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Research Paper: The Long-term Effect of Neurofeedback Therapy as Adjuvant Therapy on the Management of Tinnitus: A Prospective Clinical Trial

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ABSTRACT

Background: Recently, various studies have been performed to examine the effect of neurofeedback on treating tinnitus. However, these studies reported different results. In this process, the nervous activity of the patient is evaluated. For example, the aspects associated with brain processes are extracted through temporal processing signs, and then auditory or visual feedback is given to the person.

Objectives: The present study investigates the effect of neurofeedback sessions on treating tinnitus.

Materials & Methods: In this clinical trial study, 30 patients with tinnitus who met the inclusion criteria were included. They referred to the otorhinolaryngology clinic of Azahra and Kashani hospitals in Isfahan City, Iran. The patients underwent 20 sessions of neurofeedback and were examined at time intervals before the intervention and then 1, 3, and 5 months after the intervention. To evaluate the patients, we used tinnitus handicap inventory and visual analog scale. To examine the changes in VAS and THI data at different times, repeated measure ANOVA test was utilized. The significance level was considered less than 0.05. The analysis was performed in SPSS V. 24.

Results: Five months after the intervention, tinnitus handicap inventory ($P<0.001$) and visual analog scale ($P<0.001$) scores of the patients significantly improved. Also, no complication resulting from the use of neurofeedback was observed in the patients.

Conclusion: Usage of neurofeedback sessions as adjuvant therapy could be an effective treatment in patients who suffer from tinnitus.

Keywords: Tinnitus; Neurofeedback; Adjuvants

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Highlights

- Neurofeedback therapy could change tinnitus handicap inventory and visual analog scale scores.
- No complication was observed from the use of neurofeedback therapy in patients with tinnitus.

Introduction

Tinnitus is defined as the stable perception of the sense of hearing without its relationship with an external sound stimulus. It is heard as a kind of ringing or noise either unilaterally or bilaterally across the entire head [1, 2]. Based on the possibility of being heard by the examiner, subjective and objective types of tinnitus are propounded, where different therapeutic approaches are adopted based on their diagnosis [3]. Tinnitus is a common disorder that is mostly observed in older ages, and its prevalence has been reported to be 5.1%-42.7% in different studies [4]. Among the most important causes of this disorder is noise trauma, and it is more prevalent among individuals who work in noisy industries. Some disorders such as central nervous system diseases, ear disorders, hypertension, diabetes, toxicity, or overdose with some medications such as aspirin, infection, and head and neck trauma increase the odds of tinnitus development [3, 5]. Treatment of this condition is based on the underlying cause, such as hypertension, hyperlipidemia, thyroid dysfunction, allergy, and factors intensifying tinnitus such as consumption of some drugs or excitatory drinks such as caffeine [6]. Given the conditions of the patient, various methods such as pharmacotherapy, surgery, sound therapy, cognitive-behavioral therapies, and education therapy have been recommended. Currently, none of them has been recommended as the standard treatment [6, 7].

Biofeedback is a novel therapeutic method with a noninvasive nature and high effectiveness and is widely used in treating many neuropsychological disorders [1]. Biofeedback is a method based on relaxation, which acts through training for controlling specific autonomic acts of the body and changing reactions of the person to the distress developed by the disorder [6]. Neurofeedback Therapy (NFT) is a kind of biofeedback that shows its effect as conditioning through training the person for smart control of brain waves [8]. In this process, the nervous activity of the patient is evaluated, the aspects associated with brain processes are extracted through temporal processing signs, and then auditory or visual feedback is given to the patient [1, 8]. Some studies demonstrated that NFT could decrease tinnitus severity [9-11], but some studies indicated that NFT did not affect tinnitus [1].

The idea of developing this method has been based on older studies, which had dealt with investigating the ability of the central nervous system to change the patterns of neural activities. The success of this method in improving disorders such as stress, depression, autism, etc., on the one hand, and observation of neural abnormalities in tinnitus, on the other hand, are motivations for the use of NFT in treating this disorder [1]. Different studies have been performed in this regard and examined the results of the use of NFT in treating tinnitus. Because of different findings, therapeutic protocols with NFT have been transformed considerably along with the methods of assessing brain waves. Considering the different results of studies and adverse effects of tinnitus on daily life, we aimed to investigate the effect of long term NFT as adjuvant therapy on the treatment of tinnitus among patients referring to the otorhinolaryngology clinic of Isfahan Medical University hospitals in Iran.

