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Comparison the effectiveness of combined metacognitive therapy with transcranial electrical stimulation on reducing anxiety in chronic tinnitus sufferers

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ABSTRACT

Background and Aim: One of the most common mental problems among tinnitus patients is anxiety. Therefore, the present study was conducted with the aim of comparing the effectiveness of combined metacognitive therapy with transcranial electrical stimulation on reducing anxiety in chronic tinnitus sufferers. **Methods:** The research design was semi-experimental with a pre-test-post-test design with a control group, and the statistical population included all patients with tinnitus who referred to Rizvan Afshar Hearing Evaluation Center in Arak city in 1401. The size of the statistical sample was 30 people (15 people in the experimental group and 15 people in the control group) from the mentioned statistical population, who were selected by available sampling method and randomly placed in two control and experimental groups. During 8 sessions, the experimental group was first subjected to transcranial electrical stimulation for 20 minutes and immediately underwent metacognitive therapeutic intervention for 60 minutes, and the control group received only their usual treatment (transcranial electrical stimulation). In this research, Beck's anxiety questionnaire was used to collect data. In order to statistically analyze the obtained data, univariate analysis of covariance test was used. **Results:** The mean of scores of anxiety before and after the intervention in the experimental group were 11.13 and 7.20, respectively, and in the control group, 11.40 and 8.53, respectively. The results of covariance analysis showed that the mean anxiety in the experimental group has decreased significantly ($P<0.01$) after the combined intervention of metacognitive therapy with transcranial electrical stimulation in comparison with the control group. **Conclusion:** The results of this research indicate that the combined intervention of metacognitive therapy with transcranial electrical stimulation has significantly improved anxiety, so the use of this intervention is recommended for chronic tinnitus sufferers.

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Introduction

One of the examples of mental disorders that has received the special attention of researchers due to its pervasiveness and many shortcomings in its recognition and evaluation is ringing in the ears or tinnitus. Tinnitus means sound perception inside the ear without external factors (Han et al., 2017). Tinnitus is a disorder with complex and multifactorial causes, which are mainly sensory-neural, sensori-somatic, infectious, drug-related, neurovascular, and unknown (Cianfrone et al., 2015). Studies have shown that tinnitus can be responsible for reducing quality of life and increasing the risk of psychological problems (Parker et al., 2022). The prevalence of psychiatric disorders in tinnitus patients is high, and the presence of these disorders is related to the severity of tinnitus (Pinto et al., 2014). Mark, Mazurek and Bragman (2015) reported in a research that tinnitus is often associated with depression, anxiety and stress. Anxiety is considered a compromise response to stimuli, and its absence sometimes makes a person face serious risks. However, if anxiety exceeds its balanced limit and persists, it can no longer be considered compromised, but it should be considered as a source of helplessness (Suri et al., 2015). If the level of anxiety is so high that it leads to a person's dysfunction; It is included in the category of anxiety disorders (American Psychiatric Association, 2013).

The negative consequences of tinnitus, which manifests itself at the individual and social levels, have caused researchers and therapists to be sensitive to this issue, and so far, numerous interventions with different approaches have been carried out in order to reduce the psychological problems of people with tinnitus disorder. (Box et al., 2022). Among the educational and therapeutic approaches whose clinical effectiveness has been shown in various researches is metacognitive therapy (Burgess et al., 2021, Ashuri, 2015). On the other hand, considering that tinnitus disorder is mostly due to neurological reasons, it seems that neurological treatments such as transcranial electrical stimulation treatment can be fruitful in improving the symptoms and psychological issues of people suffering from this disorder (Yuan et al., 2018). Transcranial electrical stimulation was recognized as a reliable method for electrical brain stimulation in humans by Merton and Morton in 1980. Transcranial direct electrical stimulation is a non-invasive method to alter cortical excitability. The cerebral cortex is stimulated through a constant and weak electrical current, which can cause changes in the cortical excitability during electrical stimulation (Nietzsche & Palos, 2011).

Nowadays, treatments that have the same therapeutic effects as long-term treatments in a shorter period of time, and their therapists need little training and have lower costs, are prioritized over treatments that impose a lot of costs on both the health system and those seeking treatment based on the above. (Teasdale et al., 2000). Among the treatments with the above benefits is metacognitive therapy, which is based on the information processing model (Wells & Papageorgios, 2001; Wells & Sembi, 2004). The metacognitive approach is based on the belief that people are caught in the trap of emotional distress because their metacognitions lead to a specific pattern of responding to internal experiences, which causes the continuation of negative emotions and the strengthening of negative beliefs. This pattern is called the cognitive syndrome of attention, which includes worry, rumination, fixed attention, and self-regulation strategies or maladaptive coping behaviors (Wells, 2000; Wells, 2004).

