Original Study

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The Role of Compliance and Cost in Regulating the Effectiveness of Notched Sound Therapy Phone Applications for Tinnitus Relief: Updated Analysis of a Prospective Randomized Control Trial

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Background: Notched sound therapy (NST) is a mobile application that has been shown to provide tinnitus relief by reducing dysfunctional auditory cortex reorganization. This study aimed to evaluate the role of compliance with notched sound therapy (NST) on the effectiveness of reducing tinnitus symptoms.

Methods: A prospective randomized control trial was performed in patients older than or equal to 18 years at a tertiary referral center. Patients were randomized at enrollment to either the NST group and given a free subscription to the NST mobile application or the standard of care (SOC) group. Continued enrollment in the study, NST use, and tinnitus handicap index (THI) were evaluated at 6 weeks, 3 months, 6 months, and 12 months in the NST versus SOC group and in NST users versus non-users.

Results: Patients in the NST group were 2.2 times more likely to use NST at 6-week follow-up compared with the SOC group (70% vs. 32%, $P = 0.020$). Initial THI score, age, and tinnitus frequency and loudness did not significantly impact follow-up rates or NST use. Assignment to the NST treatment group was associated with a significantly increased reduction in THI compared with the SOC group (β: −10.02, 95% CI: −18.20, −1.83, $P = 0.017$). However, NST use was not associated with any significant changes in THI compared with NST non-users.

Conclusions: Overall, reduced cost of NST treatment was associated with greater tinnitus relief; however, compliance with treatment was not significantly associated with THI changes. Therefore, these changes may be explained by psychological factors reinforcing patient empowerment, perceived support, and accountability.

Keywords: Compliance, Cost, Mobile application, Notched sound therapy, Patient empowerment, Tinnitus, Tinnitus handicap index

Introduction

Tinnitus, the perception of sound in the absence of external acoustic stimuli, is a common condition, affecting 14% of adults, with 2% experiencing severe forms[1]. It is believed to arise from abnormal neural activity within the central auditory system[2]. Tinnitus may be triggered by high-frequency hearing loss due to noise exposure or aging, which leads to changes in auditory pathways, including enhanced neuronal synchrony, increased spontaneous firing rates, and reorganization of the tonotopic map in the auditory cortex[3]. However, several non-auditory brain regions, such as the limbic system and frontoparietal pathways are thought to be involved in the maintenance of tinnitus as it impacts quality of life[3]. Although many individuals habituate to the phantom sound, ~10% to 20% of those affected experience significant distress, which may contribute to anxiety, depression, difficulty concentrating, hyperacusis, and insomnia[4]. Because of the high variability in the experience of tinnitus, no objective measures have reliably been identified to assess its severity. Consequently, several validated questionnaires are commonly used to evaluate the impact of tinnitus on quality of life, including the Tinnitus Handicap Index (THI).

Current tinnitus management primarily focuses on addressing the emotional and physiological distress associated with the condition, through interventions like cognitive behavioral therapy (CBT) and tinnitus counseling. However, newer treatments aim to target the underlying neural pathways associated with tinnitus. One such treatment is tailor-made notched sound therapy (NST), in which patients listen to notched music, digitally altered to remove the frequency corresponding to their tinnitus. This approach promotes lateral inhibition, where neurons adjacent to the tinnitus frequency inhibit the overactive neurons responsible for tinnitus perception, thereby reducing tinnitus-related neural activity and perceived loudness. Wunderlich et al.[5] found that NST led to a significant reduction in tinnitus distress and tinnitus-related neural activity. In addition, Teismann et al.[6] demonstrated that although intensive NST over a short period provided short-term benefits, symptom relief did not persist long-term, suggesting the potential need for long-term therapy adherence to achieve significant benefits.

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Despite the promise of NST, several barriers to consistent, long-term use exist. Studies have shown that NST is effective when used for at least 2 hours daily, but this regimen requires a considerable time commitment[7,8]. This study aims to evaluate the effectiveness of NST in patients who were provided free access to the therapy, compared with the standard of care (SOC), to determine whether cost is a significant barrier to NST use or if adherence to the daily regimen plays a larger role in its effectiveness. A preliminary analysis of this prospective randomized control trial indicated that most participants experienced a decrease in THI scores after 3 months, regardless of treatment group, but few were able to comply with the NST goal of 2 hours per day. Furthermore, subjects who had free access to an NST mobile application showed increased initial therapy usage. This study seeks to provide a more comprehensive analysis, incorporating an expanded participant group and follow-up data at 6 and 12 months.

