

Efficacy of sound therapy in chronic tinnitus patients with mild hearing loss: a multicentre, double-blind, placebo-controlled randomized clinical trial

Philippe Fournier^{ID} · Hung Thai-Van · Pierre Reynard · Stéphane Gallego · Florine Liegeon · Alexandra Weckel · Paul Viudez · Vincent Loche · Ophélie Lépingle · Christine Holler-Houdoux · Valérie Villatte · Damien Bonnard · Matthieu Del Rio · Michel Kossowski · Alain Londero · Hervé Bischoff · Corinne Essebag · Arnaud Noreña · Marie-José Estève-Fraysse

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Abstract

Chronic tinnitus affects 10–15% of the population and can substantially impair quality of life. Sound therapies, including amplification and sound generators, are commonly used, but evidence from placebo-controlled trials remains limited. This multicenter, double-blind, placebo-controlled randomized trial evaluated the efficacy of sound therapy in adults with chronic bilateral tinnitus and mild hearing loss. Participants with tinnitus ($\text{THI} \geq 38$) and mild bilateral hearing loss ($\text{PTA} < 35$ dB HL at 0.5–4 kHz) were randomized (1:1:1) to receive placebo amplification, sound generators, or sound generators combined with amplification. The intervention lasted 12 weeks and included a 6-week monotherapy phase followed by a 6-week polytherapy phase, during which participants in the active arms could switch between amplification, sound generators, or a combined approach. The primary outcome, change in Tinnitus Functional Index (TFI) score, improved significantly in the active treatment arms compared with placebo (mean change: -21 and -18 vs. -6; $p < .001$). Clinically meaningful improvement on the Global Rating of Change Scale was reported by 88% of participants in the sound generator group, 77% in the combined therapy group, and 33% in the placebo group ($p < .001$). These findings support sound therapy as an effective intervention for chronic tinnitus in individuals with mild hearing loss.

Keywords Tinnitus · Sound therapy · Amplification · Sound generator · Randomized control-Trial · placebo · Mild hearing loss

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Introduction

Subjective tinnitus is defined as the perception of sound in the absence of any external acoustic stimulus. It is characterized by individual features such as location, intensity, frequency, and timbre, and is considered to reflect dysfunction within the auditory system and/or other interacting neural structures.¹ It is hypothesized to result from abnormal neural activity along the auditory pathway.² Tinnitus can manifest in various forms and be modulated by multiple factors. It may occur in isolation or in association with other clinical symptoms, most commonly hearing loss. The frequencies perceived in tinnitus often correspond to regions of hearing loss.^{3–6} When tinnitus is associated with hearing loss, the severity, audiometric configuration, and etiology can vary widely⁷, though noise-induced hearing loss and presbycusis affecting high frequencies are the most common causes.⁸

Tinnitus varies in its impact, often leading to sleep disturbances, concentration difficulties, and psychological distress including anxiety, stress, and depression.^{9–13} It affects 10–15% of the population, with approximately 20% experiencing disabling symptoms that significantly impair quality of life.^{14,15} Severity and distress are commonly assessed using validated questionnaires such as the Tinnitus Functional Index (TFI) and the Tinnitus Handicap Inventory (THI), along with visual analog scales (VAS) for annoyance and intensity. Clinical management strategies universally include directive counseling, defined as empathetic listening, patient education, and supportive guidance.^{16,17} When tinnitus severity is high and counseling alone is insufficient, additional interventions may be considered, including psychological therapies (e.g., cognitive behavioral therapy) and sound therapies.¹⁸ Sound therapy encompasses hearing aids amplification, sound generators, or combination devices offering both modalities.¹⁹ Depending on available resources, tinnitus severity, and patient preference, clinicians may recommend one or more of these approaches.

Despite the widespread use of sound therapy, there is currently no strong evidence to support or refute its use as a first-line or adjunctive intervention alongside directive counseling for chronic debilitating tinnitus with no hearing loss or mild hearing loss. Both the National Institute for Health and Care Excellence (NICE) and the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) recommend directive counseling as the foundational approach.^{20,21} Regarding sound therapy, the AAO-HNS guidelines recommend hearing aids amplification only when tinnitus is accompanied by hearing loss and suggest sound generators as an optional intervention for persistent and disabling tinnitus. The level of hearing loss is intentionally not specified in the guidelines because the authors stated that hearing loss-associated tinnitus may benefit from hearing aids even if the hearing loss is only of a mild degree, or even if there is a more severe unilateral SNHL associated with the tinnitus. The 2020 NICE guidelines recommend hearing aids for patients with tinnitus and associated hearing loss that affects speech intelligibility and allow for trial amplification in cases of moderate hearing loss without speech comprehension deficits. However, unlike AAO-HNS, NICE does not recommend standalone sound generators, citing insufficient evidence and a lack of high-quality, bias-free studies. European multidisciplinary guidelines also support hearing aids for tinnitus patients with hearing loss but do not recommend their use in cases without measurable hearing impairment.¹⁸ A Cochrane review²² evaluated studies on sound therapy using amplification, sound generators, or both. Although some studies have shown significant improvements in tinnitus severity, the review concluded that no single modality was superior and emphasized the need for future research using rigorous methodologies, including randomized, blinded, placebo-controlled designs, and adherence to CONSORT guidelines. Furthermore, a systematic review of outcome measures in tinnitus trials highlighted the importance of using validated and standardized instruments to ensure methodological rigor and enhance clinical relevance.²³

In France, the 2019 Health Law redefined the conditions for reimbursement of hearing aids by public health insurance. Eligibility is based on specific audiometric criteria, and tinnitus alone, without qualifying hearing loss, is not considered a criterion for reimbursement. An analysis of a cohort of 295 patients attending a specialized tinnitus clinic in Toulouse, France, revealed that 61% had either normal hearing or mild hearing loss not sufficient for health coverage reimbursement, yet their average THI score indicated moderate disability.²⁴ These findings support clinical observations that distressing tinnitus can occur even in the absence of significant audiometric

hearing loss, highlighting the need to consider factors beyond pure-tone thresholds in the assessment and management of tinnitus.

Given the disparities in care based on hearing thresholds rather than tinnitus severity and the lack of strong evidence supporting sound therapy, the “Association Francophone des Équipes Pluridisciplinaires en Acouphénologie (AFREPA)” initiated a multicentre, randomized, double-blind, placebo-controlled trial. AFREPA is a non-profit association of multidisciplinary teams including ENT specialists, audiologists, psychologists, and other professionals dedicated to improving the clinical care, education, and research for patients with chronic tinnitus and hyperacusis through collaborative and integrative approaches. This study, involving ENT specialists, audiologists, and researchers, aims to evaluate the efficacy of sound therapy in tinnitus patients with mild hearing loss using three treatment arms: placebo amplification, sound generators alone, and combined amplification with sound generators.

Study objectives and outcomes

The primary objective of this study was to test the hypothesis that acoustic stimulation therapy, either via sound generators alone (Arm 2) or in combination with amplification (Arm 3), reduced tinnitus-related distress and improved quality of life compared to a placebo sound therapy (placebo amplification, Arm 1). A key innovation of this research lies in its two-phase design, which was specifically developed to balance methodological rigor with clinical applicability. The initial six-week monotherapy phase imposed a fixed treatment protocol typical of double-blind randomized controlled trials. In contrast, the subsequent six-week polytherapy phase introduced flexibility, allowing participants in the active treatment arms to select among three sound stimulation programs (amplification alone, noise generator alone, or combined therapy) based on their preferences, needs, and daily circumstances.

The primary outcome was the change in tinnitus-related handicap and distress, measured by the total score on the Tinnitus Functional Index (TFI)²⁵, and validated by the Global Rating of Change Scale (GRCS).²⁶ A clinically meaningful improvement was defined as a reduction of at least 13 points on the TFI after 12 weeks of therapy, a threshold established by the TFI developers as indicative of moderate to substantial improvement. For GRCS, a clinical meaningful change was defined as at least a slight improvement in the overall condition following therapy. Secondary outcomes aimed to assess broader impacts of both monotherapy and polytherapy over the 12-week period, including sleep quality, auditory functioning, and psychological well-being. These were measured using:

- Sleep quality: Global Sleep Assessment Scale²⁷.
- Auditory functioning: Speech, Spatial and Qualities of Hearing Scale – Short Form²⁸.
- Anxiety and depression: Hospital Anxiety and Depression Scale²⁹.
- Tinnitus annoyance and intensity: Visual Analog Scales³⁰.

Secondary outcome thresholds for clinically meaningful change were defined as follows:

- Sleep quality: ≥ 2 -point improvement²⁷.
- SSQ15: ≥ 1.5 -point improvement³¹.
- HADS: ≥ 1.5 -point reduction in total score³².
- Tinnitus VAS: ≥ 2 -point reduction in both annoyance and intensity³⁰.

Methodology

Participants

A total of 145 patients were recruited between April 26, 2021, and April 2, 2024, by six multidisciplinary teams across France specializing in tinnitus management. These teams, composed of otolaryngologists and audiologists, operated in both hospital and private practice settings. All participants were recruited from routine clinical consultations where tinnitus was the primary complaint. Inclusion criteria required the presence of continuous bilateral or central tinnitus for at least three months, accompanied by mild bilateral hearing loss. The three accepted audiometric profiles of mild bilateral hearing loss are presented in Supplementary Table 1. Only patients with disabling tinnitus, defined by a score equal or greater than 38 on the validated French version of the Tinnitus Handicap Inventory (THI)³³, were eligible. According to THI scoring guidelines, scores between 38 and 56 indicate moderate handicap, 58–76 severe handicap, and 78–100 catastrophic tinnitus.³⁴ Patients with identifiable otolaryngological disorders or hearing loss not compatible with the three accepted audiometric profiles (Supplementary Table 1) were excluded. Participants who had used hearing aids, sound generators, or combination devices within the previous 12 months were excluded to reduce the risk that prior experience with these devices could influence treatment expectations. Full inclusion and exclusion criteria are detailed in Supplementary Table 1.

The ethical approval was obtained from the “Comité de Protection des Personnes Île de France IV”, ID-RCB: 2020-A02812-37, on January 7, 2021. The study was registered at the “Agence nationale de sécurité du médicament et des produits de santé” of France, on October 10, 2020.

The study was retrospectively registered in the ISRCTN registry (ISRCTN32577283) on 06/08/2026. Written informed consent was obtained from all participants prior to enrollment. All methods were performed in accordance with the relevant guidelines and regulations.

The interventions and comparator were administered as planned across all participating clinical sites. Each participant received their assigned treatment under double-blind conditions. The interventions were delivered by trained audiologists following a standardized protocol to ensure consistency across sites. Adherence was monitored through scheduled follow-up visits and participant self-reports. The fidelity of the intervention delivery was maintained through regular site coordination and protocol compliance checks. Two major deviations from the intended procedures were reported, both involving excessive delays: either between the baseline and the first assessment (V1–V4) or between the first and final assessment (V4–V5). Of the 145 enrolled, 128 participants completed the study and were included in the final analysis. Seventeen participants were excluded due to dropout (Total, $n=14$; arm 1, $n=5$; arm 2, $n=6$; arm 3, $n=3$) or protocol deviation ($n=3$, placebo group received active therapy by mistake). Final group sizes were placebo (Arm 1, $n=42$), sound generators (Arm 2, $n=42$), and combined therapy (Arm 3, $n=44$) (See Supplementary Fig. 1 for the CONSORT Flow Diagram). Demographic and audiological characteristics were comparable across groups. Mean age was 54 years (range: 25–75), with a slight male predominance (69 men, 59 women). Arm 2 participants were slightly younger (mean age: 51) than Arm 3 (mean age: 57). Audiometric thresholds, speech reception threshold, and middle ear function were similar across groups. Tinnitus characteristics were also comparable, except for stress-related tinnitus modulation, reported more frequently in Arm 2 (70%) than in Arm 1 (41%) and Arm 3 (48%). Arm 1 participants had slightly higher average loudness discomfort levels (94 dB HL) compared to Arm 2 (88 dB HL) and Arm 3 (91 dB HL). Detailed demographic and hearing thresholds data are presented in Table 1; Fig. 1.

Harms and adverse effect

Harms and adverse effects were assessed using both systematic and non-systematic approaches. Participants completed a standardized questionnaire at predefined intervals to report any adverse events (systematic assessment), while spontaneous reports were documented throughout the study period (non-systematic assessment). A

Table 1 Sociodemographic and audiological characteristics of patients by treatment arm. Bold values indicate statistically significant differences. SD=Standard Deviation.

