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An increase in the auditory steady-state response amplitudes after a period of listening to binaural beat stimuli in tinnitus patients: a pilot study

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Abstract

Background Tinnitus impact on persons' lifestyle, function, and emotion is of significant importance that has been the leader for conducting an increasing amount of research in the field of tinnitus pathophysiology, assessment, and management. Binaural beats (BB) are one of acoustic neuromodulation approaches used in psychological disorders, such as distress and anxiety. Thus, we hypothesized that binaural beat could be helpful in the relief of tinnitus distress and annoyance.

Methods Seventeen chronic tinnitus subjects participated in this quasi-experimental (quantitative research) study. In this study, the effect of binaural beat stimuli was evaluated subjectively using the tinnitus handicap inventory (THI) scores, the visual analog scale for loudness and annoyance (VAS_L, VAS_A), and objectively by the 40-Hz ASSR after 1 month of listening to binaural beats, and the correlation between these two assessments was evaluated.

Results After 1 month of binaural beat stimuli listening, all of the subjective findings were significantly improved, and the amplitude of 40-Hz ASSR was increased in the right auditory and anterior frontal regions at 2000-Hz carrier frequency. Besides, there was a high correlation between the decreasing of the subjective scores with the rising of the amplitude of 40-Hz ASSR.

Conclusion The use of binaural beat as an acoustic neuromodulation method for tinnitus management may be recommended according to the current study findings. However, more investigations on the effectiveness supported by data from controlled clinical trials and more correlations with ASSR alteration are highly suggested.

Keywords Tinnitus, Tinnitus handicap inventory, 40-Hz auditory steady-state response, Binaural beat, Tinnitus network

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Background

Tinnitus is an auditory phantom perception of sound that affects the life of 18–24% of people around the world. Tinnitus is often associated with symptoms such as annoyance, depression, sleep disorder, and insufficient concentration which are usually the result of its related distress [1].

Different theories and models concerning the generation of tinnitus have been proposed [2]. The most recent models are the tinnitus network and chaos [2, 3]. Based on the tinnitus network model, tinnitus is the result of broad network activation in which the auditory cortex is the central hub, and many other areas serve as the perception, salience, and distress-related hubs in the network [4, 5]. The prefrontal cortex is the most interconnected hub in the network. Besides, the self-perception network including the precuneus, anterior cingulate cortex (ACC)/ventromedial prefrontal cortex (VMPFC)/posterior cingulate cortex (PCC), and the superior part of the anterior parietal lobes is usually activated for the conscious perception of tinnitus [2]. Based on the chaos model in tinnitus, a small change in the brain input can bring about some huge and irregular changes in the overall brain function which can explain vast negative outcomes of tinnitus and insufficient of its current management methods [3].

In the last decades, different treatment methods have been described for the management of tinnitus. The psychological-based methods could attain evidence like cognitive behavioral therapy (CBT) and acceptance commitment therapy (ACT) [6]. Hearing aids, and the different kinds of sound therapy including total and partial masking, adaptation, and acoustic neuromodulation, are also widely used with remarkable positive effects on tinnitus loudness and annoyance [5, 7, 8]. Acoustic neuromodulation using sound therapy has been proposed to decrease tinnitus distress and its negative outcomes [9]. This method decreases the abnormal simultaneous activity of the brain neurons in different ways and manages tinnitus through controlling the simultaneous activity of the neurons involved [10]. Binaural beat (BB) is a kind of sound therapy that is used for the treatment of many problems such as attention deficit, hyperactivity, sleep disorders, and anxiety [11]. When two pure tones of slightly different frequencies are simultaneously delivered to the two ears separately, a certain beat is created whose frequency corresponds to the difference between the tones; this phenomenon is called binaural beat [11, 12]. Hearing the beats is linked to the binaural integration and the interaural time difference [11]. Clinical trials that used binaural beat have demonstrated its substantial effects in decreasing distress and anxiety [13]. Such positive outcomes of BB are the result of the changes in the neurons' activity [12]. Built on that, we supposed that BB can help decrease both tinnitus distress and annoyance by encouraging acoustic neuromodulation in the brain neurons.

