Journal of Modern Rehabilitation

Research Article

Combined Transcranial Direct Current Stimulation with Occupational Therapy Improves Activities of Daily Living in Traumatic Brain Injuries: A Pilot Randomized Clinical Trial

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Citation Afsharipoor M, Hejazi-Shirmard M, Irani A, Kalantari M, Akbarzade Baghban A. Combined Transcranial Direct Current Stimulation with Occupational Therapy Improves Activities of Daily Living in Traumatic Brain Injuries: A Pilot Randomized Clinical Trial. Journal of Modern Rehabilitation. 2024; 18(1):114-120.

Article info:
Received: Aug 28, 2022
Accepted: Nov 28, 2022
Available Online: 01 Jan 2024

Keywords:
Traumatic brain injuries; Transcranial direct current stimulation; Occupational therapy; Activities of daily living

ABSTRACT

Introduction: Traumatic brain injury (TBI) is one of the leading causes of long-term disability worldwide. Occupational therapy interventions in these patients are mainly focused on improving patients' ability to perform daily occupations. Transcranial direct current stimulation (tDCS) is a non-invasive brain stimulation technique whose potential for motor and cognitive recovery of patients with TBI has been investigated; however, its effect on functional outcomes following TBI is unknown. This study aims to determine the effectiveness of tDCS combined with routine occupational therapy on the activities of daily living in patients with TBI.

Materials and Methods: This was a single-blind, randomized clinical trial. A total of 24 patients with TBI were recruited using the convenience sampling method and were randomly assigned to the experimental (n=12) and control groups (n=12). Both groups underwent routine occupational therapy for 10 sessions (3 days per week), and the experimental group received tDCS (20 min) in addition to routine occupational therapy. Activities of daily living were assessed using the functional independence measure (FIM) at the baseline and the day after the end of the intervention.

Results: After a 10-session intervention, both groups experienced significant improvements in the cognitive subscale and the FIM total score (P<0.001). Additionally, the findings showed that these improvements were significantly higher in the experimental group (P<0.001).

Conclusion: According to the findings, although routine occupational therapy can effectively improve the ability of patients with TBI to perform daily living activities, adding tDCS as a complementary intervention can accelerate recovery in these patients.

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Introduction

Traumatic brain injury (TBI) is one of the leading causes of death and long-term disabilities, especially in low- and middle-income countries [1]. TBI is caused by an external physical force and may reduce or alter consciousness and impair cognitive, behavioral, physical, and functional abilities [2]. It consequently impacts the individuals' ability to perform activities of daily living (ADL) and necessitates long-term care [2]. Approximately 65% of patients with moderate to severe TBI suffer from temporary or permanent motor, cognitive, and mental deficits [3]; therefore, they will need close supervision or assistance to perform ADLs [4, 5].

More than half of patients with moderate to severe TBI and about 15% of patients with mild TBI experience long-lasting cognitive deficits [3]. Deficits of memory, attention, reasoning, executive functioning, and awareness of deficits are the most common cognitive impairments after TBI [3, 5]. Cognitive deficits adversely impact these patients' ability to perform ADLs more than any other residual motor deficits [6].

Occupational therapy in patients with TBI is mainly focused on improving the patient's ability to perform daily occupations, enhancing cognitive function and adaptations in the home environment [7]. Although rehabilitation is one of the critical services for these patients, regarding the devastating consequences of TBI on patients and their caregivers, finding effective and efficient interventions to accelerate and enhance recovery after TBI has been one of the goals and challenges of rehabilitation specialists. The advancement of technology in recent years has led to improving treatment outcomes for various diseases, including TBI.

Non-invasive brain stimulation (NIBS) techniques, including transcranial direct current stimulation (tDCS), are among the techniques whose promising effects have recently been reported in patients with TBI [8]. tDCS is one of the safe and cost-effective NIBS techniques that has been studied in different disorders, including TBI [6]. tDCS is the application of a low-amplitude electrical current over the scalp [9]. It changes the resting potential in the neural membrane, decreases the accumulation of gamma-aminobutyric acid, increases cortical excitability, and stimulates neural plasticity in these patients [9, 10]. Although limited studies have investigated the efficacy of tDCS in TBI [10], the potential of tDCS in facilitating the recovery of cognitive and motor function after TBI has been investigated, and promising results have been reported [8-10].

