Cognitive behaviour therapy for hyperacusis: A randomized controlled trial

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ABSTRACT

Hyperacusis, defined as unusual intolerance to ordinary environmental sounds, is a common problem for which there are no controlled trials on psychological treatment. Given the avoidance strategies present in hyperacusis, and similarities with problems such as tinnitus and chronic pain, cognitive behaviour therapy (CBT) is hypothesized to be helpful for patients with hyperacusis.

In this randomized controlled study of 60 patients with hyperacusis, CBT was compared with a waiting list control group using the Loudness Discomfort Level test (LDL), the Hyperacusis Questionnaire, the Hospital Anxiety and Depression Scales, the Quality of Life Inventory and an adapted version of the Tampa Scale of Kinesiophobia.

There were significant between-group effects in favour of the CBT group on all measures except for the HADS anxiety scale. Between-group effect sizes were moderate to high, with Cohen's $d = 0.67$ and 0.69 per ear, respectively, for the primary measure LDL, and ranging from $d = 0.32$ to 1.36 for the secondary measures. The differences between groups ceased to exist when the waiting list group was treated later with CBT, and the treatment results were largely maintained after 12 months. In conclusion, CBT is a promising treatment for hyperacusis, although more research is necessary.

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Introduction

Hyperacusis as a primary problem has been defined as "*unusual intolerance to ordinary environmental sounds*" (Vernon, 1987). Persons with hyperacusis are sensitive to sounds such as music, clatter, mechanical sounds and/or paper noises (Andersson, Lindvall, Hursti, & Carlbring, 2002), and often protect themselves from sounds in different ways such as by wearing hearing protection (when taking the bus, for example) — even when there is no confirmed risk of hearing damage (Baguley, 2003). The personal suffering related to hyperacusis has been described in the literature, with patients reporting feelings of fear, extensive use of ear protection devices, and avoidance of environments such as their places of work and settings for social activities (Baguley & Andersson, 2007; McKenna, Baguley, McFerran, 2010). A high percentage of sick leave from work has also been found in this group of patients (Jüris, Andersson, Larsen, & Ekselius, 2013).

Prevalence studies of hyperacusis are rare. In a Swedish study where data were collected via either a postal survey or the internet, the prevalence rates were 7.7% ($n = 39$) and 5.9% ($n = 28$), respectively, when excluding individuals with hearing impairment (Andersson et al., 2002). In a Finnish study, where a broader definition of hyperacusis was used, the prevalence of self-reported hyperacusis was 17.2% (Hannula, Bloigu, Majamaa, Sorri, & Mäki-Torkko, 2011).

Little has been published concerning the aetiology and natural course of hyperacusis. Disturbed metabolism of 5-hydroxytryptamine (5-HT; serotonin) has been proposed as a mechanism in hyperacusis (Marriage & Barnes, 1995) and might also account for development of hyperacusis in depression and anxiety disorders (Attri & Nagarkar, 2010). The central gain hypothesis views hyperacusis as a result of a problematic compensatory gain process in the auditory pathways (Jastreboff & Hazell, 1993). Hyperacusis is reported to co-exist with many other conditions, including migraine and William's syndrome

(Katzenell & Segal, 2001). There is also a large comorbidity between tinnitus and hyperacusis (Baguley, 2003), as 40 per cent of patients with tinnitus suffer from hyperacusis (Jastreboff & Jastreboff, 2000), and up to 86 per cent of patients with hyperacusis in clinical samples report tinnitus (Anari, Axelsson, Eliasson, & Magnusson, 1999). In a recent study almost half of the patients diagnosed with hyperacusis suffered from anxiety disorders (Jüris et al., 2013). The most common anxiety disorders were social phobia and agoraphobia, as measured with the Mini-International Neuropsychiatric Interview (MINI, Swedish version 5.0.0.) (Sheehan et al., 1998). Furthermore, the patients also displayed high scores on anxiety-related personality traits, measured with the Swedish universities Scales of Personality.

