



Evaluating time-bound efficacy of binaural beats for tinnitus treatment in individuals with normal hearing: A brainwave entrainment study

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ABSTRACT

Background: Brainwave entrainment using binaural beats has shown potential in treating tinnitus, but most studies have focused on one-month treatment durations. **Objective:** This study aimed to evaluate the time-bound efficacy of brainwave entrainment using binaural beats, comparing it to a standard tinnitus masker over a three-month duration. **Method:** Sixty-three individuals having tinnitus with normal hearing sensitivity were enrolled in the study. The participants were categorized into groups I, II, and III. They were provided with delta (4 Hz) and alpha (10 Hz) frequency binaural beats and standard tinnitus masker, respectively, for a duration of three months. The tinnitus handicap inventory (THI) scores, Visual analogue scale (VAS) rating for tinnitus distress, and quality of life parameters were measured. The reductions obtained for each measure during the end of the first, second and third month were measured and compared across the groups. **Results:** All three groups showed considerable reductions in THI and VAS scores and improvements in the quality of life domains, focusing on physical and psychological health. However, groups I and II, who received binaural beats stimuli, showed higher benefits than those who received standard tinnitus masker. **Conclusion:** The results of the current study indicated that binaural beats can be an effective treatment technique for individuals with tinnitus having normal hearing sensitivity. Clinicians and otology/audiology practitioners shall adopt this innovative treatment after further validating these findings.

KEYWORDS

Tinnitus, Tinnitus treatment, Binaural beats, Brainwave entrainment, Visual analogue scale, Quality of life.

1 Introduction

Brainwaves are 'the electrical impulses in the brain that can be typically measured using an electroencephalogram' (Adrian & Matthews, 1934). Two commonly used techniques to record brainwaves are (i) electroencephalography (EEG) and (ii) magnetoencephalography (MEG), where the former technique uses electrodes placed over various regions of the scalp to record the electrical activity, and the latter uses a magnetic field generated by the neural activity instead of electrical activity (Lopes da Silva, 2013). Based on the operating frequencies, the brainwaves are classified into different range in terms of frequency, namely, (i) delta (0.1-4 Hz), (ii) theta (5-8), (iii) alpha (8-12 Hz), (iv) beta (13-30 Hz) and (v) gamma (> 30 Hz) (Jašek et al., 2018). Brainwaves are associated with different neuro-cognitive functions and mental states (Siuly et al., 2016; Adrian & Matthews, 1934). For example, lower frequency brainwaves such as delta and theta are predominantly associated with deep sleep stages, an intensive relaxed state, or meditation. In contrast, alpha frequencies are majorly associated with activities and/or mental states involving significant cognitive

load, such as solving arithmetic, mental calculation, and processing complex sensory stimuli or tasks (Siuly et al., 2016). At the same time, higher-frequency brainwaves are associated with conditions or mental stages such as physical vigor, fight-or-flight-response events, and higher-level cognitive functioning. They are observed during psychologically triggering conditions/events such as anxiety attacks, depression, or events inducing extensive physical/mental stress (Siuly et al., 2016).

Brainwave entrainment refers to synchronizing brainwaves to external rhythmic stimulation via sensory modalities, mainly auditory and visual. The auditory stimulation for brainwave entrainment, which is also known as auditory entrainment, is achieved using rhythmically oscillating stimuli such as binaural beats, and visual entrainment, also known as photic entrainment, is stimulated using rhythmic pulsating light signals (Huang & Charyton, 2008).

A binaural beat is perceived when two individual pure tones slightly differing in frequency are presented in a dichotic fashion (Ingendoh et al., 2023; Rutschmann & Rubinstein, 1965). The resultant perceived signal would be an amplitude-modulated signal

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that has a pitch corresponding to a base frequency equal to the numerical average of the individual pure tones, wherein amplitude modulations are perceived, oscillating at a frequency that is equal to the numerical difference between the individual frequencies (beat frequency) (Becher et al., 2015). For example, presenting two pure tones of frequencies 500 and 510 Hz to each ear simultaneously would result in a base frequency signal of 505 Hz with amplitude modulations oscillating at 10 Hz.

The beat frequencies are adjusted to match the desired brainwave frequency for stimulating brainwave entrainment using binaural beat signals. The rationale of this technique is that, with constant repeated and consistent stimulations, the brainwaves get synchronized with the beat frequencies, producing changes in their corresponding associated psycho-cognitive functions (Huang & Charyton, 2008). This phenomenon has been verified and validated through various EEG studies and behavioural research works conducted on both healthy individuals and clinical populations across different disciplines (Gálvez et al., 2018; Ortiz et al., 2008; Reedijk et al., 2013a; Shekar et al., 2018a; Wahbeh, Calabrese, & Zwickey, 2007). Among these studies, auditory entrainment using brainwaves has shown to be effective in dealing with impaired or deviated psychological and cognitive measures, thereby indicating a potential utility of this technology for treating different clinical populations.

