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A Randomized Controlled Trial of Cognitive-Behavior Therapy for Tinnitus

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Abstract: This study is a randomized, waitlist-controlled trial testing the effect of a brief, "manualized," cognitive-behavioral group therapy on distress associated with tinnitus, quality of well-being, psychological distress including depression, and internal focus. Cognitive-behavioral therapy (CBT) included training in activity planning, relaxation training and, primarily, cognitive restructuring. Sixty-five participants were recruited, and 41 completed treatment. Participants were randomly assigned to receive 8 weeks of manualized group CBT either immediately or after an 8-week waiting period. Participants completed outcome measures at the time of their random assignment and at 8, 16, and 52 weeks later. Repeated-measure analysis of covariance revealed significant group-by-time interactions on measures of tinnitus distress and depression, indicating that CBT led to greater improvement in those symptoms. The current results suggest that CBT, applied in a group format using a manual, can reduce the negative emotional distress, including depression, associated with tinnitus.

Key Words: cognitive-behavior therapy; tinnitus

Cognitive-behavioral therapy (CBT) is efficacious as an intervention for psychological disorders: depression [1], anxiety disorders [2], physical disorders (nonspecific pain [3–5], spinal and low back pain [6–9], temporomandibular disorders [10,11], and other medical conditions). Research on the effects of CBT on tinnitus-related outcomes has begun to accumulate, and results are promising. A recent meta-analysis of randomized, controlled trials of CBT for tinnitus concluded that though tinnitus loudness does not seem to be affected by CBT, the quality of life for patients with tinnitus increases after CBT [12]. Incidentally, the conclusion regarding tinnitus loudness is not surprising because loudness has not been associated with distress due to tinnitus [13,14] and has not been the focus of CBT for tinnitus. In this meta-analysis, quality of life was operationalized as a "decrease of global tinnitus severity" and was measured with quality-of-life questionnaires specific to tinnitus: the Tinnitus Handicap Questionnaire, the Tinnitus Questionnaire, and the Tinnitus Reaction Questionnaire. Overall, CBT was found to have a moderate to strong effect on tinnitus-related quality of life. In fact, it was concluded that CBT increases quality of life for tinnitus sufferers significantly more than absence of intervention (waitlist control) and more than other psychological interventions [12]. However, currently unclear is whether CBT for tinnitus improves global health-related quality of life or improves only tinnitus-specific quality of life.

For several reasons, CBT may be helpful with managing tinnitus. Research has shown that tinnitus sufferers with higher levels of attention to their thoughts, feelings, and bodily sensations have greater perceived tinnitus handicap [15], and CBT may modify this attention. Maladaptive coping has been associated with higher levels of perceived tinnitus severity [16], and CBT provides training in coping skills. Individuals with tinnitus who

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report higher levels of distress also report higher levels of dysfunctional thinking about tinnitus [14]. CBT teaches individuals to be mindful of their thoughts and to look for evidence that challenges negative or dysfunctional thoughts. Finally, CBT is an effective treatment for depression and anxiety [17,18], which are problems known to be associated with tinnitus [14].

Interestingly, despite the strong association between tinnitus and depression and the well-documented treatment effects of CBT for depression, research has been inconclusive about whether CBT decreases depression for tinnitus sufferers. Small decreases in depression have been found in some [19] but not all studies of CBT for tinnitus [12]. Some researchers have suggested that more studies in this area are necessary [12,19]. It is also possible that the CBT interventions investigated in past studies have included components that are relatively less effective in alleviating depressive symptoms. Components of CBT vary; for example, relaxation techniques, cognitive restructuring, increasing pleasant activities, and goal setting may be more helpful for tinnitus, whereas others may be more helpful for depression [20].