Tinnitus is completely subjective in its perception and related distress. Therefore, subjective methods, like THI, TQ, and VAS scores, have been widely used in tinnitus assessment. The 40-Hz auditory steady-state response is one of the electrophysiologic tests supposed to be effective in assessing tinnitus [14]. Previous studies indicated that the amplitude of electrophysiologic assessments such as ASSR can change in the tinnitus patients in comparison with normal subjects [14–16]. Another study indicated that the amplitude of ASSR is directly related to the amount of tinnitus distress in the annoying chronic tinnitus. In other words, if the tinnitus distress decreases, the amplitude of the ASSR will probably increase and vice versa [17].

The current study used BB as an acoustic neuromodulation approach to relieving distress in subjects with chronic tinnitus. Both subjective and objective scales were used to assess the treatment outcomes. The study hypothesized that BB can decrease the THI and VAS score after 1 month of listening to the BB stimuli. Besides, the 40-Hz ASSR amplitude was supposed to increase after the intervention. Added to all, the study aimed to find correlations between the subjective scales' changes and ASSR amplitude alteration pre and post the treatment.

Methods

The eligible participants were selected by filling out a preliminary questionnaire (to assess the tinnitus features such as duration, location of tinnitus, and…) and the primary auditory evaluations. All patients who had ear diseases such as Meniere or otosclerosis and acute or chronic neurological/psychiatric diseases like depression, Alzheimer's, and epilepsy were excluded. To assess the absence of depression in all of the participants, they were examined by a validated Persian version of the Hospital Anxiety and Depression Scale (HADS) [18]. Other inclusion criteria were as follows: obtaining at least a score of 20 in the mini-mental state examination (MMSE) questionnaire [19], the hearing sensitivity better than 20-dB HL in the low- and mid-frequencies (250–1500 Hz), and better than 40-dB HL in the upper frequencies (2000–4000 Hz); the age range was 30–65 years. None of the subjects should have participated in any other tinnitus treatments simultaneously. All patients have filled out the research consent form.

Considering the above criteria, 35 tinnitus sufferers were screened, 11 (31%) of which did not have suitable entrance criteria for this study. From those, six subjects had hearing loss. The other three subjects had severe psychological problems, and two subjects were over 65 years of age. Twenty-four subjects had the entrance criteria, 17 of whom decided to continue through the entire tinnitus management period ($M = 53.88$, $SD = 7.73$) (nine males and eight females). The duration of the research and tinnitus management for all of the participants was 6 months. The participants' flow was shown in Fig. 1.

All participants have passed the tinnitus psychoacoustic evaluations including tinnitus loudness and pitch matching and filled out the tinnitus handicap inventory (THI) questionnaire. Besides, the amount of loudness and annoyance of tinnitus was evaluated by visual analog scale-annoyance (VAS-A) and visual analog scale-loudness (VAS-L). VAS-L and VAS-A are two important and fast scales for evaluating loudness and annoyance of tinnitus. Generally, VAS is a rating scale that patient rates his health outcome and places a corresponding mark along a printed line (0–10) [20]. All of the above evaluations were repeated after the intervention. Tinnitus loudness and pitch matching psychoacoustic evaluations were considered through the adaptation method and audiometric device. The above assessments were performed to determine the amount of improvement in the tinnitus loudness and its negative effects.

