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Development of a personalized sound therapy system and its therapeutic effect on subjective tinnitus patients

Razvoj personalizovanog sistema zvučne terapije i njegov terapijski efekat na pacijente sa subjektivnim tinitusom

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Abstract

Background/Aim. Tinnitus is a prevalent auditory condition that significantly affects the quality of life. Despite the variety of treatments available, their effectiveness is inconsistent. The aim of this study was to evaluate the impact of a newly developed sound therapy system on tinnitus patients, specifically in terms of changes in audiology, tinnitus-related tests, and tinnitus psychoacoustic characteristics. **Methods**. A total of 100 patients with tinnitus were included in the study. They were divided into two groups: the control group (CG) (n = 48) and the treatment group (TG) (n = 52). Various demographic characteristics of the patients were recorded. All patients had a thorough audiological assessment, which included pure tone audiometry and acoustic immittance testing, as well as tinnitus-specific evaluations, such as tinnitus frequency matching, tinnitus loudness matching, minimum masked level (MML), and residual inhibition (RI) examinations. In addition, psychoacoustic characteristics of tinnitus were assessed, including Tinnitus Handicap Inventory (THI), Hospital Anxiety and Depression Scale (HADS), Pittsburgh Sleep Quality Index (PSQI), and Visual Analog Scale (VAS) scores. **Results.** There were no significant differences in various demographic characteristics between CG and TG before acoustic therapy. Additionally, there were no significant differences between the groups in audiometric assessments, tinnitus-related tests, psychological acoustic characteristics before treatment, or in the distribution of tinnitus frequencies. The hearing threshold level in TG was notably lower than in CG (p = 0.0238). Tinnitus loudness was significantly reduced in TG (p = 0.0256). MML in TG tended to improve (p = 0.0532), although this difference did not reach statistical significance and showed a positive trend. Among the subscales of THI, TG demonstrated significant improvements. PSQI scores also indicated they were significantly lower in TG than in CG (p = 0.0238). The total score on HADS (16.58 ± 2.89 vs. 16.67 ± 2.76; p = 0.8730) and the total score on VAS (4.19 ± 1.48 vs. 4.22 ± 1.37; p = 0.9160) did not show a significant difference. **Conclusion.** Acoustic therapy significantly improves patients' hearing, reduces tinnitus loudness, and improves sleep quality. Our acoustic therapy system is an effective strategy for alleviating chronic subjective tinnitus.

Key words:
audiometry; hearing tests; quality of life; surveys and questionnaires; tinnitus.

Apstrakt

Uvod/Cilj. Tinitus je rasprostranjeno auditivno stanje koje značajno utiče na kvalitet života. Uprkos nizu dostupnih tretmana, njihova delotvornost je varijabilna. Cilj rada bio je da se proceni uticaj novorazvijenog sistema zvučne terapije na pacijente sa tinitusom, posebno u smislu promena u audiologiji, testova povezanih sa tinitusom i psihoakustičkih karakteristika tinitusa. **Metode.** U studiju je bilo uključeno 100 pacijenata sa tinitusom. Podeljeni su u dve grupe, kontrolnu grupu (KG) (n = 48) i terapijsku grupu (TG) (n = 52). Zabeležene su različite demografske karakteristike pacijenata. Svi pacijenti imali su temeljnu audiološku procenu, koja je obuhvatila audiometriju čistih tonova i testiranje akustičke imitanse, kao i procene specifične za tinitus, kao što su određivanje frekvencije tinitusa, određivanje jačine tinitusa, ispitavanja minimalnog maskirajućeg nivoa (*minimum masked level* – MML) i rezidualne inhibicije (RI). Pored toga, procenjene su psihoakustičke karakteristike tinitusa, uključujući rezultate Upitnika umanjenja sposobnosti zbog tinitusa (*Tinnitus Handicap Inventory* – THI), Bolničke skale za anksioznost i depresiju (*Hospital Anxiety and Depression Scale* – HADS), Pitsburškog indeksa kvaliteta sna (*Pittsburgh Sleep Quality Index* – PSQI) i Vizuelne analogne skale (*Visual Analog Scale* – VAS). **Rezultati.** Nije bilo značajnih razlika u različitim demografskim karakteristikama između KG i TG pre akustičke terapije. Dodatno, nije bilo značajnih razlika između grupa u audiometrijskim procenama, testovima povezanim sa tinitusom, psihoakustičkim karakteristikama tinitusa pre tretmana, niti u distribuciji frekvencija tinitusa. Prag sluha u TG bio je znatno niži nego u KG

