Available online at www.sciencedirect.com
SCIENCE DIRECT®
Behaviour Research and Therapy 43 (2005) 595–612
BEHAVIOUR RESEARCH AND THERAPY
www.elsevier.com/locate/brat

Does sound stimulation have additive effects on cognitive-behavioral treatment of chronic tinnitus?

Wolfgang Hiller*, Christian Haerkötter

Department of Clinical Psychology, University of Mainz, Staudingerweg 9, D-55099 Mainz, Germany

Received 17 November 2003; received in revised form 2 March 2004; accepted 28 March 2004

Abstract

Psychological and physiological habituation are major goals in the treatment of patients suffering from chronic tinnitus. This study evaluates whether sound stimulation provided by use of low level white noise generators (NG) enhances the effects of cognitive-behavioral treatment (CBT). 124 outpatients with tinnitus of >6 months received manualized group treatment and were randomly assigned to the NG/no NG conditions. Those with moderate tinnitus-related distress obtained four sessions focusing on education, while severely distressed subjects were treated according to a full 10-session CBT program. Outcome was assessed at post-treatment and at 6- and 18-month follow-up. No additive effects due to the NGs could be demonstrated. All groups improved significantly on measures of tinnitus-related distress, dysfunctional cognitions, general psychopathology, depression, hypochondriasis and psychosocial functioning. Beneficial effects of the NGs were only observed for patients with concurrent tinnitus and hyperacusis. As systematic physical stimulation of the auditory system does not further improve the effects of CBT, the importance and strength of psychological interventions are emphasized. The clinical relevance of recently developed "retraining" approaches accentuating physical stimulation should be reconsidered.

Keywords: Chronic tinnitus; Cognitive-behavioral treatment; Sound stimulation; Noise generators; Hyperacusis

*Corresponding author. Tel.: +49-6131-3922344; fax: +49-6131-3924623.
E-mail address: hiller@mail.uni-mainz.de (W. Hiller).

0005-7967/$ - see front matter © 2004 Elsevier Ltd. All rights reserved.
doi:10.1016/j.brat.2004.03.012

1. Introduction

Tinnitus is a medical symptom describing acoustic perceptions in the ear or in the head not related to environmental stimulation. It is usually not considered a disease by itself but rather part of underlying medical conditions such as sudden hearing loss, acoustic trauma, cochlear dysfunction, Menière's disease or neurological disorder (Vernon & Møller, 1995; Baguley, 2002). In many cases, however, no clear etiological factors can be detected. Medical cure is often not possible, especially when the tinnitus has already persisted for several months or even years.

Serious complications may develop from accompanying psychological and psychosomatic symptoms. Epidemiological findings indicate that while roughly one third of the general population experiences subjective noises at some time during their lives, about 1% are severely distressed and disabled (Davis, 1995). Many of these patients find it difficult to accept that no further medical treatments are available. Among the most frequent complaints are sleeping disturbances, hearing difficulties, social withdrawal and negative emotional reactions including anxiety, depression and anger (Hiller & Goebel, 1992; Rizzardo, Savastano, Maron, Mangialaio, & Salvadori, 1998; Folmer, Griest, Meikle, & Martin, 1999; Zöger, Svedlund, & Holgers, 2001).

Facing the limited value of medical treatments, several forms of psychological intervention have been developed during the last two decades. Andersson and Lyttkens (1999) conducted a meta-analysis evaluating the efficacy of these approaches. They concluded that cognitive-behavioral therapy (CBT) as applied by working groups in Sweden (e.g., Lindberg, Scott, Melin, & Lyttkens, 1989), Great Britain (e.g., Davies, McKenna, & Hallam, 1995), Australia (Henry & Wilson, 1996, 1998) and Germany (e.g., Kröner-Herwig et al., 1995; Kröner-Herwig, Frenzel, Fritsche, Schilkowsky, & Esser, 2003) was superior to other methods. CBT addresses problematic tinnitus-related cognitions, emotions and behaviors. Patients are informed about medical and psychological aspects of their tinnitus, they learn to draw their attention away from the noises, change unrealistic beliefs, and reduce avoidance and illness behaviors.

Another treatment approach was introduced some years ago from the biomedical fields of auditory neuroscience and otology (Jastreboff, 1990; Jastreboff & Hazell, 1993). It was suggested to apply continuous sound stimulation in order to enhance patients' habituation to the tinnitus. Habituation was defined as an adaptation process of the auditory system to reduce signal detection and perception. As a consequence, problematic emotional and autonomic reactions are expected to decrease. Jastreboff and Hazell (1993) recommended broadband noise generators (NGs) which produce a permanent, monotonous and "meaningless" buzzing (white noise). NGs can be attached behind the ears and worn like hearing aids. Since NGs provide a stable stimulation, it was assumed that they are superior to stimulation from usual environmental noise. This "retraining" approach is combined with counseling to enhance the patients' understanding and reduce false beliefs about the tinnitus. Although first data have been presented to demonstrate the efficacy of this treatment approach (McKinney, Hazell, & Graham, 1996; Berry, Gold, Frederick, Gray, & Staecker, 2002), controlled trials with adequate methodology are still lacking.

It remains unclear whether established CBT and sound stimulation/counseling are competing or complementary forms of treatment. The retraining method was not specifically designed to treat chronic tinnitus patients with severe psychological distress. However, from the perspective of CBT, sound stimulation seems to be an interesting technique because attentional processes (and associated interpretation) can be influenced directly. Habituation is also a major goal of CBT.

Furthermore, many tinnitus patients react in an oversensitive way to normal acoustic surroundings, adhere to the unrealistic hope to resume "absolute silence" and thus avoid numerous places and situations. As CBT aims to reduce such avoidance behaviors, permanent acoustic stimulation ("prescribed noise") could be used as a technique to enhance tinnitus acceptance and the interpretation of noise as unimportant.

The objective of the present study was to evaluate whether sound stimulation has additional effects over and above what can be achieved by CBT. We performed a randomized controlled trial treating chronic tinnitus patients either with or without NG. Another research question was whether a short treatment focusing on education would be sufficient for tinnitus patients with only moderate levels of distress. Our clinical experience showed that these patients are often not interested to participate in long treatment programs, although they actively seek professional help to better understand their complaints and improve their coping behaviors. Therefore, in addition to our standard CBT program consisting of ten weekly 120-min sessions, an abridged variant of only four sessions was developed. We evaluated the potentially additive effect of NGs also for these abridged treatments to enhance the comparability of our approach with the retraining method. Our general hypotheses were that both treatment conditions lead to clinically relevant improvements which are likely to be further enhanced through use of NGs.

