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The science behind SilentCloud™

SilentCloud is an app-centric mobile system offering advanced tinnitus management. It is based on clinical recommendations built on thorough scientific research. Insights on relevant peer-reviewed publications are listed below. They cover all therapies offered in SilentCloud, namely Cognitive Behavioral Therapy, Custom Sound Therapy and Advanced Tonal Therapy.

Cognitive Behavioral Therapy (CBT)

Replication of prior findings regarding positive effects of internet-based CBT on tinnitus-related distress and associated symptoms.

Custom Sound Therapy

For this type of sound therapy usually a broad band noise is used to reduce tinnitus burden. Custom indicates that the noise is adapted to the perceived tinnitus.

Advanced Tonal Therapy

Designed for tonal tinnitus, this is a specific form of sound therapy using a range of patterend stimuli that are tailored to the individual's tinnitus frequency. The idea of ths neuromodulation approach is to disrupt or desynchronize neural activity associated with the tinnitus percept.

Cognitive Behavioral Therapy (CBT)

Replication of prior findings regarding positive effects of internet-based CBT on tinnitus-related distress and associated symptoms.

Weise, C., Kleinstäuber, M., & Andersson, G. (2016). Internet-delivered cognitive-behavior therapy for tinnitus: a randomized controlled trial. *Psychosomatic Medicine*, 78(4), 501–510. https://doi.org/10.1097/PSY.0000000000000310

Methods

A randomized control trial with two groups and n=142 participants. Patients with severe tinnitus-related distress were randomly assigned to therapist-guided internet-based CBT (iCBT) (n = 62) or to a moderated online discussion forum DF (n = 62).

Outcome measures

Standardized self-report measures for tinnitus-related distress (Tinnitus Handicap Inventory, Mini-Tinnitus Questionnaire). Assessment of associated symptoms (tinnitus acceptance, anxiety, depression, and insomnia). All questionnaires were assessed pre- and post-intervention with a follow-up after 6 and 12 months. Clinical significance was assessed with the Reliable Change Index.

Table 1. Changes in Tinnitus-Related Measures Over Time in the internet-based CBT and Comparison Group

Measure and Condition		n	Preassessment		Preassessment		Postassessment Hedges g (95% CI)	6-mo FU		Preassessment-6-mo FU Cohen d (95% CI)	1-y FU		Preassessment-1-y FU Cohen d (95% CI)
			Mean	SD	Mean	SD		Mean	SD		Mean	SD	
THI	iCBT	62	53.39	14.90	32.56	16.50	0.83 (0.47-1.20)	34.99	20.32	1.03 (0.64-1.43)	29.14	19.87	1.38 (0,95-1.81)
	DF	62	51.55	15.20	45.77	15.06							
Mini-TQ	iCBT	62	16.19	3.52	8.51	4.47	1.08 (0.71-1.64)	8.75	4.83	1.76 (1.29-2.23)	7.76	5.29	1.88 (1.39-2.36)
	DF	62	15.69	3.63	13.26	4.27							
TAQ	iCBT	62	34.63	8.89	44.02	9.31	0.76 (0.40-1.13)	42.03	10.91	0.74 (0.37-1.12)	44.53	10.82	1.00 (0.61-1.39)
	DF	62	33.90	10.15	36.47	10.39							
HADS Anxiety	iCBT	62	9.81	3.13	6.65	3.40	0.35 (0.00-0.71)	7.00	3.86	0.80 (0.42-1.18)	6.34	3.52	1.04 (0.64-1.44)
	DF	62	8.66	3.18	7.84	3.32							
HADS Depression	iCBT	62	7.87	3.91	5.27	3.72	0.36 (0.01-0.72)	5.66	4.13	0.55 (0.18-0.91)	5.3	4.08	0.64 (0.27-1.01)
	DF	62	7.06	4.13	6.66	3.98							
ISI	iCBT	62	11.58	5.55	7.67	5.40	0.66 (0.30-1.02)	8.97	6.68	0.43 (0.07-0.78)	9.34	5.92	0.39 (0.03-0.75)
	DF	62	12.81	6.1	11.56	6.36							

CBT = Cognitive Behavioral Therapy; THI = Tinnitus Handicap Inventory; iCBT = group receiving internet-based CBT; DF = group participating in a moderated online discussion forum; Mini-TQ = Mini-Tinnitus-Questionnaire; TAQ = Tinnitus Acceptance Questionnaire; HADS = Hospital Anxiety and Depression Scale (Anxiety subscale; Depression subscale); ISI = Insomnia Severity Index; 95% CI = 95% Intention-to-treat-sample (n=124); FU = follow-up; mo = months; y = years.