Binaural beat stimuli in the range of alpha band (10 Hz) were used because this is the frequency to decrease anxiety and stress. To create the binaural beat, 10 Hz, 400-Hz pure tone, and 410-Hz pure tone were presented separately to both ears simultaneously. Both of the pure tones were built by MATLAB software with a 44,100-Hz sampling rate (Fig. 2). According to previous studies, we decided that each tinnitus patient listened to the binaural beat stimuli for 2 h a day for 1 month [21]. The presentation procedure was in four 15-min blocks in pre-determined times by personal mobile phone in stereo (hands-free) at the most comfortable intensity level (25–40 dB SL upper hearing threshold in presentation frequency). To control this time, all of the patients had to record the time and duration of hearing in the forms given to them. Also, to monitor more closely, we called them daily to assure they are dealing with it well. It should be noted that all of subjective and electrophysiologic measures were made during 24 h before and after starting and ending listening to BB stimuli.

EEG was recorded using a 32-electrode EEG cap. The electrodes were located at points FP1, FPz, FP2, F7, F3, Fz, F4, F8, FT7, FC3, FCz, FC4, FT8, T3, C5, C3, Cz, C4, C6, T4, T5, P3, Pz, P4, T6, O1, and O2 on the scalp according to the international 10–20 system [9]. The reference electrode was located on the right mastoid