2. Method

2.1. Design

This study was conducted at the Outpatient Department of the Psychological Institute of the University of Mainz, Germany. Patients were referred by their ear, nose and throat physicians (ENT) or from a local newspaper article describing our work. In the first phase of the study, we determined the patients' tinnitus history and the degree of psychological distress due to the tinnitus. The Tinnitus Questionnaire (TQ) was employed as a well validated measure to differentiate tinnitus patients with mild to moderate versus severe distress (Hiller & Goebel, 1992; Hallam, 1996). Subjects who scored above 40 were classified as severe and intended for CBT, while those with lower scores were candidates for the abridged treatment called "Tinnitus Education" (TE). This cut-off was chosen because it had discriminated best between tinnitus patients scoring high and low on scales indicating general psychopathology (unpublished results). All patients were randomly assigned to treatment groups either receiving or not receiving sound stimulation by NGs. Assessments were conducted before and after treatment and again at follow-ups after 6 and 18 months.

2.2. Initial examination

Patients were carefully examined using the Structured Tinnitus Interview (STI). This clinician-rated instrument covers all major aspects of tinnitus history, tinnitus etiology and associated complaints. It was found in previous studies to be of high reliability and validity (Hiller & Goebel, 1999; Hiller, Goebel, & Schindelmann, 1999). We additionally performed audiometric tests assessing hearing threshold, loudness discomfort level and minimal masking level.

2.3. Patients

Patients were accepted for treatment if they met the following criteria: (a) the tinnitus was characterized as chronic, i.e. lasted for at least 6 months; (b) evidence of psychological concerns or distress due to the tinnitus; (c) motivation to participate in a psychological treatment approach; (d) completion of all necessary ENT examinations and no current indication for standard medical treatments; (e) absence of current mental disorder that would require psychiatric treatment or intense individual psychotherapy, such as severe depressive, psychotic or substance-related disorder.

A total of 136 patients met these entry criteria. Of them, 70 were assigned to the TE groups and randomized into 34 with and 36 without NGs. The remaining 66 were selected for CBT and randomized into 33 with and 33 without NGs. Six patients participated in the TE treatment despite TQ scores somewhat above 40 because they were not interested in more than a relatively short treatment. Twelve patients with scores below 40 were accepted for CBT because they expressed a strong interest to undergo the more intense psychological intervention.

Twelve patients dropped out during the course of treatment. As post-treatment and follow-up data were not available for them, we had to exclude them from all further data analyses. A closer inspection of the drop-outs showed that these were three patients with external reasons (e.g., interruption because of skiing accident), five with insufficient treatment motivation or low compliance, and four who withdrew at some time during treatment for unknown reasons and did not respond to several attempts to contact them by either telephone or mail. Statistical analyses of the drop-out patients showed that there were no significant sociodemographic or tinnitus-related deviations when compared to the treated sample.

The characteristics of the four subgroups are shown in Table 1. Although the gender proportion was almost balanced across all treated subjects, the CBT without NG group included more women than the CBT plus NG group ($\chi^2 = 4.21$, df 1, $p < 0.05$). The TE plus NG patients were older than the TE group without NG ($t = 1.99$, df 62, $p = 0.051$). Other group differences were found for tinnitus duration where more subjects of CBT/NG group had their tinnitus for > 1 year ($\chi^2 = 4.27$, df 1, $p < 0.05$; compared to CBT/no NG) and more patients of the TE/NG group reported a tinnitus of > 5 years ($\chi^2 = 4.86$, df 1, $p < 0.05$, compared to TE/no NG). As expected, subjective tinnitus severity grading according to Scott, Lindberg, Lyttkens, and Melin (1985) was lower among the TE patients (grade I: tinnitus heard only in quiet surroundings, or grade II: masked by normal noise) as compared to the more severely distressed CBT patients (grade III: never masked).

Special attention was given to the presence of hyperacusis, sound induced exacerbation (SIE) and hearing loss because it is known that these conditions may lead to treatment complications. Hyperacusis is defined as a clinically significant, often highly distressing oversensitivity to common external sounds. Although many patients with hyperacusis tend to avoid situations with even average noise levels, there is evidence that continuous acoustic stimulation over longer periods strongly improves hyperacusis. SIE refers to the phenomenon that external acoustic stimulation leads to an immediate or delayed increase of tinnitus loudness. If present, patients often find it difficult to agree to a treatment strategy emphasizing habituation through noise exposure. Hearing loss was defined by $\geqslant 30$ dB HL in the range from 500 to 3000 Hz. Both hyperacusis and SIE were assessed in a standardized manner with the STI. Table 1 shows that

Table 1
Sociodemographic and tinnitus-related characteristics

	TE		CBT	
	With NG ($n = 31$)	Without NG ($n = 33$)	With NG ($n = 31$)	Without NG ($n = 29$)
Female (%)	48	39	32	59
Age (yr)	52.5 (SD = 15.3)	45.2 (SD = 14.1)	51.0 (SD = 13.2)	51.4 (SD = 10.9)
Familial status (%)				
Married	61	42	65	76
Divorced	10	9	7	10
Demand for compensation/retirement (%)	3	3	7	10
Tinnitus localization (%)				
One ear	39	46	48	55
Both ears	61	54	52	45
Tinnitus duration (%)				
> 1 yr	74	64	90	69
> 5 yr	36	12	36	31
Tinnitus severity grading (%)				
Grade I	19	30	3	14
Grade II	71	61	45	48
Grade III	10	9	52	38
MML (dB HL)	83.1 (SD = 40.5)	70.2 (SD = 31.3)	95.2 (SD = 42.6)	91.0 (SD = 34.7)
Hyperacusis (%)	29	42	48	35
SIE (%)	10	6	7	7
Hearing loss (%)	19	21	26	28
Tinnitus-related etiological factors (% presence)				
Sudden hearing loss	19	30	26	24
Acoustic trauma	7	3	13	0
Long-standing exposure to noise	16	6	16	10
Family history of tinnitus/other ear disease	32	24	7	28

Note: NG = noise generator; SIE = sound induced exacerbation; MML = minimal masking level.

hyperacusis and hearing loss were present in a relatively large number of the patients. Across all subgroups, 38% had hyperacusis and 23% had hearing loss (in one or both ears), while SIE was present in 8%.

2.4. Treatments

All treatments took place in groups with eight to ten participants. TE comprised of four 90-min weekly sessions and CBT of ten 120-min sessions. Before the first session, patients were generally informed about the concepts and aims of the treatments. Between sessions, they completed a series of homework assignments. All therapies were conducted by two clinical psychologists with several years of experience in the management of chronic tinnitus patients (C.H. and W.H.).

