



Original Article

Effects of Transcranial Direct Current Stimulation (tDCS) on Balance, Functional Performance, and Neurocognitive Function in Males with Chronic Ankle Instability: Study Protocol for a Randomized Controlled Trial

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ABSTRACT

Background: Approximately 40% of individuals who experience an ankle sprain subsequently develop Chronic Ankle Instability (CAI). Recent evidence highlights alterations in Central Nervous System (CNS) function and deficits in neurocognitive performance among this population. Therefore, there is a need for interventions that target neural excitability alongside traditional physical rehabilitation.

Methods: This study is a randomized, sham-controlled, single-blind clinical trial. Twenty participants with CAI will be randomly assigned to two groups (n=10 per group): (1) anodal Transcranial Direct Current Stimulation (a-tDCS) combined with exercise, and (2) sham tDCS combined with exercise. The intervention consists of 12 sessions (three times per week). Assessment of self-reported outcomes, balance, functional performance, and neurocognitive function (such as reaction time) will be conducted at baseline, mid-intervention (6th session), and post-intervention (12th session).

Results: As this is a study protocol, primary results are expected to demonstrate whether the combination of a-tDCS and exercise leads to superior improvements in postural balance and neurocognitive reaction time compared to exercise with sham stimulation. It is hypothesized that tDCS will enhance neural plasticity, thereby amplifying the functional gains from the exercise program and improving self-reported stability.

Conclusion: This study aims to provide empirical evidence for the role of non-invasive brain stimulation in musculoskeletal rehabilitation. If effective, tDCS could be established as a valuable complementary intervention alongside exercise therapy to address both the physical and neurocognitive deficits associated with Chronic Ankle Instability, potentially reducing the recurrence of sprains.

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Introduction

Ankle sprain is among the most common musculoskeletal injuries [1]. Up to 40% of individuals experience persistent symptoms—such as recurrent sprains, episodes of “giving way,” and a sense of instability—one year after the initial injury [2, 3], a condition known as chronic ankle instability (CAI). CAI negatively affects health-related quality of life [4], reduces physical activity levels [5], and may contribute to early-onset ankle osteoarthritis [6]. Individuals with CAI also exhibit deficits in balance and functional performance [2, 7].

Evidence suggests that CAI is not solely a peripheral pathology; rather, it is associated with central nervous system (CNS) alterations. These include reduced excitability of the primary motor cortex (M1) and altered activation patterns in the supplementary motor area (SMA) [8, 9]. Additionally, deficits in neurocognitive function—such as slower reaction time, decreased accuracy, and higher error rates—have been reported in individuals with CAI compared to healthy controls [10-12]. The persistent nature of CAI, even after rehabilitation, may be partly because most conventional rehabilitation programs primarily target peripheral impairments and do not address CNS-related adaptations.

Given these central alterations, interventions that modulate cortical excitability and enhance neurocognitive function may offer additional therapeutic benefits. Transcranial direct current stimulation (tDCS), a form of non-invasive brain stimulation (NIBS), alters cortical excitability by delivering low-intensity electrical current through surface electrodes. Anodal tDCS increases cortical excitability, while cathodal tDCS decreases it under the stimulation site [13]. Previous studies have demonstrated that tDCS can enhance cortical excitability, improve patient-reported outcomes, increase muscle activation, and enhance dynamic balance and proprioception in individuals with CAI compared to sham stimulation [14, 15].

The present single-blind randomized controlled trial (RCT) is designed to investigate the effects of tDCS on self-reported outcomes, balance, functional performance, and neurocognitive parameters in males with CAI. Because sex differences have been observed in neurocognitive performance, only male participants will be included [16]. To the best of the authors' knowledge, this is the first study to examine the effects of tDCS on neurocognitive function in individuals with musculoskeletal disorders.

Methods

Study Design

This study will employ a randomized, sham-controlled, single-blind clinical trial design. A total of 20 males with chronic ankle instability (CAI) will be recruited. Before participation, all subjects will provide written informed consent, which has been approved by the Ethics Committee of Tehran University of Medical Sciences (TUMS).