In summary, CBT has been shown to decrease the levels of tinnitus annoyance and increase tinnitus-related quality of life. However, currently unknown is whether global quality of life that is nonspecific to tinnitus can be improved with CBT. Additionally, CBT interventions have not been able to show conclusively that CBT decreases depressive symptoms. For tinnitus-related depression, the most benefit might be gained from a CBT intervention that highlights cognitive restructuring versus relaxation techniques. Theoretically, attentional control training should also be included in a CBT package and, to date, measures of internal focus (attention to bodily sensations and thoughts) have not been included as outcome measures in the evaluation of CBT on tinnitus. This study investigated the effects of a "manualized" CBT for tinnitus—that is, therapy that was modeled after a CBT manual for depression and was administered in a group format. Assessments were made after treatment and 1 year later and included measures of tinnitus-related quality of life, global quality of life, depression, psychological distress, and internal focus.

METHODS

Participants and Procedure

Participants enrolled in the study either through referral by their medical provider or by self-referral. Staff at the University of California–San Diego (UCSD) or the VA San Diego Healthcare System (VASDHC) otolaryngology or audiology clinics asked patients for permission to have a researcher contact them. Patients who agreed were then contacted by one of the research staff involved with this study. Some individuals responded to a flyer from the American Tinnitus Association or from their local audiologist.

The primary inclusion criterion was self-reported distress due to tinnitus; no level of severity or frequency of tinnitus was required. To allow for a broad and representative sample, exclusion criteria were only factors that interfered with patient ability to participate in a group for physical (e.g., unable to get to group) or psychological reasons (e.g., psychosis or dementia).

Once contacted, a member of the study staff described the study to the potential participant. If a participant was interested, a research assistant scheduled an appointment during which the participant provided consent and completed the initial assessments. Neither the staff nor the participant knew to which arm the participant was randomly assigned until after completion of initial assessments. Random assignment was made using a random number generator, and each participant had an equal chance of being assigned to begin treatment either immediately or after an 8-week waiting period. The unit of randomization was individual participants. In other words, every participant had an equal chance of being assigned to either the treatment group or to the waitlist control group; the number of participants allocated to each group was not limited to a targeted group size designed to yield equal membership between groups.

Participants began treatment either immediately after their intake or after their 8-week assessment and completed additional follow-up assessments at 16 weeks and 52 weeks (Fig. 1). Research assistants who administered assessments were psychology doctoral students, psychiatry residents, or bachelor's degree nursing staff specializing in psychiatry. Participants received treatment at no cost. Initially, participants received no compensation; however, funding became available during the course of the study, and participants received $10 for assessments.

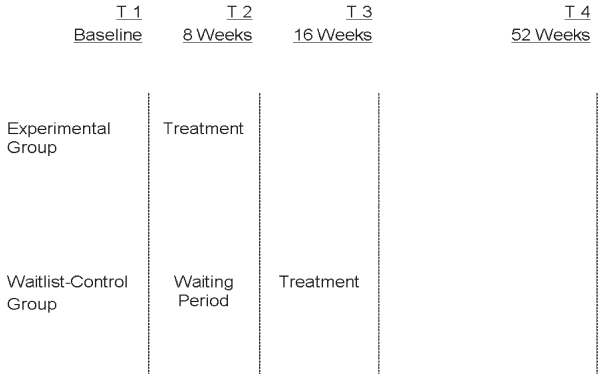

Figure 1. Treatment algorithm for participants. (*T* = time of assessment.)

Table 1. Topics Addressed at Each of the Eight Sessions of CBT

Session 1	Introduction: Thoughts, Behaviors, Stress, and Tinnitus
Session 2	Increasing Pleasant Activities
Session 3	Relaxation Techniques
Sessions 4–6	Cognitive Restructuring
Session 7	Goal Setting
Session 8	Summary and Review

Intervention

The intervention was eight sessions of manualized group CBT over 8 weeks (Table 1). The intervention emphasized cognitive restructuring, an increase in pleasant activities, and relaxation training. The intervention was based on a CBT group treatment manual for depression [21]. The original manualized treatment has been shown to be an effective intervention for depression [22]. The interventions in this study were modified to make them relevant to coping with tinnitus and stress in general. In addition, we modified the manual by adding relaxation techniques that have previously been shown to be efficacious for treating tinnitus. Homework assignments were given weekly and reviewed during the next session. (The manual created for this study can be obtained by contacting the first author [SKR].)