Redrawn from: Weise et al. (2016)

Results

The iCBT group showed a significantly larger improvement of tinnitus burden compared with the control group indicated by a reduction of THI of 39% (reduction of THI pre vs post intervention iCBT = 53.39 (SD=14.90) / 32.56 (SD=16.50); DF = 51.55 (SD=15.20) / 45.77 (SD=15.06)). Effect sizes of the between-group differences were large (Tinnitus Handicap Inventory: g = 0.83, 95% confidence interval = 0.47–1.20; Mini-Tinnitus Questionnaire: g = 1.08, 95% confidence interval = 0.71–1.64). A high percentage of iCBT participants (72.6%) showed a reliable change at post-intervention time. Effect sizes for the secondary outcome measures were lower but still significant. The follow-up data showed a maintenance of improvement (all outcome measures but sleep problems) up to 1 year.

Internet-based procedures seem to be viable alternatives to traditional advanced counseling techniques for tinnitus management.

Hesser, H., Gustafsson, T., Lundén, C., Henrikson, O., Fattahi, K., Johnsson, E., Westin, V. Z., Carlbring, P., Mäki-Torkko, E., Kaldo, V., & Andersson, G. (2012). A randomized controlled trial of Internet-delivered cognitive behavior therapy and acceptance and commitment therapy in the treatment of tinnitus. *Journal of Consulting and Clinical Psychology,* 80(4), 649–661. https://doi.org/10.1037/a0027021

Methods

Participants were randomized to treatment or control groups. The treatment groups either conducted internet-based Cognitive Behavioral Therapy (iCBT; n=32) or internet-based acceptance and commitment therapy (ACT n=35). Both treatment protocols involved a therapist to guide the participants through the materials. The control group participated in a moderated online discussion forum (DF; n=32).

Outcome measures

Tinnitus severity (Tinnitus Handicap Inventory); assessment of anxiety and depression (The Hospital Anxiety and Depression Scale); sleep problems (The Insomnia Severity Index); quality of life (The Quality of Life Inventory, Perceived Stress Scale).

In scope of the current review, only the results of the CBT group and the control group are presented hereafter.
For further results, please refer to the original publication.