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(p = 0,0238). Jačina tinitusa značajno se smanjila u TG (p = 0,0256). MML u TG imao je tendenciju poboljšanja (p = 0,0532), iako ova razlika nije dostigla statističku značajnost i pokazala je pozitivan trend. Među podskalama THI, u grupi TG je pokazano značajno poboljšanje. Takođe, rezultati PSQI pokazali su da su skorovi u TG bili značajno niži nego u KG (p = 0,0238). Ukupni rezultati na skalama HADS (16,58 ± 2,89 vs. 16,67 ± 2,76; p = 0,8730) i VAS (4,19 ± 1,48 vs. 4,22 ± 1,37; p = 0,9160), nisu pokazali značajnu razliku. **Zaključak.** Akustička terapija značajno poboljšava sluh pacijenata, smanjuje jačinu tinitusa i poboljšava kvalitet sna. Naš sistem akustičke terapije je efikasna strategija za ublažavanje hroničnog subjektivnog tinitusa.

Ključne reči:
audiometrija; sluh, ispitivanje; kvalitet života; ankete i upitnici; tinitus.

Introduction

Tinnitus is a prevalent auditory condition characterized by the perception of sound without external acoustic stimulation, with most cases classified as subjective, meaning the sounds are perceived only by the individual [1, 2]. Epidemiological studies across 16 countries reveal that the majority of research (38.5%) has been conducted in Europe, with nearly half (48.7%) of the studies published since 2010 [3]. Reported prevalence rates vary widely, ranging from 5.1% to 42.7%, while studies using consistent definitions report a narrower prevalence of 11.9% to 30.3% [4]. Data indicate that tinnitus prevalence increases with age, and males tend to have a higher incidence compared to females [5]. Recent research suggests that 9.6% of adults in the USA experienced tinnitus within the past 12 months, while in China, tinnitus patients constitute 7.5% of those seeking treatment at otolaryngology clinics [6]. Persistent tinnitus can lead to significant psychological distress, including depression and anxiety, severely impacting quality of life and causing difficulties with sleep, concentration, and emotional well-being. Comorbidities such as hypertension, diabetes, and arteriosclerosis further exacerbate the overall health burden [7–9]. Due to the lack of standardized treatment protocols, ineffective or poorly regulated treatments can lead to increased healthcare costs [10, 11]. The 2014 clinical practice recommendations from the American Academy of Otolaryngology-Head and Neck Surgery do not endorse pharmaceutical therapies, including antidepressants, anticonvulsants, and anti-anxiety drugs. Instead, cognitive behavioral therapy and the use of hearing aids are considered effective management strategies [12], particularly for patients with associated hearing impairment.

In recent years, personalized and effective acoustic therapy (AT) protocols for tinnitus patients have become a primary focus of clinical research worldwide [13–15]. Various acoustic therapies, including natural sounds [15], broadband noise [16], tailored notched music training [17], and frequency discrimination training [18], have been developed and studied. Although numerous studies have demonstrated the efficacy of acoustic therapies and conducted systematic analyses, they have concluded that more large-scale, multi-center, randomized controlled studies are necessary. Additionally, it remains unclear which specific AT protocols are most effective for different tinnitus profiles or how different therapies compare when treating the same type of patient [19–21]. Tinnitus is primarily attributed to reduced inhibitory neural modulation, overactivity, and synchronous firing of neurons at edge frequencies due to decreased auditory input [22–24]. New acoustic therapies aim to reverse these abnormal neurophysiological activities. For instance, acoustic coherence reset neuromodulation involves phase resetting and random presentation of multiple frequencies surrounding the tinnitus pitch, aiming to desynchronize aberrant neuronal activity and achieve long-term relief or elimination of tinnitus perception after treatment cessation [25]. A recent study has shown that auditory coordinated reset neuromodulation significantly reduces tinnitus symptoms, lowers Visual Analog Scale (VAS) loudness and tinnitus questionnaire scores, and maintains its efficacy over extended periods [26]. Brain wave pattern changes indicate that auditory coordinated reset neuromodulation normalizes abnormal brain activity associated with tinnitus. Acoustic therapies improve tinnitus through two main mechanisms: by correcting pathological synchronous neural activity to reduce or eliminate tinnitus perception, and by helping patients understand and habituate to their tinnitus, thereby diverting attention away from it [27, 28].

