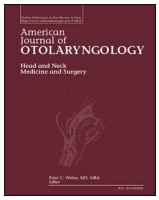
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Treatment effects of combined transcranial direct current stimulation and counseling for the treatment of chronic tinnitus

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ABSTRACT

Aims: We aimed to evaluate the comparative efficacy of three treatment modalities for chronic tinnitus: TRT-based directive counseling, transcranial direct current stimulation (tDCS), and their combination. Primary endpoints were changes in tinnitus severity and psychological distress; secondary endpoints included treatment response rates and anxiety reduction.

Methods: Forty-one patients with chronic tinnitus lasting 3 months or more of duration were enrolled who were treated at a tertiary hospital between November 2021 and December 2023. Patients were allocated to counseling ($n = 11$), tDCS ($n = 19$), or combined therapy (n = 11) based on informed preference. Treatment outcomes were assessed using the Tinnitus Handicap Inventory (THI), Visual Analog Scale (VAS), Beck's Depression Inventory (BDI), and Hospital Anxiety-Depression Scale (HADS). Statistical analysis included Wilcoxon Signed-Rank tests for within-group comparisons and Kruskal-Wallis tests for between-group analyses.

Results: Clinically significant improvement (THI reduction ≥7 points) was achieved in 70.7 % of patients overall: 63.6 % in counseling, 73.7 % in tDCS, and 72.7 % in combined therapy groups. Mean THI scores decreased significantly from 54.3 ± 22.8 to 37.7 ± 19.7 ($p < 0.01$). The combined therapy group showed superior anxiety reduction (HAD-A, $p = 0.034$) compared to single modalities. Both tDCS and combined therapy demonstrated greater improvements in multiple psychological measures compared to counseling alone.

Conclusion: Combined tDCS and counseling therapy shows enhanced efficacy in managing chronic tinnitus, particularly for patients with concurrent anxiety symptoms. This multimodal approach may provide a more comprehensive treatment strategy than single modalities alone. Future randomized controlled trials are needed to confirm these findings and establish optimal treatment protocols.

1. Introduction

Tinnitus, the perception of sound without an external auditory stimulus, affects approximately 10–15 % of the general population, with 1–2 % experiencing severe symptoms that significantly impact quality of life [1]. Beyond its primary auditory manifestation, tinnitus represents a complex neuropsychiatric condition with substantial socioeconomic implications, including reduced work productivity and increased healthcare utilization, estimated to cost healthcare systems billions annually [2].

Tinnitus is associated with various auditory disorders, including sensorineural hearing loss, vestibular schwannoma, Ménière's disease, otosclerosis and so forth. Moreover, recent research has highlighted its strong association with emotional stress, cognitive dysfunction, and autonomic nervous system alterations, leading to significant behavioral changes and functional impairments [3]. The complexity of these interactions necessitates a multifaceted treatment approach.

Current treatment modalities encompass several categories: sound therapy, pharmacological interventions, surgical treatments for specific pathologies, neuromodulation, and psychological interventions. Among

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these, Tinnitus Retraining Therapy (TRT), based on Jastreboff's neurophysiological model, combines counseling with sound therapy to promote habituation to both tinnitus perception and reaction [4,5]. While TRT has shown promise in improving quality of life and reducing perceived tinnitus intensity, recent systematic reviews indicate variable effectiveness, partly due to methodological heterogeneity across studies [6–8].

Cognitive Behavioral Therapy (CBT) has emerged as a well-validated intervention, receiving strong recommendations in recent clinical guidelines [8,9]. CBT's effectiveness stems from its ability to restructure negative thought patterns and improve emotional responses to tinnitus [10]. A newer variant, Acceptance and Commitment Therapy (ACT), emphasizes mindfulness and acceptance strategies. While some studies suggest ACT's superiority over traditional approaches, a recent meta-analysis revealed insufficient evidence for its long-term benefits in hearing-related distress or psychological well-being [11].