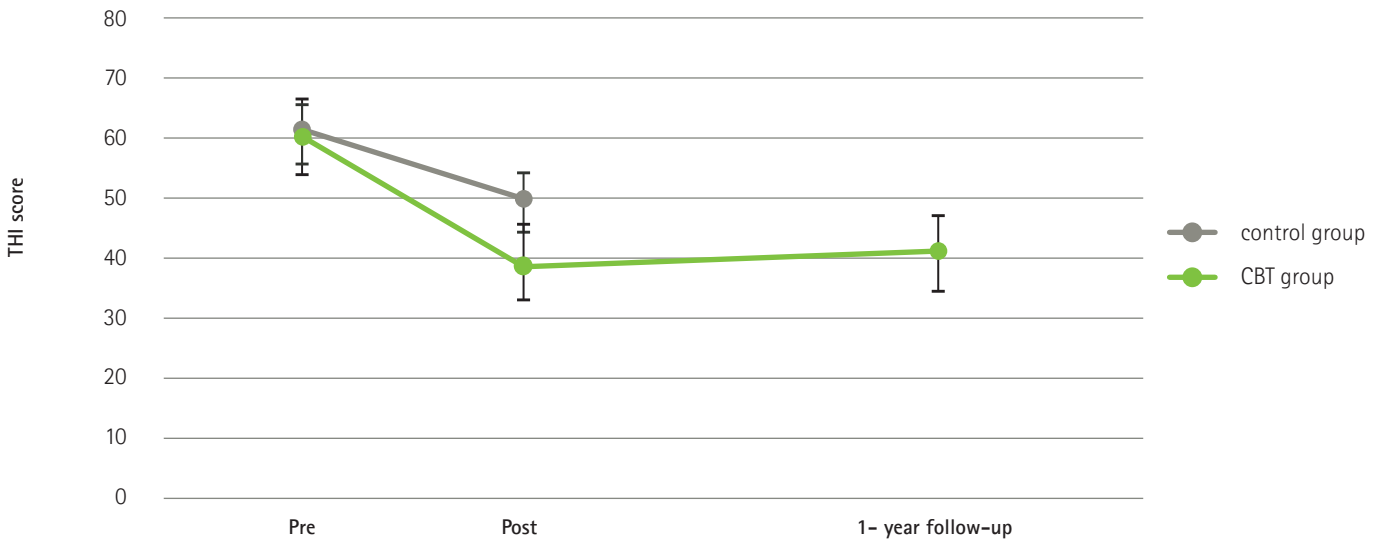


Figure 1. Observed means with 95% confidence intervals on the primary outcome by condition over time. Those in the control condition received treatment at post-assessment, and data for this condition are therefore not presented at follow-up. CBT = Cognitive Behavioral Therapy; THI = Tinnitus Handicap Inventory

Adapted from: Hesser et al. (2012)

Results

The treatment group showed a significant reduction in tinnitus burden compared with the control group. These changes were reflected in a reduction of the THI scores comparing pre vs. post-assessment of about 35% (CBT) (pre vs. post intervention THI CBT = 60.19 (SD=14.59) / 38.93 (SD=19.72)). Effect sizes were moderate (effect sizes CBT Cohen's d = 0.70). Improvements were maintained at 1-year follow-up (see figure 1). Participants showing a clinically significant change were 44% (n = 14) in CBT group, and 16% (n = 5) in the control group. The CBT group showed a significant improvement on the secondary outcome measuring anxiety (HADS-anxiety CBT -2.31, 95% CI [-4.01- 0.62]).

Comparison between face-to-face group CBT and internet-based CBT demonstrated that internet-based CBT might be an equally effective alternative.

Jasper, K., Weise, C., Conrad, I., Andersson, G., Hiller, W., & Kleinstäuber, M. (2014). Internet-based guided self-help versus group cognitive behavioral therapy for chronic tinnitus: a randomized controlled trial. *Psychotherapy and Psychosomatics,* 83(4), 234–246. https://doi.org/10.1159/000360705

Methods

Random assignment of participants to either face-to-face group therapy with CBT (GCBT n= 43) or internet-based CBT (iCBT n=41) or a control group (DF n=44) (Discussion Forum). The control group participated in an online discussion forum. For the treatment groups a weekly email interaction with a therapist was provided.

Outcome measures

Standardized self-report measures were assessed (Tinnitus Handicap Inventory, Mini-Tinnitus Questionnaire, Hospital Anxiety and Depression Scale, Insomnia Severity Index, Tinnitus Acceptance Questionnaire). Data was collected pre- and post-intervention and at a 6-month follow-up.

In the scope of this review, only the selected outcome measures are discussed. For further results, please refer to the original publication.