Therefore, developing effective AT systems holds significant clinical importance for individuals with tinnitus. In this study, to reduce the costs of AT and provide convenient and effective treatment for patients, an AT system was developed. Patients were evaluated using tinnitus history questionnaires, the Tinnitus Handicap Inventory (THI), the Self-Rating Anxiety Scale, the Self-Rating Depression Scale, and VAS. Despite various studies demonstrating the effectiveness of AT, a comprehensive review concluded that more large-scale, multi-center, controlled studies are necessary.

The aim of this study was to evaluate the impact of a newly developed sound therapy system on tinnitus patients, specifically in terms of changes in audiology, tinnitus-related tests, and tinnitus psychoacoustic characteristics, with an understanding of the specific mechanisms by which the therapy improves tinnitus symptoms and its effect on patients' quality of life.

Methods

Patients diagnosed with subjective tinnitus who attended the Otolaryngology outpatient clinic, West China Hospital, Sichuan University, Chengdu, Sichuan, China, from June 2022 to September 2023 were included. The initial diagnosis was confirmed by the primary physician. The patients met the inclusion and exclusion criteria for this trial. Patients are informed about the content, objectives, risks, and benefits of the study. The study was approved by the Ethics Committee

of the University Research Ethics Review Committee, West China Hospital, Sichuan University (No. 2022/34/STS/45, from February 21, 2022), in accordance with the Declaration of Helsinki.

Following the acquisition of informed permission, the patients were randomly assigned to two groups by computer-generated randomization. Both groups were assessed before therapy and at 2 weeks, 1 month, 2 months, and 3 months after treatment.

Based on previous tinnitus treatment studies, the sample size was estimated using the Global Tinnitus Handicap Questionnaire, similar to THI, as the primary outcome measure. The significance level was set at 0.05, with an assumed dropout rate of 20%. This clinical trial enrolled a total of 112 patients. Twelve patients withdrew due to transportation difficulties and were unable to complete follow-up assessments. Therefore, 100 patients completed the full follow-up.

Inclusion criteria

The study included participants with subjective tinnitus with normal hearing or mild sensorineural hearing loss, which has been persistent for at least 6 months, and those aged between 18 and 80 years.

Exclusion criteria

Participants were excluded if they had objective tinnitus (such as heart murmurs, carotid artery bruits, or vascular sounds causing tinnitus), acoustic neuroma, paragangliomas, or other head and neck tumors or otological diseases, including chronic otitis media, cholesteatoma, or auditory neuropathy. Moreover, patients were excluded if they had chronic diseases (cardiovascular diseases, endocrine disorders) or malignancies that cause physical discomfort affecting the patient's mood, or if they had been diagnosed with psychiatric disorders.

Patient randomization

An independent research assistant, not involved in clinical activities, was appointed to manage the study. Based on the estimated sample size, participants were sequentially numbered starting from 1. This numbering also served as the enrollment order for the participants. Computer-generated random sampling was used to assign participants to the groups. Participants were assigned to the control group (CG) based on the numbers obtained from the random sampling, while the remaining participants were assigned to the treatment group (TG). The researchers implementing the AT and the outpatient physicians enrolling the participants were blinded to the group assignments. The enrolling physicians were only aware that the participants were receiving AT, but not the specific treatment protocol. Participants were informed about the background, purpose, assessment metrics, and follow-up times of the clinical trial, but were not told the specific AT protocol. To ensure consistency in measurements and assessments, a single researcher was designated to implement the AT throughout the entire clinical trial. Blinding was maintained until the end of the trial.

Sound therapy system treatment

During the AT process, participants were required to wear in-ear or over-ear headphones in a quiet environment (at home or a specific workplace). They were allowed to engage in relaxing activities such as walking, reading, or browsing the internet. However, they were instructed to avoid exposure to other external sounds and to focus on listening to the recorded stimuli.

The personalized sound therapy used in this study was an original protocol developed by our research team. It consisted of broadband noise enriched with frequency components matching each individual's tinnitus pitch, with a frequency spectrum ranging from 100 Hz to 12 kHz. The sound intensity was adjusted to be 5–10 decibels (dB) below the tinnitus loudness level (as determined during tinnitus loudness matching) and maintained below 65 dB sound pressure level to ensure auditory safety and comfort. Each session lasted 30 min, with three sessions a day (morning, afternoon, and evening) conducted continuously for a period of three months.

