Research Article

Comparative Effectiveness of Sound Therapy, Transcranial Direct Current Stimulation, and Low-Level Laser Therapy for Chronic Tinnitus Management: A Randomized Clinical Trial

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Highlights

- Sound therapy, LLLT, and tDCS were compared for the management of chronic tinnitus
- All interventions significantly reduced tinnitus loudness and distress
- Sound therapy showed the highest clinical improvement in tinnitus symptoms

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ABSTRACT

Background and Aim: Tinnitus, the perception of sound without an external source, can significantly impact the quality of life. Although no definitive cure exists, various treatments are available to reduce tinnitus symptoms. This study aimed to compare the effectiveness of sound therapy, trnscranial Direct Current Stimulation (tDCS), and Low-Level Laser Therapy (LLLT) in managing chronic tinnitus.

Methods: In this randomized clinical trial, 78 adults with chronic tinnitus and normal hearing were divided into three groups of sound therapy, tDCS, and LLLT. The groups received interventions for six weeks. Psychoacoustically, we assessed tinnitus pitch, tinnitus loudness, Minimum Masking Level (MML), and residual inhibition (RI). Tinnitus loudness and distress were also measured using the Visual Analog Scales (VAS), and the functional impact was evaluated using the Tinnitus Handicap Inventory (THI) and Tinnitus Functional Index (TFI). Auditory Brainstem Response (ABR) test was performed to assess neural conduction.

Results: All interventions significantly reduced tinnitus loudness, MML, and distress ($p<0.05$). Sound therapy showed the most significant improvements in THI, TFI, and VAS scores. No significant changes were found in ABR latencies. Post-hoc analysis revealed greater benefits in the sound therapy group regarding THI and TFI scores compared to the tDCS and LLLT groups.

Conclusion: Sound therapy, tDCS, and LLLT are effective in reducing tinnitus symptoms, with sound therapy having greater effects. To improve procedures and investigate customized strategies, more research is recommended.
IRCT registration number: IRCT20111113008082N5.

Keywords: Tinnitus; sound therapy; transcranial direct current stimulation; low-level laser therapy

Introduction

Tinnitus, the perception of sound in the absence of an external source, can range from a minor annoyance to a debilitating condition significantly impacting a patient's quality of life [1]. Tinnitus affects people of all ages, but it is more common among those aged 50-70. Studies estimate that 10-15% of the global adult population experience tinnitus, 20% of whom find it bothersome enough to seek treatment [2]. In addition to the auditory symptoms, tinnitus can significantly affect various aspects of well-being, including psychological health, emotional state, sleep patterns, and general health [3]. Although a definitive cure remains elusive, various treatment options have been developed to manage tinnitus symptoms and improve patients' quality of life. These options include medications, counseling, and several non-invasive neuromodulatory techniques such as Transcranial Magnetic Stimulation (TMS) and transcranial Direct Current Stimulation (tDCS) [4]. Despite the diversity of available treatments, finding a universally acceptable solution for tinnitus remains a significant challenge. Cognitive Behavioral Therapy (CBT) is a psychological treatment with substantial efficiency in reducing tinnitus-related distress by changing maladaptive thoughts and emotional responses. The interventions with a direct physiological or neuromodulatory base, such as sound-based and brain stimulation therapies, allow objective and psychoacoustic outcome quantities, which are less commonly seen in CBT. Non-invasive approaches, such as tDCS, Low-Level Laser Therapy (LLLT), and sound therapy, have shown promising effects in previous studies; however, the results for each therapy is inconsistent; some studies have shown improvements such as reduced tinnitus intensity, improved quality of life, and long-term relief, while others have indicated no significant benefit [5]. Yadollahpour et al. [6], reported that tDCS reduced tinnitus-related distress and loudness in patients. Bashir et al. [7], confirmed the potential efficiency of LLLT in reducing tinnitus symptoms, while outcomes varied according to treatment limitations and patient features. Boedts et al. [8], showed that sound therapy alone led to clinically significant tinnitus relief after six weeks, confirming its effectiveness in symptom reduction. There is a lack of studies for the comparison of these therapies in chronic tinnitus. Understanding how these therapies differ is crucial for optimizing treatment strategies. Each therapy targets tinnitus through different mechanisms; comparing their effects may reveal which treatment is most effective for patients with a specific profile or tinnitus characteristics.

