBTSR intervention is demanding and for this reason, may dissuade patients from choosing to participate. It is also labor-intensive for the group facilitator to be both trained and lead the MBTSR course. This may

prevent many clinicians from wanting to be trained in the method. The present research is an exploratory study and based on the results we will be better able to appropriately power future studies. Future studies may choose to explore whether the number of hours of home practice and participants' reading of course materials are significantly correlated with the degree of change in tinnitus severity perception and quality of life. Use of a group facilitator who does not have access to participant data, combined with a research investigator who does not have contact with participants for the length of the study, may help control for experimenter bias, subject expectancy, and attention from the facilitator. While perception of tinnitus severity and awareness appeared to improve over the 8-week MBTSR intervention, lack of follow-up data makes it unclear if benefits of the intervention are only available during the length of the intervention.

It is not clear whether the mechanisms for positive changes can be better accounted for by the psychological benefits of participating in the group rather than any reduction in tinnitus distress, per se. One participant mentioned that they gained significant insight into their experience with tinnitus by "just being in the group discussing a problem that everyone is sharing." This comment may point to the fact that non-specific effects of the treatment, such as group support, may have influenced treatment benefit. The attention paid to participants by the group instructor may also have had an influence on treatment results. A future study may wish to include an active control group, such as an 8-week Tinnitus Instructional Counseling Program covering topics such as nutrition, exercise, sleep management, and cognitive counseling without the training in mindfulness meditation component. Including an active control group such as this may help to account for possible group effects and the effects of attention paid to subjects.

Results from the study of Sadlier et al. (2008) indicated significant reductions in tinnitus variables in both the active and wait-list control groups using a combination treatment of CBT and meditation offering four 1-h sessions to participants. Using a 6-week program, Philippot et al. (2011) also found that for interventions targeting the psychological consequences of tinnitus, training in mindfulness may be a useful addition to psychoeducation. The findings of the present study extend the results of previous research of Sadlier et al. (2008) and Philippot et al. (2011) by implementing the MBTSR program. The current study follows more closely the 8-week MBSR program including a full day of mindfulness practice (Kabat-Zinn 1982, 2005), validated for duration and content, while tailoring the MBSR program to specifically address the management of tinnitus. Philippot et al. (2011) reported that participants found the 6 weeks of training insufficient. Another important distinction between the current study and the Philippot et al. (2011) study is the implementation of the MBSR method, applied mostly to the treatment of somatic symptoms and psychological conditions, rather than the MBCT method applied mainly for the treatment of treatment resistant depression. Further studies with larger samples, active control groups, and follow-up measurements are indicated to confirm our results and to explore the mechanisms of such healing effects.

Observed trends in the data, if duplicated in a larger study, would provide significant subjective benefit to people suffering with tinnitus after participating in an 8-week MBTSR training program. The current study adds to the literature by exploring a mindfulness-based intervention that is specifically focused on managing tinnitus symptoms. Should further research confirm the current findings, MBTSR is likely to be an effective adjunct treatment for chronic tinnitus.

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