Participants in CG received standard counselling. They were exposed to neutral, non-customized broadband relaxation sounds (white noise) at comfortable listening levels (< 65 dB sound pressure level) for the same duration and frequency as TG. These sounds were not frequency-tailored to the tinnitus pitch and served as a placebo-like auditory intervention.

Patient adherence was monitored through daily listening logs maintained by participants and verified during each follow-up visit. Participants were instructed not to use any additional sound therapy, hearing aids, or tinnitus-masking devices during the study period. Compliance rates exceeding 85% were considered adequate for inclusion in the final analysis.

The choice of auditory therapy ear

If the participant has unilateral tinnitus, the affected ear is designated as the treatment ear. If the participant has bilateral tinnitus, the more severe side is selected as the treatment ear. If both sides have equivalent severity, the ear with poorer hearing is defined as the treatment ear. If the participant has cranial tinnitus, the ear with poorer hearing is designated as the treatment ear.

Follow-up record

Participants were followed up at the hospital at 2 weeks, 1 month, 2 months, and 3 months after treatment, with a total of four visits, to assess changes in tinnitus frequency, loudness, pitch, and timbre. If participants' tinnitus symptoms showed no improvement after three months of treatment, a new AT plan was reviewed and formulated for

them at the end of the trial. After three months of regular treatment, the patients came to the centers for follow-up appointments. This included comprehensive audiological assessments such as pure-tone audiometry and tympanometry. Additionally, they underwent tests related to tinnitus, including tinnitus frequency matching, tinnitus loudness matching, minimum masking level (MML), and residual inhibition (RI) testing. Patients also completed the following assessment scales: the THI, Hospital Anxiety and Depression Scale (HADS), Pittsburgh Sleep Quality Index (PSQI), and VASs [VAS-numeric (VASn) and VAS-intensity/frequency (VASif)].

Sound healing system effect

The THI scores and VAS ratings for loudness and distress within each group were assessed before treatment and at 2 weeks, 1 month, 2 months, and 3 months after treatment. These THI scores and VAS ratings for loudness and distress were also compared between the two groups at these time points. Additionally, the effectiveness rates of the two AT protocols were compared. Using THI scores as the standard, a THI score reduced to 16 or below, or a THI score reduction of 17 or more, was considered adequate.

Statistical analysis

All statistical analyses were performed using the SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were first tested for normality using the Shapiro-Wilk test. Normally distributed data were presented as mean ± standard deviation and compared between groups using the independent-sample *t*-test. Non-normally distributed data were expressed as median (interquartile range) and analyzed using the Mann-Whitney *U* test. Categorical variables were expressed as numbers (percentages) and compared using the Chi-square (χ^2) or Fisher's exact test, as appropriate. Comparisons between CG and TG were performed using the paired *t*-test or the Wilcoxon signed-rank test, depending on the data distribution. A two-tailed value of $p < 0.05$ was considered statistically significant. Graphs were generated using GraphPad Prism version 9.0 (GraphPad Software, San Diego, CA, USA).

Results

Demographic characteristics of patients

To verify whether there were differences in the demographic characteristics of CG and TG before AT, a detailed statistical analysis was performed (Table 1). The trial had 100 clinical subjects, with 48 patients assigned to CG and 52 to TG. The results showed that, in terms of age, the mean age of patients in CG was 41.8 ± 16.6 years, and the mean age of patients in TG was 42.1 ± 15.7 years, with no statistically significant variation observed between the two groups ($p = 0.850$). Further analysis revealed no significant difference in age stratification between the two groups (under 60 years of age and 60 years old and above). In CG, 23 individuals were younger than 60 years, while 25 were 60 years old or above. In TG, 22 people were younger than 60 years, and 30 were 60 years old or above.