Neuromodulation, which modulates neuronal activities and functional connectivity includes repetitive transcranial magnetic stimulation, transcranial direct current stimulation (tDCS) and vagus nerve stimulation. Of these, tDCS is a one of the non-invasive techniques which delivers controlled electrical stimulation through scalp electrodes, modulating neural activity and enhancing neuroplasticity [12]. Several studies have demonstrated tDCS's potential in reducing tinnitus-related distress and loudness, particularly when targeting the dorsolateral prefrontal cortex [13–15]. Our previous research identified bifrontal tDCS as a promising adjunctive treatment, especially for severe tinnitus distress [16].

Despite these advances, significant research gaps remain. First, while both psychological interventions and neuromodulation show individual efficacy, their combined effects are poorly understood. Second, the optimal timing and sequencing of combined interventions remain unclear. Third, patient-specific factors predicting treatment response have not been well established [17]. In this study, we aimed to to evaluate the comparative efficacy of three treatment modalities for chronic tinnitus: TRT-based directive counseling, tDCS, and their combination. Primary endpoints were changes in tinnitus severity and psychological distress; secondary endpoints included treatment response rates and anxiety reduction.

2. Material and methods

This study was conducted at the tinnitus clinic of a tertiary university hospital between November 2021 and December 2023. The study protocol was approved by the institutional review board (IRB number: 2024-04-012).

We enrolled patients aged 18–75 years with chronic non-pulsatile subjective tinnitus persisting for more than three months who completed the full treatment course with available pre- and post-treatment evaluation data. Patients were excluded if they had objective or pulsatile tinnitus, active neurological or psychiatric conditions requiring medication changes during the study period, contraindications to tDCS such as metal implants in the head or history of seizures, or inability to complete questionnaires independently.

At baseline, all participants underwent comprehensive audiological assessment including pure-tone audiometry from 250 to 8000 Hz. A detailed medical history focused on tinnitus characteristics and comorbidities was obtained. Psychological evaluation was conducted using several validated instruments: the Tinnitus Handicap Inventory (THI; range 0–100), Visual Analog Scale for tinnitus severity (VAS; range 0–10), Beck's Depression Inventory (BDI), Beck's Anxiety Inventory (BAI), Hospital Anxiety-Depression Scale (HAD-A, HAD—D), and Brief Encounter Psychosocial Instrument (BEPSI).

Treatment allocation was based on informed preference after detailed discussion of each modality's benefits, limitations, and time commitments. The participants were distributed across three treatment groups: counseling ($n = 11$), tDCS ($n = 19$), and combined therapy (n = 11). This non-randomized approach reflects real-world clinical practice while potentially introducing selection bias, which was addressed in our analysis.

The directive counseling protocol consisted of a single 60-min session conducted by an otolaryngologist with more than 15 years of tinnitus management experience. Sessions were conducted in a group format with a maximum of four participants. The counseling content covered education on tinnitus neurophysiology, assessment of individual tinnitus characteristics, identification of modulating factors, instruction in coping strategies, and implementation strategies for daily living, followed by an interactive question-and-answer session.

For tDCS therapy, treatment was administered using the DC-Stimulator Plus (neuroConn GmbH, Germany). Electrodes were positioned according to the 10–20 EEG system, with the cathode at F3 and anode at F4 using 5 × 7 cm electrodes. The stimulation protocol delivered a current of 1.5 mA for 20 min, with 10-s ramp-up and ramp-down periods. Patients received treatments twice weekly for six sessions over three weeks, with a minimum 48-h interval between sessions.

Patients in the combined therapy group received the counseling session first, followed by the tDCS protocol beginning within one week of counseling. The parameters for both interventions remained identical to their individual protocols.

The primary outcome measures included changes in THI score, with clinically significant improvement defined as a reduction of seven or more points, and changes in VAS score [18]. Secondary outcomes encompassed changes in psychological parameters measured by BDI, BAI, HAD-A, HAD—D, and BEPSI, as well as overall treatment response rate and patient satisfaction. Follow-up evaluations were conducted four weeks after completing treatment. All 41 participants completed the THI, VAS, and BDI assessments, while 22 participants completed the full battery including BAI, BEPSI, and HADS.