Category	Variable	Placebo (<i>n</i> =42)	Sound Generator (SG) (<i>n</i> =42)	SG+Amplification (<i>n</i> =44)	<i>p</i> -value
Demographic					
	Age in years (SD)	54 (11)	51 (12)	57 (9)	= 0.023
	Sex (F/M)	15 / 27	22 / 20	22 / 22	n.s.
Middle ear function					
	Otoscopy (normal / retracted eardrum)				
	- RE	42 / 0	41 / 1	43 / 1	n.s.
	- LE	42 / 0	42 / 0	44 / 0	n.s.
	Tympanometry (N.A. / Type A / Type B/ Type C)				
	- RE	1 / 41 / 0 / 0	2 / 40 / 0 / 0	2 / 41 / 1 / 0	n.s.
	- LE	1 / 40 / 1 / 0	2 / 39 / 0 / 1	2 / 40 / 2 / 0	n.s.
Hearing thresholds in dB HL					
	Low frequency PTA (SD)				
	- RE	10 (7)	10 (6)	10 (6)	n.s.
	- LE	10 (7)	11 (6)	10 (5)	n.s.
	Mid-frequency PTA (SD)				
	- RE	16 (6)	16 (7)	16 (8)	n.s.
	- LE	16 (7)	15 (8)	15 (7)	n.s.
	High-frequency PTA (SD)				
	- RE	31 (14)	29 (11)	32 (12)	n.s.
	- LE	32 (13)	30 (12)	33 (12)	n.s.
Tinnitus					
	Baseline mean THI (SD)	59 (14)	57 (13)	60 (17)	n.s.
	Baseline mean TFI (SD)	55 (17)	55 (15)	53 (15)	n.s.
	Pitch (High, Low, Noise, Unknown)	39 / 1 / 1 / 1	37 / 3 / 2 / 0	41 / 0 / 1 / 2	n.s.
	Localisation (Both ears / Head)	37 / 5	38 / 4	37 / 7	n.s.
	Tinnitus duration in years (SD)	8 (11)	6 (5)	8 (9)	n.s.
	Somatosensory modulation (yes/no)	12/30	13/29	11/33	n.s.
	Stress modulation (yes/no)	17/25	30/12	21/23	= 0.01
	Noise reactive (yes/no)	21/21	26/16	16/28	n.s.
	Noise masking (yes/no)	27/15	22/20	26/18	n.s.
Speech intelligibility					
	Average speech reception thresholds in dB HL (SD)				
	- RE	16 (6)	16 (6)	16 (6)	n.s.
	- LE	17 (6)	16 (6)	16 (6)	n.s.
Hyperacusis					
	Hypersensitivity to sound (yes/no/I don't know)	25 / 14 / 3	30 / 9 / 3	22 / 16 / 6	n.s.
	Average loudness discomfort levels in dB HL (SD)				
	- RE	93 (10)	87 (9)	91 (9)	= 0.022
	- LE	95 (10)	89 (9)	91 (9)	= 0.033
Hearing aids					
	Manufacturer (1 / 2 / 3)	15 / 9 / 18	17 / 15 / 10	14 / 19 / 11	n.s.

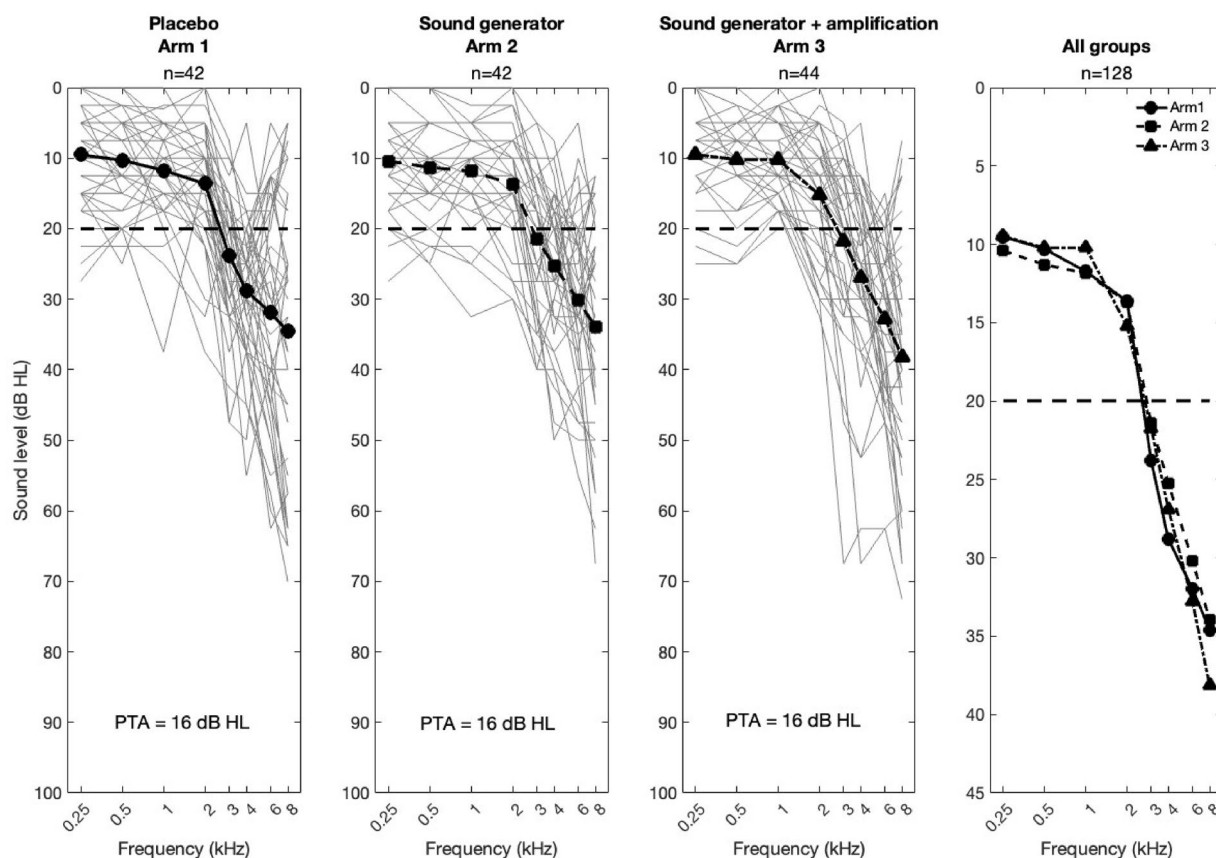


Fig. 1 Audiometric thresholds (dB HL) at standard frequencies (0.25 to 8 kHz) for patients in the three treatment arms. PTA refers to the average hearing thresholds (dB HL) at 0.5, 1, 2, and 4 kHz.

total of five adverse events (AEs) were recorded, including one incident that may qualify as a harm. Four AEs were related to illness: two cases of cancer, one COVID-19 & tonsillitis infection, and one case of influenza (Arm 1, $n=1$; Arm 2, $n=2$; Arm 3, $n=1$). Additionally, one participant reported a sensation of eardrum vibration in the left ear occurring during treatment (Arm 3). In this instance, while considered improbable, the involvement of the treatment (Arm 3) could not be definitively excluded.

Randomisation and allocation

Randomisation was performed by an independent statistician from the external firm Axiodis (France) using a minimization algorithm. The allocation was stratified by hearing aid brand (Phonak, Signia, Starkey), clinical site (Lille, Paris, Toulouse, Lyon, Nantes, Bordeaux), and tinnitus severity (THI score), ensuring balanced distribution across the three parallel treatment arms. Ten randomisation simulations were conducted for a total of 150 patients. Chi-squared tests confirmed independence between treatment arms and stratification variables (p -values: 0.9166 for clinical site, 0.7167 for THI score, and 0.6781 for hearing aid brand), supporting the reliability of the randomisation process. Due to the high number of strata (36), perfect balance across all strata was not feasible, but overall allocation remained robust. The random allocation sequence was generated by the statistician at Axiodis, and no blocking was used. Only the independent statistician from the external firm Axiodis (France) had access to the random allocation sequence. The personnel responsible for enrolling participants and assigning them to interventions were blinded to the sequence, ensuring allocation concealment and minimizing selection bias.

Patient and public involvement

There was no patient or public involvement in the design, conduct, reporting, or dissemination plans of this research.

Changes to trial protocol

No changes were made to the trial protocol after the commencement of the study.

Experimental measures

Audiometric thresholds, speech perception abilities, and psychoacoustic features of tinnitus were assessed at each site using calibrated clinical audiometers compliant with ANSI S3.6-2018 standards.

Pure-tone and speech audiometry

Hearing thresholds were measured bilaterally at 0.25, 0.5, 1, 2, 4, 6, and 8 kHz in all participants, and at 10 and 12 kHz in most participants using an adaptative method. Thresholds between 0.25 and 8 kHz were used to determine study eligibility, whereas extended high-frequency thresholds were collected for exploratory analyses and are not reported in the present manuscript. Pure tones were presented at clearly audible levels; if the patient responded, the intensity was decreased, and if not, it was increased in 5 dB steps. This process continued until the lowest level consistently detected by the patient was identified as the hearing threshold.³⁵

Loudness discomfort levels (LDLs) were measured monaurally in both ears using pure tones. Stimuli were gradually increased in 5 dB steps until the patient reported discomfort, just below the pain threshold. Stimulus duration was kept short (≤ 3 s) to ensure safety.³⁶

Speech audiometry assessed speech reception threshold and phoneme discrimination. Speech-in-noise testing was performed using the “Rapid Speech-in-Noise Test”³⁷, which uses sentence lists from the “Marginal Benefit from Acoustical Amplification” corpus and a global speech-shaped noise at varying signal-to-noise ratios. The signal-to-noise ratio at which 50% of key words were correctly identified (SNR-50) was determined for each participant.

Tympanometry

Tympanometry is a non-invasive test used to assess middle ear function. A probe was inserted into the ear canal to vary air pressure in a sealed environment. All measurements were performed using clinically validated equipment.

Psychoacoustic tinnitus measures

Pitch, Timbre, and Loudness: Tinnitus timbre was estimated using pure tones, narrowband noises, and white noise. Participants selected the stimulus that most closely resembled their tinnitus percept. The selected stimulus was then used to estimate the dominant tinnitus pitch by adjusting its center frequency. If white noise was selected, the pitch-matching procedure was not performed. Loudness was estimated by comparing the tinnitus percept to a pure tone presented at 1000 Hz and at the dominant tinnitus pitch. Starting from the hearing threshold, intensity was increased in 1-dB steps until the perceived loudness matched that of the tinnitus.

Minimum masking level (MML) was determined by presenting a narrowband noise centered on the dominant tinnitus pitch, beginning at threshold and increasing in 1-dB steps until the tinnitus was just masked.

Questionnaires

Tinnitus Handicap Inventory (THI): The French version of the THI³³ includes 25 items scored as “Yes” (4 points), “Sometimes” (2 points), or “No” (0 points). Total scores range from 0 to 100, with severity categories: slight (0–16), mild (18–36), moderate (38–56), severe (58–76), and catastrophic (78–100). The Tinnitus Handicap Inventory (THI) was administered as part of the screening process to determine eligibility based on the severity of tinnitus-related distress. A French validated version of the THI was used.³³

Tinnitus Functional Index (TFI): Designed to assess symptom severity and treatment responsiveness²⁵, the TFI includes 25 items rated on numeric scales (0–10 or 0–100). The total score is calculated by summing item scores, dividing by 25, and multiplying by 10 to yield a score out of 100. Severity categories: mild (10–20), moderate (30–40), severe (40–60), very severe (60–90). A reduction of ≥ 13 points is considered clinically meaningful. A French (France) version of the TFI was provided by the Oregon Health & Science University. To our knowledge, this version has never been validated.

Speech, Spatial and Qualities of Hearing Scale – Short Version (SSQ15): The SSQ15 assesses auditory abilities including sound localization, speech understanding, and listening effort. A French validated version was used here²⁸, it includes 15 items rated on a 0–10 scale, where 10 indicates full ability and 0 indicates inability.

Hospital Anxiety and Depression Scale (HADS): The HADS is a validated screening tool for anxiety and depression. It consists of 14 items scored from 0 to 3, with seven items assessing anxiety and seven assessing depression. Each subscale yields a score ranging from 0 to 21.²⁹ A French validated version was used here.³⁸

Sleep scales

Sleep-related questions included a numeric scale assessing overall sleep quality.²⁷ Patients rated the overall quality of their sleep on a scale from 0 to 10, considering factors such as ease of falling asleep and total sleep duration. Additionally, three visual analog scales (VAS) were used to assess physical and alertness states upon waking. Patients marked their physical state between “very tired” and “very refreshed”, and their alertness between “very sleepy” and “fully awake”. A tinnitus-specific question was also included, asking patients to rate the impact of tinnitus on their sleep quality using a VAS ranging from “no impact” to “very significant impact”. These items were adapted from previous research on tinnitus and sleep.³⁹

Global rating of change scale (GRCS)

The GRCS is a simple and widely used tool for self-assessing therapeutic progress in both clinical and research settings. It has strong face validity. The version used in this study included seven response options, offering an optimal balance between patient preference, discrimination ability, and test-retest reliability.⁴⁰ The question was phrased: “Please select the statement that best reflects your overall impression of the effect of sound therapy on your tinnitus and general condition compared to the beginning of the study”. The scale included: “Very much improved”, “Moderately improved”, “Slightly improved”, “No change”, “Slightly worse”, “Moderately worse”, and “Very much worse”.

