

Psychophysiological Treatment of Chronic Tinnitus: A Randomized Clinical Trial

WINFRIED RIEF, PhD, CORNELIA WEISE, DIPLPSYCH, NADINE KLEY, DIPLPSYCH, AND ALEXANDRA MARTIN, PhD

Background: Tinnitus seems to be associated with psychophysiological over-activation (e.g., of head and shoulder muscles). Therefore we aimed to develop and evaluate a new intervention program including a psychophysiological approach. **Methods:** Forty-three tinnitus sufferers were randomized to 2 groups, one receiving a psychophysiological intervention lasting 7 intervention sessions (plus 2 assessment sessions), whereas the other group waited for a comparable time period. Afterward, patients on the waiting list also received the intervention. Physiological variables were muscle activity of head and shoulders and electrodermal activity. Psychological assessments took place at pretreatment, post-treatment, and 6 months later. Follow-up data were available from 95% of participants. Major outcome variables were self-rating scales (e.g., tinnitus annoyance assessed by the Tinnitus Questionnaire), and diary data (self-control, daily time of perceiving the tinnitus). **Results:** On most tinnitus specific variables, patients in the treatment group improved significantly more than patients on the waiting list. Main effect sizes for tinnitus-specific variables were up to 0.89. Muscle reactivity of head muscles at the beginning predicted significant treatment effects. **Conclusion:** Compared with meta-analytical reviews of psychological interventions for tinnitus sufferers, the presented treatment is brief and in the upper range of effectiveness. **Key words:** tinnitus, physiological activity, biofeedback, self-control, cognitive-behavioral therapy, randomized clinical trial.

ES = effect size; GSI = General Symptomatic Index (mean score of Brief Symptom Inventory); IG = intervention group; MG = merged group; SCL-90R = symptom check list; TQ = Tinnitus Questionnaire; WLG = waiting list group.

INTRODUCTION

The prevalence of the presence of ear noise in the absence of auditory stimulation is about 10 to 15%. This sensation is often heard as a ringing or buzzing sound and is called tinnitus. If the tinnitus is chronic (duration >6 months) spontaneous remission is rare. Many people with tinnitus can cope successfully, although a subgroup of 1 to 2% of the general population suffer from highly disabling ear noises, with frequently developing comorbid problems such as depression, demoralization, avoidance behavior, social withdrawal, etc.

Although medical treatment for chronic tinnitus typically does not eliminate the ear noises if it is chronic, psychological interventions have been shown effective in reducing tinnitus-related distress (1). In a meta-analytical review, Andersson and Lyttkens (2) summarized controlled studies of psychological tinnitus treatments and found effect sizes in the range of 0.5 to 0.86, and for follow-up data $d = 0.48$. Especially for long-term effects, psychological interventions seem to be beneficial compared with medical treatment (3,4). Kröner-Herwig et al. (5) suggest a sequential scheme for the treatment of chronic tinnitus based on cost-effectiveness considerations. Andersson and Kaldo (6) developed an internet-based cognitive behavioral therapy program for tinnitus to provide a psychological intervention on a low-cost basis.

One problem in providing psychological interventions for tinnitus sufferers is the discrepancy between patients' organic illness attributions and the psychological intervention ap-

proach. As treatment expectations are strong predictors for treatment selection and treatment outcome, we have to be aware that a lot of tinnitus sufferers do not accept psychological interventions. A telephone interview of more than 3000 tinnitus sufferers in Germany revealed that 81% of them were seeking medical treatment, especially in ear, nose, and throat (ENT) offices. However, only 2% received psychological interventions (7). Therefore, it might be helpful to combine psychological interventions with physiological approaches to increase the treatment acceptance. Further evidence to include physiological variables in the treatment of tinnitus comes from a recently published experiment. We demonstrated that tinnitus sufferers have increased muscle reactivity (e.g., electromyographic activity of trapezius and masseter muscles). Heart rates also increased while listening to their own tinnitus and while listening to an external tinnitus simulation compared with listening to enjoyable music (8). In sum, this study indicated that tinnitus might be associated with increased physiological reactivity (e.g., in the head and shoulder muscles).