Statistical analysis was performed using SPSS version 29.0 (IBM Corp.) and R version 4.3.0 (R Studio 2023.06.0) with significance set at $p < 0.05$. Given the sample size and data distribution, non-parametric tests were employed. Within-group comparisons (pre- vs post-treatment) were conducted using the Wilcoxon Signed-Rank test, while between-group comparisons utilized the Kruskal-Wallis test. Categorical variables were analyzed using Fisher's exact test.

To control for multiple comparisons, the Holm-Bonferroni sequential procedure was applied to adjust *p*-values within each treatment group using the p.adjust function in R. This approach provides stronger control of Type I error rate while maintaining better statistical power compared to the traditional Bonferroni correction. Medians and interquartile ranges (IQR) were reported for continuous variables to align with the non-parametric analysis approach. Missing data, which comprised less than 5 % of the total dataset, were handled using the last observation carried forward method.

3. Results

Among the 41 enrolled patients, 27 were male (65.9 %) and 14 were female (34.1 %), with a mean age of 51.9 years (range: 21–73 years). The average duration of tinnitus was 46.12 months (range: 3–480 months). Baseline characteristics, including age, gender distribution, tinnitus duration, and initial questionnaire scores, were comparable across the three treatment groups. Patient characteristics are detailed in Table 1.

Post-treatment evaluation revealed significant improvements across all questionnaire scores, indicating reductions in tinnitus-related distress, depression, anxiety, and stress-related emotional symptoms. The overall THI score showed a significant decrease from a median of 54.00 (IQR: 35.00–75.00) to 34.00 (IQR: 24.00–53.00) ($p < 0.01$). Analysis of THI subscales demonstrated consistent improvements: the functional subscale decreased from a median of 26.00 (IQR: 14.00–34.00) to 18.00 (IQR: 10.00–24.00), the emotional subscale from a median of 18.00 (IQR: 13.00–25.00) to 12.00 (IQR: 7.00–16.00), and

Table 1
Patient characteristics.

Group	Total ($n = 41$)	Counseling ($n = 11$)	tDCS ($n = 19$)	Counseling+ tDCS (n = 11)	*P* value
Age(years)	51.90 ± 12.02	53.50 ± 13.38	48.05 ± 11.88	56.67 ± 9.75	0.070
Sex (Male/ Female)	27/14	6/4	13/6	8/4	0.413
Tinnitus duration (months)	46.12 ± 84.32	48.50 ± 74.42	22.42 ± 22.63	81.67 ± 134.65	0.182
Tinnitus laterality (Right/Left/ Both)	10/9/ 22	1/3/7	3/3/13	2/1/8	0.554
Average hearing thresholds (Right, dB HL)	27.55 ± 19.90	23.90 ± 9.93	26.74 ± 23.48	32.27 ± 20.59	0.712
Average hearing thresholds (Left, dB HL)	21.88 ± 16.59	23.30 ± 7.04	18.21 ± 16.03	26.91 ± 22.60	0.745
Types of tinnitus					0.529
Pure Tone	26	6	13	7	
Narrow Band Noise	11	4	3	4	
Warble tone	2	1	1	0	
Can Not Test	2	0	2	0	
Tinnitus pitch (kHz)	4.90 ± 3.72	4.91 ± 3.11	4.72 ± 4.20	5.18 ± 3.79	0.952
Tinnitus loudness (dBHL)	44.27 ± 26.93	37.27 ± 24.33	40.29 ± 29.34	43.64 ± 28.38	0.866
Tinnitus loudness (dBSL)	5.00 ± 7.70	4.09 ± 0.70	6.47 ± 7.02	3.64 ± 6.74	0.547
Minimal Masking level (dBSL)	18.03 ± 25.06	16.00 ± 19.97	25.35 ± 27.35	8.89 ± 25.59	0.558
Residual inhibition					0.881
Complete	6	1	4	1	
Partial	12	4	5	3	
No change	23	6	10	7	

the catastrophic subscale from a median of 10.00 (IQR: 7.00–16.00) to 8.00 (IQR: 3.00–12.00) ($p < 0.01$ for all comparisons).

