# 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)

**Phone**
+98 31 3792 5007

**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**
Isfehan

**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 Sciences, Isfahan, ran

**City**

Isfahan

**Province**

Isfehan

**Postal code**

81746-73461

**Phone**

+98 31 3792 5007

**Email**

z.shafizadegan@rehab.mui.ac.ir

## 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

**City**

Isfahan

**Province**

Isfehan

**Postal code**

81746-73461

**Phone**

+98 31 3792 3060

**Email**

research@mui.ac.ir

**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

**Street address**
Hazar Jarib Street, Isfahan University of Medical Sciences, Isfahan, Iran

**City**
Isfahan

**Province**
Isfehan

**Postal code**
81746-73461

**Phone**
+98 31 3792 5007

**Email**
z.shafizadegan@rehab.mui.ac.ir

## Person responsible for scientific 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

**Street address**
Hazar Jarib Street, Isfahan University of Medical Sciences, Isfahan, Iran

**City**
Isfahan

**Province**
Isfehan

**Postal code**
81746-73461

**Phone**
+98 31 3792 5007

**Email**
z.shafizadegan@rehab.mui.ac.ir

## Person responsible for updating data

**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

**Street address**
Hazar Jarib Street, Isfahan University of Medical Sciences, Isfahan, Iran

**City**
Isfahan

**Province**
Isfehan

**Postal code**
81746-73461

**Phone**
+98 31 3792 5007

**Email**
z.shafizadegan@rehab.mui.ac.ir

## 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