

Comparison of the Effectiveness of Emotion Regulation-based Cognitive Therapy and Transcranial Direct Current Stimulation on Impulsivity of Students with Special Learning Disorders

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Abstract

Background: Special Learning Disorder is a neurodevelopmental disorder which is considered to be from biological origin and causes abnormalities at the cognitive level. This study aimed to compare the effectiveness of emotion regulation-based cognitive therapy and transcranial direct current stimulation on impulsivity of students with special learning disorders.

Methods: This study was quasi-experimental and based on a pretest-posttest design with a control group. The participants were the second elementary school (fourth, fifth, and sixth grades) pupils with particular learning difficulties and were enrolled in Tabriz schools, Tabriz, Iran during the academic year 2019–2020. 54 students with unique learning difficulties who were randomly chosen from among those with exceptional learning disorders and allocated to three groups made up the study sample. The first experiment group underwent cognitive regulation therapy based on the emotion regulation for eight sessions of 45 minutes per week; the second experiment group received 20 sessions of direct transcranial Current stimulation on a daily basis, and the control group did not receive any treatment. Colorado Learning Disorder Questionnaire and the Barratt Impulsivity Scale were used to collect data. The collected data were analyzed using a Univariate analysis of covariance with SPSS version 22.

Results: Based on the demographic findings, the mean age and standard deviation of the cognitive therapy group based on emotion regulation was 11.05 ± 0.872 , in the direct transcranial electrical stimulation group was 10.83 ± 0.83 and in the control group was 11.11 ± 0.8 . The results showed that both cognitive emotion regulation treatments and transcranial direct electrical stimulation had an effect on the components of impulsivity, motor impulsivity ($P=0.012$), impulsivity Cognitive ($P=0.001$), and lack of planning ($P=0.001$). However, transcranial direct electrical stimulation had a greater effect on the cognitive impulsivity component of students with specific learning disorders.

Conclusions: It can be concluded that direct transcranial stimulation can have a greater effect on cognitive impulsivity.

Keywords: Emotion Regulation-based Cognitive Therapy, Transcranial Direct Current Stimulation, Impulsive Behavior, Specific Learning Disorder

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1. Introduction

Today, the world educational societies face various psychological problems for students at different levels of education. One of the issues that have occupied the minds of specialists in recent years is specific learning disorder. Neurodevelopmental disease is seen as being of biological origin and causing anomalies at the cognitive level, according to the Diagnostic and Statistical Manual of Mental Disorders (fifth edition). Despite being in a suitable educational environment, as well as the absence of obvious biological damage and the absence of acute social and psychological problems, they are

not able to learn in special fields (reading, writing, calculation) (1). One of the main features of a specific learning disorder is persistent problems in core academic skills, which include reading fluency, reading comprehension, written expression, and mathematical reasoning. According to the American Psychiatric Association, the prevalence of this disorder in school children is 3 to 17.5%, a figure that requires clinical attention (2). Learning disorders are making a daily increase in the number of kids who qualify as having particular learning disorders. In 2012, this number amounted to 2.8 million (3). According to the experts, clinical studies of early childhood and adolescence showed

that one of the most noticeable changes which can be seen during the student period for many people around is severe mood swings, frequent outbursts of anger and aggression. This increase in aggressive and impulsive outbursts during childhood and adolescence has led the American Psychiatric Association to consider a special disorder called "mood disorder" in its latest Diagnostic and Statistical Manual of Mental Disorders (2). Today, impulsivity is conceptualized as a cognitive dimension in the sense that impulsivity, with no cognitive inhibition, is associated with a slow and incomplete decision of emotional instability in individuals (4). A review of studies on impulsivity showed that impulsive behaviors are the core of many mental disorders such as Attention Deficit/ Hyperactivity Disorder, Behavioral Disorder, Impulse Control Disorder, Drug Abuse, Bulimia, Suicidal Behavior, Personality Disorders and Disorders Learning (5-7). Considering the unpleasant consequences that impulsivity can have on human life, especially in students, countless studies from the past to the present were descriptive, explanatory and interventional studies in this field (8, 9). Findings indicated that aggression and impulsivity are the most common clinical problems among students, which are more common among boys than girls (10). Research showed that impulsivity is higher in students with learning disorders than in normal students (11, 12). Since not obtaining a timely diagnosis and not delivering the intervention in time might expose the student to a range of psychological difficulties in the future, impulsivity is a category that logically demands specific professional care (13, 14). One of the therapies whose effectiveness on impulsivity of students with special learning disorders has received less attention is cognitive therapy based on emotion regulation. According to research reports, one of the factors which are increasingly considered and mediated in the pathology of a wide range of disorders today is emotions, and in particular its management, which is known as emotion regulation (15). Cognitive strategies that are involved in emotion regulation are considered. Cognitive strategies based on emotion regulation are unconscious cognitive-emotional responses that are used when emotional events occur to moderate the intensity of individuals' emotional experiences (16). Emotion regulation refers to a wide range of biological, social and behavioral processes by which people penetrate their emotions and affect