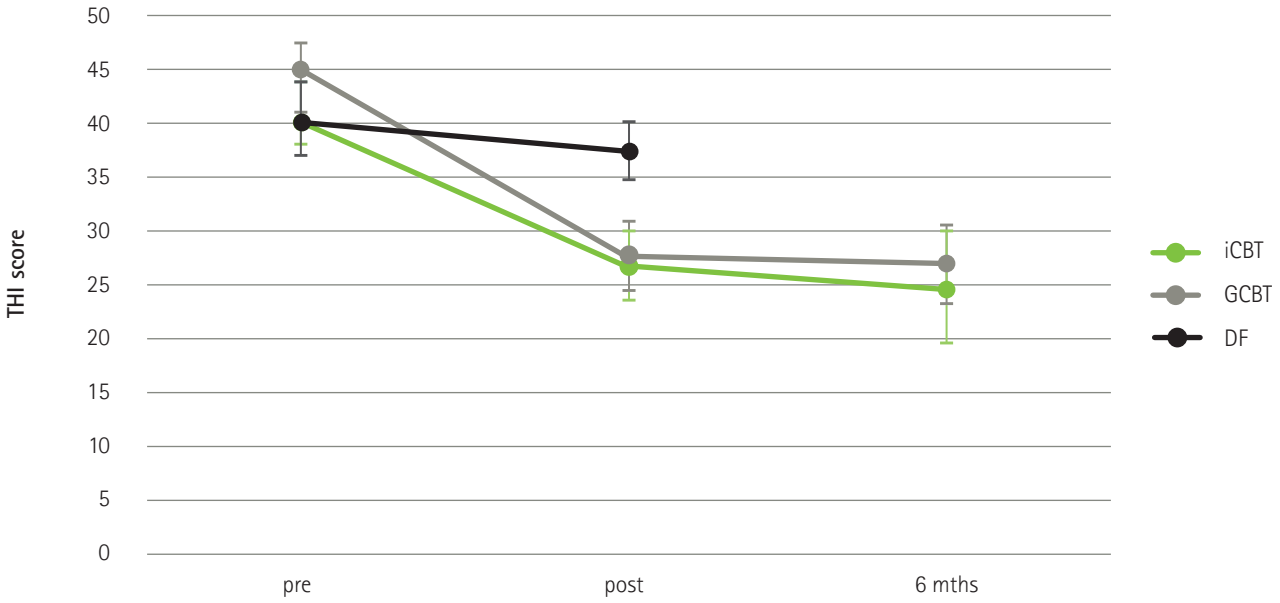


Figure 2. Changes in THI (means with standard error) for the three groups over time. The control group (DF) was not assessed at follow-up. iCBT = internet-based CBT; GCBT = group-based CBT; DF = discussion forum control group; THI = Tinnitus Handicap Inventory

Adapted from: Jasper et al. (2014)

Results

iCBT showed a significant reduction of tinnitus distress compared with the control group (THI reduction pre vs. post assessment iCBT 40.34 (SD=17.64) / 26.67 (SD=20.75); DF 40.23 (SD=20.54) / 37.46 (SD=18.94)). Within-group effect sizes were medium to large for the iCBT improvement compared with the control group ($0.39 \leq d \leq 0.96$). The iCBT and the GCBT group showed on average very similar outcome. iCBT showed a decrease of THI scores of 34% whereas GCBT showed a reduction of 37.5%. The difference between groups was not significant (iCBT=40.34 (SD=17.64) / 26.67 (SD=20.75); GCBT= 44.33 (SD=19.17) / 27.70 (SD=21.93); $F(1,82) = 0.01 - 1.45$, $p = .232 - .929$). A clinically relevant improvement was seen for 41% of the iCBT group after the intervention based on the THI, and for 50% for the GCBT group. Similar results were achieved at 6-months follow-up (iCBT = 49%; GCBT = 51%).

Custom Sound Therapy

A masking noise in combination with counseling provided a significant improvement of tinnitus burden for tinnitus patients. Effects remained constant over time.

Henry, J. A., Schechter, M., Zaugg, T., Griest, S., Jastreboff, P., Vernon, J., Kaelin, C., Meikle, M., Lyons, K., & Stewart, B. (2006). Clinical trial to compare tinnitus masking and tinnitus retraining therapy. *Acta Oto-Laryngologica,* 126 (sup556), 64–69. https://doi.org/10.1080/03655230600895556

Methods

Tinnitus sufferers (n=123) were (quasi randomly) assigned into two groups. One group received Tinnitus Masking (TM = using sound to provide the greatest immediate relief), the other Tinnitus Retraining Therapy (TRT = adjusting the sound to habituate to tinnitus). Both groups received counseling. Participants were clustered into groups based on their severity level.

Outcome measures

Tinnitus Handicap Inventory (THI), Tinnitus Handicap Questionnaire (THQ), Tinnitus Severity Index (TSI)

In the scope of this review, only the selected outcome measures are discussed. For further results, please refer to the original publication.