2.4.1. Tinnitus education (TE)

Patients are informed about the physiology and anatomy of the hearing process, the nature of tinnitus, etiological mechanisms and treatment options. The neurophysiological model of tinnitus and its implications for everyday life are explained in detail. In accordance with this model, all patients are advised to avoid silence in their everyday environments. Additionally, the "vicious cycle" and "coping cycle", common elements of psychological programs, are introduced and applied to the participants' personal situations. All patients are invited to ask open questions, discuss the hand-out materials and compare their experiences with those of the other participants.

2.4.2. Cognitive-behavioral therapy (CBT)

This program includes all major "classical" components of the cognitive-behavioral approach which were adapted to focus on the special problems and needs of chronic tinnitus patients. An overview is provided in Table 2. The treatment was strictly manualized. Patients received a set of written materials for each session to enhance understanding, facilitate more detailed practicing and motivate transferring the new knowledge and insights into their daily routine.

2.5. The sound stimulation method

Each patient of the NG subgroups received behind-the-ear (bte) broadband white NGs, one for each ear. They were attached with individually designed earmoulds to make sure that wearing the devices was as comfortable as possible and did not interfere with hearing. This cannot be achieved with in-the-ear devices. The NGs provide a volume control for the patients' use, starting from zero, as well as frequency- and volume-presets to adjust the sound to different audiological features. All patients in the sound stimulation condition were carefully instructed on how to use the devices and to wear them as often as possible, especially in quiet surroundings. All further instructions followed the general guidelines of Jastreboff for the use of NGs in the treatment of chronic tinnitus (see Jastreboff, 1998). In particular, patients were instructed to wear their devices for at least 6 h every day.

2.6. Measures

After initial evaluation with the STI (see above), subjects completed a battery consisting of measures related to tinnitus and general psychopathology. These included:

(a) *Tinnitus Questionnaire* (TQ): This 52-item-scale is a well-established instrument to assess the broad spectrum of tinnitus-related psychological complaints. Areas of complaint include emotional and cognitive distress, intrusiveness, auditory perceptual difficulties, sleep disturbances and associated somatic complaints. The total TQ score represents the general level of psychological and psychosomatic distress. The TQ was shown to be reliable and valid in several previous studies (e.g., Hallam, Jakes, & Hinchcliffe, 1988; Hiller & Goebel, 1992).

(b) *Tinnitus Cognition Scale* (T-Cog): This questionnaire was designed especially for this study to assess dysfunctional beliefs and attitudes concerning the tinnitus. 33 cognitions such as "Someday this sound will drive me mad" or "If my tinnitus gets worse, it will damage my hearing" are listed. The patients can express the degree of agreement on a scale from 0 ("I don't

Table 2
Contents and components of CBT

Session	Contents and interventions
1	*Warming up and general orientation*: Patients exchange information about their tinnitus and previous treatment/coping experiences; expectations and treatment goals are discussed; therapists inform about contents/treatment methods.
2	*Education* I: Anatomy and physiology of the auditory system; definition and prevalence of tinnitus; potential causes of tinnitus and overview of treatment options; patients learn that tinnitus is a frequent phenomenon and in most cases not a dangerous disease; introduction into progressive muscle relaxation technique (CDs are handed out to the patients).
3	*Education* II: Comprehensive tinnitus model according to Jastreboff; differentiation between triggering and maintaining factors; vicious circle models involving cognitions, emotions and behavior; patients learn that avoiding silence is contra-indicated to achieve habituation; progressive relaxation.
4	*Cognitions* I: A general cognitive-behavioral model (A-B-C model) is introduced and illustrated with examples given by the patients; patients learn to differentiate between thoughts and emotion; progressive relaxation.
5	*Cognitions* II: The cognitive-behavioral model is applied to tinnitus; dysfunctional cognitions are identified and restructured; inter-dependence between cognition, emotion and reaction is demonstrated; brief version of progressive relaxation.
6	*Perception*: The role of attentional processes for tinnitus perception is demonstrated; imagery training is introduced; patients learn strategies of attention diversion and to reduce tinnitus awareness; 2-min version of progressive relaxation.
7	*Tinnitus and everyday activities* I: Common consequences of the tinnitus are discussed and analyzed, especially avoidance behaviors and social withdrawal; patients learn to differentiate between short- and long-term consequences, and between favorable and dysfunctional tinnitus-related cognitions and behaviors.
8	*Tinnitus and everyday activities* II: Definition of illness behavior with examples from tinnitus-related reactions of the patients; potential positive consequences of the tinnitus (e.g., withdrawal from unpleasing obligations) are discussed.
9	*Tinnitus and the health care system*: Criteria to consult ENT physicians and other health professionals are analyzed (with special emphasis on the "doctor-shopping" phenomenon); patients practice to be clear and purposeful in their patient–doctor contacts.
10	*Relapse prevention*: Strategies to cope with tinnitus-related crises are collected and discussed ("emergency plan").

agree") to 4 ("I totally agree"). The internal consistency of this scale was high with a value of 0.90 (Cronbach' s α).

(c) *Tinnitus diary*: Patients were instructed to rate tinnitus loudness, unpleasantness (i.e., subjective distress due to the tinnitus), general mood and perceived controllability of the tinnitus on 0–100 visual analog scales (VAS) every evening for 7 consecutive days. The diary was completed by the patients before and after treatment and at the 6-month follow-up (it was omitted at the 18-month follow-up).

(d) *Symptom Checklist* (SCL-90R): This is one of the most widely used questionnaires to assess general psychopathology (Derogatis, 1983).

(e) *Whiteley Index* (WI): This scale comprises of 14 items and is an international standard self-rating scale to assess general hypochondriacal attitudes and behaviors (Hiller, Rief, & Fichter,

2002). It was used in the present study to control whether health anxieties of tinnitus patients are of general nature or rather tinnitus-specific.

(f) *Dysfunctional Analysis Questionnaire* (DAQ): This instrument contains 45 items describing complaint-related impairments in different areas of psychosocial functioning (social, vocational, personal, familial, cognitive). Each item is rated on a five-point scale, comparing the present level of functioning with that before the onset of the complaints. The DAQ is reliable and well validated (Hiller, Rief, & Fichter, 1997).

2.7. Follow-up evaluation

We received follow-up questionnaire data from 116 patients (93.5%). Two patients with missing follow-up data had been treated under the TE and six under the CBT condition. It had not been possible to re-contact these patients because they had either moved or did not respond to repeated calls or letters, or had not returned the questionnaires despite multiple requests. Exactly half of these patients had been treated with a NG. From another 17 subjects (eight TE and nine CBT), follow-up data were available only for one point of measurement, i.e. either at 6- or 18-month follow-up. At the second follow-up, we additionally attempted to reach each patient by telephone to conduct a semi-structured interview.