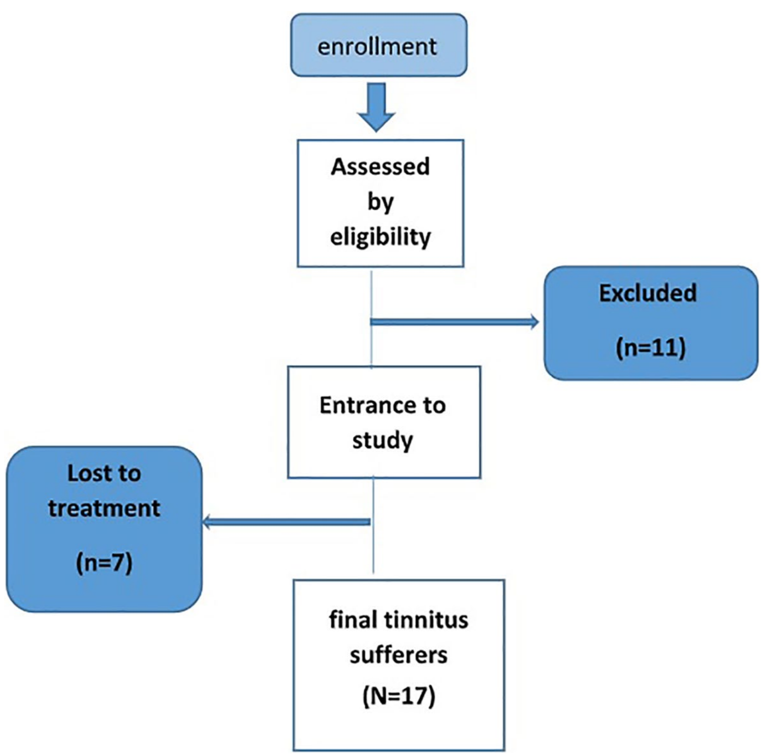

Fig. 1 Participant flow

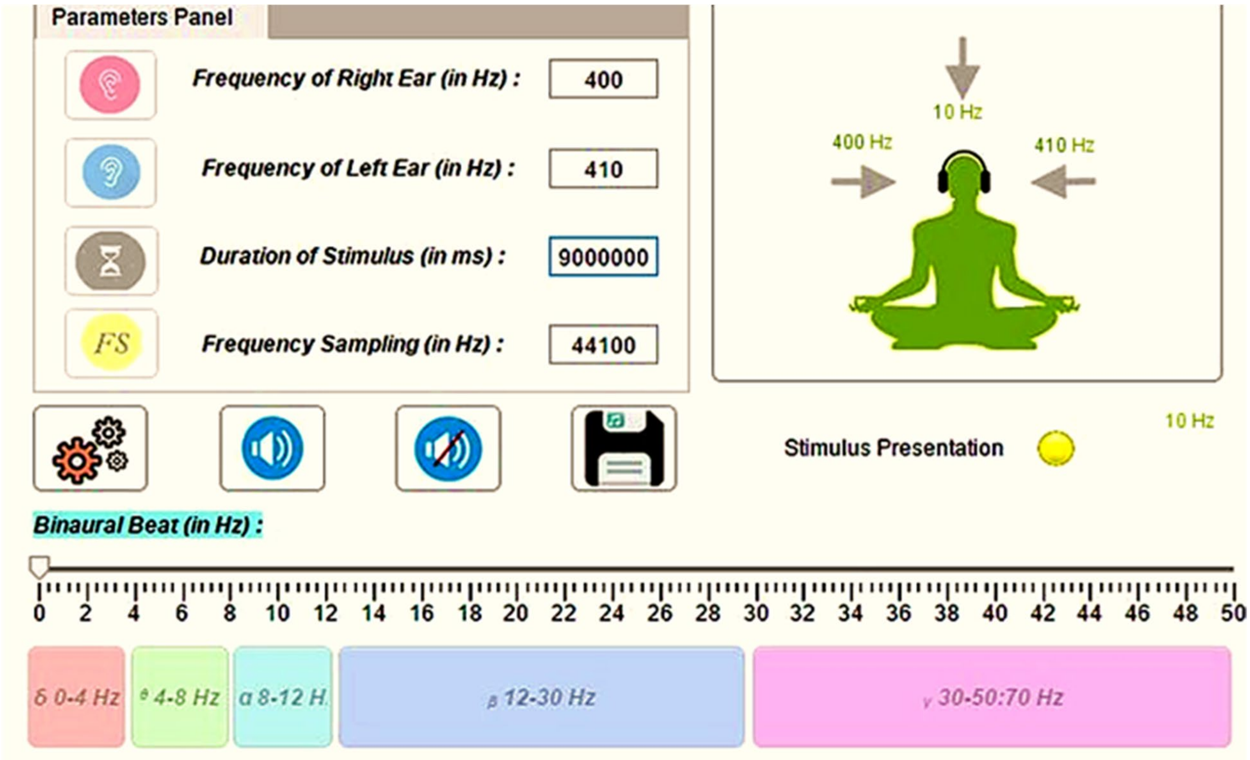

Fig. 2 Software for making binaural beat stimuli

prominence and the ground electrode on the forehead. Electrooculograms were monitored by two electrodes located below and near the outer canthus of the left eye. Electrode impedances were kept below ten Ω, and the online sampling frequency was 512 Hz with a band-pass filter of 0.04–200 Hz. A custom-designed micro-controller device received digital interface events and triggered the stimuli events. The subject was stimulated by two loudspeakers located 1 m in front of the seat at a 45° angle from the midline. They were asked to relax and avoid eye and body movements and to disregard the ASSR auditory stimuli. They were encouraged to stay awake by watching a subtitled silent documentary movie that was shown on a monitor in front of them during the EEG recording.

The ASSR stimuli included three amplitude-modulated carrier frequencies delivered at low (500 Hz), mid (2 kHz), and high (4 kHz). The frequencies were created digitally in MATLAB and presented using presentation software (version 0.71, Neurobehavioral Systems, USA) at the most comfortable level for each subject, with a modulation rate of 37 Hz, the modulation depth of 100%, and duration of 8129 ms, with 20 ms onset and offset cosine ramps. To acquire appropriate ASSR responses, each AM stimulus was delivered 50 times repeatedly. Interstimulus intervals varied randomly from 800 to 1200 ms [15].

MATLAB was used to analyze the ASSR responses. After removing the eye and body movements and noise, the responses were transformed into the frequency domain by fast Fourier transform, and the presence or absence of responses was assessed by the F-ratio test. Two regions of interest (ROI) that most closely correspond to the ASSR network and tinnitus-distress network were chosen to analyze and compare the ASSR amplitude. These were the anterior frontal (F3, Fz, F4) and right auditory (C4, T4, C6) regions [17].