The first [SRK] and last author [JRM] trained all clinicians in the manualized CBT intervention. Clinicians were a psychiatrist [SRK] and master's-level clinicians (psychology doctoral students). Each clinician received weekly supervision from the first author throughout the study.

MEASURES

Tinnitus

Tinnitus severity was assessed using a one-item Likert scale, with 0 indicating "no problem" and 10 signifying "unbearable." Tinnitus annoyance was assessed using a one-item Likert scale (used in previous studies), with 0 indicating "not at all annoying" and 100 indicating "extremely annoying."

The (Iowa) Tinnitus Handicap Questionnaire (THQ) is a 27-item self-report questionnaire that assesses specific areas of tinnitus handicap and patients' perceived severity of the handicaps associated with tinnitus, including (1) the physical, emotional, and social consequences of tinnitus, (2) hearing ability of the patient, and (3) "the patients' view of tinnitus" [23]. Items are scored on a Likert scale from 0 to 100 ("strongly disagree" to "strongly agree"), with two items reverse-scored; total scores are presented in this study. Total scores have high internal consistency (Cronbach's $\alpha = .94$ [24]), high test-retest reliability ($r = .89$ [25]), and good construct validity [23].

The Tinnitus Reaction Questionnaire (TRQ) is a 26-item self-report questionnaire that measures psychological distress related to tinnitus, including general distress, interference with activities, severity of distress, and avoidance of activities [26]. Items are scored 0 to 4 ("not at all" to "almost all the time"); total scores are presented in this study. The TRQ has high internal consistency (Cronbach's $\alpha = .96$), test-retest reliability ($r = .88$), and good construct validity demonstrated by moderate to high correlations with measures of depression and anxiety ($r = .58–.87$) [26].

The Tinnitus Handicap Inventory (THI) is a 25-item self-report questionnaire that quantifies the effect of tinnitus on daily living by assessing functional, emotional, and catastrophic response reactions to tinnitus [27]. Items are scored 0, 2, 4 ("no," "sometimes," "yes"), and total scores are presented here. Test-retest reliability is high ($r = .92$), as is internal consistency (Cronbach's $\alpha = .93$) [27].

The Tinnitus (Effects) Questionnaire (TQ) is a 52-item self-report questionnaire, of which only 41 items are scored [28]. Items are scored 0–2 ("not true," "partly true," "true"), and total scores are presented here. This questionnaire assesses emotional-cognitive distress, intrusiveness, auditory perceptual difficulties, sleep disturbance, and somatic complaints [29]. Internal consistency (Cronbach's $\alpha = .93$) and test-retest ($r = .94$) reliability are high [30].

Internal Focus

The Modified Somatic Perception Questionnaire (MSPQ) is designed to measure somatic sensations and awareness of bodily sensations [31]. The MSPQ is a 13-item self-report questionnaire with items scored 0 to 3 ("not at all" to "extremely/could not have been worse"). Total scores are presented here. Test-retest reliability (all items: $r \geq .60$) is good. Construct validity has been shown by its relationship to emotional distress; for example, a correlation of .54 to the Zung Depression Inventory has been found [31].

The Private Self-Consciousness Scale (PSC) is a subscale of the Self-Consciousness Scale, a self-report questionnaire designed to assess stable dispositions of self-focused attention—that is, internal thoughts, sensations, and feelings [32]. Ten items are scored 0 to 4 ("extremely uncharacteristic" to "extremely characteristic") with total scores presented. The test-retest reliability is .79 [32].