Methods

Participant selection

A randomized controlled trial was conducted from September 2019 to May 2023, including patients aged 18 years or older with subjective tinnitus. Participants with either bilateral or unilateral tinnitus, and comorbidities such as sensorineural hearing loss, anxiety, a history of craniotomy, or traumatic brain injury, as well as those who had previously tried other tinnitus therapies, were eligible for inclusion. Exclusion criteria included patients with pulsatile tinnitus, objective tinnitus, significant cognitive impairments, or severe hearing loss that would prevent them from using sound-based therapy. In addition, participants lacking access to a mobile or desktop device for administering NST were excluded.

Enrollment

Participants with a chief complaint of tinnitus were recruited from the Department of Otolaryngology's neurotology practice at Northwell Health. All participants provided informed consent before enrollment. This study was approved by the Northwell Health Institutional Review Board (IRB number: 25-0171). At enrollment, participants underwent a comprehensive evaluation, including medical history, neurotological and otomicroscopic examination, and assessment of any comorbidities. After enrollment, each participant completed a full audiogram, including speech reception and discrimination scores, pure tone evaluations, tympanometry, and audiological pitch matching. This included matching the frequency and loudness of their subjective tinnitus, as well as determining the type of noise and masking level. In addition, all participants completed the THI questionnaire.

Randomization was performed using institutional randomization software, dividing participants into the NST group (which received a free subscription to the AudioNotch NST mobile app) and the SOC group (which had the option of using NST for a fee). Informational pamphlets were provided to all participants, detailing standard tinnitus treatments and information about NST platforms, such as AudioNotch, a mobile app offering customized NST. AudioNotch is commercially available for $19/month or $99.99/year, with this pricing transparently communicated to participants through the pamphlet. The NST treatment group received a free subscription to AudioNotch, whereas the SOC group had to pay to access the therapy. Within the app, users input the frequency and amplitude of their tinnitus as measured during their enrollment visit. The app then generates notched music by removing sounds within 2 equivalent rectangular bandwidths of the tinnitus frequency, with technical support provided for this process.

Table 1

Demographics and characteristics of NST and SOC groups

	NST Group	SOC Group	*P*
N	33	32	NA
% male (N)	48.5 (16)	46.9 (15)	NA
Median age (IQR), y	55.0 (17.0)	58.0 (11.0)	0.071
Tinnitus loudness, dB (median, IQR)	46.5 (29.2)	50.0 (35.0)	0.25
Tinnitus frequency, Hz (median, IQR)	6000.0 (4000.0)	4000.0 (4000.0)	0.79
THI score (median, IQR)	36.0 (32.0)	41.0 (24.5)	0.44

Baseline characteristics of patients in the NST group were compared with those in the SOC group. A Mann-Whitney *U* test was used to assess significant differences between the groups.
IQR indicates interquartile range; N, number of patients; NST, notched sound therapy; SOC, standard of care; THI, Tinnitus Handicap Index.

Follow-Up

Both groups were informed of the need for follow-up visits at 6 weeks, 3 months, 6 months, and 12 months. At each follow-up, participants completed the THI, reported their use of NST and compliance with the prescribed treatment regimen of 2 hours per day, and were asked to identify any barriers to using NST. If participants experienced a change in their hearing status or worsening tinnitus during the study, they were informed that a repeat audiogram with tinnitus pitch matching would be conducted, and alternative treatments would be considered. Follow-up visits during the COVID-19 pandemic were conducted virtually, although all enrollment visits took place in person.

Outcomes

The outcome measures included independent variables such as demographics (age and sex), tinnitus pitch (frequency), and tinnitus amplitude (loudness). The dependent variables included the THI score and compliance (both general use and use of $\geq$2 h/day).

