

Study Protocol



Impact of Combined Bifrontal Transcranial Direct-Current Stimulation and Conflict Processing Training on Tinnitus: A Protocol for Single-Blind Randomized Controlled Trial

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Highlights

- Conflict processing training has not been used for tinnitus rehabilitation
- Auditory Stroop training will be applied along with tDCS for control of tinnitus

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ABSTRACT

Background and Aim: The deficit in cognitive functions and central executive function is one of the popular hypotheses on the underlying cause of tinnitus. These factors are not only the complications of tinnitus but are also involved in the generation of it. In this study, bifrontal transcranial Direct Current Stimulation (tDCS) and conflict processing will be used in the form of auditory Stroop training to improve cognitive performance and inhibition control for tinnitus management.

Methods: This study will be carried out on 34 chronic tinnitus patients. The initial evaluations include the tinnitus psychoacoustic evaluations, determination of the tinnitus handicap through tinnitus handicap inventory, and examining the annoyance and loudness of tinnitus through the visual analog scale after which the participants will be investigated in two groups. The first group will receive sessions of tDCS followed by six sessions of conflict processing training. The second group will first receive tDCS in the form of sham, to be followed by six sessions of auditory Stroop. The evaluations will be repeated after each intervention.

Discussion: Studies have shown that successive sessions of conflict processing training can enhance cognitive plasticity and inhibition function. As conflict processing training has not been addressed as rehabilitation training in the people suffering from tinnitus, these processes will be designed in four tasks as rehabilitation exercises in Farsi language and applied along with tDCS to the people with chronic tinnitus to decrease and control tinnitus by improving cognitive and inhibition control.

Trial registration: Iranian Registry of Clinical Trials (IRCT20120215009014N366) on Sep 17th, 2020.

Keywords: Tinnitus; conflict processing; Stroop training; inhibition



Introduction

Tinnitus is a phantom perception of sound in the ears or the head in the absence of any external source. Ten to thirty percent of adults are suffering from this heterogeneous disorder. In 6–25% of the cases, tinnitus may influence the quality of life of the patients giving rise to anxiety, depression, distress, lack of concentration, cognitive disorders, and sleeping disturbance [1-3]. The pathophysiology of tinnitus is not completely clear and there is no definite cure for it.

Studies have proposed various effective factors in the generation of tinnitus. Numerous theories have been also developed to explain the mechanism of tinnitus mostly emphasizing the central origin of tinnitus [4-6]. Based on deafferentation theory, peripheral disorders in the cochlea or auditory nerve will result in a series of hierarchical variations including enhanced spontaneous activities, plastic changes in the central nervous system, abnormal neural synchrony, and cortical reorganization. The global workspace hyperactivity theory discusses the enhancement in the overall activities of the central nervous system. In this way, deafferentation alone is not sufficient for the conscious perception of tinnitus. Tinnitus will be rather perceived when accompanied by impaired top-down inhibitory functions [5, 6]. Brain imaging of various regions has indicated the engagement of non-auditory parts such as prefrontal, parietal and limbic systems in the cases of tinnitus [7, 8]. Some studies also have suggested maladaptive plasticity in various cerebral regions and abnormal activities in the auditory and non-auditory cortical regions related to the attention and cognitive functions as the underlying causes of tinnitus [9, 10]. It is suggested that the tinnitus experience is a consequence of several parallel activities in the awareness network (fronto-parietal regions), distress network (anterior cingulate cortex insula and amygdala), and memory (hippocampus and parahippocampus) which are related to various aspects of tinnitus [6, 11]. Moreover, the annoyance of tinnitus cannot be justified by its sole psycho-acoustic features as it is rather correlated with the cognitive and emotional aspects. The attention and focus on tinnitus can prolong and increase its related distress. Individuals suffering from tinnitus struggle with problems in cognitive control, central executive function, and top-down processing, which are regarded as the factors involved in the generation of tinnitus rather than its complications [12, 13].

This study is based on the hypothesis that the cognitive functions are probably disturbed due to the reduced

inhibition in chronic tinnitus. Therefore, the use of approaches capable of reinforcing the inhibition control can be effective in tinnitus management.

