

Controlled prospective study of tinnitus retraining therapy compared to tinnitus coping therapy and broad-band noise generator therapy

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In a controlled study we investigated the efficacy of pure broad-band Noise Generator Therapy (NGT) in comparison to Tinnitus Retraining Therapy (TRT) and pure behavioural Tinnitus-Coping Therapy (TCT). In the first part of our study, 52 patients with chronic decompensated tinnitus and unimpaired hearing were randomly assigned one type of outpatient treatment while waiting for placement in our clinic: (1) The NGT group were fitted with noise generators (Silent Star-Viennatone™). A brief counselling by telephone regarding the theory and use of NG was included. (2) The TRT group participated in outpatient group tinnitus coping therapy (groups of about 8 patients, 4 Saturdays during 4 months). Additionally, they were fitted with NG. (3) The TCT group received the same treatment as the TRT group, only without NG therapy. (4) The patients in the control group (waiting-list WLG) received no therapy.

At the end of a six to eight weeks inpatient therapy we randomly selected 51 other patients with the same inclusion criteria and randomly assigned them to different types of ongoing outpatient treatment. (5) In the "Post-NGT-group," patients were fitted with NG when leaving the clinic (NGT-post), or (6) participated in booster sessions similar to TCT (TCT-post). (7) The "TCT-refusal-group" consisted of patients who did not want to join in the "Post-TCT-group" and therefore received no further treatment. (8) The "Post-Control-group" received no specific therapy (Control-post).

The treatments were evaluated using the Tinnitus Questionnaire (TQ), Visual Analogue Scales (VAS) reflecting tinnitus annoyance, tinnitus control and hyperacusis, the Beck Depression Inventory (BDI) and Symptom-Check-List (SCL-90-R) regarding general symptoms.

Results: Due to the restrictive selection of patients, both studies are still in progress, so the results presented here are preliminary. The psychiatric comorbidity of all participating patients was high (DSM-IV; SCL-90-R). While the participants who have already completed the TRT or the TCT displayed clinically relevant improvements regarding tinnitus annoyance (TQ; $p < 0.05$), tinnitus control ($p = < 0.05$), and depressiveness (BDI $p = < 0.05$), the results in the NGT-group are unsatisfactory. There were no differences between the groups regarding tinnitus control or hyperacusis in the pre-admission period.

The post-discharge interventions showed no specific effect on the course of tinnitus annoyance.

Preliminary conclusions: For patients with decompensated tinnitus, the effect of NGT is advantageous only with a strong focus on counselling with cognitive interventions. Intensive cognitive-behavioural oriented coping treatments which by far surpass the requirements stated by Jastreboff and Hazell [1], supported by technical aids (TRT), is equally effective after four months to behavioural coping treatment (TCT).

Introduction

Recently, Tinnitus Retraining Therapy (TRT) as conceived by Jastreboff [1,2] has received an increasing amount of attention in the general as well

as scientific media on treatment methods for chronic tinnitus. Jastreboff's theoretical conception of tinnitus as a neurophysiological disorder has been evaluated and found to be supported by some evidence. The interaction between neuroacoustical and emotional processes is, however, neither new nor has it been sufficiently elaborated in regard to the underlying psychological factors. The TRT interventions with its main components 'directive

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counselling' and the use of 'noise generators' are theoretically grounded. According to Jastreboff, TRT does not encompass psychotherapy [3], however, the TRT therapist should be very experienced in counselling and should have as much experience with tinnitus patients as possible. The lack of controlled randomised group studies and the potential consequence that differing interventions are offered under the name of TRT poses a scientific problem and is criticised [4,5,6,7]. By contrast, there is more substantial empirical support for the efficacy of cognitive-behavioural interventions in reducing tinnitus annoyance and tinnitus-related suffering. The necessity of methodologically well-designed studies to determine effectiveness of TRT and compare it with other techniques, especially cognitive-behavioural (TCT) is evident. In addition, it is of interest whether the effects of TRT can be traced back mainly to partial tinnitus masking or to the intensive counselling part of treatment. The study presented here is designed to meet these demands.

Methods

Design

The experimental conditions were: pure broad-band Noise Generator Therapy (NGT), Tinnitus-Retraining Therapy (TRT), Tinnitus Coping Therapy (TCT) and a waiting-list control (WLC). Patients who refused to participate in post-dismissal TCT were re-examined in a follow-up study (control-post). The design is summarised in Table 1.