Statistical analysis

All statistical analyses were performed using Python programming through Google Colab, a cloud-based platform developed by Google Research that allows users to write and execute Python code in a browser. Demographic data and tinnitus characteristics were analyzed for both the NST and SOC groups, including age, initial THI, tinnitus frequency, and tinnitus loudness. *t* tests were performed to assess significant differences between the treatment groups. The proportion of participants in each group who used NST was calculated, and a line graph was created to visualize these data. Again, a *t* test was used to evaluate for significant differences in NST use at each visit. The change in THI scores from baseline was calculated at each follow-up visit, and comparisons were made between the NST and SOC groups, as well as between NST users as indicated (at least 2 h/day) and non-users, using *t* tests and line graphs to illustrate the outcomes. Demographic factors and tinnitus characteristics were compared between NST users, non-users, and those lost to follow-up to

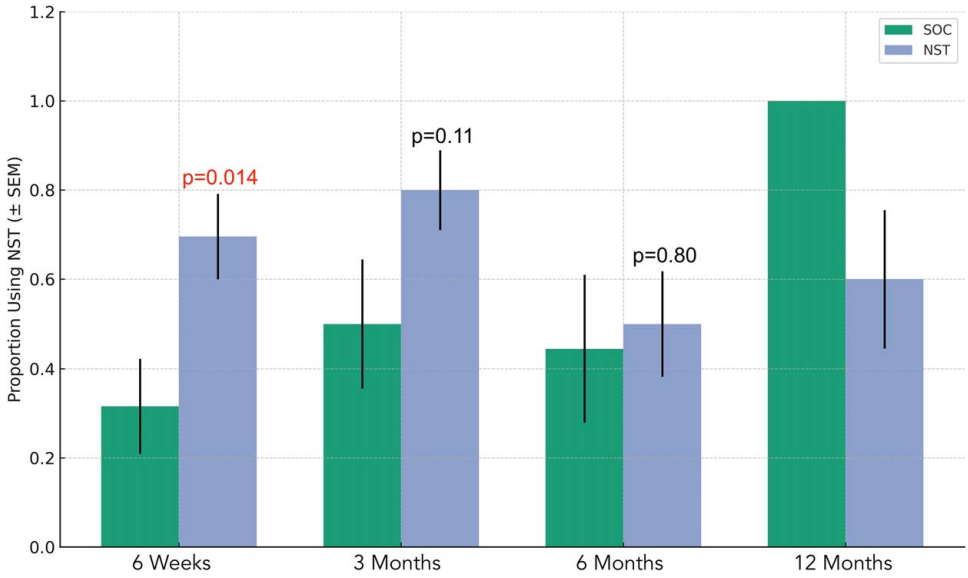

Figure 1. Proportion of participants using NST at each visit assigned to NST versus SOC groups. The average proportion of patients using notched sound therapy (NST) in those assigned to the NST group compared with the those assigned to the standard of care (SOC) group. As there were only 2 patients with recorded data at 12 months in the SOC group so SEM and *P*-value could not be calculated.

assess the effects of these variables on NST use and follow-up participation. Finally, a linear regression analysis was performed to evaluate associations between NST use as indicated and changes in THI scores from baseline. A power analysis was conducted to determine the required sample size to achieve 80% power for detecting significant differences in THI changes between the NST and SOC groups, with an alpha level of 0.05. On th basis of this, it was determined that 38 participants per treatment group would be needed, which was nearly achieved in this study.

Results

Demographics and characteristics

A total of 65 patients participated in the study; 33 patients were randomized to the NST group and 32 patients to the SOC group. 23 patients were lost to follow-up at 6 weeks, 33 at 3 months, 38 at 6 months, and 53 at 12 months. The median age was 57 years and participants were 47.7% male. The demographics and tinnitus characteristics of participants in NST and SOC groups were recorded in Table 1, including age, sex, tinnitus frequency, tinnitus loudness, and initial THI score. No significant differences