Visual analog scales (VAS) for tinnitus annoyance and intensity

Two VAS were used to assess tinnitus severity. One scale measured perceived intensity while the other assessed annoyance. Patients marked the point that best represented their experience. These scales are widely used in tinnitus research to evaluate treatment efficacy. A change of at least two points on a 10-point scale is considered clinically meaningful.³⁰

Design trial and sound therapy protocol

This study was a multicentre, double-blind, placebo-controlled randomized clinical trial with three parallel arms and an allocation ratio of 1:1:1. The trial was conducted within a superiority framework to evaluate the effectiveness of sound therapies compared to placebo. The three treatment arms were: two active sound therapies and one placebo sound therapy referred to as “transparent amplification”. All participants received bilateral fittings with two open-fit hearing aids performed by licensed audiologists. Open-fit domes are preferred for high-frequency hearing loss, allowing low-frequency sounds to enter the ear naturally while high frequencies are amplified. A total of 290 hearing aids from three manufacturers—Signia Pure 7x, Starkey Livio 2400, and Phonak Marvel 90—were evenly distributed across the three arms. The technical specifications of these devices were considered equivalent. All manufacturers generously provided the devices on loan for the duration of the study.

Arm 1: Transparent amplification (Placebo)

In the placebo condition, hearing aids were programmed to provide no actual amplification, with an insertion gain of 0 dB. Insertion gain is defined as the difference in sound pressure level (SPL) at the eardrum with and without the hearing aid. Thus, environmental sounds were transmitted but not amplified. This placebo amplification configuration has been previously validated in a double-blind RCT.⁴¹ To enhance credibility, participants could hear their own voice through the device, the activation tones for the change in volume and the battery alert, these features were enabled.

Arm 2: Sound generators only

In this condition, hearing aids emitted a noise tailored to each participant’s audiogram, simulating white noise for a person with normal hearing. White noise has equal power spectral density across all frequencies. To individualize the noise, in-situ audiometry was performed through the hearing aids rather than using the hearing thresholds obtained through standard audiometric headphones, thereby accounting for ear canal acoustics and dome insertion effects. The resulting thresholds were used to generate a personalized noise spectrum. The mixing point was determined by progressively increasing the sound generator level in 1-dB steps until the participant reported that the generated sound blended with the tinnitus percept without completely masking it and without causing discomfort. When a clear mixing point could not be identified, the sound generator was set at 7 dB SL above the detection threshold to provide an audible and comfortable acoustic stimulus.

Arm 3: Amplification + Sound generators

This arm combined the sound generators configured as described for Arm 2 with amplification tailored to each participant’s hearing loss. In-situ thresholds were used to calibrate amplification, aiming to balance hearing across frequencies and ears. To standardize fitting across centers, all audiologists used the DSLio prescriptive formula, which optimizes speech intelligibility and is recommended for tinnitus management.^{42,43} In some centers, amplification settings were additionally verified using real-ear measurements when the necessary equipment was available; however, this procedure was not standardized across study sites and was therefore not part of the study protocol.

Program flexibility at six weeks

Starting at week six, participants in Arms 2 and 3 were given access to three distinct hearing aid programs: (1) sound generators only, (2) amplification only, and (3) combined sound generator and amplification. This allowed for a personalized continuation of the initial treatment. Using a push-button interface, participants could switch

between programs at any time, choosing one or multiple configurations based on their preferences and daily environments. The noise and amplification settings were maintained as described above. Device usage data (“data logging”) revealed that the amplification-only program was used more than 50% of the time on average in both groups. Detailed usage statistics, including program selection and total hours of device use, are presented in Table 2. Participants in the placebo group (Arm 1) continued with the same transparent amplification configuration throughout the entire study.

This dual-phase design, that is, rigid monotherapy followed by flexible polytherapy, reflects the need for personalized approaches in evaluating technological interventions like hearing aids and sound generators. Unlike pharmacological treatments, the effectiveness of sound therapy may vary depending on individual needs and environmental contexts. For example, a sound generator may be helpful in quiet settings (e.g., a library) but disruptive in speech-heavy environments (e.g., meetings). This flexible model aligns with principles of personalized care and precision rehabilitation.⁴⁴

Concomitant care

During the trial, participants in all three treatment arms were allowed to continue their usual care routines for conditions unrelated to tinnitus. No additional tinnitus-specific treatments (e.g., other sound therapy, cognitive behavioral therapy, or else) were permitted during the study period. The distribution of concomitant care was monitored and only two occurrences of concomitant treatments were reported one to treat a bacterial infection (amoxicillin) and another one to promote sleep (mianserin).

Procedure

Initial consultation and baseline assessment

The study timeline of the RCT is provided in Fig. 2. The initial consultation including tinnitus and hearing loss evaluation, audiological assessment, informed consent signing, and baseline data collection was conducted by the ENT investigator at participating centers. A detailed description of all initial assessment procedures is provided in Supplementary Table 2. During the consultation, the ENT specialist explained the study protocol and provided the patient with an information sheet. After reviewing the document, the patient was invited to sign the informed consent form. Once consent was obtained, the ENT conducted all evaluations, including pure-tone and speech audiometry, tympanometry, tinnitus assessment using a standardized questionnaire, and administration of all other study questionnaires. Standardized counseling was provided to all patients, regardless of their individual profiles. This included explanations about the different types of tinnitus, a simplified overview of the presumed pathophysiology, and factors that may exacerbate or alleviate symptoms. The counseling was delivered empathetically and consistently across all six centers to ensure uniformity. To support standardization, participating

Table 2 Percentage of use for each of the three hearing aid programs during the polytherapy phase (V4-V5) for the two active treatment arms (Arm 2 and Arm 3), and average daily usage hours of hearing aids across the full study duration, including both the monotherapy and polytherapy phases. SD= Standard Deviation. HA=Hearing Aid; P1, P2 and P3 are the hearing aids programs.

	Arm 1 (n=42)	Arm 2 (n=42)	Arm 3 (n=43)	p-value
V4-V5				
- P1 : amplification alone	n.a.	59%	52%	n.s.
- P2 : Sound generator alone	n.a.	22%	21%	n.s.
- P3 : Sound generator+amplification	n.a.	19%	27%	n.s.
- P1 : Placebo amplification	100%	n.a.	n.a.	
HA usage (mean hours per day)	9.2	9.4	9.8	n.s.

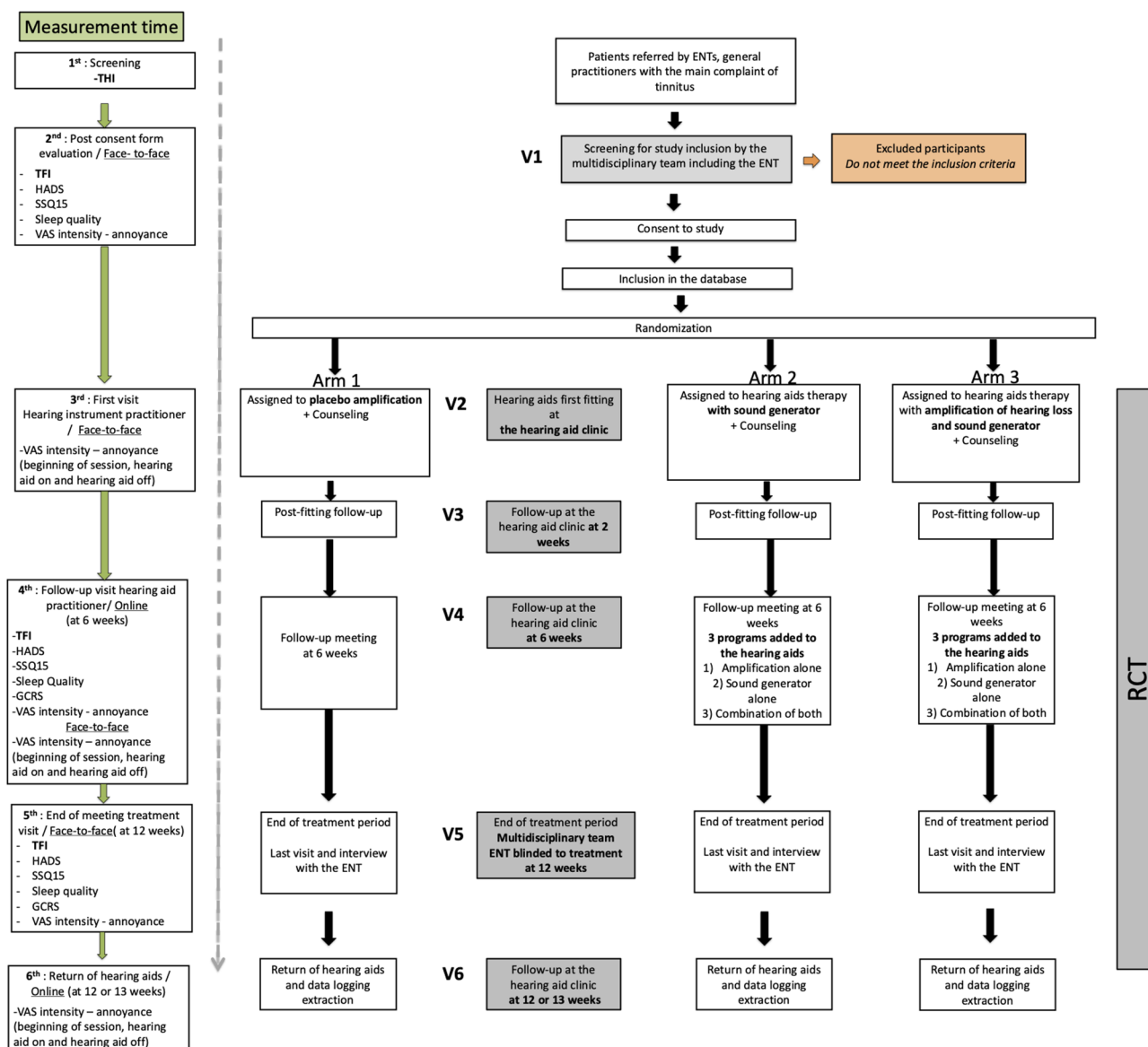


Fig. 2 Study Timeline of the RCT. Evaluation points for each measurement time are shown on the left (green arrow). The six patient visits conducted during the study are labeled V1 through V6.

otolaryngologists were provided with written guidance outlining the key educational content and counseling messages to be delivered during study visits. All participating clinicians were experienced tinnitus specialists practicing in dedicated tinnitus referral centers.

Randomization and audiologist intervention

Following the ENT consultation and data entry into the study management portal called Exagis (Axiadis, France) an email was sent exclusively to the audiologist in charge of the patient. This email contained the randomization results, including the assigned treatment arm and the brand of hearing aid to be used. Throughout the study, only the audiologists were aware of the treatment allocation; patients, ENT specialists, and researchers remained blinded. To maintain blinding, participants weren't aware that the study included a placebo, the amplification provided in arm 1 was presented to patients as the clinical gold standard for sound therapy. Blinding was maintained

throughout the study and was only lifted after the final follow-up (V6). Within a maximum of 14 working days, the ENT referred each patient to a senior audiologist specializing in tinnitus management. During the first audiologist visit (V2), patients underwent in-situ audiometry measurements necessary for optimal hearing aid fitting, including hearing thresholds and discomfort levels. Devices were programmed according to the assigned treatment arm: placebo amplification, sound generator alone, or a combination of both. Patients received comprehensive instructions on device handling and maintenance. Additionally, standardized counseling specific to audiologists was provided including again explanations about the different types of tinnitus, a simplified overview of the presumed pathophysiology, and factors that may exacerbate or alleviate symptoms. The minimum required usage time, at least 6 h per day, was explained to participants. At the end of the session, visual analog scales (VAS) measuring immediate tinnitus annoyance and intensity were administered both with the hearing aid turned off and on (with appropriate settings). This simple measure allowed for direct assessment of the device's impact on tinnitus. Previous research has identified this masking effect as a key predictor of long-term treatment success.⁴⁵

Follow-up and compliance monitoring

A follow-up visit (V3) was scheduled two weeks after therapy initiation to verify device maintenance, functionality, and patient comfort. Treatment adherence was assessed using the hearing aid's data logging feature. Patients who did not meet the average daily usage requirement of 6 h were asked about barriers to compliance and encouraged to improve adherence. At Visit 3, only one participant in the placebo arm (Arm 1) failed to meet the usage requirement. In the active treatment arms (Arms 2 and 3), four participants did not meet the threshold. After six weeks of therapy (Visit 4), patients completed all primary and secondary outcome questionnaires via an online portal called Exagis (Axiodis, France). The audiologist repeated checks on device maintenance and usage, again using data logging. At this point, no participants in the placebo group failed to meet the usage requirement; one participant in Arm 2 and three in Arm 3 did not comply. These differences were not statistically significant across groups. During Visit 4, three programs were added to the hearing aids for participants in Arms 2 and 3: P1: Amplification only, P2: Sound generator only, P3: Combined amplification and sound generator. This phase, referred to as the “polytherapy phase” allowed patients to freely choose which program(s) to use based on personal preference and daily life constraints. Patients could continue with their initial therapy or switch approaches for the remaining six weeks. Finally, for participants in the placebo amplification group, this visit primarily involved the audiologist verifying the proper fitting and functionality of the hearing aids.