2.8. Statistical methods

To identify differences between the groups, analyses of variance with the factors group (or subgroup) and time (repeated measurement of the outcome variable) were performed. For each variable, we will present separate analyses comparing the post-treatment, 6- and 18-month follow-up data with the pre-treatment condition. Within group changes across time were additionally analyzed by *t*-tests. The significance level was conventionally set to 0.05. To determine the magnitude of change between two points of assessment, effect sizes (ES) using the *d* statistic of Cohen (1988) were calculated for each treatment modality and outcome variable. We subtracted the post-treatment mean from the pre-treatment mean and divided the result by the pooled pre-/post-treatment standard deviation of the measure.

3. Results

3.1. General treatment effects

Patients of both treatments improved significantly when the pre- and post-treatment TQ scores were compared (Fig. 1; $t = 6.80$, df 60, for CBT and $t = 7.94$, df 63, for TE; both $p < 0.01$). The ES for the TE group was somewhat larger (0.99) than for the CBT group (0.76), although the group by time interaction remained statistically insignificant ($F = 1.02$, df 1, 122, $p = 0.31$). While the long-term effects remained more or less unchanged in the TE group, the scores of the CBT patients continued to improve moderately during the follow-up-period. Both groups showed comparable overall results at the 18-month follow-up. The reduction between pre-treatment and

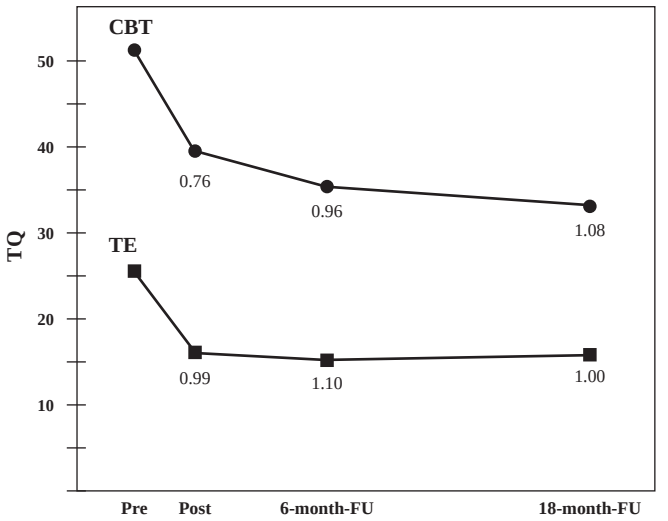

Fig. 1. Treatment effects measured by the Tinnitus Questionnaire (TQ). *Note*: Values at each point of measurement indicate ESs comparing this point of measurement with pre-treatment.

18-month follow-up was from 51.1 (SD = 12.7) to 33.1 (18.2) in the CBT group (−35.2%) and from 25.6 (9.8) to 15.9 (9.2) in the TE group (−37.9%).

3.2. TE with or without NGs

There was no overall significant difference between the TE subgroups with and without NGs (Table 3), although a weak tendency towards better effects in the group without NG became apparent. The TQ reduction between pre-treatment and 18-month follow-up was −41.4% in the TE/no NG group and −35.3% in the TE/NG group. Patients without NG improved more on the VAS tinnitus loudness after six months and on the WI after 18 months, although the pre-treatment WI scores of this subgroup had been higher ($t = 2.38$, df 60, $p < 0.05$). Data for general psychopathology (SCL-90R) and psychosocial dysfunction (DAQ) are not reported in Table 3 because the mean scores in the TE group were not pathological.

3.3. CBT with or without NGs

Similar results were found for patients treated with CBT (Table 4). There were no significant differences between both subgroups on all outcome variables except for the WI. The TQ reduction at 18-month follow-up was −43.6% in the CBT/no NG group and −29.2% in the CBT/NG group, indicating a trend of slightly better improvement in patients without NG. The WI scores of CBT/NG patients remained largely unchanged, whereas those treated without NG reached significant improvement. The initial WI scores were somewhat higher in the group without NG although the difference was not statistically significant ($t = 1.48$, df 55, $p = 0.15$).

Table 3
Treatment effects in the TE group

Measures[a]		*n*	With NG	Effect size	*n*	Without NG	Effect size	Significance of difference between both groups[b]
TQ	Pre	31	26.9 (10.7)	—	33	24.4 (9.0)	—	—
	Post	31	17.9 (9.3)	0.89	33	14.5 (9.0)	1.1	n.s.
	6-month FU	28	17.2 (7.9)	1.08	31	13.4 (9.9)	1.14	n.s.
	18-month FU	29	17.4 (9.3)	0.92	28	14.3 (8.9)	1.1	n.s.
T-Cog	Pre	31	27.8 (12.1)	—	33	27.2 (10.8)	—	—
	Post	31	19.0 (11.4)	0.75	33	17.2 (7.7)	1.09	n.s.
	6-month FU	28	19.5 (11.1)	0.69	30	17.9 (9.6)	0.95	n.s.
	18-month FU	28	21.1 (10.6)	0.59	28	19.9 (9.4)	0.67	n.s.
VAS tinnitus loudness	Pre	31	49.5 (20.0)	—	30	43.6 (13.6)	—	—
	Post	31	40.3 (18.8)	0.48	30	33.4 (20.9)	0.59	n.s.
	6-month FU	27	43.9 (22.3)	0.33	27	28.8 (20.3)	0.94	$p<0.05$
VAS tinnitus unpleasantness	Pre	31	30.2 (18.3)	—	28	25.3 (14.5)	—	—
	Post	31	23.9 (17.1)	0.35	28	24.0 (20.0)	0.07	n.s.
	6-month FU	27	24.5 (17.6)	0.36	26	18.8 (19.3)	0.39	n.s.
VAS control of tinnitus	Pre	30	27.9 (25.3)	—	28	20.4 (18.3)	—	—
	Post	30	32.4 (28.7)	0.17	28	27.0 (21.5)	0.33	n.s.
	6-month FU	27	29.1 (25.6)	0.02	26	28.2 (28.6)	0.38	n.s.
WI	Pre	30	2.47 (2.09)	—	32	3.75 (2.16)	—	—
	Post	30	2.01 (2.02)	0.22	32	2.81 (2.19)	0.44	n.s.
	6-month FU	28	2.11 (2.83)	0.06	30	2.73 (2.92)	0.39	n.s.
	18-month FU	28	2.24 (2.01)	0.16	28	2.35 (2.56)	0.58	$p<0.05$

Note: Means and standard deviations (in brackets) are displayed. NG = noise generator.

[a]TQ, Tinnitus Questionnaire, global score; T-Cog, Tinnitus Cognition Scale; VAS, Visual Analogue Scale; WI, Whiteley Index; higher scores indicate higher levels of distress and symptoms on all measures except for VAS control of tinnitus.

[b]*p* values refer to analysis of variance group × time interactions comparing the point of measurement with pre-treatment.