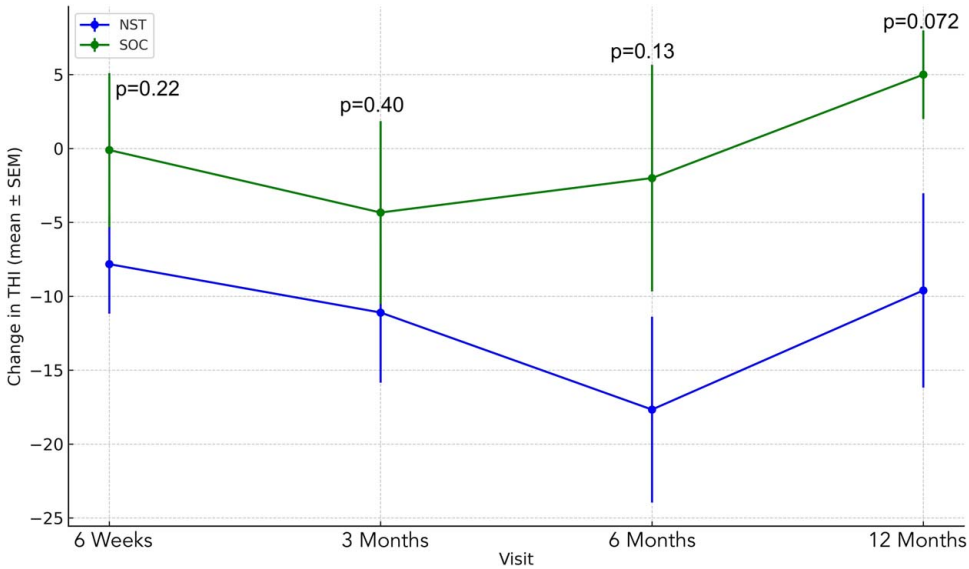

Figure 2. Change in THI score from baseline to follow-up in NST versus SOC group. For each patient, the baseline Tinnitus Handicap Index (THI) score was subtracted from the THI score at each follow-up visit. The mean ± SE of the mean (SEM) was then calculated for patients assigned to the notched sound therapy (NST) group compared with those in the standard of care (SOC) group using a *t* test.

Table 2

Linear regression of the association between NST assignment or reported NST use and change in THI score from baseline to 12-month follow-up

Group	β	SE	95% CI Lower	95% CI Upper	*P*
Assignment to NST treatment group	−10.02	4.13	−18.20	−1.83	0.017
NST use	1.50	4.23	−6.89	9.88	0.72

Linear regression was used to assess the association between assignment to the NST group and change in THI score from baseline to 12-month follow-up, as well as the association between actual NST use and change in THI score over the same period. *P*-values were derived from 2-sided Wald *t* tests of the regression coefficients.
NST indicates notched sound therapy; THI, Tinnitus Handicap Index.

were found between the demographics or characteristics of the 2 groups.

Cost and tinnitus relief

In the SOC group, a larger proportion of patients were lost to follow-up at each visit: 40.6% (6 wk), 62.5% (3 mo), 71.9% (6 mo), and 93.8% (12 mo) compared with NST: 30.3% (6 wk), 39.4% (3 mo), 45.5% (6 mo), and 69.7% (12 mo). In addition, few patients overall used NST as indicated but more patients in the NST group provided with a free subscription were using the application as indicated at each follow-up visit, although not statistically significant (Supplemental Table 1, Supplemental Digital Content 1, http://links.lww.com/MAO/C261). However, NST use overall was higher at the first 6-week follow-up visit in those provided with a free subscription compared with the SOC group (69.6% vs. 31.6%, $P = 0.014$) (Fig. 1).

The change in THI from baseline at different timepoints showed no significant differences between the NST and SOC groups. However, by 12 months, patients in the NST group showed a trend toward a reduction in THI (mean change: −9.6, SEM: 6.57), whereas patients in the SOC group demonstrated a mean increase in THI (5.0, SEM: 3.0) ($P = 0.072$) (Fig. 2). Linear regression analysis revealed a significant association between assignment to NST treatment group and greater improvement in THI compared with those assigned to the SOC group (β: −10.02, 95% CI: −18.20, −1.83, $P = 0.017$) (Table 2).

Compliance and tinnitus relief

Overall, no other factors affected NST use or follow-up rates at other visits including initial THI, age, tinnitus frequency, and tinnitus loudness as no differences were seen between NST users, non-users, and participants lost to follow-up based on these factors (Fig. 3). In terms of compliance, there were no significant differences in change in THI from baseline between NST users and non-users (Fig. 4). In addition, there were no significant associations between NST use and changes in THI from baseline (β: 1.50, 95% CI: −6.89, 9.88, $P = 0.72$) (Table 2).