Psychiatric Symptoms

The Hamilton Rating Scale for Depression 17-Item Version (HRSD) is an interview assessment of depressive

symptoms and severity [33]. Items are scored 0–2 or 0–4 ("symptom not present" to "present in an extreme form"), and total scores are presented here. Previous studies have inter-rater reliability coefficients above .85 in seven of eight studies [34]. The HRSD has been found to correlate at .84 with clinical assessments of depression [35]. Scores higher than 17 indicate moderate to severe depression.

The Beck Depression Inventory (BDI) is a standard self-report measure of depressive symptoms [36]. The BDI has 21 items and is scored 0 to 4 ("not at all" to "extreme"); the total scores are presented here. It has been found to have high internal consistency for psychiatric and nonpsychiatric samples (Cronbach's $\alpha = .82$ in nonpsychiatric samples) and high content validity [37]. The BDI has been found to correlate at .77 with global clinical assessments [35].

The Symptom Checklist 90, revised (SCL-90-R), is designed to assess presence and severity of distress by participants experiencing symptoms of psychiatric disorders [38]. It includes 90 items scored 0 to 4 ("not at all" to "extremely"), and mean scores are presented here. Reliability is adequate [38], with Cronbach's α scores ranging from .77 to .97 [39].

Quality of Well-Being

The Quality of Well-Being Scale, (self-administered version (QWB-SA), is designed to assess patient's quality of well-being and functional impairment among patients with medical disorders [40]. The QWB is an 85-item questionnaire, with 79 items being scored as either yes or no. Items are weighted, and scores are presented as 0 to 1 ("dead" to "complete functioning"). Evidence for the construct validity of the QWB-SA has been presented [41]. Test-retest reliability of the QWB-SA has been shown, and QWB scores have been shown to be responsive to clinical change [42].

Data Analysis

The primary hypotheses were tested using orthogonal planned contrasts in a repeated-measures analysis of covariance (ANCOVA) with one between-participants factor (group: treatment versus waitlist) and one repeated factor with four levels (baseline, 8 weeks, 16 weeks, and 52 weeks). A separate ANCOVA was completed for each outcome measure. We tested the linear, quadratic, and cubic contrasts over time to determine whether change over time differed for the two treatment groups. We included the quadratic and cubic contrasts because we predicted that the curve over time would differ for our two groups. Specifically, we anticipated that those receiving immediate treatment would report lower tinnitus distress, psychological symptoms, internal focus, and improved well-being at 8 weeks but that, after 16 weeks (when the waitlist control condition had completed treatment), the two conditions would be equivalent—that is, that the waitlist condition would now have a significant decrease in symptoms leading to a nonlinear curve. Finally, we predicted that the main effect for time would be significant for all outcome measures.

We conducted a power analysis and identified a goal of recruiting 60 patients total, 30 per group, to be able to detect a moderate effect size at a power of .8 and a p value of .05 for our primary outcome.

For all measures, missing items on questionnaires were handled in one of two ways. If 90% of the items on a questionnaire were answered, we substituted the mean of the other items from the questionnaire for the missing data and calculated a total score. If fewer than 90% of the items had been answered, we did not calculate a total score for that measure.

Consistent with current statistical practices, we carried the last observation forward for any person having at least two data points among the outcome measures. All analyses used a p value of .05 to determine significance.

RESULTS

Participant Characteristics

Sixty-five participants consented to treatment and completed the baseline assessments. At baseline, participants ranged in age from 35 to 77 years (mean = 55.0; standard deviation = 11.28). Fifty-two percent of the sample was male. Eighty-eight percent of the sample was white. Forty-five percent of the sample had a college degree. Participants reported having experienced tinnitus for an average of 11.0 years (range, 1 month to 42 years). Two of the participants had experienced tinnitus for less than 6 months. Twenty-five percent of the sample had moderate to severe depression. Twelve percent of the sample reported their tinnitus to be "unbearably" severe, and 29% reported that they were "extremely" annoyed by their tinnitus. Unknown is how many patients had hearing loss, vertigo, or hyperacusis.