As no underlying medical condition can be found in the large majority of affected patients (Baguley, 2003), researchers have suggested that hyperacusis is maintained and exacerbated by avoidance of sounds and increased anxiety (Schaaf, Klofat, & Hesse, 2003). It has been shown that persons who do not suffer from hyperacusis become more sensitive to sounds when they overprotect their ears (Formby, Sherlock, & Gold, 2003), while exposure to low-level noise treatment later desensitizes the same subjects. In another study, hyperacusis was found to be associated with noise-related avoidance behaviour and anxiety (Blaesing & Kroener-Herwig, 2012). This is in accord with the fear-avoidance model, which deals with fear of pain and focuses on the individual response of either confronting or avoiding the pain itself (Lethem, Slade, Troup, & Bentley, 1983; Vlaeyen & Linton, 2000). The avoidance of pain is assumed to predict further avoidance and increased fear of pain, leading to inactivity, which in itself leads to further disability. This model has found support in the literature (Vlaeyen & Linton, 2012). In a study of healthy participants, fear-avoidance beliefs were quite rare. When present, however, they increased the risk of future pain episodes (Linton, Buer, Vlaeyen, & Hellsing, 2000). Fear-avoidance is also a risk factor for poor health in patients suffering from burns (Willebrand, Andersson, Kildal, Gerdin, & Ekselius, 2006). To our knowledge, there are no published randomized controlled trials (RCT) of any psychological treatment for hyperacusis. We assume that most patients who suffer from hyperacusis receive an audiological examination and some form of counselling, or are prescribed ear attenuation devices at their audiology clinic. An existing method for treating tinnitus, and also hyperacusis, is Tinnitus Retraining Therapy (TRT) (Jastreboff & Hazell, 1993), but there are few published controlled studies focusing on hyperacusis (Formby et al., 2013). Treatments involving measures to help patients avoid ear protection and promote exposure to increasing levels of pink noise have been reported to have good effect (Vernon, 1987).

Cognitive behaviour therapy (CBT) is effective for a range of psychiatric disorders and could be considered the primary psychosocial treatment of choice for many, if not most, patients with mild to moderate psychiatric problems (Tolin, 2010). CBT is also effective as an adjunct for many somatic problems such as chronic pain (Eccleston et al., 2012). For the psychological problems associated with tinnitus, CBT is the treatment of choice (Hesser, Weise, Westin, & Andersson, 2011; Martinez-Devesa, Perera, Theodoulou, & Waddell, 2010). CBT is also effective for anxiety disorders (Hofmann & Smits, 2008), and has been proposed as a reasonable strategy for treating anxiety and stress associated with hyperacusis (Baguley, 2003), as there are similarities between anxiety disorders and hyperacusis. For persons with hyperacusis, avoidance behaviour protects the individual from the instant unpleasantness of certain sounds, but in the long run overprotecting the ears exacerbates hyperacusis (Vernon, 1987), and may lead to isolation and a depressed mood. Similar behavioural avoidance is also an important factor in the development of anxiety disorders, and motivates the use of exposure treatment (Murphy, Lindsay, & Williams, 1997; Salkovskis, Clark, Hackmann, Wells, & Gelder, 1999).

The aim of this study was to investigate whether CBT could be helpful for patients with hyperacusis. The hypothesis was that patients with hyperacusis would benefit from CBT, as measured by loudness discomfort levels, hyperacusis symptoms, anxiety and depressive symptoms, quality of life, and fear of injury/reinjury due to exposure to sounds.

Methods

The study was registered, and its International Clinical Trial registration number is NCT01321814. In addition, the study was approved by the Uppsala University Ethics Committee. All patients gave their written informed consent to participate, in accordance with recommendations in the Declaration of Helsinki.

Participants

For inclusion in the study patients had to: a) report hyperacusis as their primary audiological problem; b) present with average loudness discomfort levels (LDL) under 90 dB at the frequencies of 500, 1000 and 2000 Hz in at least one ear (Anari et al., 1999); c) have hearing levels better than 40 dB in the best ear; d) be between 18 and 65 years of age; e) understand and speak Swedish fluently. A total of 81 individuals were considered for the study, of which 74 were consecutive patients referred to the Ear, Nose and Throat Department at Uppsala University Hospital, and the remaining seven patients were self-referred.

Measures

The primary outcome measure
Loudness discomfort levels test (LDL). Audiometry was performed using ascending technique (Arlinger & Kinnefors, 1989) on an AC 40 audiometer from Interacoustics, calibrated in accordance with standards (ISO 1963/2001). Audiological assessments took place in a soundproof test room. The measurements were administered by an audiologist, blinded to whether the patients belonged to the treatment or the control group, and also blinded to which stage of the project the patients were in. The LDL was defined as the average of the sound levels in dB (HL) that first became uncomfortable in each ear, as indicated verbally by the patient. The measured frequencies were 250, 500, 1000, 2000, 3000 and 4000 Hz for both ears.