Various tools are commonly employed to evaluate the severity and impact of tinnitus. The most widely used tools are the Tinnitus Handicap Inventory (THI) and the Tinnitus Functional Index (TFI), both of which are reliable tools designed to assess the emotional and functional problems of tinnitus patients [9, 10]. In addition to these self-report measures, the Auditory Brainstem Response (ABR) test has been utilized in research settings to investigate possible neurophysiological changes in individuals with tinnitus, particularly those with normal hearing thresholds. However, inconsistent results have cast doubt on its diagnostic ability [11]. In this study, we aimed to compare the effectiveness of sound therapy, tDCS, and LLLT in managing chronic tinnitus since they all are non-invasive, with a different proposed mechanism of action (acoustic stimulation, cortical neuromodulation, and peripheral photobiomodulation, respectively), and are amongst the most studied and clinically employed interventions in tinnitus management.

Methods

Participants

This randomized controlled clinical trial was conducted on 78 adult men and women with chronic tinnitus were recruited from an audiology clinic in a teaching hospital in Baghdad, Iraq. All participants met specific criteria: age 18-55, a normal hearing threshold (≤25 dBHL), chronic unilateral tinnitus persisted for at least six months, no history of certain illnesses or drugs, such as Meniere's disease, traumatic brain injury, epilepsy, pregnancy, or cardiac pacemakers, and not taking ototoxic, antipsychotic, antiepileptic drugs, tricyclic antidepressants, or benzodiazepines one month before the study. Only patients with unilateral tinnitus were included to minimize variability and enhance sample homogeneity. Then, using random allocation software and the block randomization technique, they were randomized to three intervention groups, each with 26 participants. All patients were informed about the study process, and their written informed consent was obtained before their involvement in the study. To systematically evaluate changes and treatment effects, all evaluations were carried out at baseline and after treatment. Iranian Registry of Clinical Trials (IRCT) code is IRCT20111113008082N5.

Psychoacoustic tinnitus assessment

Tinnitus pitch, loudness, and Minimum Masking Level (MML) were assessed using an audiometer (AD226, Interacoustics, Denmark). Tinnitus pitch was determined using a two-alternative forced choice (2AFC) procedure at a frequency range of 0.25-16 kHz [9]. Participants compared the pairs of tones with their tinnitus pitch, selecting the tone that most closely matched their tinnitus. The tone presentation occurred at a sensation level of 15 dBSPL. Pitch matches were verified by comparison with tones one octave above and below. The intensity of a tone at the tinnitus pitch was progressively increased until it matched the perceived loudness of the tinnitus in order to measure tinnitus loudness. The MML was determined similarly, with participants indicating when the presented sound masked their tinnitus. Residual Inhibition (RI) was evaluated to assess post-masking tinnitus suppression. After 60 seconds of broadband noise at 10 dB above MML, participants were asked to report any changes in the volume of their tinnitus. Responses were categorized as: worsening, no change, partial reduction, or complete suppression of tinnitus. For partial or complete RI, the duration of tinnitus suppression was recorded.

Questionnaires

The study utilized standardized questionnaires, including the Arabic version of the THI [7] and the TFI, to evaluate the impact of tinnitus on daily activities and overall well-being. The THI is a 25-item, three-choice scale. It uses a 100-point scale to categorize tinnitus severity into five grades: slight (0-16), mild (18-36), moderate (38-56), severe (58-76), and catastrophic (78-100) [9]. The TFI is a questionnaire designed to assess tinnitus severity and its negative impact. It has 25 items rated from 0 to 10 or from 0 to 100 to calculate the overall, with higher scores indicating more severe tinnitus [10]. Additionally, the participants' tinnitus loudness or distress was assessed using the 10-point Visual Analog Scale (VAS), where 0 indicates no tinnitus and 10 represents tinnitus at its loudest. Tinnitus-related distress was also evaluated using the VAS, where 0 shows no distress and 10 indicates a suicidal level of distress [12]. The Clinical Global Impression (CGI) scale provided a global assessment of tinnitus severity and change after each intervention session. It is rated from 1 to 7, with 1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse and 7=very much worse [13, 14]. To ensure that the effects of treatment could be expressed, only individuals with a clinically significant level of tinnitus-related distress were included. This was achieved by considering grades falling within at least the moderate range on the THI or TFI. Participants with minimal or non-distressing tinnitus were excluded from the study.