In the treatment of anxiety, metacognitions control, moderate and interpret the thinking process (Wells & Cartwright-Houghton, 2004) and shape the evaluations and types of strategies we use to regulate thoughts and feelings (Mahmoudi, 2010). In metacognitive therapy, metacognitive beliefs have a central effect on the way of responding to negative thoughts, beliefs, symptoms, and emotions, and the treatment should include removing worry, letting go of threat detection strategies, and helping people to experience disturbing thoughts without avoiding them (Wells, 2004). In connection with people suffering from chronic tinnitus, Ferraro et al. (2019) conducted a study with the aim of metacognitive therapy effect on the understanding of tinnitus, and anxiety and depression associated with this disorder. The results showed that distress caused by tinnitus and anxiety decreased significantly, maintaining this result at 3-month follow-up, while depression scores did not change. Participants reported being able to develop new responses to replace the negative thoughts triggered by tinnitus, and to ruminate

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less about tinnitus and in their daily lives. It seems that the use of metacognitive therapy is promising in reducing the participants' perception of buzzing and anxiety and reduces the importance of disturbing thinking.

This treatment is theoretically based on the self-regulatory executive functioning model, which states that psychopathology arises as a result of a persistent thinking style called cognitive attention syndrome (CAS) (Fajeh et al., 2019). Cognitive attention syndrome involves dysfunctional coping strategies that a person uses as an attempt to manage distressing thoughts and feelings, including worry, threat detection, avoidance, rumination, thought control strategies, and reassurance seeking (Wells, 2009).

Thus, in the context of comparing the effectiveness of transcranial electrical stimulation with metacognitive therapy on the anxiety of tinnitus patients, various studies have reported conflicting results. So far, there has been no research on the effectiveness of combining transcranial electrical stimulation therapy with metacognition therapy on anxiety and comparing the effectiveness of the investigated treatment methods. Suppose the side effects of the use of drugs in the treatment of anxiety symptoms and the phenomenon of adaptation to the drug, which reduces the effectiveness of the treatment; Moreover, suppose the partial and not complete success of psychotherapy including metacognitive therapy in the treatment of anxiety and its manifestations. Therefore, it is important to search for newer options in the treatment as well as supplements in improving the symptoms of anxiety and sleep disorders in tinnitus disorder. In addition, adopting integrated and combined approaches is more efficient than single-factor approaches, which can both speed up the treatment process and prevent the return and recurrence of the disease.

Therefore, in order to fill the research gap and respond to the contradictions of previous researches, the present study seeks to answer the question whether there is a difference between the effectiveness of transcranial electrical stimulation and its combined treatment with metacognitive therapy on reducing the anxiety of chronic tinnitus sufferers?

Method

The research was quasi-experimental with a pre-test and post-test design with a control group. The statistical population of the research included all patients with tinnitus problems referred to Rizvan Afshar Hearing Evaluation Center in Arak city. Due to the uncertainty of the number of the statistical population, the volume determination formula was used using GPower software to calculate the number of samples. According to the data analysis method (analysis of covariance), considering the statistical power of 95% and with the effect size of 0.5, significance level of 0.05, the number of the sample group was estimated to be 30 people; Therefore, 30 people from the mentioned society were selected using the purposeful sampling method and randomly replaced in 2 groups (experimental and control). Inclusion criteria were: having tinnitus disorder with anxiety; not having obvious hearing loss; not suffering from other ear diseases; not suffering from cardiovascular diseases; lack of brain disorders and nervous system diseases; not suffering from other severe or chronic psychological disorders; Age between 20 and 40 years; Consent to participate in the research; Education at least diploma. Exclusion criteria: absence of more than two sessions in the experimental intervention; Participation in other psychological interventions was concurrent.

Materials

1. Beck Anxiety Questionnaire: Similliar to the Beck Depression Questionnaire, this questionnaire includes 21 options and each item is scored between 0 and 3, and the range of scores is between 0 and 63. Beck and Steer reported its internal consistency equal to 0.93. They also reported a test-retest reliability coefficient of 0.75 after one week (Beck & Steer, 1990). The psychometric properties of this questionnaire have been confirmed by various researches in Iran. Rafiei and Saifi (2013) have reported the reliability of the scale or the use of Cronbach's alpha coefficient of 0.92 (Rafiei & Saifi, 2013).