3.4. Influence of the patients' acceptance of the NGs

One crucial factor likely to influence the results could be the patients' acceptance of the NGs and their ability to handle them correctly. We therefore controlled whether patients were still wearing their devices at post-treatment and at the 6-month follow-up. The length of daily NG use was recorded in the patients' diaries.

Of the 31 TE patients treated with an NG, 29 still wore the NG more than one hour daily at post-treatment and 23 still did so at the 6-month follow-up. Their development in the TQ at the end of treatment and six months later was practically identical to those patients not wearing the NG any more (all $p>0.05$; ESs of patients with correct use of NGs between 0.92 and 1.18). Results were comparable for the CBT group where 24 of the 31 patients treated with an NG reported to still use them more than one hour daily at post-treatment and 13 at the 6-month

Table 4
Treatment effects in the CBT group

Measures[a]		*n*	With NG	Effect size	*n*	Without NG	Effect size	Significance of difference between both goups[b]
TQ	Pre	31	53.4 (12.4)	—	29	48.8 (12.8)	—	—
	Post	31	42.9 (18.7)	0.67	29	36.1 (15.7)	0.89	n.s.
	6-month FU	27	38.6 (18.9)	0.92	24	31.8 (17.4)	1.02	n.s.
	18-month FU	26	37.8 (18.6)	1.02	22	27.5 (16.4)	1.25	n.s.
T-Cog	Pre	30	41.4 (16.0)	—	27	39.7 (13.4)	—	—
	Post	30	35.7 (15.6)	0.36	27	31.8 (12.0)	0.62	n.s.
	6-month FU	26	32.0 (16.3)	0.58	24	29.3 (14.2)	0.75	n.s.
	18-month FU	25	32.1 (17.1)	0.52	22	26.7 (10.4)	1.03	n.s.
VAS tinnitus loudness	Pre	30	56.7 (18.1)	—	23	55.6 (15.9)	—	—
	Post	30	52.0 (20.8)	0.24	23	46.7 (20.6)	0.49	n.s.
	6-month FU	26	53.1 (24.7)	0.13	21	50.0 (22.8)	0.36	n.s.
VAS tinnitus unpleasantness	Pre	30	44.3 (19.0)	—	23	43.0 (17.9)	—	—
	Post	30	40.3 (20.3)	0.2	23	37.6 (20.6)	0.28	n.s.
	6-month FU	26	41.2 (23.5)	0.14	21	37.7 (24.2)	0.25	n.s.
VAS control of tinnitus	Pre	30	25.3 (18.7)	—	21	24.4 (20.1)	—	—
	Post	30	44.1 (26.0)	0.84	21	42.4 (29.1)	0.73	n.s.
	6-month FU	25	40.8 (23.2)	0.7	20	33.1 (28.3)	0.41	n.s.
SCL-90R (PSDI)	Pre	31	1.59 (0.41)	—	26	1.61 (0.53)	—	—
	Post	31	1.54 (0.44)	0.13	26	1.40 (0.46)	0.43	n.s.
	6-month FU	26	1.46 (0.35)	0.36	22	1.34 (0.50)	0.57	n.s.
	18-month FU	26	1.48 (0.38)	0.31	19	1.38 (0.42)	0.47	n.s.
SCL-90R (depression)	Pre	31	1.03 (0.63)	—	27	0.94 (0.86)	—	—
	Post	31	0.98 (0.62)	0.08	27	0.64 (0.58)	0.43	n.s.
	6-month FU	27	0.81 (0.71)	0.31	23	0.52 (0.54)	0.69	n.s.
	18-month FU	26	0.69 (0.58)	0.57	21	0.54 (0.71)	0.51	n.s.
WI	Pre	31	4.23 (2.70)	—	26	5.36 (3.07)	—	—
	Post	31	5.21 (3.26)	—	26	4.41 (2.86)	0.32	$p<0.01$
	6-month FU	27	4.67 (2.68)	—	23	4.01 (3.24)	0.31	$p=0.07$
	18-month FU	26	3.99 (2.69)	—	22	3.32 (3.40)	0.53	$p<0.05$
DAQ	Pre	31	57.9 (9.6)	—	28	54.5 (12.3)	—	—
	Post	31	57.4 (10.6)	0.05	28	51.7 (15.5)	0.2	n.s.
	6-month FU	28	55.2 (12.2)	0.28	30	48.6 (13.8)	0.41	n.s.
	18-month FU	27	52.3 (12.5)	0.49	28	49.6 (14.6)	0.26	n.s.

Note: Means and standard deviations (in brackets) are displayed. NG = noise generator.

[a]TQ, Tinnitus Questionnaire, global score; T-Cog, Tinnitus Cognition Scale; VAS, Visual Analogue Scale; SCL-90R, Symptom Checklist; PSDI, Positive Symptom Distress Index; DAQ, Dysfunctional Analysis Questionnaire; WI, Whiteley Index; higher scores indicate higher levels of distress and symptoms on all measures except for VAS control of tinnitus.

[b]*p* values refer to analysis of variance group × time interactions comparing the point of measurement with pre-treatment.

follow-up. There were no significant subgroup by time interactions between those wearing or not wearing the NGs (ESs of patients with correct use of NGs between 0.67 and 1.16).

3.5. Controlling for other potentially confounding variables

We carefully evaluated whether the presence of hyperacusis, hearing loss or SIE influenced the treatment effects. Fig. 2 demonstrates the findings for the TE group. Treatment course was somewhat more favorable for patients with concurrent hyperacusis (maximum ES = 1.74 at the 6-month follow-up) and hearing loss (maximum ES = 1.49), as compared to the complete sample of TE treated patients. In the CBT group, patients with hyperacusis also performed recognizably better (maximum ES = 1.19) but results were worse for those with associated hearing loss (Fig. 3). These findings indicate therefore that hearing loss is a positive predictor only for mild to moderately distressed tinnitus patients. Presence or absence of SIE had no impact on treatment outcome.

We also controlled for other sociodemographic and tinnitus-related variables that had not been distributed equally between the subgroups (see Table 1). There was no systematic and statistically significant influence of sex distribution, age and tinnitus duration on treatment outcome.