Electrophysiologic assessment

To evaluate the brainstem auditory pathways, the ABR test was conducted by measuring the latency and amplitude of waves I, III, and V, which provides information about auditory nerve conduction and brainstem function. The ABRs were recorded in the first 12 ms using the Eclipse 25 (Interacoustics Co., Denmark) in a sound-attenuated, electrically shielded chamber. Participants were in a supine position. Surface electrodes were placed on the scalp; an active electrode was put on the forehead, a reference electrode on the mastoid of the tested ear, and a ground electrode on the opposite mastoid. For each ear, 1000-2000 alternating polarity clicks (2-4 kHz, 80 dB hearing level) were delivered at a rate of 12 clicks per second through earphones. Differences in responses between the vertex and the contralateral/ipsilateral mastoid electrodes were recorded, filtered (between 100 and 2500 Hz), and averaged [10]. Analyzed parameters included the absolute latencies of waves I, III, and V.

Interventions

Participants in the sound therapy group used a free open In the Canal (ITC) sound generator (Microson, Spain) with wide dynamic range compression. Devices were programmed based on tinnitus pitch and loudness. By digitally programming the ITC device, the microphone was disabled, allowing only the generated noise to serve as the sound source. After loading the pure tone audiometry into the device, the sound generator was programmed, and the noise level provided to the patient was adjusted until it reached an appropriate level that did not exceed the hearing threshold and was inaudible to the patient. Patients were asked to wear the sound generator with tinnitus masking activated for a minimum of eight hours per day for six weeks [15]. They were encouraged to use the sound therapy for eight hours per day. They were required to report their daily usage time online over six weeks. Additionally, the sound generator's usage data could be retrieved by connecting the device to the software, offering an alternative method for tracking usage hours.

The tDCS was administered using the Neurostim2 device (Medina Teb Gostar Ltd., Iran) at 12 sessions (twice a week, each for 20 minutes) for six weeks [16, 17]. During each session, a weak electrical current (1 mA) was applied using electrodes placed strategically on the head. To ensure patient comfort and gradual adaptation to the stimulation, the intensity of tDCS was not fixed at 1 mA throughout the study. It began at 1 mA at the first session to minimize discomfort and familiarize participants with the procedure. From the second session onward, the intensity increased to 2 mA, which was maintained for the remaining sessions, provided that the participants tolerated it. This stepwise increase was implemented to improve patient compliance and avoid early withdrawal due to discomfort. Rubber electrodes (35 cm^2) were embedded in saline-soaked (0.85% NaCl) sponges to enhance conductivity and minimize discomfort during stimulation, according to the method proposed by Dundas et al. [18]. Based on the International 10-20 System, the cathode was positioned over the left Dorsolateral Prefrontal Cortex (DLPFC) or F3 and the anode over the right DLPFC (F4) [16]. Patients were closely monitored during the sessions for any potential side effects, including itching, burning, headaches, or dizziness.

In the LLLT group, the TinniTool EarLaser4 (Switzerland) was used to apply 660 nm wavelength light at 100 mW to the external auditory canal. The LLLT was provided at 20 sessions of 20 minutes, every other day, for six weeks. The laser probe was aligned horizontally in the canal for optimal exposure [18, 19].

Statistical analysis

Statistical analyses were conducted using SPSS v. 19 (IBM SPSS Statistics). The Kolmogorov-Smirnov test was employed to assess the normality of data distribution for the psychoacoustic characteristics of tinnitus, questionnaire scores, and the ABR waveform latencies. Paired t-tests were performed to compare pre- and post-intervention values for these variables. Additionally, a univariate ANOVA was conducted to examine differences in mean changes of psychoacoustic characteristics and questionnaire scores across intervention sessions. Tukey's post-hoc test was used for pairwise group comparisons. Statistical significance was set at 0.05. Since baseline comparisons can be deceptive and are not regarded as meaningful, statistical testing of baseline scores was not done, as recommended for randomized trials [20].