Final evaluation and device return

The therapy period concluded at 12 weeks. A final visit (V5) was scheduled with the ENT to assess primary and secondary treatment outcomes and gather patient feedback. The ENT remained blinded to the treatment allocation. An additional visit (V6) was scheduled between weeks 12 and 13 with the audiologist to return the hearing aids and extract usage data via data logging. This visit marked the end of blinding for the patient, who was informed of their treatment group. Patients in the placebo group were offered the opportunity to try the most effective active treatment or the therapy of their choice for an additional 12 weeks. All participants were allowed to keep their hearing aids free of charge, as manufacturers agreed to provide the devices at a preferential rate equivalent to the standard reimbursement price under France's “100% santé” program, a national healthcare initiative introduced in 2019 that ensures full reimbursement for certain essential health products, including hearing aids, dental prostheses, and eyeglasses. Under this program, eligible patients receive these items without any out-of-pocket expenses, as costs are fully covered by public health insurance and complementary private insurance.

Clinical monitoring and data validation

To ensure protocol compliance and data integrity, clinical research associates from an external firm, Axiodis (France), conducted site visits at each participating center following the inclusion of the first participants. These visits focused on verifying inclusion and exclusion criteria as well as the accuracy of primary outcome measures. A second round of monitoring was performed at the end of the study to confirm the consistency and completeness of the collected data.

Sampling and sample size

This three-arm study was based on an interaction between a within-subject factor (Time: Start / Midpoint / End of treatment) and a between-subject factor (Treatment: Placebo / Sound Generator / Amplification + Sound Generator). A literature review has shown that most studies investigating tinnitus treatment through amplification report moderate to large effect sizes (Shekhawat, Searchfield, & Stinear, 2013). However, these studies often lacked appropriate control conditions, such as a placebo group. Given this context, we adopted a conservative hypothesis, assuming a small effect size ($\eta^2 = 0.02$) for the present study. Sample size calculations were performed using G*Power 3.1.9.6 (Heinrich Heine University Düsseldorf, Germany; <https://www.psychologie.hhu.de/arbeitsgruppen/allgemeine-psychologie-und-arbeitspsychologie/gpower>)⁴⁶. The analysis indicated that, for a small effect size, there is a 90% probability of rejecting the null hypothesis, i.e., detecting a significant interaction between treatment and time, with a total sample of 129 participants, or 43 per group. To account for an anticipated 90% retention rate, the initial plan was to recruit 5 additional participants per group (approximately 10% more per group), resulting in a final target of 48 participants per group, for a total sample size of 144 participants.

Statistical analysis

The primary objective of this study was to test the hypothesis that acoustic stimulation therapy, either through a sound generator alone or in combination with amplification, reduces tinnitus-related distress more effectively than a placebo sound therapy after six weeks of treatment. Additionally, we hypothesize that a flexible sound therapy approach, allowing patients to choose daily between amplification alone, sound generator alone, or the combined approach, will be more effective in reducing tinnitus-related distress than any single, fixed therapy. Both parametric and non-parametric statistical tests were used to compare outcomes across the three treatment groups. These included mixed-design ANOVA (to assess interactions between time and treatment group), Student's t-tests, and Chi-square tests. Comparisons were made at two key time points: (1) after six weeks of fixed therapy (monotherapy) and (2) after an additional six weeks of flexible therapy (polytherapy). The main hypothesis tested was the presence of an interaction between treatment arm and time. Primary outcome variables included tinnitus-related handicap and distress, as measured by the TFI. Secondary outcomes included improvements in associated comorbidities such as: Sleep quality, Depressive and anxiety symptoms, Auditory abilities. All secondary outcomes were assessed using validated questionnaires and/or homemade questionnaires. Prior to analysis, the distribution of continuous outcome measures was evaluated using visual inspection and the Shapiro–Wilk test. Statistical methods were selected according to the characteristics of each outcome measure, with parametric analyses applied to continuous variables when assumptions were judged to be adequately met.

There were no missing values for the primary outcome measures, the TFI and GRCS, at baseline (V1) and at the final follow-up (V5). However, at the intermediate visit (V4), four participants did not complete the TFI and five did not complete the GRCS. These missing data were attributed to technical issues with the online platform used for questionnaire completion at that time. The distribution of missing data was balanced across treatment arms: none in Arm 1, one in Arm 2, and two in Arm 3 for TFI and one in Arm 1, one in Arm 2, and two in Arm 3 for the GRCS. Given the small number of missing values, their balanced distribution, and their occurrence at an intermediate time point, no imputation or special statistical treatment was applied; analyses were conducted using

available data. A similar approach was used for secondary outcome measures, with missing data handled through complete case analysis without imputation. Again, most missing values for secondary outcomes occurred at V4 and were linked to the online platform issues. Additionally, some missing data for the VRB measure were due to technical problems with the equipment at certain clinical sites. In addition to the outcomes reported herein, the original study protocol included collection of SF-12 data as a measure of health-related quality of life. These data are not reported in the present manuscript. This represents a deviation from the original study protocol.

Results

Primary outcomes

Total score on the tinnitus functional index (TFI)

Statistical analysis of the total TFI score was conducted using a mixed-design repeated measures ANOVA, with Time as a within-subject factor (Baseline–V1 / Midpoint–V4 / End of Treatment–V5) and Treatment Group as a between-subject factor (three arms). The analysis revealed a significant interaction between Time and Treatment Group, $F(4, 244) = 5.363$, $p = .001$, $\eta^2 = 0.081$. Mean TFI scores at each time point, along with post-hoc comparisons, are presented in Table 3 and illustrated in Fig. 3. In summary, significant changes in TFI scores between

Table 3 Mean Scores for the Tinnitus Functional Index (TFI), Visual Analog Scale (VAS) for Tinnitus Intensity, and Tinnitus annoyance Across Three Key Assessment Time Points and Treatment Arms. Values are presented as means, with standard deviations in parentheses. Bold values indicate statistically significant differences.

Primary outcome measures		V1	V4	V5	p-value
TFI					
	All participants	54.6 (15.9)	47.2 (18.8)	39.5 (21.4)	** $p < .001$
	Arm 1	54.6 (17.2)	48.9 (22.6)	48.4 (23.2)	n.s.
	Arm 2	55.7 (15.3)	48.3 (16.3)	34.3 (19.1)	** $p < .001$
	Arm 3	53.5 (15.5)	44.4 (17.0)	35.6 (19.3)	** $p < .001$
	Between groups				
	p-values	n.s.	n.s.	*$p = .004$	
VAS-annoyance					
	All participants	6.8 (1.8)	5.8 (2.3)	4.9 (2.6)	** $p < .001$
	Arm 1	6.8 (1.9)	6.0 (2.5)	6.0 (2.6)	n.s.
	Arm 2	6.7 (1.8)	5.8 (2.0)	4.2 (2.3)	** $p < .001$
	Arm 3	6.9 (1.8)	5.6 (2.3)	4.5 (2.7)	** $p < .001$
	Between groups				
	p-values	n.s.	n.s.	*$p = .01$	
VAS-intensity					
	All participants	7.0 (1.8)	6.0 (2.1)	5.3 (2.5)	** $p < .001$
	Arm 1	6.8 (1.8)	6.1 (2.3)	6.3 (2.2)	* $p = .049$
	Arm 2	7.0 (1.8)	6.1 (2.0)	4.6 (2.4)	** $p < .001$
	Arm 3	7.3 (1.9)	5.9 (2.1)	4.9 (2.6)	** $p < .001$
	Between groups				
	p-values	n.s.	n.s.	*$p = .01$	

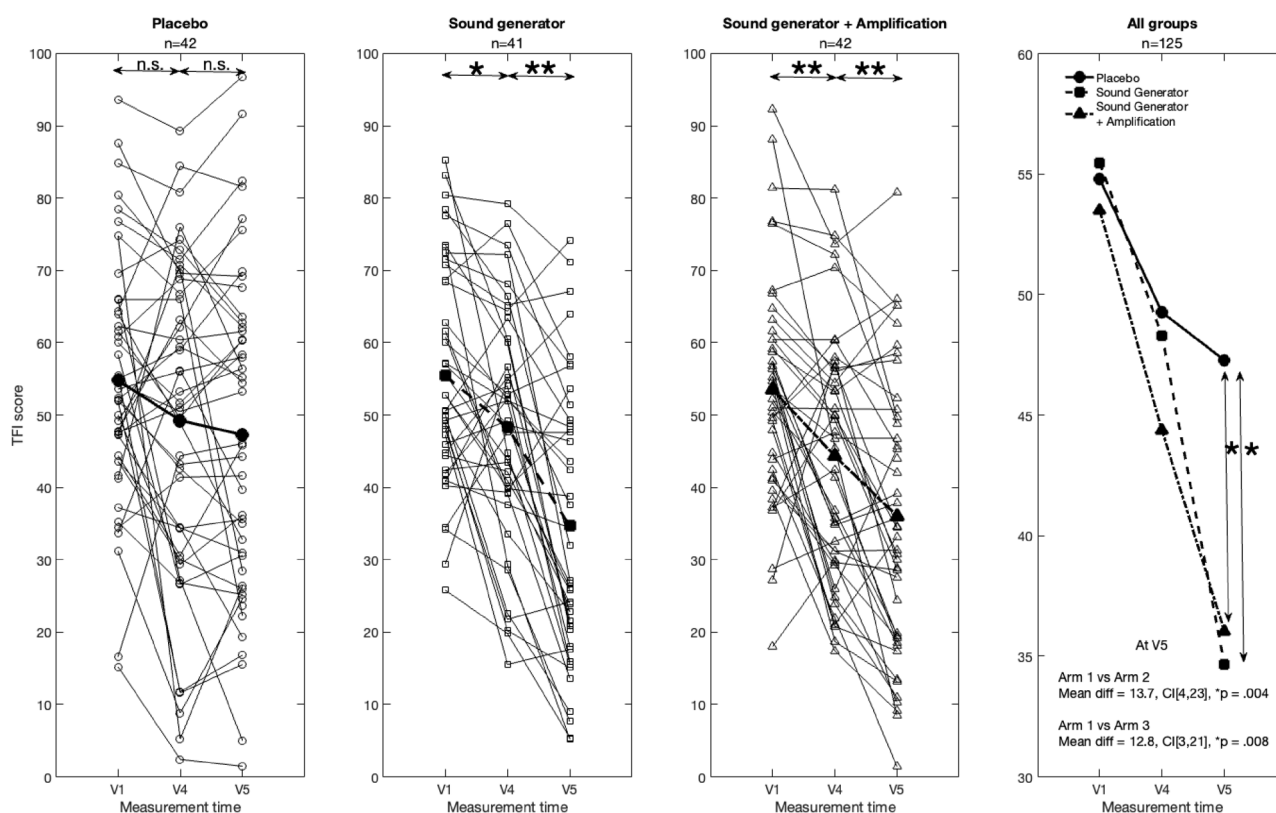


Fig. 3 Individual and Mean Tinnitus Functional Index (TFI) Scores Across Three Time Points for Each Treatment Arm. Individual participant scores and group means are shown for baseline (V1), mid-treatment (V4), and post-treatment (V5) visits across the three treatment groups. Asterisks indicate statistically significant differences: $p < .05$ (*), $p < .001$ (**). CI = 95% Confidence Intervals.

Table 4 Changes in Total Scores on the Tinnitus Functional Index (TFI), Visual Analog Scale (VAS) for Tinnitus intensity (VAS-i), and Tinnitus annoyance (VAS-a) Between the Three Main Assessment Time Points Across the Three Treatment Arms. 95%CI = 95% confidence intervals.

	Arm 1	<i>p</i> -values	95%CI	Arm 2	<i>p</i> -values	95%CI	Arm 3	<i>p</i> -values	95%CI
TFI mean difference (SD)									
V1-V4	5.6 (20)	n.s.	[-1,12]	7.4 (15)	=0.009*	[3,12]	9.2 (15)	<0.001**	[4,14]
V4-V5	0.5 (12)	n.s.	[-3,4]	14 (15)	<0.001**	[9,19]	8.8 (13)	<0.001**	[5,13]
V1-V5	6.2 (20)	n.s.	[0,12]	21.4 (22)	<0.001**	[14,28]	18 (18)	<0.001**	[12,23]
VAS-a mean difference (SD)									
V1-V4	0.7 (2.5)	n.s.	[-0.1,1.5]	0.9 (2.0)	=0.021*	[0.3,1.5]	1.3 (2.3)	=0.003*	[0.6,2]
V4-V5	0 (1.4)	n.s.	[-0.5,0.5]	1.5 (2.2)	<0.001**	[0.9,2.2]	1.1 (1.9)	<0.001**	[0.5,1.7]
V1-V5	0.9 (2.5)	n.s.	[0.1,1.7]	2.4 (2.7)	<0.001**	[1.5,3.2]	2.4 (2.5)	<0.001**	[1.6,3.2]
VAS-i mean difference (SD)									
V1-V4	0.7 (2.1)	n.s.	[0.1,1.4]	0.9 (1.9)	=0.009*	[0.3,1.6]	1.4 (2.3)	<0.001**	[0.7,2.1]
V4-V5	-0.2 (1.1)	n.s.	[-0.5,0.1]	1.5 (2.0)	<0.001**	[0.8,2.1]	1 (2.1)	=0.012*	[0.3,1.7]
V1-V5	0.7 (2.2)	n.s.	[0.1,1.4]	2.4 (2.4)	<0.001**	[1.6,3.1]	2.4 (2.6)	=0.003*	[1.6,3.2]

V1 and V4, V4 and V5, and V1 and V5 were observed only in the active treatment groups (Arms 2 and 3). These time-point comparisons are detailed in Table 4.