Participants will be randomly assigned to the anodal tDCS (a-tDCS) or sham tDCS group in a 1:1 ratio. Randomization will be performed using block randomization with four blocks, generated via the *Random Allocation Software* to ensure equal group distribution and reduce allocation bias.

The intervention period will span four weeks, with participants attending three sessions per week (12 sessions in total). Self-reported questionnaires will be administered at baseline (Session 1) and at the end of the intervention (Session 12). All other outcome measures—including balance, functional performance, and neurocognitive tests—will be assessed at baseline (Session 1), mid-intervention (Session 6), and post-intervention (Session 12).

Inclusion Criteria

Participants will be included if they meet all of the following criteria: 1) Males aged 18 to 40 years; 2) right-handed; 3) A history of at least one significant ankle sprain occurring ≥ 12 months before study enrollment; 4) A history of at least two episodes of ankle “giving way” during the 6 months before enrollment; 5) A score of ≤ 24 on the Cumberland Ankle Instability Tool (CAIT); 6) Scores of $< 90\%$ and $< 80\%$ on the Foot and Ankle Ability Measure (FAAM) Activities of Daily Living (ADL) and Sports subscales, respectively; 7) Presence of unilateral ankle instability; 8) Minimum educational attainment of a high school diploma.

Exclusion Criteria

Participants will be excluded if they meet any of the following criteria: 1) Presence of neurological or orthopedic conditions that could impair balance; 2) History of lower limb fracture or surgery; 3) Uncorrected auditory or visual impairment; 4) Presence of metallic implants (e.g., pacemaker); 5) History of head injury accompanied by loss of consciousness; 6) History of seizure; 7) History of migraines; 8) Scalp or skin disorders (e.g., psoriasis); 7) Use of medications that may alter seizure threshold or cognitive function.

Additionally, participants will be instructed to abstain from caffeine and alcohol consumption for at least 12 hours before each study session.

Sample Size Estimation

The sample size was calculated using G*Power 3.1.9.7 based on choice reaction time (RT) [11]. Using a one-tailed test, an alpha level of 0.05, an effect size of $d = 1.75$, and an allocation ratio (N_2/N_1) of 1, the required sample size was determined to be 8 participants in the a-tDCS group and 8 in the sham group. To account for an anticipated attrition rate of 25%, the final sample size was increased to 10 participants per group.

Blinding

This study will employ a single-blind design in which participants will remain unaware of their group allocation. The researcher administering the intervention will not be blinded and will be responsible for conducting the assessments, delivering the

intervention, and performing data analysis.

Ethical Consideration

This study has been reviewed and approved by the Ethics Committee of Tehran University of Medical Sciences (TUMS) under approval ID **IR.TUMS.FNM.REC.1401.165**, dated 6 February 2023. All procedures will be conducted in accordance with national ethical guidelines and standards for medical research in Iran. The study has also been registered in the Iranian Registry of Clinical Trials. All participants will be fully informed about the study objectives and procedures and will provide written informed consent before participation.

Outcome Measures

CAIT

The Persian version of the Cumberland Ankle Instability Tool (CAIT) will be used as both a background measure and a dependent variable. Consistent with the International Ankle Consortium criteria, scores equal to or less than 24 will be considered indicative of CAI [3]. The Persian version has demonstrated acceptable validity and reliability, with a test–retest reliability of 0.90 [17]. CAIT consists of nine items, with total scores ranging from 0 to 30. A score of 0 represents severe instability, whereas a score of 30 indicates normal ankle stability [17].

Foot and Ankle Ability Measure (FAAM)

The Persian version of the Foot and Ankle Ability Measure (FAAM) will also be used as a background measure and a dependent variable. According to the International Ankle Consortium, CAI is defined by scores below 90% on the Activities of Daily Living (ADL) subscale and below 80% on the Sports subscale [3]. Higher scores reflect better functional status [18]. The Persian version has demonstrated high validity and reliability, with a test–retest reliability of 0.98 for both subscales [18].

Neurocognitive Function

Neurocognitive function will be evaluated using the Speed Anticipation Reaction Time (SART) Test software, whose validity and reliability have been previously established [19]. Visual reaction time (RT), auditory RT, and anticipatory skills will be assessed as key neurocognitive parameters.