A study by (Kliempt et al., 1999) revealed a reduction in fentanyl requirement for the surgery for the group of individuals who underwent binaural beats stimulation compared to those who received classical music as a placebo stimulation, thereby suggesting the potential effectiveness of brainwave entrainment in psychophysical perceptual changes. Wahbeh et al. (2007) reported a reduction of anxiety levels and improvement in the quality of life of individuals who underwent 30-minute delta frequency binaural beat stimulation for a 60-day experimental trial. Similarly, several behavioural, and cognitive functions such as working memory, word recall capacity, short-term memory, attention, vigilance, mood states, and sleep quality have been reported by several researchers worldwide, highlighting the extent of the potential efficacy of this non-invasive and non-pharmacological technique with least or no side effects, with added advantages of the feasibility of usage, versatility, and minimized patient burden for follow up and remote access for the clinicians (Gálvez et al., 2018; Ortiz et al., 2008; Reedijk et al., 2013a; Wahbeh, Calabrese, & Zwickey, 2007). Till date, the technique of brainwave entrainment has been widely utilized in the fields of psychology and psychiatry that have reported variable treatment outcomes, where the researchers and professionals have justified some of the contradictory findings as methodological influences such as the brainwave frequency opted, stimuli used, duration of overall treatment and duration of stimulation. However, considering the potential advantages of the technique and the lack of available literature in the specific discipline, there is a need to experiment and validate the scope and extent of adaptability of the innovative method in the field of otolaryngology and audiology.

Tinnitus is a heterogeneous disorder with diverse handicap levels (Jastreboff, 1990). Primary reasons for this would be the different aetiologies resulting in the phantom perception that could be associated with auditory pathologies such as hearing loss resulting from ototoxicity, noise exposure, middle ear infections, and neural degenerative conditions or incidence involving non-auditory causes such as vascular abnormalities, temporomandibular dysfunctions, hypertension, and psychogenic factors (Eggermont, 1990; Jastreboff, 1990; Langguth et al., 2013). Another interesting

aspect is the possible influence of past life events and experiences of the individual and his/her psychological resilience, which is a crucial factor that influences the worsening of tinnitus, turning it out to be a disorder that triggers secondary negative emotions such as anxiety, annoyance, stress, depression, sleep disturbances, hence affecting the sufferer's overall quality of life (Deklerck et al., 2020; Eggermont, 1990; Minen et al., 2014). This mechanism has been explained by Jastreboff's neurophysiological model of tinnitus, where phantom perceptions and its linkage with the autonomous and limbic nervous system aggravate the severity of this sub-clinical condition, which is often ignored by a considerable percentage of patients with hearing and/or balance disorders or relevant otological condition/history (Jastreboff, 1990). Considering all the aspects mentioned above, it can be implied that irrespective of the psychoacoustical parameters of tinnitus, such as loudness and pitch characteristics, the disorder can have diverse extremities of handicap symptoms (Hiller & Goebel, 2006; Xin et al., 2022).

Several techniques have been proven to be effective in treating tinnitus and its handicap symptoms. Cognitive behavioural therapy (CBT), tinnitus retraining therapy (TRT), sound therapy, cranial nerve stimulations, and hearing aids are a few of them (Langguth et al., 2013; Makar et al., 2017). However, there is variability in treatment outcomes due to the abovementioned factors, thereby unable to have a 'golden' treatment approach for treating individuals suffering from tinnitus (Hoare et al., 2011; Makar et al., 2017). Hence, constant exploration for expanding treatment options and improvising existing techniques are essential for effectively rehabilitating the tinnitus population.

In the field of auditory health, tinnitus is a disorder that has been effectively managed through brainwave entrainment techniques, specifically using binaural beats. David et al., (2010), first reported the potential benefits of adapting binaural beats technology in combination with CBT which he referred to as 'Tinntrain- a multifactorial approach' for treating tinnitus. Recent studies by Moosapour Bardsiri et al., (2022) and Prakash & Konadath, (2024) revealed a significant improvement in tinnitus symptoms over 30 days of treatment using alpha and delta-frequency binaural beats, respectively. In the study by Moosapour Bardsiri et al., (2022), military personnel (with and without hearing loss) who reported considerable tinnitus handicap symptoms were provided with 30-minute alpha (10 Hz) binaural beats mixed with classical music. Compared to the control group, which was provided with classical music stimulus alone, there was a significant reduction of tinnitus symptoms observed in the binaural beats group.