Since the frontal lobe and its related circuits have a critical role in cognitive functions and considering that cognitive function is one of the strongest predictors of functional recovery [3], the use of tDCS in the dorsolateral prefrontal area to enhance cognitive function may improve the patient's ability to perform ADLs. To the best of our knowledge, there is no evidence relating to the effectiveness of tDCS in improving these patients' ability to perform ADLs, which are composed of multiple motor and cognitive tasks. Although evidence suggests the efficacy of tDCS in improving ADLs in stroke survivors [11], the mechanism of recovery and neuroplasticity in patients with TBI may be different from that of stroke survivors [12]. Accordingly, the present study investigates the effectiveness of tDCS combined with routine occupational therapy on the ability of patients with TBI to perform ADLs.

Materials and Methods

Study participants

A total of 24 patients with TBI participated in this pilot randomized clinical trial. The eligible participants were recruited from consecutive admissions to the Pasteur Hospital in Bam City, Iran. The inclusion criteria were as follows: Being in the age range of 18-40 years, having motor injury mainly on the right side of the body, scoring 10-24 on the mini-mental state examination (MMSE), having no history of epilepsy or other neurological and neuropsychiatric disorders, and absence of metal implants in the body.

The patients receiving other therapeutic interventions and individuals who were absent in more than two sessions were excluded.

Study intervention

The participants were evaluated at baseline using the Persian version of the Functional Independence Measure (FIM) [13]. Then, they were randomly assigned to one of the experimental or control groups using the random-number table. All participants received routine occupational therapy 3 days per week for 10 sessions. The experimental group also received tDCS at the intensity of 2 mA and density of 0.057 mA/cm^2 for 20 minutes. The anode electrode was located on the left dorsolateral prefrontal cortex, and the cathode electrode was on the right dorsolateral prefrontal cortex [14].

In the control group, the duration of treatment sessions was the same as the experimental group, and the electrodes were placed similarly. Still, the device was turned on for 25 seconds, and the current was turned off automatically (sham condition) [14]. Both groups received routine occupational therapy interventions, including upper and lower limb stretching and strengthening exercises, range of motion exercises, balance exercises, and functional task practice. An experienced occupational therapist provided the intervention in both groups. Again, participants were assessed 24 hours after the last treatment session. Baseline and post-intervention evaluations were performed by an experienced occupational therapist unaware of group allocation.

Data collection instrument

Functional Independence measure

The participant's ability to perform ADLs was evaluated using the FIM. The FIM is one of the most common tools to assess the level of disability in various neurological disorders [15]. It was designed by Corrigan et al. to evaluate the level of disability. It consists of 18 ADLs that fall into one of two motor (self-care, sphincter control, transfers, and locomotion) or cognitive subscales (communication and social cognition). Each activity is scored on a 7-point scale from 1 (completely dependent) to 7 (completely independent). Higher scores indicate greater functional independence [16]. FIM is a valid, reliable, and highly sensitive tool for assessing functional independence in patients with TBI [16, 17].

Statistical analysis

The Kolmogorov-Smirnov test assessed the normal distribution assumption. The test demonstrated the normal distribution of the total score of the FIM and its motor subscale in both groups. Still, the normal distribution of the cognitive subscale scores was not approved in the control group. The independent t-test and paired sample t-test were used for between-group and within-group comparisons. The statistical significance was set at $P<0.05$.

Results

A total of 29 patients with TBI were included in the study. Two participants from the experimental group (due to COVID-19 infection) and 3 participants from the control group (one was infected with COVID-19, and two received other treatments during the study) were excluded. Finally, 24 participants (12 participants in each group) completed the study (Figure 1). No significant differences were observed between the groups in the main baseline variables. The participants in both groups had moderate to severe TBI (Glasgow coma scale score of 5-13) [18] and experienced moderate cognitive deficits (MMSE score of 14-24). The demographic characteristics of the participants were comparable between the two groups (Table 1).

