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## Key Words

Tinnitus

Elderly

Cognitive behavioural therapy

# Treatment of tinnitus in the elderly: a controlled trial of cognitive behavior therapy

## Tratamiento del acúfeno en ancianos: una prueba controlada de terapia conductual cognitiva

### Abstract

The aim of the study was to investigate the effects of cognitive behavioral therapy (CBT) in elderly people with tinnitus (<65 years). Thirty-seven patients were called in for a structured interview. Following exclusion, twenty-three participated in the trial. All participants underwent medical ear, nose, and throat (ENT) examination, audiometry, and tinnitus matchings. A randomized controlled design with a waiting list control group was used. A CBT treatment package was delivered in six weekly two hour group sessions. Outcome was measured using validated self-report inventories and daily diary ratings of annoyance, loudness and sleep quality for one week pre-treatment, post-treatment. A three month follow-up was included at which time all participants had received treatment, but in a shorter format for the control group. Results showed statistically significant reductions of tinnitus-related distress. Thus, CBT was better than no treatment, but the particular aspects of CBT that contributed to the effects can not be established. In conclusion, the findings give some support for the use of group CBT for elderly people with tinnitus.

### Sumario

El objetivo de este estudio fue investigar los efectos de la terapia conductual cognitiva (CBT) en ancianos con acúfeno (<65 años). Se llamaron 37 pacientes para una entrevista estructurada y de ellos 23 participaron en la prueba después de un proceso de exclusión. Todos los participantes fueron objeto de un examen médico ORL, audiometría y acufenometría. Se usó un diseño controlado al azar con un grupo de control de una lista de espera. Se dio un paquete de tratamiento en sesiones grupales de 2 horas seis veces por semana. Los resultados se midieron usando cuestionarios de autoreporte y las anotaciones diarias del índice de molestia, intensidad subjetiva y calidad del sueño durante una semana previa y una posterior al tratamiento, pero en un formato corto para el grupo control. Los resultados muestran reducciones estadísticamente significativas del malestar relacionado con el acúfeno. Así, la CBT se considera mejor que la ausencia de tratamiento. Pero los aspectos particulares de la CBT que contribuyeron a obtener esos efectos no pueden ser establecidos. En conclusión, los hallazgos apoyan en alguna forma el uso de CBT grupal para ancianos con acúfeno.

Tinnitus is common among the elderly (Nondahl et al, 2002; Rosenhall & Karlsson, 1991), and a substantial proportion of older people suffer from their tinnitus (Davis & Rafaie, 2000; Rubinstein et al, 1992). It has been suggested that older persons with tinnitus suffer more than their younger counterparts (Davis & Rafaie, 2000). One possible factor is hearing loss, which is one of the best-known precursors of tinnitus, and also increasingly more common in old age. In addition, aging is accompanied by a decline in several sensory and cognitive functions. Elderly people do not receive help for their health problems to the same extent as do younger people (Haley et al, 1993), and this is likely the case with tinnitus.

Tinnitus in older adults has received some interest from researchers, but much less is known regarding the effects of tinnitus rehabilitation for this group. It is not easy to draw any firm conclusions from the research that has been conducted so far. Hazell (1991) found that disability resulting from tinnitus did not increase with age. However, in their population based study, Axelsson and Ringdahl (1989) found no age effect for the men, while older women experienced tinnitus as worse than younger women did. Other researchers have also found that tinnitus annoyance increases with age (Davis & Rafaie, 2000).

Cognitive behavioral therapy (CBT) is a relatively brief psychological treatment approach directed at identifying and modifying maladaptive behaviors and cognition by means of behavior change and cognitive restructuring. Positive results have been reported for use with the elderly (Gerson et al, 1999) and in the treatment of tinnitus (Andersson, 2001; Andersson & Lyttkens, 1999; Henry & Wilson, 1996), but to our knowledge there is no controlled trial of CBT for older patients with tinnitus.

The aim of this study was to investigate the effects of CBT for tinnitus in older adults (>65 years) using a randomized controlled design.