Similar findings were observed in the study by Prakash & Konadath, (2024) where they reported an advantage of faster improvement in tinnitus symptoms in binaural beats groups compared to those who received a standard tinnitus masker for one month. The experimental stimulus was delta wave (4 Hz) binaural beats, and the standard tinnitus masker was white noise, both of 20-minute duration. The findings of both studies suggest the adaptation of the brainwave entrainment technique for the treatment of tinnitus. Despite the promising results of prior research, questions remain about the long-term sustainability of treatment benefits and the potential effects of an extended treatment duration. To address these gaps, the present study was designed to evaluate and compare the time-bound efficacy of binaural beats stimulation in the management of tinnitus over a three-month period. Additionally, the use of more comprehensive tools, such as visual analogue scales and measures of the impact of tinnitus on quality of life, was incorporated to facilitate a deeper analysis of the various aspects affected by the condition. The objectives of the

study were to compare the pre-and post-treatment measures obtained for (i) tinnitus handicap scores, (ii) visual analogue scale for tinnitus handicap, and (iii) quality of life of individuals with tinnitus having normal hearing sensitivity across the delta and alpha frequency binaural beats and a standard tinnitus masker.

2 Method

Sixty-three individuals who reported bothersome tinnitus, which was continuous in nature (with a minimum of three months duration since onset), were enrolled in the study after meeting detailed audiological evaluation and further inclusionary criteria. The overall age range of the participants was 18 to 39 years (mean age = 28.5 years; S.D. = 6.7 years). All participants had a minimum educational qualification of graduate level and were proficient in writing and reading in English.

Ethical considerations: All procedures in this study adhered to non-invasive techniques and followed standard clinical assessment and management protocols. Ethical approval was obtained from the institutional ethics review committee for bio-behavioural research involving human participants. The study was conducted in accordance with the Declaration of Helsinki guidelines. All the participants were informed regarding the objectives, steps to follow, duration of the research experiment, schedules of follow-up, and possible clinical implications of the treatment if found to be effective before their enrolment, and written consent was obtained from all the participants.

2.1 Participant selection

Individuals who reported continuous tinnitus, which included ringing, buzzing, hissing, roaring sensations, or a combination of these, having a Tinnitus Handicap Inventory (THI) score falling under mild or higher degree, were recruited for the study. Cases that presented with both unilateral and bilateral tinnitus were included. The duration since the onset varied between three months and less than a year. No participant had undergone any treatment (such as pharmacological/sound-based/cognitive behavioural-based approaches) for tinnitus before enrolling in the study. All the participants underwent an otoscopic evaluation (to rule out normal superficial anatomy of the tympanic membrane and ear canal) and a detailed audiological evaluation comprising case history that aimed to rule out any possible otological/audiological factors affecting outer ear/middle ear/cochlear functioning/auditory processing difficulties, neurological/degenerative disorders, psychological or psychiatric conditions and corresponding medication which were considered to be the exclusionary criteria. After collecting the case history and systematically ruling out potential factors that met the exclusion criteria, participants were successfully excluded. Subsequently, immittance audiometric evaluations and pure tone audiometry were conducted. All participants with either 'A' or 'As' type tympanogram with acoustic reflex thresholds present within normal sensation levels were considered for the study. All the subjects had pure tone averages of 500, 1 k, 2 k, and 4 k Hz frequencies less than or equal to 15 dB HL with individual air conduction thresholds not exceeding 25 dB HL at octave frequencies ranging from 250 to 8 kHz and speech identification scores $\geq 90\%$. The distortion product otoacoustic emissions (DPOAE) evaluations were carried out at 4 points per octave for test frequencies ranging from 1 kHz to 6 kHz to ensure healthy cochlear functioning. Those participants who met a 6 dB SNR (signal-to-noise ratio) criteria for the majority of test frequencies were considered 'PASS' for the DPOAE evaluation

and hence included in the study.

As a part of the candidacy evaluation, all the participants underwent an assessment for somatosensory tinnitus in accordance with the instructions and manoeuvre provided in the

'Tinnitus Holistic Simplified Classification' (THoSC) model given by [Cianfrone et al. \(2015\)](#) and those who presented with somatosensory tinnitus were excluded from the study. Individuals presented with intermittent tinnitus, acute onset (less than three months), and who were susceptible to experience objective tinnitus such as vascular abnormalities, hypertension etc., were excluded from the study.

Assessment of tinnitus handicap and psychological impacts

The tinnitus handicap scores were evaluated using the tinnitus handicap inventory (THI) given by [\(Newman, 1998\)](#). The questionnaire focused mainly on the emotional and psychological challenges faced by tinnitus patients. It consisted of 25 items, with a maximum possible score of 100. Each item offered three response options: yes, sometimes, or no, scoring 4, 2, and 0 points, respectively. The final score is then compared to severity classifications, which categorize the scores into varying levels of severity, from minimal or no handicap to catastrophic [\(Newman et al., 1998\)](#). The perceptual rating of distress experienced by the tinnitus patients was assessed using the visual analogue scale (VAS) that ranged from 1 to 10, where '1' indicated the least negative impact of tinnitus, whereas '10' indicated the maximum impact of tinnitus [\(Torrance et al., 2001\)](#). The VAS ratings were obtained for loudness of perceived tinnitus, annoyance, and impact of tinnitus on overall quality of life. The World Health Organization (WHO-BREF) quality of life questionnaire was used to rate the participants' quality of life (QOL) [\(Suárez et al., 2018\)](#). The questionnaire assessed the quality of life through four major domains, namely (1) physical health, (2) psychological health, (3) social relationship, and (4) environmental health. The transformed scores for the WHO-BREF questionnaire were obtained out of 20 by following the instructions and the conversion scales provided in the manual for their original versions. All three tools used for the present study were available in English and were self-administered questionnaires and rating scale. There were no differences in the psychometric function or the severity classifications for the Indian versions of the questionnaire; hence, the English versions were used in the study to obtain the data. Once the preliminary evaluations were completed, the participants were categorized into groups I, II, and III.