Materials and Methods

This study is a prospective clinical trial without randomization, a control group, and blinding. The study was conducted on 30 patients with tinnitus referring to the otorhinolaryngology clinic of Azahra and Kashani hospitals affiliated with Isfahan University of Medical Sciences in 2019-2020. The inclusion criteria were patients with subjective tinnitus resistant to medical treatments older than 18 years, with the normal hearing threshold (10-20 dB). The exclusion criteria were patients' reluctance to participate in this study at any time of the study having other neurological disorders such as epilepsy, Parkinson disease, Alzheimer disease and etc. All unilateral and bilateral tinnitus were enrolled in the study, but most cases were unilateral.

Once the patients were included in this study according to the inclusion criteria, they were given a written informed consent form. Then, a particular form was completed for each patient who had the patient's name, age, gender, disease history, and other underlying diseases. Based on the results, NFT sessions were specified and planned for every patient, and they underwent NFT for 20 sessions once weekly until 5 months.

The NFT sessions were designed by a psychiatrist, performed by a neurotherapist via an 8-channel ProComp

Infiniti device (Thought Technology) with Tinnitus Suit in BioGraph Infiniti Software. This software has an open display session, whereby the psychiatrist decides when the sessions should be terminated. This software has been designed based on two scripts: Tinnitus training script according to Dr. Dorhman protocol [9] and general tinnitus training script designed by Linda Walker [9].

The first case includes a single feedback animation for 30 min, while the second case involves 3 10-min tasks with different feedback animations. In both methods, there are 2 minutes of pre- baseline and post-baseline. All scripts focus on parameters that include alpha/delta peak to peak ratio at f3, f4, fc1, and fc2. Besides, in open display sessions coupled with EEG assembly, other parameters such as alpha only, delta only, and gamma are also investigated. Alternatively, some parameters are defined by the psychiatrist.

Before beginning the NFT sessions, Tinnitus Handicap Inventory (THI) [12] and Visual Analog Scale (VAS) were completed for all patients. Furthermore, after the termination of decisions related to NFT and 1, 3, and 5 months after that, all patients were invited through phone contact to the ENT clinic, and in addition to taking the patient's history, the questionnaire and scale were re-completed for them.

THI is a 25-item questionnaire that examines the problems and complications related to tinnitus. Every item has 3 options, including "yes", "no", and "sometimes", receiving 4, 0, and 2 scores, respectively. The scores acquired from each item are summed up together eventually and recorded as the score gained from the questionnaire [13]. Also, high validity (0.93) and reliability (0.95) of THI was demonstrated in Iran [14].

VAS is a quantitative scoring scale through which the patients can report the intensity of tinnitus from 0 to 10. Based on that, the intensity of tinnitus of patients is determined and compared before receiving the NFT sessions and then 1, 3, and 5 months later.

The sample size was calculated based on the formula $\{N=\frac{(Z_1+Z_2)^2}{ES^2}\}$, where Z1 and Z2 were obtained for the confidence interval of 0.95 and test power of 0.8 equal to 1.96 and 0.84, respectively. ES was also the test effect size, which was considered 0.4.

All information related to the patients was introduced into SPSS V. 24. The quantitative data were expressed regarding mean and standard deviation, while the qualitative data were stated regarding number and percentage. Furthermore, to examine the changes in VAS and THI data at different times, a repeated measure ANOVA test was utilized. In all analyses, the significance level was considered less than 0.05.

Results

In this study, 30 patients (19 men and 11 women with the Mean±SD age of 51.56±14.19 years, range: 18-75 years) participated, and all patients were followed up until the end of the study (without any drop). There was no significant difference between the genders regarding age (P=0.07). The Mean±SD THI scores before the intervention, and 1, 3, and 5 months after the intervention were 59.86±26.16, 39.46±22.28, 29.06±18.84, and 20.83±15.09, respectively. There was no significant difference between the two genders given THI scores before and 1, 3, and 5 months after the intervention (P>0.05). Furthermore, the VAS Mean±SD

Table 1. The mean values of tinnitus handicap inventory and visual analog scale score before and after the intervention (n=30)

Variables		Min.	Max.	Mean±SD	P*
THI**	Before the intervention	20	100	59.86±26.16	<0.001
	One month after the intervention	10	88	39.46±22.28	
	Three months after the intervention	8	68	29.06±18.84	
	Five months after the intervention	4	54	20.83±15.09	
VAS***	Before the intervention	2	10	5.86±2.59	<0.001
	One month after the intervention	1	8	4.01±2.08	
	Three months after the intervention	1	7	2.83±1.91	
	Five months after the intervention	0	5	1.86±1.59	

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*Repeated measure ANOVA; **Tinnitus handicap inventory; *** Visual analog scale (scale for evaluating tinnitus severity).

scores before the intervention and 1, 3, and 5 months after the intervention were 5.86±2.59, 4.01±2.09, 2.83±1.91, and 1.86±1.59, respectively. There was no significant difference between the two genders regarding VAS scores before and 1, 3, and 5 months after the intervention (P>0.05). Note that according to repeated measure ANOVA, the changes in THI and VAS scores after the intervention were significantly different from the pre-intervention (P<0.001) (Table 1). Also, no side effect caused by NFT was observed in the patients.