Considering the organic illness attribution of patients and the psychophysiological correlates of tinnitus, it seems useful to develop a treatment program combining the well-founded psychological approaches with the assessment and feedback of physiological variables. We hypothesize that this biofeedback-oriented approach will be effective and highly acceptable for tinnitus sufferers. We will not use the term biofeedback in this article, because this term is sometimes associated with mere training of reduction of physiological activity, whereas our approach combines physiological attempts with cognitive and behavioral strategies. As a first step in the evaluation of this new treatment approach, we wanted to demonstrate its efficacy in comparison to a waiting list group. The results of this evaluation are reported in this article.

METHODS

Sample

Inclusion criterion was the persistence of tinnitus for at least 6 months, and participants had to agree that the tinnitus was disturbing. They rated tinnitus annoyance on a visual analogue scale from 0 to 10; only subjects with ratings >3 were included. The sample size was determined to allow the

From the Department of Clinical Psychology, University of Marburg, Germany.

Address correspondence and reprint requests to Winfried Rief, Department of Clinical Psychology and Psychotherapy, University of Marburg, Gutenbergstrasse 18, D- 35032 Marburg, Germany. E-mail: rief@staff.uni-marburg.de

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detection of effect sizes greater than 0.7 with a statistical power of 0.8. Forty-three tinnitus sufferers fulfilled the inclusion criteria. Only 2 of them discontinued treatment; all of the other patients participated until follow-up (95% completers; 1 patient declined treatment after the first assessment resulting in 42 patients with complete data at the beginning; the other drop-out subject discontinued treatment after a few treatment sessions). Details about sample characteristics are shown in Table 1, whereas design and patient flow according to the CONSORT criteria are shown in Figure 1.

Procedure

We announced the provision of a new treatment approach for chronic tinnitus sufferers in ENT-offices, on the website of the tinnitus self-help group, as well as in local newspapers. If patients fulfilled the inclusion criteria, they were randomized either to a waiting list group (8 weeks) or to the treatment group. A list of a random sequence was prepared at the beginning of the study specifying the sequence of intervention versus waiting condition; subsequent patients fulfilling inclusion criteria got the next condition indicated on the list. No blinding procedure was used. Eight weeks later the second assessment took place. At this point treatment was started for the

waiting list group, and another 8 weeks later, post-treatment assessment for this group was conducted. In both groups, 6 months after the end of treatment a follow-up investigation took place (see Figure 1). All investigations and treatment sessions took place in the psychotherapy outpatient clinic at the University of Marburg, Germany. The recruitment period was from October 2002 until December 2002, while the follow-up assessments took place from June 2003 until November 2003.

Assessment Instruments

Primary outcome measure was global tinnitus severity/tinnitus annoyance as assessed by the total score of the Tinnitus Questionnaire. This is a 52 item self-rating scale originally developed by Hallam (9), translated into German, and modified by Goebel and Hiller (10). Whereas the total score of the Tinnitus Questionnaire (TQ) is the sum of items, the instrument also allows the computation of subscales; the most relevant ones are tinnitus associated cognitive distress and emotional distress. Retest reliability varies from 0.94 (total score) to 0.89 (emotional distress, cognitive distress), and split-half-reliability is again very high (0.93). Total scores above 30 indicate medium

