# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 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)

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+98 23 3365 4180

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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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**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
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**Other areas of specialty/work**
Physiotherapy
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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MSc Student

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**Other areas of specialty/work**
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**Email**
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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