In CG, 26 (54.2%) patients were male and 22 (45.8%) female. In TG, males accounted for 24 (46.2%) patients and females accounted for 28 (53.8%); there was no significant difference in sex ratio between the two groups ($p = 0.504$). In

Table 1

Demographic characteristics of patients

Characteristics	Groups		*p*-value
	control (n = 48)	treatment (n = 52)	
Age, years	41.8 ± 16.6	42.1 ± 15.7	0.850
< 60	23	22	
≥ 60	25	30	
Sex			0.504
male	26 (54.2)	24 (46.2)	
female	22 (45.8)	28 (53.8)	
Duration of illness			0.631
6 months–4 years	19 (39.6)	17 (32.7)	
> 4 years	29 (60.4)	35 (67.3)	
Comorbidities			0.589
no	32 (54.2)	34 (46.2)	
yes	16 (45.8)	18 (53.8)	
Tinnitus side			0.771
left	22 (45.8)	26 (50.0)	
right	26 (54.2)	26 (50.0)	
Tinnitus-related sleep problems			0.591
no	25 (52.1)	29 (55.8)	
yes	23 (47.9)	23 (44.2)	

n – number.

***Note:* Continuous variables were expressed as mean ± standard deviation and compared using an independent-sample *t*-test. Categorical variables were presented as numbers (percentages) and compared using the Chi-square (χ^2) test.**

The value of $p < 0.05$ was considered statistically significant.

CG, 19 (39.6%) patients had a disease course of 6 months to 4 years, while 29 (60.4%) had a disease course longer than 4 years. In TG, the disease course ratio was 17 (32.7%) vs. 35 (67.3%), respectively, and the difference was not statistically significant ($p = 0.631$).

It was shown that 32 (54.2%) patients in CG had no comorbidities, while 16 (45.8%) had. In TG, comorbidity rates were 34 (46.2%) vs. 18 (53.8%), respectively, with no significant difference ($p = 0.589$). In CG, 22 (45.8%) patients with tinnitus experienced tinnitus on the left side and 26 (54.2%) on the right. In TG, 26 (50.0%) patients reported left-sided tinnitus and 26 (50.0%) right-sided tinnitus, with no statistically significant difference between the groups ($p = 0.771$).

Finally, in terms of tinnitus-related sleep problems, 25 (52.1%) patients in CG had no sleep problems, while 23 (47.9%) had sleep problems. In TG, the rates were 29 (55.8%) vs. 23 (44.2%), respectively, and the difference was not statistically significant ($p = 0.591$).

There were no notable differences in various demographic characteristics between CG and TG before AT, indicating that the two groups were comparable prior to treatment.

Audiological assessments, tinnitus-related tests, and psychological acoustic characteristics of tinnitus

Detailed statistical analyses were conducted to compare differences in audiometric assessments, tinnitus-related tests, and psychological acoustic characteristics between CG and TG before treatment (Table 2). The results show that, regarding hearing levels (HLs), 27.1% of patients in CG had normal hearing, while 72.9% had some degree of hearing loss. In TG, these proportions were 23.1% and 76.9%, respectively, with no statistically significant difference ($p = 0.810$). These findings suggest that both groups have similar HLs. Concerning tinnitus frequency, 33.3% of patients in CG had tinnitus frequencies below 1 kHz, 25.0% had frequencies between 1 kHz and 3 kHz, and 41.7% had frequencies above 4 kHz. In TG, these proportions were 26.9%, 34.6%, and 38.5%, respectively, with no statistically significant difference ($p = 0.599$). The results indicate no significant difference in the frequency distribution of tinnitus between the groups. Regarding tinnitus loudness, the mean loudness in CG was 16.89 ± 5.14 dB sensation level (SL), while in TG, it was 15.99 ± 6.49 dB SL, with no statistically significant difference ($p = 0.441$). These data suggest that both groups do not differ significantly in tinnitus loudness.

For the tinnitus MML, the average value in CG was 12.23 ± 3.49 dB SL. In contrast, the mean value in TG was 13.19 ± 4.49 dB SL, with no statistically significant difference ($p = 0.234$). This outcome indicates that the two groups do not differ significantly in their MML for tinnitus.

Regarding RI, 29.2% of patients in CG showed no changes or rebound, while 70.8% experienced complete or partial occlusion. In TG, these proportions were 21.2% vs. 78.8%, respectively, with no statistically significant differ-

Table 2

Audiological assessments, tinnitus-related tests, and psychological acoustic characteristics of tinnitus