The data were statistically analyzed using SPSS software version 19. All of the data had a normal distribution. The paired t-test was used to compare the results of ASSR 40-Hz amplitude pre- and post-measurement, as well as to compare the results of subjective evaluations pre- and post-binaural beat stimulation. Also, we have used the Pearson correlation test to investigate the relation between the subjective findings and the amplitude of ASSR 40 Hz. A P-value of < 0.05 was considered statistically significant. The study was approved by the ethics committee of Iran university of medical sciences.

Results

Table 1 shows the clinical and demographic features of the tinnitus sample at the enrollment time. The outcomes of the paired *t*-test revealed that there was a significant difference between the THI score before and after the intervention (P-value $= 0.017$). Besides, there was a difference in the scores of VAS-L and VAS-A (P-value < 0.001). The psychoacoustic tinnitus loudness evaluation presented another difference between the averages of tinnitus loudness in these two periods (P-value < 0.001). Table 2 and Fig. 3 a and b show the results of these measurements.

The amplitude of ASSR 40 Hz in pre- and post-tinnitus management was compared individually in those two regions (right auditory and anterior frontal) at three frequencies (low (500 Hz), mid (2000 Hz), and high (4000 Hz)) using paired *t*-test. Table 3 shows the results of these comparisons. The amplitude of ASSR 40 Hz at right auditory area at mid-frequency showed a statistically significant increase (P-value $= 0.004$) after tinnitus management.

In anterior frontal region, the amplitude of ASSR 40 Hz at mid-frequency also yielded a statistically significant increase (P-value $= 0.005$) after tinnitus management, but at low and high frequencies, no significant difference was observed between pre- and post-ASSR 40-Hz amplitude. Figure 4 reveals a map graphic of ASSR 40-Hz amplitude in right auditory and anterior frontal regions before and after tinnitus management with binaural beat stimuli. We used a Pearson correlation test to assess the relationship between the subjective evaluation results and the ASSR 40-Hz amplitude changes. In this section, we examined the correlation between the amount of change in the scores of subjective variables (THI, VAS-L, VAS-A, tinnitus loudness) before and after intervention with the amount of change of ASSR 40-Hz amplitude at mid-frequency and both the regions of interest before and after the intervention. The findings showed that there was a moderate negative correlation between the change of scores of THI and VAS-L with the changes of ASSR 40-Hz amplitude at both regions (right auditory and anterior frontal) at mid-frequency. Besides, a highly negative correlation between the changes of tinnitus loudness and the changes of ASSR 40-Hz amplitude was observed in the right auditory region. This means that the lower the tinnitus loudness or the lower the THI/VAS-L scores, the higher the ASSR 40-Hz amplitude. Table 4 shows the results of the correlations.

Table 1 The clinical and demographic features of tinnitus patients

Tinnitus subjects	**17**
Age(years)	53.88 ± 7.73
Male/female	9/8
Tinnitus type	
Tonal/NBN	13/4
Tinnitus laterality	
Right/left/both	4/3/10
Tinnitus duration (months)	62.35 ± 88.94
Tinnitus loudness	6.76 ± 3.09
Tinnitus pitch matching	5.17 ± 1.91

Discussion

In this study, we used binaural beat stimulation as an acoustical neuromodulation method for tinnitus management. The results of our study revealed that the patients experienced a significant decline in the severity and annoyance of their tinnitus as well as a significant increase in the ASSR 40-Hz amplitude after listening to these stimuli.