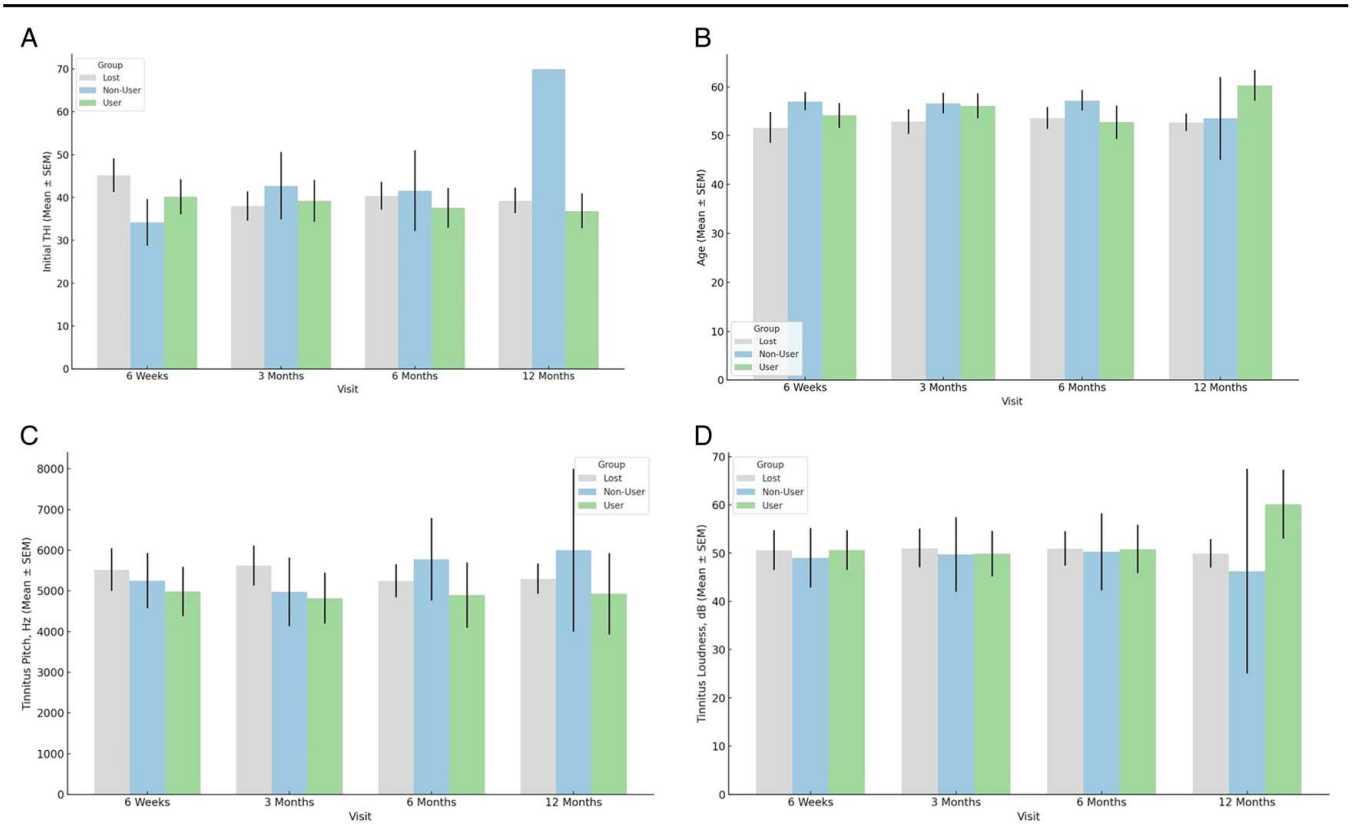

Figure 3. Factors affecting NST use at follow-up visits. Each bar represents the mean, error bars represent 1 standard error of the mean in users of notched sound therapy (NST), non-users of NST, and those lost to follow-up for (*A*) Initial tinnitus handicap index (THI) score, (*B*) Age, (*C*) initial tinnitus frequency, and (D) initial tinnitus loudness.