After completion of the baseline assessments, 38 participants were randomly assigned to the immediate treatment condition, and 27 participants were randomly assigned to the waitlist control condition. Mean pretreatment scores on outcome measures are shown in Table 2 for each group. The immediate treatment condition and the waitlist condition did not differ significantly in regard to age, gender, ethnicity, education, number of months with tinnitus, HRSD, BDI, SCL-90-R, TQ, THI, MSPQ, or PSC. Tinnitus severity was significantly higher in the immediate treatment condition than in the

Table 2. Mean Pretreatment Scores on Outcome Measures

	Experimental (Treatment) Group Mean (SD)	Waitlist-Control Group Mean (SD)
Tinnitus		
Duration in months	119.15 (117.82)	134.50 (151.56)
Severity*	7.70 (1.63)	6.70 (2.30)
Annoyance	81.06 (25.64)	72.87 (27.94)
THQ	59.18 (24.52)	47.55 (24.33)
TRQ*	53.00 (22.54)	38.04 (23.40)
THI	60.21 (22.08)	50.82 (26.24)
TQ	47.93 (14.19)	42.55 (17.27)
Internal focus		
MSPQ	8.89 (6.03)	7.38 (7.98)
PSC	20.90 (6.83)	20.66 (7.21)
Psychiatric		
HRSD	12.79 (7.74)	11.37 (6.16)
BDI	16.32 (11.03)	13.16 (7.20)
SCL-90-R	1.17 (0.73)	1.01 (0.67)
Quality of well-being	0.49 (0.16)	0.57 (0.13)

BDI = Beck Depression Inventory; HRSD = Hamilton Rating Scale for Depression; MSPQ = Modified Somatic Perception Questionnaire; PSC = Private Self-Consciousness Scale; SCL-90-R = Symptom Checklist 90, revised; SD = standard deviation; THI = Tinnitus Handicap Inventory; THQ = (Iowa) Tinnitus Handicap Questionnaire; TQ = Tinnitus (Effects) Questionnaire; TRQ = Tinnitus Reaction Questionnaire.
*$p < .05$.

waitlist condition (F[1,64] = 4.139; p = .046). The TRQ score was also significantly higher in the treatment group than in the waitlist condition (F[1,64] = 6.657; p = .012).

Twenty-six of 38 participants in the treatment condition and 15 of 27 participants in the waitlist condition completed at least six sessions (of a total of eight possible sessions), for a total of 41 "completers." Twenty-four participants (37%) were unable to complete the study. Seven participants dropped out because of comorbid medical conditions. Nine participants reported being too busy to attend at least six sessions. Two participants decided they did not feel distressed enough to make participation worth the effort. Two participants decided they did not wish to make the commute from Los Angeles to San Diego. One participant relocated during the trial. Three participants completed the intervention but did not provide the 8-week follow-up data.

Study noncompleters had experienced tinnitus for significantly longer than had completers (F[1,60] = 5.565; p = .022). Completers were more likely to have finished college than were non-completers (χ^2 [1, n = 65] = 5.925; p = .020), and we noted a trend for completers to have more severe tinnitus (F[1,63] = 3.753; p = .057). There were no significant differences between the completers and non-completers on demographic variables (i.e., age, gender, ethnicity) or on the primary outcome measures (HRSD, BDI, SCL-90-R, MSPQ, PSC, THQ, TQ, TRQ, THI, QWB-SA) or on the number of people in the immediate treatment or waitlist condition that completed treatment.

Tests of Hypotheses

The primary test of each hypothesis (improvement in tinnitus-related quality of life, global quality of life, psychological distress, and internal focus) was a treatment group–by–time period ANCOVA, with a test of the quadratic function, on all of the outcome measures: tinnitus, psychiatric symptoms, internal focus, and quality of well-being. To reduce unaccounted variance, we included gender, age, education, and duration of tinnitus as covariates.