The grouping was done so that every group had an equal number of participants falling under specific severity. This was done to ensure maximal similarity of clinical characteristics across the groups. The groupwise demographic information of the tinnitus patients have been depicted in [Table 1](#).

2.2 Stimulus preparation

Both the stimuli for binaural beats and standard masker were generated using Adobe Audition software (version 3.0). The binaural beats were generated at a 500 Hz beat frequency by using pairs of pure tones: 498 Hz and 502 Hz for delta frequency stimuli and 495 Hz and 505 Hz for alpha frequency stimuli. The base frequency of 500 Hz was chosen based on the literature reported by [\(Perrott & Nelson, 1969\)](#), where they observed maximal perception of binaural beats around base frequencies ranging from 450 to 500 Hz. To maintain uniformity, the lower frequency was diverted into the left channel, and the higher was diverted into the right channel in the stereo pane of the software for the delta and alpha frequency beats stimuli. White noise was generated in a stereo

Table 1 Table 1 shows the groupwise demographic information of the tinnitus patients (N = 63).

	Group I	Group II	Group III	p
N (Total = 63)	21	21	21	-
Age (in years)	26.8 ± 4.4	27.4 ± 3.7	26.7 ± 5.2	> 0.05
Mean pure tone averages (in dB HL)	12.85 ± 2.1	11.17 ± 3.2	11.9 ± 2.6	> 0.05
Gender	10 M / 11 F	8 M / 13 F	12 M / 9 F	-
Unilateral/Bilateral	14 U/L, 7 B/L	15 U/L, 6 B/L	16 U/L, 5 B/L	-
Tinnitus Handicap Scores (pre-treatment)	63.65 ± 18.1	62.48 ± 15.2	59.3 ± 19.8	> 0.05
Duration since onset (in months)	5 ± 2	7 ± 2	6.5 ± 2.3	> 0.05
Mean listening duration (in mins)	17.9 ± 1.7	18 ± 0.3	18.2 ± 1.1	> 0.05

channel for the standard masker stimuli. Both the stimuli (beats and the white noise) were of 20-minute duration and converted into '.wav' format.

2.3 Procedure

Once the pre-treatment baselines evaluation and successful grouping of the participants were carried out, the patients attended a demonstration session in which the clinician explained the 'Neurophysiological Model of Tinnitus' and discussed how tinnitus can evolve into a disorder that triggers secondary negative emotions, thereby affecting an individual quality of life. Groups I, II, and III were provided with delta, alpha, and white noise, respectively. After the demonstration, the subjects were provided with a customized android application (BeatsTrain) through which the treatment stimuli were presented. The application was designed to obtain the daily playback duration data logs to track the treatment activity. The number of days played and daily playback duration were displayed against each user's database, which was accessible to the authors. The stimuli were presented using the participants' earphones connected to their mobile phones at a minimum volume level, completely masking their tinnitus (minimum masking level-MML) while listening to the stimulus. The participants were advised to listen to the stimulus daily in a calm and silent atmosphere for three months at perceptually reported most comfortable loudness (MCL) levels without changing the volume levels at any point during the three-month study period. A participant was considered to be 'dropped out' and excluded from the analyses up to not meeting the minimum monthly average duration of 15 minutes per day, consequently skipping three or seven or more total days in a month. The THI scores, VAS ratings, and QOL scores were collected one, two, and three months after the initiation of treatment.

2.4 Statistical Analyses

The statistical analyses of the data were performed using Statistical Package for Social Sciences (SPSS), version 27.0 (Armonk, NY: IBM Corp). The Shapiro-Wilk test was conducted to assess whether the data followed a normal distribution. The results revealed that pre-treatment baseline scores for the THI, VAS, and Quality of Life (QOL) domains showed a normal distribution ($p > 0.05$). Hence, to verify the similarity of pre-treatment scores across the groups, a parametric Analysis of Variance (ANOVA) was performed, which revealed no significant difference for the pre-treatment THI, VAS (loudness, annoyance, and impact on quality of life) scores and the four QOL domains across the three groups ($p > 0.05$).