The primary outcome criterion, defined as a reduction of at least 13 points in the total TFI score after 12 weeks of therapy, was met by participants in both active treatment arms, with mean reductions of 21 and 18 points in Arms 2 and 3, respectively. In contrast, participants in the placebo group (Arm 1) showed a mean reduction of

only 6 points over the same period. Significant differences in mean TFI scores between the three treatment arms were observed exclusively at the final visit (V5). These findings suggest that both monotherapy and polytherapy approaches are more effective in reducing tinnitus-related distress compared to placebo treatment.

Global rating of change scale (GRCS) results

At the mid-treatment visit (V4) and the final ENT visit (V5), participants were asked to complete the GRCS, selecting the option that best reflected their overall impression of change in their condition following monotherapy (V4) and combination therapy (V5) for the two active treatment arms (Arms 2 and 3). At visit V5, participants in the placebo group (Arm 1) evaluated the same therapy initially prescribed.

The GRCS included seven response options: *Very much worse*, *Moderately worse*, *Slightly worse*, *No change*, *Slightly improved*, *Moderately improved*, *Very much improved*. A clinically meaningful change was defined as at least a slight improvement in condition following therapy. At the mid-treatment visit (V4), the proportion of participants reporting at least slight improvement was Arm 1 (Placebo) 26%; Arm 2 (Sound generator) 51% & Arm 3 (Sound generator+amplification) 79% ($\chi^2(10, 124)=30.475, p = .001$). At the final ENT visit (V5), the proportions were Arm 1, 33%; Arm 2, 88% & Arm 3, 77% ($\chi^2(10, 128)=35.983, p < .001$). Additionally, at the final hearing aid provider visit (V6), participants were given the option to keep or return their hearing aids. The proportion of participants who chose to keep their devices was Arm 1, 43%; Arm 2, 93% & Arm 3, 95% ($\chi^2(10, 128)=42.51, p < .001$). These findings, summarized in Fig. 4, suggest that patients in the active treatment arms

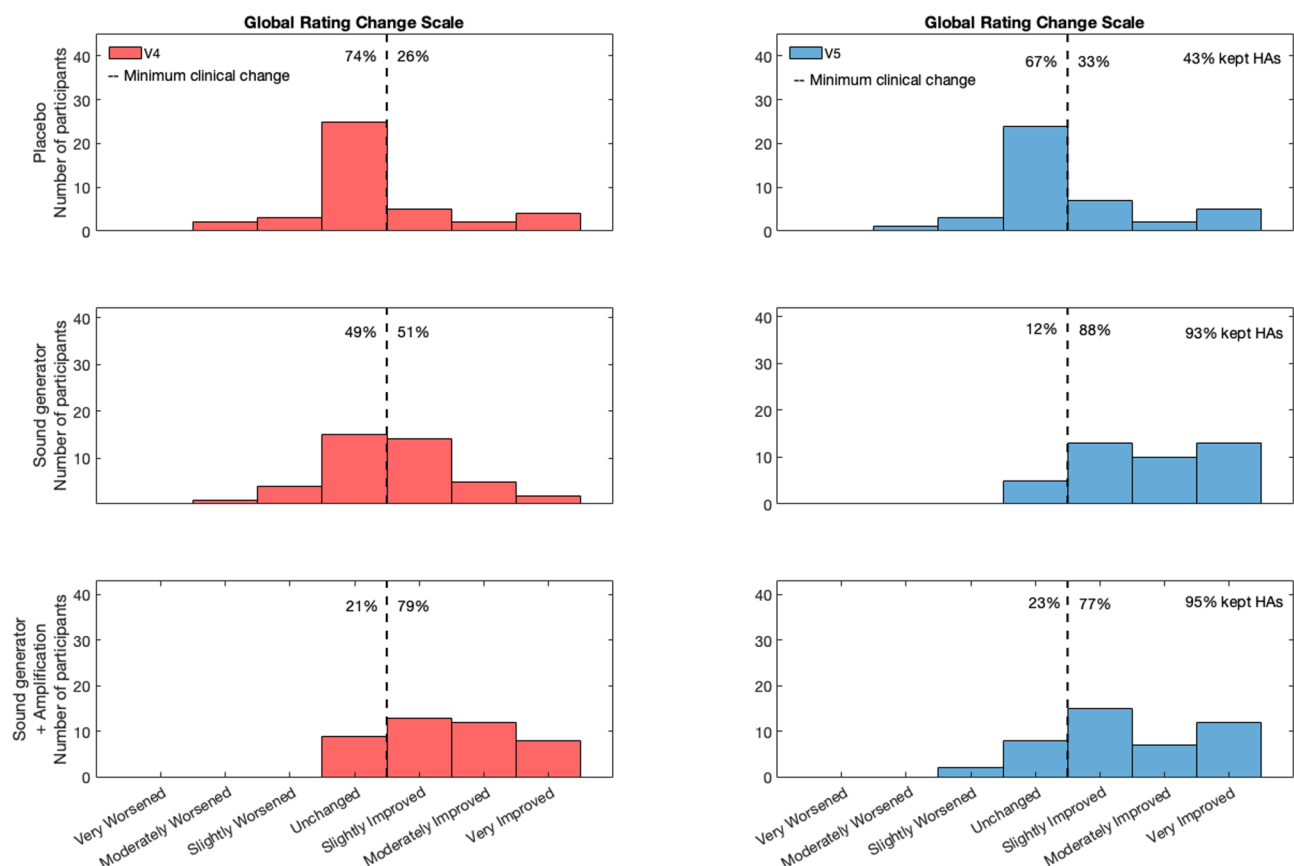


Fig. 4 Distribution of Patients Across the Three Treatment Arms According to Their Global Perception of Change Following Therapy at Mid-Treatment (V4) and End of Study (V5). The figure also indicates the percentage of patients in each treatment arm who chose to keep their hearing aids at the final audiologist visit (V6) (kept HAs). The number of participants that responded to the GRCS per treatment arms were 41, 41 and 42 for V4, and 42, 42, 44 for V5, for arm 1, 2 and 3, respectively.

(Arms 2 and 3) experienced greater perceived improvement in their condition compared to those in the placebo group.

Secondary outcomes

VAS for tinnitus intensity and annoyance: main effect

At the baseline (V1) and final ENT visit (V5), as well as during the mid-treatment online assessment (V4), participants rated the intensity and annoyance caused by their tinnitus using visual analog scales (VAS). This time points correspond to those used for the Tinnitus Functional Index (TFI) assessments. Participants were asked to assess the level of intensity and annoyance of their tinnitus causes in their daily life, ranging from no tinnitus to the maximum imaginable intensity and from no annoyance at all to the maximum imaginable annoyance caused by tinnitus. Statistical analyses of the VAS scores followed the same mixed-design repeated measures ANOVA approach as described for the TFI scores. The analyses revealed a significant interaction between Time and Treatment Group for both tinnitus intensity ($F(4, 242)=6.64, p < .001, \eta^2 = 0.099$) and tinnitus annoyance ($F(4, 242)=6.64, p = .001, \eta^2 = 0.071$).

Mean VAS scores for intensity and annoyance at each time point, along with post-hoc comparisons, are presented in Table III and illustrated in Fig. 5. In summary, significant changes in scores between V1–V4, V4–V5, and V1–V5 were observed only in the active treatment arms (Arms 2 and 3). Individual and mean VAS scores for both intensity and annoyance were significantly different between treatment arms only at the final assessment (V5). The primary clinical outcome was defined as a reduction of at least 2 points on the VAS after 12 weeks of therapy. This threshold was met by participants in the active treatment arms, with mean reductions of 2.5 and 2.4 points for annoyance and 2.4 and 2.4 points for intensity in Arms 2 and 3, respectively. In contrast, the placebo group (Arm 1) showed only modest improvements, with mean reductions of 0.8 points for annoyance and 0.5 points for intensity. These findings suggest that both sound generator alone and sound generator+amplification are more effective in reducing tinnitus intensity and annoyance than placebo.

VAS for Tinnitus intensity and annoyance: effect of clinical management

The impact of clinical management and directive counseling provided by ENT specialists was assessed by comparing VAS scores between the initial ENT visit (V1) and the first visit with the hearing aid provider (V2), during which the VAS was completed with the hearing aid turned off. Statistical analysis was conducted using a mixed-design repeated measures ANOVA with Time (V1 vs. V2) as a within-subject factor and Treatment Group (three arms) as a between-subject factor, analyzed separately for tinnitus intensity and annoyance. No significant interaction or main effect involving the treatment group was found for either measure. However, a significant main effect of Time was observed for tinnitus annoyance: $F(1, 125)=36.611, p < .001, \eta^2 = 0.23$ and for tinnitus intensity: $F(1, 125)=40.83, p < .001, \eta^2 = 0.25$. These results suggest that all participants, regardless of treatment group, experienced a reduction in tinnitus annoyance and intensity between V1 and V2, with average decreases of 1 point for annoyance and 1.3 points for intensity. This finding supports the hypothesis that clinical management, including directive counseling, contributes positively to the perceived reduction in tinnitus severity and annoyance.

VAS for tinnitus intensity and annoyance: immediate effect

At each visit with the hearing aid provider (V2, V3, V4, and V6), participants rated the immediate intensity and annoyance of their tinnitus using visual analog scales (VAS) under two conditions: with hearing aids worn but turned off, and with hearing aids turned on. These assessments were conducted to evaluate the immediate effect

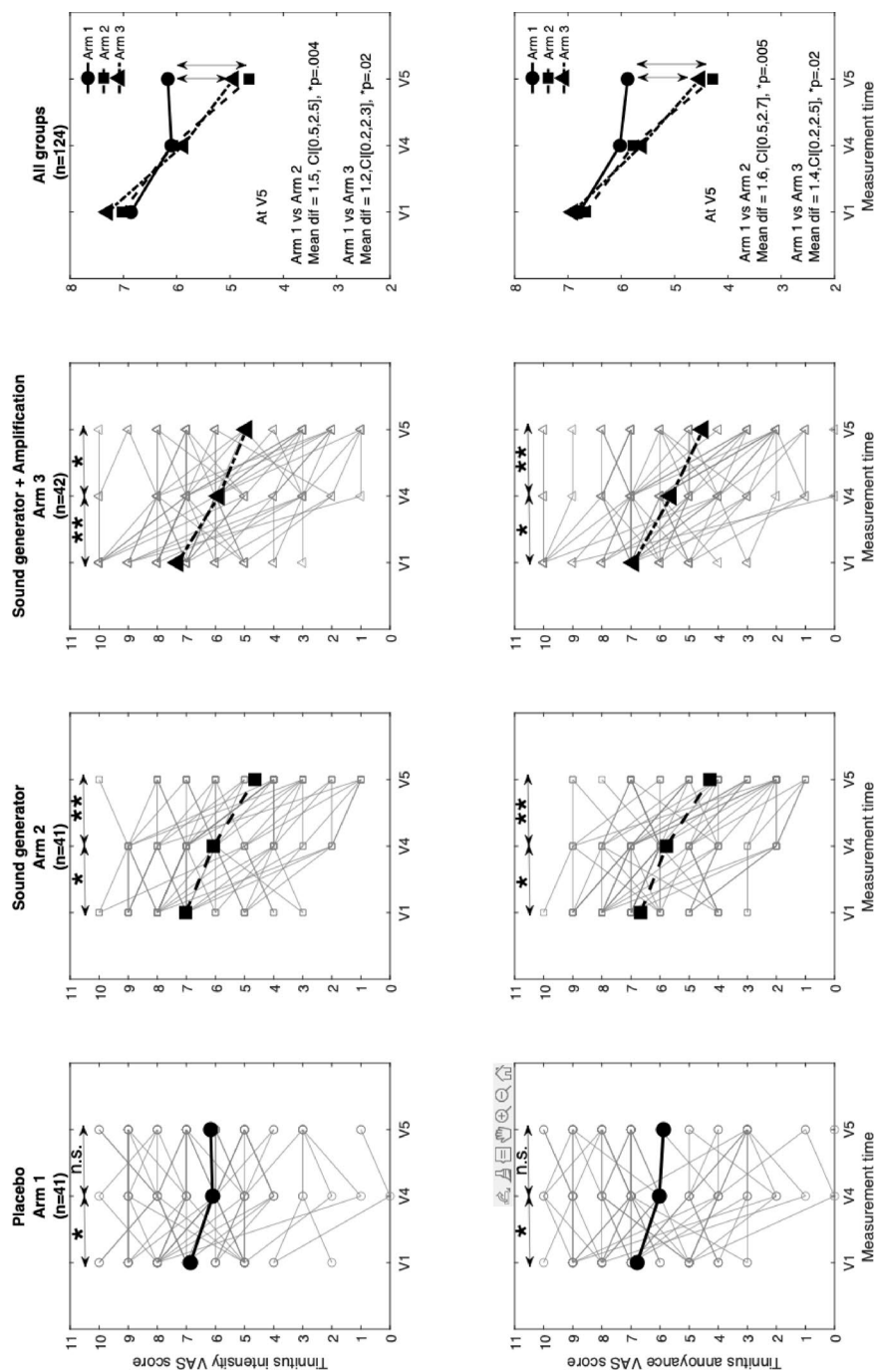


Fig. 5 Individual and Mean Scores on Visual Analog Scales (VAS) for Tinnitus intensity and annoyance Across the Three Main Assessment Time Points (V1, V4, V5) for Each Treatment Arm. The number of participants that responded to the VAS per treatment arms were 41, 41 and 42 for V4, and 42, 42, 44 for V5, for arm 1, 2 and 3, respectively. Asterisks indicate statistically significant differences: $p < .05$ (*), $p < .001$ (**), $p < .0001$ (***). CI = 95% confidence intervals.

of hearing aid use. Therefore, patients were asked to rate the immediate intensity and annoyance of their tinnitus, rather than the usual levels typically assessed at the main outcome time points.