### Methods

#### *Patient selection and procedure*

Following advertisement, eligible participants were called in for a structured interview (Andersson et al, 1999). Inclusion criteria were that firstly the patients should have problems with their tinnitus (for example tinnitus is audible in many acoustic environments, disturbs sleep, or is a dominating problem that affects quality of life). No formal cut-off score on an established

tinnitus handicap questionnaire was used for inclusion (e.g. Kuk et al, 1990). Moreover, patients should have had duration of tinnitus for at least six months, and be able to come to sessions, which included walking the stairs to the therapy room. Patients were excluded if they 1) received previous psychological treatment for tinnitus, 2) had a depression score above 22 on the Beck Depression Inventory (Beck et al, 1961), 3) a score above 2 on item 2 (hopelessness) and item 9 (suicidal ideation), or 4) had medical reasons for not taking part in the treatment. A total of 62 persons responded to the advertisement. Following a telephone interview, 37 were called in for medical examination and structured interview. Of these, fourteen were excluded because of low level of distress ( $n=12$ ) or medical reasons for not taking part in the treatment ( $n=2$ ). A total of 23 patients (eleven female and twelve male) participated in the trial. Mean age was 70.1 years ( $SD=3.90$ , range 65–79 years), and the average duration of tinnitus was thirteen years ( $SD=12.5$ ) with a range between 1 and 50 years (median = 8.5 years). Pure-tone average for the better ear (0.5, 1, 2, and 3 kHz) was 28.3 dB HL ( $SD=13.3$ ). 22% of the patients, had been fitted with hearing aid(s) previously (25% in the treatment group and 18% in the control group). Minimal masking level with white noise was on average  $M=57.7$  dB HL ( $SD=15.8$ ). Following interview, patients were randomly allocated to either treatment ( $n=12$ ) or to serve as waiting list controls ( $n=11$ ). Then followed a baseline registration period of one week. After this, treatment began and lasted five weeks, which was followed by another week of diary recordings.

All patients completed a three month follow-up after their last treatment session, including one week of diary ratings. However, for ethical reasons all patients had received treatment at this point, and hence the data are not experimental and will be reported separately. In addition, controls were given four instead of six group sessions. The institutional review board approved the protocol.

#### Cognitive behavioral therapy (CBT)

CBT interventions are aimed at decreasing the psychological distress associated with tinnitus and are not targeted towards the loudness of tinnitus, which is usually unaffected by the treatment. The CBT protocol tested in this study has been described elsewhere (Andersson, 2001). In brief, it consisted of six weekly two hour sessions. Covered during these six sessions were information about tinnitus, applied relaxation (which is presented during four sessions), cognitive restructuring, behavioral activation, positive imagery, sound enrichment (by means of environmental sounds rather than noise generators), exposure to tinnitus, advice regarding hyperacusis, hearing tactics, and relapse prevention. All sessions were held in small groups ( $n=6$ ) with two therapists. Homework assignments were included in all sessions and comments on assignments were made at the beginning of each session.

#### Outcome measures

Four outcome measures were used in the present study.

The Tinnitus Reaction Questionnaire (TRQ) (Wilson et al, 1991) was included for measurement of tinnitus distress and this was the main outcome measure in the study. The TRQ consists of 26 items used for assessing tinnitus-related distress. Wilson et al (1991) reported an internal consistency of .96 and a test-retest

correlation of  $r=.88$ . A zero-to four-point scale assesses the responses to each of the 26 items, which are summed into a total score.

The Hospital Anxiety and Depression scale (HADS) (Zigmond & Snaith, 1983) is a measure of current emotional distress specifically created to be administered in health care settings. The scale includes two subscales: anxiety and depression. The scale has good psychometric qualities (Bjelland et al, 2002).

Fear of anxiety-related somatic sensations was measured with the Anxiety Sensitivity Index (ASI); a questionnaire containing sixteen items (Reiss et al, 1986). The scale has been translated into Swedish and tested in a sample of tinnitus patients with excellent psychometric properties (Andersson & Vretblad, 2000).