TABLE 1. Sample Characteristics

Variable	First Intervention Group	Waiting List Group	Significance
N	22	20	
Age	45.5 (12.8)	48.0 (15.3)	$T = .57$; $df = 40$; NS
Percent females	40.9%	60.0%	$\chi^2 = 1.53$; $df = 1$; NS
Married	63.6%	65.0%	$\chi^2 = 3.35$; $df = 4$; NS
Illness duration (years)	4.5 (5.3)	8.3 (7.7)	$T = 1.85$; $df = 40$; NS
Illness severity (0 . . . 10)	6.5 (1.7)	5.9 (1.6)	$T = 1.2$; NS
Comorbid depressive disorder	36.4%	35.0%	$\chi^2 = 0.1$; NS
Emotional distress 1st assessment (0–24; TQ)	9.18 (4.6)	9.40 (3.6)	$F = 0.03$; $df = 1,41$; NS
Emotional distress 2nd assessment (0–24; TQ)	6.77 (3.9)	10.15 (4.3)	$F_{interaction} = 9.66$; $df = 1,41^{**}$ pre-post: $g = 0.83$
Cognitive distress 1st assessment (0–16; TQ)	5.68 (3.9)	5.70 (3.2)	$F = 0.00$; $df = 1,41$; NS
Cognitive distress 2nd assessment (0–16; TQ)	4.86 (3.4)	6.45 (3.9)	$F_{interaction} = 3.67$; $df = 1,41$; $p = .063$ pre-post: $g = 0.44$
Tinnitus distress 1st assessment (0–84; TQ total score)	32.32 (15.4)	33.95 (9.2)	$F = 0.17$; $df = 1,41$; NS
Tinnitus distress 2nd assessment (0–84; TQ total score)	27.14 (13.3)	36.25 (15.4)	$F_{interaction} = 6.74$; $df = 1,41^*$ pre-post: $g = 0.64$
Self-efficacy 1st assessment	28.55 (4.7)	28.10 (5.1)	$F = 0.09$; $df = 1,41$; NS
Self-efficacy 2nd assessment	30.77 (5.3)	27.75 (5.4)	$F_{interaction} = 6.53$; $df = 1,41^*$ pre-post: $g = 0.56$
Psychological symptoms 1st assessment (GSI)	0.68 (0.5)	0.56 (0.4)	$F = 0.55$; $df = 1,41$; NS
Psychological symptoms 2nd assessment (GSI)	0.57 (0.4)	0.60 (0.4)	$F_{interaction} = 1.62$; $df = 1,41$; NS pre-post: $g = 0.08$
Health life satisfaction 1st assessment	43.95 (39.7)	46.80 (34.3)	$F = 0.06$; $df = 1,41$; NS
Health life satisfaction 2nd assessment	63.22 (36.4)	47.20 (35.4)	$F_{interaction} = 4.40$; $df = 1,41^*$ pre-post: $g = 0.45$
Tinnitus loudness (diary) 1st assessment	4.84 (1.8)	4.62 (1.2)	$F = 0.18$; $df = 1,40$; NS
Tinnitus loudness (diary) 2nd assessment	4.57 (2.0)	4.39 (1.4)	$F_{interaction} = 0.03$; $df = 1,40$; NS pre-post: $g = 0.10$
Time per day listening to tinnitus (diary) 1st assessment	480.41 (349.3)	515.14 (300.6)	$F = 0.12$; $df = 1,40$; NS
Time per day listening to tinnitus (diary) 2nd assessment	427.43 (352.3)	503.14 (337.4)	$F_{interaction} = 0.68$; $df = 1,40$; NS pre-post: $g = 0.22$
Controllability (diary; 0 . . . 10) 1st assessment	1.01 (1.7)	1.29 (1.6)	$F = 0.30$; $df = 1,40$; NS
Controllability (diary; 0 . . . 10) 2nd assessment	3.03 (1.8)	1.40 (1.9)	$F_{interaction} = 18.87$; $df = 1,40^{***}$ pre-post: $g = 0.89$

* $p < .05$, ** $p < .01$, *** $p < .001$.

$$g_{Hedges} = \frac{\bar{X}_{EG} - \bar{X}_{CG}}{\sqrt{\frac{(n_{EG} - 1)s_{EG}^2 + (n_{CG} - 1)s_{CG}^2}{n_{EG} + n_{CG} - 2}}}$$

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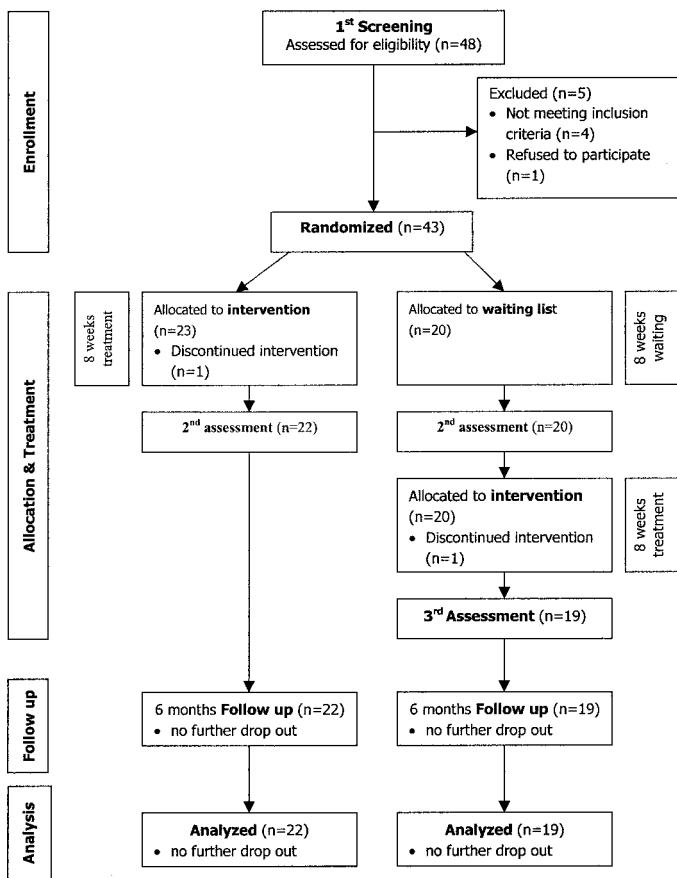