Statistical analyses were performed using a mixed-design repeated measures ANOVA with two within-subject factors—Time (V2, V3, V4, V6) and Condition (unaided vs. aided)—and one between-subject factor, Treatment Group (three arms). Analyses were conducted separately for tinnitus intensity and annoyance. For tinnitus intensity, results revealed a significant interaction between Condition and Treatment Group: $F(2, 125)=18.849$, $p < .001$, $\eta^2 = 0.232$, a significant main effect of Time: $F(3, 375)=2.926$, $p = .04$, $\eta^2 = 0.023$ and no significant interactions involving Time. For tinnitus annoyance, results were similar with a significant interaction between Condition and Treatment Group: $F(2, 125)=17.272$, $p < .001$, $\eta^2 = 0.217$, a significant main effect of Time: $F(3, 375)=17.730$, $p = .001$, $\eta^2 = 0.044$ and no significant interactions involving Time.

Individual and mean scores, along with post-hoc analyses, are presented in Fig. 6. In both active treatment arms (Arms 2 and 3), VAS scores for tinnitus intensity and annoyance were consistently and significantly lower in the aided condition compared to the unaided condition at all time points. In the placebo group (Arm 1), significant reductions between the two conditions were observed only at visits V3 and V4, which corresponds to follow-up visit to the audiologist to fine tune the hearing aid fitting. These findings suggest that it is possible to detect a placebo effect of wearing hearing aids on tinnitus intensity and annoyance using VAS. More importantly, they indicate that hearing aids delivering effective acoustic stimulation tailored to the patient's hearing loss although mild produce an immediate and clinically meaningful reduction in tinnitus symptoms that exceeds the placebo effect.

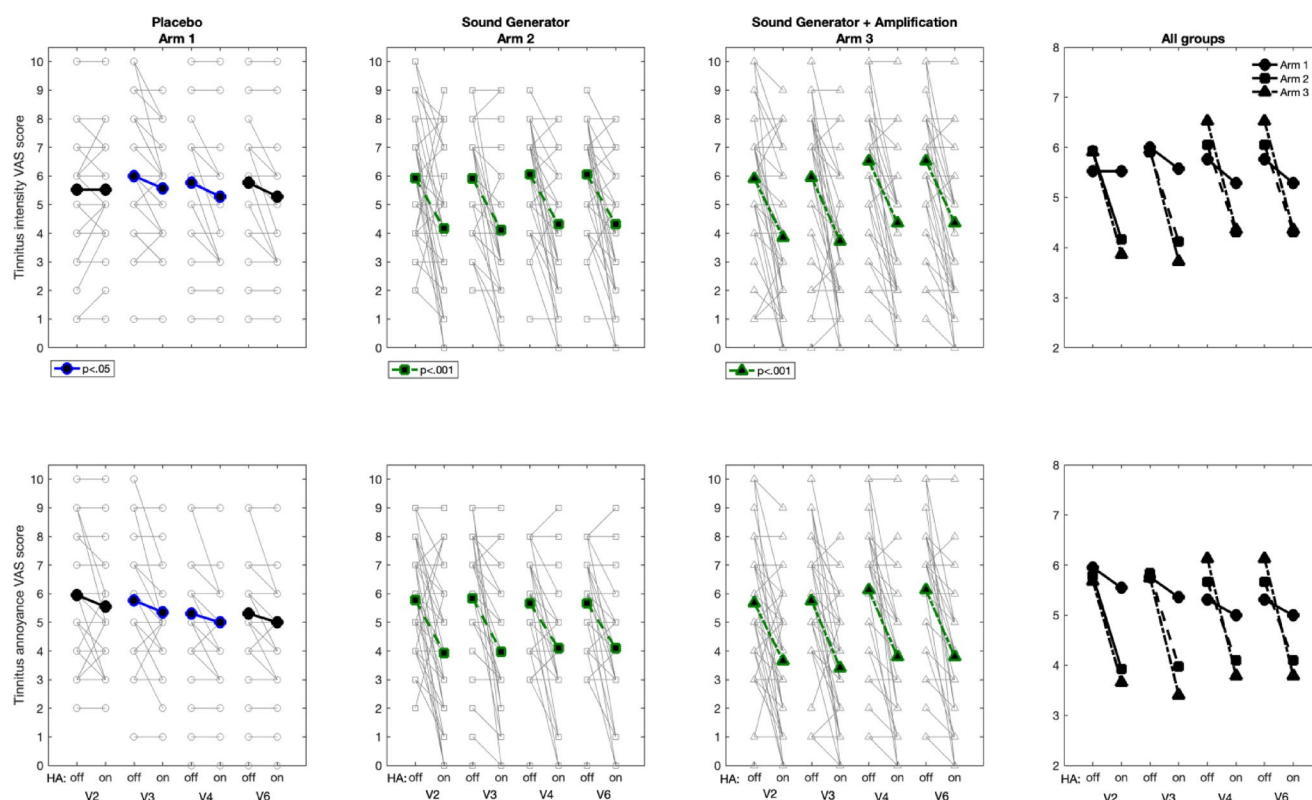


Fig. 6 Individual and Mean Scores on Visual Analog Scales (VAS) for Tinnitus Intensity and Annoyance Across Four Audiologist Visits (V2, V3, V4, V6) for Each Treatment Arm (Arm 1, $n=42$; Arm 2, $n=42$, Arm 3, $n=44$), Under Unaided (HA-off) and Aided Conditions (HA-on). Colored indicators highlight significant within-subject effects: blue= $p < .05$; green= $p < .001$.

Tinnitus comorbidities: sleep, anxiety, depression, and listening abilities

Statistical analyses of questionnaire scores assessing anxiety and depression (Hospital Anxiety and Depression Scale, HADS), sleep quality (Global Sleep Quality Scale and Tinnitus Sleep Impact Scale), and listening abilities (Speech, Spatial and Qualities of Hearing Scale, SSQ) followed the same mixed-design repeated measures ANOVA approach used for the TFI. Overall, no significant interactions between Time and Treatment Group were found for these measures. However, general improvements were observed across all groups (see Table 5). Measures related to sleep onset and morning alertness did not show significant changes over time. However, tinnitus impact on sleep was significantly reduced for all three groups. Notably, listening abilities improved over time only in the two active treatment groups (Arms 2 and 3). Furthermore, anxiety and depression scores showed significant improvement exclusively in Arm 2, which also had the highest proportion of participants reporting tinnitus modulation by stress (see Table I). These findings suggest that while general improvements in comorbid symptoms were observed, the most notable changes occurred in the active treatment groups.

Additional outcome measures

Assessment of adverse effects of sound therapy

At the mid-treatment visit (V4) and the final ENT visit (V5), participants were asked to report any adverse effects related to sound therapy using a standardized questionnaire. For each listed side effect, participants indicated whether they had experienced it by selecting “Yes” or “No”. The proportion of patients reporting adverse effects

Table 5 Mean Scores on Questionnaires Assessing Common Tinnitus-Related Comorbidities Across Three Treatment Arms and Three Key Assessment Time Points. This table presents average scores for anxiety and depression (HADS), sleep quality (Global Sleep Quality Scale and Tinnitus Sleep Impact Scale), and listening abilities (SSQ), measured at baseline (V1), mid-treatment (V4), and post-treatment (V5).

Secondary outcome measurements	V1	V4	V5	<i>p</i> -value
Hospital Anxiety & Depression Scale (HADS)				
All participants (<i>n</i> =119)	14.6 (6.9)	13.8 (6.9)	12.9 (6.8)	**<i>p</i> < .001
Arm 1 (<i>n</i> =41)	15.2 (7.3)	14.7 (7.1)	14.1 (6.7)	n.s.
Arm 2 (<i>n</i> =38)	14.1 (6.5)	13.3 (6.8)	11.9 (7.3)	*<i>p</i> = .004
Arm 3 (<i>n</i> =40)	14.6 (6.8)	13.4 (6.9)	12.6 (6.4)	n.s.
Between groups p-values	n.s.	n.s.	n.s.	
Speech, Spatial and Qualities of Hearing scale (SSQ)				
All participants (<i>n</i> =124)	7.2 (1.8)	7.4 (1.6)	7.7 (1.8)	**<i>p</i> < .001
Arm 1 (<i>n</i> =41)	7.2 (1.9)	7.4 (1.9)	7.3 (2.0)	n.s.
Arm 2 (<i>n</i> =41)	7.3 (1.5)	7.4 (1.4)	7.8 (1.5)	*<i>p</i> = .029
Arm 3 (<i>n</i> =42)	7.2 (2.0)	7.4 (1.6)	7.9 (1.7)	*<i>p</i> = .005
Between groups p-values	n.s.	n.s.	n.s.	
Global sleep Quality				
All participants (<i>n</i> =115)	5.1 (2.3)	5.5 (2.4)	5.7 (2.3)	*<i>p</i> = .023
Arm 1 (<i>n</i> =37)	4.5 (2.2)	4.8 (2.4)	5.2 (2.4)	n.s.
Arm 2 (<i>n</i> =41)	5.5 (2.3)	5.9 (2.5)	6.2 (2.3)	n.s.
Arm 3 (<i>n</i> =37)	5.4 (2.2)	5.6 (2.2)	5.6 (2.3)	n.s.
Between groups p-values	n.s.	n.s.	n.s.	
Impact of tinnitus on sleep				
All participants (<i>n</i> =124)	5.7 (2.9)	4.9 (2.7)	4.3 (3.1)	**<i>p</i> < .001
Arm 1 (<i>n</i> =41)	5.9 (2.7)	4.8 (2.9)	4.9 (3.0)	*<i>p</i> = .024
Arm 2 (<i>n</i> =41)	5.6 (2.9)	5.2 (2.6)	4.0 (3.3)	*<i>p</i> = .004
Arm 3 (<i>n</i> =42)	5.6 (3.3)	4.6 (2.5)	4.0 (2.9)	*<i>p</i> = .021
Between groups p-values	n.s.	n.s.	n.s.	

in each treatment arm is presented in Table 6. Overall, the most reported side effects were discomfort related to increased auditory sensitivity, affecting 38% and 48% of participants at V4 and V5 respectively for noise annoyance, and 32% and 38% for increased sound sensitivity at the same time points.

These effects were more frequently reported by participants in Arm 3 at mid-treatment (V4), and by those in Arms 2 and 3 at the end of the study (V5). These findings suggest that amplification in cases of mild hearing loss may contribute to increased sound sensitivity and discomfort. Additionally, participants in Arm 2 reported more listening difficulties than those in the other treatment arms at the mid-treatment visit. This result suggests that the sound generator may interfere with speech perception, potentially impacting communication.

Assessment of other beneficial effects of sound therapy

At the mid-treatment visit (V4) and the final ENT visit (V5), participants were asked to report any perceived benefits of sound therapy using a standardized home-made questionnaire. For each listed benefit, participants indicated whether they had experienced it by selecting “Yes”, “No” or “n.a.” (not applicable). The proportion of patients reporting beneficial effects in each treatment arm is presented in Table 7. Overall, the most frequently reported benefit was better coping with tinnitus, cited by 62% of participants at V4 and 68% at V5. This benefit was more commonly reported by participants in Arms 2 and 3 at both time points. Additionally, participants in Arm 3 reported a higher proportion of benefits at mid-treatment, including: improved tolerance to loud sounds, better speech perception in quiet and noisy environments, enhanced sound localization and improved recognition of environmental sounds. A similar trend was observed at the final visit (V5), with Arms 2 and 3 showing higher proportions of reported benefits compared to Arm 1. These findings suggest that hearing aid amplification not only helps patients better cope with tinnitus but also enhances various auditory abilities, particularly in those receiving active treatments.

