Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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.
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
+98 23 3365 4180
Email
fatemehehsani59@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Abasali Vafaie
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan.
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 23 3345 1336
Email
sem.ums.res@gmail.com
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
Street address
Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.
City
Semnan
Province
Semnan
Postal code

3513138111

Phone
+98 23 3365 4180

Email
fatemehehsani59@yahoo.com

Person responsible for scientific 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

Street address
Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.

City
Semnan

Province
Semnan

Postal code
3513138111

Phone
+98 23 3365 4180

Email
fatemehehsani59@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Mohammad Rasool Mallaki

Position
MSc Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.

City
Semnan

Province
Semnan

Postal code
3513138111

Phone
+98 23 3365 4180

Email
rasoolmallaki@gmail.com

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