In addition, participants completed daily registrations one week prior to treatment and one week immediately following treatment on visual analogue scales (0–100 mm), rating annoyance caused by tinnitus (not at all – maximal annoyance), tinnitus loudness (minimal – maximal), and quality of sleep (much pleased- not at all pleased) (Scott et al, 1985).

#### Statistical analyses

Results were analyzed with a mixed design repeated measures analysis of variance (ANOVA). Significant interactions were followed by separate t-tests. A significance level of  $P<.05$  was endorsed. T-tests were used as post-hoc tests.

## Results

There were no between group differences on the background variables following randomization. Means and SD's for each of the questionnaire measures at pre-treatment and post-treatment are presented in Table 1.

#### Questionnaires

Results on the TRQ were analyzed with a  $2 \times 2$  repeated measures ANOVA with one group factor and one time factor. This resulted in a significant interaction [ $F(1,21)=6.4$ ,  $P=.02$ ]. Post-hoc t-tests showed that the treatment group improved

**Table 1.** Results on self-report inventories at pre-treatment and post-treatment for treatment group ( $n=12$ ) and control group ( $n=11$ )

| Measure   | Pre-treatment | Post-treatment |
|-----------|---------------|----------------|
| TRQ       |               |                |
| Treatment | 16.9 ± 13.5   | 9.7 ± 5.8      |
| Control   | 29.4 ± 18.0   | 32.5 ± 19      |
| HADS-dep  |               |                |
| Treatment | 4.0 ± 3.4     | 3.2 ± 2.9      |
| Control   | 6.1 ± 4.1     | 6.4 ± 5.0      |
| HADS-anx  |               |                |
| Treatment | 3.4 ± 1.8     | 2.7 ± 1.4      |
| Control   | 6.5 ± 4.0     | 6.7 ± 3.5      |
| ASI       |               |                |
| Treatment | 12.7 ± 6.0    | 11.6 ± 5.1     |
| Control   | 18.9 ± 10.0   | 26.3 ± 10.5    |

TRQ = Tinnitus Reaction Questionnaire; HADS-dep = Hospital Anxiety and Depression Scale, depression subscale; HADS-anx = Hospital Anxiety and Depression Scale, anxiety subscale; ASI = Anxiety Sensitivity Index; VAS = Visual Analogue Scale

[ $t(11) = 2.5, P = .03$ ] whereas the controls did not ( $P = .30$ ). Between group differences were statistically significant at post-treatment [ $t(21) = 4.0, P = .0006$ ]. However, as the groups almost differed significantly at pre-treatment ( $P = .08$ ), we also conducted an ANCOVA with pre-treatment values as covariates. The between group difference at post-treatment remained significant ( $P = 0.014$ ). The proportion of clinically significant improvement was defined as a 50% decrease in mean TRQ scores (Henry & Wilson, 1996). At post-treatment this criteria was reached by 42% of the treated patients, and nobody in the control group.

Scores on the HADS-dep did not result in any significant interaction. A similar picture was seen regarding the HADS-anx where no interaction was found.

Anxiety sensitivity scores (ASI) resulted in a significant interaction [ $F(1,21) = 6.1, P = .02$ ]. However as seen in Table 1, this was caused by a near significant increase in the control group ( $P = .052$ ). The between group differences was significant at post-treatment [ $t(21) = 4.3, P = .0003$ ].

#### Daily registrations

Results for the daily registrations are displayed in Figure 1.

Mean annoyance ratings showed a clear interaction effect [ $F(1,21) = 15.1, P = .0008$ ]. Subsequent paired t-tests showed that the treatment group improved from pre-treatment to post-treatment [ $t(11) = 3.6, P = .004$ ]. No improvement was found in the control group. Between group differences were significant at post-treatment [ $t(21) = 4.2, P = .0004$ ].

Analysis of daily registrations of tinnitus loudness did not show a significant interaction.

Ratings of sleep quality finally did not show any significant interaction.