Results

Characteristics of participants

The demographic and clinical characteristics of the participants are summarized in Table 1. No significant differences were found between the three intervention groups in terms of age, gender, tinnitus duration, or baseline values for tinnitus loudness, MML, RI time, THI, TFI, and VAS scores. All mean differences between groups at baseline were less than 0.2 standard deviations, indicating group homogeneity.

Comparison based on psychoacoustic characteristics of tinnitus

All three groups significantly reduced tinnitus loudness and MML, and a notable increase in the RI was reported after intervention ($p<0.05$) (Table 2). There were no significant differences among the three groups in tinnitus loudness ($F(2,75)=1.13$, $p=0.328$), MML ($F(2,75)=4.44$, $p=0.065$), or RI ($F(2,75)=0.29$, $p=0.744$). These improvements were observed consistently in the post-intervention phase.

Comparison based on the tinnitus handicap inventory score

All groups demonstrated significant reductions in the THI score after intervention. The ANOVA results showed significant differences in THI scores among the groups ($F(2,75)=6.35$, $p=0.003$). The sound therapy group showed the most significant decrease (mean difference=-13.32; 95% CI:-15.41 and -11.23; $p<0.001$) compared to the tDCS (mean difference=-8.93; 95% CI:-10.78 and -7.07;

Table 1. Baseline demographic and clinical characteristics of participants

Characteristics	Sound therapy group (n=26)	tDCS group (n=26)	LLLT group (n=26)
Female, NO.	10	16	8
Age, mean±SD, y	40.73±10.58	39.35±8.04	41.27±9.38
Tinnitus duration, NO.			
6-12 m	9	15	15
13-24 m	11	6	8
>24 m	6	5	3
TFI, mean±SD	97±19	99±19	105±21
THI, mean±SD	54±9	55±8	55±9
VASL, mean±SD	6±0.90	6±0.86	6±1.15
VASA, mean±SD	7±1.02	7±1.02	8±0.99
Tinnitus pitch, mean (min-max), Hz	4000 (3000-7000)	4000 (1500-6000)	4000 (1500-6000)
Tinnitus loudness, mean±SD, dBHL	43±15	47±14	48±3
Minimal masking level, mean±SD, dBHL	24±6	28±8	20±5
Residual inhibition, mean±SD, ms	3±1	3±1	3±1
ABR latency, mean±SD, ms			
Wave I	1.89±0.02	1.88±0.01	1.89±0.02
Wave III	3.91±0.01	3.91±0.02	3.91±0.01
Wave V	5.89±0.02	5.89±0.03	5.89±0.03
Wave I-III	2.45±0.03	2.44±0.04	2.44±0.03
Wave III-V	2.42±0.02	2.42±0.01	2.42±0.01
Wave I-V	4.58±0.05	4.58±0.05	4.57±0.05

tDCS; transcranial direct current stimulation, LLLT; low-level laser therapy, TFI; tinnitus functional index, THI; tinnitus handicap inventory, VASL; visual analog scale loudness, VASA; visual analog scale annoyance, ABR; auditory brainstem response
$p>0.05$

$p\leq0.001$) and LLLT (mean difference=-7.67; 95% CI:-10.80 and -4.54; $p\leq0.01$) groups (Figure 1).

Comparison based on the tinnitus functional index score

The TFI scores declined significantly in all groups after intervention. The difference among the groups was significant according to the ANOVA results ($F(2, 75)=4.03$, $p=0.022$). The greatest improvement was observed in the sound therapy group (mean difference=-16.76; 95% CI:-21.89 and -11.64; $p\leq0.001$), compared to the tDCS (mean difference=-10.88; 95% CI:-13.00 and -8.76; $p\leq0.001$) and LLLT (mean difference=-7.67; 95% CI:-10.80 and -4.54; $p\leq0.001$) groups (Figure 1). According to the Minimum Clinically Important Difference (MCID) estimates ranging from 7.3 to 9.4, all interventions exceeded the threshold for clinically significant improvement, reinforcing the effectiveness of the applied treatment approaches.