Figure 1. Design and patient flow.

distress, whereas total scores above 46 indicate serious tinnitus-associated distress.

Structured Tinnitus Interview

This is a structured interview that evaluates medical characteristics and psychological aspects in the development and maintenance of tinnitus (11).

International Diagnostic Check-List

For the most frequent mental disorders (12), the International Diagnostic Check List guidelines for structured interviews were used to assess ICD-10 diagnosis for depressive episode, dysthymia, panic disorder, agoraphobia, social phobia, and somatoform disorders.

Tinnitus Diary

For 1 week before treatment, 1 week at the end of treatment, and 1 week at follow-up, patients filled in a tinnitus diary rating the subjective loudness of their tinnitus, subjective control over their tinnitus (both on 0–10 scales) and the duration of their tinnitus perception (in minutes). Subjects were instructed to rate these variables three times per day, one rating for the morning hours (6–12 AM), one for the afternoon (12–6 PM), and one for the evening (6–12 PM).

Brief Symptom Inventory

This shortened version of the Symptom Check-List SCL-90R (13) asks for 53 mental and psychosomatic symptoms during the last 7 days.

Health-Related Life Satisfaction

This questionnaire assesses 8 health-related issues (such as “physical power” (14)); subjects have to rate the importance of each item, as well as

their satisfaction with the item, leading to a composite index for health-related life satisfaction.

Self-Efficacy

With 10 items, we assessed general self-efficacy (German adaptation of Bandura’s scale (15)).

Psychophysiological Assessment

During all treatment sessions, we assessed muscle activity of the frontalis-region, trapezius-region (neck), the masseter-region (jaw) as well as electrodermal activity. Registration was done by Flexcomp from Thought Technology Devices. Filters for most muscle activities were highpass >20 Hz with a notch filter at 50 Hz, whereas trapezius muscle activity was filtered band-pass 100 to 200 Hz to exclude artifacts of the heart activity. At the beginning and at the end of each session, subjects were instructed to relax for 5 minutes. This allowed the assessment of physiological relaxation responses and intra-session and inter-session comparisons. To compute mean scores for physiological activity, artifact correction consisted of the exclusion of data >SD.

The Treatment Program

Training consisted of 1 preassessment session, 7 treatment sessions, and a final session summarizing the intervention strategies and conducting the postassessment (see Table 2). All sessions lasted approximately 1 hour. The training was manual-guided and also included handouts (e.g., on the following topics: basic information on ear and the hearing system; information processes involved in tinnitus; the vicious circle of tinnitus annoyance, muscular reactivity, and selective attention; and aspects of tinnitus maintenance, modulating factors, coping strategies, etc.¹).

Therapists

Therapists were 5 graduate students under supervision of experienced psychotherapists.

Statistical Procedure

First we compared the baseline scores of the treatment and waiting list groups to analyze whether the randomization procedure resulted in comparable groups. Second, we compared pre- and post-scores of the treatment and the waiting list group using analysis of variance with one group factor and one repeated measurement factor. Treatment effects should result in significant interactions between these two factors. Moreover, we also computed effect sizes (ES) comparing treatment effects in the treatment group in relation to the control group (see formula, bottom of Table 1).