Clinically meaningful improvement, defined as a THI reduction of seven or more points, was achieved in 29 patients (70.7 %) across all groups. The response rates were distributed as follows: counseling group 7/11 (63.6 %), tDCS group 14/19 (73.7 %), and combined therapy group 8/11 (72.7 %). Fisher's exact test revealed no significant differences in these response rates between groups ($p > 0.05$).

The counseling group demonstrated significant improvements in VAS ($p = 0.010$) and BDI scores ($p = 0.042$) ($p < 0.05$), indicating reductions in perceived tinnitus discomfort and depressive symptoms. However, other psychological measures did not show significant changes in this group.

The tDCS group exhibited broader improvements, with significant reductions observed across multiple measures including THI, VAS, BDI, BEPSI, and both HAD-A and HAD-D subscales ($p < 0.05$). Similarly, the combined therapy group showed significant improvements in THI, VAS, and HAD-A scores ($p < 0.05$). However, after applying the Holm-Bonferroni correction for multiple comparisons, this difference did not maintain statistical significance in the combined therapy group ($p > 0.05$).

Comparative analysis revealed no significant differences between groups for most outcome measures ($p > 0.05$ for THI, VAS, BDI, BEPSI, and HAD-D). However, anxiety-related outcomes, specifically HAD-A scores, showed significant variation between groups ($p = 0.009$) (Fig. 1.). For post-hoc analysis, Mann-Whitney *U* tests were performed with Holm-Bonferroni correction. Both tDCS and combined therapy groups showed significantly greater anxiety reduction compared to the counseling group (adjusted $p = 0.01$ and $p = 0.007$, respectively), while no significant difference was found between tDCS and combined therapy groups (adjusted $p = 0.619$). These findings suggest that both tDCS and combined therapy were more effective than counseling alone in reducing anxiety symptoms.

Analysis of THI subscales within each treatment group revealed that the combined therapy group achieved significant reductions across all subscales ($p < 0.05$) (Fig. 2.). The tDCS group showed similar improvements, except for the emotional subscale, which approached but did not reach statistical significance ($p = 0.050$). In the counseling group, no subscales showed significant improvement ($p > 0.05$). However, between-group comparisons showed no statistically significant differences in the changes of all THI subscales (catastrophic, emotional, and functional) among the three treatment groups, although the combined therapy group showed a trend toward greater improvement in the emotional and functional subscales.

To investigate whether hearing status affected treatment response, patients were divided into two groups based on hearing threshold: those with normal hearing and those with hearing loss (defined as hearing threshold ≥20 dB in at least one ear). Kruskal-Wallis tests were performed to compare treatment outcomes across the three intervention

