

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effects of transcranial direct current stimulation on static balance in people with knee osteoarthritis

Protocol summary

Study aim

Evaluation of the effect of tDCS on static postural balance in subjects with KOA during static standing

Design

This study is a Double-blind, crossover, randomized, sham-controlled clinical trial. This experiment explores the effect of tDCS on static postural balance parameters in people with mild to moderate KOA. Static postural balance parameters will be assessed while standing barefoot on a force plate under open and closed eye conditions.

Settings and conduct

This study is a Double-blind, crossover, randomized, sham-controlled clinical trial that will be conducted in the Musculoskeletal Research Center at Isfahan University of Medical Sciences. The participants will be masked to the stimulation condition. A researcher (assessor), unaware of the stimulation conditions (real and sham), will assess static balance in two conditions of open and closed eye, before and after the interventions (real and sham).

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age of 45–70 years, Radiological signs of mild to moderate knee osteoarthritis according to K-L scale, Pain and tenderness in medial side of knee joint (VAS > 3), Walking without use of assistive devices

Exclusion Criteria: Any neurological disorders that would influence balance, Taken medication that affects balance control, Previous knee injury or surgery, Fracture of either lower extremity within 6 months, Any congenital or acquired musculoskeletal disorder in lower extremity, Presence of any inflammatory arthritis, Any contraindication to apply tDCS such as head implants, history of epilepsy/seizure or brain tumors, and pregnancy

Intervention groups

Each participant will be exposed counterbalanced randomly to two experimental conditions, including real tDCS and sham tDCS with a one-week washout period.

Main outcome variables

Static Balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160423027554N3**

Registration date: **2023-03-25, 1402/01/05**

Registration timing: **prospective**

Last update: **2023-03-25, 1402/01/05**

Update count: **0**

Registration date

2023-03-25, 1402/01/05

Registrant information

Name

Zohreh Shafizadegan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

zanbagh625@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of transcranial direct current stimulation on static balance in people with knee osteoarthritis

Public title

The effects of transcranial direct current stimulation on static balance in people with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 45–70 years Radiological signs of mild to moderate knee osteoarthritis according to K-L scale Pain and tenderness in medial side of knee joint (VAS > 3) Walking without use of assistive devices

Exclusion criteria:

Obesity with body mass index (BMI) >30 kg/m² Any neurological disorders that would influence balance Taken medication that affects balance control Previous knee injury or surgery / prior arthroplasty of any joint of lower extremity Fracture of either lower extremity within 6 months Any congenital or acquired musculoskeletal disorder in lower extremity Presence of any inflammatory arthritis Any contraindication to apply tDCS such as head implants, history of epilepsy/seizure or brain tumors, and pregnancy

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

This study does not have a control group. All participants will be exposed counterbalanced randomly to two experimental conditions, including real tDCS and sham tDCS with a one-week washout period. All participants will be randomly assigned (1:1), using a web-based randomisation system (<http://www.randomization.com>), to receive real and sham tDCS, based on the block randomization method, in which the block size is 2 and the number of blocks is 13. The researcher who assigns the volunteers to groups based on the random list is different from the researcher who performs the treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants will be masked to the stimulation condition. A researcher (assessor), unaware of the stimulation conditions (real and sham), will assess static balance in two conditions of open and closed eye, before

and after the interventions (real and sham).

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics Committees of Isfahan University of Medical Sciences and Health Services

Street address

Hezar Jarib Street, Isfahan University of Medical Sciences, Isfahn.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2023-02-21, 1401/12/02

Ethics committee reference number

IR.MUI.REC.1401.055

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Static Balance

Timepoint

Before and after the intervention

Method of measurement

Measurement of static balance parameters using the force plate

Secondary outcomes

1

Description

Strength of the quadriceps and hamstring muscles
Timepoint
Before and after the intervention
Method of measurement
Dynamometer

2

Description
Pain intensity
Timepoint
Before and after the intervention
Method of measurement
Visual Analog Scale (VAS)

Intervention groups

1

Description
Intervention group: real tDCS: All participants will be received real and sham tDCS with a counterbalanced crossover design within a one-week interval. The electrode montages for the sham and real tDCS conditions are identical. The anode electrode will be place on the vertex (Cz based on the 10-20 system) and the return electrode will be fixed centrally over the supraorbital area. The intensity and duration of real tDCS will be 2 mA and 20 minutes, respectively. This study does not have a control group.
Category
Rehabilitation

2

Description
Intervention group: sham-tDCS: All participants will be received real and sham tDCS with a counterbalanced crossover design within a one-week interval. The electrode montages for the sham and real tDCS conditions are identical. The anode electrode will be place on the vertex (Cz based on the 10-20 system) and the return electrode will be fixed centrally over the supraorbital area. For sham-tDCS, stimulation will be conducted for 30 seconds, and then the stimulator will be turned off without the participant's awareness. This study does not have a control group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Musculoskeletal Research Center of Faculty of Rehabilitation Sciences at Isfahan University of Medic
Full name of responsible person
Dr. Zohreh Shafizadegan
Street address
Hazar Jarib Street, Isfahan University of Medical

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr GholamReza Asqari
Street address
Hazar Jarib Street, Isfahan University of Medical Sciences, Isfahan, Iran
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Dr Zohreh Shafizadegan
Position
Lecturer, Musculoskeletal Research Center,

Department of Physical Therapy, Isfahan University of Med

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable