Research Article

Effect of Binaural Beat and Tailor-Made Notched Music Training on Reducing the Loudness and Annoyance of Chronic Tinnitus: A Controlled Trial Study

Selva Samaei[1], Yones Lotfi[1], Nasrin Yazdani[2,3], Mohsen Vahedi[4], Moslem Shaabani[1,5]

[1.] Department of Audiology, School of Rehabilitation, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran
[2.] Otorhinolaryngology Research Center, Amir A'lam Hospital, Tehran University of Medical Sciences, Tehran, Iran
[3.] Department of Otorhinolaryngology-Head and Neck Surgery, Tehran University of Medical Sciences, Tehran, Iran
[4.] Department of Biostatistics and Epidemiology, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran
[5.] Pediatric Neurorehabilitation Research Center ,University of Social Welfare and Rehabilitation Sciences, Tehran, Iran

ORCID ID:
Selva Samaei: 0009-0000-7533-0483
Yones Lotfi: 0000-0001-8563-312X
Nasrin Yazdani: 0000-0003-1006-289X
Mohsen Vahedi: 0000-0002-4645-6770
Moslem Shaabani: 0000-0002-3614-1011

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* **Corresponding Author:** Department of Audiology, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran. mo.shaabani@uswr.ac.ir

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Highlights:

- TMNMT alone led to significant reductions in tinnitus parameters over four weeks
- TMNMT+BBS led to significant reductions in tinnitus parameters over four weeks
- Numerically greater improvements were observed in the TMNMT+BBS group

ABSTRACT

Background and Aim: Tinnitus is a persistent perception of sound without an external source and is often accompanied by emotional distress. Tailor-Made Notched Music Therapy (TMNMT) and Binaural Beat Stimulation (BBS) are non-invasive auditory approaches proposed to alleviate tinnitus symptoms. This study compared the effects of TMNMT alone and TMNMT combined with BBS in adults with chronic subjective tinnitus.

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Methods: In this randomized controlled trial, 24 adults with chronic tinnitus were allocated to either the TMNMT group or the TMNMT+BBS group. Individualized music files were created by removing the tinnitus frequency band; in the combined group, an 8-Hz alpha-range binaural beat was embedded at –20 dB. Participants listened to the audio stimuli twice daily for four weeks. Outcomes included the Tinnitus Handicap Inventory (THI), Beck Depression Inventory (BDI), and Visual Analog Scales for tinnitus Loudness (VAS-L) and Annoyance (VAS-A).
Results: Both groups showed significant improvement across all outcome measures ($p<0.01$). Greater mean reductions were observed in the TMNMT+BBS group for THI ($\Delta=17.33\pm13.11$ vs. 9.00 ± 8.16) and BDI ($\Delta=4.08\pm1.79$ vs. 1.83 ± 1.26), though between-group differences were not statistically significant. Effect sizes (Cohen's $d=0.76$-1.46) favored the combined intervention.
Conclusion: TMNMT and TMNMT+BBS effectively reduced tinnitus-related distress and depressive symptoms. The addition of binaural beats produced stronger clinical gains; however, these differences were not statistically significant and therefore should be interpreted cautiously. Larger trials with extended follow-up are recommended.
Trial Registration Number: IRCT20250215064735N1
Keywords: Tinnitus; notched music therapy; binaural beats; auditory plasticity; alpha oscillations

Introduction

Tinnitus is defined as the perception of sound in the absence of an external auditory stimulus and affects approximately 10-15% of the global population. In 1-2% of individuals, it becomes chronic and distressing, interfering with mood, attention, and quality of life [1]. Tinnitus persistence is linked to maladaptive cortical reorganization and hyperactivity in auditory-limbic networks, resulting in aberrant neural activity and phantom sound perception [2].

Various therapeutic approaches have been explored for tinnitus, among which Tailor-Made Notched Music Therapy (TMNMT) has gained attention as a non-invasive, individualized method to promote adaptive cortical plasticity [3]. In TMNMT, a narrow frequency band centered on the tinnitus pitch is removed from preferred music to promote lateral inhibition and reduce tinnitus-related hyperactivity [3]. Although several studies report improvements in tinnitus loudness and handicap, results are variable, suggesting that TMNMT alone may not fully normalize auditory network activity [3, 4].

Binaural Beat Stimulation (BBS) is a non-invasive auditory approach that modulates brain activity and emotional regulation by presenting slightly different frequencies to each ear, producing a perceived rhythmic beat. This beat entrains neural oscillations, commonly in the alpha (8-12 Hz) or theta (4-7 Hz) ranges, and has been associated with enhanced relaxation, attention, and emotional control [5, 6]. Studies indicate that binaural beat stimulation can reduce tinnitus-related distress by promoting cortical synchronization and relaxation. For example, Prakash and Konadath reported significant reductions in Tinnitus Handicap Inventory (THI) scores following delta and alpha beat stimulation [7], while Sadeghijam et al. observed decreased tinnitus loudness and annoyance after exposure to music embedded with binaural beats [8]. Electrophysiological studies further suggest that binaural beats enhance neural synchrony in auditory and prefrontal regions, supporting emotional regulation and attentional control [8].

Combining TMNMT with BBS may produce complementary effects, as TMNMT primarily drives bottom-up auditory cortical reorganization, whereas BBS modulates top-down attentional and emotional processes [9]. Neuroimaging studies shows that tinnitus-related distress involves both auditory and limbic-prefrontal networks, including the amygdala and anterior cingulate cortex [10]. Accordingly, interventions targeting both auditory and emotional circuits may offer enhanced clinical benefit [11].

Tinnitus severity often correlates with anxiety and depression, amplifying its impact on quality of life [12]. Moreover, therapeutic improvements in tinnitus perception frequently coincide with reductions in emotional distress [13]. Evaluating both perceptual (e.g., loudness, handicap) and affective (e.g., depression) outcomes thus provides a more comprehensive assessment of efficacy. Recent advances in auditory neuroscience suggest that rhythmically synchronized sound therapies, especially those modulating alpha oscillations, can restore functional connectivity and reduce tinnitus-related cortical dysregulation [14].

Based on this evidence, the present study aimed to compare the effects of TMNMT alone and in combination with BBS in adults with chronic tinnitus. We hypothesized that both interventions would significantly reduce tinnitus-related distress and depressive symptoms, with greater improvement expected in the combined group

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due to its dual mechanism of action. By addressing both perceptual and emotional aspects of tinnitus, this study sought to contribute to the evidence supporting integrated, neuroadaptive sound-based treatment.

Methods

Participants and trial design

This randomized controlled clinical trial was conducted at the Audiology Clinic of Rofeideh Rehabilitation Hospital in Tehran, Iran. Participants were recruited from adults presenting with chronic subjective tinnitus through outpatient referrals and clinic announcements between September 2023 and April 2024. The purpose of recruiting from a single specialized center was to ensure a relatively homogeneous population in terms of clinical presentation, audiological status, and treatment history.

All candidates underwent a comprehensive otological and medical examination conducted by an experienced otolaryngologist to rule out middle ear pathology, neurological disease, or psychiatric comorbidity. Baseline audiological assessment included otoscopy, tympanometry, acoustic reflex testing, and pure-tone audiometry at octave frequencies between 250 and 8000 Hz, performed in a double-walled sound-treated booth using a Madsen Astera audiometer (Otometrics, Denmark). The evaluation further incorporated detailed tinnitus psychoacoustic profiling, which consisted of pitch matching, loudness matching, Minimum Masking Level (MML), and residual inhibition testing.

Eligible participants were adults aged 18-60 years who reported continuous tonal tinnitus for at least six months, described as a ringing, hissing, or buzzing sound perceived in one or both ears. Only those with tinnitus frequencies below 8000 Hz and with mild to moderate symmetric sensorineural hearing loss (pure-tone average <70 dB HL) were included. Exclusion criteria comprised pulsatile or fluctuating tinnitus, negative residual inhibition, active neurological or psychiatric disorders, and any ongoing participation in other tinnitus interventions or use of hearing aids. Individuals with a history of otologic surgery or significant cognitive impairment were also excluded.

After screening, 28 eligible participants (12 males and 16 females) were enrolled and randomly allocated into two treatment arms: 14 participants were assigned to the TMNMT group and 14 to the TMNMT+BBS group. During the intervention period, two participants from each group withdrew, resulting in 12 participants per group (n=24; 9 males and 15 females) who completed the study.

Randomization was performed using a computer-generated block randomization sequence (block size of four), ensuring balanced allocation. Group assignments were concealed in sequentially numbered opaque envelopes opened only after baseline assessment. Both participants and the examiner conducting outcome evaluations were blinded to the intervention type to minimize assessment bias. Although outcome assessors were blinded, complete participant blinding could not be ensured because the binaural beat stimulus is perceptually distinguishable from notched music alone. All participants continued to receive routine standard-of-care tinnitus management during the study. This included weekly telephone-based counseling and tinnitus education provided by an audiologist. Therefore, the experimental sound therapies were delivered as adjunctive interventions, and participants were not deprived of recommended guideline-based care.

The sample size (n=24) was determined based on prior tinnitus sound therapy studies reporting moderate-to-large effect sizes for within-group THI changes (Cohen's d≈0.8). Given the exploratory design and feasibility constraints, this sample was considered adequate for preliminary evaluation. Although no formal a priori power analysis was performed, the observed within-group improvements and moderate-to-large effect sizes support the adequacy of this sample for detecting clinically meaningful changes.

A formal a priori power analysis was conducted using standard sample size calculation formulae with $\alpha=0.05$ and $1-\beta=0.80$. Based on parameters from a comparable published study [15, 16], the minimum required sample size was 11 participants per group. To account for possible attrition, 14 participants per group (28 in total) were recruited.

Intervention protocol

Preparation of audio stimuli

For each participant, customized auditory stimuli were generated using Audacity (version 3.0) software. Participants selected pieces of music from their preferred genre, ensuring a strong degree of personal engagement with the auditory material. To create the individualized notched music (TMNMT), a narrow frequency band

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centered on each participant's tinnitus pitch was digitally removed using a Q-factor of 0.4. This notching process was intended to reduce cortical overrepresentation at the tinnitus frequency through lateral inhibitory mechanisms. The same processing chain and sampling rate (44.1 kHz) were used for every file to ensure consistency across subjects.

For participants assigned to the experimental group, a Binaural Beat Signal (BBS) was generated by combining two pure tones differing by 8 Hz (440 Hz presented to the right ear and 448 Hz to the left ear), corresponding to the alpha frequency range (8-12 Hz) associated with relaxation and cortical synchronization. This binaural beat track was then embedded into the notched music at a relative amplitude of –20 dB relative to the music signal, ensuring that the musical component remained the dominant auditory stimulus while still facilitating alpha-band neural entrainment. The final audio files were rendered in stereo MP3 format (44.1 kHz sampling rate). We acknowledge that MP3 is a compressed audio format and may introduce some spectral alterations; however, all files were processed using an identical procedure and sampling rate to minimize variability across participants. The potential impact of compression on notch fidelity is considered in the Limitations section.

Listening procedure

Participants were instructed to listen to their assigned auditory stimuli, either TMNMT alone or TMNMT combined with BBS, using stereo headphones. Both TMNMT and TMNMT+BBS stimuli were delivered binaurally through stereo headphones to ensure consistent auditory presentation across participants. Listening sessions were conducted in a quiet environment, typically at home, twice daily (once in the morning and once in the evening), for 20 minutes per session over four consecutive weeks. This 4-week, twice-daily 20-minute schedule was selected to approximate the total stimulation dose used in previous TMNMT and binaural-beat interventions that demonstrated clinical benefit while remaining feasible for home implementation [15, 16].

Participants listened to the audio stimuli using their own personal stereo headphones. Because headphone models were not standardized or acoustically calibrated, variability in frequency response and output level may have occurred. To reduce loudness inconsistency, all participants were instructed during the initial supervised session to adjust the volume to a comfortable, non-loud level and maintain the same setting throughout the intervention. Participants were advised to remain seated and relaxed during each session and to avoid simultaneous exposure to other sound sources or activities requiring significant concentration. Compliance with the listening regimen was encouraged through weekly telephone and social-media reminders, and participants were asked to complete a simple adherence checklist documenting each completed session. Any adverse effects or discomfort were to be immediately reported to the research team, though none were observed during the study. The first group received TMNMT only, while the second group received TMNMT with embedded 8-Hz binaural beat stimulation. All participants underwent outcome assessments at two time points: before the start of the intervention (T0) and immediately after completion of the four-week listening period (T1). This design allowed for both within-group and between-group comparisons of treatment effects.

Psychoacoustic and psychometric evaluation

All psychoacoustic assessments were conducted once at baseline to characterize the tinnitus percept and to guide the development of individualized auditory stimuli. Tinnitus Pitch Matching test (PMT) was conducted using frequency-modulated pure tones in one-third octave steps between 125 Hz and 12 kHz, while Loudness Matching Test (LMT) was determined by presenting tones at the matched frequency in 1-dB increments above threshold until the perceived loudness equaled that of the tinnitus percept. PMT and LMT were performed monaurally using the Madsen Astera audiometer (Otometrics, Denmark) to determine each participant's tinnitus pitch and loudness level. These parameters were not reassessed following the intervention, as their primary function was to establish the frequency notch for sound file generation rather than to serve as outcome measures.

To assess tinnitus-related distress and emotional burden, participants completed validated Persian versions of the THI [17], Beck Depression Inventory (BDI) [18], and Visual Analog Scales for tinnitus Loudness (VAS-L) and Annoyance (VAS-A). The THI consists of 25 items covering functional, emotional, and catastrophic subdomains, yielding a total score from 0 to 100, with higher scores indicating greater handicap. The BDI includes 21 items measuring depressive symptoms on a scale of 0-63, where higher scores reflect more severe depression. VAS-L and VAS-A consisted of 10-centimeter horizontal lines anchored by "no tinnitus" at 0 and "worst imaginable" at 10, on which participants marked their perceived tinnitus loudness and annoyance. All questionnaires were administered by the same trained audiologist to ensure consistency across sessions.

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Statistical analysis

Data were analyzed using IBM SPSS Statistics version 17.0 (Armonk, NY, USA). Continuous variables are reported as mean±SD for normally distributed data or median (interquartile range) for non-normal data, while categorical variables are presented as frequencies and percentages. Normality was assessed using the Shapiro-Wilk and Kolmogorov-Smirnov tests.

Baseline between-group comparisons were performed using independent-samples t-tests or Mann-Whitney U tests, as appropriate. Within-group pre- to post-intervention changes were analyzed using paired-samples t-tests or Wilcoxon signed-rank tests. Categorical variables were compared using Chi-square or Fisher's exact tests. To control for baseline differences, analysis of covariance (ANCOVA) was conducted with baseline values entered as covariates.

A two-tailed $p<0.05$ was considered statistically significant. Effect sizes were calculated using Cohen's d (0.2=small, 0.5=moderate, ≥0.8=large). Data were screened for outliers and missing values prior to analysis.

Results

Participant characteristics

A total of 24 participants (9 males, 15 females) with chronic subjective tinnitus completed the study. The mean age of participants was 40.75±11.75 years in the TMNMT group and 44.08±12.31 years in the TMNMT+BBS group, with no statistically significant difference between groups ($t=–0.678$, $p=0.505$).

Regarding gender distribution, 2 participants (16.7%) in the TMNMT group and 7 (58.3%) in the TMNMT+BBS group were male, while 10 (83.3%) and 5 (41.7%) were female, respectively. Although a chi-square test indicated a trend toward gender imbalance ($p=0.035$), Fisher's exact test confirmed that this difference was not statistically significant ($p=0.089$). Baseline psychoacoustic characterization revealed that the median tinnitus pitch (PMT) was 7000 Hz (interquartile range: 5500 Hz) in the TMNMT group and 5000 Hz (IQR: 5500 Hz) in the TMNMT+BBS group. The median tinnitus loudness match (LMT) was 6.5 dB SL (IQR: 6 dB) in both groups. Mann-Whitney U tests showed no significant group differences for PMT ($z=–0.337$, $p=0.755$) or LMT ($z=0.378$, $p=0.713$), indicating comparable tinnitus psychoacoustic profiles at baseline. These findings confirm that both groups were homogeneous in demographic and tinnitus characteristics before intervention, ensuring a valid comparison of treatment outcomes.

All participants reported bilateral tinnitus; therefore, tinnitus laterality was fully balanced and could not confound the results. Baseline audiometry showed mild to moderately severe sensorineural hearing loss (20–70 dB HL) in both groups, with no significant differences in pure-tone averages (0.5–4 kHz; $p>0.05$). Thus, the TMNMT and TMNMT+BBS groups were comparable in age, gender, tinnitus characteristics, and hearing status, supporting the validity of subsequent between-group comparisons.

Tinnitus handicap inventory scores

At baseline, the mean THI scores did not differ significantly between the TMNMT group (60.67±25.71) and the TMNMT+BBS group (61.17±20.35; $p>0.05$), confirming initial equivalence. Following the 4-week intervention, both groups demonstrated a significant within-group reduction in THI scores.

In the TMNMT group, mean THI decreased from 60.67±25.71 to 51.67±28.05 ($t=3.822$, $p=0.003$), whereas in the TMNMT+BBS group, scores declined from 61.17±20.35 to 43.83±23.17 ($t=4.58$, $p<0.001$). The within-group effect size (Cohen's d) was larger in the combined intervention group ($d=1.32$) compared to TMNMT alone ($d=1.10$), indicating a stronger clinical effect when BBS was added. As illustrated in Figure 1A, both groups showed a clear downward shift in THI scores from pre- to post-intervention, with the TMNMT+BBS group exhibiting a numerically larger mean reduction despite the absence of a statistically significant between-group difference.

Between-group comparison of post-intervention THI scores revealed no statistically significant difference ($t=–0.53$, $p=0.958$). However, the mean reduction (ΔTHI) was greater in the TMNMT+BBS group (17.33±13.11) compared with the TMNMT group (9.00±8.16), and this trend approached significance ($t=–1.87$, $p=0.075$), with a moderate to large effect size ($d=0.76$). Overall, both interventions significantly reduced tinnitus-related handicap, and the combined therapy demonstrated a clinically stronger though statistically no significant improvement. Table 1 summarizes the baseline and post-intervention scores (THI, BDI, VAS-L, VAS-A) for both study groups.

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Beck depression inventory scores

Baseline BDI scores were similar between groups (TMNMT: 13.17±3.41; TMNMT+BBS: 13.33±2.96; t=–0.128, p=0.899). After the 4-week intervention, both groups exhibited significant reductions in depressive symptoms. In the TMNMT group, mean BDI decreased from 13.17±3.41 to 11.33±4.14 (t=5.01, p<0.001), while in the TMNMT+BBS group, it decreased from 13.33±2.96 to 9.25±3.05 (t=7.93, p<0.001). The effect size was large for both groups but more pronounced in the TMNMT+BBS group (Cohen's d=2.29) than in TMNMT alone (d=1.44), suggesting that the combined auditory therapy exerted a stronger influence on emotional well-being.

Between-group analysis of post-treatment BDI scores showed no statistically significant difference (t=1.40, p=0.174). However, the mean change (ΔBDI) was significantly larger in the TMNMT+BBS group (4.08±1.79) than in the TMNMT group (1.83±1.26), indicating a meaningful improvement in depressive symptoms (t=–3.57, p=0.002; Cohen's d=1.46). These results demonstrate that both interventions effectively alleviated depressive symptoms associated with tinnitus, with the combined TMNMT+BBS protocol yielding significantly greater benefit. Figure 1B, visually presents the pre- and post-treatment BDI changes, highlighting the greater decline in depressive symptoms in the TMNMT+BBS group, consistent with the larger change scores observed in the statistical analysis.

Visual analog scale scores

At baseline, no significant differences were observed between groups for either VAS-L or VAS-A, confirming comparability before intervention.

For VAS-L, the TMNMT group reported a mean score of 7.08±2.00 at baseline, which decreased significantly to 4.50±2.11 after treatment (z=–2.77, p=0.006). Similarly, the TMNMT+BBS group showed a reduction from 7.33±2.30 to 4.50±2.30 (z=–2.68, p=0.007). Although both groups demonstrated significant within-group improvement, the between-group comparison of change scores (ΔVAS-L) did not reveal a statistically significant difference (z=0.001, p=0.999). As shown in Figure 1C, both groups demonstrated similarly pronounced reductions in tinnitus loudness, with overlapping post-intervention values reflecting the non-significant between-group comparison.

For VAS-A, baseline mean values were 8.08±1.73 in the TMNMT group and 8.00±2.25 in the TMNMT+BBS group. Post-intervention, scores decreased significantly to 6.75±2.66 (p=0.019) and 5.50±1.97 (p=0.003), respectively. The reduction in annoyance was numerically greater in the TMNMT+BBS group, though the between-group difference was not statistically significant (z=1.68, p=0.101). Figure 1D, illustrates the decrease in tinnitus annoyance across both groups, with the TMNMT+BBS group showing a larger numerical decline, although the difference was not statistically significant.

Overall, both interventions significantly reduced tinnitus loudness and annoyance. While between-group differences did not reach statistical significance, the greater mean reductions in the TMNMT+BBS group indicate a trend toward enhanced clinical benefit when binaural beats were incorporated into the therapy protocol.

Discussion

This randomized controlled trial compared TMNMT alone and TMNMT combined with BBS on tinnitus-related and psychological outcomes. Both interventions led to significant within-group improvements, supporting the benefit of sound-based therapies. Although between-group differences were not statistically significant, the TMNMT+BBS group showed numerically greater improvements and larger effect sizes, indicating a possible complementary pattern.

These findings are consistent with previous research demonstrating that sound-based interventions can modulate neural activity and reduce tinnitus perception. For instance, Okamoto et al. and Pantev et al. found that notched music induces frequency-specific cortical plasticity, leading to decreased tinnitus loudness and handicap [3, 19]. Similarly, Munro et al. reported that natural sounds with or without embedded binaural beats reduced tinnitus perception, supporting the role of sound enrichment in auditory modulation [20].

These converging findings across multiple studies suggest that general auditory enrichment, regardless of whether binaural beats are included, may play a major role in symptom relief. At the same time, other trials such as Moossapour Bardsiri et al. and Sadeghijam et al. showed stronger improvements or neural changes with binaural beats, highlighting variability in patient responsiveness and the importance of including physiological outcomes in future work [8, 21].

To our knowledge, this is one of the first randomized controlled trials to evaluate the combined use of TMNMT and BBS, offering preliminary evidence for an integrated frequency- and rhythm-based auditory intervention.

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Combined effects on tinnitus handicap, depression, and perceptual measures

Both groups demonstrated significant reductions in tinnitus handicap (THI), depressive symptoms (BDI), tinnitus loudness (VAS-L), and annoyance (VAS-A) after four weeks. The larger mean reductions observed in the TMNMT+BBS group suggest a possible complementary effect, although these trends were not statistically significant and should be interpreted cautiously.

TMNMT and BBS may exert complementary bottom-up and top-down effects, with TMNMT promoting auditory cortical reorganization and BBS enhancing alpha-band oscillatory entrainment associated with relaxation and emotional regulation [4, 22]. BBS, in contrast, entrains oscillatory activity, particularly within the alpha range, associated with relaxation and attentional disengagement.

Similar synergistic trends have been noted in Ibarra-Zárate et al., where both BB and music therapy reduced tinnitus perception, yet BB produced additional modulation of cortical oscillations measured via electroencephalography [23].

Chaieb et al. found that auditory beat stimulation enhanced mood and cognitive performance [24], while Solcà et al. and Gao et al. observed increased alpha coherence and emotional stability in response to binaural beats [25, 26].

The co-occurrence of tinnitus and mood symptoms may be partially explained by overlapping neural networks. Research by Zeman et al. and Trevis et al. suggests that tinnitus distress and depressive symptoms share overlapping neural substrates involving the anterior cingulate cortex, amygdala, and prefrontal regions, areas influenced by alpha oscillatory rhythms [27, 28].

In contrast to studies reporting stronger emotional effects of binaural beats, the modest BDI reductions observed here may relate to the absence of clinically significant depression at baseline [21, 29].

Neural and psychological integration

Combining TMNMT and BBS may influence both perceptual and affective neural networks involved in tinnitus, which extends beyond the auditory system [2]. These findings also underscore the heterogeneity of tinnitus, suggesting that treatment response may vary across individuals.

A similar pattern was reported by Bakhtarikia et al., in which music combined with binaural beats produced larger, though not statistically significant, improvements compared with music alone [15]. The use of THI, VAS-L, VAS-A, and BDI enabled a multidimensional assessment of outcomes, consistent with prior evidence linking tinnitus severity and emotional burden [13, 30].

Clinical implications and relevance

From an audiological standpoint, these findings suggest that sound-based interventions may serve as accessible, non-invasive tools within tinnitus management programs. Although the mechanisms underlying improvement were not directly assessed in this study, previous literature suggests that sound enrichment and frequency-specific stimulation may influence auditory and emotional processing [24, 25].

Consistent with Munro and Searchfield [20] and Bakhtarikia et al. [15], our findings support the notion that both simple and enriched auditory stimuli may reduce tinnitus perception, and that binaural beats are not universally superior but may offer added benefit for selected individuals. Mood-related improvements should be interpreted cautiously, as participants were not clinically depressed at baseline.

Overall, the present findings demonstrate short-term behavioral improvements but underscore the need for future work incorporating EEG, Auditory Steady-State Response, or functional imaging to clarify underlying neural mechanisms and identify which patients may benefit most from combined TMNMT+BBS protocol.

Limitations and future directions

Several limitations should be acknowledged. The small sample size, short intervention duration (four weeks), and lack of follow-up assessments may have limited the ability to detect between-group differences and to evaluate the durability of treatment effects. Future studies should include larger samples, longer interventions, and follow-up assessments.

The study relied on self-report measures, and no objective neurophysiological assessments (e.g., EEG or fMRI) were included to verify underlying mechanisms. Acoustic control was limited because participants used non-

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standardized personal headphones and listening levels were not calibrated; thus, variability in frequency response and MP3 compression may have affected stimulus fidelity.
Complete participant blinding was not feasible due to the perceptual nature of binaural beats, introducing potential expectancy bias. Finally, the absence of a standard-care or placebo control group limits treatment-specific interpretation. These methodological issues should be addressed in future controlled trials.

Conclusion

This preliminary randomized controlled trial evaluated the effects of Tailor-Made Notched Music Therapy (TMNMT) alone and combined with Binaural Beat Stimulation (BBS) in adults with chronic tinnitus. Both interventions led to significant reductions in tinnitus loudness, annoyance, handicap, and depressive symptoms over four weeks. Although between-group differences were not statistically significant, numerically greater improvements were observed in the TMNMT+BBS group.
Given the study's methodological limitations, including small sample size, short intervention duration, lack of follow-up, reliance on self-report measures, and incomplete blinding, these findings should be interpreted cautiously and regarded as hypothesis-generating. Larger, well-controlled studies with objective measures and extended follow-up are warranted.

Ethical Considerations

Compliance with ethical guidelines

All participants provided written informed consent before enrollment, and the study protocol was approved by the Ethics Committee of the University of Social Welfare and Rehabilitation Sciences (approval code: IR.USWR.REC.1402.092) and registered in the Iranian Registry of Clinical Trials (IRCT20250215064735N1).

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Authors' contributions

SS: Study design, acquisition of data, interpretation of the results, statistical analysis, and drafting the manuscript; YL: Study design, and interpretation of the results; NY: Study design, and interpretation of the results; MV: Study design, statistical analysis, and drafting the manuscript; MS: Study design, interpretation of the results, statistical analysis, and drafting the manuscript.