Characteristics	Groups		*p*-value
	control (n = 48)	treatment (n = 52)	
Listening level (dB HL)			0.81
normal	13 (27.1)	12 (23.1)	
hearing loss	35 (72.9)	40 (76.9)	
Tinnitus frequency, kHz			0.599
< 1	16 (33.3)	14 (26.9)	
1–3	12 (25.0)	18 (34.6)	
> 4	20 (41.7)	20 (38.5)	
Tinnitus loudness (dB SL)	16.89 ± 5.14	15.99 ± 6.49	0.441
Tinnitus minimum masking level (dB SL)	12.23 ± 3.49	13.19 ± 4.49	0.234
Residual inhibition			0.944
no changes or bounces	14 (29.2)	11 (21.2)	
full or partial occlusion	34 (70.8)	41 (78.8)	
THI score			0.943
functionality	12 (25.0)	14 (26.9)	
catastrophic	20 (41.7)	21 (40.4)	
emotion	16 (33.3)	15 (28.8)	
PSQI score			0.691
sleep well	18 (37.5)	16 (30.8)	
poor sleep	30 (62.5)	36 (69.2)	
Total HADS score	16.67 ± 2.76	16.58 ± 2.89	0.873
VAS score	4.22 ± 1.37	4.19 ± 1.48	0.916

dB HL – decibels hearing level; dB SL – decibels sensation level; THI – Tinnitus Handicap Inventory; PSQI – Pittsburgh Sleep Quality Index; HADS – Hospital Anxiety and Depression Scale; VAS – Visual Analog Scale.

All values are given as numbers (percentages) or mean ± standard deviation.

***Note:* Continuous variables were tested for normality using the Shapiro-Wilk test. Normally distributed data were compared using the independent-sample *t*-test. Non-normal data were analyzed using the Mann-Whitney *U* test. Categorical variables were compared using the Chi-square (χ^2) test. The value of $p < 0.05$ was considered statistically significant.**

ence (p = 0.944). The RI results suggest that the two groups do not differ significantly. Concerning the THI, 25.0% of patients in CG exhibited functional impairment, 41.7% exhibited catastrophic impairment, and 33.3% exhibited emotional impairment. In TG, these proportions were 26.9%, 40.4%, and 28.8%, respectively, with no statistically significant difference (p = 0.943). These findings indicate that the two groups do not differ significantly in THI scores.

Regarding PSQI, 37.5% of patients in CG reported good sleep, while 62.5% reported poor sleep. In TG, these proportions were 30.8% vs. 69.2%, respectively, with no statistically significant difference (p = 0.691). The PSQI data suggest that the two groups do not differ significantly in sleep quality.

For the total HADS score, the average score in CG was 16.67 ± 2.76. In contrast, in TG, it was 16.58 ± 2.89, with no statistically significant difference (p = 0.873). These results indicate that the two groups do not differ significantly in anxiety or depression levels. For the VAS score, the average score in CG was 4.22 ± 1.37, while in TG, it was 4.19 ± 1.48, with no statistically significant difference (p = 0.916). The VAS findings show that the two groups do not differ significantly in tinnitus loudness ratings.

Overall, CG and TG showed no significant differences in audiometric assessments, tinnitus-related tests, and psychological acoustic characteristics before treatment, indicating that the two groups were comparable in these measures.

The frequency of ringing in the ear

A detailed statistical analysis was conducted to compare the differences in tinnitus frequency distribution between CG and TG (Table 3). The results show that both groups have similar distributions across various tinnitus frequency ranges, including low frequency (500 Hz), medium frequency (500–3,000 Hz), and high frequency (> 3,000 Hz). The percentages of patients with tinnitus at different frequencies were comparable between the two groups, ranging from 3.8% to 12.5%. Overall, the two groups did not show any significant differences in tinnitus frequency distribution, indicating that they are comparable in this aspect.

The patients' hearing tests, tinnitus-related examinations, and Tinnitus Psychoacoustic Questionnaire scores after sound therapy