3.6. Comparing responders and non-responders

We further analyzed whether response to treatment was predictable from a categorical point of view. Patients were considered responders if their TQ score was reduced 20% or more over at least two of the three assessments after treatment. According to this criterion, 45 (70%) of the TE patients were classified as responders and 19 (30%) as non-responders. There were no significant differences between responders and non-responders concerning sex, age, use of NG, hearing loss,

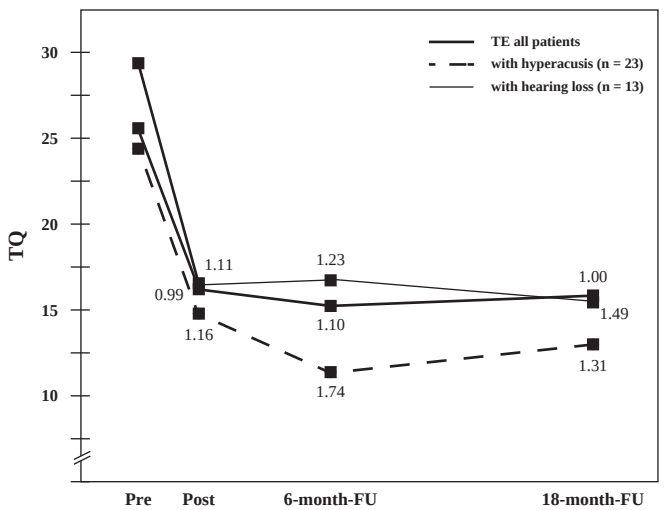

Fig. 2. Differential effects in the TE treatment group. *Note*: Values at each point of measurement indicate effect sizes ESs comparing this point of measurement with pre-treatment.

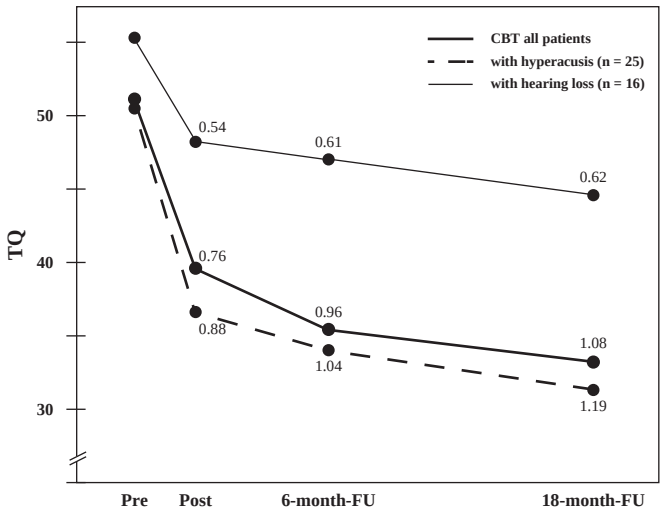

Fig. 3. Differential effects in the CBT treatment group. *Note*: Values at each point of measurement indicate ESs comparing this point of measurement with pre-treatment.

minimal masking level or SIE. In accordance with the quantitative results reported above, there was a tendency for more patients with hyperacusis (83%) than without hyperacusis (63%) to be classified as responders ($\chi^2 = 2.60$, df 1, $p = 0.11$). Of the CBT group, 33 (55%) were classified as responders and 27 (45%) as non-responders. Again, no sociodemographic and tinnitus-related variables except for the presence of a hearing loss differentiated between responders and non-responders. Only 19% of patients with hearing loss were responders as compared to 68% without hearing loss ($\chi^2 = 11.6$, df 1, $p < 0.01$).

3.7. Influence of initial tinnitus-related distress

Another question to be answered was whether the initial degree of the patients' psychological distress had any influence on the treatment effects. Interestingly, a relatively high Pearson correlation between the pre-treatment TQ scores and the degree of improvement was found for the TE group. The exact values were: pre-treatment TQ correlated 0.55 ($p < 0.01$) with post-treatment outcome (difference between pre- and post-treatment) and 0.60 ($p < 0.01$) with 18-month outcome (difference between pre-treatment and 18-month scores). The corresponding values for the CBT group were 0.08 ($p > 0.05$) and 0.29 ($p < 0.01$). These findings indicate that patients with higher distress before treatment reached larger improvements, especially those treated under the TE condition.

3.8. Applying a strict criterion for severely distressed patients

As mentioned in the method section, twelve patients were included in the CBT groups although their initial TQ scores were below 40. It could be argued that these patients did not unambiguously belong to the highly distressed population. However, as they expressed a strong

wish to participate in the more intense program, we decided not to force them into the TE groups. To evaluate whether this decision influenced the results, we repeated the statistical analyses after excluding them from the sample. The TQ scores of the remaining patients improved from 55.8 (SD = 9.4) at pre-treatment to 43.9 (16.4) at post-treatment, 39.7 (18.2) at 6-month follow-up, and 37.3 (18.4) at 18-month follow-up. The corresponding ESs were 0.92, 1.17 and 1.33, thus somewhat higher than those obtained for the complete sample (see Fig. 1). There were no differences in the distressed subgroup concerning whether or not patients used NGs.

3.9. Patients' long-term appraisal of the NGs

The telephone interviews at the 18-month follow-up allowed us to gain a detailed picture of how the patients appraised the use of the NGs. We were able to conduct the interview with 30 of the 31 TE/NG patients (96.8%) and 29 of the 31 CBT/NG patients (93.5%). More patients treated with TE than with CBT still wore the devices and the opinion concerning their usefulness was generally more positive among the TE-treated patients (Table 5). Examples of positive comments were "NG has helped a lot", "helps me to calm down" or "I don't listen to tinnitus all the time any more". When statements were negative, patients mostly complained about difficulties handling the NGs (e.g., pressing against the ear, skin wounded, uncomfortable in warm weather), their visibility (e.g., felt less attractive because other people could see their "handicap") or the NG-sound was experienced as annoying (e.g., nervous and tense because of permanent buzzing) or distracting (especially when using the telephone).

4. Discussion

This study attempted to investigate whether two promising treatment approaches for chronic tinnitus can be combined. CBT is an established method that has proven to be effective in several studies during the past 15 years (Andersson & Lyttkens, 1999; Andersson, 2002). The goal of psychological intervention is to change the way patients' perceive and react to their tinnitus. The

Table 5
Results of the telephone interview (18-month follow-up)

	TE/NG patients ($n = 30$)	CBT/NG patients ($n = 29$)
Current statuts of NG use		
Still using NG	16 (53.3%)	11 (37.9%)
Had stopped using NG because treatment successful	6 (20.0%)	3 (10.3%)
Had stopped using NG because no sufficient improvement	8 (26.7%)	15 (51.7%)
Opinion about NG		
Positive	22 (73.3%)	12 (41.4%)
Negative	7 (23.3%)	15 (51.7%)
Neutral	1 (3.3%)	2 (6.9%)

second approach, often referred to as "retraining therapy" (Jastreboff & Hazell, 1993), is based on a neurophysiological model assuming that the auditory system is able to reorganize dysfunctional patterns of information processing. Accordingly, the goal of treatment is to initiate an adaptation process in a way that continuous acoustic stimulation (such as tinnitus signals) are no longer experienced as "noise" or "annoying". NGs are thought to enhance this adaptation because they produce a permanent acoustic background stimulation to which habituation may be reached more easily.