The secondary outcome measures
The Hyperacusis Questionnaire (HQ). The HQ measures hyperacusis severity and was developed for use in the quantification and characterization of hyperacusis (Khalfa et al., 2002). The questionnaire has been translated into Swedish (Blomberg, Rosander, & Andersson, 2006) and consists of 14 items that are rated on a 4-point Likert scale with alternatives from "no" = 0 points to "yes, a lot" = 3 points. An example of an item is: "Do you ever use earplugs or earmuffs to reduce your noise perception (Do not consider the use of hearing protection during abnormally high noise exposure situations)?". Three dimensions have been isolated by principal component analysis: attentional, social, and emotional impact, with satisfactory internal consistency reliability values of 0.66, 0.68 and 0.67, respectively, as assessed by the Cronbach coefficient alpha (Khalfa et al., 2002).

The Hospital Anxiety and Depression Scale (HADS). The HADS was developed for use with somatic patients and measures symptoms of anxiety and depression (Zigmond & Snaith, 1983). The instrument has been recommended for use in patients with hyperacusis (Baguley & Andersson, 2007) and consists of 14 items divided into

two subscales, with seven items measuring anxiety and seven measuring depression. An example of an anxiety item is: "I feel tense or wound up". An example of a depression item is: "I still enjoy the things I used to enjoy". The test−retest reliability of the scale is $r = 0.80$. The internal consistency is 0.80−0.93 for the anxiety scale and 0.81−0.90 for the depression scale (Lisspers, Nygren, & Soderman, 1997).

The Tampa Scale for Kinesiophobia (TSK). The TSK measures fear-avoidance beliefs and fear of (re)injury due to movement (Miller, Kori, & Todd, 1991), and has been used frequently in pain research. All 17 items were adapted to hyperacusis, with the aim of investigating fear of (re)injury due to exposure to sounds. To illustrate, an example of an item is: "If I were to try to overcome my sound sensitivity, it would increase". Each item is rated on a 4-point Likert scale with scoring alternatives ranging from "strongly disagree" to "strongly agree". The scale has not been validated for this population.

The Quality of Life Inventory (QOLI). The QOLI (Frisch et al., 2005) includes both importance and satisfaction ratings of 16 different areas of life such as health and self-esteem, and has been used in studies of tinnitus (Westin, Hayes, & Andersson, 2008) and chronic pain (Buhrman, Nilsson-Ihrfeldt, Jannert, Strom, & Andersson, 2011). The test−retest reliability of the scale has been reported to be between 0.80 and 0.91, and the internal consistency between 0.77 and 0.89 (Frisch et al., 2005).

Design and procedure

An initial 81 patients were screened for participation via telephone. Three individuals were not included, as they reported hearing impairment and their hearing levels were actually worse than 40 dB according to their medical journals. A further two patients were not included because they reported tinnitus as their primary audiological problem, and two patients declined participation. The remaining 74 patients were invited for further evaluation at the clinic, and 62 of them were later found to fulfil the inclusion criteria. Out of the 12 patients who were not included based on the clinical evaluation, six had normal LDLs. At this point, two patients realized that tinnitus, rather than hyperacusis, was their primary audiological problem. One patient declined further participation, specifically measurement of the LDL. Three patients suffered from severe psychological problems that were deemed likely to interfere with participation in the study (suicidality in two cases and psychotic disorder in one case). They were immediately referred to a psychiatric clinic. In all, 62 patients were included. Two of these 62 patients declined further participation when offered treatment after six months on the waiting list. As they did not take part in the second part of the evaluation, they were excluded, and the material was reduced from 62 to 60 patients. See Fig. 1 for a flow chart.

The baseline evaluation included information about the project, a medical examination, audiological testing, a clinical interview, and a structured psychiatric interview. The results of the psychiatric evaluation are presented elsewhere (Jüris et al., 2013). The patients also completed the HQ, HADS, TSK and QOLI questionnaires. After evaluating whether the patients were eligible for inclusion in the study, randomization was done by the test leader (author LJ) who randomly picked a carefully folded piece of paper, with either "treatment" or "control" written on it, out of a box. In this way patients were assigned to the treatment or waiting-list group. The treatment group received CBT as soon as possible, in general starting within one week after randomization. The patients in the waiting-list group remained on the waiting list for six

months, and were then evaluated again audiologically and by means of the questionnaires mentioned above (the pre-treatment assessment). The waiting-list patients then received CBT. After treatment, and again after 12 months, all patients were evaluated audiologically and by means of the HQ, HADS, TSK and QOLI questionnaires. All treatment and evaluation sessions were free of charge for the patients.

A total of five patients dropped out of treatment at different stages, two from the CBT group and three from the control group. In the treatment group, one patient discontinued treatment after the first session and one after the second. Two of the dropouts in the control group left during their treatment phase (after sessions two and four, respectively), and one after completing the post-measurement phase. The reasons for dropping out were moving abroad in one case, a personal crisis due to illness in a close relative in another, and three of the dropouts did not state any reason.