Conflict processing training and the ability to correctly respond to these tasks play a crucial role in cognitive control [14]. Stroop is one of the best tasks to evaluate executive performances in terms of conflict processing and inhibition control [15]. Stroop can be carried out both visually and in an auditory manner. In the visual Stroop, the title of the color is written by another color (i.e. “black” is written in “green” font) and the participants are asked to express the color regardless of its font color. Some studies have shown the improvement of inhibitory control in elder adults, after visual Stroop training [17-19]. In the auditory Stroop, acoustic and semantic conflicts are used [16]. Few studies have been conducted using conflict processing in form of auditory Stroop. During the Stroop task, the participant pays attention to one aspect of the stimulus while neglecting the other aspect. In the “high/low paradigm”, known as auditory Stroop, the words are presented either in a high-pitched or low-pitched voice. In the semantic task, the participant must attend to word meaning while ignoring voice pitch, and in the voice task, must focus on the pitch and ignore the meaning of words [18, 19]. Christensen et al. used another version of auditory Stroop in 26 healthy subjects. They used masculine words such as “brother” or feminine words such as “princess”, presented by male or female speakers. The participant should notice gender in the voice test and ignore the meaning of words and reverse on semantic task. Results of these studies revealed that there was a longer reaction time with words spoken by mismatched voice [19]. According to fMRI studies middle lateral prefrontal, cingulate cortex, and anterior insula are involved in the Stroop [20]. These regions overlap with distress and attention network.

Transcranial direct current stimulation (tDCS) is a potent treatment modality for chronic tinnitus. Some studies have reported the effect of frontal tDCS on the improvement of the inhibition [21-23] and cognitive learning functions [24, 25] in addition to the significant role of the dorsolateral prefrontal cortex (DLPFC) in regulating the cognitive functions. Therefore, electrical stimulation of this region can alter the executive functions and enhance the inhibition functions from this region to the other regions of the cortex including the primary auditory cortex, hence, providing better control on the parasitic tinnitus signal [26-28]. Regarding the role of conflict processing in cognitive control, auditory Stroop can also reduce tinnitus through reinforcing physiologic inhibition and improving cognitive control. So far, separate

methods have been applied to manage tinnitus; while the dual treatments with proper outcomes have been rarely addressed. tDCS was utilized along with music in some studies [29, 30]. Based on our knowledge this is the first study that uses conflict processing in the form of auditory Stroop training for the management of tinnitus.

In this research, transcranial direct current stimulation and conflict processing training (acoustic-semantic, in the form of auditory Stroop) will be used to enhance the inhibition action to improve the cognitive functions and effectively provide control on the tinnitus signals. The outcome will be assessed by tinnitus handicap inventory (THI) and visual analog scale (VAS) for loudness and annoyance of tinnitus pre and post-intervention and one month later.

Methods

Participants: The effect of auditory Stroop and tDCS will be investigated on 34 chronic tinnitus patients (experiencing tinnitus for more than six months) meeting the inclusion criteria. The participants will be randomly divided into two groups. The first group will receive six sessions of tDCS after primary evaluations; then the effect of tDCS will be determined by repeating the evaluations. They will then undergo six sessions of Stroop after which the evaluations will be repeated. In the second group, tDCS will be carried out in the sham mode after primary evaluations. Then, Stroop tasks will be conducted. Similar to the first group, the evaluations will be repeated after each stage and their results will be compared with the primary evaluations.

The inclusion criteria can be listed as follows, non-pulsatile unilateral or bilateral tinnitus existing for more than six months, no hyperacusis, no use of hearing aid, no serious psychological disorders such as severe depression (based on the diagnosis of a psychiatrist), the minimum score in the Mini Mental State Exam, hearing threshold less than 35 dB in 250–8000Hz, no ear disease or nervous system problems (based on the diagnosis of a neurologist), receiving no treatment for tinnitus, being right-handed, no medical restriction to use electrical stimulations (pregnancy, cardiac pacemaker, etc.). The exclusion criteria were: no cooperation or failure in following the program, loss of the inclusion criteria.

Study protocol

This study is a single-blinded clinical trial on patients with chronic tinnitus referring to the Audiology Clinic of Hamadan University of Medical Sciences. The sub-

jects will be randomly divided into two groups after the initial evaluations. The participants of the first group will receive tDCS while the second group will receive it in sham mode. The subjects will be unaware of the mode of tDCS treatment (sham or stimulus). Then both groups will take part in six sessions of conflict processing training in the form of an auditory Stroop. The participants will be registered consequently in numerical order by a secretary unaware of the research project. The even numbers will be placed in the first group while those having the odd numbers will be classified in the second group. The group members will be matched in terms of age, sex, and auditory level. The evaluations will be repeated after each stage and compared with the pre-intervention results.