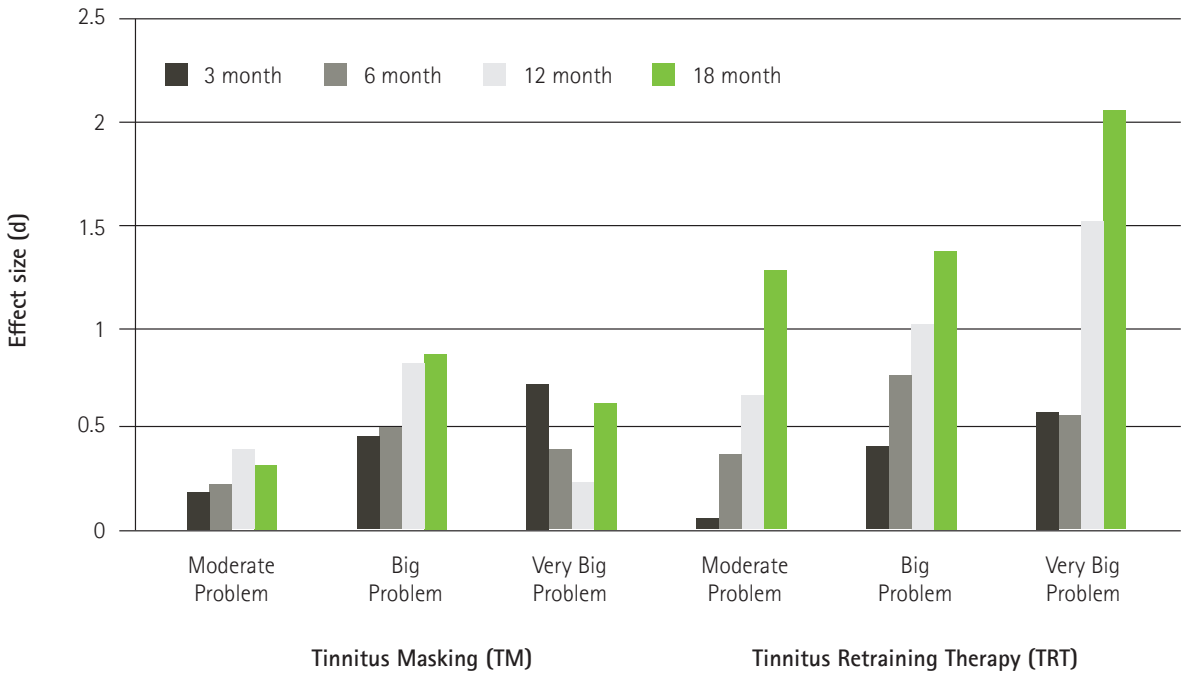


Figure 3. Effect sizes (in SD units, i.e. 'd') based on outcomes from Tinnitus Handicap Inventory (THI). All patients had severe tinnitus requiring long-term therapy, and were placed alternately into treatment with either tinnitus masking (TM) (n=59) or tinnitus retraining therapy (TRT) (n=64).

Adapted from: Henry et al. (2006)

Results

Both groups achieved a decrease in tinnitus severity measured with the THI. For the TM group the change after 3 months was 9.8% and 27.9% after 18 months (Baseline: N= 27 THI = 59.7 SD= 21.2; 3 months N=14 THI reduction = -5.9 SD= 12.9, effect size = 0.46; 18 months n=22 THI reduction =-16.7 SD=19.5, effect size = 0.86). TM showed better results at early stages of treatment (3 months) whereas TRT outperformed TM after 12 and 18 months of treatment.

Advanced Tonal Therapy

The Advanced Tonal Therapy for tinnitus shows clinically significant reduction in tinnitus loudness and symptoms.

Tass, P. A., Adamchic, I., Freund, H.-J., Von Stackelberg, T., & Hauptmann, C. (2012). Counteracting tinnitus by acoustic coordinated reset neuromodulation. *Restorative Neurology and Neuroscience*, 30(2), 137–159. https://doi.org/10.3233/RNN-2012-110218

Methods

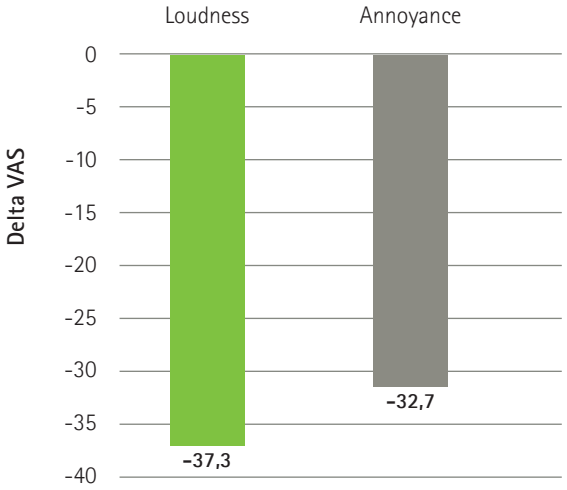
Randomized control trial with very different group sizes. N=63 participants, randomly assigned to the one of the treatment groups (G1 to G4, n total = 58) or the control group (G5 n=5). Only the outcome for treatment group G1 is reported here (n=22). The treatment group was stimulated with a specific tonal signal reflecting the logarithmic tonotopic organization of the auditory cortex and tailored to the matched tinnitus. The treatment group received stimulation for 12 weeks and were assessed again 4 weeks after treatment. Stimulation lasted for 4-6 hours per day.