Treatment

CBT was given in an individual format by licensed psychologists trained in CBT. Four psychologists were involved in the study and they all received supervision during the trial. The treatment included six therapy sessions; the first was 90 min long and the following five were 45 min each. A treatment manual developed for this study was used in which general CBT principles were applied, such as Socratic questioning and goal-setting. See Table 1 for an overview of the treatment. The treatment further consisted of psychoeducation, exposure therapy, applied relaxation and behavioural activation. The psychoeducation consisted of information about the auditory system and hearing, sound levels and assessment of sounds, and information about the present CBT-model for the development and treatment of hyperacusis. Exposure to sounds was used both as a traditional CBT-technique that is used when treating specific phobias, for example, but there was also a focus on environmental sound enrichment. The first type of exposure was graded, and targeted the fear or anxiety reactions to sounds that many hyperacusis patients experience. The patients compiled situations including exposure to sounds hierarchically, assigning them numbers from 0 to 100 in difficulty to endure due to the loudness. Exposure then started around level 30−40 in the sessions, and patients continued with the same task as homework. The aim of the sound enrichment was to normalize the patients' reactions to sounds in accordance with the central gain theory. The focus was on increasing general sound levels at the patients' homes, workplaces and other locations of importance to the individual patients, such as by decreasing the use of ear protection devices in everyday situations. A short version of applied relaxation (Öst, 1987), which is often used in CBT for tinnitus (Kaldo & Andersson, 2004), was practiced with the aim of stress reduction. Another aim of applied relaxation was to provide the patient with a tool, when needed, for facilitating more difficult situations during exposure therapy. A condensed version of behavioural activation (Dimidjian, Barrera, Martell, Munoz, & Lewinsohn, 2011) was also included in the treatment. As it is common to avoid activities within certain sound environments, this part of the treatment aimed at gradually restarting activities patients had given up due to hyperacusis. Each therapy session ended with homework assignments, such as practicing applied relaxation in the home environment.

Statistical analysis

Demographic and baseline differences were tested with *t*-test for continuous data and chi-square test for categorical data.

Analysis of covariance (ANCOVA) was used to evaluate treatment effects in the two groups. The baseline measure was entered
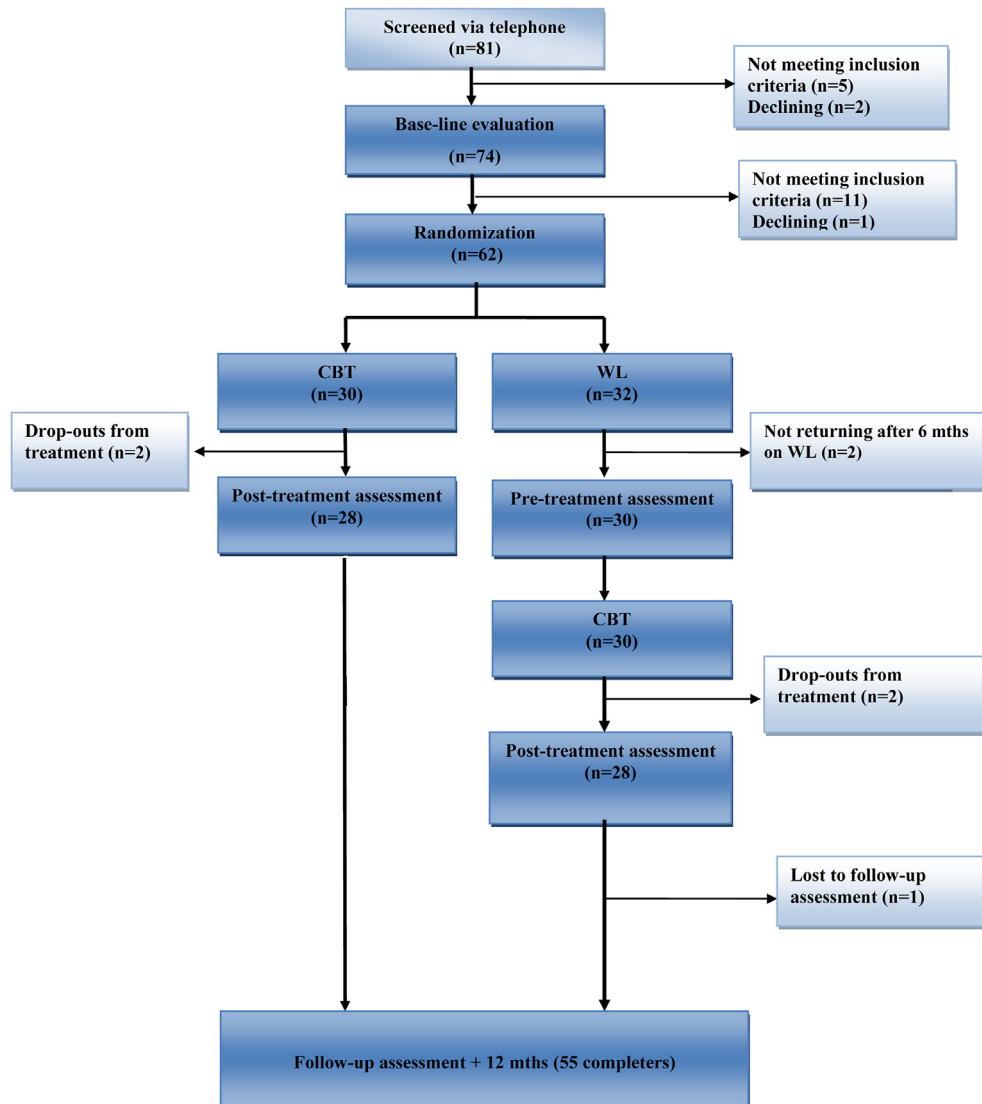
Fig. 1. Flow chart.