Table 2. Pre- and post-intervention changes in psychoacoustic tinnitus characteristics by group

			95% confidence Interval of the difference				
	Groups	**Mean(SD)**	**Lower**	**Upper**	**t**	**df**	**p**
Sound therapy	**loudness**	–1.30(0.88)	–1.66	–0.95	–7.54	25	≤0.001
	MML	–0.20(1.02)	0.15	0.21	–1.01	25	0.022
	RI	0.34(0.48)	0.15	0.54	3.63	25	0.001
tDCS	**loudness**	–1.03(0.77)	–1.35	–0.72	–6.84	25	0.001
	MML	–1.58(3.06)	–2.82	–0.35	–2.64	25	0.014
	RI	0.46(0.58)	0.22	0.69	4.04	25	≤0.001
LLLT	**loudness**	–1.00(0.74)	–1.30	–0.69	–6.81	25	≤0.001
	MML	–0.23(0.77)	0.54	0.98	–1.51	25	0.003
	RI	0.42(0.57)	0.19	0.65	3.73	25	0.001

MML; minimum masking level, RI; residual inhibition, tDCS; transcranial direct current stimulation, LLLT; low-level laser therapy

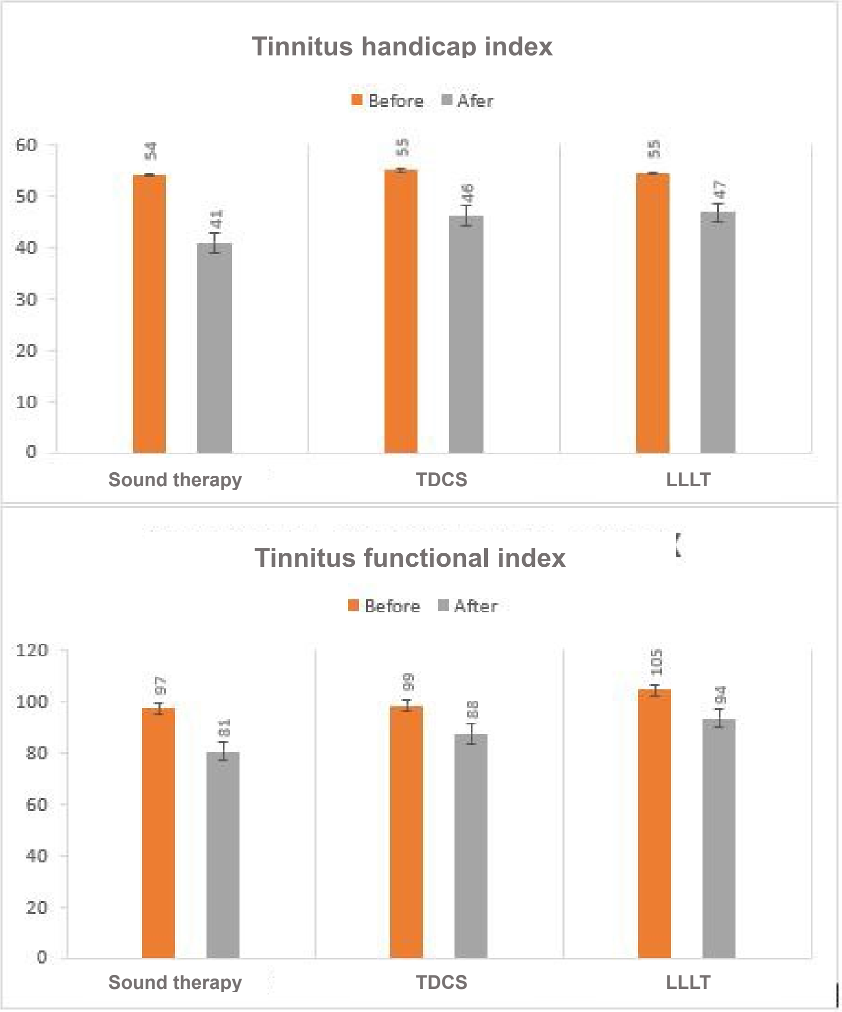

Figure 1. Changes in tinnitus functional index and tinnitus handicap inventory scores after intervention (error bars represent standard error). tDCS; transcranial direct current stimulation, LLLT; low-level laser therapy