For all group results please refer to the original publication.

Outcome measures

Visual Analog Scale (VAS); Tinnitus Questionnaire (TQ).

Change in VAS for loudness and annoyance in respect to baseline after 12 weeks of treatment



TQ scores before and after 12 weeks of treatment

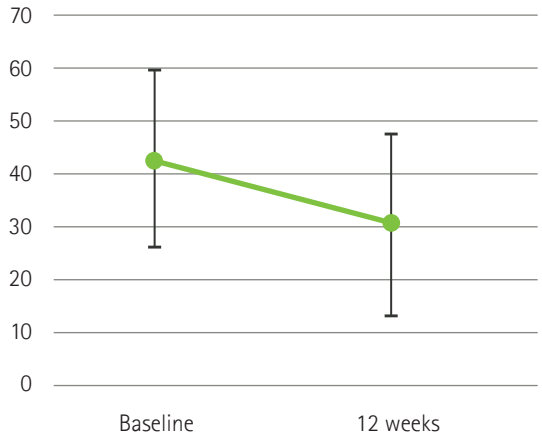


Figure 4. **Left:** Difference in VAS for loudness and annoyance comparing baseline to assessment after 12 weeks of treatment. VAS values reported are for the simulation-on condition. **Right:** TQ score at baseline and after 12 weeks of treatment. TQ values reported are for the simulation-off condition.

Adapted from: Tass et al. (2012)

Results

The VAS showed a reduction of tinnitus loudness of 52.6% after 12 weeks of treatment in the stimulation-on condition (VAS loudness Baseline = 70.9 (SD=14.9); post-treatment =–37.3 (SD=24.7)). Tinnitus annoyance showed a reduction of 49.2% (VAS annoyance Baseline = 66.4 (SD=17.3); post-treatment =–32.7 (SD=23.2)). Tinnitus severity measured with the TQ showed a reduction of 28.8% after 12 weeks of treatment (TQ Baseline = 43.1 (SD=16.7); post-treatment = –12.4 (SD=8.9)).

Advanced Tonal Therapy

Advanced Tonal Therapy in form of Acoustic Coordinated Reset Neuromodulation shows comparable efficacy to Cognitive Behavioral Therapy (CBT).

Theodoroff, S. M., McMillan, G. P., Schmidt, C. J., Dann, S. M., Hauptmann, C., Goodworth, M.-C., Leibowitz, R. Q., Random, C., & Henry, J. A. (2022). Randomised controlled trial of interventions for bothersome tinnitus: DesyncraTM versus cognitive behavioural therapy. *International Journal of Audiology*, 61(12), 1035–1044. https://doi.org/10.1080/14992027.2021.2004325

Methods

Randomized controlled trial with 61 patients with tonal tinnitus receiving either tailored tonal sound therapy (n = 29) or CBT (n = 32). The goal of the trial was to compare the efficacy of tailored tonal sound therapy to that of CBT, which is considered the gold standard in tinnitus management. Patients were instructed to use the sound therapy for 4–6 hours daily over a period of 24 weeks. Since some participants were hearing aid users, hearing aid use was considered in the randomization allocation and taken into account in the statistical analyses.

Outcome measures

Tinnitus Questionnaire (TQ).