Participants will sit on a chair positioned 2 meters in front of a 24-inch LCD monitor (Samsung 68-2555 A). The examiner will operate a laptop connected to the monitor via interface ports; the laptop screen will remain out of the participant's view. At the start of each session, the examiner will open the software, select the “new session” option, and enter the participant's name and age. Each test generates both a printable text output and an Excel file.

For RT assessments, the mean value of all trials will be used. Anticipatory skills will be quantified as the absolute difference between the actual stimulus time and the participant's predicted time. Participants will hold a joystick with both hands and will respond using only the right thumb. Practice trials will be performed to ensure familiarization with the testing system.

All neurocognitive assessments will be conducted in a noise-minimized environment and at a consistent time of day to control for circadian influences [20].

Visual RT Tests

Visual reaction time (RT) will be assessed using two test types: choice RT and complex choice RT. During these tests, four colored lamps (red, yellow, green, and blue) will appear on the LCD monitor.

For the visual choice RT test, one of the four lamps will illuminate, and participants must press the corresponding joystick button as quickly as possible. Buttons 1, 2, 3, and 4 will correspond to the red, yellow, green, and blue lamps, respectively.

For the visual complex choice RT test, one of the four lamps will illuminate, and participants will be instructed to press the *reverse* button as quickly as possible. Specifically, they will press button one instead of 3 and vice versa, and button two instead of 4 and vice versa [20].

Auditory RT Tests

Auditory reaction time (RT) will be assessed using two protocols: choice RT and complex choice RT. Four auditory stimuli with different frequencies will be presented. For the auditory choice RT test, participants will be instructed to press the corresponding joystick button as quickly as possible upon hearing each tone. Buttons 1, 2, 3, and 4 will correspond to frequencies of 500 Hz, 1000 Hz, 3000 Hz, and 7000 Hz, respectively.

For the auditory complex choice RT test, participants will be required to press the *reverse* button as quickly as possible after hearing each tone. Specifically, button one will be pressed instead of 3 and vice versa, and button two will be pressed instead of 4 and vice versa [20].

Both visual and auditory choice RT tests will consist of 5 sets, each containing 10 repetitions. All stimuli will be presented with a randomized delay. Measurement accuracy will be 0.001 seconds. The maximum allowable error rate is one error per set. If participants exceed this limit, the word “Abnormal” will appear on the screen, and the set will be repeated.

Anticipatory Skill Tests

A football pitch will be displayed on the screen, and a soccer ball will move at a constant speed from the right side of the field toward the goal on the left side. A checkered square will be positioned in front of the goal. The ball will disappear as soon as it reaches this checkered area. Participants must estimate the moment the ball would cross the goal line—based on its trajectory and speed before disappearance—and press button one at their estimated time.

Anticipatory skill performance will be quantified using the SART software by computing the difference between the participant's estimated time and the actual time the ball crosses the goal line. Negative values indicate delayed responses, whereas positive values indicate early responses. As previously noted, the absolute values of these differences will be used for statistical analysis.

Two types of anticipatory skill tests will be

performed: low-speed (120 m/s) and high-speed (170 m/s) conditions. Each condition will consist of 3 sets, with 10 repetitions per set. Measurement precision will be set at 0.001 seconds [20].

Static Balance

Static balance will be assessed using the foot-lift test. Participants will close their eyes and stand on their involved leg on a firm surface, with hands placed on the iliac crests. The stance limb's knee and hip will be positioned in slight flexion. Participants will be instructed to maintain this position for 30 seconds.

The examiner will record the number of errors, defined as: 1) Loss of contact of the stance foot with the surface; 2) Contact of the non-stance foot with the surface; and 3) One additional error counted for each second the non-stance foot remains in contact with the surface.

Participants will perform three test trials following one practice trial, with at least 30 seconds of rest between trials. The average number of errors across the three trials will be used for data analysis [21].

Dynamic Balance

Dynamic balance will be assessed using the Star Excursion Balance Test (SEBT). According to Hertel et al. [22], measuring reach distances in all eight directions is not necessary to detect functional performance deficits in individuals with chronic ankle instability (CAI).

