

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of Transcranial Direct Current Stimulation with Postural Training on Static and Dynamic Balance During Single and Dual Cognitive Tasks in Patients with Chronic Ankle Instability

Protocol summary

Study aim

The Effect of Transcranial Direct Current Stimulation with Postural Training on Static and Dynamic Balance During Single and Dual Cognitive Tasks in Patients with Chronic Ankle Instability

Design

A controlled, double-blind, single-center, randomized clinical trial with 40 participants in 2 groups of 20.

Settings and conduct

In the Neuromuscular Rehabilitation Research Center patients will conduct the therapeutic intervention for 4 weeks, 3 sessions per week, in 2 groups; the first group will receive tDCS electrical stimulation along with postural exercises. The second group will receive sham-tDCS stimulation along with postural exercises.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 18 and 30 years; History of ankle sprain more than one year ago; Report of at least 2 repetitions of the patient's perception of ankle instability or giving way in the past six months that affects the person's daily activities; Score below 24 on the CAIT (Cumberland Ankle Instability Tool) questionnaire. Exclusion Criteria: Report of any neurological disease that affects the patient's movement control (multiple sclerosis, history of stroke, Parkinson's, neuropathy); Received tDCS interventions in the last three months; Attendance at a rehabilitation program other than the current study; Score above 24 on the CAIT questionnaire

Intervention groups

Intervention group 1: In this group, according to the protocol, patients receive postural exercises on the device for 20 minutes simultaneously with tDCS stimulation in the M1 area of the cerebral cortex. Intervention group 2: In this group, according to the protocol, patients receive postural exercises on the device for 20 minutes simultaneously with Sham-tDCS

stimulation in the M1 area of the cerebral cortex.

Main outcome variables

Anterior-posterior stability index; Overall stability index; Mediolateral stability index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250606066090N1**

Registration date: **2025-06-08, 1404/03/18**

Registration timing: **prospective**

Last update: **2025-06-08, 1404/03/18**

Update count: **0**

Registration date

2025-06-08, 1404/03/18

Registrant information

Name

Mohammad Rasool Mallaki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4180

Email address

rasoolmallaki@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-22, 1404/04/01

Expected recruitment end date

2025-09-23, 1404/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Transcranial Direct Current Stimulation with Postural Training on Static and Dynamic Balance During Single and Dual Cognitive Tasks in Patients with Chronic Ankle Instability

Public title
The Effect of Transcranial Direct Current Stimulation with Postural Training on Static and Dynamic Balance During Single and Dual Cognitive Tasks in Patients with Chronic Ankle Instability

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 18 and 30 years History of ankle sprain that has been more than one year Report of at least 2 repetitions of the patient's perception of ankle instability or giving way in the past six months that affects the person's daily activities Score below 24 on the CAIT (Cumberland Ankle Instability Tool) questionnaire
Exclusion criteria:
 Report of any neurological disease that affects the patient's movement control (multiple sclerosis, history of stroke, Parkinson's, neuropathy) Receiving tDCS interventions in the last three months Attending a rehabilitation program other than the current study Score above 24 on the CAIT questionnaire

Age
From **18 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
40 participants will be randomly divided into 2 groups (Group 1 or 2) through random selection of fully sealed, coded envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, one group receives postural exercises with tDCS, and the other group receives postural exercises with sham tDCS stimulation. The study is double-blinded, so that the participants are unaware of the grouping and intervention of the other group; in addition, the therapist and the evaluator, who are separate from each other, are

also unaware of the group of participants.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Semnan University of Medical Sciences
Street address
 Semnan University of Medical Sciences, Basij Blvd, Semnan
City
 Semnan
Province
 Semnan
Postal code
 3514799442
Approval date
 2025-05-19, 1404/02/29
Ethics committee reference number
 IR.SEMUMS.REC.1403.135

Health conditions studied

1

Description of health condition studied
Chronic Ankle Instability

ICD-10 code
S93.4

ICD-10 code description
Sprain of ankle

Primary outcomes

1

Description
Anterior-posterior stability index

Timepoint
Before the intervention, after the intervention and one month after the intervention

Method of measurement
Biodex device (made in the USA)

2

Description
Overall Stability Index

Timepoint
Before the intervention, after the intervention and one

month after the intervention
Method of measurement
Biodex device (made in the USA)

3

Description
Mediolateral Stability Index
Timepoint
Before the intervention, after the intervention and one month after the intervention
Method of measurement
Biodex device (made in the USA)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, according to the protocol, patients receive postural exercises on the device for 20 minutes simultaneously with tDCS stimulation in the M1 region of the cerebral cortex.
Category
Rehabilitation

2

Description
Intervention group: In this group, according to the protocol, patients receive postural exercises on the device for 20 minutes simultaneously with Sham-tDCS stimulation in the M1 region of the cerebral cortex.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Neuromuscular Rehabilitation Research Center
Full name of responsible person
Fatemeh Ehsani
Street address
Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Fatemeh Ehsani
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
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Position

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Latest degree

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Full name of responsible person

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Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available