Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of Transcranial Direct Current Stimulation (tDCS) on Clinical Symptoms and Neurocognitive Function in Males with Chronic Ankle Instability (CAI)

Protocol summary

Study aim

Investigation the effects of Transcranial Direct Current Stimulation (tDCS) on Clinical Symptoms and Neurocognitive Function in Males with Chronic Ankle Instability (CAI)

Design

Randomized, single-blind, sham-controlled, parallel-group clinical trial on 20 patients. Block randomization with Random Allocation Software

Settings and conduct

20 men with chronic ankle instability will be screened for inclusion and exclusion criteria, and those eligible will complete baseline assessments. Then they will be randomly divided into intervention and control groups. Interventions will be conducted for 4 weeks and a total of 12 sessions (3 sessions per week) at the Faculty of Rehabilitation of Tehran University of Medical Sciences. The evaluations will be done at the beginning of the first session and at the end of the last session. This study is single blinde and the participants are blinded to study groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men aged 18-40 years with a history of unilateral and severe sprains and frequent episodes of ankle giving way; CAIT score less than or equal to 24; FAAM score in the ADL subgroup less than 90% and in sports subgroup less than 80%; No pain in the involved area. Exclusion criteria: Balance disorder; History of lower limb fracture or surgery; Uncorrected vision or hearing problems; Presence of any metal implants, pacemakers, intracranial electrodes, surgical clips; History of migraines, seizures, head trauma resulting in loss of consciousness; Disease or skin involvement in electrode placement area

Intervention groups

Intervention group (anodal tDCS along with exercises). Control group (sham tDCS along with exercises)

Main outcome variables

Visual and auditory choice reaction time; Visual and auditory complex choice reaction time; Low speed and high speed anticipatory skill; Static and dynamic balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230208057352N1**
Registration date: **2023-02-20, 1401/12/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-20, 1401/12/01**
Update count: **0**

Registration date

2023-02-20, 1401/12/01

Registrant information

Name

Sara Asadi Abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 8468

Email address

s-asadiabadi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Transcranial Direct Current Stimulation (tDCS) on Clinical Symptoms and Neurocognitive Function in Males with Chronic Ankle Instability (CAI)

Public title

Effects of Transcranial Direct Current Stimulation (tDCS) in Males with Chronic Ankle Instability (CAI)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Males, 18-40 yrs; with a history of at least 1 significant ankle sprain (associated with pain, swelling, and/or dislocation) occurred at least 12 months prior to study enrollment Participants should report at least 2 episodes of giving way in the 6 months prior to study enrollment Cumberland Ankle Instability Tool (CAIT) score ≤ 24. Foot and Ankle Ability Measure (FAAM): ADL subscale <90%, Sports subscale <80% No pain in involved ankle Participants should be right-handed Instability should be unilateral

Exclusion criteria:

Neurologic or orthopedic disorders wich may cause balance impairments History of lower extremity fracture or lower-extremity surgery Uncorrected hearing or visual impairments Have any metallic implants, pacemakers, intracranial electrodes, surgical clips A history of migraines, seizure, or head injury resulting in a loss of consciousness If contact with the scalp is not possible Have a scalp or skin condition (e.g., psoriasis or eczema) Using medications that may alter seizure threshold or cognitive performance If participants consume alcohol or caffeine 12 hours before the sessions

Age

From **18 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using Random Allocation Software and based on the random block method with a block size of 4 and with an allocation ratio of 1:1.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blind study and in fact, the participants do not know which group they are in (experimental or control). Of course, before entering the study, the participants will be informed in a consent form that they may be placed in one of the two experimental or control groups, but they will not be informed of which group they will enter. The experimental group will receive real anodal tDCS and the control group will receive sham current, and in the sham group the current will be cut off without the knowledge of the participants after 30 seconds.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

Street address

School of Rehabilitation of Tehran University of Medical Sciences, Piche-Shemiran, Enghelab Ave.

City

Tehran

Province

Tehran

Postal code

1148965111

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.TUMS.FNM.REC.1401.165

Health conditions studied

1

Description of health condition studied

Chronic Ankle Instability

ICD-10 code

M24.2

ICD-10 code description

Instability secondary to old ligament injury

Primary outcomes

1

Description

Visual choice reaction time

Timepoint

Before starting the intervention (the beginning of the first session) and after completion of 12 intervention sessions (the end of the last session)

Method of measurement
Speed Anticipation Reaction Time Test (SART) software

2

Description
Auditory choice reaction time
Timepoint
Before starting the intervention (the beginning of the first session) and after completion of 12 intervention sessions (the end of the last session)
Method of measurement
SART software

3

Description
Visual complex choice reaction time
Timepoint
Before starting the intervention (the beginning of the first session) and after completion of 12 intervention sessions (the end of the last session)
Method of measurement
SART software

4

Description
Auditory complex choice reaction time
Timepoint
Before starting the intervention (the beginning of the first session) and after completion of 12 intervention sessions (the end of the last session)
Method of measurement
SART software