as a covariate to adjust for initial differences between groups. Twelve-month follow-up values for the treatment condition were compared with post-treatment values to test if treatment effects were sustained.

Between and within-group effect sizes were measured with Cohen's *d*. A Cohen's *d* of 0.2 was considered a small effect, 0.5 a medium effect and 0.8 a large effect (Cohen, 1977).

Predictive Mean Matching (PMM) was used to impute missing data. Due to the relatively small percentage of missing data, we considered it satisfactory to impute data for the primary outcome measure only.

P-values less than 0.05 were considered statistically significant for all analyses. Analyses were carried out using SPSS 21.0.

Results

Demography

Demographic data for the final 60 patients are presented in Table 2. Their ages ranged from 18 to 61 years with a mean of 40.2 years (SD = 12.2). Forty-five (75%) patients were women. The average duration of hyperacusis was 12.2 years (SD = 15.2;

range 1–60). The median duration was 5.0 years (calculated, as 10 patients claimed they had always suffered from hyperacusis).

The patients had mean hearing thresholds of 10.8 dB (SD = 9.9) in the right ear and 12.6 dB (SD = 9.8) in the left ear for the frequencies 500, 1000, 2000 and 3000 Hz (clearly within the range of normal hearing). There was an expected significant difference in the average hearing thresholds between the right and left ears, with the right ear outperforming the left ($t = 2.76$, $p < 0.01$). The mean LDLs ranged from 69.3 (SD = 12.1) to 76.0 (SD = 11.7) on average for the frequencies 250, 500, 1000, 2000, 3000 and 4000 Hz. There were no significant differences in LDL values between the right and left ears.

Baseline differences

Table 2 describes patient characteristics. *T*-tests showed no statistically significant differences between the groups either for the variables of sex, age and tinnitus, or for any of the outcome measures at baseline. In Table 3, mean values and standard deviations at baseline, pre-treatment for the waiting-list group, post-treatment and follow-up are presented for the outcome measures.

Table 1
Overview of the treatment program.

	Psychoeducation	Work in sessions	Homework assignments
Session 1	CBT model for treatment Applied relaxation	Treatment planning Goal setting Applied relaxation 1	Psychoeducative material Applied relaxation
Session 2	CBT model for treatment Applied relaxation	Applied relaxation 2 Exposure therapy	Psychoeducative material Applied relaxation Sound enrichment Exposure therapy
Session 3	Risk assessment regarding sound Applied relaxation	Applied relaxation 3 Exposure therapy	Psychoeducative material Applied relaxation Sound enrichment Exposure therapy
Session 4	Applied relaxation	Applied relaxation 4 Exposure therapy	Psychoeducative material Applied relaxation Sound enrichment Exposure therapy
Session 5	Behavioural Activation	Applied relaxation 5 Exposure therapy	Applied relaxation Exposure therapy Sound enrichment Behavioural Activation
Session 6	Behavioural Activation Relapse prevention	Exposure therapy Goal evaluation Relapse prevention	Applied relaxation Exposure therapy Sound enrichment Behavioural Activation

Effect on the primary outcome measure

The ANCOVAs showed a significant between-group effect on the LDL test for both ears (right ear $F(1, 57) = 14.2$, $p < 0.001$, left ear $F(1, 57) = 11.6$, $p < 0.001$), as illustrated in Fig. 2. Without imputation, values were similar (right ear $F(1,55) = 12.5$, $p < 0.001$, left ear $F(1,55) = 10.1$, $p < 0.01$). Between-group effect sizes (Cohen's d) were moderate, $d = 0.67$ for the right ear and $d = 0.69$ for the left ear. The within-group effect size in the CBT group was also moderate, $d = 0.56$ for the right ear and $d = 0.51$ for the left ear. Effect sizes are presented in Table 4.