Comparison based on the visual analog scale score

The VAS scores for loudness (VAS-L) and distress (VAS-Annoyance) showed considerable reductions in each group after intervention (Table 3). The ANOVA results identified significant differences in VAS-L and VAS-Annoyance (VAS-A) scores among the groups (VAS-L: F(2, 75)=13.83, p<0.001; VAS-A: F(2, 75)=8.70, p<0.001). Tukey's post-hoc test results revealed that the sound therapy group had significantly more improvements in VAS-L compared to both the tDCS group (mean difference=-1.37, p<0.001) and the LLLT group (mean difference=-1.37, p<0.001). Similarly, for VAS-A, the sound therapy group showed significantly more reduction compared to the tDCS group (mean difference=-0.46, p=0.033) and the LLLT group (mean difference=-0.46, p=0.033. Table 3 summarizes the pre- and post-intervention changes in VAS-L and VAS-A for each group.

Comparison based on the clinical global impression

There were no significant differences in the CGI score among the three groups ($F_{(2,75)}$=0.61, p=0.543). All groups showed improvement in the CGI scores as reported by the participants.

Electrophysiologic assessment results

In contrast to the positive findings from patient-reported tinnitus questionnaires, ABR wave latencies (waves I, III, V, I-III, I-V, and III-V) were not significantly different in any groups after intervention compared to the pre-intervention phase, and no significant difference was found among the groups (p>0.05).

Discussion

This study evaluated the effectiveness of three interventions for tinnitus management including sound therapy, tDCS, and LLLT. All participants demonstrated improvements after sound therapy which was the most effective intervention. Improvements were observed in tinnitus loudness, MML, and RI time. Additionally, all interventions reduced tinnitus-related handicap, negative impacts, and distress.

In this study, tinnitus was reduced using a sound generator with built-in masking sounds in a shorter time (8 hours daily for 6 weeks) compared to Jin et al.'s study [21], who used white noise through an app in a more extended period (3-5 hours daily for 3 months). This suggests potential benefits of a more personalized approach using the sound generators, even with shorter treatment times. Another study compared different sound types and discovered that both broadband noise and nature sound improved tinnitus, with broadband noise having a slight advantage [22]. Although our study did not specifically investigate sound types, future research is recommended to investigate their effectiveness in the sound generators. Scherer and Formby [23] investigated tinnitus retraining therapy, which combines sound therapy with counseling. While their study showed improvement in all groups

Table 3. Pre- and post-intervention changes in tinnitus loudness and distress (visual analog scores) by Group

	Groups	Mean of change(SD)	95% confidence interval of the difference: Lower	Upper	t	df	p
Sound therapy	VASL	–2.91(1.56)	–3.54	–2.28	–9.52	25	≤0.001
	VASA	–2.26(1.06)	–2.69	–1.83	–10.80	25	≤0.001
tDCS	VASL	–1.54(1.05)	–1.97	–1.11	–7.45	25	0.001
	VASA	–1.80(1.17)	–2.27	–1.32	–7.86	25	0.001
LLLT	VASL	–1.54(1.05)	–1.97	–1.11	–7.45	25	≤0.001
	VASA	–1.80(1.17)	–2.27	–1.33	–7.86	25	≤0.001

tDCS; transcranial direct current stimulation, LLLT; low-level laser therapy, VASL; visual analog scale loudness, VASA; visual analog scale annoyance regardless of treatment type, it suggests that sound therapy with counseling might not be significantly superior to standard care alone [23]. Our study focused on sound therapy using a sound generator (a fully digital, free, open ITC device).