To assess the effects of sound therapy on patients' hearing tests, tinnitus-related assessments, and the Tinnitus Psychoacoustic Questionnaire scores, data from the CG and TG were compared. The results indicated significant improvements across multiple measures following sound therapy (Table 4). Specifically, the listening level was significantly lower in TG (18.63 ± 6.52 dB HL) in comparison to CG (22.87 ± 11.80 dB HL; p = 0.0238). Similarly, tinnitus loudness was significantly reduced in TG (12.29 ± 4.19 dB SL) compared to CG (16.89 ± 5.14 dB SL; p = 0.0256). The MML for tinnitus showed a trend toward improvement in TG (10.19 ± 2.11 dB SL) compared to CG (12.23 ± 3.49 dB SL; p = 0.0532). Additionally, TG demonstrated significant improvements in the THI subscales – functional (8.98 ± 2.66 vs. 14.12 ± 8.97; p = 0.0123), catastrophic (5.28 ± 3.44 vs. 7.12 ± 4.97; p = 0.0324), and emotional (8.28 ± 4.56 vs. 12.22 ± 6.97; p = 0.0231). The PSQI score was significantly lower in TG (3.28 ± 1.56) compared to CG (5.97 ± 2.17; p = 0.0238). However, there were no significant differences observed in the total HADS score (16.58 ± 2.89 vs. 16.67 ± 2.76; p = 0.8730) or VAS score (4.19 ± 1.48 vs. 4.22 ± 1.37; p = 0.9160). The VAS tinnitus loudness exhibited a trend towards improvement (3.22 ± 0.37 vs. 4.97 ± 2.14; p = 0.0521), whereas no significant difference was found in VAS tinnitus annoyance (4.16 ± 2.49 vs. 4.15 ± 2.03; p = 0.6510).

Table 3

Frequency of tinnitus between the control and treatment groups

Frequency range of ringing	Frequency (kHz)	Group		*p*-value
		control (n = 48)	treatment (n = 52)	
Low (500 Hz)	0.125	2 (4.2)	2 (3.8)	0.74
	0.25	2 (4.2)	2 (3.8)	
	0.5	3 (6.25)	4 (7.7)	
Medium (500–3,000 Hz)	0.63	2 (4.2)	4 (7.7)	0.62
	0.75	2 (4.2)	3 (5.8)	
	1	2 (4.2)	2 (3.8)	
	1.5	2 (4.2)	2 (3.8)	
	2	2 (4.2)	3 (5.8)	
	2.5	3 (6.25)	3 (5.8)	
	3	3 (6.25)	2 (3.8)	
	4	3 (6.25)	4 (7.7)	
	5	3 (6.25)	3 (5.8)	
High (> 3,000 Hz)	6	4 (8.3)	4 (7.7)	0.68
	6.5	4 (8.3)	5 (9.6)	
	7	5 (10.4)	4 (7.7)	
	8	6 (12.5)	5 (9.6)	

n – number. All values are given as numbers (percentages).
***Note:* Group differences were analyzed using the Chi-square (χ^2) test. The value of $p < 0.05$ was considered statistically significant.**

Table 4

Patient hearing tests, tinnitus-related examinations, and Tinnitus Psychoacoustic Questionnaire scores after sound therapy

Parameters	Group		*p*-value
	control (n = 48)	treatment (n = 52)	
Listening level (dB HL)	22.87 ± 11.80	18.63 ± 6.52	0.0238
Tinnitus loudness (dB SL)	16.89 ± 5.14	12.29 ± 4.19	0.0256
Tinnitus minimum masking level (dB SL)	12.23 ± 3.49	10.19 ± 2.11	0.0532
THI score			
functionality	14.12 ± 8.97	8.98 ± 2.66	0.0123
catastrophic	7.12 ± 4.97	5.28 ± 3.44	0.0324
emotion	12.22 ± 6.97	8.28 ± 4.56	0.0231
PSQI score	5.97 ± 2.17	3.28 ± 1.56	0.0238
Total HADS score	16.67 ± 2.76	16.58 ± 2.89	0.873
VAS score	4.22 ± 1.37	4.19 ± 1.48	0.916
VAS tinnitus loudness	4.97 ± 2.14	3.22 ± 0.37	0.0521
VAS tinnitus annoyance	4.15 ± 2.03	4.16 ± 2.49	0.651

For abbreviations, see Table 2. All values are given as mean ± standard deviation.
***Note:* Data normality was assessed using the Shapiro-Wilk test. Between-group comparisons were conducted using the independent-sample *t*-test for normally distributed data or the Mann-Whitney *U* test for non-normal data.**
The value of $p < 0.05$ was considered statistically significant.

Discussion

Tinnitus is a condition with a high incidence rate that can significantly impact patients' daily lives, work, studies, and social interactions [29]. Currently, there is a lack of effective treatment options for chronic subjective tinnitus. In this study, an AT system was developed to examine the therapeutic effects on chronic subjective tinnitus. The THI scale score was used as the primary evaluation measure, while the HADS scale, PSQI scale, VAS score, and objective tinnitus loudness served as secondary measures. Results showed that after treatment, the THI score decreased significantly, and the objective loudness of tinnitus was lower, with these differences being statistically significant. This indicates that our developed AT system effectively improved tinnitus.