As there was no significant difference in the pre-treatment scores obtained for all the parameters, the overall change in scores

observed after the first, -second, and -third months of treatment was calculated to evaluate and compare the treatment effects across the groups. The reduction in THI and VAS scores observed post- one-, two-, and three- month were calculated by subtracting the scores obtained after the first, second, and third months from their pre-treatment baseline values. As the improvement in the quality of life following a positive ordinal scale, the changes in QOL domain scores observed post- one-, two-, and three- months were calculated by subtracting the pre-treatment scores from the scores obtained from the first, second, and third months.

Analysing the changes in scores obtained by the three groups for the different parameters using the Shapiro-Wilk test, it was found that the reduction in THI scores showed normal distribution. In contrast, the changes in VAS scores and QOL domain scores showed non-normal distribution. Hence, further comparison of the changes in scores for THI, VAS, and QOL scores were performed using appropriate parametric and non-parametric tests. The figures were created using the GraphPad Prism version 8.2 for Windows (GraphPad Software, San Diego, California, USA).

3 Results

A total of 82 participants were enrolled in the study. Based on the number of days skipped and average listening duration per day, 19 participants were excluded from the analysis for not meeting the cut-off criteria. Sixty-three participants (21 in each group) completed the three-month treatment schedule and were included in the final analysis. The mean listening duration (in minutes) obtained by groups I, II, and III were 17.9 ± 1.7 , 18 ± 0.3 , and 18.2 ± 1.1 , respectively, which did not differ across the groups ($p > 0.05$).

3.1 Comparison of reduction of tinnitus handicap scores

The reduction in THI scores across the groups was analyzed using a parametric mixed ANOVA. All three groups showed a significant reduction in THI scores, with a considerable difference between the groups ($F = 251.51$; $p < 0.001$; $\eta_p^2 = 0.81$). A pairwise comparison was performed with a Bonferroni adjusted α value of 0.017. Compared to group III, who received white noise stimulus, group I and II, who received delta and alpha frequency binaural beats, respectively, showed a significantly higher reduction in THI scores ($p < 0.001$). However, no differences in treatment efficacy were observed between groups I and II (delta and alpha) ($p > 0.05$). The mean and standard deviation of the reduction of THI scores observed for the three groups have been depicted in Figure 1.

Groupwise analyses were performed to compare the treatment

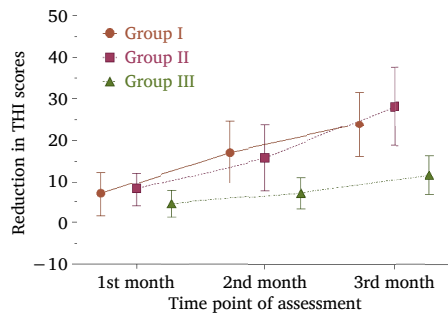


Figure 1 Figure 1 shows the mean and standard deviation of the reduction in Tinnitus Handicap Inventory scores observed for groups I, II and III during different time points of treatment.

across the first, second, and third months of treatment. All three groups showed significant differences in THI scores across the first, second, and third months ($p < 0.001$), with groups I and II having a greater effect size ($\eta_p^2_{\text{delta}} = 0.83$; $\eta_p^2_{\text{alpha}} = 0.84$) when compared to group III ($\eta_p^2_{\text{white noise}} = 0.69$).

3.2 Comparison of VAS scores

As the reduction in VAS scores showed non-normal distribution, non-parametric tests were used to analyse the statistical significance of the changes in scores obtained by the three groups. The Friedman test was used to compare the reduction in VAS scores obtained post the first, second, and third months of treatment by the groups. The results of the Friedman test have been depicted in Table 2.

The Wilcoxon Signed-Rank Test was used to carry out the pairwise comparison of the reduction in scores observed across different time points. This step was individually performed for each VAS parameter.

For the loudness of the tinnitus perception and annoyance resulting from tinnitus, the VAS ratings showed a significantly higher reduction in every succeeding month for all three groups, except for group II, for whom a significant difference was

observed for the first month ($p < 0.001$) but not post second and third month ($p > 0.05$). These findings were verified using the pairwise comparison with an adjusted α value of 0.017 ($p < 0.017$). However, for the impact of tinnitus on the quality of life, only groups I and II revealed a reduction across the different time points ($p < 0.017$) where group I showed a significant reduction post-second and third month, and group II showed a significant changes in scores obtained post all the three months ($p < 0.017$). Group III showed no significant reduction in scores during post all the time points ($p > 0.05$). The groupwise reduction of scores obtained for the VAS parameters has been shown in Figure 2.

To analyse the treatment efficacy across the groups, the scores obtained by the groups during the first, second, and third months were compared using the Kruskal-Wallis test. No significant differences were observed in the reduction in loudness between the groups ($p > 0.05$) at any time point during the treatment. In contrast, for annoyance and impact on quality of life, groups I and II showed a higher reduction of scores compared to group III ($p < 0.01$) during all treatment time points.