2. Transcranial electrical brain stimulation (tDCS): In this study, according to the new protocols, a current intensity of 2 milliamps was presented for 20 minutes in 8 sessions. (Stag, Antal, & Nietzsche, 2018; Sarmiento, San Juan, & Prasat, 2016); The target area was the left dorsolateral prefrontal cortex (DLPFC) and anodic stimulation was placed on the left DLPFC (F3) and cathodal stimulation was placed on the right DLPFC (F4).

3. Metacognitive therapy: The members of the experimental group underwent metacognitive therapy in each session immediately after tDCS, which is summarized in the table below.

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Table 1. Cognitive therapy based on metacognitive approach	
Session	Objective
1	Getting to know the group, calling metacognitions, metacognitive profile and explaining the logic of treatment.
2	Teaching the technique of getting rid of preoccupation;
3	Postponing technique training;
4	Reviewing the progress of references;
5	the technique of changing the situational focus of attention;
6	correcting positive and negative superstitions with self-questioning technique;
7	Positive verbal self-talk
8	Monitoring progress, recovery and relapse prevention

Implementation

After obtaining the necessary permits from the research vice-chancellor of the university to implement the project, 30 people were selected by referring to the hearing evaluation center according to the entry and exit criteria mentioned in the method section. Based on ethical principles, a written consent was obtained from the participants and brief information was provided to the participants about the subject and objectives of the research. It was explained to all subjects that they can withdraw from the study at any stage of the project and all their information will be kept completely confidential. It was also assured that non-participation in the study or non-continuation of cooperation does not have any effect on the medical services provided to them and does not create a disruption in their treatment process. In none of the stages of data collection and preparation of the final report, the information of the studied sample or their names was not disclosed and was not given to any natural or legal person. Also, participating in the research did not have any financial burden for the applicant. Questionnaires were first completed by both groups; Then the experimental group was first subjected to transcranial electrical stimulation for 20 minutes and immediately underwent transcognitive therapeutic intervention for 60 minutes during 8 sessions (Table 1) and the control group received only their usual treatment (tDCS). After the end of the treatment sessions, both groups answered Beck's anxiety questionnaire in the post-test phase. Finally, the data were analyzed using descriptive (frequency, mean and standard deviation) and inferential statistics (Shapiro-Wilk test, M-box test, Levene's test and univariate covariance analysis test) in SPSS-26 software.

Results

Based on the findings of demographic data, the mean of the age of the experimental group was 3.30±49.66 and the mean of the age of the control group was 2.89±51.26 years. In the following, the descriptive statistics of the pre-test and post-test scores of the research variables by groups are reported in Table 2.

Table 2. Descriptive indices of research variables by research groups					
Variable		Exp. Group		Control Group	
		Pre-test	Post-test	Pre-test	Post-test
Anxiety	Mean	11.13	7.20	11.40	8.53
	SD	1.35	1.20	1.18	1.80

As can be seen in Table 2, the scores of the experimental group in the anxiety variable have decreased more than the control group in the post-test stage, but in the control group, the scores are not significantly different. In order to analyze the data, univariate analysis of covariance test was used, so first the underlying assumptions of this test were examined. The Shapiro-Wilk test was used to check the normality of the distribution of scores. The results showed that the presumption of normality of data distribution is established (P>0.01). Levine's test was also used to meet the assumptions of the covariance test, the results of which showed that the scores of the research groups in the post-test of the dependent variables have homogeneous variance (P>0.617, F=0.439). In addition, the interaction between the group and the pre-test is not significant in the post-test stage, so this hypothesis was not rejected (P>0.05). In this way, the necessary conditions for performing the univariate covariance analysis test are established.

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Table 3. Results of univariate covariance analysis to investigate the difference between the experimental and control groups in the pre-test and post-test

Source	SS	df	MS	F	P	Effect size
Pre-test	10.503	1	10.503	13.613	0.001	0.335
Group	53.643	1	53.643	69.530	0.001	0.720
Error	20.831	27	0.772			

The results of Table 3 showed that there is a significant difference between the mean anxiety scores in the post-test stage after controlling for the pre-test effect between the combined treatment group (transcranial electrical stimulation combined with metacognitive therapy) and the control group. In other words, combined therapy (transcranial electrical stimulation combined with metacognitive therapy) had a significant effect on anxiety in the post-test phase. According to the eta square, it can be said that 72% of these changes or improvements were caused by the intervention.