Subject selection

From patients with chronic decompensated tinnitus (global score 40 to 70 points on the German Tinnitus Questionnaire TQ) referred consecutively for inpatient behavioural psychotherapy, a sample of 52 with unimpaired hearing (hearing threshold <30 dB) [8] were chosen and randomly assigned to different groups. Since the aim of the study was to evaluate the efficacy of interventions in stable decompensated chronic tinnitus [9], patients with Menière's disease, acoustic neurinoma, otosclerosis, severe general health problems, and psychoses were excluded. We also excluded patients previously treated with noise generators resp. maskers. Most exclusions were pronounced due to disturbances of auditory function. Patients with a TQ-global score >70 were excluded for ethical reasons. These patients were admitted as quickly as possible. All patients were thoroughly checked for neurological and otological disease, and psychoacoustic parameters (intensity, minimal masking level, MML, loudness discomfort level LDL, etc.) were documented. During the course of the study, the patients received no medication relevant for tinnitus.

Measures and assessment sequence

The TQ [9,10] was used to assess the dependent variable "tinnitus severity". It is one of the most

sensitive instruments and scores highly in validity and reliability [11]. Its global score (range 0-84) correlates with the visual analogue scales (VAS) tinnitus annoyance" and volume around $r = 0.75$ [10]. Additionally, the variables "tinnitus annoyance", "tinnitus control", "hyperacusis", NG protocol, Hopkin's Symptom Check-List (SCL-90-R; [12]) and Beck's Depression Inventory (BDI; [13]) were collected. We evaluated psychiatric co-morbidity according to DSM-IV. Measurement times were application for inpatient therapy resp. beginning of the pre-admittance outpatient therapy (T0), the end of the pre-admittance outpatient treatment resp. admittance (T1); discharge (T2); end of the post-discharge outpatient treatment, resp. 6-month follow-up (T3). The total observation period was up to 14 months.

Treatment procedures

The TCT and TRT groups consisted of 7 to 10 participants each. Altogether, there were 4 Saturday sessions of four-and-a-half hours each, given in the Klinik Roseneck. On the basis of behavioural therapy, the participants received detailed counselling concerning tinnitus causes and maintenance, methods of tinnitus and stress coping, interventions towards changes in attitudes, and exercises in attention focusing. Patients in the TRT group were also fitted with a broad-band noise generator (Silent Star-Viennatone™) with an open auricle-piece, and were given detailed instructions as to its use and effects. The neurophysiological tinnitus model [1,2] is part of the therapeutic concept.

Patients in the NGT group received the same noise generator (Silent Star-Viennatone™) and were given instructions by mail or by telephone about its use. In the control groups (WLC, Control-post), no therapy was offered.

Psychiatric Co-morbidity

Since we included only patients with a medium-to-high severity score in the TQ, nearly all groups displayed comparably high rates of psychiatric co-morbidity (Table 1). The extent of current overall complaints can be gauged by the high "Global Symptom Index" (GSI) of the Hopkin's-Symptom-Check-List SCL-90-R [12].

Sociodemographic data

The samples consisted of altogether 65 males and 38 females. The tinnitus history encompassed an average of 35 months (± 40 months; range 0.6 to 111 years). The groups displayed comparable psychosocial statistics: mean age 44 ± 13 years; range 27 to 62 years; married: 70%, divorced: 10%, unmarried: 10%, university-qualifying education: 30 to 40%, employed: 70%, retired: 20%.

Statistics

The data were analysed using the statistics software SPSS 4.0. First, a multivariate variance analysis

Table 1 Psychiatric Co-morbidity (prevalence, multiple diagnoses according to Diagnostic and Statistical Manual of Mental Disorders DSM-IV of the American Psychiatric Association) in patients with chronic decompensated tinnitus [TQ global score ≥ 40 - ≤ 70 ; [11]. GSI = "Global Symptom - Index" of the Hopkin's-Symptom-Check-List SCL-90-R [12].