The results of the paired samples test exhibited significant changes between baseline and post-intervention in the total score of the FIM and its subscales in both groups. The results of the independent samples t-test showed no significant difference between the two groups in the total score of the FIM and its subscales at the baseline; however, it demonstrated significant differences between the two groups for the total score of the FIM and its cognitive subscale at post-intervention (Table 2). In other words, both control and experimental groups experienced significant improvement in the total scores of the FIM and its subscales. However, the experimental group demonstrated greater improvement in the FIM and cognitive subscale than the control group. According to Table 2, routine occupational therapy, in addition to tDCS, was more effective in improving cog-

Table 1. Demographic characteristics of the participants

Characteristic	Control (n=12)	Experimental (n=12)	P
Sex (male/female)	9/3	8/4	0.83
Age (y)	28.25±5.97	29.67±6.28	0.07
Education (high school/university)	12/0	11/1	0.83
Mini-mental state examination	18.67±3.63	19.67±3.23	0.53
Glasgow coma scale	9±2.79	8.75±2.56	0.51

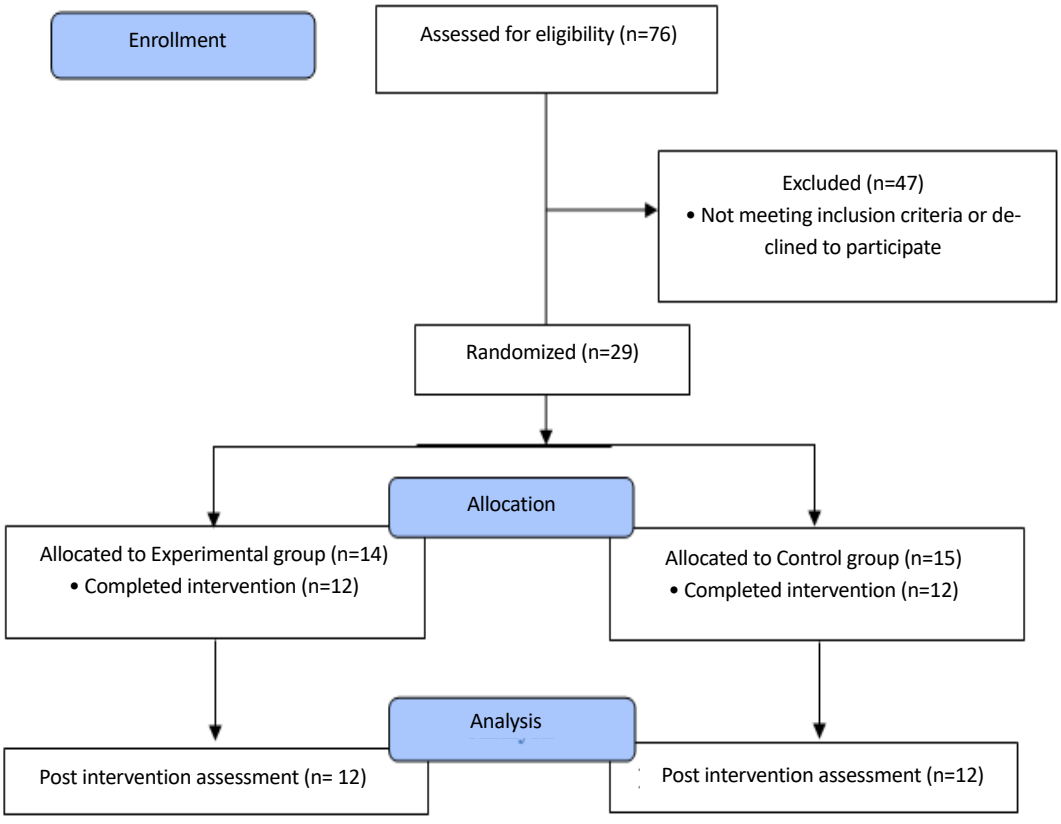

Figure 1. Flow diagram of the participants through the trial

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Table 2. Comparison of Functional Independence Measure in participants

Outcome Measure	Evaluation Time	Mean±SD		P
		Control (n=12)	Experimental (n=12)	
FIM total score	T0	47.75±2.42	49.33±2.15	≤0.001
	T1	72.33±5.45	82.92±3.03	
	P	≤0.001	≤0.001	
Motor subscale	T0	36.08±2.75	38.42±1.78	0.081
	T1	52.92±5.98	52.42±3.47	
	P	≤0.001	≤0.001	
Cognitive subscale	T0	11.67±1.49	10.92±1.83	≤0.001
	T1	19.42±4.29	30.50±1.83	
	P	≤0.002	≤0.001	

Notes: T0=baseline and T1=post-intervention.

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FIM: Functional independence measure; SD: Standard deviation.

nitive function and disability level than routine occupational therapy alone.