Conflict of interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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Table 1. Baseline and post-intervention outcomes in the tailor-made notched music therapy and tailor-made notched music therapy +binaural beat stimulation groups

	TMNMT (n=12)		TMNMT+BBS (n=12)	
Outcome	**Baseline**	**Post**	**Baseline**	**Post**
THI (mean±SD)	60.67±25.71	51.67±28.05	61.17±20.35	43.83±23.17
BDI (mean±SD)	13.17±3.41	11.33±4.14	13.33±2.96	9.25±3.05
VAS-L (mean±SD)	7.08±2.00	4.50±2.11	7.33±2.30	4.50±2.30
VAS-A (mean±SD)	8.08±1.73	6.75±2.66	8.00±2.25	5.50±1.97

TMNMT; tailor-made notched music therapy, BBS; binaural beat stimulation, THI; tinnitus handicap inventory, BDI; beck depression inventory, VAS-L; visual analog scale for tinnitus loudness, VAS-A; visual analog scale for tinnitus annoyance

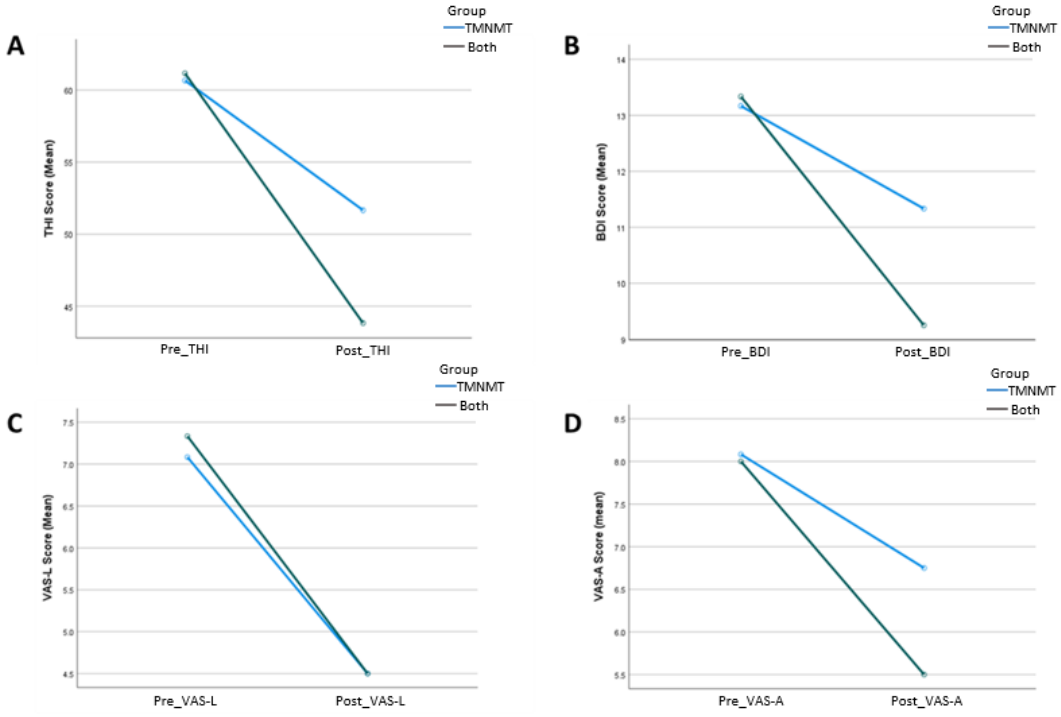


Figure 1. Pre- and post-intervention mean scores for (A) tinnitus handicap inventory, (B) beck depression inventory, (C) visual analog scale for tinnitus loudness, and (D) visual analog scale for tinnitus annoyance in the Tailor-Made Notched Music Therapy (TMNMT) and Tailor-Made Notched Music Therapy (TMNMT)+binaural beat stimulation (BBS) groups. TMNMT; tailor-made notched music therapy, THI; tinnitus handicap inventory, BDI; beck depression inventory, VAS-L; visual analog scales for tinnitus loudness, VAS-A; visual analog scales for tinnitus annoyance