Psychoacoustic measures of tinnitus

Statistical analyses of psychoacoustic measures including pitch matching, loudness matching (at 1 kHz and at the tinnitus frequency), and minimum masking level (MML) were conducted using the same mixed-design repeated measures ANOVA approach described for the TFI. No significant interactions were found for any of these measures. Overall, there were no significant changes over time and no major differences between treatment groups, with one exception: patients in Arm 3 exhibited a slightly higher MML at the initial visit. Notably, this group was

Table 6 Proportion of Patients Reporting Adverse Effects Following Mono-therapy (V4) and Poly-therapy (V5) Across the Three Treatment Arms. This table presents the percentage of participants in each treatment group who reported experiencing specific adverse effects related to sound therapy at mid-treatment and at the end of the study.

Adverse effect	Pla- cebo (Arm 1)	Sound generator (Arm 2)	Sound genera- tor + Amplification (Arm 3)	p-value
V4				
Noise annoyance with HA-on (yes/no)	10/32	16/25	21/20	* $p = .036$
Higher sound sensitivity with HA-on (yes/no)	9/33	10/31	21/20	* $p = .006$
Physical discomfort with HA (yes/no)	12/30	16/25	12/29	n.s.
Hearing difficulties with HA-on (yes/no)	3/38	13/28	4/37	* $p = .004$
Localizing difficulties with HA-on (yes/no) Difficulty adapting to HAs	3/39 7/35	1/40 9/32	1/40 6/35	n.s. n.s.
V5				
Noise annoyance with HA-on (yes/no)	11/31	24/18	26/18	* $p = .003$
Higher sound sensitivity with HA-on (yes/no)	10/32	19/23	19/25	n.s.
Physical discomfort with HA (yes/no)	9/33	16/26	12/32	n.s.
Hearing difficulties with HA-on (yes/no)	4/38	6/36	7/37	n.s.
Localizing difficulties with HA-on (yes/no) Difficulty adapting to HAs	4/38 4/38	1/41 10/32	3/41 10/34	n.s. n.s.

Table 7 Proportion of Patients Reporting Beneficial Effects Following Monotherapy (V4) and Polytherapy (V5) Across the Three Treatment Arms. This table presents the percentage of participants in each treatment group who reported experiencing specific benefits from sound therapy at mid-treatment and at the end of the study. (n.a. = non applicable, n.s. = not significant)

Other beneficial effect	Placebo (Arm 1)	Sound generator (Arm 2)	Sound generator + Amplification (Arm 3)	p-value
V4				
Better support tinnitus (yes/no)	13/29	29/12	34/8	$**p < .001$
Better support loud sounds (yes/no/n.a.)	8/28/6	13/24/4	14/12/16	$*p = .001$
Better understand speech (yes/no/n.a.)	9/24/9	5/30/6	21/7/14	$**p < .001$
Better localized sound (yes/no/n.a.)	4/25/13	4/23/14	14/9/19	$*p = .001$
Better recognized soundscape (yes/no/n.a.)	5/24/136/27/9	5/23/13	14/7/21	$**p < .001$
Better understand speech in noise (yes/no/n.a.)		8/26/7	21/10/11	$**p < .001$
V5				
Better support tinnitus (yes/no)	16/26	36/5	36/8	$**p < .001$
Better support loud sounds (yes/no/n.a.)	12/29/1	18/18/6	11/20/13	n.s.
Better understand speech (yes/no/n.a.)	7/30/5	22/13/7	26/9/9	$**p < .001$
Better localized sound (yes/no/n.a.)	4/31/7	14/14/14	17/13/14	$**p < .001$
Better recognized soundscape (yes/no/n.a.)	5/31/6	15/13/14	15/18/11	$*p = .002$
Better understand speech in noise (yes/no/n.a.)	6/31/5	19/17/6	24/14/6	$**p < .001$

also the only one to show a significant reduction in MML over the course of the study. These findings suggest that while most psychoacoustic characteristics of tinnitus remained stable across time and treatment groups, combination therapy (Arm 3) may have a specific effect on reducing the minimum masking level, potentially indicating improved tinnitus suppression. All psychoacoustic measurement results are presented in Table 8.

Speech-in-noise perception assessment

Statistical analyses of speech-in-noise perception (VRB), assessed both unaided and with hearing aids turned on, followed the same mixed-design repeated measures ANOVA approach used for the TFI. No significant interactions were found between time and treatment group. Overall, speech-in-noise perception improved over the course of the study, both with and without hearing aids in use, $F(2, 216) = 8.483$, $p < .001$, $\eta^2 = 0.073$. However, no significant differences were observed between treatment groups at any time point.

Notably, Participants in Arm 2 (noise generator only during monotherapy) showed a significant improvement in unaided speech-in-noise perception between V1 and V4. Participants in Arm 3 (combination of amplification and sound generator) demonstrated a significant improvement in speech-in-noise perception when tested with hearing aids turned on, only. These findings suggest that both sound generators alone and in combination with amplification may enhance speech-in-noise perception. However, speech-in-noise performance improves over time in the unaided condition for participants using the sound generator alone, whereas in the combination therapy group, benefits are observed only when the amplification function of the hearing aids is actively engaged. A pair-sample T-test was run between the performance between the aided and unaided condition for the placebo group, and no significant difference was found suggesting that the placebo hearing aid fitting was not affecting (hinder or improved) speech perception performance. All results from the speech-in-noise perception test are presented in Table 9.

Discussion

The primary objective of this study was to evaluate the hypothesis that sound therapy, either through a noise generator alone (Arm 2) or in combination with amplification (Arm 3), reduces tinnitus-related distress and improves quality of life in individuals with mild bilateral hearing loss, compared to a placebo sound therapy (transparent amplification, Arm 1). A key innovation of this research lies in its two-phase design. The initial six-week

Table 8 Results of Psychoacoustic Measurements of Tinnitus Over Time for Patients in the Three Treatment Arms. This table presents changes in tinnitus pitch, loudness (at 1 kHz and at the tinnitus frequency), and minimum masking level across key assessment time points for each treatment group.

Psychoacoustic measures of tinnitus	V2	V4	V6	<i>p</i> -value
Pitch matching in kHz				
All participants (<i>n</i> =128)	6.6 (3.5)	6.2 (3.6)	6.2 (3.4)	n.s.
Arm 1 (<i>n</i> =42)	7.6 (3.9)	6.6 (4.2)	6.5 (3.8)	* <i>p</i> = .035
Arm 2 (<i>n</i> =42)	5.8 (3.0)	5.4 (3.2)	5.4 (3.0)	n.s.
Arm 3 (<i>n</i> =44)	6.5 (3.3)	6.7 (3.4)	6.7 (3.4)	n.s.
Between groups p-values	n.s.	n.s.	n.s.	
Loudness matching (dB SL) at tinnitus pitch				
All participants (<i>n</i> =126)	5 (5)	6 (6)	6 (6)	n.s.
Arm 1 (<i>n</i> =42)	6 (6)	6 (6)	7 (8)	n.s.
Arm 2 (<i>n</i> =42)	5 (3)	6 (4)	5 (3)	n.s.
Arm 3 (<i>n</i> =42)	6 (5)	6 (7)	6 (5)	n.s.
Between groups p-values	n.s.	n.s.	n.s.	
Loudness matching (dB SL) at 1 kHz				
All participants (<i>n</i> =126)	10 (8)	10 (7)	10 (8)	n.s.
Arm 1 (<i>n</i> =42)	9 (8)	10 (7)	11 (9)	n.s.
Arm 2 (<i>n</i> =42)	11 (8)	9 (7)	9 (7)	n.s.
Arm 3 (<i>n</i> =42)	10 (7)	10 (6)	10 (6)	n.s.
Between groups p-values	n.s.	n.s.	n.s.	
Minimum masking levels				
All participants (<i>n</i> =126)	13 (14)	12 (12)	11 (9)	n.s.
Arm 1 (<i>n</i> =42)	10 (10)	12 (13)	10 (10)	n.s.
Arm 2 (<i>n</i> =42)	12 (13)	11 (10)	11 (9)	n.s.
Arm 3 (<i>n</i> =42)	17 (17)	13 (12)	10 (8)	* <i>p</i> = .016
Between groups p-values	* <i>p</i> = .033	n.s.	n.s.	

Table 9 Results of the Speech-in-Noise Test (VRB) Under Unaided (Without HA) and Aided (With HA On) Conditions Across Key Assessment Time Points for Patients in the Three Treatment Arms.

Speech perception test	V2	V4	V6	<i>p</i> -value
VRB – without HA				
All participants (<i>n</i> =112)	3.6 (1.7)	3.3 (1.6)	3.2 (1.6)	** <i>p</i> < .001
Arm 1 (<i>n</i> =38)	3.7 (1.8)	3.4 (1.7)	3.3 (1.5)	n.s.
Arm 2 (<i>n</i> =37)	3.8 (1.8)	3.3 (1.4)	3.4 (1.7)	* <i>p</i> = .005
Arm 3 (<i>n</i> =37)	3.4 (1.6)	3.2 (1.5)	3.0 (1.7)	n.s.
Between groups p-values	n.s.	n.s.	n.s.	
VRB – with HA on				
All participants (<i>n</i> =112)	3.4 (1.9)	3.0 (1.6)	2.8 (1.5)	** <i>p</i> < .001
Arm 1 (<i>n</i> =38)	3.7 (2.5)	3.4 (1.6)	3.2 (1.6)	n.s.
Arm 2 (<i>n</i> =37)	3.3 (1.6)	3.0 (1.6)	2.8 (1.5)	n.s.
Arm 3 (<i>n</i> =37)	3.0 (1.6)	2.7 (1.6)	2.5 (1.5)	* <i>p</i> = .003
Between groups p-values	n.s.	n.s.	n.s.	

monotherapy phase imposed a fixed treatment protocol typical of double-blind randomized controlled trials. In contrast, the subsequent six-week polytherapy phase introduced flexibility, allowing participants in the active treatment arms to select among three sound stimulation programs (amplification alone, noise generator alone, or combined therapy) based on their preferences, needs, and daily circumstances. This second phase was intentionally designed to increase the ecological validity of the intervention and better reflect real-world tinnitus management. Unlike pharmacological interventions, the effectiveness and acceptability of sound therapy may vary

according to individual preferences and listening environments. This was reflected in the present study, where participants initially assigned to two distinct treatment arms ultimately converged toward similar patterns of hearing aid use, with amplification-based programs accounting for more than 50% of overall use in both groups for the polytherapy phase. Consequently, the 12-week outcomes should be interpreted as reflecting the effectiveness of a personalized sound therapy strategy rather than the efficacy of strictly maintained monotherapy conditions.

A total of 145 patients with chronic, disabling tinnitus and mild bilateral hearing loss were recruited from six specialized tinnitus clinics in France. Participants were randomly assigned to one of the three treatment arms and were comparable across sociodemographic and audiological characteristics. Results from the primary outcome measures (TFI and GRCS) indicated significantly greater improvement in the active treatment arms (Arms 2 and 3) compared to the placebo. Similarly, secondary outcomes based on visual analog scales for tinnitus intensity and annoyance showed greater improvement in the active arms. While standardized questionnaires assessing sleep quality, anxiety and depression symptoms, and listening abilities revealed improvements across all groups, no significant differences were found between treatment arms. Additional questionnaires assessing perceived adverse and beneficial effects highlighted that sound discomfort and increased auditory sensitivity were the most frequently reported side effects, likely attributable to amplification. Conversely, amplification also appeared to contribute to several beneficial effects, including improved speech perception in quiet and noisy environments, enhanced sound localization, and better awareness of environmental sounds.

Efficacy of sound therapy for tinnitus management with mild hearing loss

This study clearly demonstrates that sound therapies combining amplification and sound generators, whether integrated into a single program or offered as separate options, significantly reduce tinnitus-related distress and disability compared to placebo sound therapy in patients with chronic, disabling bilateral tinnitus and mild hearing loss over a 12-week period. Both primary outcome measures, the total score on the TFI and the GRCS, showed significantly greater improvements in the active treatment arms (Arms 2 and 3) compared to the placebo group. Moreover, only the active treatment groups exceeded the predefined clinical thresholds for meaningful change, while the placebo group failed to meet these criteria.