Contrary to our expectations, the data of this study could not confirm that the combination of both approaches results in additive effects. Patients of all treatment conditions improved substantially and there was no advantage for those who additionally received a NG. We even observed a (non-significant) tendency of patients without NG improving slightly better. Although sensory habituation usually takes time and effects due to NG-based stimulation may occur delayed, there was no evidence of better outcomes for the NG condition at the 6- and 18-month follow-up. This finding was also confirmed when the patients' ability and willingness to correctly use the devices was controlled for. NG acceptance was generally good and a large proportion of the patients still used the device when interviewed 18 months after the end of the treatment. Our primary outcome variables were tinnitus-related subjective complaints, but results obtained with broader measures of general psychopathology, depression and psychosocial functioning also confirmed that differences between patients with and without NG were not present. Furthermore, the failure to reveal specific effects due to the NGs was not influenced from sociodemographic variables or characteristics such as tinnitus duration or tinnitus severity grading.

Although little research exists about the effects of systematic sound stimulation, our results correspond with findings of other groups. McKinney et al. (1996) found no group differences 12 months after retraining treatment between patients receiving counseling alone and counseling plus NGs. Dineen and colleagues (Dineen, Doyle, & Bench, 1997; Dineen, Doyle, Bench, & Perry, 1999) compared four treatments where patients received either information alone, information plus NGs, information plus relaxation, or information, NGs and relaxation. The authors reported that although subjects treated with all three components initially showed the greatest improvement on a coping ability scale, no general group differences were found 12 months later. In this study, NGs neither altered tinnitus awareness nor the minimum masking level. It was therefore assumed that sound stimulation influences cognitive reactions rather that the physical perception of tinnitus (Dineen et al., 1999).

What are the reasons that NGs apparently do not contribute to treatment efficacy? One possible explanation is that sensory habituation can also be initiated through psychological intervention. As patients learn to shift their attention away from the tinnitus and gradually change their tinnitus-related interpretations from "danger" to "meaningless", basic perceptional processes may be altered. CBT influences a broad spectrum of psychological processes, whereas effects arising from habituation due to physical stimulation may be comparably narrow and small. In addition, patients may have experienced increased environmental sound stimulation even if not wearing a NG. The tinnitus model was introduced and explained as part of our treatments and patients were consequently encouraged to avoid silence. Therefore, it can be hypothesized that ordinary acoustic stimulation is sufficient and the benefit of additional permanent and monotonous stimulation is likely to be overestimated (Wilson, Henry, Andersson, Lindberg, & Hallam, 1998; Kroener-Herwig et al., 2000). It is remarkable that the results of our study are in

accordance with the habituation model of Hallam, Rachman, and Hinchcliffe (1984) which predated the above described neurophysiological model.

Despite the low value of NGs for the average patient treated in our study, one important exception became apparent, as patients with concurrent hyperacusis had a more favorable course under the NG condition. Hyperacusis is a generalized oversensitivity of the auditory system, most likely to be caused by central processes although in many cases initially triggered by minimal or temporary inner ear dysfunction (Katzenell & Segal, 2001; Andersson, Lindvall, Hursti, & Calbring, 2002). It is assumed that inadequate withdrawal from usual external noise plays an important role as a maintenance factor for hyperacusis. Because noise-avoiding behavior is consistently interrupted by wearing a NG, patients can be helped to gradually re-adjust to normal acoustic stimulation. However, the role of NGs for hyperacusis treatment needs to be evaluated in more detail.

Another major result of our study is that improvements were found both for highly and moderately distressed patients. We offered an abridged treatment focusing on education to patients below the ''decompensation'' level, because there was clinical evidence that a full CBT program would neither be necessary nor meet the specific demands of this group. The four-session TE is similar to the counseling procedure described by Jastreboff and Hazell (1993), although we preferred the group format instead of individual counseling. The effects reached in our TE groups were high and comparable to those of the CBT. We believe that such treatment is required for many patients especially within the first year after the onset of the tinnitus, as these patients are at risk to develop more serious psychological complications in the long term.

From a methodological point of view, however, it could be argued that there was no complete combination of all factors in our study. Accordingly, nothing can be said about the potential usefulness of TE for severely distressed patients or of CBT for those with only moderate levels of distress. One might consider to evaluate the effects of both treatment conditions for tinnitus patients irrespective of their levels of psychological distress. In our opinion, however, offering only a narrow treatment to patients with severe symptoms might rise ethical problems, and would also be somewhat inconsistent with the assumption that dysfunctional cognitions and behaviors need to be addressed specifically to achieve large and enduring changes. Researchers applying intense CBT to only moderately distressed patients would have to face a problem of insufficient motivation and willingness in a substantial subgroup of this clinical population.

There are some limitations of this study which should be mentioned. First, the treatments were conducted in a University outpatient clinic which is not representative for the usual health care system. It remains to be studied whether NGs are more useful in other clinical settings, for example when applied by private audiologists who can usually provide only short counseling due to time constraints. One the other hand, our study is a good example of interdisciplinary cooperation between physicians and specialized clinical psychologists. A second restriction of our study comes from the relatively heterogeneous sample because patients with and without hyperacusis, SIE and hearing loss had been included. It is possible that beneficial effects of NGs exist for patients with specific combinations of these tinnitus-related characteristics. Since sample sizes of such subgroups were too small in our study, these aspects should be addressed in future research.

To summarize, this study underlines the importance of psychological treatment for patients with chronic tinnitus. Additional sound stimulation, however, seems to be of little relevance and is

most probably overestimated by retraining approaches. Although these conclusions are drawn for chronic tinnitus as a general clinical group, more studies are needed to evaluate whether specific subgroups exist for whom additional sound therapy might be helpful.

Acknowledgements

This study was financially supported by the German Tinnitus Association, Deutsche Tinnitus-Liga, Wuppertal, Germany. Further support came from the hearing-aid manufacturer Interton GmbH, Bergisch Gladbach, Germany, who provided the behind-the-ear broadband NGs, and from Audioplast GmbH, Offenbach, Germany, who produced the individualized earmolds. We are grateful to the regional ear, nose and throat physicians who cooperated with us to conduct all necessary medical tests. Dipl.-Psych. Tanja Pfaff contributed to this study by conducting the 18-month follow-up interviews.

References

Andersson, G. (2002). Psychological aspects of tinnitus and the application of cognitive-behavioral therapy. *Clinical Psychology Review*, *22*, 977–990.

Andersson, G., Lindvall, N., Hursti, T., & Calbring, P. (2002). Hypersensitivity to sound (hyperacusis): a prevalence study conducted via the internet and post. *International Journal of Audiology*, *41*, 545–554.

Andersson, G., & Lyttkens, L. (1999). A meta-analytic review of psychological treatments for tinnitus. *British Journal of Audiology*, *33*, 201–210.