DSM- IV- diagnosis:	NGT-pre n = 16	TRT-pre n = 10	TCT-pre n = 7	WLC n = 19	NGT-post n = 5	TCT-post n = 15	refusers n = 12
no disorder	27%	15%	14%	16%	0%	5%	18%
Major Depression	64%	60%	43%	36%	84%	77%	48%
Dysthymia	10%	6%	14%	32%	21%	22%	27%
Anxiety disorder	55%	30%	56%	26%	51%	49%	29%
Somatoform disorder	36%	28%	27%	20%	37%	22%	19%
SCL-90-R:							
GSI; abnormal > 0.62	1.0 ± 0.5	0.9 ± 0.4	1.1 ± 0.5	1.0 ± 0.6	0.9 ± 0.4	0.8 ± 0.5	0.9 ± 0.6

(MANOVA) was performed to discover time or interactional effects between the groups. With T-tests for dependent samples, we examined in which groups significant changes between measurement times could be found.

Results

A summary of the means and standard deviations for each dependent variable at pre-treatment, post-treatment and follow-up assessments is provided in Table 1.

Attention to the mean values may result in some concern over possible differences between groups: Similarly to the WLC, the NGT-pre group had the highest annoyance value at both measurement times ($F = 8.1$; $p = < 0.01$), the highest value for hyperacusis (70 ± 23 ; $F = 3.2$; n.s., not listed in the tables) and the highest TQ-Score ($F = 4.7$; $p = < 0.05$; Table 2). This cannot be explained by the psychiatric co-morbidity (Table 1), nor by depressive complaints (BDI). The TRT-pre- and TCT-pre-groups have similar primary scores except for the BDI, which was highest in the TCT-pre-group ($F = 6.1$; $p = < 0.001$). In the post-study, the patients in the TCT group did not differ from the control group (Table 3).

Taking into account that the patients in the NGT-pre-group had a higher score to begin with, and that the examined time frame was four months, the "pre"-study reveals that the TRT and TCT groups have outcomes superior to NGT with regard to improvement of the variables annoyance" ($F = 6.1$) and "tinnitus severity" as measured with the TQ ($F = 12.8$; $p = < 0.01$; Table 2). The most profound effect of TCT was measured in the variable "control" ($p = < 0.05$) and equal to TRT in the variable TQ ($F = 3.0$; $p = < 0.05$). On the general symptom level (GSI in SCL-90-R), no significant differences were found between the groups, whereas depressiveness (BDI) declined more in the TRT group than in the other groups ($F = 3.9$; $p = < 0.05$; Table 2). In four months, NGT was shown to be ineffective with regard to the measured variables. We plan to complete the study including examinations of how the patients from different study arms react to inpatient psychotherapy. The data collected so far are insufficient to permit conclusions at this point.

Table 2 Pre-study; Means and standard deviations (\pm); BDI = Beck Depression Inventory [13]; TQ = Global Score of the Tinnitus Questionnaire TQ [10]. Significant differences are marked with asterisks *; for sign. results of the variance analysis see section on results.

groups	variables	first contact	admission
Pre-study	Annoyance	T0	T1
NGT-pre	n = 16	75 ± 20	70 ± 22
TRT-pre	n = 10	53 ± 12	45 ± 18
TCT-pre	n = 7	57 ± 25	42 ± 16
WLC	n = 19	75 ± 21	$70 \pm 25^*$
Control		T0	T1
NGT-pre	n = 16	36 ± 25	35 ± 26
TRT-pre	n = 10	51 ± 16	55 ± 20
TCT-pre	n = 7	39 ± 30	$62 \pm 17^*$
WLC	n = 19	28 ± 25	21 ± 24
	TQ	T0	T1
NGT-pre	n = 16	56 ± 9	55 ± 13
TRT-pre	n = 10	47 ± 9	$39 \pm 12^*$
TCT-pre	n = 7	51 ± 15	$41 \pm 12^*$
WLC	n = 19	54 ± 8	54 ± 8
	BDI	T0	T1
NGT-pre	n = 16	17 ± 6	18 ± 8
TRT-pre	n = 10	17 ± 7	$12 \pm 6^*$
TCT-pre	n = 7	23 ± 13	$16 \pm 6^*$

In Table 3, pre-admission data has been included to illustrate the spontaneous course of tinnitus variables without (T0 vs. T1) and with multimodal inpatient therapy (T1 vs. T2). The inpatient treatment of 6 to 7 weeks (mean) was similarly effective in most of the post" groups. This reflects data of earlier studies [11,14]. Only those patients who did not participate in the "booster session" of TCT at the end of inpatient treatment (TCT-refusals), were then the patients with the smallest therapeutic success.