Primary assessment

Participants having the inclusion criteria will be examined by an experienced audiologist in terms of audiometry and tinnitus psycho-acoustic features. Audiometry assessments will be carried out using a two-channel audiometer (INVENTIS piano made in Italy) at the frequency range of 250–8000 Hz for the air conduction and 250–4000 Hz for the bone conduction by the modified Hughson-Westlake method. In the psycho-acoustic assessments, the pitch and loudness of the tinnitus will be determined by matching an external sound with the tinnitus in the opposite ear. A two-choice technique will be employed to determine the pitch. For this purpose, based on the tinnitus type (tone or noise), two pure noises or two narrowband noises with different frequencies (f_1 , f_2 , $f_1 < f_2$) will be sent and the subject will be asked to select the one whose pitch is closer to the tinnitus. This process is continued until the tinnitus pitch is completely determined. In the loudness assessments, the subject is asked to match the delivered tone intensity of determined tinnitus pitch with the loudness of the tinnitus s/he is experiencing. For this purpose, first, the threshold of tinnitus pitch is determined and then it will be increased in 1-dB intervals until it equals the loudness of the tinnitus [31]. Participants will fill out the Persian version of THI (whose reliability and validity are investigated); while the annoyance and loudness of the tinnitus will be explored by VAS before and after the intervention [32]. All these assessments will be carried out before and after interventions and repeated four weeks later.

Transcranial direct current stimulation protocol

With a tDCS device (Segalstim Farmed Tajhiz Co.LTD made in IRAN) a direct current of 2 mA will be applied through a pair of 35 cm² electrodes impreg-

nated with normal saline solution. Anode and cathode will be placed on f4 (right DLPFC) and f3 (left DLPFC). [26, 33]. The members of the first group will receive 6 twenty-minute sessions of tDCS every other day; while the second group will receive it in a sham mode. The electrodes will be arrayed according to the 10-20 system. In the sham group, the electrode arrangement will be the same; the only difference is that the device will be turned off 30 s after being turned on without informing the patients. Both groups will fill up the questionnaires to evaluate tinnitus handicap, annoyance, and loudness as well as psycho-acoustic assessment forms before and after tDCS.

Auditory conflict processing training

Auditory Stroop with acoustic-semantic conflict processing will be carried out in four different tasks. In the first one, the sex-related words (man, woman) will be presented along with neutral words by a male or female speaker. The patients will be asked to determine the speaker's gender regardless of the meaning of the word. In the second task, the participants will determine that the presented word is related to which sex regardless of the speaker's sex. In the intensity-related conflict processing training, the words loud and soft will be used along with the neutral two-syllable words. Half of these words are randomly pronounced loudly and the other half is presented in a soft manner in the congruent (soft at a lower intensity and loud at a higher intensity) and incongruent (soft with high intensity and loud with lower intensity). In the conflict task, the terms long, short, and neutral words will be uttered congruently and incongruently. In each condition, the reaction time and the score of the participants will be determined based on the number of correct responses under congruent and incongruent conditions. In the successive sessions, the percentage of the incongruent words will be increased from 20 to 40, 60, and 80% respectively while the time interval between the utterances will decline from 5 s to 3 and 1.5 s to enhance the conflict level.

Since the auditory Stroop exercise has not been conducted in Persian, the words will be extracted from a Persian dictionary of the commonly-used words. To avoid habit formation, each series of words in the first and second tasks will be recorded with three male and three female speakers. Each series of words include 60 items half of which are uttered by a male and the other half are pronounced by a female presenter. Various series of words with different percentages of incongruent words (20–80%) will be set at diverse intervals (1.5, 3, and 5 s). Prior to applying the tasks to the tinnitus sub-

jects, their content will be presented to 10 normal people with no tinnitus to determine their clarity, difficulty enhancement by changing the intervals, and frequency of incongruent words (scored by 1–5). The results will be used to increase attention engagement by changing the percentage of the incongruent words and shortening the time interval between their pronunciations. The order of the words will be randomly changed. The words will be recorded under acoustic conditions (in a studio) using a Labtec microphone.

The tasks are designed and implemented by DMDX software. The participants will listen to the words using a headphone. Since the verbal response will cause higher conflict, the patients will be asked to respond verbally.