Effect on the secondary outcome measures

After controlling for differences in pre-test scores, there were significant group effects in favour of the treatment group on all secondary outcome measures except for the HADS anxiety scale (see Table 3).

Table 2
Demography.

	CBT ($n = 30$)	WL ($n = 30$)
Marital Status (married/single)	14/16	18/12
Education		
>2 years university	16	20
<2 years university	5	0
Upper secondary school	9	8
Elementary school	0	2
Co-morbid tinnitus (y/n)	23/7	26/4
	M (SD)	M (SD)
Age	38.3 (11.1)	42.1 (13.1)
Hearing Threshold Right	11.2 (10.8)	10.3 (9.0)
Hearing Threshold Left	13.3 (11.3)	12.0 (8.2)

Table 3
Means and standard deviations for baseline, pre-treatment (for the WL group only), post-treatment and follow-up measures.

	CBT		WL		Total
	M (SD)	N	M (SD)	N	N
LDL Right ear					
Baseline	71.88 (10.75)	30	72.22 (10.79)	30	60
Pre-treatment (WL)	–	–	70.17 (12.19)	30	30
Post-treatment	78.55 (13.00)	30	79.06 (10.17)	30	60
12-month follow-up	80.09 (11.13)	30	79.89 (9.08)	30	60
LDL Left ear					
Baseline	73.47 (10.73)	30	72.94 (10.85)	30	60
Pre-treatment (WL)	–	–	70.44 (13.64)	30	30
Post-treatment	79.54 (12.80)	30	78.09 (9.95)	30	60
12-month follow-up	81.26 (10.17)	30	79.81 (9.87)	30	60
HQ					
Baseline	29.77 (5.49)	30	29.83 (6.33)	30	60
Pre-treatment (WL)	–	–	29.90 (6.24)	30	30
Post-treatment	21.50 (8.44)	28	25.71 (6.09)	28	56
12-month follow-up	20.21 (8.39)	28	24.52 (6.46)	27	55
HADS Anxiety					
Baseline	7.67 (4.66)	30	7.63 (3.64)	30	60
Pre-treatment (WL)	–	–	7.07 (4.03)	30	30
Post-treatment	5.75 (4.29)	28	5.86 (3.53)	28	56
12-month follow-up	5.78 (4.65)	27	6.07 (3.96)	27	54
HADS Depression					
Baseline	6.63 (3.84)	30	5.80 (3.75)	30	60
Pre-treatment (WL)	–	–	5.63 (4.00)	30	30
Post-treatment	4.21 (3.55)	28	4.68 (2.97)	28	56
12-month follow-up	3.81 (3.09)	27	4.63 (3.83)	27	54
TSK					
Baseline	44.30 (8.29)	30	42.87 (8.64)	30	60
Pre-treatment (WL)	–	–	41.17 (9.92)	30	30
Post-treatment	29.18 (7.49)	28	32.89 (9.51)	28	56
12-month follow-up	30.07 (6.58)	28	31.67 (10.08)	27	55
QOLI					
Baseline	1.49 (1.60)	30	0.97 (2.04)	30	60
Pre-treatment (WL)	–	–	1.30 (2.00)	30	30
Post-treatment	2.17 (1.38)	28	1.64 (1.95)	28	56
12-month follow-up	2.36 (1.35)	28	1.61 (1.98)	27	55

The Hyperacusis Questionnaire

The ANCOVA showed significant group effects for hyperacusis severity ($F(1,55) = 27.5$, $p < 0.001$). The between-group effect size was large, $d = 1.13$, and the within-group effect size for the CBT group was also large, $d = 1.16$.

The Hospital Anxiety and Depression Scale

The ANCOVA showed significant group effects for the depression scale ($F(1, 55) = 8.1$, $p < 0.01$), but not for the anxiety scale ($F(1, 55) = 3.9$, $p = 0.054$), although there was a trend in favour of the CBT group. Between-group effect sizes for depression were small, $d = 0.38$, and the within-group effect size for the CBT group was moderate, $d = 0.73$.

The Quality of Life Inventory

A significant treatment effect was shown on the QOLI ($F(1,55) = 4.3$, $p < 0.05$). The between-group effect size was moderate, $d = 0.51$, and the within-group effect size for the CBT group was small, $d = 0.46$.