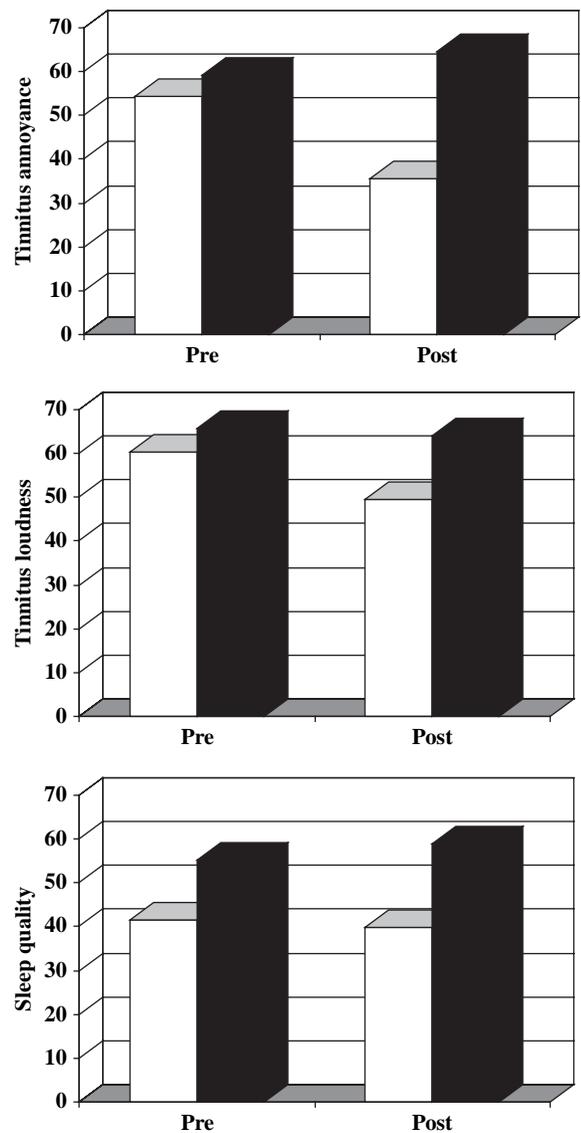
#### Three month follow-up

As stated above, the follow-up data were non-experimental, as all patients had received treatment at this point. The data will not be subjected to any statistical analyses, but are presented here for descriptive purposes. For the main outcome measure, TRQ mean scores at follow-up were 10.2 ( $SD = 7.9$ ) for the treatment group and 22.3 ( $SD = 22.7$ ) for the former waiting list control group. The percentage of patients who reached the criteria off 50% reduction of TRQ scores at the three month follow-up was 25% in the treatment group, and 27% in the former waiting list control group. Scores on HADS-dep at the three month follow-up were 2.0 ( $SD = 2.5$ ) in the treatment group and 5.4 ( $SD = 4.3$ ) in the former waiting list group. For the HADS-anx corresponding scores were 1.7 ( $SD = 0.9$ ) and 4.1 ( $SD = 3.5$ ). For the final questionnaire ASI, scores were 11.8 ( $SD = 5.6$ ) and 16.0 ( $SD = 8.5$ ), respectively.

Ratings on VAS showed mean scores of 27.8 ( $SD = 14.1$ ) and 53.5 ( $SD = 23.3$ ) for tinnitus annoyance for the treatment and former waiting list groups. Tinnitus loudness ratings had corresponding scores of 40.3 ( $SD = 16.5$ ) and 64.1 ( $SD = 16.5$ ), and sleep quality finally 31.3 ( $SD = 18$ ) and 44.0 ( $SD = 22.3$ ), for the two groups.