3.3 Comparison of changes in quality-of-life domain scores

The changes in QOL domain scores in the first, second, and third months were compared using the Friedman test. The results of the Friedman test are depicted in Table 3.

The pairwise comparison across different treatment time points was carried out for individual groups using the Wilcoxon Signed-Rank Test with an adjusted α value of 0.017. For domain 1, both groups I and II showed significant improvement in scores in every succeeding month ($p < 0.01$), and group III showed improvement during the first and second month ($p < 0.01$) but not during the third month ($p > 0.05$). For domain 2, all three groups showed significant improvement during all treatment time points.

For domain 3, no significant improvement was observed for any group during any time point of the treatment period ($p > 0.05$). For domain 4, group I showed significant progress during the second and third months ($p < 0.001$), whereas for groups II and III, there were no changes observed across the time points

Table 2 Table 2 shows the results of the Friedman test performed to compare the reduction in VAS scores for loudness, annoyance and quality of life parameters for the three groups across different time points of treatment.

	VAS-Loudness		VAS-Annoyance		VAS-Quality of Life	
	Chi-Square (χ^2)	p	Chi-Square (χ^2)	p	Chi-Square (χ^2)	p
Delta	23.52	< 0.001	34.27	< 0.001	31.68	< 0.001
Alpha	24.98	< 0.001	27.06	< 0.001	31.08	< 0.001
White noise	21.66	< 0.001	26.32	< 0.001	4.93	0.09

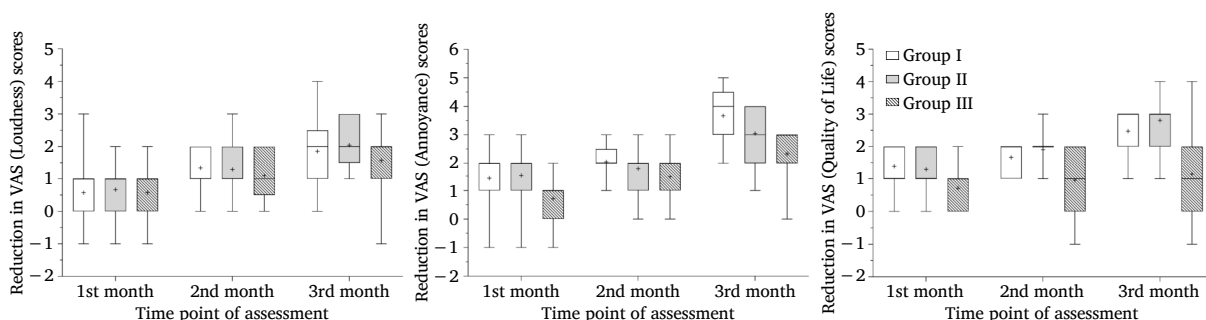


Figure 2 Figure 2 showing the reduction Visual Analogue Scale ratings for the loudness, annoyance and impact on quality of life observed for groups I, II and III across different time points of the treatment.

Table 3 Table 3 shows the result of Friedman test performed to compare the changes the Quality-of-Life Domain scores observed for each group during different time points of treatment.

	QOL-Domain 1		QOL-Domain 2		QOL-Domain 3		QOL-Domain 4	
	Chi-Square (χ^2)	<i>p</i>	Chi-Square (χ^2)	<i>p</i>	Chi-Square (χ^2)	<i>p</i>	Chi-Square (χ^2)	<i>p</i>
Delta	37.39	< 0.001	37.54	< 0.001	10.08	0.07	12.51	0.002
Alpha	31.71	< 0.001	32.07	< 0.001	2.94	0.23	1.72	0.42
White noise	24.75	< 0.001	32.38	< 0.001	0.29	0.98	4.48	0.1

($p > 0.05$). The descriptive findings of the QOL domain scores observed for the groups have been depicted in Figure 3.

The Kruskal-Wallis test was performed to compare the scores obtained during all three time points for each domain to compare the treatment efficacy across the groups. For all three time points for domains 1 and 2, there was a significantly higher improvement in scores demonstrated by groups I and II ($p < 0.01$). In contrast, for domain 3, no differences were observed between the groups during any time points. For domain 4, group I showed a significantly higher increase in scores compared to II and III post the first month of treatment ($p < 0.017$).

4 Discussion

Recent advances in research over the past decade have unveiled expanding possibilities of application of brainwave entrainment using binaural beats technology in the field of psychology/psychiatry as well as among healthy populations due to its non-invasive nature, non-involvement of side effects such as pharmacological/medical approaches, convenience of usage and ease of customization (Banerjee, 2020; Huang & Charyton, 2008). Several

neuro-cognitive behavioural measures have been observed to be influenced by binaural beat stimulation (Huang & Charyton, 2008). A study by Ortiz et al., (2008) revealed an improvement in word recall scores after 15 days of stimulation of theta frequency (5 Hz) binaural beats. In contrast, no immediate improvements were observed during the initial trial when assessed word recall scores were followed by 30 minutes of stimulation of binaural beats. The authors inferred that immediate effects were not elicited/observed after a single brainwave entrainment session. However, the same was achieved after 15 days of regular stimulation, highlighting the impact of brainwave entrainment when applied consistently over an extended duration.