Among the tinnitus measures, only the TRQ showed a significant group-by-time interaction (F[3,120] = 3.18; p = .03). The planned contrasts demonstrated a significant quadratic effect (F [1,40] = 5.74; p = .02) and cubic effect [F (1,40) = 6.59; p = .01]. Post hoc analysis indicated that significant change occurred from baseline to time 2 (8 weeks) for the TRQ (in the hypothesized direction). This change was not maintained at times 3 (16 weeks) and 4 (52 weeks; Fig. 2).

Among the psychiatric measures, the BDI showed a significant group-by-time interaction (F[3,117] = 3.82; p = .01). The contrasts demonstrated a quadratic effect (F[1,39] = 6.78; p = .01) and cubic effect (F[1,39] = 7.72; p = .01). Post hoc analysis indicated that significant change occurred from baseline to time 3 and was maintained to time 4 (in the hypothesized direction; Fig. 3). Additionally, the SCL-90-R showed a significant group-by-time interaction (F[3,87] = 5.542; p = .01). The contrast demonstrated a quadratic effect (F[1,29] = 14.800; p = .01) and cubic effect (F[1,29] = 5.659; p = .02). Post hoc analysis indicated that significant change occurred from baseline to time 2, baseline to time 3, and baseline to time 4 (Fig. 4).

There were no significant results for internal focus and quality of well-being.

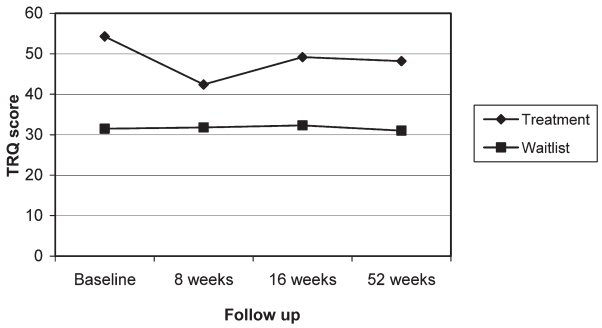

Figure 2. Tinnitus Reaction Questionnaire (*TRQ*) scores from baseline to 1-year follow-up for waitlist and immediate treatment.

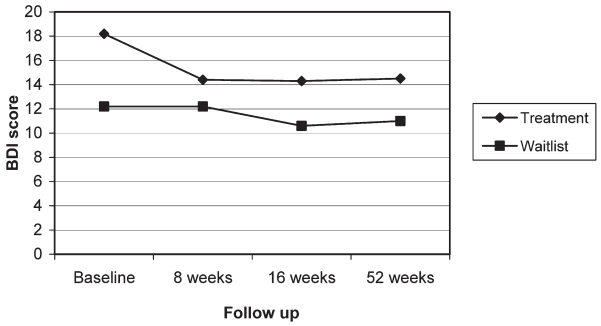

Figure 3. Beck Depression Inventory (*BDI*) scores from baseline to 1-year follow-up for waitlist and immediate treatment.

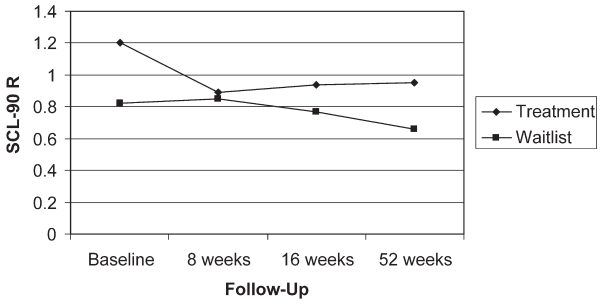

Figure 4. Symptom Checklist 90, revised (*SCL-90-R*), scores baseline to 1-year follow-up for waitlist and immediate treatment.

DISCUSSION

Similar to the results of other studies investigating CBT for tinnitus, this study found significant improvements in tinnitus distress as compared to a waitlist control. However, we found significant results on only one of four tinnitus measures. Possibly this intervention was too brief, and perhaps additional components could lead to better outcomes. It is also reasonable to consider that our high dropout rate may have contributed to our difficulty in detecting improvements on all measures. One important consideration should be that there was no severity requirement to enter this study. General studies that have required high severity of tinnitus to enter have found more positive results. Only 12% of our patients reported unbearably severe tinnitus, and only 29% reported that they were extremely annoyed by their tinnitus.