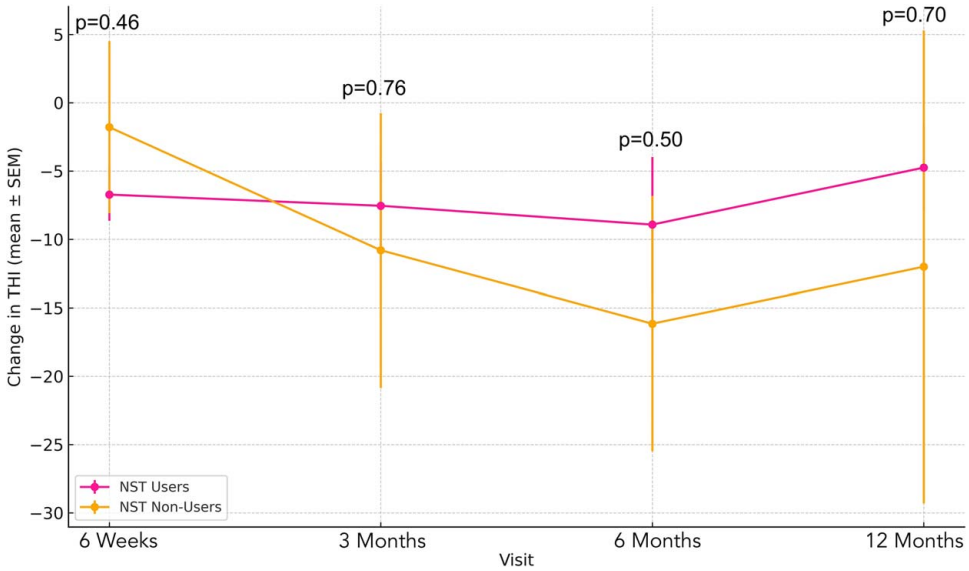

Figure 4. Change in THI score from baseline to follow-up in NST users versus non-users. Each patient's baseline Tinnitus Handicap Index (THI) score was subtracted from follow-up scores at each visit. The mean ± SE of the mean (SEM) was then calculated for patients who used notched sound therapy (NST) and compared with those who did not use NST using a *t* test.

Discussion

This study demonstrates that providing free access to NST, even without consistent use, may meaningfully influence the perception of tinnitus handicap through psychological mechanisms rather than the direct effects of the therapy alone. Patients randomized to receive a free NST subscription showed significantly greater overall improvement in THI scores than those receiving the standard of care despite variable adherence. Notably, there was no association between actual therapy usage and THI improvement, suggesting that factors beyond auditory masking were contributing to changes in perceived handicap. This finding differs from previous studies showing that tailor-made music therapy does lead to improvements in THI in patients with chronic subjective tinnitus[8,9]. However, most prior studies enforced strict adherence to a daily regimen of 2 hours or more. In contrast, most patients in this study did not meet that threshold despite self-reporting therapy use, which may explain its lack of efficacy.

In addition, at the initial 6-week follow-up, there was significant increase in NST use among patients who received a free subscription compared with the SOC group. Offering NST for free eliminated the financial opportunity cost, lowering the barrier to initial engagement and encouraging higher short-term use. However, over time, the time commitment, effort, and competing demands of daily life likely outweighed the perceived benefits of the therapy, contributing to the decline in long-term compliance. Finally, no baseline factors, including initial THI score, age, tinnitus pitch, or tinnitus loudness, were associated with NST use or follow-up rates, suggesting that worse initial handicap or louder tinnitus alone does not drive greater therapy engagement.

The improvement in THI scores in the NST group despite actual increased therapy utilization may be attributed to patient empowerment through providing personalized care[10]. By offering free access to NST and framing it as a special opportunity, patients may feel more supported by their providers, leading to an increased sense of agency, self-efficacy, and psychological ownership over their care. Economic principles may further explain these findings. The reciprocity norm explains how receiving something of perceived value can foster a sense of obligation to give back, even if only through internal behavioral changes[11]. In this study, the act of providing a free service, combined with structured provider follow-up, likely made patients feel more supported and cared for, encouraging greater engagement in their overall treatment and helping to lessen the psychological burden of their tinnitus.

Limitations

This study has several limitations. High attrition rates, particularly at later follow-ups, may introduce bias and limit the generalizability of the results. In addition, adherence to the prescribed NST regimen was low, which reduces the ability to assess the efficacy of NST as an acoustic intervention directly and complicates comparisons with prior studies that enforced stricter use criteria, and therapy use was self-reported, introducing potential reporting bias. In addition, the sample size was relatively small, and it may have been underpowered to detect subtle differences in secondary outcomes, such as compliance rates or subgroup effects based on demographic or tinnitus characteristics. Also, formal psychological assessments were not performed, limiting the ability to fully explore the mechanisms underlying improvements in tinnitus perception with NST randomization. Future studies should incorporate objective compliance monitoring, larger samples, and validated psychological measures to better characterize these effects.

Conclusions

Overall, due to the psychologically complex nature of tinnitus, interventions may not need to rely solely on direct acoustic or neuromodulatory effects. This study suggests that providing free access to sound therapies, such as those now available through streaming platforms or smartphone tools, may offer clinical

benefits when combined with provider engagement and structured follow-up. Providers should consider offering inexpensive or free sound therapies and following up with patients through a brief phone survey at the intervals outlined in this study to reinforce patient empowerment, perceived support, and accountability, which can significantly modulate tinnitus symptom perception even without strict treatment adherence.

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