The binaural beat can affect the responses of brain neurons through entrainment is the phenomenon in which the frequency of the brain activity becomes equal to the frequency of an external stimulus [13, 22]. The

Table 2 The results of the subjective and psychoacoustic evaluations before and after tinnitus management

	Mean (pre)	**Mean (post)**	**Paired difference**					***T***	**Sig. (2 tailed)**
			Mean	**Std. deviation**	**Std. error mean**	**95% confidence interval of the difference**			
						Lower	**Upper**		
Loudness	6.76	4.7	2.05	1.39	0.33	1.34	2.77	**0.000**	6.1
VAS_L[a]	6.05	4.88	1.17	1.01	0.24	0.62	1.69	**0.000**	4.71
VAS_A[b]	6.76	4.7	2.05	1.56	0.378	1.25	2.85	**0.000**	5.44
THI[c]	52.88	43.35	9.52	14.79	3.58	1.92	17.13	**0.017**	2.65

[a] Visual analog scale-loudness, [b]visual analog scale-annoyance, [c]tinnitus handicap inventory

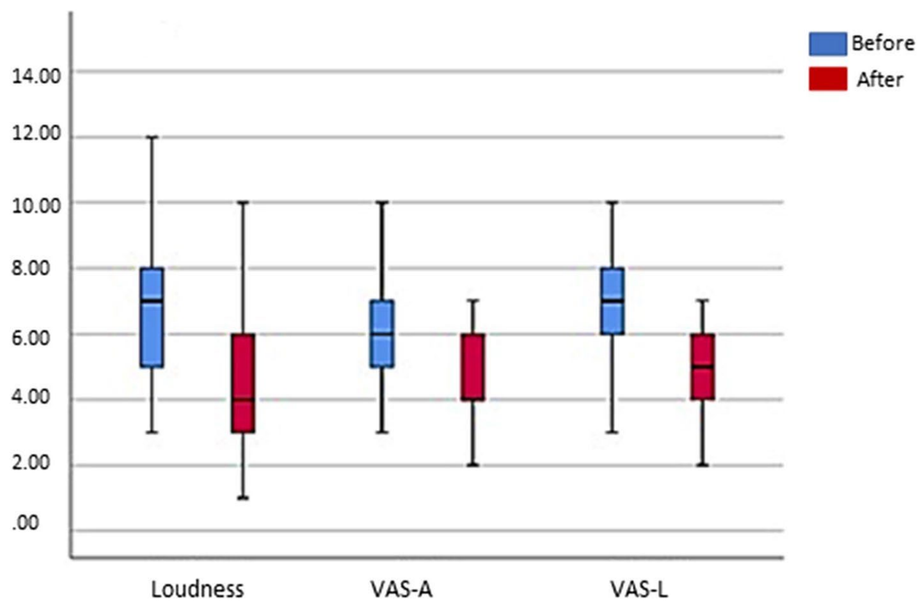

Fig. 3 The boxplot curve of loudness, VAS-L and VAS-A measurements in tinnitus patients before and after BB exposure

entrainment is generated in the brainstem as a result of a continuous activity from a group of neurons. These responses are phase locked to the envelope of the periodic stimuli and/or particular segments of an external sound. This phenomenon is the result of the frequency following response (FFR) generation. The binaural beat can induce the FFR of the same frequency to synchronize the brainwaves with them by which the brain processing will change [22]. As reported by previous studies, the binaural beat stimuli seem to reduce the anxiety and distress in the patients. We used BB of the alpha-frequency range (8–10 Hz) to decrease anxiety and stress since the predominant frequency of human brainwaves in an awake and calm state is the alpha-frequency band [11, 23, 24]. Many studies have demonstrated decreased activity of alpha band in tinnitus distress network [25]. Our findings showed that the annoyance and anxiety of tinnitus have been decreased which suggests that the binaural beat stimuli may have been able to reduce the activity of the distress network associated with the tinnitus network by inducing the alpha band frequency in the brain.

Our results showed that the score of THI and VAS-A decreased after 1 month of listening to the binaural beat, indicating that the intervention had been able to reduce handicap and anxiety of tinnitus. Gao et al. showed that the alpha binaural beat can induce an increase in the power of the alpha band and a decrease in the theta band [23]. Since the increase of the brain alpha rhythm power helps in relaxation, it can be concluded that listening to alpha binaural beat for a month could bring relaxation to patients which leads to a decrease of tinnitus anxiety and handicap.