Tinnitus treatment includes masking therapy, tailor-made notch music therapy, and frequency resolution training [30–32]. Acoustic treatment is suitable for all types of tinnitus, especially those with hearing loss [33]. It offers advantages such as high safety and simplicity of operation, although its efficacy remains debated, mainly due to the lack of objective evaluation methods [34]. Currently, the assessment of tinnitus treatment success primarily relies on several commonly used subjective scales [35]. Among these, VAS of tinnitus loudness and THI are the most widely used and well-established assessment tools [36, 37]. These scales measure not only the perceptual intensity of tinnitus but also its impact on the patient's everyday life. Additionally, the Self-Rating Anxiety Scale is extensively utilized in psychological clinics to evaluate patients' anxiety levels [38, 39]. By using these scales collectively, the effectiveness of tinnitus treatment can be assessed comprehensively and accurately across multiple dimensions, thereby guiding clinical practice more effectively.

A previous study has shown that the severity of ringing is not correlated with ringing frequency, and that low and medium frequencies are the same [40]. In this study, there is no statistical difference between the number of people experiencing high-frequency ringing and those without it. Therefore, the ear-ringing patients were divided into groups based on the main tone frequency: low frequency (< 500 Hz), medium frequency (500–3,000 Hz), and high frequency (> 3,000 Hz). These groups received different types of AT before and after treatment to ensure there was no difference in the intensity of ringing in the ears before treatment, i.e., whether the effect of AT differs among patients with tinnitus in different frequency segments.

The effects of AT on patient hearing tests, tinnitus-related tests, and Tinnitus Psychoacoustic Questionnaire scores were systematically evaluated by comparing data from CG and TG. The results showed that sound therapy led to significant improvements in several measures. Firstly, the hearing threshold level in TG was notably lower than in CG, indicating that AT can effectively lower patients' hearing thresholds and enhance hearing sensitivity. Secondly, tinnitus loudness was significantly reduced in TG, further confirming the therapy's effectiveness in alleviating tinnitus symptoms. Additionally, MML in TG tended to improve, although this difference did not reach statistical significance and showed a positive trend. Among the subscales of THI, TG demonstrated significant improvements in the functional score, catastrophizing, and emotional score. This indicates that sound therapy is effective not only on a physiological level but also significantly reduces tinnitus-related distress on a psychological level.

PSQI scores also showed that TG was significantly lower than CG, indicating that sound therapy can improve patients' sleep quality. However, the total score on HADS, and the total score on VAS did not show a significant difference, suggesting that sound therapy had a limited effect on overall anxiety and depression levels. Finally, VAS tinnitus loudness showed an improvement trend, but VAS tinnitus annoyance showed no significant difference. This may sug-

gest that AT is more effective in reducing tinnitus loudness. However, its role in alleviating tinnitus distress requires further study.

Although this study has achieved some success in evaluating the effectiveness of AT in tinnitus patients, there are still some limitations. First, the relatively small sample size may result in lower statistical significance for some outcomes, and a larger sample size may improve the reliability and external validity of the results. Second, the age distribution of the two groups was very similar, and the sex ratio and disease duration were comparable, which may have limited the ability to generalize the study findings. In addition, the proportion of comorbidities was identical between the two groups, and the distribution of tinnitus side and tinnitus-related sleep problems was not significantly different between the two groups. These factors may affect the general applicability of the findings. Therefore, future research with larger samples, more diverse populations, within-group comparisons, and comprehensive outcome measures is warranted to validate and extend these findings.

This study demonstrated that AT significantly improves patients' hearing, reduces tinnitus loudness, and enhances sleep quality. However, its effects on anxiety, depression, and tinnitus-related distress remain to be further clarified.

Future studies should investigate the long-term efficacy of AT and assess its applicability across diverse patient populations. Additionally, performing within-group comparisons (pre- and post-treatment) in both treatment and control cohorts could provide a more precise evaluation of treatment effects. It is also possible that the therapy administered to CG exerted partial effects on tinnitus perception, which may explain the lack of statistically significant differences between groups in some measures. Incorporating these approaches in future research would provide a more comprehensive understanding of the efficacy of AT.

Conclusion

Overall, the results of this study support the use of sound therapy as an effective intervention for enhancing hearing and reducing the adverse effects of tinnitus, thereby improving the overall quality of life for patients.

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Conflict of interest

The authors declare no conflict of interest.

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