The percentage of the correct responses will be also determined by the software. Depending on the responses, if the percentage of the correct answers exceeds 80%, a series with higher percentages of incongruent words will be used to enhance the engagement. In this way, at least 4 trials with sixty-item will be addressed. To determine the reaction time, the subjects press the shift button on the right or left side of the keyboard to respond. The shift button on the right side is for the female terms, slow intensities, and short delay; while the shift button on the left side is allocated to the male terms, loud noises, and long delays. The reaction time of the participant will be calculated in milliseconds (ms) from the onset of the stimulus presentation until the response onset. The reaction time and percentage of the correct answers in the first session before the tasks will be compared with those obtained after six sessions.

Outcome assessment

The quantitative (tinnitus pitch and loudness matching and VAS for loudness and annoyance) and qualitative (THI) measurements will be assessed in each participant. The initial evaluation will be carried out one day before the tDCS intervention and immediately after six sessions of tDCS. One day after the exercises, an auditory Stroop is initiated. The reaction time of the participants and the percentage of the correct responses will be determined in any of the tasks and compared with those obtained in the last session. At the end of the auditory Stroop, THI and tinnitus loudness and annoyance, as well as the psycho-acoustic evaluations, will be repeated and compared with their corresponding results before and after tDCS. The influence of Stroop (alone) on the tinnitus handicap, annoyance, and loudness will be examined by comparing the results of the two groups. Moreover, the effect of

adding Stroop exercises will be addressed in any of the mentioned parameters.

A comparison between the reaction time and percentage of correct responses at the beginning of the Stroop and that of the last session can present the changes in the inhibition control as well as the effect of the exercises.

Statistical assessments

One-way and two-way repeated measure ANOVA analyses will be employed to determine and compare the effect of tDCS and Stroop (either alone or in combination) on the Stroop scores, loudness, handicap, and annoyance of tinnitus. In the case of significant results, the posthoc Bonferroni test will be applied and in order to determine which treatment gives the best outcome, effect size measurements will be calculated.

Sample size

To determine the sample size, the mean difference and respective standard deviation from Talanow and Vannešte's study was used. By considering the power of 80% and error of = 0.05, the sample size is 17 members in each group [34, 35].

$$n = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}$$

According to long term sessions of treatment, 20% drop out will be considered and 20 members in each group will be used.

Dissemination

The data of this study will be collected till Sep 2021. The results of this research can be used by audiologists as well as neurologists and Otolaryngologists.

Discussion

A great percentage of the people referring to the Otolaryngology clinics suffer from tinnitus. On the other hand, the number of people exposed to tinnitus is increasing as its risk factors such as aging, hearing loss, and noise have increased with industrialization. Despite the relatively high prevalence of tinnitus, there is no definite cure for that and the studies are continuing. As the majority of the theories on tinnitus formation have mentioned the decline of inhibition in the central nervous system, it seems that the enhancement of inhibition can help in decreasing tinnitus by conflict processing training.

Moreover, regarding the effectiveness of tDCS in regulating the cognitive functions and improving the inhibition performance and neuropsychologic disorders including tinnitus, the use of conflict processing tasks in the form of auditory Stroop and tDCS electrical stimulation in the frontal region can more effectively decrease the tinnitus symptoms. The studies in this field have mentioned the lower scores in Stroop tasks and longer reaction times of the tinnitus patients compared to the controls.

Up to now, the repeated bifrontal tDCS sessions combined with auditory Stroop training have not been used as a rehabilitation exercise for controlling tinnitus. Upon efficacy, this method can be added to the treatment agenda of tinnitus in the form of auditory Stroop for the inhibition performance to improve the results as well as providing more stable mechanisms for tinnitus management and treatment.

Ethical Considerations

Compliance with ethical guidelines

All the methods used in this study are approved by the Ethics Committee of Iran University of Medical Sciences (IR.IUMS.FMD.REC.1399.379). Prior to the study, the research methods, objectives, advantages, and possible side effects will be completely explained to the patients and the participants will sign a written consent form. The study is registered in the registry center of clinical studies of Iran as a clinical trial (IRCT20120215009014N366).

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Authors' contributions

ME: Study design, acquisition of data, interpretation of the results, statistical analysis, and drafting the manuscript; MA: Study design, interpretation of the results, and drafting the manuscript; AM: Study design, interpretation of the results, and drafting the manuscript; SJ: Statistical analysis; RT: Interpretation of the results and drafting the manuscript.

Conflict of interest

The authors declare that they have no conflicting interests.

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