As the waiting list group also received treatment after the waiting period, we finally compared the pretreatment, post-treatment scores, and follow-up scores 6 months after treatment of both groups. To estimate the overall efficacy of the intervention, effect sizes comparing pre- versus post-scores and pre- versus follow-up-scores will be reported for both groups, as well as for the total sample (formula for effect size see Table 3, bottom). Because of the high completion rate, intend-to-treat analyses were not considered as necessary. Changes of physiological activity and other variables are analyzed as possible predictor variables using *t* and *F* statistics; if multiple predictors are found, regression analyses were planned.

RESULTS

Group Comparison of Baseline Scores

The treatment and waiting list groups did not differ on pretreatment scores such as tinnitus annoyance (TQ total score), psychological symptoms (Brief Symptom Inventory (shortened version of SCL-90R)), subjective loudness of tinnitus (diary), subjective duration of tinnitus perception per day

¹Training manual and handouts of the treatment are available from the first author on request.

TABLE 2. Session Ingredients

Session	Contents
Preassessment	Assessment (e.g., structured tinnitus interview, tinnitus questionnaire).
Session 1	Information about biofeedback, tinnitus, and hearing. Assessment of muscle activity and highly reactive physiological variables. Selection of highly reactive physiological variables.
Session 2	The Influence of stress, alertness, and cognitions on hearing and tinnitus. Demonstration of physiological reactions after distressing events (cognitive stressor). Training to modify physiological variables without further instruction (unstructured training).
Session 3	Selection of situations with negative effects on tinnitus; development of coping strategies for these situations. Training to modify physiological variables while listening to loud noise (emotional stressor).
Session 4	Evaluating and modifying tinnitus-cognitions. Generalization training to everyday situations. Training to modify physiological variables with and without feedback.
Session 5	Demonstration and training of relaxation techniques. Training to modify physiological variables while listening to the tinnitus during silent conditions (individual stressor).
Session 6	Information about effects of selective attention on tinnitus. Training to direct attention. Demonstration of effects of attention control on physiological variables.
Session 7	Training to modify physiological variables under individually most distressing conditions. Repeating the exercises.
Postassessment	Summarizing helpful strategies of the training. Summarizing the improvement after the training. Postassessment of the psychological variables.

TABLE 3. Comparison of Pretreatment, Post-treatment, and Follow-up Scores

Variable		Before Treatment	After Treatment	6 Months Later	ES
N		22	20		
Emotional distress (0–24; TQ)	IG	9.18 (4.6)	6.77 (3.9)	6.23 (5.7)	$g = 0.86. T = 5.45; p < .001$
	WLG	10.15 (4.3)	6.79 (4.3)	7.16 (4.14)	
	MG	9.49 (4.4)	6.78 (4.0)	6.66 (5.0)	
Cognitive distress (0–16; TQ)	IG	5.68 (3.9)	4.86 (3.4)	4.50 (4.1)	$g = 0.44. T = 2.85; p < .01$
	WLG	6.45 (3.9)	5.05 (3.9)	4.37 (4.0)	
	MG	5.85 (3.7)	4.95 (3.2)	4.44 (4.0)	
Tinnitus distress (0–84; TQ total score)	IG	32.32 (15.4)	27.14 (13.3)	24.82 (17.9)	$g = 0.72. T = 4.62; p < .001$
	WLG	36.25 (15.4)	28.47 (14.5)	28.11 (17.5)	
	MG	33.80 (15.3)	27.76 (13.7)	26.34 (17.6)	
Self-efficacy	IG	28.55 (4.7)	30.77 (5.3)	29.64 (4.6)	$g = 0.08. T = 0.52; NS$
	WLG	27.75 (5.4)	28.74 (4.9)	27.63 (5.9)	
	MG	29.02 (6.5)	31.34 (6.2)	30.49 (7.0)	
Psychological symptoms (GSI)	IG	0.68 (0.5)	0.57 (0.4)	0.53 (0.4)	$g = 0.34. T = 2.17; p < .05$
	WLG	0.60 (0.4)	0.42 (0.3)	0.48 (0.4)	
	MG	0.64 (0.5)	0.50 (0.4)	0.50 (0.4)	
Health life satisfaction	IG	43.95 (39.7)	63.22 (36.4)	54.00 (35.4)	$g = 0.09. T = 0.79; NS$
	WLG	47.20 (35.4)	62.68 (33.1)	46.53 (45.2)	
	MG	46.17 (37.5)	62.55 (34.8)	50.03 (40.3)	
Tinnitus loudness (diary)	IG	4.84 (1.8)	4.57 (2.0)	4.04 (2.0)	$g = 0.54. T = 3.45; p = .001$
	WLG	4.39 (1.4)	3.63 (1.3)	3.87 (1.7)	
	MG	4.64 (1.7)	4.12 (1.76)	3.97 (1.85)	
Time per day listening to tinnitus (diary)	IG	480.41 (349.3)	427.43 (352.3)	356.29 (323.6)	$g = 0.69. T = 4.37; p < .001$
	WLG	503.14 (337.4)	372.39 (289.1)	395.33 (316.3)	
	MG	487.60 (329.3)	401.29 (321.0)	373.85 (316.9)	
Controllability (diary; 0 . . . 10)	IG	1.01 (1.7)	3.03 (1.8)	2.35 (2.4)	$g = 0.63. T = 3.91; p < .001$
	WLG	1.40 (1.9)	2.55 (2.1)	1.94 (1.8)	
	MG	1.28 (1.8)	2.80 (1.0)	2.17 (2.1)	