The score of VAS-L and psychoacoustic tinnitus loudness also decreased after the BB intervention. According to the aforementioned tinnitus mechanism, as a consequence of the imbalance between excitation and inhibition, a new auditory map reorganization and plasticity can be created [5]. The current study suggests that tinnitus loudness might be reduced by the decrement of the aberrant synchronization of neural activity due to using BB; however, such a claim needs more investigation. In addition, tinnitus network is a large network, and that the temporal bone is its comprehension part [25]. On the other hand, temporal bone is one of the most important areas affected by BB [22]. So, it makes sense that BB is able to change the tinnitus activities in this part.

As previously mentioned, the ASSR 40-Hz amplitude increased in both the auditory and frontal regions. Few studies have demonstrated similar findings; Roberts et al. showed that the stimulations of 40-Hz frequency modulation could increase the ASSR 40-Hz amplitude in tinnitus as a training approach. He also suggested that after presenting a masking noise in the range of tinnitus pitch, the ASSR 40-Hz amplitude increased at the carrier frequencies of the same region [26, 27].

The temporal lobe is the original site of detection and perception of environmental and speech sounds and showing a definite tonotopic map. The tonotopic map changes in the tinnitus patients as a result of auditory deafferentation leading to an aberrant reorganization of

Table 3 The results of ASSR 40-Hz (μv) amplitude comparison in two regions of interest

	Mean (pre)	Mean (post)	Paired difference					T	Sig. (2 tailed)
			Mean	Std. deviation	Std. error mean	95% confidence interval of the difference			
						Lower	Upper		
Anterior frontal (low frequency)	236.65	218.06	18.58	111.76	27.1	−38.87	76.05	0.68	0.5
Anterior frontal (mid-frequency)	167.18	249.82	−82.64	105.13	25.49	−136.7	−2859	−3.24	**0.005**
Anterior frontal (high frequency)	144.18	140.12	4.05	107.52	26.07	−51.22	59.34	0.156	0.87
Right auditory (low frequency)	225.08	201	24.05	128.08	31.06	−41.79	89.91	0.774	0.45
Right auditory (mid-frequency)	128.94	219.89	−90.88	109.72	26.61	−147.29	−34.46	−3.41	**0.004**
Right auditory (high frequency)	124	133.41	−9.41	100.19	24.3	−60.92	42.1	−0.38	0.74

the central auditory system [28, 29]. On the other hand, the original area of ASSR generation is the primary auditory cortex [28]. Increased ASSR amplitudes in the temporal lobe after BB suggest that the auditory neurons were not able to function well at this stimulation rate before treatment because of an aberrant tonotopic map. However, after the intervention, it seems that the auditory neurons become more inclined to activate at this stimulation rate, and their activity has got more simultaneous. On the other hand, in subjects with tinnitus with high distress (high score of THI), the activity of the tinnitus network is affected by the distress network [30]. While after intervention, the binaural beat has probably downregulated the activity of distress network. Since the tinnitus network is interconnected to the major stress network, it seems that any increase in the amplitude of ASSR is probably due to the downregulation in the tinnitus network which can be related to reducing anxiety in tinnitus patients.

Also, in the frontal lobe, the ASSR amplitude increased after the intervention. The frontal lobe, especially in the anterior segments, is responsible for controlling anxiety and distress and emotional responses [1, 30]. Research has shown that neural activity increases as a result of tinnitus distress in this region [1]. Therefore, it can be concluded that by using the binaural beat, the aberrant increase of stress-induced inhibitory neurotransmitters decreases, and consequently, the ASSR amplitude increases [1, 31].