The Tampa Scale of Kinesiophobia (adapted to hyperacusis)

The ANCOVAs showed significant group effects ($F(1, 55) = 47.1$, $p < 0.001$). The between-group effect size was large, $d = 1.36$, and the within-group effect size for the CBT group was also large, $d = 1.91$.
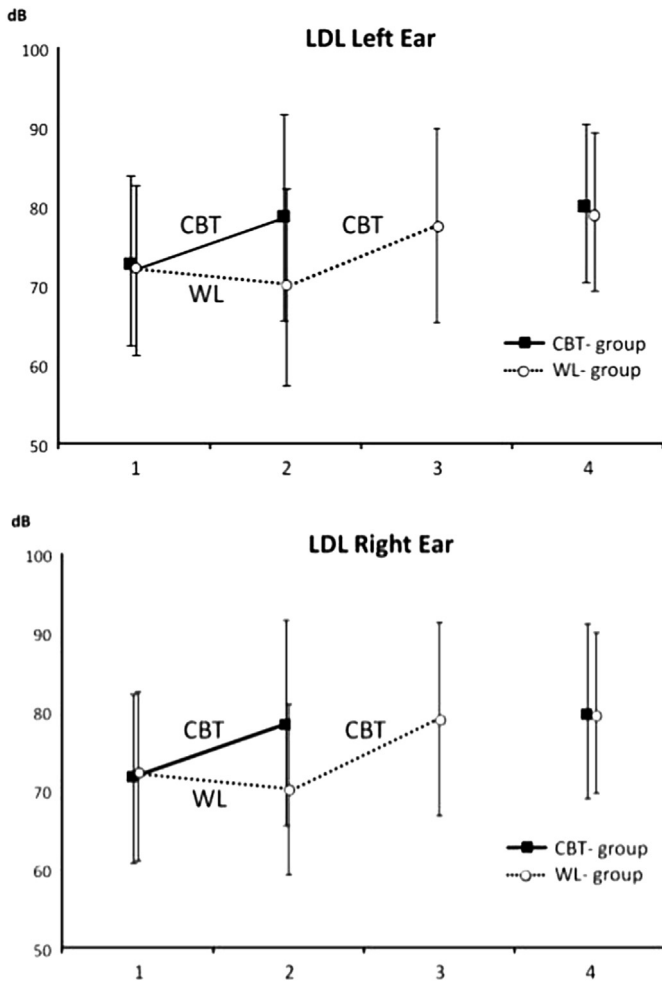
Fig. 2. Results for the LDL-test at the four assessments: 1 = baseline; 2 = post treatment for the CBT-group and pre-treatment for the WL-group; 3 = post-treatment for the WL-group, and 4 = 12-month follow-up for both groups. Significant differences exist between CBT- and WL-groups at assessment 2 for both ears.

Table 4
Effect sizes, Cohen's *d*. WL-group has received CBT at the 12-month follow-up.

	Within-group effect sizes		Between-group effect sizes
	CBT	WL	CBT vs WL
LDL Right ear			
Post-treatment	0.56	0.18	0.67
12-month follow-up	0.75	0.90	0.02
LDL Left ear			
Post-treatment	0.51	0.20	0.69
12-month follow up	0.74	0.79	0.14
HQ			
Post-treatment	1.16	0.01	1.13
12-month follow-up	1.35	0.85	0.58
HADS Anxiety			
Post-treatment	0.49	0.15	0.32
12-month follow-up	0.46	0.25	0.07
HADS Depression			
Post-treatment	0.73	0.04	0.38
12-month follow-up	0.90	0.26	0.24
TSK			
Post-treatment	1.91	0.18	1.36
12-month follow-up	1.90	0.95	0.19
QOLI			
Post-treatment	0.46	0.16	0.51
12-month follow-up	0.59	0.16	0.44

Comparison between the treatment condition and the waiting-list group after receiving treatment

When the waiting-list group later received CBT, the outcomes were similar. No significant differences were observed (see Table 4 for effect sizes).

Follow-up

The follow-up assessment was conducted 12 months after treatment, and was completed by 55 patients. Improvements were maintained at the group level for all measures in the CBT group. At follow-up the differences due to group on the HQ were significantly different in favour of the treatment group ($F(1,52) = 5.3$, $p < 0.05$). The HADS anxiety scale showed a significant improvement in the treatment group from baseline to follow-up, and also in the waiting-list group from pre-treatment to follow-up after they had also received CBT.