5

Description
Low speed anticipation skill
Timepoint
Before starting the intervention (the beginning of the first session) and after completion of 12 intervention sessions (the end of the last session)
Method of measurement
SART software

6

Description
High speed anticipation skill
Timepoint
Before starting the intervention (the beginning of the first session) and after completion of 12 intervention sessions (the end of the last session)
Method of measurement
SART software

7

Description
Static balance: Foot-lift test
Timepoint
Before starting the intervention (the beginning of the first session) and after completion of 12 intervention sessions (the end of the last session)
Method of measurement
Calculation of the average number of errors in three tests

8

Description
Dynamic balance: Modified Star Excursion Balance Test
Timepoint
Before starting the intervention (the beginning of the first session) and after completion of 12 intervention sessions (the end of the last session)
Method of measurement
Tape measure

9

Description
Single-leg side-hop test
Timepoint
Before starting the intervention (the beginning of the first session) and after completion of 12 intervention sessions (the end of the last session)
Method of measurement
Stopwatch

Secondary outcomes

1

Description
The Cumberland Ankle Instability Tool's score
Timepoint
Before starting the intervention, after the completion of 12 intervention sessions (end of the last session)
Method of measurement
The Cumberland Ankle Instability Tool

2

Description
The Foot and Ankle Ability Measure questionnaire (FAAM) score
Timepoint
Before starting the intervention, after the completion of 12 intervention sessions (end of the last session)
Method of measurement
The Foot and Ankle Ability Measure questionnaire (FAAM)

Intervention groups

1

Description
Intervention group: In this group, anodal transcranial direct current stimulation (tDCS) and exercises are used. Sessions are held 3 days a week for 4 weeks (12 sessions in total) and the duration of each session is estimated to be around 40 minutes. tDCS is applied using the

Neurostim2 device of Medinateb Gostar company. Electrodes are placed in a sponge soaked with sterile salt (%0.09 NaCl). The active electrode (anode) is placed on M1 on the opposite side of the involved leg (C3 in cases of right ankle involvement and C4 in cases of left ankle involvement, according to the International 10-20 system). We place the reference electrode (cathode) over the forehead area on the side of the involved wrist. Anodal current is applied with an intensity of 2 mA and for 20 minutes. At first, the current is gradually increased for 30 seconds (ramp up) until it reaches 2 milliamps. During the entire stimulation time, we monitor the person for safety. In the end, the current is reduced for 30 seconds (ramp down) until it reaches zero. After applying tDCS, participants will perform progressive strength and balance exercises. Strength exercises using Thera-band are performed in 4 directions: plantar flexion, dorsiflexion, inversion, and eversion. The movements should be performed in 3 sets with 10 reps in each direction. Every three sessions, the exercises will progress and the Thera-band with more resistance will be used. Single-leg stance exercises are performed in 3 repetitions and 2 positions with eyes open and closed. Each activity (eyes open and closed) has 7 levels of difficulty. The exercise will progress to the next level whenever the participant can do 3 repetitions without errors.

Category

Rehabilitation

2

Description

Control group: In the control group, the same exercises are performed as in the intervention group. Also, in this group, tDCS is used with the same electrode placement as the intervention group, but the current is only maintained for 30 seconds and then it stops (sham)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person

Sara Asadi Abadi

Street address

School of Rehabilitation, No. 336, Next to Safialishah Street, Piche Shemiran, Enghelab Ave.

City

Tehran

Province

Tehran

Postal code

1148965111

Phone

+98 21 7753 3939

Email

s-asadiabadi@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Vice Chancellor for Research and Technology, 6th floor, Central University Organization, Corner of Qods St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sara Asadi Abadi

Position

MSc. student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation, Piche-Shemiran, Enghelab Ave.

City

Tehran
Province
Tehran
Postal code
1148965111
Phone
00 21 77528468
Email
s-asadiabadi@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Azadeh Shadmehr
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
School of Rehabilitation, Piche-Shemiran, Enghelab Ave.
City
Tehran
Province
Tehran
Postal code
1148965111
Phone
+98 21 7752 8468
Email
Shadmehr@tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sara Asadi Abadi
Position
MSc. student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
School of Rehabilitation, Piche-Shemiran, Enghelab Ave.
City
Tehran
Province
Tehran
Postal code
1148965111
Phone
+98 21 7752 8468
Email
s-asadiabadi@razi.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
Access period starts 3 months after the articles are published
To whom data/document is available
For researchers working in academic, scientific, and hospital institutions and clinicians
Under which criteria data/document could be used
Researchers working in the field of neuroscience and rehabilitation of musculoskeletal disorders
From where data/document is obtainable
Applicants for documentation can contact Sara Asadi Abadi via email. s-asadiabadi@razi.tums.ac.ir
What processes are involved for a request to access data/document
After receiving the request and stating the reasons for the need for the data, the request will be answered within a maximum period of one month
Comments