

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effects of transcranial direct current stimulation (M1 and DLPFC) on knee joint proprioception, balance, muscles activity, movement function and reaction time speed, after neuromuscular fatigue in female amateur athletes.

Protocol summary

Study aim

A comparison of the effects of tDCS focuses on M1 and DLPFC on knee joint proprioception, balance, muscle activity, and movement function, after neuromuscular fatigue in female amateur athletes.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 45 subjects. Random number generator software was used for randomization.

Settings and conduct

Subjects who meet the conditions to enter the study will be invited to the study. After that, the demographic characteristics of the subjects and the results of the study will be evaluated in the pre-test. The warm-up process will be performed by running on a treadmill for 10 minutes at a selected speed. Then the neuromuscular fatigue protocol will be applied and immediately the results of the study will be re-evaluated in the pre-test. Next, transcranial direct current stimulation will be applied for 5 consecutive days. On the seventh day, the neuromuscular fatigue protocol will be applied again and the results of the study will be evaluated immediately.

Participants/Inclusion and exclusion criteria

Entry: Woman with regular sports activity in ball fields
Prohibition of entry: injury in the trunk and lower limbs, mental problems and epilepsy, presence of metal parts in the forehead or neck

Intervention groups

In this research, stimulation of 1M and DLPFC regions will be used in experimental groups and deceptive stimulation in the control group. In sham stimulation mode, after 30 seconds of active stimulation, the electric current will be cut off and will remain so until the end. After installing the electrodes, the subjects will receive anodal electrical stimulation with an intensity of 2

milliamperes for 20 minutes in sitting conditions and without any verbal communication.

Main outcome variables

Knee joint proprioception, balance, muscles activity, movement function and reaction time speed

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240513061781N1**

Registration date: **2024-11-18, 1403/08/28**

Registration timing: **prospective**

Last update: **2024-11-18, 1403/08/28**

Update count: **0**

Registration date

2024-11-18, 1403/08/28

Registrant information

Name

Samaneh Valadbeigi

Name of organization / entity

Razi University

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-21, 1403/10/01
Expected recruitment end date
2025-03-20, 1403/12/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of transcranial direct current stimulation (M1 and DLPFC) on knee joint proprioception, balance, muscles activity, movement function and reaction time speed, after neuromuscular fatigue in female amateur athletes.

Public title
Investigating the effect of TDCS on knee proprioception, balance, muscle EMG, movement function and reaction time speed, after neuromuscular fatigue.

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Having regular sports activity. Sports fields with jumping-landing skills or changing direction.
Exclusion criteria:
Having a history of injury in the trunk and lower limbs in the last six months. Skeletal-muscular diseases. visual, vestibular (such as vertigo) or sensory (such as diabetes) disorders. People with mental problems and epilepsy. Use of neuroleptics.

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects will be randomly assigned to one of the experimental or control groups based on the output of the random number generator software by a person not involved in the research. The sequentially numbered opaque sealed envelope (SNOSE) method will hide the allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
Subjects and outcome assessors will not be aware of the assigned group. The random assignment of subjects to groups is done by a person not involved in the research, and the assigned group for each subject is placed in a

sealed envelope and will be available to the laboratory expert. After evaluating the results of the study before the test, each subject will be provided with the envelope related to the person applying the stimuli, in this way, neither the subject nor the evaluator will be informed of the type of intervention.

Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Kermanshah Razi University
Street address
Zakariya Razi Blvd, Kermanshah, Kermanshah Province
City
Kermanshah
Province
Kermanshah
Postal code
6714414971
Approval date
2024-04-17, 1403/01/29
Ethics committee reference number
IR.RAZI.REC.1403.007

Health conditions studied

1

Description of health condition studied
Controlling the effect of fatigue on factors such as balance, proprioception, electrical activity of the muscles acting on the knee and movement performance
ICD-10 code
Injury to
ICD-10 code description
S83.7

Primary outcomes

1

Description
Degree of knee joint proprioception
Timepoint
Proprioceptive measurement at the beginning of the study and 7 days after the tDCS stimulation intervention
Method of measurement
goniometer

2

Description

Balance check

Timepoint

Balance measurement at the beginning of the study and 7 days after the tDCS stimulation intervention

Method of measurement

Y-Balance test

Secondary outcomes

1

Description

Electrical activity of knee muscles

Timepoint

Examining the electrical activity of the knee muscles at the beginning of the study and 7 days after applying tDCS stimulation intervention

Method of measurement

Noraxon electromyography device

Intervention groups

1

Description

The first Intervention group: receiving tDCS stimulation of the M1 point, with a current intensity of 2 mA for 20 minutes in each session with a number of 5 sessions.

Category

Prevention

2

Description

The second Intervention group: Intervention group: receiving tDCS stimulation of the DLPFC point, with a current intensity of 2 mA for 20 minutes in each session with a number of 5 sessions.

Category

Prevention

3

Description

Control group: Sham (inactive) tDCS stimulation, after 30 seconds of active stimulation, the electric current is cut off until the end of 20 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi University

Full name of responsible person

Samaneh Valadbeigi

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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

Razi University

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

Razi University

Full name of responsible person

Samaneh Valadbeigi

Position

Student
Latest degree
Bachelor
Other areas of specialty/work
Sport pathology
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Person responsible for updating data

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information about study outcomes will be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Research in the relevant work area

From where data/document is obtainable

Samaneh Valadbeigi - s.valadbeigi.99@gmail.com

What processes are involved for a request to access data/document

Sending the request from the applicant, checking it from the researcher and responding immediately

Comments