them in an automatic or controlled manner and on a conscious to unconscious level (17). In addition, interventional studies showed that it is possible to manipulate this variable to make positive changes; in other words, emotion regulation training can ultimately reduce and control negative emotions and learn how to use emotions positively (18, 19). Experimental studies showed that difficulty in regulating emotion is one of the main factors in the etiology of many chronic and acute mental disorders (20, 21). On the other hand, considering the key role of attention as one of the basic components of cognitive emotion regulation, in Gross model, most of the emotions are the result of attention to the situation or emotional stimuli (16).

In addition to emotion regulation, one of the neuropsychological interventions used today to treat emotional disorders, especially those with neurodevelopmental etiology, is direct transcranial electrical stimulation (tDCS), which stimulates or inhibits skills (22). One of the non-invasive techniques is transcranial direct electrical stimulation intervention, which relies on the magnetic field's capacity to penetrate through the skull and meninges and, as a result, create electrical current in brain tissue. Anode stimulation is utilized to stimulate the cortex more during transcranial direct electrical stimulation, whereas cathode stimulation inhibits it. The direction of the electric current affects the efficiency of transcranial direct electrical stimulation. Anodic stimulation raises alertness and increases brain activity, while rhythmic stimulation lowers activity (23). The current that reaches this area charges the neurons with electricity and causes positive and negative polarization, which leads to a change in the activity of that area. In other words, in this type of electrical stimulation, points of the head are targeted using weak electrical currents. Direct transcranial electrical stimulation increases excitability in target brain areas, and increased excitability in specific areas of the brain causes changes in cognitive and behavioral function in individuals (24). A review of an interventional study suggested that this type of electrical therapy may be used in the future as a viable method to treat various psychological disorders at young and old ages (25). Other research suggested that this kind of non-psychological therapy may be useful in improving a variety of cognitive-behavioral processes (26, 27). However, studies showed that

there is a gap in the literature that needs to be filled in order to fully understand the efficacy of this novel form of intervention. Therefore, according to research statistics, the effectiveness of direct transcranial stimulation on this type of cognitive function in students with special learning disorders is increasing (28), but in the case of other variables, a deep gap is still evident. Finally, it can be stated that considering that the method of transcranial direct stimulation is a painless, safe and effective method, several efforts with research and therapeutic goals are investigating this type of intervention (29). In general, given the growing importance of students' problems with various learning disorders and behavioral problems, and given that the world of psychology is examining the effectiveness of a variety of psychological and non-psychological interventions; this study aimed to compare these two types of interventions in the form of comparisons. In fact, the present study sought to answer the question "Is the effectiveness of cognitive therapy based on emotion regulation and direct transcranial electrical stimulation on students' impulsivity different from learning disorders?"

2. Methods

2.1. Research Design

The method of the present study was quasi-experimental and based on a pretest-posttest design with a control group.

2.2. Selection and Description of Participants

The statistical population of present study consisted of all male and female students of the second elementary school (fourth, fifth, and sixth) with special learning disorders who were studying in schools of Tabriz, Iran in the academic year of 2019-2020.

The Colorado Learning Disabilities Questionnaire was initially used to identify students with specific learning disorders. 93 students with particular learning difficulties were found, as per the Colorado questionnaire. 54 kids with learning difficulties were chosen as a sample from the screening pupils using a random selection technique and a table of random numbers. Finally, a lottery was used to randomly divide the chosen sample into three groups (two experimental

groups and one control method). Each randomly chosen participant chose a ball that represented their research group by choosing it from among 54 balls that included their names, the names of the experimental and control groups. The specified sample size was selected based on G*Power statistical software with an effect size of 85%, a significance level of 0.05, and a test power of 0.8 (30). Furthermore, to categorize the participants in the intervention or the control groups, a simple random coin-throwing method was used. The ethical standards including obtaining informed consent, guaranteeing privacy and confidentiality were observed. Moreover, before the intervention, at the time of completing the consent form, the individuals were informed about leaving the research at any time and they were assured that their information would remain confidential and this was fully observed.