Baguley, D. M. (2002). Mechanisms of tinnitus. *British Medical Bulletin*, *63*, 195–212.

Berry, J. A., Gold, S. L., Frederick, E. A., Gray, W. C., & Staecker, H. (2002). Patient-based outcomes in patients with primary tinnitus undergoing tinnitus retraining therapy. *Archives of Otolaryngology Head and Neck Surgery*, *128*, 1153–1157.

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences* (2nd ed.). Hillsdale, NJ: Lawrence Earlbaum Associates.

Davies, S., McKenna, L., & Hallam, R. S. (1995). Relaxation and cognitive therapy: a controlled trial in chronic tinnitus. *Psychology and Health*, *10*, 129–143.

Davis, A. C. (1995). *Hearing in adults*. London: Whurr.

Derogatis, L. R. (1983). *The SCL-90-R manual: scoring administration procedures for the SCL-90-R*. Baltimore: Johns Hopkins University School of Medicine, Clinical Psychometrics Unit.

Dineen, R., Doyle, J., & Bench, J. (1997). Managing tinnitus: a comparison of different approaches to tinnitus management training. *British Journal of Audiology*, *31*, 331–344.

Dineen, R., Doyle, J., Bench, J., & Perry, A. (1999). The influence of training on tinnitus perception: an evaluation 12 months after tinnitus management training. *British Journal of Audiology*, *33*, 29–51.

Folmer, R. L., Griest, S. E., Meikle, M. B., & Martin, W. H. (1999). Tinnitus severity, loudness, and depression. *Archives of Otolaryngology—Head and Neck Surgery*, *121*, 48–51.

Hallam, R. S. (1996). *Manual of the Tinnitus Questionnaire (TQ)*. London: Psychological Corporation.

Hallam, R. S., Jakes, S. C., & Hinchcliffe, R. (1988). Cognitive variables in tinnitus annoyance. *British Journal of Clinical Psychology*, *27*, 213–222.

Hallam, R. S., Rachman, S., & Hinchcliffe, R. (1984). Psychological aspects of tinnitus. In S. Rachman (Ed.). *Contributions to medical psychology*, Vol. 3 (pp. 31–53). Oxford: Pergamon.

Henry, J. L., & Wilson, P. H. (1996). Psychological management of tinnitus: comparison of a combined cognitive educational program, education alone and a waiting-list control. *International Tinnitus Journal*, *2*, 1–12.

Henry, J. L., & Wilson, P. H. (1998). An evaluation of two types of cognitive intervention in the management of chronic tinnitus. *Scandinavian Journal of Behavioral Therapy*, *27*, 156–166.

Hiller, W., & Goebel, G. (1992). A psychometric study of complaints in chronic tinnitus. *Journal of Psychosomatic Research*, *36*, 337–348.

Hiller, W., & Goebel, G. (1999). Assessing audiological, pathophysiological and psychological variables in chronic tinnitus: a study of reliability and search for prognostic factors. *International Journal of Behavioral Medicine*, *6*, 312–330.

Hiller, W., Goebel, G., & Schindelmann, U. (1999). Developing a structured interview to assess audiological, aetiological and psychological variables of tinnitus. In J. Hazell (Ed.). *Proceedings of the sixth international tinnitus seminar* (pp. 277–282). London: The Tinnitus and Hyperacusis Centre.

Hiller, W., Rief, W., & Fichter, M. M. (1997). How disabled are patients with somatoform disorders?. *General Hospital Psychiatry*, *19*, 432–438.

Hiller, W., Rief, W., & Fichter, M. M. (2002). Dimensional and categorical approaches to hypochondriasis. *Psychological Medicine*, *32*, 707–718.

Jastreboff, P. J. (1990). Phantom auditory perception (tinnitus): mechanisms of generation and perception. *Neuroscience Research*, *8*, 221–254.

Jastreboff, P. J. (1998). Tinnitus. The method of Pawel J. Jastreboff. In G. Gates (Ed.). *Current therapy in otolaryngology—head and neck surgery* (pp. 90–95). St. Louis: Mosby Year Book.

Jastreboff, P. J., & Hazell, J. W. P. (1993). A neurophysiological approach to tinnitus: clinical implications. *British Journal of Audiology*, *27*, 7–17.

Katzenell, U., & Segal, S. (2001). Hyperacusis: review and clinical guidelines. *Otology & Neurotology*, *22*, 321–327.

Kroener-Herwig, B., Biesinger, E., Gerhards, F., Goebel, G., Greimel, K. V., & Hiller, W. (2000). Retraining therapy for chronic tinnitus. A critical analysis of its status. *Scandinavian Audiology*, *29*, 67–78.

Kröner-Herwig, B., Frenzel, A., Fritsche, G., Schilkowsky, G., & Esser, G. (2003). The management of chronic tinnitus. Comparison of an outpatient cognitive-behavioral group training to minimal-contact interventions. *Journal of Psychosomatic Research*, *54*, 381–389.

Kröner-Herwig, B., Hebing, G., van Rijn-Kalkmann, U., Frenzel, A., Schilkowsky, G., & Esser, G. (1995). The management of chronic tinnitus—comparison of a cognitive-behavioural group training with yoga. *Journal of Psychosomatic Research*, *39*, 153–165.

Lindberg, P., Scott, B., Melin, L., & Lyttkens, L. (1989). The psychological treatment of tinnitus: an experimental evaluation. *Behaviour Research and Therapy*, *27*, 593–603.

McKinney, C. J., Hazell, J. W. P., & Graham, R. L. (1996). Retraining therapy—outcome measures. In G. E. Reich, & J. A. Vernon (Eds.). *Proceedings of the fifth international tinnitus seminar 95* (pp. 524–525). Portland, OR: American Tinnitus Association.

Rizzardo, R., Savastano, M., Maron, M. B., Mangialaio, M., & Salvadori, L. (1998). Psychological distress in patients with tinnitus. *The Journal of Otolaryngology*, *27*, 21–25.

Scott, B., Lindberg, P., Lyttkens, L., & Melin, L. (1985). Psychological treatment of tinnitus. An experimental group study. *Scandinavian Audiology*, *14*, 223–230.

Vernon, J. A., & Møller, A. R. (1995). *Mechanisms of tinnitus*. Boston: Allyn & Baker.

Wilson, P. H., Henry, J. L., Andersson, G., Lindberg, P., & Hallam, R. S. (1998). A critical analysis of directive counselling as a component of tinnitus retraining therapy. *British Journal of Audiology*, *32*, 273–286.

Zöger, S., Svedlund, J., & Holgers, K. M. (2001). Psychiatric disorders in tinnitus patients without severe hearing impairment: 24 month follow-up of patients at an audiological clinic. *Audiology*, *40*, 133–140.