Our study found improvements in depression on the basis of BDI but not on the HRSD; this is similar to the results from meta-analyses [12,19]. This study also found improvements in overall psychiatric symptoms on the SCL-90-R. Improvements were seen on only one of two depressive measures, possibly because depression was not specifically addressed in the group sessions. Also, possibly a floor effect impaired our ability to detect a change in depression because only 25% of our patients were moderately or severely depressed. Though the CBT intervention had a component designed to educate participants about attention control techniques, such as increasing pleasant activities and relaxation techniques, a reduction in internal focus after treatment was not found. Despite the instruction on increasing pleasant activities and use of relaxation techniques, the possibility of using these or other techniques as distraction from tinnitus was not explicitly stated to the participants. It is also possible that distraction is not the ideal approach with tinnitus, and a more mindful approach may be more fruitful. Finally, despite improvement in tinnitus-related quality of life (as measured by the TRQ) and depression (as measured by the BDI), global quality of life (QWB-SA) did not improve, suggesting that the benefits from this treatment do not generalize.

This study suggests that the current intervention provided some initial relief from tinnitus distress, but the benefits were not maintained. Despite failure to maintain improvements in diminishing tinnitus distress, improvements in lessening depressive symptoms were sustained on the basis of the BDI. This study indicates that this treatment needs refining to address long-term maintenance of treatment gains and to target tinnitus symptoms more directly. Future studies could also benefit from assessing patient satisfaction and assessing which components are most effective.

Strengths of this study include a manualized intervention that can be used by others to replicate results and a waitlist control condition. However, waitlist controls may not be optimal because the condition does not discern whether improvement was due to CBT techniques or to nonspecific factors, such as the opportunity to receive feedback and support from other group members. Ideally, a control condition in which participants meet in a group setting with a health care professional without receiving treatment would shed light on whether improvement was associated with therapy or nonspecific factors. This type of control condition has been used in other areas in which participants have been provided with general health information about topics other than the topic under study (e.g., diet and exercise information, the importance of breast, prostate, skin, or colorectal cancer screening). However, the waitlist condition does control for natural recovery.

Limitations of this study include the use of blind raters only at the end of the study instead of throughout the entire study and the absence of external validation of adherence to our treatment manual. Additionally, all tinnitus measures were of the self-reporting type. We conducted no objective measures of tinnitus, such as tinnitus matching. Though this may be seen as a limitation by some, little evidence demonstrates that CBT would produce a change in tinnitus matching based on pitch and frequency of tinnitus.

Interesting questions about CBT and its use in the treatment of distress related to tinnitus, which ought to be studied in the future, include the optimal length of each session, optimal number of sessions and use of booster sessions, an assessment of which skills learned were helpful and which were not helpful, and whether a specific subgroup of tinnitus patients exists for whom CBT would be beneficial. In our study, participants who were more distressed were more likely to complete treatment. Possibly, CBT is very effective for those who are distressed but not for those who are not distressed. Additionally, the etiology of tinnitus may be correlated to those responding to a certain type of treatment. Looking for mediators of response to treatment may also be important; for example, tinnitus patients who use more effective coping skills may benefit more than tinnitus patients who do not use effective coping skills. Future studies should address each of these questions, and consideration should be given to combining treatment approaches, such as medications and therapy to provide optimal outcomes—as is often seen in depression and anxiety studies.

In conclusion, evidence from this and other studies suggests that CBT is helpful at decreasing distress related to tinnitus; however, more research is needed in determining whether there is a specific group of participants who benefit, what the crucial elements of treatment are, and how long treatment should last. Thought should be given to establishment of a network of tinnitus researchers across the country and around the world to implement studies with a sufficiently large and diversified population to answer these questions.

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