2.3. Data Collection Tools

2.3.1. Colorado Learning Difficulties Questionnaire

To diagnose students with special learning disorders and determine the extent of their learning disorders, this Colorado Learning Disabilities Questionnaire was used which has 20 questions. This questionnaire is completed by students' parents. This questionnaire, which consists of 20 items is completed by the students' parents. The answer to each expression on a 5-point Likert scale is from (1) to forever (5). In order to check the validity of the Colorado Learning Problems Questionnaire, two methods of internal consistency and retesting were used. The convergent validity of the components of this questionnaire with the standard academic achievement questionnaires has been reported as follows: reading: 0.64; Mathematics: 0.44; Social cognition: 0.64; Social anxiety: 0.46 and spatial anxiety: 0.30 (31). In Iran, Hajloo and Rezaie Sharif reported the validity of the Colorado Learning Difficulties Questionnaire using the test-retest method of 0.94 (32).

2.3.2 Barat Impulsivity Scale

The impulsivity scale is made by Barratt (33). This scale has 30 items, and subjects responded to these items in four degrees (never, occasionally, often, and almost always). In the eleventh version, Barratt explains the impulsivity questionnaire based on the following three axes: 1- Self-

movement in the sense of acting without thinking, 2- Careful planning or attention to detail, and 3- Stability of adaptation means the ability to look ahead. This scale evaluates the three factors of cognitive impulsivity, motor impulsivity and lack of planning. The reliability of the scale using Cronbach's alpha for the whole test is 0.83 and for the subscales of movement, attention and Non-Planning are: 0.74, 0.73 and 0.71, respectively (33). In Iran, Ekhtiari and colleagues reported an alpha coefficient of 0.78 for attention impulsivity, 0.63 for motor impulsivity, 0.47 for unplanned impulsivity and 0.83 for the whole test (34).

2.4. Protocol

2.4.1. Cognitive Therapy Based on Emotion Regulation

Emotion-based cognitive therapy: Emotion-focused cognitive therapy is an empirical approach that considers emotion as the basis of experience in relation to adaptive and non-adaptive functions (35). Cognitive therapy based on emotion regulation was designed by Barlow. In this treatment, cognitive therapy techniques with emotion regulation were used (36). These methods are broken down into four groups in general: 1) how emotions are formed at various times and locations in connection to ideas, situational triggers, and situations; 2) Reporting your emotional states at the time of an accident or disorder; 3) Using the technique of gathering evidence and cognitive distortions with the aim of objectifying the individual's thoughts and their relationship with positive and negative emotions; 4) Discovering and identifying the professions and beliefs that affect a person's emotions when an accident occurs; and 4) Finding and identifying your emotional states at the time of an accident or disorder.

Summary of Cognitive Emotion Regulation Training Sessions:

Session 1: Introduction: Familiarity of group members with each other; Expression of logic and stages of intervention; Familiarity with the cognitive infrastructure of emotions and the need for emotion regulation.

Session 2: Choosing a position: Providing emotional training: 1) Normal and problematic emotions 2) Emotional self-awareness. Assess the

vulnerability and skills of members.

Session 3: Choosing a position.

Session 4: Modifying the situation: Making changes in emotion-provoking situations, which include: preventing social isolation and avoidance; Problem solving strategy training; Interpersonal skills training (conversation, assertiveness, and conflict resolution), as well as the therapist reviews the cognitive assessment review in detail and answer remaining questions and problems.

Session 5: Attention Development: Attention training aimed at stopping rumination and worry.

Session 6: Complete Cognitive Assessment, Changing Cognitive Assessments, which includes identifying miscalculations and their effects on emotional states, and training marketing strategy (reassessment).

Session 7: Modifying the Answer: Changing the Behavioral and Physiological Consequences of Emotion

Session 8: Application Evaluation: In the final session, the therapist reviews the individual's ongoing need to cope with emotion. In this session, the person gets information about the underlying beliefs and thoughts of emotions and knows what emotions he experiences according to different situations and also what kind of emotions these are.