Contrary to the finding reported by (Ortiz et al., 2008), there was a reduction in the participants' word recall performance observed in a study carried out by Wahbeh et al., (2007). These discrepancies were due to several factors, which the authors addressed by suggesting that more reliable outcomes could be achieved over a longer duration of experiments. In support of this statement, several parameters, including chronic pain, anxiety and stress levels, working memory capacity, attention skills, and reaction

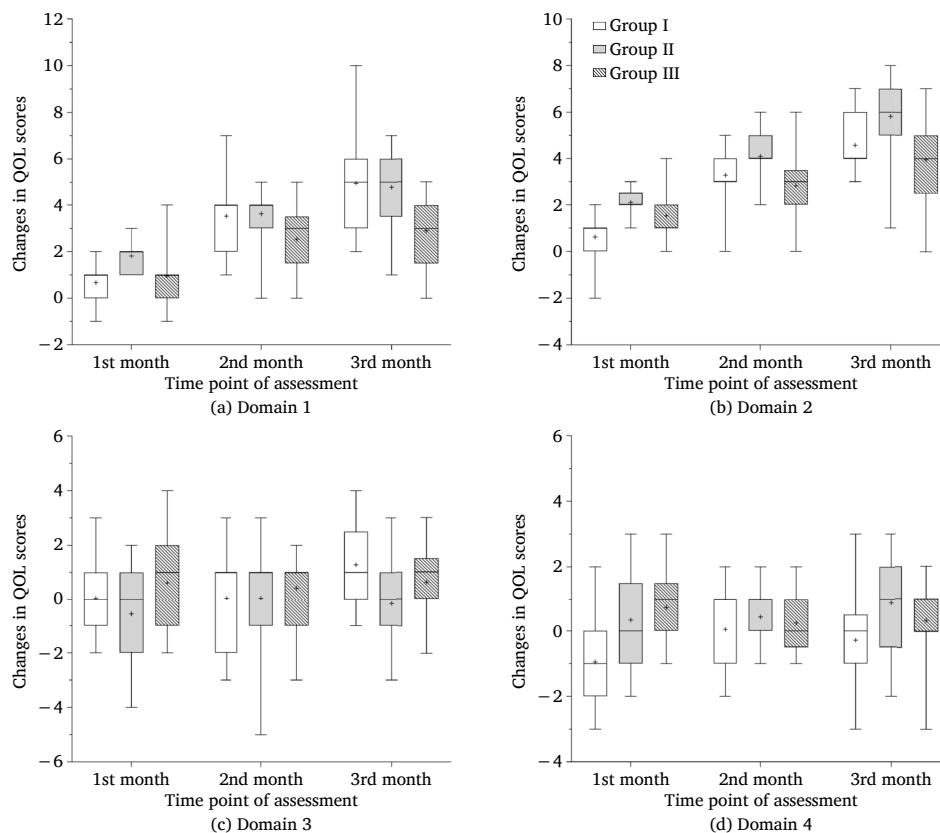


Figure 3 Figure 3 showing the changes in Quality-of-Life domain scores observed for groups I, II and III during different time points of the treatment. (Note: Domain 1- Physical health, 2- psychological health, 3-social relationships. And 4-environmental health).

time, showed significant improvements when brainwave entrainment stimulation was administered over a period ranging from two to eight weeks (Colzato et al., 2017; Ecsy et al., 2017; Gkolias et al., 2020; Kraus & Porubanova, 2015; Reedijk et al., 2013b; Shekar et al., 2018b; Wahbeh et al., 2007). These findings highlighted the scope for reliable and extensive benefits of adopting a more extended treatment duration.

The first study that reported the effectiveness of brainwave entrainment in the treatment of tinnitus patients who presented with clinically normal hearing sensitivity was by Prakash & Konadath (2024), where they used 20-minute delta-frequency binaural beats, which showed to be beneficial to the tinnitus population. Previous research reports by David et al. (2010) and Moosapour Bardsiri et al. (2022) revealed a similar efficacy of this innovative technique in treating tinnitus populations (with and without hearing loss).

Furthermore, the current study extended the treatment duration to three months, revealing the sustained benefits of brainwave entrainment in reducing tinnitus handicap and addressing long-term outcomes. This extended timeline also helped rule out any potential placebo effects, offering a more reliable evaluation of treatment efficacy. In addition, the inclusion of alpha-frequency binaural beats as a treatment stimulus enabled a deeper understanding of its relative benefits compared to delta-frequency beats and the standard white noise masker. These findings build upon and expand the insights from Prakash & Konadath (2024), providing a broader, comparative analysis of binaural beat stimuli tailored to delta and alpha brainwave frequencies. This comprehensive approach underscores the adaptability and efficacy of binaural beats, particularly when compared to sound therapy, which remains a conventionally accepted treatment technique for tinnitus.