Discussion

To the best of our knowledge, this is the first study to investigate the effects of tDCS on the ADL of patients with TBI. The findings showed that routine occupational therapy and routine occupational therapy plus tDCS lead to significant improvements in ADL of patients with TBI (FIM and its subscales); however, improvement in the patients who received tDCS in addition to routine occupational therapy intervention is significantly higher. In other words, tDCS, and especially the stimulation of areas related to cognition, can accelerate functional recovery in these patients.

It seems that tDCS, like other non-invasive brain stimulation techniques stimulates structural and functional neuroplasticity through synaptic strengthening and dendritic sprouting, and subsequently boosts or accelerates clinical recovery. tDCS can target different brain networks, including motor or cognitive networks, and impact motor or cognitive performance [9]. Although studies that have examined the effectiveness of tDCS in patients with TBI are scarce, and most have several methodological biases (e.g. the lack of blinding and randomization), they have reported improvements in cognitive, neuropsychological, and neurophysiological performance [9, 19].

The dorsolateral prefrontal cortex regions were stimulated in the present study to affect the participants' cognitive performance. The dorsolateral prefrontal cortex is one of the brain areas that, similar to other parts of the prefrontal lobe, plays an essential role in multiple cognitive functions, mainly divided attention and working memory [20]. Cognitive function plays a critical role in performing daily activities. It is one of the predictors of functional recovery in various neurological disorders, such as stroke, Parkinson disease, multiple sclerosis, and traumatic brain injuries [6, 21-23]. On the other hand, a small improvement in cognitive function may increase people's ability to perform ADL [19]. Improving the ability of patients to perform daily activities in the present study may also be related to improving their cognitive functions. In other words, since cognitive performance is one of the strong predictors of people's ability to perform tasks and even for mobility [20], improving people's ability to perform daily activities can be attributed to enhancing their cognitive performance.

The findings showed that the more significant improvement in cognitive performance of the experimental group is associated with greater improvements in the ability to perform ADLs. As mentioned earlier, the evidence of the effectiveness of tDCS on the cognitive performance of patients with TBI is still in its infancy. Our findings are similar to the results of Lee et al. (2018), who reported improved cognitive function following tDCS on the dorsolateral prefrontal cortex in patients with TBI [24] but were not following the findings of Lesniak et al. (2014), who did not find any positive effects of tDCS on memory and attention in patients with severe TBI. However, this finding may be due to the higher severity of TBI in patients in Lesniak's study [25].

The present research was a pilot study on the effectiveness of tDCS in TBI patients. The findings showed that although a 10-session routine occupational therapy program is efficacious in improving the ability of patients to perform ADLs, adding tDCS to routine occupational therapy may induce more significant recovery. In other words, as a complementary intervention alongside routine occupational therapy, tDCS can facilitate recovery in these patients, although more studies are warranted.

One of the main limitations of the present study was the lack of a follow-up phase; in other words, the maintenance of the results was not investigated. Therefore, it is suggested that a follow-up phase be conducted in future studies to evaluate the maintenance of the results. Secondly, this study was conducted in relatively young patients, and since age negatively influences physical and cognitive functions, it is suggested to include older people in future studies to increase the generalizability of the findings. Finally, the participants in this study had a Glasgow coma scale score between 5 and 13; therefore, they had moderate to severe TBI [18]. Hence, the findings should be cautiously generalized to patients with mild lesions. Additionally, it is suggested that similar studies be conducted in patients with mild lesions.

Conclusion

Cognitive impairments are among the most disabling consequences of traumatic brain injuries, and few interventional approaches are known for these deficits. Based on the findings of this pilot study, stimulation of the prefrontal areas through tDCS, along with routine occupational therapy, can boost the improvement of cognitive function and, subsequently, the ability of patients with TBI to perform daily living activities, although more studies are needed.

Ethical Considerations

Compliance with ethical guidelines

This research was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences (Code: IR.SBMU.RETECH.REC.1399.1089).

Funding

Shahid Beheshti University of Medical Sciences funded this research.

Authors' contributions

Conceptualization and study design: Mehrnaz Afsharipor, Minoo Kalantari and Ashkan Irani; Data analysis: Alireza Akbarzade Baghban; Data interpretation: Mehrnaz Afsharipor and Minoo Kalantari; Writing the original draft: Minoo Kalantari and Mahnaz Hejazi-Shirmard; Review and editing: Mahnaz Hejazi-Shirmard.

Conflict of interest

The authors declared no conflict of interest.

Acknowledgments

The authors would like to thank all participants and their caregivers for their cooperation.

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