Table 4 The results of the correlation between the changes of subjective evaluations and the changes of ASSR 40-Hz amplitude in two regions of interest

	Right auditory		Anterior frontal	
	Correlation index	*p*-value	Correlation index	*p*-value
THI[a]	**−0.573**	**0.016**	**−0.549**	**0.023**
VAS-L[b]	**−0.538**	**0.026**	**−0.558**	**0.02**
VAS-A[c]	0.334	0.19	−0.01	0.971
Loudness	**−0.604**	**0.01**	0.512	0.319

[a] Tinnitus handicap inventory, [b]visual analog scale-loudness, [c]visual analog scale-annoyance

Previous studies suggested a correlation between tinnitus psychoacoustic findings and neural activity in the brain indicating the tinnitus impact on the neural activities [32]. Some studies yielded similar correlation between subjective and objective findings after treatment showing the efficacy of therapeutic approaches [33, 34]. Our findings revealed a negative correlation (more than 50%) between the decrease in THI and VAS-L scores and the increase of ASSR amplitude in both regions of interest. There was a negative correlation between the decrease of tinnitus loudness and the increase of ASSR amplitude in the right auditory region. Our findings are consistent with earlier studies [33] indicating the usefulness of binaural beat stimuli as an acoustical neuromodulator. Finally, lack of a control group was one of the limitations of this work. So, we recommend new research using BB stimuli (as a kind of sound therapy method) with a control group and a greater number of tinnitus subjects. In addition, it is better that the long-term effects of BB are also checked.

Conclusion

According to findings from the present study suggesting good correlation between subjective and objective changes, binaural beat stimuli could be considered an acoustical neuromodulator that improves a patient's quality of life. Needless to say, this was a pilot study, and to considering the binaural beat stimuli as a clinical method, it is essential to assess its efficiencies by a controlled clinical trial.

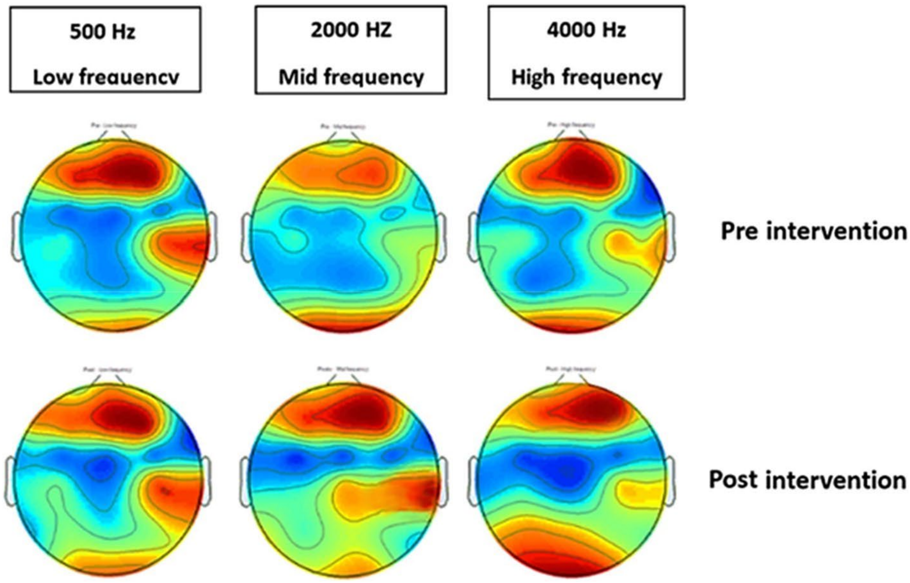

Fig. 4 The graphic map of ASSR 40-Hz amplitude changes after tinnitus management with binaural beat stimuli at three carrier frequencies

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Authors' contributions
MS designed and performed experiments, collected and analyzed data and wrote the paper; AM helped to design and write the paper; MA helped to design experiments; AY analyzed ASSR data; HH provided statistical analysis and SM helped to write the paper. All authors read and approved the final manuscript.

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Availability of data and materials
All of the data and material of this study are available.

Declarations

Ethics approval and consent to participate
The study was approved by the ethics committee of Iran University of Medical Sciences (IR.IUMS.REC 1395.9211303211). All participations filled out consent form to participant in this study.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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