Participants will place their involved foot at the center of a grid with three lines oriented in the anterior (A), posteromedial (PM), and posterolateral (PL) directions. The angle between the posterior lines will be 90°, and the angle between the anterior line and each posterior line will be 135°. Participants will stand on their involved limb, hands on their hips, and reach with the opposite limb as far as possible in each direction.

The reach distance will be measured from the center of the grid to the reach point in centimeters. Participants will perform four practice trials followed by three test trials in each direction, with 30 seconds of rest between trials. Reach distances will be normalized to leg length, measured as the distance from the anterior superior iliac spine (ASIS) to the distal end of the medial malleolus in a supine position. The normalized reach distance will be calculated as follows: The sum of the three trials' reach distances in each direction will be divided by leg length multiplied by 3, and the final score will be defined as a percentage [23].

The test will be stopped and reassessed under the following conditions: 1) If the participant bears significant weight on the reaching limb; 2) If the involved foot is not fully in contact with the ground; 3) If the participant loses balance on the involved limb; and 4) If the participant removes their hands from the hips [24, 25].

Functional Assessment

Functional performance will be assessed using the single-leg side hop test. Two parallel lines, spaced 30

cm apart, will be drawn on the ground. Participants will hop laterally between the lines as quickly as possible. Each side-to-side hop counts as one repetition, and the test comprises 10 repetitions.

Participants will perform 3–4 practice trials at a normal pace to familiarize themselves with the task, followed by two timed test trials. A minimum of 60 seconds of rest will be provided between timed trials. The time for each trial will be recorded to the nearest 0.01 seconds, and the shorter time of the two trials will be used for data analysis [21].

Interventions

At the beginning of each session, participants will receive either anodal tDCS (a-tDCS) or sham tDCS for 20 minutes. Following the tDCS application, both groups will perform a structured program of resistive and balance training.

tDCS

A Neurostim2 device (Medina-Teb Gostar, Iran) will be used to deliver tDCS. Before stimulation, all equipment—including sponge electrodes, rubber electrodes, and the stimulator—will be inspected to ensure proper functioning. The participant's scalp and overall condition will be checked for any contraindications to tDCS. The target scalp area will then be cleaned with an alcohol pad.

Sponge electrodes (5 × 5 cm) will be saturated with 0.09% saline, with the rubber electrodes placed inside them and secured to the scalp using straps. The anode will be positioned over the primary motor cortex (M1) contralateral to the involved ankle (C3 for right ankle involvement, C4 for left), according to the international 10–20 EEG electrode placement system [14, 26]. The cathode will be placed over the ipsilateral supraorbital area.

For the a-tDCS group, a 2 mA anodal current will be applied for 20 minutes, including a 30-second ramp-up and a 30-second ramp-down. Participants will be continuously monitored throughout the stimulation. The Neurostim2 device continuously monitors electrode contact quality to minimize the risk of skin injury.

For the sham group, electrode placement will be identical, but the two mA current will be applied for only 30 seconds at the beginning to mimic the sensation of stimulation [27].

Resistive Training

Resistive training will be performed using Thera-Band tubes. Participants will sit on a bed with the knee fully extended and perform plantarflexion, dorsiflexion, inversion, and eversion movements. They will be instructed to focus on ankle movement while minimizing involvement of the knee and hip.

The doubled Thera-Band will be attached to the bed's suspension frame, and participants will place the involved foot into the looped end of the band. A target stretch length will be calculated by adding 70% of the Thera-Band's resting length to its original length, and this distance will be marked on the bed. Participants will stretch the Thera-Band to this mark while

performing the ankle exercises [28].

Each exercise will consist of 3 sets of 10 repetitions. Every three sessions, the training intensity will progress to the next resistance level by changing the Thera-Band color, following the sequence: red, green, blue, and black [21].

Balance Training

Single-leg balance training will be implemented progressively, with exercises performed with eyes open and eyes closed. Each level will consist of 3 repetitions, and participants will advance through 7 progression levels.

Eyes-open levels will include: 1) Single-leg stance on a hard surface with arms across the chest for 60 s; 2) Single-leg stance on a foam pad with arms across the chest for 30 s, 60 s, and 90 s; 3) Single-leg stance on a foam pad with arms across the chest while tossing a medicine ball for 30 s, 60 s, and 90 s.