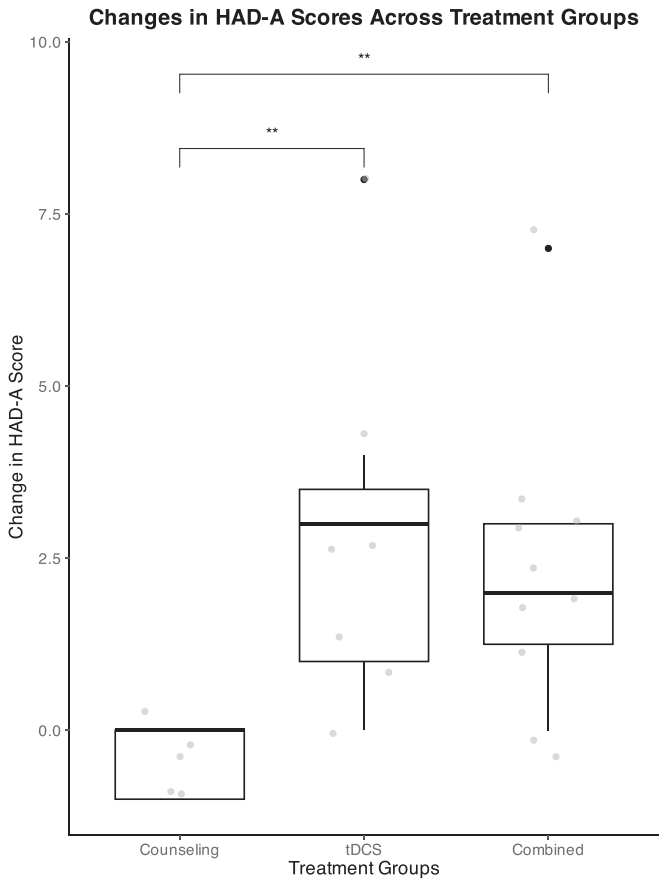


Fig. 1. Changes in HAD-A Scores Across Treatment Groups. Boxplots illustrating the differences in Hospital Anxiety and Depression Scale-Anxiety (HAD-A) score changes across treatment groups. Both tDCS and combined therapy groups showed significantly greater anxiety reduction compared to the counseling group (** $p < 0.01$). There was no significant difference between tDCS and combined therapy groups in anxiety reduction. Higher values indicate greater improvement (reduction in anxiety scores from pre- to post-treatment).