Conclusion

The present study was conducted with the aim of comparing the effectiveness of combined treatment of transcranial electrical stimulation with metacognitive therapy on reducing anxiety in chronic tinnitus sufferers. The results of the research showed that combined therapy (transcranial electrical stimulation combined with metacognitive therapy) is effective in reducing the anxiety of chronic tinnitus sufferers, it is confirmed. The results of the above hypothesis showed that there is a significant difference between the overall anxiety score of the experimental group and the control group. In fact, the result confirms that with the post-test control, there is a significant difference in terms of anxiety between people who received combined treatment (tDCS with metacognitive therapy) (experimental group) and people who only received tDCS (control group). This finding was consistent with some of the results of the following studies: Ghayorkazemi et al. (2015); Mami, Sharifi and Mahdavi (2015); Ashuri (2015); Sadeghpour (2016); Akhori and Madiha (2022); Dalbo et al. (2022); Bruni et al. (2021); Ching et al. (2022); Nishida et al. (2022); Shinda et al. (2021); Hosseini Ashkazri et al. (2021); Narimani et al. (2016) is consistent.

In the explanation of the findings, it can be stated that electrical stimulation in the prefrontal cortex area can improve the efficiency of cognitive-behavioral issues and exploit higher levels of cognitive functions, thus reducing anxiety symptoms (Aristo et al., 2020). In explaining the effectiveness of metacognitive therapy on anxiety, it can be said that this therapy pays attention to cognitive-attentional syndrome, rumination and anxiety of people. With different techniques, instead of engaging with thoughts, people observe and manage thoughts. Challenging metacognitive beliefs makes people believe that they are in control of their thoughts and that rumination and worry are pointless. Using the techniques helps people to reduce their anxiety and avoidance and to perform better. Also, paying attention to the external characteristics of the situations reduces the self-evaluation of the person from the external observer's point of view and also reduces the attribution of others' reactions to oneself and threat detection. In addition, by using techniques, people's positive experiences increase and they find more motivation in using techniques, and the unhealthy cycle of metacognitive beliefs, rumination, anxiety and avoidance behaviors that they experience in different situations is broken (Ghiorkazemi et al., 2015). On the other hand, the way of interpreting intrusive thoughts is an important factor in determining the severity of discomfort and anxiety caused by the consequences of these thoughts, so that the interpretation of intrusive thoughts can be affected by cognitive biases. Metacognitive therapy corrects cognitive biases and informs a person about the influence of disturbing thoughts and the feelings of anxiety and worry caused by them, and leads to a reduction in the confusion of the patient's thoughts. Metacognitive therapy techniques, with emphasis on paying attention to the present moment and a non-judgmental and goal-focused approach, determine the boundaries between thought and feeling, thought, event and action, and prevent them from mixing, and as a result, reduce the anxiety of patients. (Mami et al., 2015). In addition, the method of metacognition therapy by teaching the strategy of changing

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attention from anxiety-inducing stimuli to other stimuli and the strategy of temporarily postponing reduces the symptoms of anxiety, and the continuous use of these two strategies significantly reduces anxiety. Another explanation is that he mentioned the use of hats in this treatment method. Especially the yellow hat: in this hat, the person looks at the stressful situation as an opportunity for growth; Green hat: the person creates a new solution for anxiety-provoking situations; Blue hat: It is considered the most key solution and a person learns to monitor and manage the activities of other hats by using this hat. Finally, these factors cause the positive effect of this treatment method in reducing anxiety symptoms (Ashuri, 2015).

In general, the results of this research showed that when metacognitive therapy is combined with transcranial electrical stimulation therapy, its effectiveness on reducing the anxiety symptoms of tinnitus patients is greater than transcranial electrical stimulation therapy. The present study had some limitations, which include: the use of available sampling method, the implementation of the research on patients with tinnitus disorder in Tehran, the use of self-report questionnaires as a data collection tool, and the short-term follow-up period. Therefore, choosing a random sample can control the influencing intervening variables in the research to a greater extent. It is also suggested that future studies should consider longer long-term follow-ups, the use of diagnostic interviews and observation as a complementary method to self-report questionnaires to collect data and conduct a study on patients with tinnitus disorder in other cities. Finally, based on the results obtained in the present study that the combined treatment of tDCS with metacognitive therapy is more effective than tDCS on the anxiety of patients with tinnitus disorder, it is suggested to use transcranial electrical stimulation as a complementary method along with metacognitive therapy.

Conflict of Interest

According to the authors, this article has no financial sponsor or conflict of interest.

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