2.4.2. Direct Transcranial Stimulation Protocol

Electrical stimulation of the brain from the skull is a technique for modulating and correcting brain function, which is used today as a healthy and effective procedure for the treatment of most neuroscience and medical conditions, as well as improving cognitive activities. This research employed transcranial direct current stimulation (tDCS) to stimulate regions associated with impulsivity and aggressiveness in order to assess the efficacy of performance in kids with learning impairments, particularly dyslexia. According to the EEG 10-20 system, the cathode electrode was put on the opposite shoulder and the anode electrode was placed on the left lateral anterior forehead region, which is in charge of regulating complicated motions (37). Participants sit in a

comfortable chair in a quiet room with no other sensory stimuli and electrical brain stimulation by tDCS (Mindlife brand device made in Canada) in 20 minutes with constant current between 1.5 to 2 mA (intensity in proportion to the tolerance of the references) was instilled in the students. The sessions were performed once a day for 20 sessions, using a pair of 5 x 5 cm square rubber electrodes covered with a synthetic sponge impregnated with a normal saline solution and placed in the desired areas.

3. Results

Inclusion criteria also included: a) having a specific learning disorders; B) willingness to participate in the study; C) having moderate and higher intelligence and d) not having other psychiatric disorders; Exclusion criteria included: a) absence from more than one intervention session; B) simultaneous participation in other intervention programs; c) Dissatisfaction with continued cooperation. The control group did not receive any treatment. The control group had two training sessions to learn about ethics after the intervention. It should be highlighted that the parents of the participants were given the assurance that their children's involvement in the research was entirely voluntary, they would be allowed to decline, and their identities would not be included in the questionnaire. Additionally, just the results will be disclosed and their personal information would be kept private. Descriptive statistical methods such as mean and standard deviation

were used, and Kolmogorov-Smirnov test was used to check the normality of the distribution. SPSS software version 22 was used and the significance level was considered as 0.05. Based on the demographic findings, the mean age and standard deviation of the cognitive therapy group based on emotion regulation was 11.05 ± 0.872 , in the direct transcranial electrical stimulation group was 10.83 ± 0.83 and in the control group was 11.11 ± 0.8 . Kolmogorov-Smirnov test was used to check the normality of the distribution. The findings demonstrated that all variables had significance levels larger than 0.05, and because every variable data had a normal distribution, the parametric test was used to determine normal distribution of each variable. To evaluate the variance homogeneity of variables, Levene's error parity test was used. Based on the obtained level of significance, the results showed that the variances are homogeneous ($P=0.151$). To increase the internal validity of the study, the homogeneity of the studied groups in terms of age and sex was compared. Based on the results of the analysis, it was found that there was no difference in terms of age in the three groups ($P=0.573$; $F=0.563$). Furthermore, the results of Chi-square test analysis indicated that no difference in terms of gender was observed among the groups ($\chi^2=0.667$; $P=0.091$).

After confirming the homogeneity of the groups and the assumptions of the analysis, the components of impulsivity were compared in three groups, before which a descriptive table is presented.

Table 1: Evaluation of impulsivity in groups of students with special learning disorders during the study

Variable	Group	Pre-test		Post-test		Within groups	Between groups	
		M	SD	M	SD	P	P	
Impulsivity	Non-Planning	Emotion Regulation-based Cognitive Therapy	23.611	5.791	18.388	3.696	0.001	0.001
		Transcranial Direct Current Stimulation	24.00	6.18	17.05	3.81	0.003	
		Control	25.83	4.61	23.83	5.37	0.121	
Motor	Emotion Regulation-based Cognitive Therapy	Emotion Regulation-based Cognitive Therapy	25.50	3.79	17.77	2.734	0.015	0.001
		Transcranial Direct Current Stimulation	24.72	3.56	15.50	2.85	0.001	
		Control	23.38	6.77	21.50	5.64	0.325	
Cognitive	Emotion Regulation-based Cognitive Therapy	Emotion Regulation-based Cognitive Therapy	25.22	4.42	14.94	3.26	0.021	0.001
		Transcranial Direct Current Stimulation	24.44	6.08	11.55	3.31	0.001	
		Control	24.33	5.07	22.27	4.49	0.110	

As can be seen in Table 1, there is a difference among the scores of impulsivity components in the experimental and control groups.