Similarly, patients in the active arms also surpassed the clinical thresholds on the VAS for tinnitus intensity and annoyance, reinforcing the findings from the primary measures. It is unlikely that these differences are due to a failure of the placebo condition, as a measurable placebo effect was observed in the group receiving transparent amplification. Although not statistically significant, patients in the placebo arm improved by an average of 6 points on the TFI, and 33% reported clinically meaningful improvement on the GRCS at the end of the 12 weeks trial. Additionally, the immediate effect of acoustic stimulation, measured via VAS during audiologist visits with hearing aids turned off and on, showed small but significant reductions in tinnitus intensity and annoyance for the placebo group at visits V3 and V4. During these visits, audiologists spent time adjusting the devices, even though no actual amplification was provided. This suggests that the placebo effect may have been influenced by social desirability bias, with patients unconsciously responding positively to the clinician's efforts. Notably, the immediate effects observed in the active treatment groups were consistently stronger and statistically significant across all four measurement points.

Interestingly, the current study provides evidence that sound therapy can be an effective approach for managing chronic, disabling tinnitus in patients with very mild bilateral hearing loss. In this cohort, hearing loss was minimal, with a pure-tone average of 16 dB HL across four frequencies (0.5, 1, 2, and 4 kHz). As previously noted, international guidelines do not systematically recommend sound therapy, including amplification, sound generators, or their combination, for such mild hearing losses.^{18,20,21} Nevertheless, the results obtained here align with previous trials suggesting that sound therapy, whether through hearing aids⁴⁷ or sound generators⁴⁸, may be beneficial when combined with informational counseling for patients with debilitating tinnitus and mild hearing loss. Importantly, this is the first study to demonstrate that the therapeutic benefit observed in this specific population with mild hearing loss is not attributable to placebo effects.

Utility of visual analog scales in clinical research

The VAS for tinnitus intensity and annoyance proved highly valuable throughout the study. These simple and rapid tools enabled continuous tracking of tinnitus changes across the patient journey. Importantly, they revealed a significant reduction, approximately one point, between the initial ENT visit and the first audiologist visit, supporting current clinical guidelines that recommend directive counseling as a first-line intervention for tinnitus management.^{18,20,21} The VAS also validated the overall therapeutic effect across the main time points (V1, V4, and V5), with results closely mirroring those obtained from the standardized TFI questionnaire. Finally, the VAS allowed for the assessment of immediate acoustic stimulation effects, by comparing patient responses in unaided versus aided conditions. Collectively, these findings strongly support the use of VAS in clinical research settings for tinnitus.

Impact on tinnitus-related comorbidities

Regarding secondary outcomes related to common tinnitus comorbidities including sleep disturbances, anxiety, depression, and listening difficulties, all treatment groups showed significant improvements, with no differences between arms. This suggests that improvements in these domains may be more closely linked to clinical management and directive counseling than to the specific sound therapy used. However, a greater proportion of patients in the active treatment arms reported improvements in auditory abilities such as speech perception in quiet and noise, sound localization, and environmental sound awareness. These benefits were most pronounced in groups receiving actual amplification, indicating that hearing aid use may contribute to broader auditory improvements beyond tinnitus relief.

Monotherapy vs. Polytherapy: The role of amplification

The effects observed during the monotherapy phase, defined as the initial six weeks of assigned treatment, were more modest compared to those seen during the polytherapy phase. Intergroup comparisons across the three treatment arms revealed no statistically significant differences in TFI scores or VAS ratings at the end of the monotherapy period. However, intragroup analyses showed significant improvements from baseline to the end of monotherapy in both active treatment arms, suggesting greater efficacy compared to the placebo group. Furthermore, a significantly higher proportion of participants in the active treatment groups reported clinically meaningful improvement on the GRCS at the end of the monotherapy phase, reinforcing the superior efficacy of active sound therapies over placebo after six weeks.

Following the monotherapy phase, participants in the placebo group showed no further improvement across primary and secondary tinnitus outcome measures, whereas those in the active treatment arms continued to demonstrate progress. Notably, participants in Arm 3, who received a combination of sound generators and amplification during monotherapy, maintained their improvements throughout the polytherapy phase, with TFI score reductions averaging 9 points during monotherapy and 8.8 points during polytherapy. In contrast, participants in Arm 2, who received sound generators alone during monotherapy, experienced a twofold increase in improvement during the polytherapy phase, with average TFI score reductions rising from 7.4 points during monotherapy to 14 points during polytherapy. Intragroup analyses confirmed significant improvements between the start and end of the polytherapy phase for both active treatment arms.

During polytherapy, participants in both active arms converged in their use of the three available sound therapy programs: amplification alone was used approximately 50% of the time, the sound generator alone about 25%, and the combined program (amplification plus sound generator) the remaining 25%. This convergence in program selection highlights one of the key rationales underlying the study design. The objective of the polytherapy phase was not to preserve strict separation between treatment modalities but rather to determine whether allowing participants to adapt sound therapy to their needs and listening environments would enhance clinical outcomes.

The observed preference for amplification-based programs, which accounted for more than 75% of overall use, suggests that participants actively selected the options they perceived as most beneficial. From a clinical perspective, these findings support the view that sound therapy should not necessarily be considered a fixed intervention but rather a flexible rehabilitative strategy that may require individualization to maximize adherence and therapeutic benefit. The greater improvement observed during this phase among participants who initially received sound generators alone may be attributable to the addition of amplification. This hypothesis is supported by the increased reports of auditory benefits, such as improved speech perception, sound localization, and environmental sound awareness during the polytherapy phase in this group.

Dissociation between psychoacoustic and subjective outcomes

Although psychoacoustic measures remained largely unchanged, significant improvements were observed in tinnitus-specific patient-reported outcomes. This apparent dissociation may reflect the limited sensitivity of conventional psychoacoustic measures to detect clinically meaningful changes in tinnitus perception. An alternative explanation is that sound therapy primarily modifies patients' reactions to tinnitus rather than the tinnitus percept itself. However, this interpretation should be considered with caution. Improvements in anxiety, depression, and sleep were observed across treatment groups, whereas improvements in tinnitus-specific outcomes were primarily observed in the active treatment arms. In addition, amplified and generated sounds produced immediate reductions in tinnitus intensity and annoyance while the hearing aids were in use. Furthermore, a significant reduction in minimum masking levels was observed in the treatment arm receiving amplification throughout the entire 12-week study period (arm 3). Taken together, these findings suggest that the benefits of sound therapy may not be fully explained by generalized improvements in psychological well-being or by habituation alone. Rather, they support the possibility that sound therapy may exert direct effects on tinnitus perception that are not fully captured by conventional psychoacoustic measures. Further research is needed to better understand the relationship between psychoacoustic outcomes and patient-reported measures of tinnitus severity and distress.

Limitations

This study has several important limitations. First, the absence of a treatment arm evaluating the efficacy of amplification alone during the monotherapy phase limits the interpretation of the current findings. Although multiple indicators suggest that amplification may be the most beneficial component of the polytherapy, given that it was used over 75% of the time, it remains difficult to isolate its specific effect, as it was only available in combination with other approaches during the polytherapy phase. A future study comparing amplification alone, placebo amplification, and a flexible approach incorporating various sound therapy programs (similar to the polytherapy phase) would help disentangle the unique contribution of amplification from that of combined interventions. Second, analyses were conducted using complete-case data and therefore did not follow a strict intention-to-treat approach. No imputation procedures were applied for missing data resulting from participant withdrawal. However, attrition was relatively low (11.7%) and balanced across treatment groups. Third, a 6-week period may not have been sufficient for some participants, particularly for those who self-reported hypersensitivity to sound and using amplification, to fully acclimatize to their hearing aids. More so, the three-month therapy period is relatively short and does not allow for assessment of the long-term effects of the different sound therapy approaches. An annual follow-up of participants from the current study could help determine whether patients continue to use sound therapy and whether its efficacy increases, stabilizes, or diminishes over time. Fourth, a formal assessment of blinding success was not performed at study completion. Consequently, it remains unknown whether participants were able to correctly identify their treatment allocation. However, participants in the placebo group demonstrated significant reductions in tinnitus intensity and annoyance following fitting sessions, suggesting that nonspecific treatment effects and patient expectations remained active within the control condition. Nevertheless, the effectiveness of blinding cannot be directly established without a formal assessment.

Finally, the conclusions regarding the efficacy of sound therapy apply only to patients with characteristics similar to those included in this study, namely, individuals with mild bilateral hearing loss and chronic bothersome tinnitus. It remains unclear whether this approach is effective for patients with normal hearing or more severe hearing loss. Future studies using a similar methodology could help establish the efficacy of sound therapies in these other clinical populations.

Conclusion

Sound therapies that combine amplification and sound generators, whether integrated into a single program or offered as separate options, significantly reduce tinnitus-related distress and handicap compared to placebo in patients with chronic, bothersome bilateral tinnitus associated with mild hearing loss over a 12-week period. The effect sizes observed in this study were moderate, and the changes were clinically meaningful. Adverse effects were infrequent, with the most reported being sound sensitivity and discomfort, which appear to be associated with amplification. In contrast, beneficial effects on auditory abilities, particularly speech perception, were frequently reported by participants receiving amplification. Overall, the findings support the use of sound therapy in the management of chronic, disabling tinnitus associated with mild bilateral hearing loss. To our knowledge, this study represents one of the first multicenter, double-blind, randomized placebo-controlled trials evaluating sound therapy delivered through hearing aids for tinnitus management. The absence of comparable RCTs limits direct comparisons but underscores the need for further research using similarly rigorous designs. These results contribute to the growing body of evidence supporting sound-based interventions and underscore the importance of individualized, flexible therapeutic approaches.

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Data availability The datasets generated and analyzed during the current study are not publicly available due to participant confidentiality and institutional data sharing policies but are available from the corresponding author upon reasonable request.

Declarations

Competing interests The authors declare no competing interests.

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Authors and Affiliations

Philippe Fournier^{1,2,3,4}  · **Hung Thai-Van**^{4,5,6} · **Pierre Reynard**⁵ · **Stéphane Gallego**⁷ · **Florine Liegeon**^{4,7} · **Alexandra Weckel**⁸ · **Paul Viudez**⁹ · **Vincent Loche**¹⁰ · **Ophélie Léplinge**¹¹ · **Christine Holler-Houdoux**¹² · **Valérie Villatte**¹³ · **Damien Bonnard**¹⁴ · **Matthieu Del Rio**¹⁵ · **Michel Kossowski**²⁰ · **Alain Londero**¹⁷ · **Hervé Bischoff**¹⁸ · **Corinne Essebag**¹⁹ · **Arnaud Noreña**^{3,4} · **Marie-José Estève-Fraysse**^{4,8,16}

✉ Philippe Fournier
philippe.fournier@fmed.ulaval.ca

✉ Marie-José Estève-Fraysse
frayssemariejose@gmail.com

¹ School of Rehabilitation Department, Faculty of Medicine, Laval University, G1V 0A6, Pavillon Ferdinand-Vandry, 1050 Av. de la Médecine, QCQuébec, Canada

² Centre interdisciplinaire de recherche en réadaptation et en intégration sociale (CIRRIS), Centre Intégré Universitaire de Santé et de Services Sociaux de La Capitale-Nationale (CIUSSS-CN), QCQuébec, Canada

³ Centre National de la Recherche Scientifique, Aix-Marseille University, Marseille, France

⁴ Université Paris Cité, Institut Pasteur, AP-HP, INSERM, CNRS, Fondation Pour l'Audition, Institut de l'Audition, IHU reConnect, Paris F-75012, France

⁵ Service d'Audiologie et Explorations Otoneurologiques, Hôpital Edouard Herriot, Pavillon U, 5 place d'Arsonval, Lyon 69003, France

⁶ Université Lyon 1, 43 Bd du 11 Novembre 1918, Villeurbanne 69100, France

⁷ Centre Audition Conseil Lyon 1, 22 Rue Constantine, Lyon 69001, France

⁸ Hôpital de Purpan CHU Toulouse (service ORL), Bâtiment Pierre Paul Riquet, 1 Place Du Docteur Baylac, Toulouse 31300, France

⁹ AUDIAL, 32 rue de Metz, Toulouse 31000, France

¹⁰ Hôpital Claude Huriez (service ORL), Rue Michel Polonowski, Lille 59000, France

¹¹ Les Laboratoires Renard, 50 rue Nationale, Lille 59000, France

¹² Nouvelles Cliniques Nantaises, 2-4 rue Éric Tabarly, Nantes 44200, France

¹³ Villatte Audition, 27 boulevard des Martyrs Nantais de la Résistance, Nantes 44200, France

¹⁴ CHU Hôpitaux de Bordeaux (service ORL), Place Amélie Raba-Léon, 33076 Bordeaux Cedex, France

¹⁵ Caudéran Audition, 43, Av. du Général Leclerc, 33200 Bordeaux, France

¹⁶ Clinique de l'Oreille à Paris, 7 Bis Rue du Louvre, Paris 75001, France

¹⁷ Université Paris Cité, Institut Pasteur, AP-HP, Hôpital Lariboisière, Service ORL, INSERM, Fondation Pour l'Audition, IHU reConnect, Paris, France

¹⁸ Audika, Paris 8e 24 Avenue de Friedland, 75008, Paris, France

¹⁹ Amplifon, 113 Amplifon Boucicaud 117 Rue De La Convention, 75015 Paris, France

²⁰ Hôpital Paris Saint-Joseph, 185 rue Raymond Losserand, 75014 Paris, France