IG = intervention group; WLG = waiting list group; MG = merged group.

$$\text{Effect Sizes: } g_{diff} = \frac{\bar{X}_{i2} - \bar{X}_{i1}}{\sqrt{s_{i1}^2 + s_{i2}^2 - 2r_{i1i2}s_{i1}s_{i2}}}$$

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(diary), self-efficacy or feelings of controllability (see Table 1; lines for first assessment). The intervention group and control group also did not differ on variables such as tinnitus location, mean tinnitus duration, tinnitus persistence for the whole day (90%), or hearing problems (57%).

Treatment Outcome

No patient reported spontaneously any side effects or adverse events of the treatment. Comparing pre- and post-treatment scores of the treatment group with the pre- and post-waiting scores of the waiting list group revealed significant interactions for most variables (see Table 1). For the main variable tinnitus annoyance, a significant interaction was found for the total score of the tinnitus questionnaire ($F = 6.7$; $df = 1,41$; $p < .05$). This effect was mainly attributed to a reduction in emotional distress in the treatment group ($F = 9.7$; $df = 1,41$; $p < .01$). Health-related life satisfaction and self-efficacy also improved substantially in the treatment group without significant changes in the waiting list group. No specific treatment effect was found for psychological symptoms (general symptomatic index of the Brief Symptom Inventory; this was mainly attributed to low baseline scores). The diary data revealed strong effects for an increase in controllability in the treatment group, whereas changes in tinnitus loudness were not specific to the intervention group. Although we found a substantial decrease in daily time perceiving the tinnitus in the treatment group, the statistical interaction failed to be significant because of high variance in both groups.

As the waiting list group got the same treatment after the waiting period, we combined the pre-, post-treatment, and follow-up data of both groups (see Table 3) to estimate the effect size of the treatment. The overall effect size for tinnitus annoyance (tinnitus questionnaire total score) was found to be 0.72, again mainly attributed to significant changes in emotional distress ($ES = 0.86$). Tinnitus loudness also decreased substantially, but because the waiting list group also decreased in this variable during the waiting period, this effect cannot be unequivocally attributed to the treatment. Substantial improvements were also found for feelings of controllability and daily time perceiving the tinnitus.

Physiological Data

It was expected that physiological data would show significant reductions in activity during the relaxation periods of session 1 and session 7. This was demonstrated for the frontalis activity ($F = 5.6$; $p < 0.05$) and masseter activity ($F = 5.5$; $p < 0.05$); for the neck muscle activity (muscle trapezius; $F = 0.1$; NS) no significant differences were found. Intra-session comparisons revealed significant reductions from the first to the last relaxation period for the frontalis activity ($F = 19.4$; $p < 0.01$), whereas differences failed to be significant for the other muscles.

Predictors of Treatment Success

Final analysis focused on possible variables predicting treatment outcome. For this reason, treatment success was computed as difference scores of the TQ at pretreatment minus follow-up. Considering the fact that 5 therapists were involved, group comparisons did not reveal a significant therapist effect. Gender of the patient was not shown to be a significant predictor ($t = 1.4$; $df = 40$; NS). Also comorbidity with mental disorders did not significantly predict treatment outcome, although a trend could be found ($t = 1.68$; $df = 40$; $p < .10$). Age and illness duration had only marginal associations with treatment success ($-0.10 < r < -.05$). Interestingly, some variables of physiological reactivity at pretreatment predicted treatment success: the greater the decrease in physiological activity of the frontalis ($r = -.43$; $p < .01$) and the masseter ($r = -0.48$; $p < .01$) during the first treatment session (activity during the last 5 minutes minus the first 5 minutes of the first treatment session), the more pronounced the treatment success. As these were the only significant predictors, multivariate analyses (e.g., regression analyses) were not performed. Baseline scores of tinnitus annoyance (TQ) and self-efficacy at pretreatment did not have any significant influence.

