Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Samaneh Valadbeigi

Name of organization / entity
Razi University

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Iran (Islamic Republic of)

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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

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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

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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
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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