The results of our study showed that binaural beats were more effective than the standard tinnitus masker over a three-month treatment period. Higher reductions in THI scores were noted for the delta and alpha groups compared to those who received white noise masker. Binaural beats may help reduce tinnitus by promoting relaxation through brainwave entrainment, which can partially or completely mask the tinnitus depending on its pitch and characteristics of perceived tinnitus. These results align with previous studies by David et al. (2010), Moosapour Bardsiri et al. (2022), and Prakash & Konadath (2024). However, this study showed a steady improvement in symptoms month after month with ongoing treatment, which was revealed by the significant reduction in THI scores over the first, second, and third months.

A similar trend was observed in the reduction in VAS ratings, where all three groups showed significant decrements in loudness and annoyance ratings. All three groups showed similar effects in reducing the loudness of tinnitus. This could be attributed to the masking effect of the stimuli, where both binaural beat stimuli showed a similar effect to that of a standard tinnitus masker. However, considering the annoyance parameter, binaural beats stimuli showed an advantage over the white noise during each time point of treatment (refer to Figure 2). A similar trend was observed for VAS ratings for the impact of tinnitus on quality of life. The soothing and relaxing effects of consistent stimulation using low-frequency oscillating beats and its corresponding functional neuroplastic changes would be the reason for these effects (Huang & Charyton, 2008; Prakash & Konadath, 2024).

The concept of 'quality of life' is a broad term encompassing a variety of subjective and external factors, including mental and physical well-being, social interactions, environmental conditions,

and occupational satisfaction. To thoroughly understand and document the effects of tinnitus treatment across these diverse areas, we used a combination of assessment tools. Alongside the Visual Analog Scale (VAS), which provides a straightforward measure of symptom severity from the patient's perspective, we employed the WHO-BREF Quality of Life questionnaire. This tool allowed a comprehensive evaluation by examining the quality of life across multiple domains- physical health, psychological well-being, social relationships, and environmental factors.

In the current study, domains 1 and 2, which focus on physical and psychological health, showed significant improvements in groups I and II, who received binaural beats stimulation, compared to those exposed to white noise. At the same time, no differences were seen between any groups for domains 3 and 4, which emphasized social relationships and environmental factors. A possible explanation for this effect would be that domains 1 and 2 of the questionnaire mainly covered aspects of daily life that are likely to be impacted by tinnitus. These included activities of daily living, pain, energy levels, work capacity, sleep quality, and rest. Additionally, the domains addressed emotional well-being, such as feelings of positivity and negativity, cognitive functions like thinking and concentration, and self-esteem (Eggermont, 1990; Jastreboff, 1990; Langguth et al., 2013; Makar et al., 2017). These areas are closely related to how tinnitus can affect overall quality of life. At the same time, the test items in 3 and 4 domains were less likely to be influenced by tinnitus.

Among the groups, the delta group showed a significant difference during the second month in domain 4 scores; however, the validity of this finding must be further validated as there were no differences were observed post-third month of the treatment and theoretically lacks a correlation that is mentioned above.

The groups that received the delta and alpha waves showed similar improvements during the study. This could be a possible effect of a comparatively smaller sample size or because delta and alpha waves are falling in lower brainwave frequency closely associated with a relaxed state of mind, such as in light/deep sleep or meditation (Siuly et al., 2016).

The result of the current study highlights that binaural beats could be adapted as an effective treatment technique for tinnitus. Extending the experiment for three months revealed improvement in a small portion of participants that remained in the lower quartile (refer to Figures 2 and 3), which also significantly improved during the following months. This innovative technique has proven to be relatively quicker in showing results, and it is both convenient to customize and easy to access for follow-up.

Limitations and future directions

As the study followed a purposive sampling, randomized allocation was not possible. Hence, future research experiments shall be conducted randomly on a larger sample with treatment across patients. This technique should be used alongside existing tinnitus treatments to enhance the speed of improvement and supplement the overall efficacy of the treatment. The effects of higher-frequency binaural beats shall be explored in future experiments,

5 Conclusion

The present study was performed to monitor and compare the efficacy of brainwave entrainment using binaural beats stimulation compared to standard tinnitus masker over three months of treatment duration. The results indicated that binaural beats can be an effective treatment technique for individuals with tinnitus having normal hearing sensitivity. To sum up, these results emphasize the

wider clinical importance of managing tinnitus, pointing to the necessity for long-term strategies that not only address immediate concerns but also support individuals in managing the ongoing challenges of living with tinnitus. The method shall be adopted by the clinicians and otology/audiology practitioners after further validation of these findings through randomized controlled trials.

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