Discussion

In the present study it was shown that CBT can be helpful for persons suffering from hyperacusis. The results were stable over 12 months, with effect sizes generally moderate immediately after treatment, and larger at follow-up, which is logical if patients have continued applying the CBT principles in their lives following the active treatment period. To our knowledge, this is the only published RCT focusing on psychological treatment for hyperacusis, and it provides evidence for the CBT model outlined in the introduction: the noise-related avoidance behaviour in patients with hyperacusis is important in maintaining hyperacusis and needs to be targeted in treatment. In CBT the patient learns new behaviours for dealing with hyperacusis that mainly comprise exposure to sounds in a controlled and step-wise fashion, thereby reducing avoidance and also audiological sensitivity. Therefore, the present improvement is likely to be due both to a psychological impact on emotion as well as to changes in the auditory pathway.

In this study there was a statistically significant effect on the primary effect measure, the LDL test. Whether this implies clinical significance can be discussed in terms of a physical law, *the inverse square law*. The sound intensity from a point source will obey this law in that it states that 6 dB corresponds to twice the amplitude, which means a doubling of the volume of the sound. It is likely that an individual will experience a change of 6 dB as clinically significant, which is also our clinical impression. Loudness is the term describing the subjective dimension of the sound. In research, a change of 1 dB is perceived as a volume change of 10 per cent (Luxon, 2003), and 10 dB as a doubling of the perceived volume (Stevens, 1955). In the present study, the average changes in LDL values for the right and left ears immediately after treatment, both for the treatment group and for the control group after receiving CBT, were between 6.1 dB and 8.9 dB, and at follow-up they were between 7.5 dB and 9.8 dB. Consequently, it seems safe to conclude that a clinically significant change has been shown in this study. Out of all the patients measured post-treatment ($n = 56$), including the patients who received CBT after the waiting-list period, 32 individuals were found to have a positive change of at least 6 dB in one ear. At follow-up ($n = 55$), 35 patients were considered responders. It is conceivable that this improvement can make it possible to take part in many more activities in life than was previously the case, such as work and social activities.

The validity and reliability of the LDL test have been discussed (Baguley, 2003) and criticized for being sensitive to differences in instruction (Bornstein & Musiek, 1993). The measure was chosen for this study because of its customary use in audiology and because there is evidence that LDLs are decreased in patients with hyperacusis (Anari et al., 1999). To strengthen the reliability of this test, the

audiologists' instructions were standardized, and they were blinded to which group and phase the subject was in. Due to the testing procedure, it can also be argued that the LDL test might be a more objective measure than self-administered scales, as the individual cannot know his or her relative results when replying to test items.

Regarding the results of the secondary outcome measures, there were significant group effects on all measures except the HADS scale for anxiety. Such an effect would have been reasonable, according to our hypothesis, based on the similarities and comorbidity between hyperacusis and anxiety disorders, and there was actually a trend in that direction. HADS-anxiety decreased significantly from pre-treatment to follow-up in both groups, which may have been due to anxiety levels dropping in general, as all patients learned at the baseline evaluation that they were to receive treatment for hyperacusis. It is worth noting that when the study took place, six months was a normal length of time to wait for ordinary treatment at the clinic.

There are some limitations in this study. The patients in the control group received no active treatment and remained on the waiting list, although another credible treatment or an active control group would have been preferred. This design choice was based on the difficulty in finding another relevant treatment with which to compare CBT, as there is no recommended evidence-based treatment for hyperacusis. In our experience the most likely treatment a patient receives consists merely of an audiological examination, including the measurement of LDLs, which those on the waiting list received during the evaluation. These patients did not improve or deteriorate significantly on any measure while on the waiting list.

Questions can be raised about the representativity of the sample as almost all patients in this study had been referred to a hospital audiology clinic and were probably more distressed than persons with hyperacusis in the general population. More patients also had academic professions as compared with the general population. The inclusion criteria were broad, and it is therefore likely that some patients were included in the study who would have benefitted more from treatment for other psychiatric problems. The evaluated treatment consisted of only six sessions, a total of around five hours of treatment over two months, which proved enough to accomplish clinically relevant results. For a CBT-trained therapist with basic knowledge in behavioural medicine, the protocol should not be either too difficult or too time-consuming to implement. For the patient, his or her problems can be relieved in just a few months. The protocol is easy to prolong if the timeframe is too short for the individual patient. Perhaps a few more sessions of CBT could produce even better results for this patient group. An obstacle to providing patients with this treatment is the dearth of trained CBT-therapists, especially those working in the field of audiology where these patients are often found. In conclusion, CBT is a promising method for treating patients with hyperacusis, although further investigation is necessary.

Acknowledgements

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