Discussion

According to our results, the NFT sessions had a good effect on the tinnitus of patients, such that after 5 months, THI and VAS score diminished significantly. Studies have shown that most patients with tinnitus have abnormal oscillatory brain activities. In light of this, some methods can normalize these pathological brain activities through NFT techniques. This method has been developed based on progress in Tau activities, which has oscillatory activities in the presylvian part of the brain and generates alpha waves with the frequency of 8-12 Hz and continuously decreases the power of delta waves. These activities are recorded by electrodes placed on the frontal part of the skull. Studies have suggested that using this method can reduce the intensity of tinnitus in patients [9]. Another research has indicated that patients with tinnitus can decrease the signs associated with tinnitus through changing auditory activities trained through NFT. This study has indicated that patients with tinnitus following NFT experience significantly lower auditory activities [10]. Another research has suggested that NFT therapy in patients with tinnitus and those with normal hearing could improve the scores related to the tinnitus signs intensity questionnaire and reduce it in patients [11]. Also, there is a study examining the therapeutic effect of NFT in patients with tinnitus. It has revealed that no changes developed in the extent of loudness of tinnitus following NFT, but all patients were satisfied with these sessions, possibly suggesting the psychological effects of NFT in patients with tinnitus [15].

In 2013, in a study by Hartmann, it was observed that NFT caused a significant reduction in the symptoms of tinnitus and elevated alpha power in the right auditory regions. In this study, for the first time, it was stated that increased alpha activity was effective in reducing tinnitus [16]. In a review study, it was noted that NFT is also useful for treating chronic tinnitus [1]. In a study in Iran on the effect of NFT on tinnitus treatment, 12 patients with tinnitus were included and underwent 15 sessions of NFT. After a 3-month follow-up, NFT had resulted in a diminished intensity of the tinnitus and significantly improved the quality of life of patients. Besides, no side effect was observed in them, and also in this study. NFT was recommended as adjuvant therapy in treating patients with tinnitus [17]. Also, in a case report, it was noted that NFT as slow cortical potential causes treatment of chronic tinnitus [18].

Conclusion

In our study, 20 sessions of NFT during 5 months in patient's tinnitus resulted in a significant reduction in disease intensity and had no side effects. Thus, as NFT sessions were useful for treating tinnitus, it seems that it could be used as adjuvant therapy. The limitations of the study were lack of control group, small sample size, and not investigating the effect of NFT on the reduction of hearing in tinnitus patients. However, the THI questionnaire examined some aspects of diminished hearing. Thus, it seems that further studies are required in this regard.

Ethical Considerations

Compliance with ethical guidelines

The present study was approved by the Iranian Registry of Clinical Trial (IRCT20130311012782N30) and the Ethics Committee of Isfahan University of Medical Sciences (IR.MUI.MED.REC.1397.039). All study procedures were done in compliance with the ethical guidelines of the 2013 version of the Declaration of Helsinki.

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Authors contributions

Conceptualization: Seyed Hamidreza Abtahi, Seyed Mojtaba Abtahi, and Seyedeh Mahbobe Nazari; Methodology: Seyed Hamidreza Abtahi, Seyed Mojtaba Abtahi, Seyedeh Mahbobe Nazari, Mohammad Hossein Nilforoush, and Shirin Arjmandi Rad; Software: Motahare Mirdamadi, Mohammad Hossein Nilforoush, and Shirin Arjmandi Rad; Validation and resources: Motahare Mirdamadi; Formal analysis and investigation: Seyed Hamidreza Abtahi, Seyed Mojtaba Abtahi, Seyedeh Mahbobe Nazari, Motahare Mirdamadi; Data curation: Seyed Hamidreza Abtahi, Seyed Mojtaba Abtahi, Seyedeh Mahbobe Nazari, and Motahare Mirdamadi; Writing the original draft: Seyedeh Mahbobe Nazari; Writing, review, and editing: Seyed Hamidreza Abtahi, Seyed Mojtaba Abtahi, Motahare Mirdamadi, Mohammad Hossein Nilforoush, Shirin Arjmandi Rad, and

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Conflict of interest

The authors declared no conflict of interest.

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