## Discussion

The participants in this study were recruited via advertisement, and may not be representative of older patients seen in regular



**Figure 1.** Results on diary recordings on visual analog scales (aggregated for one week) at pre-treatment and post-treatment for treatment group ( $n = 12$ ) and control group ( $n = 11$ ). For all diary ratings, high scores indicate more problems. Data presented for annoyance (A), perceived loudness (B), and quality of sleep (C), with low scores indicating better sleep quality. Open bars represent the treatment group and black bars the control group.

clinic. One further potential problem with the sample was that only 23/62 (37%) of the persons showing an interest actually took part in the study. It is interesting to note that a substantial number ( $n = 13$ ) had to be excluded because of low levels of distress. This finding is contrary to what is usually found in epidemiological studies, where older persons in the general population tend to be more annoyed by their tinnitus (Davis & Rafaie, 2000). One possible factor could be that older persons with comorbid conditions (such as chronic pain) to a lesser extent seek help for their tinnitus, and that our sample in this respect should be a healthier sample. The findings of the study should be replicated with older patients recruited from the clinic.

The effects found in the study compares well to what has been found in previous studies with adult samples (Andersson & Lyttkens, 1999). The proportion of patients reaching clinical significant improvement (50% decrease) was about 1/3 – 1/4 at the three month follow-up. This is what was found in a trial investigating the effects of CBT administered via the Internet (Andersson et al, 2002). A decrease in effect was observed at the three month follow-up, which corresponds to previous CBT studies (Jakes et al, 1992), suggesting that while the effects remain some relapse tends to occur. However, in a longitudinal study we found some long-term effects with an average follow-up duration of five years after CBT (Andersson et al, 2001). The treatment that was provided in this study was brief and group-based. This might, of course, have effects on the efficacy in this trial. Henry and Wilson (1996, 1998) showed somewhat larger effects in their studies, and had more sessions. However, they did use a group format, and there are no indications in the literature that individual CBT should be superior to group CBT for tinnitus (Andersson & Lyttkens, 1999). Several alternative treatments exist for tinnitus (Dobie, 1999), but to our knowledge there are only a few open trials published on the method of Tinnitus Retraining Therapy (Berry et al, 2002; Jastreboff & Jastreboff, 2000).

There are several methodological issues that are critical in this study. The sample was small, and despite the fact that we did find significant effects, a larger sample would have given more statistical power to detect differences. Still, in our initial power calculations we aimed for at least 30 patients in each group. However, as we had to exclude patients due to low levels of distress, the study did not include as many patients as was desirable.

Another issue concerns the treatment given. While CBT was better than no treatment, the particular aspects of CBT that contributed to the effects could not be established. Indeed, it might very well be that some components are more effective than others, but this remains to be established in future research.

The main outcome measure was the TRQ, and while this measure has excellent psychometric properties (Noble, 2000), it emphasizes psychological distress. Other alternative questionnaire measures such as the Tinnitus Handicap Inventory (THI) (Newman et al, 1996) are rather similar, but could be used together with the TRQ, and is also more well known for the otolaryngology community. In two recent unpublished trials we have used both the TRQ and the THI and found very similar results. Indeed, different measures of tinnitus distress have been found to be highly correlated (Baguley et al, 2000).

Previous research on CBT for tinnitus has used daily registrations of tinnitus (Lindberg et al, 1989; Scott et al, 1985), and this has also been recommended in tinnitus treatment outcome research (Axelsson et al, 1993). In the present study, we found effects on annoyance, but for loudness and sleep quality the interactions did not reach statistical significance. Again, insufficient statistical power can explain this lack of statistical interaction. Means in Table shows that the control group had higher pre-treatment scores than the treatment group. Again, the small sample size explains the pre-treatment differences as randomization with small samples can by chance generate pre-treatment differences. On the other hand, groups did not differ as much on the daily registrations.

The present study suggests that CBT can be adapted for use with older persons with tinnitus, and although the trial was small and replication is needed, the outcome was in line with previous studies with middle-aged tinnitus patients. The group format represents a cost-effective way to present the treatment, but in some cases individual sessions might be needed. Future research should focus on the long-term outcome of tinnitus treatment in the elderly as they are the largest group of people with tinnitus, and that research shows that they are also often much distressed by their tinnitus. Alternative measures of tinnitus distress and quality of life could be included in future trials as well as comparisons with alternative treatments such as tinnitus retraining therapy.

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