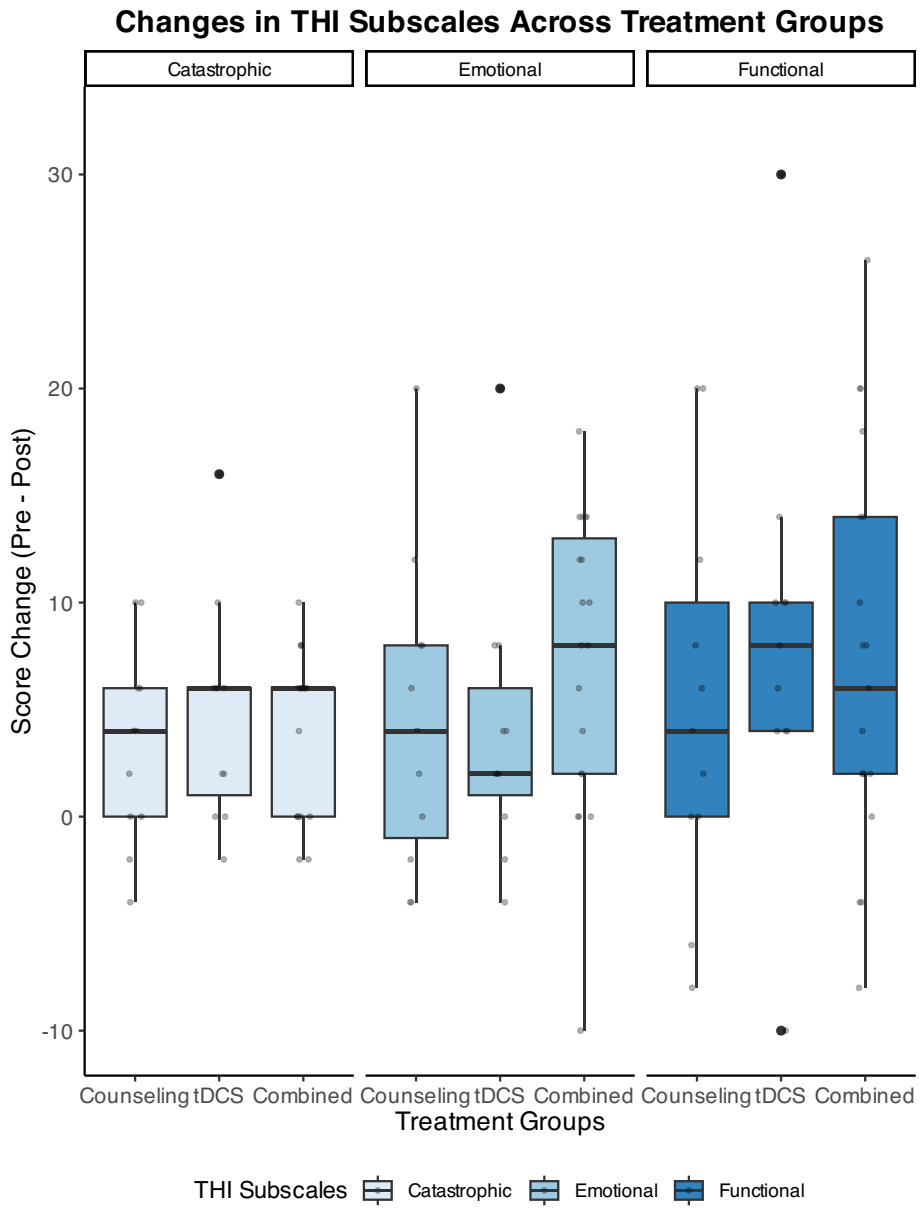


Fig. 2. Changes in THI Subscales Across Treatment Groups. Boxplots showing the changes in Tinnitus Handicap Inventory (THI) subscales (Catastrophic, Emotional, and Functional) across the three treatment groups (Counseling, tDCS, and Combined therapy). The combined therapy group demonstrated the greatest improvements in all three subscales, particularly in the emotional and functional domains. Higher values indicate greater improvement (reduction in THI scores from pre- to post-treatment).

groups within each hearing status category. No significant differences were found in treatment responses (THI, VAS, BDI, or HAD-A score changes) between patients with and without hearing loss across all three treatment groups ($p > 0.05$). This suggests that the efficacy of directive counseling, tDCS, and combined therapy was comparable regardless of patients' hearing status.

4. Discussion

In this study, we compared the efficacy of three therapeutic approaches for chronic tinnitus management. Overall, 70.7 % of patients showed clinically meaningful improvement (THI reduction ≥7 points), indicating all treatment modalities were effective. Although not reaching statistical significance, the tDCS (73.7 %) and combined therapy groups (72.7 %) demonstrated higher response rates compared to counseling alone (63.6 %), supporting the potential benefits of neuromodulation in tinnitus management [12–14,16].

The most notable finding was the superior effect on anxiety measures in the combined therapy group, particularly evident in HAD-A scores ($p = 0.034$). This enhanced anxiety reduction likely reflects synergistic effects between psychological intervention and neuromodulation, consistent with recent research demonstrating strong associations between tinnitus and anxiety disorders [20]. However, the discrepancy between HAD-A and BAI responses suggests differential sensitivity of anxiety measures in the tinnitus population, with HAD-A potentially being more sensitive to clinical anxiety in medical settings [19].

The effectiveness of combined therapy may stem from its dual mechanism of action. According to De Ridder et al. [21], tinnitus-related distress involves various brain networks including the salience network (processing tinnitus relevance), the default mode network (integrating tinnitus into self-perception), and the central executive network (affecting cognitive performance). The bifrontal tDCS component modulates neural activity in the dorsolateral prefrontal cortex, while counseling addresses cognitive and emotional responses to tinnitus [5].

Recent neuroimaging studies have demonstrated that tDCS can induce structural plasticity, potentially enhancing the effects of concurrent psychological interventions [15].

While our findings indicate positive outcomes for tDCS treatment, particularly when combined with counseling, it is important to acknowledge that the literature shows mixed results regarding tDCS efficacy for tinnitus. A recent double-blind, randomized, sham-controlled trial by Martins et al. [22] reported no significant improvement in tinnitus severity, annoyance, or loudness following five consecutive sessions of anodal tDCS targeting the left temporoparietal area. Their study found no difference between active and sham tDCS groups, suggesting potential placebo effects. The contrasting results between their study and ours might be attributed to several factors, including differences in electrode montage (left temporoparietal vs. bifrontal in our study), stimulation parameters, patient selection criteria, or outcome measures. Notably, Martins et al. applied tDCS as a standalone treatment, whereas our study included a combined therapy approach that showed enhanced efficacy, particularly for anxiety symptoms. These divergent findings underscore the importance of optimizing tDCS protocols and potentially combining neuromodulation with psychological interventions to maximize therapeutic benefits. Furthermore, they highlight the need for identifying patient characteristics that might predict response to specific tDCS montages or treatment combinations.