As seen in Table 2 Paired comparison between groups shows a significant difference in lack of planning between the control group with emotion regulation (I-J=6.27; P=0.001) and the control group with transcranial direct current stimulation (P=0.001; I-J=7.50). But this difference was not significant in two treatment groups. The examination of motor impulsivity showed that unlike the control group, there is no difference between two treatments. However, a group comparison of known impulsivity indicated that there was a significant difference between the two treatment groups (I-J=-7.43; P=0.001). Comparison of adjusted means showed that the means of transcranial direct electrical stimulation group decreased significantly (M=11.72) with emotion regulation treatment (M=14.81), thus Transcranial Direct Current Stimulation was more effective in reducing impulsive behavior.

4. Discussion

This study aimed to compare the effectiveness of direct transcranial electrical stimulation and cognitive therapy based on emotion regulation on impulsivity of students with special learning disorders. Based on the first finding of this study, it was found that cognitive therapy based on emotion regulation had a positive effect on impulsivity (lack of planning, motor and cognitive). This finding is consistent with the results of Narimani and co-workers (38). As a result, research showed that children with special learning disorders exhibit high levels of impulsive behaviors and disruption

in interpersonal relationships, as well as a variety of issues with interpersonal conflict resolution, internal-external adjustment issues, impulsivity (39, 40), and low levels of socially positive behaviors. Impulsive behaviors are sometimes also defined as risky behaviors that include a wide range of actions that occur without thinking, quickly and without proper planning and are high risk. A review of studies on impulsivity showed that impulsive behaviors are the core of many mental disorders such as hyperactivity/ attention deficit disorder, conduct disorder, impulse control disorder, substance abuse, bulimia, suicidal behavior, personality disorders, and learning disorders (5-7).

It seems that students with special learning disorder have many problems in the field of social interactions due to the use of impulsivity and withdrawal patterns and also due to the lack of ability to decode non-verbal signs. A review of the literature and psychological studies showed that cognitive emotion regulation strategies are associated with a reduction in negative emotions and emotional events, and a focus on positive emotion regulation strategies enhances people's understanding of emotion management (41). Moreover, anger recognition and emotion regulation, positive adjustment; and recognizing humiliation, fear, and sadness predict negative adjustment. One and all Axis Two disorders are signs of emotional regulation failure. Therefore, in cognitive regulation of emotions, the student learns how to control destructive emotions and express positive emotions, which in turn reduces their impulsivity. Based on another finding of this study, it was found that direct transcranial electrical stimulation has an effect on the impulsivity of students with learning disorders,

Table 2: Summary of pairwise comparisons by the Bonferroni's Method for the components of impulsivity

Variable	Group (I)	Group (J)	Mean difference (I_J)	Standard error	P
Non-Planning	Emotion Regulation	Control	-6.27	1.41	0.001
	Transcranial Direct Current Stimulation		-1.22	1.37	0.378
	Emotion Regulation	Control	6.27	1.41	0.001
	Transcranial Direct Current Stimulation		7.50	1.40	0.001
Motor	Emotion Regulation	Control	-3.39	1.33	0.014
	Transcranial Direct Current Stimulation		2.39	1.31	0.075
	Emotion Regulation	Control	3.39	1.33	0.014
	Transcranial Direct Current Stimulation		5.79	1.32	0.001
Cognitive	Emotion Regulation	Control	-7.43	1.24	0.001
	Transcranial Direct Current Stimulation		3.08	1.27	0.019
	Emotion Regulation	Control	7.41	1.24	0.001
	Transcranial Direct Current Stimulation		10.51	1.25	0.001

which is consistent with the results of Gilmore and colleagues (41). Brain defects are one of the best predictors of impulsive and aggressive behaviors. Neurological research showed that patients with frontal cortex injury behave more aggressively than others. Impulsivity involves a decrease in a person's sensitivity to the negative consequences of behavior, a rapid and unwanted reaction to a stimulus before a complete evaluation of the information, and disregard for the long-term consequences of the behavior. Impulsivity is associated with a number of psychological harms in society, such as violence, antisocial behaviors, and crime (42). Today, impulsivity is conceptualized as a neurobiological dimension, meaning that impulsivity progresses with a lack of cognitive inhibition and is associated with neurotransmitters and emotional instability in individuals (4). According to Miller, the high level of impulsivity and its dimensions in adolescents can explain their problems in delaying needs and inhibiting behaviors. Therefore, children's impulsive behavior can be caused by their inability to control their impulses (43). People with impulsivity syndrome experience significantly higher aggression. Aggression can be the result of genetic or environmental factors or the interaction between these two factors (12).