Eyes-closed levels will include: 1) Single-leg stance on a hard surface with arms out for 30 s.; 2) Single-leg stance on a hard surface with arms across the chest for 30 s and 90 s; 3) Single-leg stance on a foam pad with arms out for 30 s; and 4) Single-leg stance on a foam pad with arms across the chest for 30 s, 60 s, and 90 s.

Participants will progress to the next level only after completing three repetitions without errors. Errors include: Opposite limb touching the surface, removing the arms from the prescribed position, bracing the stance limb with the opposite limb, and excessive lateral flexion of the trunk [29].

Data Analysis

Data will be analyzed using SPSS version 24. The normality of the variables will be assessed using the Shapiro-Wilk test. Descriptive statistics, including mean and standard deviation (SD), will be reported.

For demographic comparisons between groups, either the Independent Samples t-test or the Mann-Whitney U test will be used, depending on the data's normality.

For within-group analyses of the CAIT, FAAM-ADL, and FAAM-Sports subscales, the Paired Samples t-test or the Wilcoxon signed-rank test will be used, depending on the results of the normality test. For between-group comparisons of these variables, either the Independent Samples t-test or the Mann-Whitney U test will be employed.

For all other outcome variables, Repeated Measures Analysis of Variance (ANOVA) or Friedman's test will be used as appropriate. A significance level of 0.05 will be adopted for all analyses.

Discussion

The presented study will aim to explore the impacts of anodal tDCS on self-reported questionnaires, balance, functional performance, and neurocognitive function in male subjects with CAI. Evidence has demonstrated that subjects with CAI show lower region-specific outcomes, including CAIT and FAAM, compared to healthy controls. Therefore, improvements in these measures following tDCS could have meaningful clinical implications.

Recent research has indicated that tDCS combined with eccentric exercises can enhance perceived

disability, although ankle-specific function may remain unchanged [14]. Beyond motor effects, studies in both healthy and patient populations have reported cognitive improvements following tDCS [30, 31]. The primary motor cortex (M1) is involved not only in motor control but also in cognitive processes [32]. Consequently, increasing M1 excitability through anodal stimulation may confer benefits for both motor and neurocognitive functions in males with CAI.

Maintaining postural balance requires integration of multiple sensory systems, including somatosensory, vestibular, and visual inputs [33]. This integration is often impaired in CAI, with affected individuals demonstrating deficits in sensory reweighting and a compensatory reliance on visual information [34]. Facilitating M1 excitability via tDCS may enhance the processing and integration of sensory information, potentially improving postural control. Supporting this, recent studies have reported positive effects of tDCS on dynamic balance in CAI populations [14, 15].

Additionally, a-tDCS may improve functional performance by activating cortical networks and increasing neural excitability [14, 35]. Prior research has demonstrated enhancements in lower-limb functional performance in both young and older healthy adults following tDCS [35, 36]. One study found that combining tDCS with eccentric exercises improved functional performance in both anodal and sham groups, highlighting the potential additive benefits of neuromodulation with conventional training [14].

Overall, the findings of the present study could provide a promising approach to integrating novel neuromodulatory interventions, such as a-tDCS, with traditional physiotherapy for CAI. tDCS is a non-invasive, cost-effective, easy-to-use, well-tolerated, and safe intervention with minimal adverse effects [37-39]. Its clinical application may offer numerous benefits, including enhanced motor function, improved neurocognitive performance, and better postural control in individuals with chronic ankle instability.

Trial Status

The study is currently recruiting participants.

Author Contributions

The authors confirm their contributions as follows: study conception and design: Azadeh Shadmeh, Michael A.Nitsche; data collection: Sara Asadi Abadi, Sara Fereydounnia; analysis and interpretation of results: Sara Asadi Abadi, Azadeh Shadmeh, Sara Fereydounnia, Azita Yazdani; draft manuscript preparation: Sara Asadi Abadi, Azadeh Shadmeh, Zeinab Shiravi, Sara Fereydounnia. All authors reviewed and approved the final version of the manuscript.

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Conflict of Interest: All authors declare that they have no conflicts of interest.

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