Mazurek et al. reviewed the complex relationship between tinnitus and its comorbidities, proposing a vulnerability-stress-reaction model to understand tinnitus-related distress [23]. This model posits that individual vulnerabilities interact with stressors to trigger and perpetuate tinnitus distress. The authors highlighted key comorbidities including depression, anxiety, stress, pain experiences, hearing loss, and cognitive difficulties, emphasizing their interconnectedness and influence on tinnitus development and chronicity. They recommended an individualized, multidimensional, and interdisciplinary approach to diagnosis and treatment, combining audiological interventions with psychotherapeutic approaches to address the psychological aspects of tinnitus distress [23]. Recently, we reported found increased neural synchronization in temporal-limbic connections in patients with improved cognition after tinnitus treatment, while enhanced connectivity in prefrontal-limbic and parietal-occipital areas was associated with reduced tinnitus distress [24]. These findings support Mazurek et al.'s recommendation for an individualized, multidimensional approach that addresses both auditory symptoms and psychological aspects of tinnitus.

Our findings suggest that treatment selection should be tailored to individual patient profiles [25,26], particularly considering the presence of anxiety symptoms. The enhanced efficacy of combined therapy supports an integrated treatment approach, especially for patients with significant psychological comorbidities [17]. The group counseling format may provide additional benefits through peer support and shared experiences, consistent with previous studies on group interventions in tinnitus management [27].

Our subgroup analysis based on hearing status revealed that treatment outcomes were not significantly influenced by the presence of hearing loss. This finding aligns with Wang et al.'s recent longitudinal study [28], which found no significant differences in tinnitus relief between patients receiving educational counseling alone versus those receiving both hearing aids and counseling, despite all participants having hearing loss. Their findings suggested that counseling itself may be a powerful intervention regardless of whether auditory amplification is provided. Similarly, in our study, the comparable efficacy across hearing status groups indicates that the mechanisms underlying tinnitus improvement through both neuromodulation and counseling may operate independently of peripheral auditory function. This is particularly relevant for tDCS, which primarily targets central auditory processing and associated neural networks rather than peripheral hearing mechanisms. These findings collectively suggest that central mechanisms and psychological factors may play a more crucial role in tinnitus management than previously thought, and that treatment selection should not be primarily determined by hearing status.

From a cost-effectiveness perspective, while implementing tDCS programs requires initial investment in equipment and training, the potential reduction in long-term healthcare utilization through improved symptom management may offset these costs. The observed benefits in anxiety reduction could have broader implications for overall mental health outcomes and quality of life [25].

Several methodological limitations should be considered: First, the non-randomized treatment allocation and small sample size may have introduced selection bias. The relatively small sample sizes in the counseling ($n = 11$) and combined therapy groups ($n = 11$) limit statistical power for subgroup analyses. Second, the lack of long-term follow-up data prevents assessment of treatment durability, an important consideration given the chronic nature of tinnitus [29]. Third, the absence of a sham tDCS control group makes it difficult to fully account for placebo effects. Fourth, while our treatment response definition (THI reduction $\geq$7 points) is well-validated [18], the heterogeneity in tinnitus characteristics and comorbidities may influence individual responses to treatment [17].

Future research should address these limitations through prospective randomized controlled trials with larger sample sizes and extended follow-up periods. Investigation of optimal stimulation parameters and counseling protocols, along with identification of patient-specific predictive factors for treatment response, would further advance the field. Integration of neuroimaging and electrophysiological measures could help elucidate the mechanisms underlying observed synergistic effects [12,13].

5. Conclusion

In conclusion, this study provides evidence supporting the efficacy of combined tDCS and counseling therapy for chronic tinnitus, particularly in managing anxiety-related symptoms. The findings suggest that integrating neuromodulatory and psychological approaches provides a more comprehensive treatment strategy, especially beneficial for patients with psychological comorbidities. Future research should focus on optimizing treatment protocols and identifying patient-specific factors that predict treatment success, ultimately moving toward more personalized tinnitus management strategies.

CRediT authorship contribution statement

Zoo Young Lee: Data curation, Writing – original draft. **Seung-Ho Shin:** Methodology, Supervision, Validation. **Sung Wan Byun:** Supervision, Software, Validation. **Soo Hee Oh:** Supervision, Validation, Methodology, Visualization. **Ho Yun Lee:** Formal analysis, Visualization, Supervision, Validation, Data curation, Methodology, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no competing interest.

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