For tDCS, we applied stimulation parameters and an electrode placement technique that have previously shown clinical efficacy, resulting in reduced tinnitus loudness and modulation of cortical activity [24, 25]. Our short-term intensive protocol may offer advantages over the longer-term spaced protocols employed by other studies [26]. A recent meta-analysis indicated a potential decrease in tinnitus distress after tDCS; however, it recommended further investigation [27]. While some studies show reductions after tDCS, others did not report any reduction. Our findings are consistent with those reported a decrease in tinnitus loudness [28, 29]. Pal et al. [26] found no significant improvement using real tDCS compared to sham tDCS, highlighting the importance of sham-controlled designs in tinnitus studies.

For LLLT, a prior study using a different wavelength (650 nm) and shorter duration (4 weeks) showed no significant improvements [30] compared to our study (using a 660-nm wavelength for 6 weeks). Another study using a similar laser and protocol (650-nm wavelength, 20 minutes daily for three months) reported a decrease in tinnitus loudness only in the active LLLT group [31], which is consistent with our findings. Our study also showed a significant decrease in MML, a metric that was not explored in the mentioned research. Similar to an earlier study [32], findings indicated reductions in tinnitus handicap across all groups. Both studies suggested a potential sex-based difference, warranting further exploration.

The MCID estimates were integrated into the results section to underscore the clinical relevance of the observed outcomes. In Engelke et al.'s study [33], the MCID for THI ranged from 7.8 to 12 points. Meikle et al. [12] considered a reduction ≥13 in THI or TFI scores as a significant MCID. Only the sound therapy group showed reductions in both THI and TFI scores that surpassed this threshold, indicating clinically significant improvement. While the tDCS and LLLT groups also showed statistically significant reductions, they did not reach this level of clinical significance [33]. In our study, all intervention groups exceeded this threshold, demonstrating clinically significant improvements in tinnitus-related distress.

Sound therapy works by introducing external sounds, which can lead to a perceived relief from tinnitus. It influences brain regions associated with relief processing (precuneus/posterior cingulate cortex), auditory processing (angular gyrus), sensory information processing (thalamus), self-awareness and emotional regulation (inferior frontal gyrus), as well as emotional processing and pain perception (anterior cingulate cortex) [34]. This approach may downregulate tinnitus-related neural activity through habituation and attentional redirection [35]. The tDCS works by sending weak electrical currents to specific brain areas, influencing neuronal activity [36]. It can disrupt ongoing abnormal neural activity associated with tinnitus or promote neuroplastic changes for a sustained reduction [37]. Targeting the DLPFC is thought to reduce tinnitus-related distress by influencing emotional processing and regulation [38], targeting the anterior cingulate cortex may directly suppress tinnitus perception by modifying neural activity within auditory processing networks. Repeated sessions with proper electrode placement and optimized parameters are crucial [29]. Potential mechanisms of LLLT include enhanced microcirculation, direct cellular stimulation [19], reduced inflammation, and modulation of nerve activity in the auditory pathway [20]. However, evidence for the effectiveness of LLLT remains contradictory, underscoring the need for further controlled trials [30].

Limitations

The relatively small sample size (n=78) of this study can limit the generalizability of its findings to the larger tinnitus population. Additionally, the six-week intervention period may not be adequate to evaluate long-term treatment outcomes. While including a control group is worthy, the potential placebo effects associated with interventions, particularly sound therapy, could introduce confounding variables. Moreover, the use of customized sound therapy presents challenges in standardization, reproducibility, and generalizability, as individual variations complicate comparisons, hinder the broader application of findings, and necessitate advanced calibration that may not always be feasible in clinical settings.

Conclusion

This study provided valuable insights into the effectiveness of sound therapy, transcranial direct current stimulation, and low-level laser therapy in managing tinnitus, among which sound therapy is the most effective intervention. Additional research is needed to optimize treatment protocols, explore personalized approaches, and clarify the underlying mechanisms of action for each intervention.

Ethical Considerations

Compliance with ethical guidelines

The Research Ethics Committee of the School of Nursing and Midwifery and Rehabilitation, Tehran University of Medical Sciences, granted ethical approval for the study under the ethical code IR.TUMS.FNM.REC.1402.016.

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Authors' contributions

BANA: Methodology, investigation, writing original draft; GM: Supervision, data curation, writing review and editing; NR: Data analysis, writing original draft, visualization.

Conflict of interest

The authors declare that they have no conflicts of interest.

Availability of Data and Materials

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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