In the "post"-study, neither TCT nor NGT had a significant effect on the further course of tinnitus variables. Over the course of the whole study (T0 vs. T3), TCT after discharge was not superior to control group results in the variable "tinnitus severity" (measured with TQ). NGT offered for 6 months after discharge was also ineffective as compared to controls. The effect of NGT on "hyperacusis", measured with VAS (not listed in the tables), showed no advantage over other therapies, but due to the low mean score (30 ± 27), this does not seem particularly relevant. TCT had no significant effect

Table 3 Post-study: Significant differences are marked with asterisks* (T0/T1), ** (T1/T2); **** (T0/T3); the "post"-study deals with the differences between T2 and T3; for sign. results of the variance analysis see section on results

groups	variables	first contact	admission	discharge	follow up
Post-study	Annoyance	T0	T1	T2	T3
NGT-post	n = 5	90 ± 6	84 ± 9	46 ± 19**	42 ± 27 ****
TCT-post	n = 15	73 ± 16	59 ± 21*	66 ± 13	65 ± 12 ****
TCT-refusals	n = 12	60 ± 19	74 ± 13	54 ± 11**	54 ± 23
Control-post	n = 18	68 ± 21	81 ± 15	56 ± 23**	60 ± 21
NGT-post	Control	T0	T1	T2	T3
NGT-post	n = 5	18 ± 10	10 ± 12	54 ± 31**	56 ± 23 ****
TCT-post	n = 15	41 ± 29	30 ± 20	43 ± 22**	54 ± 17 ****
TCT-refusals	n = 10	44 ± 26	25 ± 18	55 ± 18**	51 ± 27
Control-post	n = 18	33 ± 27	34 ± 22	50 ± 27**	62 ± 24 ****
NGT-post	TQ	T0	T1	T2	T3
NGT-post	n = 5	52 ± 12	56 ± 10	39 ± 20**	44 ± 9 ****
TCT-post	n = 15	55 ± 10	55 ± 10	49 ± 13**	49 ± 9 ****
TCT-refusals	n = 13	52 ± 12	53 ± 7	50 ± 15**	47 ± 22 ****
Control-post	n = 18	58 ± 11	59 ± 7	43 ± 18**	47 ± 16 ****
TCT-post	BDI	T0	T1	T2	T3
TCT-post	n = 15			17 ± 10	16 ± 9
Control-post	n = 18			17 ± 8	13 ± 9

on depressive symptoms (BDI; Table 3) or other general symptoms (GSI; not listed in the tables). The patients who refused to participate in the TCT offered them, displayed no differences from other groups with regard to the pre-admission course (T0 - T2).

Discussion and conclusions

With our findings, the efficacy of TRT, modified in accordance with the German standard of treatment by qualified psychologists [7], is confirmed in a prospective, randomised and controlled study for the first time. This is shown especially by a score reduction in the TQ [10,11]. Thus, our study confirms the findings of Biesinger *et al.* [5], who treated a similarly affected sample without hearing impairment in an uncontrolled and individual outpatient study. Of interest is the high psychiatric comorbidity of our samples, which made it necessary to offer therapeutic support beyond Jastreboff's TRT-curricula. Other evaluations in a 4-week TRT cannot be compared with ours, since a patient group with low-grade impairment (exclusion of patients with a TQ score ≥ 40 points) was treated with lower levels of psychiatric co-morbidity. Compared with our results, the same researchers achieved even more pronounced effects with a group of similarly affected patients during a 10-week TCT [15].

A further result in our study is that TRT, conducted by a psychologist with experience in tinnitus, is just as effective as TCT. Moreover, both therapeutic options alleviate depressive symptoms (BDI). It is unclear why the therapies offered after discharge (TCT) were unable to further affect depressive symptoms.

The decisive element of TRT is counselling.

Thus, in our severely compromised patients treated with NGs alone, there is no effect on tinnitus-specific variables. Although certain patients did improve, others displayed a further deterioration of their condition. Even if the observation time of less than 6 months is taken into account, on the average, improvements should show. TCT offered after discharge does not improve tinnitus complaints.

Further studies in addition to the continuation of the research presented here will need to answer the question to what extent psychological treatment (TCT, TRT) or NGT before admission to a clinic is beneficial either to enhance subsequent inpatient behavioural-psychotherapeutic treatment or even to replace it.

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