Also, it can be inferred that students with high impulsivity suffer from central nervous system arousal, which reflects the importance of these people working hard to achieve the desired arousal to calm down and stimulate. Electricity in the P4 region increases dopamine in them, which in turn reduces impulsivity in these students. Based on the latest findings of this study, it was found that direct transcranial electrical stimulation was more effective than cognitive therapy based on emotion regulation in the cognitive impulsivity component of students with specific learning disorders. This finding is consistent with the results of Monastera and colleagues (44). They argued that cognitive or pharmacological therapies appear to be a form of preventive intervention that induces aggressive manifestations and symptoms in children without causing lasting changes in their behavior (44). But bio psychiatric treatments alter a person's behavior permanently. One of the non-invasive techniques is electrical stimulation of the brain, which relies on the capacity of an electric current to pass through the brain's membranes and skull and induce an electrical current in the brain tissue. With this

technique, the potential of the activated cells slowly changes while they are at rest, which enhances how well brain neurons interpret information. It can be inferred that impulsivity involves a decrease in a person's sensitivity to the negative consequences of behavior, a rapid and unwanted reaction to a stimulus before the complete evaluation of information, and disregard to the long-term consequences of the behavior. Impulsivity is associated with a number of psychological harms in society, such as violence, antisocial behaviors and crime (44). Today, impulsivity is conceptualized as a neuro-biological dimension, meaning that impulsivity is accompanied by a lack of cognitive inhibition and is associated with neurotransmitter defects and emotional instability in individuals (4). The current finding offers crucial new insights into the function of a cerebral component that may be crucial in controlling the violent reactions that often follow issues with either blocking or boosting each person's brain systems. According to research, persons who are impulsive and violent need regular brain stimulation to feel energized and at ease (45, 46). This helps to control the brain stimulation that results in impulsive and aggressive emotions.

4.1. Limitations

One of the limitations of this study was using limited volume samples. Because this study was conducted on a small sample of students, the generalization of the results is limited. Another is that the present study's sample was limited to children with learning disorders in Tabriz, which affects the generalizability of research findings. Moreover, data collection in this study was based on self-reported scales. Another limitation of this research is related to measurement; this is because these reports are prone to distortion in terms of unconscious defenses, bias in response, methods of personal introduction, and social desirability in general. Finally, regarding transcranial direct electrical stimulation and emotion regulation-based cognitive therapy were examined in the short term; there was no opportunity to conduct a follow-up test and review the long-term results of research in the natural environment. Therefore, considering the mentioned limitations, it is suggested that since the present study is a quantitative research, in the next research, a qualitative research (contextual theory based on semi-structured interview) be used based on the opinions of clients, experts and previous literature. Moreover, in terms of

the greater effect of direct transcranial electrical stimulation therapy on the impulsivity of students with special learning disorders, it is suggested that workshops be held on the effect of this important treatment to increase their mental health and mental health for professionals, counselors and parents and be provided in the form of educational and psychological services in centers related to education to students with special learning disorders in order to prevent their attention, impulsivity, and aggression problems during and after school.

5. Conclusions

Based on the findings of this study, it can be concluded that direct transcranial stimulation can have a greater effect on reducing cognitive impulsivity. Since the stimulation of neurons in the brain is reliant on the capacity of electric current to flow, it appears that impulsive and aggressive individuals continually need to stimulate the brain to experience the release of energy and relaxation. Because it is made of the brain's membranes and the skull, electrical induction occurs in the brain tissue. By stimulating and inhibiting the brain, it fulfills cerebral arousals that cause impulsivity and violence. Thus, it is clear that direct transcranial stimulation can have a greater impact on reducing the impulsivity of students with specific learning disorders.

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Ethical Approval

The Ethics Review Board of the university approved the present study with the code of IR.IAU.TABRIZ.REC.1398.106. Also, written informed consent was obtained from the participants.

Conflict of Interest: None declared.

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