

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

The Effect of transcranial direct stimulation of different brain cortex areas plus the traditional physical therapy on pain intensity and clinical functional ability of subjects with knee osteoarthritis: “A randomised controlled trial”

Protocol summary

Study aim

the effect of transcranial direct current stimulation of different regions of the cerebral cortex with the traditional physiotherapy treatment on pain intensity and clinical functional ability of people with knee osteoarthritis

Design

A: PT with M1 a-tDCS B: PT with S1 a-tDCS C: PT with DLPFC1 a-tDCS D: PT with Sham tDCS Randomization: simple sample size: cochrane formula

Settings and conduct

This study is a double-blind, randomized controlled trial, that will be carried out at the Musculoskeletal Rehabilitation Center of Ahvaz Rehabilitation school. The assessor physiotherapist and participants will be blind. After initial evaluation, they will be treated ten sessions for two weeks

Participants/Inclusion and exclusion criteria

1- Individuals aged 50-70 years 2- Individuals with grades 2 and 3 of OA to the diagnosis of orthopedics by Kellgren and Lawrence system 3. Have at least 3 signs of the 6 clinical symptoms of American College of Rheumatology 4- People with dominant right leg involvement (in the case of bilateral, the right lesion is also dominant) 5- Minimal pain 4 according to the visual scale of pain 6. People with limited knee range

Intervention groups

A: PT with M1 a-tDCS B: PT with S1 a-tDCS C: PT with DLPFC a-tDCS D: PT with Sham tDCS

Main outcome variables

Pain; function; range of motion; strength

General information

Reason for update

Acronym

tDCS

IRCT registration information

IRCT registration number: **IRCT20181216042010N1**

Registration date: **2018-12-25, 1397/10/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-25, 1397/10/04**

Update count: **0**

Registration date

2018-12-25, 1397/10/04

Registrant information

Name

Fatemeh Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of transcranial direct stimulation of different brain cortex areas plus the traditional physical therapy on pain intensity and clinical functional ability of subjects with knee osteoarthritis: "A randomised controlled trial"	
Public title	The Effect of transcranial direct stimulation of different brain cortex areas plus the traditional physical therapy on pain and function of subjects with knee osteoarthritis
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Individuals aged 50-70 years Individuals with grades 2 and 3 of OA to the diagnosis of orthopedics by System Kellgren and Lawrence Having at least 3 signs of the 6 clinical symptoms of the American College of Rheumatology People with dominant right leg involvement (in the case of bilateral, the right lesion is also dominant) Minimal pain 4 according to the visual scale of pain Exclusion criteria: Having knee surgery for the last six months Replacing the knee joint or tibia osteotomy on the affected side Neurological conditions affecting organ function (Parkinson's disease, stroke and multiple sclerosis) Inability to walk without help History of another rheumatic disease that causes secondary osteoarthritis People with lack of sensation and epilepsy whom pain modification techniques are prohibited
Age	From 50 years old to 70 years old
Gender	Both
Phase	N/A
Groups that have been masked	- Participant - Outcome assessor
Sample size	Target sample size: 40
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization is a simple randomization method that is performed using 4 sealed envelopes containing group names based on the type of intervention.
Blinding (investigator's opinion)	Double blinded
Blinding description	The assessor physiotherapist and participants are blind
Placebo	Used
Assignment	Parallel
Other design features	NO
Secondary Ids	empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapour University of Medical Sciences

Street address

Golestan high way

City

Ahvaz

Province

Khouzestan

Postal code

61357- 15794

Approval date

2018-10-20, 1397/07/28

Ethics committee reference number

IR.AJUMS.REC.1397.519

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Unilateral primary osteoarthritis of knee

Primary outcomes

1

Description

pain

Timepoint

before initiation of treatment, 10 session, 1 month ago

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

function

Timepoint

before initiation of treatment, 10 session, 1 month ago

Method of measurement

questionnaire and tests

2

Description

strength of muscle

Timepoint

before initiation of treatment, 10 session, 1 month ago

Method of measurement

dynamometer

3

Description

range of motion

Timepoint

before initiation of treatment, 10 session, 1 month ago

Method of measurement

goniameter

Intervention groups

1

Description

Intervention group: traditional Physiotherapy(Ultrasound, Infra-Red, Trans- cutaneous Electrical Nerve Stimulation, Exercise therapy) with trans-cranial direct current stimulation of primary motor cortex for ten sessions

Category

Rehabilitation

2

Description

Intervention group: traditional Physiotherapy traditional Physiotherapy(Ultrasound, Infra-Red, Trans- cutaneous Electrical Nerve Stimulation, Exercise therapy) with transcranial direct current stimulation of primary sensory cortex for ten sessions

Category

Rehabilitation

3

Description

Intervention group: traditional Physiotherapy traditional Physiotherapy(Ultrasound, Infra-Red, Trans- cutaneous Electrical Nerve Stimulation, Exercise therapy) with transcranial direct current stimulation of dorsolateral perfrontal cortex for ten sessions

Category

Rehabilitation

4

Description

Control group: traditional Physiotherapy traditional Physiotherapy(Ultrasound, Infra-Red, Trans- cutaneous Electrical Nerve Stimulation, Exercise therapy) with sham transcranial direct current stimulation for ten sessions

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of rehabilitation school,Jundishapour university,

Golestan Highway, Ahvaz

Full name of responsible person

Gholamhosein Nassaj

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Clinic of rehabilitation school,Jundishapour university,
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nassadj@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Gholmhosein Nassaj

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

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

Title and more details about the data/document

The total potential data can be shared after unidentified individuals

When the data will become available and for how long

6 months after publishing

To whom data/document is available

Data will only be available to researchers in academic and scientific institutes

Under which criteria data/document could be used

If someone want to do a similar research project

From where data/document is obtainable

Gholamhosein Nassaj

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

through E-mail and note the cause and purpose

Comments