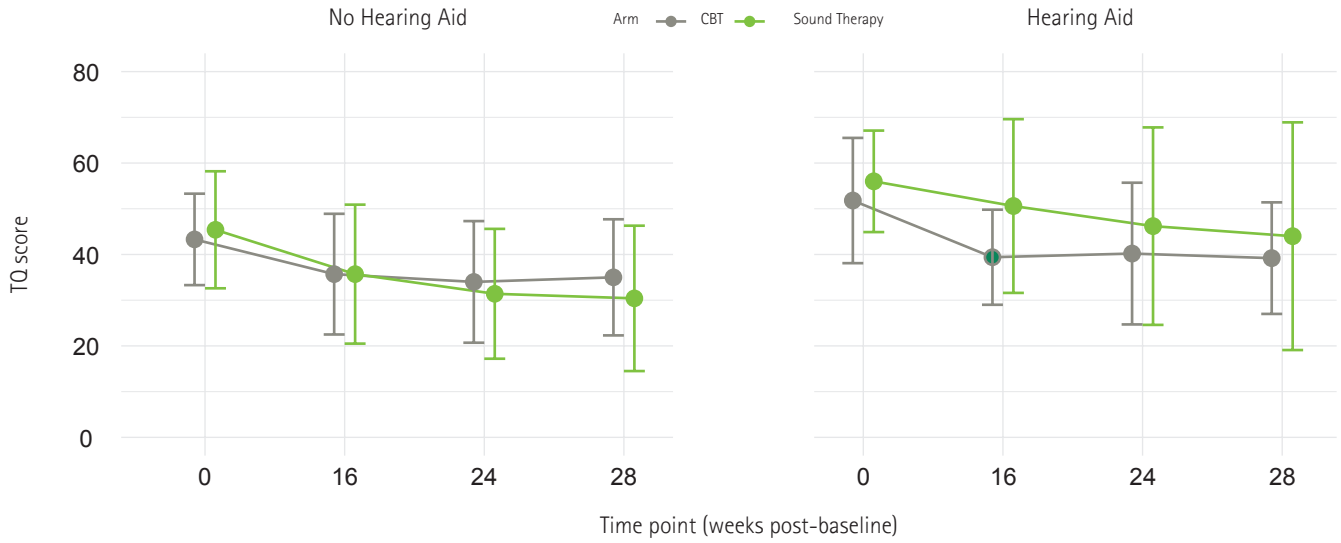


Figure 4. Mean TQ scores over time. The gray lines represent the sample mean TQ score at each time point within each hearing aid stratum for the CBT group, the green lines represent the same for the sound therapy group. TQ = Tinnitus Questionnaire.

Adapted from: Theodoroff et al. (2022)

Results

Data were analyzed at 24 and 28 weeks post-baseline. Here, the results from the 28-week follow-up are presented. Both treatment groups showed a reduction in tinnitus-related distress as measured by the TQ. For CBT, the mean TQ score decreased from 43.3 to 35 points between baseline and 28 weeks for the non hearing aid users and from 51.8 to 39.2 points for the hearing aid users. Patients that received sound therapy not using hearing aids showed a reduction of 45.4 to 30.4 points from baseline to 28 weeks, while hearing aid users showed a reduction from 56 to 44 points. Statistical analyses comparing the two therapies suggest that sound therapy is just as effective or more so than CBT in reducing tinnitus distress.

Advanced Tonal Therapy

Advanced Tonal Therapy in the form of Acoustic Coordinated Reset Neuromodulation seems to provide long lasting benefit for tinnitus patients.

Hauptmann, C., Ströbel, A., Williams, M., Patel, N., Wurzer, H., von Stackelberg, T., Brinkmann, U., Langguth, B., & Tass, P. A. (2015). Acoustic coordinated reset neuromodulation in a real life patient population with chronic tonal tinnitus. *BioMed Research International, 2015,* Article 569052. https://doi.org/10.1155/2015/569052

Methods

Prospective, open-label, nonrandomized, noncontrolled multicenter clinical study (23 study sites). N=198 participants. Patients used the acoustic stimulation for 12 months with additional visits after 3 and 6 months. Participants were asked to use stimulation every day for 4-6 hours.

Outcome measures

German version of Tinnitus Handicap Inventory (TBF-12, Tinnitus-Beeinträchtigungs-Fragebogen); Numeric rating scale (comparable to the Visual Analog Scale) (NRS).

Results

The TBF-12 showed a reduction of tinnitus severity of 37.9% after 12 months of treatment (baseline TFB-12=10.8 (SD=5.0) vs 12 months TFB-12=6.7 (SD=5.0). The NRS for loudness was reduced by 18.9% (NRS loudness Baseline = 58.6 (SD=21.9); 12 months = 47.5 (SD=24.9)) whereas the values for annoyance were reduced by 25.2% after 12 months of treatment (NRS annoyance Baseline = 58.3 (SD=25.2); 12 months = 43.6 (SD=25.7)).

Do you have any questions or want to find out more about SilentCloud? Get in touch with us.

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