DISCUSSION

We developed a new treatment approach for chronic tinnitus sufferers that combined cognitive strategies with psychophysiological interventions. This study demonstrated that this new intervention approach resulted in significant improvements (compared with a waiting list group) in many tinnitus-specific variables. For most variables, the treatment effects were maintained or even improved during the 6-month follow-up. Only variables with small treatment effects (self-efficacy, health-related life satisfaction) showed no long-term effects.

The very low drop-out rate allows us to interpret the results with confidence. This low drop-out rate also demonstrates a high acceptance of the treatment. Moreover, the use of diaries to assess tinnitus-related variables can be considered a strong and conservative evaluation approach. Diary data highlighted a substantial increase in feelings of subjective control, which could be attributed to the treatment. Although there was some decrease over the follow-up period, the overall effect size was still 0.63. Although tinnitus loudness (diary data) also showed a significant reduction from pretreatment to follow-up, this reduction could not be attributed to the treatment because the waiting list group also showed a reduction in tinnitus loudness from the beginning to the end of the waiting period. Therefore it is possible that the assessment procedure and the use of diaries alone were already associated with the reduction of subjective tinnitus loudness. Another diary variable was the rating of how many hours per day patients were aware of ear noise. For this variable, we found a reduction from 483 minutes at baseline to 376 minutes at 6-month follow-up, which is a mean reduction of 22% or 107 minutes per day.

The effect sizes for the Tinnitus Questionnaire found in our study are in the upper range compared with the meta-analyt-

ical review of Andersson (2). The follow-up effect sizes of tinnitus-related variables are substantially better in this study than in the meta-analysis. Our data can be compared with results of the cognitive-behavioral intervention of a recently finished study by Hiller and Haerkötter (16). As sound therapy is frequently combined with counseling or cognitive-behavioral strategies (17,18), Hiller and Haerkötter investigated the additional use of a noise masker (behind-the-ear broadband white noise generator) to a cognitive-behavioral approach. Although they didn't find any additional effect for noise maskers, noise generators might offer another option to address more organic-oriented treatment needs of patients and to increase treatment acceptance.

The question arises why new psychological treatment strategies should be developed, if existing interventions have already demonstrated efficacy. However, not all patients with tinnitus accept a psychological intervention that is based merely on cognitive and behavioral strategies. Treatment motivation and acceptance can be a crucial point in psychological interventions for tinnitus sufferers (19). Therefore it is better to have 2 effective but different interventions to offer treatment options to patients with different interests. Kröner-Herwig et al. (5) suggest stepped-care approaches for tinnitus sufferers, with tinnitus education as a first step and intensive cognitive-behavioral therapy as a last step. This treatment cascade can now be expanded with our medium cost, psychophysiological oriented treatment. We expect that psychophysiological oriented treatment will be more acceptable to organically-oriented tinnitus sufferers than a purely psychological intervention. As others have pointed out, the physiological approach cannot only modify physiological activity but can also be a "Trojan horse" to introduce cognitive concepts to patients with strongly organic illness beliefs (20). Another new approach that is in the process of evaluation is transcranial magnetic stimulation (21). However, the greater acceptability of psychophysiological-oriented approaches versus purely psychological interventions needs to be tested in a new study involving more patients and specific instruments to assess treatment acceptance.

Although our analyses of predictor variables were exploratory in nature and should not be over-interpreted, we were surprised by the prediction of treatment success by physiological reactivity at the beginning of treatment. It may be that physiological reactivity is associated with tinnitus maskability, a variable that has been shown to predict tinnitus outcome in other studies (4). These results need to be confirmed by future studies. Although this study has the typical shortcomings of pilot studies (small sample size; lack of another treatment comparison group), its promising results prompt

further evaluation of this alternative treatment approach to tinnitus.

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